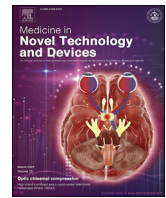


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Sensitivity, repeatability and reproducibility study with a leg prototype of a recently developed knee arthrometer: The DYNEELAX®

Théo Cojean^{a,1,*}, Cécile Batailler^{a,b}, Henri Robert^c, Laurence Cheze^a^a Univ Lyon, Univ Gustave Eiffel, Univ Claude Bernard Lyon 1, LBMC UMR_T 9406, F-69622, Lyon, France^b Hôpital de La Croix-Rousse, Lyon, France^c Centre Hospitalier Du Haut Anjou, Château-Gontier, Sur-Mayenne, France

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ABSTRACT

Sagittal knee laxity is often quantified using arthrometers. Adding rotational laxity and compliance measurements is relatively new and could bring new information for anterior cruciate ligament (ACL) injury diagnosis. The DYNEELAX® is a new knee arthrometer able to evaluate simultaneously tibial translation and rotation. The purpose is to assess the sensitivity, reproducibility and repeatability of the DYNEELAX® with a prototype leg to provide accurate instructions before using it in clinical practice. Sensitivity is studied by varying 7 parameters (positioning and sensors), and reproducibility by repeating measurement series with a group of two experienced operators and a group of two non-experienced operators. Repeatability is assessed throughout the study. The results showed that DYNEELAX® is poorly sensitive to the angle and the position of the displacement sensor, and the angle of the rotation sensor. It is a bit sensitive to positioning of patella and ankle supports. It is very sensitive to the tightening of the patella and ankle supports. It exists a significant difference only between groups ($p < 0.001$), but there is no significant difference between the two experienced operators ($p > 0.215$), or between the two non-experienced operators ($p > 0.229$). Variation coefficients for intra-series are on average inferior to 5% for translation and rotation tests. Then, the DYNEELAX® presented encouraging results with a good accuracy and a good reliability but operators must be careful about positioning.

1. Introduction

Defining and measuring knee laxity is a complex task due to the variability of mechanical characteristics of knee joint structures and the wide choice of assessment devices. Usually, good history and clinical tests such as the Lachman test or the pivot shift test are enough to detect an anterior cruciate ligament (ACL) rupture [1,2]. But in cases of equivocal clinical diagnosis, supplementary diagnostic aids can help. Laximetry was introduced to supplement patients' medical histories and examinations to enhance the accuracy of assessment methods that diagnose ACL injuries. Laximeters such as the KT-1000, the Rolimeter, the GNRB or the Telos, are commonly used to compute the side-to-side difference (SSD) of laxity between two knees of a patient, and then obtain objective measurements [3–5]. However, some studies reported a poor reproducibility and accuracy of these devices [6–11], except for the

GNRB® who has shown better performances [12–16]. All these devices perform only measurements in translation in the sagittal plane by applying a force under the calf to reproduce the Lachman test, whereas a number of clinical and biomechanical studies state that ACL plays a role to limit anterior tibial translation and also internal rotation [17,18]. Indeed, knee laxity is a complex and three-dimensional motion and can be assessed by the pivot shift test combining a translational movement in the sagittal plane and rotational movements around the longitudinal axis of the tibia. The interest to measure rotational laxities with devices is relatively new and arose as a consequence of the lack of rotational control provided by the techniques of ACL reconstruction which were performed a decade ago [19,20]. Some devices allow rotational laxity measurements such as the Rotab [21] and the Rotam [22], applying a torque to turn inward or outward the tibia and then create a torsion (internal or external rotation) and have made it possible to move forward on this

* Corresponding author.

E-mail addresses: theo.cojean@etu.univ-lyon1.fr (T. Cojean), cecile.batailler@chu-lyon.fr (C. Batailler), henri.robert36@gmail.com (H. Robert), laurence.cheze@univ-lyon1.fr (L. Cheze).¹ Present address: Université Gustave Eiffel - Campus de Bron, Laboratoire de Biomécanique et Mécanique des Chocs, 25 Avenue François Mitterrand, 69,500 Bron, France.<https://doi.org/10.1016/j.medntd.2023.100254>

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subject and to carry out several studies. Another diagnostic parameter that can be considered in addition to laxity is compliance. It is the opposite of stiffness and is defined by the ratio between the deformation and the applied force. Bercovy was one of the first to introduce the notion of compliance in the assessment of knee injury, finding that laxity alone did not adequately characterize ACL behavior [23]. Several authors subsequently used compliance when studying ACL grafts and knee stability during post-operative rehabilitation [24,25].

There is no lack of data documenting laxity thresholds for translation tests using devices shown above to detect ACL injuries [5,9,11,26–28]. Nevertheless, results vary, influenced by the precision of measurement device, operators or anatomical factors, the force exerted to carry out the translation or the rotation, and the tightening to attach the femur. Few consider combined anterior and rotational knee laxity, making the clinical utility of laxity as a method of diagnosing an ACL injury more difficult to evaluate [29,30]. Moreover, laxity measurements are still used in the majority of cases, unlike compliance. Mouton et al. were the only authors found in the literature who combine anterior and rotational laxity with compliance to demonstrate that could improve the diagnosis of ACL injuries [29,31]. But in our study, different devices were used and, at this time, no device in current practice was able to measure anterior tibial translation and rotational laxity simultaneously with compliance.

To meet this need and carry out new studies on this subject, a new arthrometer was developed (Genourob, Laval, France), the DYNEELAX®, and currently no studies exist on it in literature. This new device is able to combine tibial translations in the sagittal plane and internal/external tibial rotations around the longitudinal tibial axis to provide assistance in ACL tears diagnostic. This new device is the upgrade of the GNRB® arthrometer. Before using it in a clinical framework, we wanted to assess through this study with a leg prototype the repeatability, reproducibility and sensitivity of the DYNEELAX® and thus optimize its use for physicians. The study is divided into three parts: first, the validation of the leg prototype to ensure that the study could continue and justify the use of a leg prototype for the rest. Once the prototype validated, we used it to assess the sensitivity of the DYNEELAX® in a second part by varying many positioning and sensor parameters to see if the results are sensitive to it. Third, the reproducibility is assessed by repeating measurement series on this same prototype leg with four operators, where two are experimented and the two others are not. Finally, the repeatability is assessed throughout the study with many series of measurements.

2. Material and methods

2.1. Study design

The ethics committee of our institution approved our study protocol and amendments (n°22.04729.000226). All participants provided informed consent before participation. For the first part, the prototype validation, 32 participants with healthy knees were enrolled in order to build laxity corridors. It was single-center and single-operator. They were between 18 and 54 years old, with an average of 30 ± 8 years old. 13 participants were women (40.6%) and 19 were men (59.4%). All participants had DYNEELAX® measurements. Inclusion criteria were as follows: be over 18, and have no knee pathology. Exclusion criteria were: patients who have already undergone a ligamentoplasty, if a knee is painful and lack of participant consent. The second part, the sensitivity, was single-center and single-operator and did not require any participants, all measurements were performed on the prototype leg. The last part, the reproducibility, was single-center and multi-operator where four men were involved to perform measurements on the leg prototype with the DYNEELAX®. Two were experienced and two were non-experienced in the use of the device. They all provided their consent for the participation as an operator, they had not DYNEELAX®

measurements.

2.2. The DYNEELAX® and the leg prototype

The DYNEELAX® is an automated device for laxity measurement of anteroposterior tibial translation and internal/external tibial axial rotations of the knee at 20° knee flexion. In a clinical use with a patient, the leg is placed in a rigid adjustable leg support with the knee at 0° internal/external rotation. A comparison is done between the two knees of the patient exerting thrust forces with a linear jack (up to 300 N) under the calf, and rotation torques with a small motor (up to 10Nm) on the boot where the foot is placed. According to the standardized protocol, a series of measures is composed of 1×134 N test (TR134), 1×150 N test (TR150) and 3×200 N tests (TR200) for translations and 1×3 Nm test (IR3 and ER3), and 3×5 Nm tests (IR5 and ER5) for internal and external rotations. The knee and the ankle must be tightly held under the supports to avoid unwanted displacements. The tight value under the patellar support is displayed on the DYNEELAX® user interface for operator guidance. However, there is no tightening sensors for the ankle part and the good fit of the ankle in the boot must be done at the appreciation of the operator with his experience. A displacement transducer records the relative displacement of the anterior tibial tubercle (ATT) and a tibial rotation sensor records relative internal/external tibial rotations with respect to the femur. A hole on the patella support, numerous markers on the device (graduations, arrows) as well as different numerical information with a color code on the user interface help the operator to perform and repeat the measurements. Results are plotted on the DYNEELAX® user interface with several curves for translations (mm/N) and rotations (deg/Nm). A point is created every 1 N for translations and every 0.1Nm for rotations. The compliance is obtained for each test by calculating the mean of each slope between all points in the defined boundaries. There is the primary compliance (PC_{tr}) and the secondary compliance (SC_{tr}) for translation curves, respectively computed between 30 N and 70 N, and between 100 N and the maximal force applied (last point). For internal and external rotations, there is only one compliance (respectively C_{ri} and C_{re}) computed between 2Nm and the maximal torque applied (last point). For the rest of the study, all different types of translation tests will be named TR134, TR150 and TR200. For internal and external rotation tests, it will be IR3, IR5 and ER3, ER5 respectively.

In order to assess the sensitivity, reproducibility and repeatability of the DYNEELAX®, a homemade prototype leg was used. First, it has been validated upstream by comparing the results with data collected on healthy participants for all translation and rotation tests. The leg is a small plastic mannequin leg filled with insulating foam. Sections were deliberately made at the level of the tibial plateau under the patella and at the level of the ankle to allow translations and rotations. We chose to perform measurements on a prototype leg instead of healthy participants or anatomic legs for ease of use and control. Indeed, the prototype leg enabled to carry out a large number of measurements which would not have been possible on human subjects. Positioning of sensors and clamping elements could directly be controlled and adjusted, which allowed to focus only on the machine performances. It was voluntary to exclude the morphological diversity aspect within a population such as weight, height, age, sex or even sport activity which could influence the results according to several studies [32–37]. That limited the variability of the measurements related to a human leg, and allowed to study only the variability of the measurements related to the DYNEELAX® and the operators. As the machine offers a number of parameters to be taken into account, this is the really first step to guide operator on how the device should be used before using it in a clinical practice. Fig. 1 presents the DYNEELAX® device with the prototype leg used for this study.

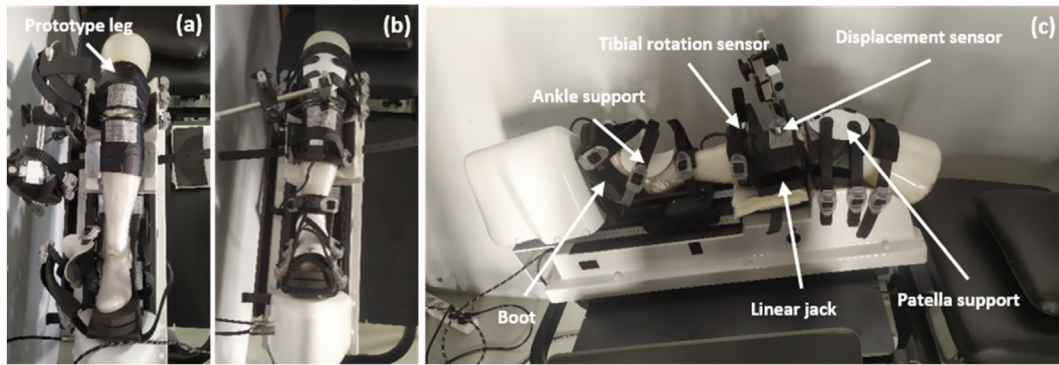


Fig. 1. Prototype leg used for the study. On (a), the leg is only placed in the DYNEELAX®, on (b) and (c), the leg is positioned in the device with all sensors.

2.3. Protocols

2.3.1. Prototype leg validation

All healthy participants involved to create laxity corridors and validate the prototype leg underwent series of measurements on the DYNEELAX according to the standard protocol explained in section 2.2 with all parameters in reference configuration. It represents 32 data for TR134, TR150, RI3, RE3, and 96 data for TR200, RI5, RE3, for a total of 424 data. The prototype leg was then tested following the same protocol for positioning by performing successively 30 measurements for all translation and rotation tests (30xTR134, 30xTR150, 30xTR200 and 30xIR3, 30xIR5, 30xER3, 30xER5). Fig. 2 presents graphically the comparison between the prototype leg and healthy participants results. All curves are included in the corridors and the “mechanical” behavior of the leg corresponds to what is expected with a healthy knee, even if it was a bit stiffer for rotations. Therefore, the prototype leg could be used for the rest of the study.

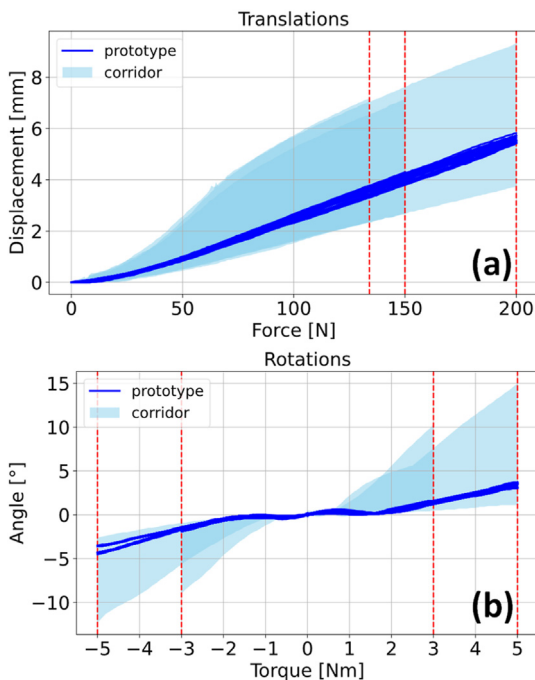


Fig. 2. Prototype leg validation by comparing results obtained with the prototype in blue and results obtained with healthy participants in light blue. Translation tests (TR134, TR150 and TR200) are presented on the graph (a). Internal and external rotations tests (IR3, IR5, ER3, ER5) are presented on the graph (b) where negative values are for internal rotations and positive values for external rotations. Vertical dotted red line are the values where all results are recorded.

2.3.2. Sensitivity

The sensitivity of the DYNEELAX® is assessed by varying seven parameters (positioning and sensors) presented in Table 1. For each of them, a reference configuration is defined according to the user guide designed by Genourob. Each parameter is studied in isolation when the others are put back in reference position. The aim was to compare results of all configurations of a parameter to the reference (see Table 2).

Table 1

All individual parameters studied for the sensitivity of the DYNEELAX®. For each of them, several configurations are compared to a reference position according to the manufacturer. Different tests are performed, such as translations, internal/external rotations or both.

Param.	Name	Configurations	Ref.	Tests
P1	Angle of the displacement sensor	80°, 85°, 90°, 95° and 100°	90°	Translations (TR)
P2	Position of the displacement sensor	Centered (C), Centered Left (CL), Centered Right (CR), Proximal Centered (PC), Proximal Left (PL), Proximal Right (PR), Distal Centered (DC), Distal Left (DL) and Distal Right (DR)	Centered (C)	Translations (TR)
P3	Angle of the rotation sensor	-5°, 0°, 5°	0°	Internal and External Rotations (IR and ER)
P4	Position of the patella support	Centered (C), Centered Left (CL), Centered Right (CR), Proximal Centered (PC), Proximal Left (PL), Proximal Right (PR), Distal Centered (DC), Distal Left (DL) and Distal Right (DR)	Centered (C)	Translations (TR)
P5	Position of ankle support	Centered (C), Left (L) and Right (R)	Centered (C)	Internal and External Rotations (IR and ER)
P6	Tightening of the patella support	40 N, 60 N, 80 N, 100 N, 120 N and 140 N	80 N	Translations (TR), Internal and External Rotations (IR and ER)
P7	Tightening of the ankle support	Tight (T) and Not Tight (NT)	Tight (T)	Internal and External Rotations (IR and ER)

Table 2

Results obtained for parameters including translation tests for the sensitivity part. For each translation test (TR134, TR150 and TR200), results are recorded at 134 N, 150 N and 200 N if they exist. Means for laxity and compliance results are computed with their standard deviations and their associated variation coefficients in parenthesis.

Test	134 N [mm]	150 N [mm]	200 N [mm]	PC _{tr} [μ m/ N]	SC _{tr} [μ m/ N]	
P1	TR134	3.68 \pm 0.05 (1.48%)	/	/	27.12 \pm 0.75 (2.76%)	35.14 \pm 1.17 (3.34%)
	TR150	3.68 \pm 0.05 (1.24%)	4.18 \pm 0.04 (1.05%)	/	27.31 \pm 0.82 (3.02%)	33.48 \pm 0.59 (1.77%)
	TR200	3.59 \pm 0.08 (2.14%)	4.08 \pm 0.08 (1.94%)	5.57 \pm 0.1 (1.82%)	27.69 \pm 0.7 (2.53%)	30.69 \pm 0.68 (2.21%)
P2	TR134	3.68 \pm 0.15 (3.95%)	/	/	28.18 \pm 1.04 (3.69%)	33.32 \pm 1.65 (4.94%)
	TR150	3.69 \pm 0.15 (4.1%)	4.19 \pm 0.17 (4.15%)	/	28.51 \pm 1.17 (4.11%)	32.48 \pm 1.48 (4.56%)
	TR200	3.68 \pm 0.16 (4.38%)	4.17 \pm 0.19 (4.44%)	5.63 \pm 0.27 (4.75%)	28.86 \pm 1.26 (4.36%)	30.44 \pm 1.67 (5.47%)
P4	TR134	3.16 \pm 0.52 (16.43%)	/	/	24.35 \pm 5.4 (22.19%)	27.76 \pm 3.91 (14.08%)
	TR150	3.14 \pm 0.51 (16.32%)	3.6 \pm 0.55 (15.22%)	/	24.31 \pm 5.47 (22.5%)	27.74 \pm 3.39 (12.51%)
	TR200	3.06 \pm 0.47 (15.23%)	3.5 \pm 0.51 (14.5%)	4.91 \pm 0.6 (12.19%)	24.14 \pm 4.87 (20.17%)	27.51 \pm 2.53 (9.21%)
P6	TR134	3.75 \pm 1.32 (35.1%)	/	/	26.6 \pm 7.15 (26.88%)	35.41 \pm 14.25 (40.23%)
	TR150	3.79 \pm 1.34 (35.45%)	4.35 \pm 1.53 (35.05%)	/	27.1 \pm 7.33 (27.05%)	35.43 \pm 13.89 (39.2%)
	TR200	3.76 \pm 1.38 (36.62%)	4.3 \pm 1.38 (36.22%)	5.87 \pm 1.84 (31.44%)	27.27 \pm 7.45 (27.33%)	33.03 \pm 9.91 (30%)

These seven parameters were chosen according to the standard protocol described in section 2.2 which are essential to start an exam. Each of them needs to be carefully positioned by the operator during an exam. For P1, P2 and P3, we can easily suppose that if the sensors are positioned differently, it could change the results. It is the same for P4, P5, P6 and P7 for clamping elements, if the patella and/or the ankles supports are positioned and tight differently, it could also influence tibial translation and rotation. These clamping elements exist to isolate tibial movements as much as possible. If the patella is not correctly tight, the femur can be dragged with the tibia and thus distort the translation measurement. It is the same for rotation, if the foot is not correctly tight in the boot, a rotation of the ankle can appear in addition of tibial rotation.

2.3.3. Repeatability

Machine repeatability was assessed first with the measurements carried out during the prototype leg validation part, and also by performing again successively 30 measurements for all translation and rotation tests for all configurations presented in Table 1. Boundaries for all parameters were defined in order to reproduce as many positioning situations as possible according to the conditions of use of the machine. As the tightening of the ankle support is not available unlike the patella, P7 was defined as Tight (T) or Not Tight (NT).

2.3.4. Reproducibility

Reproducibility was assessed involving four operators: two

experimented operators (OP1 and OP2) in the first group (GR1), and two non-experimented operators (OP3 and OP4) in the second group (GR2).

OP1 and OP2 have more than 6 months of experience, while OP3 and OP4 have never used the device and got only two training sessions before the study. There were two sessions per group, where one week separated each session. During a session, operators passed one after the other. Every time, they removed the leg from the DYNEELAX® and put it back in position in order to do a new series of measurements. Each operator performed 10 series of measures on the prototype leg (10 series of 1xTR134, 1xTR150, 3xTR200 and 1xIR3, 3xIR5, 1xER3, 3xER5). We recorded two types of data: first, all positioning parameters for each operator after each series, presented for the sensitivity part of this study, with only the time in addition. After, all laxity and compliance results obtained by all operators. The objective was to show if results are operator-dependent, and if there is a difference between experimented and non-experimented operators.

2.4. Statistic methods

Means, standard deviations and coefficients of variation were used for this study and assess sensitivity, repeatability and reproducibility. Basically, coefficient of variation $\leq 10\%$ is good and indicates that the mean is representative of the groups of curves. Between 10% and 20% it is acceptable, between 20% and 30% it is bad, and $\geq 30\%$ it's unacceptable, which means that there are problems in data or the experiment is out of control [38].

Pearson coefficients were computed between the different groups of curves, namely the TR134/TR150, TR150/TR200 and TR134/TR200 test curves (the same for the groups of rotating test curves) to observe their correlation.

Equivalence tests (TOST) were used to assess the sensitivity. In statistics, two means may be significantly different, but the result may still be clinically acceptable. We must therefore establish a margin of equivalence, noted δ , within which we can define whether or not a result is clinically correct. This margin has been defined at 10%, using laxity thresholds values found in literature to define healthy ACL, partial ACL tears and complete ACL tears [8,12,15,26–28,39–41]. The method to obtain this margin will not be detailed in this study. The equivalence is satisfied when the difference including confidence interval at 95% (CI95%) stays in a range $[-10\%; 10\%]$ around the reference.

For the reproducibility part, ANOVA tests were performed to assess differences between operators and between groups for laxity and compliance results and also positioning parameters.

3. Results

Pearson coefficients were always superior to 0.97 between different translation tests, and always superior to 0.89 for rotation tests.

Intra-series results for repeatability (e.g. intra-series results for the 30 measurements for TR134, P1, 90°) were as followed: first for translation tests, standard deviations are always inferior to 0.07 mm for laxity results, except for P6 for TR134 with 40 N tightening where it reaches 0.12 mm. This gives a maximal variation coefficient of 2.24%. About compliances, standard deviations for PC_{tr} do not exceed 0.73 μ m/N (2.58%) and SC_{tr} 0.69 μ m/N (2.36%), except for low tightening again for P6, where it could reach 2.5 μ m/N (5.18%). Second for rotation tests, standard deviations are inferior to 0.19° (8.13%) for laxity results and inferior to 0.17°/Nm (14.98%) for compliances. But by distinguishing between IR3 and IR5 (respectively ER3 and ER5), it decreases results to 0.11° (4.97%) for laxities and 0.05°/Nm (4.98%).

For the sensitivity part, Fig. 3 shows curves obtained per configuration for all parameters. Means are computed and plotted inside a corridor which represents the 30 measurements of a series. References are in red and vertical dotted lines indicate at which values recorded results are presented in Table 3 and Table 4.

The DYNEELAX® is poorly sensitive to the angle and the position of

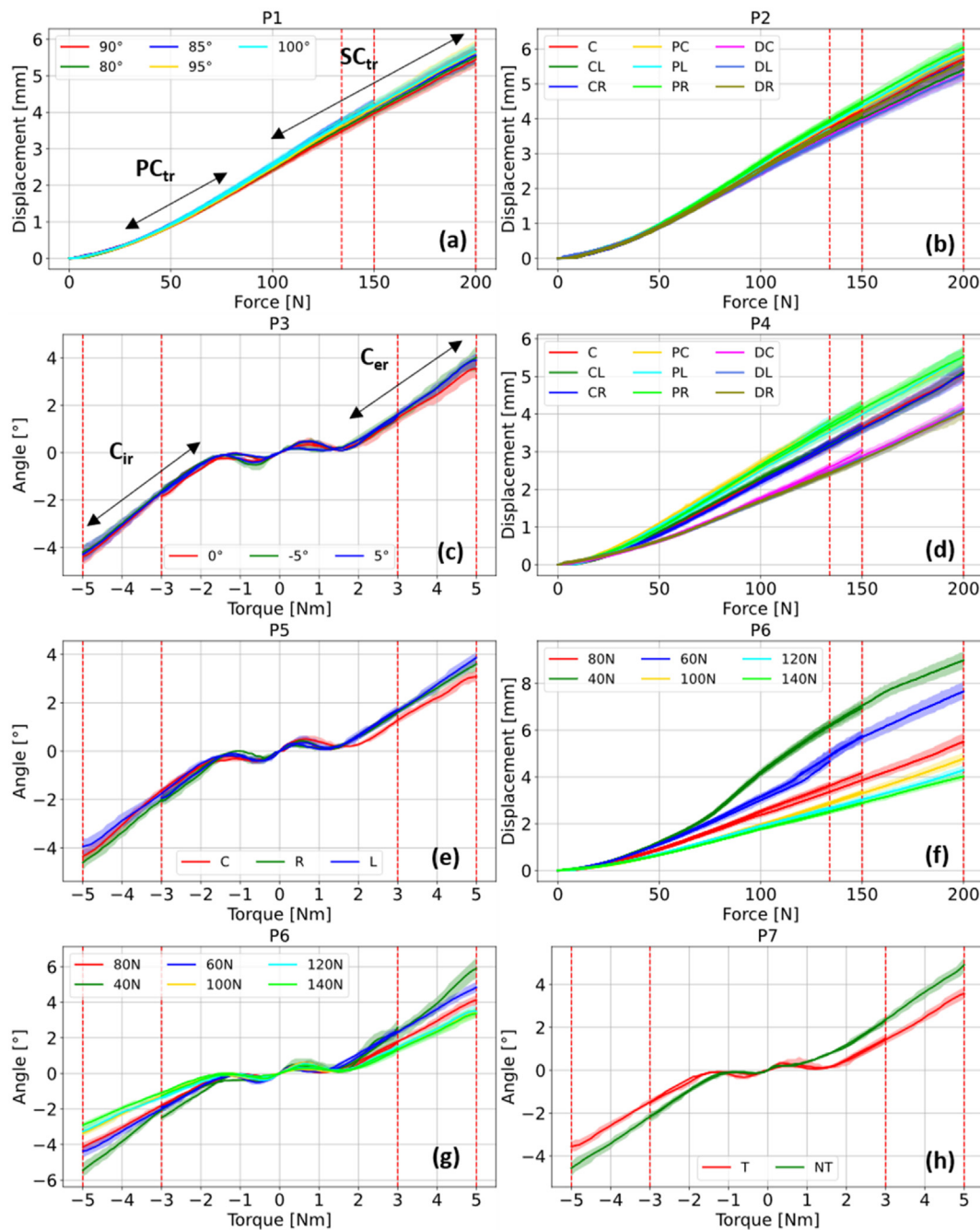


Fig. 3. Graphs obtained for translation and internal/external rotation tests for all parameters after performing measures on the prototype leg. For translations (a), (b), (d), (f), there are three different tests: TR134, TR150 and TR200. The primary compliance PC_{tr} is the average slope between 30 N and 70 N, and the second compliance SC_{tr} between 100 N and the maximal value. For rotations (b), (c), (e), (h), negative values are for internal rotations and positive values for external rotations. There are two tests per rotation: 3IR, 5IR, 3 ER and 5 ER. The compliance C_{ir} for internal rotations, and C_{er} for external rotations, are computed between 2Nm and the maximal value. All results are displayed with their means in corridors which represent all measures (30 per test). Vertical dotted red line are the values where all results are recorded.

the displacement sensor (P1 et P2), and the initial angle of the rotation sensor (P3). The maximal difference in laxity with the reference is 0.22 mm for P1, and 0.45 mm for P2. Compliances show very few divergences with small standard deviations. All variation coefficients are inferior to 5.47%, which is very good. Equivalences are satisfied ($p < 0.001$) for all configurations with the reference at 134 N, 150 N and 200 N. For P3 the maximal difference is 0.46° and the equivalence is satisfied according to TOST at 3Nm and 5Nm. Standard deviations and variation coefficients are slightly higher but still inferior to 10%, which is acceptable. But equivalence is satisfied only for internal rotations ($p < 0.001$), for

external rotations values are on the very limit of the 10% margin and equivalence is not satisfied ($p = 0.16$).

After, the DYNEELAX® is a bit sensitive to positioning of patella and ankle supports (P4 and P5). For P4, three groups of curves can be identified on the graphs according to the vertical positions: proximal, centered and distal. However, horizontal positions do not change a lot results. Standard deviations and variation coefficients increase and become acceptable or even bad. The maximal difference is 1.01 mm. For centered positions (C, CL, CR) the equivalence is satisfied at 134 N, 150 N and 200 N ($p < 0.001$). For proximal positions (PC, PL, PR), results are

Table 3

Results obtained for parameters including internal and external rotation tests for the sensitivity part. For each rotation test (IR3, IR5, ER3 and ER5), results are recorded at 3Nm, and 5Nm if they exist. Means for laxity and compliance results are computed with their standard deviations and their associated variation coefficients in parenthesis.

Test	3Nm [°]	5Nm [°]	C _{ir} /C _{er} [°/Nm]	
P3	IR3	1.71 ± 0.12 (7.15%)	/	1.14 ± 0.11 (9.66%)
	IR5	1.65 ± 0.05 (3.07%)	4.28 ± 0.1 (2.38%)	1.27 ± 0.03 (2.25%)
	ER3	1.5 ± 0.11 (7.09%)	/	1.13 ± 0.11 (9.92%)
	ER5	1.56 ± 0.11 (6.89%)	3.83 ± 0.24 (6.25%)	1.11 ± 0.06 (4.98%)
P5	IR3	1.92 ± 0.15 (7.92%)	/	1.13 ± 0.07 (6.27%)
	IR5	1.8 ± 0.17 (9.64%)	4.31 ± 0.28 (6.54%)	1.23 ± 0.07 (5.51%)
	ER3	1.65 ± 0.07 (4.14%)	/	1.01 ± 0.07 (7.05%)
	ER5	1.52 ± 0.18 (12.03%)	3.51 ± 0.34 (9.59%)	1.01 ± 0.07 (6.82%)
P6	IR3	1.72 ± 0.43 (24.97%)	/	1.06 ± 0.19 (17.94%)
	IR5	1.59 ± 0.39 (24.54%)	3.92 ± 0.86 (22.03%)	1.13 ± 0.22 (19.66%)
	ER3	1.82 ± 0.49 (27.1%)	/	1.22 ± 0.29 (24%)
	ER5	1.77 ± 0.43 (24.15%)	4.19 ± 0.94 (22.42%)	1.2 ± 0.25 (20.86%)
P7	IR3	1.82 ± 0.32 (17.34%)	/	1.08 ± 0.16 (14.43%)
	IR5	1.82 ± 0.36 (19.9%)	4.06 ± 0.52 (12.75%)	1.13 ± 0.08 (7.06%)
	ER3	1.92 ± 0.44 (22.77%)	/	1.12 ± 0.14 (12.82%)
	ER5	1.9 ± 0.14 (25.56%)	4.25 ± 0.69 (16.17%)	1.14 ± 0.1 (8.78%)

just a bit inferior to the 10% limit and are finally included at 200 N: the equivalence is not satisfied at 134 N and 150 N (p = 1.000) and satisfied at 200 N (p < 0.001). For distal positions (DC, DL, DR), the equivalence is not satisfied (p = 1.000). For P5, the maximum difference is 0.78° but here standard deviations are correct and variation coefficients remain inferior to 10%. Equivalence is not satisfied for external rotations for all values (p = 1.000) and satisfied for internal rotations at 5Nm (p < 0.001) except for (R) at 3Nm (p = 1.000).

Finally, the DYNEELAX® is very sensitive to the tightening of the patella and ankle supports (P6 and P7). For P6, there are big differences observable on the graph, and tables show unacceptable results. Equivalence is not satisfied for all configurations for each test (p = 1.000) except for internal rotations with a tightening of 60 N (p < 0.001). For P7, only one configuration is compared to the reference. The maximum difference is 1.33° and the equivalence is not satisfied for all values (p = 1.000).

For reproducibility part, GR1 performed an average of one series of tests in 05:47min ± 00:47 and GR2 in 08:17min ± 01:17. According to ANOVA tests, there is a significant difference between operators and between groups for all positioning parameters (p < 0.026) except for: the angle of the rotation sensor (p = 0.704 between operators and p = 0.27 between groups), the position of the displacement sensor (p = 0.432 between operators and p = 0.189 between groups), and the tightening only between operators (p = 0.08).

Fig. 4 shows all curves obtained with the 10 series of measurements per operator. Means are plotted in a corridor which represents all measurements of all series and are presented in Tables 4 and 5. For intra-operator results, variation coefficients are acceptable or even good for translations, except for TR134 tests. SC_{tr} increases suddenly which indicates many divergences. Moreover, laxity results tend to decrease when the intensity of tests increases: results for TR200 are lower than TR150 and TR134. For rotation tests, all results are bad or unacceptable for all tests at 3Nm, but it becomes acceptable at 5Nm. The same observation can be done about the laxity, results for IR5 are lower than IR3 (respectively ER5 and ER3). According to ANOVA tests for inter-operator results, it exists a significant difference between operators (p < 0.032) except for 134 N tests and 3Nm tests (respectively p = 0.235 and p =

Table 4

Translation results obtained for all operators for the reproducibility part. For each translation test (TR134, TR150 and TR200), results are recorded at 134 N, 150 N and 200 N if they exist. Means for laxity and compliance results are computed with their standard deviations and their associated variation coefficients in parenthesis. OP1 and OP2 are the experimented operators and they form the group GR1. OP3 and OP4 are the non-experimented operators and they form the group GR2.

Test	134 N [mm]	150 N [mm]	200 N [mm]	PC _{tr} [μm/N]	SC _{tr} [μm/N]			
OP1	TR134	4.67 ± 0.68 (14.56%)	/	/	29.21 ± 2.91 (9.95%)	51.85 ± 12.41 (23.93%)		
		TR150	4.09 ± 0.49 (11.85%)	4.95 ± 0.62 (12.61%)	/	29.69 ± 2.88 (9.7%)	43.0 ± 7.27 (16.9%)	
			TR200	3.81 ± 0.47 (12.3%)	4.36 ± 0.54 (12.38%)	6.41 ± 0.52 (8.11%)	29.51 ± 3.08 (10.43%)	37.73 ± 3.19 (8.45%)
	OP2	TR134	4.86 ± 0.57 (11.71%)	/	/	29.11 ± 2.91 (9.84%)	56.35 ± 10.09 (17.9%)	
			TR150	3.95 ± 0.23 (5.73%)	4.89 ± 0.25 (5.2%)	/	28.06 ± 2.16 (7.68%)	44.46 ± 3.95 (8.88%)
		TR200		3.51 ± 0.25 (7.12%)	4.03 ± 0.29 (7.19%)	6.18 ± 0.27 (4.36%)	26.16 ± 2.27 (8.67%)	37.75 ± 3.56 (9.43%)
	OP3	TR134	4.61 ± 0.77 (16.71%)	/	/	25.46 ± 2.67 (10.47%)	54.41 ± 13.8 (25.36%)	
			TR150	3.6 ± 0.32 (8.91%)	4.44 ± 0.3 (6.74%)	/	24.51 ± 3.29 (13.41%)	41.04 ± 4.03 (9.82%)
				TR200	3.26 ± 0.31 (9.5%)	3.77 ± 0.33 (8.75%)	5.68 ± 0.3 (5.28%)	24.23 ± 2.94 (12.13%)
OP4		TR134	4.39 ± 0.83 (18.91%)	/	/	26.56 ± 2.77 (10.43%)	49.91 ± 15.88 (31.82%)	
			TR150	3.58 ± 0.37 (10.43%)	4.31 ± 0.52 (12.02%)	/	26.16 ± 3.07 (11.73%)	37.52 ± 6.3 (16.79%)
		TR200		3.31 ± 0.31 (9.36%)	3.8 ± 0.36 (9.47%)	5.56 ± 0.29 (5.21%)	25.32 ± 2.87 (11.33%)	32.61 ± 3.56 (10.91%)

0.059). In details, we can see that this difference exists only between groups GR1 and GR2 (p < 0.001), but there is no significant difference between OP1 and OP2 (p > 0.215), or between OP3 and OP4 (p > 0.229).

4. Discussion

The most important finding of this study is that the DYNEELAX® is a device with an excellent repeatability intra-series and a good reproducibility. Measurements are nevertheless sensitive to some positioning parameters to which operators must pay attention.

Initially, the prototype leg had to be tested and validated in order to continue the present study. Results allowed us to conclude that the leg has a “mechanical” behavior similar to that of a healthy participant’s leg. There are both advantages and disadvantages to using a prototype leg. First of all, we could perform an unlimited number of tests on the leg, which allowed us to collect a lot of data. The other advantage of having a single leg in a repeatability/reproducibility study is that we limit the variability of the measurements related to the piece (here the leg), which allowed us to study only the variability of the measurements related to the DYNEELAX® and the operators. The major limitation is that this leg does not represent the biomechanical behavior of a real leg with the ACL and peripheral knee structures. A prospective study on cadaveric legs or on healthy subjects should be carried out to confirm the results we found.

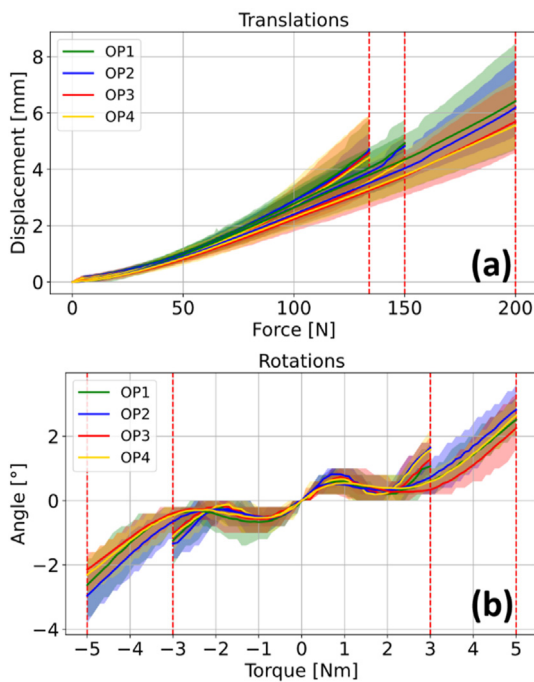


Fig. 4. Graphs obtained for translation and internal/external rotation tests by all operators after performing series on the prototype leg. Translation tests (TR134, TR150 and TR200) are presented on the graph (a). Internal and external rotations tests (IR3, IR5, ER3, ER5) are presented on the graph (b) where negative values are for internal rotations and positive values for external rotations. All results are displayed with their means in corridors which represent all measures (30 per test). Vertical dotted red line are the values where all results are recorded.

During the sensitivity part, 30 measurements were carried out in translation for each type of test (TR134, TR150 and TR200), and also 30 in internal and external rotations (IR3, ER3, IR5 and ER5) to assess the machine repeatability. For the translational tests in the entire study, the DYNEELAX® showed very good repeatability with at least acceptable intra-series coefficients of variation, which shows that an average of a series of measurements carried out without changing the position of the leg and without touching any parameter is representative of the series. For internal and external rotations tests, the results are also very good. Even if all tests were highly correlated (TR134/TR150, TR150/TR200 and TR134/TR200 for translations, IR3/IR5 and ER3/ER5 for rotations), on several occasions the rotational measurements have shown less stability for 3Nm tests (IR3 and ER3). Variability is higher in the results, and correlations lower than 0.9 with 5Nm tests (IR5 and ER5). As laxity results are slightly different at 3Nm between 3Nm tests and 5Nm tests, with also a small divergence observed on compliances, it is recommended to always start the rotational series with 3Nm tests (IR3 for internal rotations and ER3 for external rotations), and use it as a calibration. The same observation is done between TR134 tests and TR150/TR200 tests thus the same advice can be applied for translations with starting series with TR134 tests.

For the sensitivity part, 7 parameters were studied with several configurations with one reference. Results were not very sensitive to changes in the angle and the position of the displacement sensor (P1 and P2), or to changes in the angle of the rotation sensor (P3). In contrast, we begin to see differences for the changes in the positions of the patella support (P4) and the ankle support (P5). Indeed, for P4, only vertical displacements had an influence. This refers to a certain mechanical logic: higher the cup is, less the patella is held by it, which accentuates the translation because the femur is less attached. On the opposite, if the cup is low, it can press on the “patellar tendon” (if it was a real leg), and thus also hold the tibia and prevent tibial translation. For the ankle support,

Table 5

Rotation results obtained for all operators for the reproducibility part. For each rotation test (IR3, IR5, ER3 and ER5), results are recorded at 3Nm, and 5Nm if they exist. Means for laxity and compliance results are computed with their standard deviations and their associated variation coefficients in parenthesis. OP1 and OP2 are the experimented operators and they form the group GR1. OP3 and OP4 are the non-experimented operators and they form the group GR2.

	Test	3Nm [°]	5Nm [°]	C _{ir} /C _{er} [°/Nm]
OP1	IR3	1.24 ± 0.37 (30.22%)	/	0.98 ± 0.33 (33.6%)
	IR5	0.42 ± 0.19 (45.87%)	2.62 ± 0.23 (8.77%)	0.98 ± 0.18 (18.51%)
	ER3	1.1 ± 0.33 (30%)	/	0.9 ± 0.3 (33.54%)
	ER5	0.61 ± 0.21 (34.45%)	2.52 ± 0.24 (9.52%)	0.99 ± 0.07 (7.46%)
OP2	IR3	1.32 ± 0.42 (32.10%)	/	1.04 ± 0.36 (34.88%)
	IR5	0.64 ± 0.25 (38.41%)	2.94 ± 0.25 (8.5%)	1.09 ± 0.16 (14.61%)
	ER3	1.66 ± 0.26 (15.66%)	/	1.38 ± 0.11 (8.23%)
	ER5	0.73 ± 0.16 (21.91%)	2.83 ± 0.26 (9.18%)	1.05 ± 0.12 (11%)
OP3	IR3	1.04 ± 0.3 (28.38%)	/	0.84 ± 0.3 (35.14%)
	IR5	0.4 ± 0.17 (42.09%)	2.16 ± 0.19 (8.79%)	0.79 ± 0.12 (15.17%)
	ER3	1.3 ± 0.36 (27.38%)	/	1.07 ± 0.31 (28.57%)
	ER5	0.36 ± 0.17 (47.54%)	2.27 ± 0.2 (8.81%)	0.93 ± 0.13 (13.97%)
OP4	IR3	1.08 ± 0.36 (32.9%)	/	0.9 ± 0.29 (31.86%)
	IR5	0.46 ± 0.21 (46.61%)	2.3 ± 0.31 (13.51%)	0.83 ± 0.11 (13.65%)
	ER3	1.56 ± 0.31 (19.86%)	/	1.32 ± 0.23 (17.78%)
	ER5	0.59 ± 0.17 (29.31%)	2.64 ± 0.24 (11.97%)	1.06 ± 0.16 (15.21%)

equivalence was satisfied only for internal rotations. Notice that it was the same for P3, even if values for external rotations were on the limit of the corridor. This could be explained by the lack of control about the tightening and positioning of the support. Finally, the DYNEELAX® is very sensitive to the tightening of the patella and ankle assembly. Indeed, more the tightening is important, more the patella will be maintained in position under the support with the femur to avoid displacements, as well as the ankle. With a weak tightening, parasitic movements can occur, such as translation of the whole knee instead of the tibia, or a rotation of the ankle, which would amplify the variability of the results leading to bad precision. It is therefore essential to position the leg correctly in the DYNEELAX® in order to position the patella support properly on the lower part of the patella, then to tighten sufficiently the whole leg. This will partly determine the quality of the results, and therefore impact ACL injury diagnosis and its management.

Indeed, currently MRI is the most common non-invasive screening tool for detecting an ACL tear, but many studies have shown good diagnostic performance on complete ACL tears, but few consider partial tears [42,43] and MRI is mainly used to assess associated tears in case of knee injury. The challenge is thus to improve ACL tears management by detecting correctly the type of tear [44–47]. Combining laximetry tests with MRI seems to be a good solution to improve the management and medical care [48]. The differentiation between a partial or a complete ACL tear using laxity thresholds is small: 1.5 mm and 3 mm for Robert et al., 1.3 mm and 3 mm for Cojean et al. [28,48]. Therefore, according to our results, it is important for the practitioner to pay attention to positioning of all parameters, especially if too much variation leads to significant differences such as the tightening and position of the patella and ankle supports. A bad exam could create false negatives or false positives.

Second, we studied the reproducibility of the DYNEELAX® with four operators, two (OP1 and OP2) with experience of using the device (GR1),

and the two others (OP3 and OP4) with no experience (GR2). First of all, concerning the positioning of the leg, for the angle of the displacement sensor, there is a significant difference between the operators, and between GR1 and GR2. However, we have seen previously that this parameter had little influence on the results. For the rotation sensor angle, there is no significant difference, neither between the operators, nor between the two groups. This can be explained by the fact that the value of the angle is indicated on the user interface, which helps the operator during the positioning. For the tightening of the patella support, there is no significant difference between the operators, but a difference exists between the two groups and it seems that experimented operators dare to tight harder. We have indicated previously that tightening had a huge impact on the results. All operators positioned correctly the displacement sensor with no significant differences. They all centered it on the ATT with an angle of $84.12^\circ \pm 2.32^\circ$, but we saw that it did not impact results. For the patella support position, all operators centered it except for OP1 who tended to put it slightly above. We saw earlier that this could slightly impact the results.

Results presented a good intra-operator repeatability but some differences exist with the inter-operator repeatability. Even if there were some significant differences between operators and groups for leg positioning, measurements are quite homogeneous between the groups, but few differences exist between operators. We saw that there were no significant intra-group differences, unlike the inter-groups results. If we consider that GR1 is the reference because of its experience, differences between means of GR1 and GR2 remain inferior to 11.14% for all values found for each input in translation and inferior to 5.56% for external rotations, which is very close to an equivalence of 10%. However, the maximal difference reaches 20.97% for internal rotations. The lack of experience for OP3 and OP4 with the accumulation of small discrepancies in the positioning parameters may lead to these results. The tightening of the ankle assembly is not quantifiable and we have seen that this can influence the results. In addition, we studied only positions in rotation of the tibial rotation sensor (-5° , 0° and 5°), but not the vertical position (whether it is positioned near or far from the ATT), which could also have an influence. It would be interesting to know after how much time of use, an inexperienced operator could become experienced, i.e. establishing a learning curve. The DYNEELAX® has many assistance tools to guide the operator and thus allow the same test conditions to be reproduced for the series of measurements to be performed. Moreover, it would be interesting to validate all these observations in a prospective study among subjects.

Considering that no studies exist about the DYNEELAX® device yet, we can compare some results with GNRB® where several studies were performed in the literature. First, we have noticed that through all reliability studies of the GNRB®, authors do not provide many details about positioning parameters. Bouguennec et al. [13] performed measures on 60 healthy knees at 6-month interval and took into account the tightening, they excluded tightening under 30 N and positioned the patella support as recommended by the manufacturer. They obtained standard deviation of 0.23 mm and 0.25 mm for 134 N tests, but no information was given about the number of operators and measures. Alqathani et al. [49], mentioned that a difference of tightening superior to 10 N could have a significant influence on results, which confirm our analysis. Mourbes et al. [50] also described that laxity varies with the tightening, they differentiate tightening between 75 N and 90 N, and over 90 N. Here, a single operator performed only one test at 134 N and one test at 200 N on 30 pairs of healthy knees in two different sessions and obtained standard deviations between 0.8 mm and 1.5 mm. Colette et al. [14] used three protocols in order to assess the GNRB®: first using multiple sessions with two experienced operators on one healthy subject, second with fifteen operators in one session on one healthy subject, and the last one with two operators in one session on fifteen healthy subjects. Standard variations ranged between 0.1 mm and 1.3 mm. Finally, Vauhnik et al. [51] computed ICC (IntraClass Correlation) and found standard deviations between 1 mm and 2 mm, and variation coefficients between 5%

and 28%. For rotations, no studies have been found about repeatability and reproducibility on such devices. Thus, studies and results are numerous and showed that GNRB® was a reliable device. Compared to what is found in literature, the DYNEELAX® seems to be as efficient as the GNRB® for translation tests.

5. Conclusion

In conclusion, this study investigated the influence on results of different positioning parameters of a leg prototype in the DYNEELAX®. This device is the first automated knee arthrometer combining translation and rotation tests. It could bring new perspectives in some studies and clinical investigations. We evaluated the sensitivity and repeatability of the device by studying 7 parameters individually. For each parameter, several configurations were tested and compared to a reference position. The DYNEELAX® proved to be a device with very good repeatability with low variation coefficients and standard deviations. However, it is a device that is sensitive to leg positioning. The results are not sensitive to changes in the angle and the position of the displacement sensor, or the angle of the rotation sensor. The device becomes slightly sensitive to the positioning of the ankle and patella supports. Finally, we found that it is very sensitive to the tightening of the patella and ankle supports. DYNEELAX® also has good reproducibility despite significant differences between the experienced and inexperienced operator groups. The DYNEELAX® offers powerful tools to help operators for positioning as this step is decisive and could have a significant influence on the quality of results.

Author contribution

Théo Cojean: data analysis and interpretation, writing of the manuscript Laurence Cheze, Cécile Batailler, Henri Robert: supervision and revision of the manuscript All authors approved the final version of the manuscript.

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Ethical approval and informed consent

The ethics committee of our institution approved our study protocol and amendments (n°22.04729.000226).

Patient consent

All participants provided informed consent before participation.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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