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Original article

Experimental validation of the GNRB® for measuring anterior tibial translation

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ABSTRACT

Introduction: The objective of this study was to validate the technique used to measure anterior tibial translation in cadaver knees using the GNRB® device by comparing it with the gold standard, the OrthoPilot® navigation system.

Hypothesis: Simultaneous measurement of anterior tibial translation by the GNRB® and the OrthoPilot® in the chosen experimental conditions will result in significant differences between devices.

Material and methods: Five fresh frozen cadavers were used. The knee was placed in 20° flexion. Four calibrated posterior-anterior forces (134 N to 250 N) were applied. For each applied force, the anterior tibial translation was measured simultaneously by both devices. Two conditions were analyzed: anterior cruciate ligament (ACL) intact and ACL transected. The primary criterion was anterior tibial translation at 250 N. The measurements were compared using a paired Student's *t*-test and the correlation coefficient was calculated. Agreement between the two methods was determined using Bland-Altman plots. Consistency of the measurements was determined by calculating the intraclass correlation coefficient.

Results: For all applied forces and ligament conditions, the mean difference between the GNRB® and the navigation system was 0.1 ± 1.7 mm (n.s). Out of the 80 measurements taken, the difference between devices was less than ± 2 mm in 66 cases (82%). There was a strong correlation, good agreement and high consistency between the two measurement methods.

Discussion: The differences between the measurements taken by the GNRB® and the navigation system were small and likely have no clinical impact. We recommend using the GNRB® to evaluate anterior knee laxity.

Level of evidence: II controlled laboratory study.

1. Introduction

Increased anterior tibial translation raises the suspicions of an injury to the anterior cruciate ligament (ACL) of the knee. Measuring this increase relative to the contralateral side enhances the accuracy of the diagnosis [1,2], and is an important element of postoperative monitoring after ACL reconstruction [3–5]. Quantification of anterior tibial translation by a single clinical examination is inaccurate and not very reproducible [2]. Instrumented methods such as dynamic radiographs [1] and the KT-1000 [6] are more reliable but have a significant error margin.

The GNRB® device was developed to improve the accuracy and reproducibility of anterior tibial translation measurements [7]. The early clinical results were encouraging [5,8–10]. The intra- and inter-observer reproducibility of this device has been measured in a clinical context [7,10]. However, the GNRB® has never been compared experimentally with the gold standard method.

Computer-assisted surgical navigation systems have been validated for measuring anterior tibial translation [11–13] and can be considered as the gold standard in the context of an experimental study. A previous study [9] found small but statistically significant differences between the anterior tibial translation measured with the GNRB® and a navigation system when both tools were used in the same patient; however, the measurement conditions differed.

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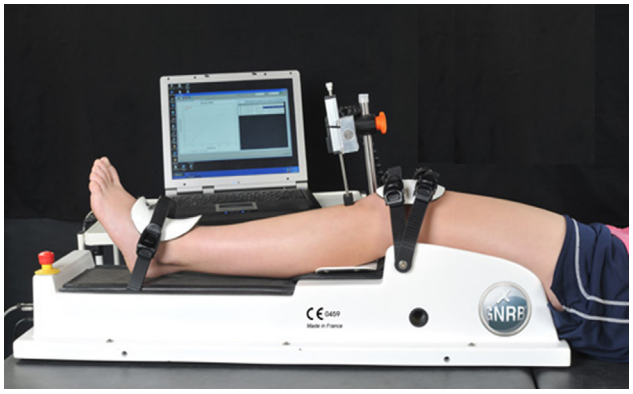

Fig. 1. GNRB® system.

Consequently, we felt it was relevant to compare the measurements generated by these two systems when used simultaneously.

The objective of this study was to validate the technique used to measure anterior tibial translation in cadaver knees with the GNRB® device by comparing it with the gold standard, a surgical navigation system. We hypothesized that simultaneous measurement of anterior tibial translation by the GNRB® and the navigation system in the chosen experimental conditions will result in significant differences between devices.

2. Materials and methods

This study was carried out in accordance with our institution's ethics regulations and the 1964 Helsinki declaration and its amendments. Five fresh frozen cadavers were used after they had been thawed at room temperature for 24 hours. There were 3 women and 2 men, ranging from 63 to 89 years of age. The right knee was analyzed first in all subjects. A medial parapatellar arthrotomy was done to confirm that the ACL was intact and that no chondral lesions were present, and then it was immediately re-closed. None of the 10 knees were excluded. Navigation markers were fixed to the distal femur and proximal tibia, 10 cm on either side of the joint line. These were used to track the bone positions in three-dimensions with a surgical navigation system (OrthoPilot®, B-Braun Aesculap, Tuttlingen, Germany). The anatomical and kinematic data were recorded according to the manufacturer's recommendations [14]. The knee was placed in 20° flexion in a molded support in order to reproduce the typical Lachman test position, according to the recommendations of the GNRB® manufacturer (Genourob, Laval, France) [7] (Fig. 1). The thigh and calf were secured to the support with two crepe bandages. A servomotor applied an increasing calibrated posterior-anterior force (134 N, 150 N, 200 N and 250 N) to the upper part of the calf. A transducer in the GNRB® measured the translation of the tibial tuberosity relative to the femur. For each applied force, the anterior tibial translation was measured simultaneously by the navigation system (4 measurements per knee). Next, the medial arthrotomy was reopened, the ACL was cut at its tibial insertion using a scalpel, and the arthrotomy was re-closed. The measurements were repeated as described above. The left knee was then analyzed in the same manner as the right knee.

2.1. Statistical analysis

This was a non-inferiority study. The primary criterion was the difference between the anterior tibial translation measured by the two devices. A pilot clinical study found that the anterior tibial translation measured by the GNRB at all force levels in ACL-deficient patients was 4 mm ± 2 mm in the healthy knee and 8 mm ± 3 mm in the injured knee, with an average translation of 6 mm. A sample size calculation was done before the study in order to detect a 2 mm difference between the two measurement systems with an alpha risk of 0.05 mm and a beta risk of 0.90. A minimum of 72 paired measurements were needed. The difference between the GNRB® measurements and the navigation system measurements (80 paired measurements) were compared at each force level and in each ligament condition using a paired Student's *t*-test; the correlation coefficient was also calculated (Table 1). The agreement between the two sets of measurements was determined using Bland-Altman plots. The consistency between the two measurement systems was determined using the intraclass correlation coefficient (ICC). All statistical tests were done with a 5% threshold.

Table 1
Number of measurements done in each condition.

	GNRB® system	OrthoPilot® system
Overall comparison	80	80
Force-based analysis		
134 N	20	20
150 N	20	20
200 N	20	20
250 N	20	20
Effect of ligament condition		
Intact ACL	40	40
Transected ACL	40	40

Table 2
Results in mm (mean ± standard deviation).

	GNRB® system	OrthoPilot® system
Overall comparison	7.4 ± 3.2	7.3 ± 3.8
Force-based analysis		
134 N	5.9 ± 2.7	5.9 ± 2.8
150 N	6.4 ± 2.7	6.3 ± 3.4
200 N	7.9 ± 3.0	7.8 ± 3.9
250 N	9.3 ± 3.3	9.2 ± 4.2
Effect of ligament condition		
Intact ACL	5.5 ± 2.4	4.6 ± 2.1
Transected ACL	9.2 ± 2.8	10.0 ± 3.1

3. Results

The results are summarized in Table 2.

3.1. Overall analysis

The mean difference between the GNRB® and the navigation system during simultaneous measurement of anterior tibial translation, independent of the force applied and ligament condition, was 0.1 ± 1.7 mm (n.s). Out of the 80 measurements taken, the difference between devices was less than ± 2 mm in 66 instances (82%). The two sets of measurements were strongly correlated ($R^2 = 0.64$) (Fig. 2). There was a good agreement between the two sets of measurements ($R^2 = 0.13$) with a 0.1 mm systematic difference (bias) (Fig. 3). The two sets of measurements were highly consistent (ICC = 0.88).

3.2. Force-based analysis

The mean difference between the GNRB® and the navigation system during simultaneous measurement of anterior tibial translation was 0.0 ± 0.9 mm at 134 N, 0.1 ± 1.4 mm at 150 N, 0.1 ± 1.7 mm at 200 N and 0.1 ± 2.5 mm at 250 N (n.s.). The two sets of measurements were strongly correlated (R^2 ranging from 0.67 to 0.90). There was a good agreement between the two sets of measurements (R^2 ranging from 0.004 to 0.052) with a bias of 0.0 to

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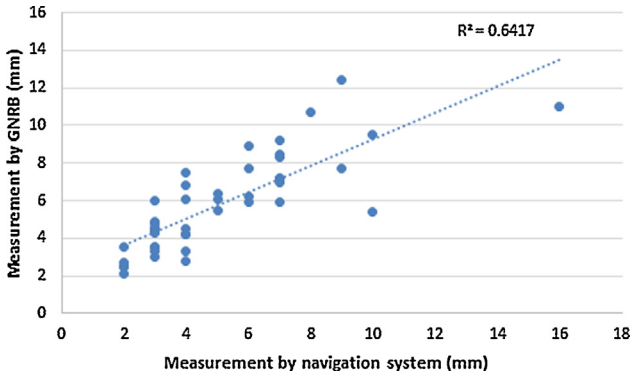

Fig. 2. Correlation between GNRB® measurements of anterior tibial translation and those of the navigation system.

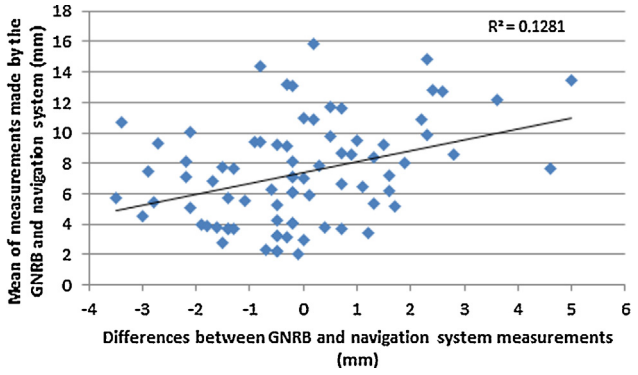

Fig. 3. Bland-Altman plots were used to compare the GNRB® measurements of anterior tibial translation with those of the navigation system.

0.1 mm. The two sets of measurements were highly consistent (ICC ranging from 0.78 to 0.95).

3.3. Effect of ligament condition

The mean difference between the GNRB® and the navigation system during simultaneous measurement of anterior tibial translation was 1.00 ± 1.5 mm when the ACL was intact and -0.8 ± 1.5 mm when the ACL was cut (n.s.). The two sets of measurements were strongly correlated ($R^2 = 0.67$). There was a good agreement between the two sets of measurements ($R^2 = 0.0026$) with a bias of 1.0 and −0.8 mm, respectively. The two sets of measurements were highly consistent (ICC ranging from 0.78 to 0.88).

4. Discussion

The working hypothesis was not confirmed. The main finding of this study was that simultaneous measurement of anterior tibial translation by the GRNB® and the navigation system did not differ, no matter the test configuration.

Measurement of anterior knee laxity is an essential element of ACL reconstruction surgery, either to evaluate the initial laxity or the success of the procedure. Instead of an unreliable clinical assessment, this measurement, whether done pre- or postoperatively, is generally done with instrumented methods such as dynamic X-rays with anterior drawer [1], the Rolimeter [15] or the KT-1000 [6]. However, the reliability of all these methods is questionable [6,16]. The initial studies with the GNRB® suggest that quantification of the anterior drawer in an ACL-deficient knee is significantly more reproducible with this device [7,8,17,18]. Yet, the accuracy of this device had not been evaluated up to now. The GNRB® has already been validated in a clinical setting by comparing it to a surgical navigation system [9]. However, that study had several limitations. The main one was that the force applied intraoperatively to produce the anterior drawer was not controlled, thus could have caused significant bias. This may have made the comparison with the GNRB® potentially incorrect, as this system applied a fully calibrated force. Since there was no existing non-biased experimental validation of this device, we designed the current study to eliminate the potential biases of the prior study, which had been done by the same research team.

Surgical navigation systems, including the one used for this study, are validated devices for measuring anteroposterior or rotational laxity of the knee, in both a clinical [2,9,11–13] and experimental context [19,20]. There is no formal validation of this application in comparison to more sophisticated techniques such a robot-assisted systems or stereoradiography techniques. However, various experimental validation studies are available in the area of knee arthroplasty implants, and the reliability of this OrthoPilot® system for measuring angles is under 1° for all lower limb alignment measurements [21]. Since the materials and algorithms are not significantly different for an ACL surgery-specific application, we can assume the accuracy and reproducibility of this navigation system are maintained. Thus, it seemed logical to use this tool as the gold standard for validating the measurements produced by a novel method, such as the GNRB® device.

No difference, either a mathematical one or one that would be clinically significant, was found between the anterior tibial translation measurements by the GNRB® and the navigation system, independent of the force applied or condition of the ACL. In addition, there was a strong correlation, good agreement and high consistency between the two measurement systems. These results suggest that the GNRB® is a reliable tool for measuring anterior tibial translation in the context of a potential ACL tear or after ACL reconstruction.

The current study has a number of limitations. The subjects were much older than the patients who typically undergo ACL reconstruction. The physical properties of the soft tissues can be greatly altered by aging, and this study's findings may have been different if the subjects were younger. However, it is much more difficult to obtain younger cadavers. Only 10 knees were analyzed. The *a priori* sample size calculation showed that this would be sufficient to detect a difference that could be clinically significant. The variability between measurements was low, and the probability that we were unable to detect a true difference appears limited. The reproducibility of the GRNB® device was not evaluated; however, other studies have shown good measurement reproducibility [22]. While using a GNRB® clinically requires a bilateral examination to determine the difference in anterior translation between the injured and healthy knee, only one knee was analyzed in this study and no comparison was made between healthy and injured knees. However, the goal of this study was to compare two measurement techniques simultaneously and under the same test conditions, which made a bilateral comparison less relevant. The experimental nature of this study eliminates any potential bias due to muscle activity that can interfere with these measurements, which is an essential difference with the clinical context. Since the goal of this study was to compare two measurements made simultaneously, it is not very likely that muscle activity would have appreciably affected the measurement difference between the two methods.

The current study has several strengths. The navigation system that we used can be considered as the gold standard for the measurements in question, hence, the validation of a new method relative to the gold standard appears justified. The experimental device used for the GNRB® system resembles the one used clinically, thus, the results should be the same as in a typical clinical setting. Multiple force levels were used; the differences between these levels were small. We have no evidence that one force level

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is superior to the others [23]. The anterior tibial translation was measured simultaneously by the devices, which eliminates the secondary bias of non-controlled tibial displacement when two measurements are done sequentially.

5. Conclusion

Based on this study's findings, we can conclude that the GNRB® system is a valid tool for measuring anterior tibial translation in a normal knee or after an ACL tear. We recommend using this system for all knee evaluations, before or after ACL reconstruction. However, the reproducibility of this procedure must still be defined.

Disclosure of interest

B.P. declares that he has no competing interest.

J.Y.J. receives royalties from Aesculap is a paid consultant for Exactech, is an unpaid consultant for FH Orthopedics, is treasurer of CAOS-International, and is a member of the board of the French hip and knee society (SFHG).

G.S. is employed by B-Braun Medical France; his participation consisted of verifying that the navigation system was used in a manner consistent with the manufacturer's recommendations; he did not participate in the data collection or data analysis.

S.H. is employed by Genourob; his participation consisted of verifying that the GNRB® system was used in a manner consistent with the manufacturer's recommendations; he did not participate in the data collection or data analysis.

P.C. is a paid consultant for Mitek and Tornier, is a member of the board of the French arthroscopy society (SFA) and is a member of the editorial board of the journal OTSR. No funding was received for this study.

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