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Reliability evaluation of the DYNEELAX[®], a new knee arthrometer

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1. Introduction

Rupture of the anterior cruciate ligament (ACL) is a common injury of the knee (Georgoulis et al. 2010). Nevertheless, objective quantification of anterior tibial translation is a decisional aid for surgeons. Today, laxity measurements are commonly obtained using arthrometers: The KT-1000TM, the RolimeterTM or the TelosTM. Nonetheless, many authors provided their inaccuracy and low reproducibility (Forster et al. 1989; Klasan et al. 2020). Another arthrometer, the GNRB[®] (Genourob, Laval, France), has shown a better reproducibility and accuracy than the other devices (Collette et al. 2012; Lefevre et al. 2014). Since 2019, a new arthrometer was developed (Genourob, Laval, France), the DYNEELAX[®]. This device is the upgrade of the GNRB[®], which combines tibial translation and tibial rotation evaluations. The aim of this study is to assess with a leg prototype the repeatability, reproducibility and sensitivity of the DYNEELAX[®].

2. Material and methods

2.1. The new knee arthrometer DYNEELAX[®]

The DYNEELAX[®], presented on Figure 1, is an automated device for laxity measurement of anteroposterior tibial translation and internal/external tibial axial rotations of the knee. A comparison is done between the two knees exerting thrust forces (134N, 150N or 200N) under the calf, and rotation couples (3N.m, 5N.m and 8N.m) on the boot where the foot is placed. Sensors record the relative displacement and internal/external rotations of the anterior tibial tubercle with respect to the femur. The knee and the ankle must be tight to avoid displacements. Markers and holes on supports allow the operator to position them correctly. Results are plotted with several curves for translations (mm/N) and rotations (deg/N.m). Thus, characteristics of the ACL and all peripheral collagenous structures can be assessed.

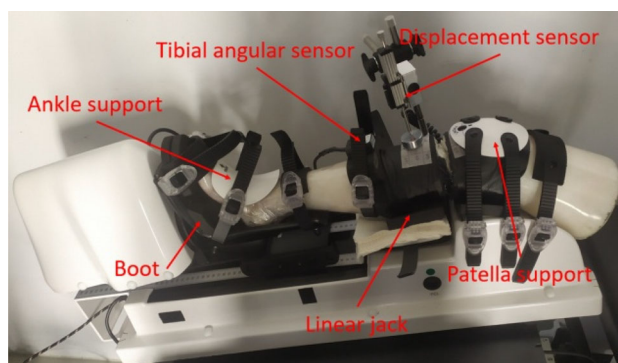


Figure 1. DYNEELAX[®] device with the prototype leg in reference position.

2.2. Prototype and protocol

This reliability evaluation was performed with a leg prototype which has been validated upstream by comparing the results with clinical data. In a second part, the DYNEELAX[®] was assessed in different positioning configurations by varying 7 parameters. Parameters are: the angle of the displacement sensor (P1) (varying between 80° and 100° every 5°) obtained with an inclinometer, the position of the displacement sensor (P2) (centered (C), high (CH), down (CD), left (CL), right (CR), upper left (HL) and right (HR), down left (DL) and right (DR)), the angle of the rotation sensor (P3) (−5°, 0°, 5°) obtained with the software, the position of the patella support (P4) (same configurations as the displacement sensor), the position of ankle support (P5) (centered (C), left (L) and right (R)), the tightening of the patella support (P6) (varying between 40N and 140N every 20N) obtained by the software, and the tightening of the ankle support (P7) which was subjectively assessed by the operator (tight and not tight). 30 measurements were successively performed for each test for all series (30x134N, 30x150N, 30x200N and 30x3N.m, 30x5N.m, 30x8N.m). The aim was to see if the variation of a parameter could have an influence on the final result. Standard deviations (STD) and coefficients of variation (CV) were used for intra-series studies. For each parameter, there is a reference configuration according to the user guide of the DYNEELAX[®] (see Table 1). The difference of means (Δm) was computed between the reference and each parameter configuration. Intervals were created in order to sum results and see their extents. Finally, reproducibility was assessed with an inter-operator study. Four operators were involved: the group 1 with two experimented operators (OP1 and OP2 with more than 6 months of experience) and the group 2 with two non-experimented operators (OP3 and OP4 who have never used the device and got only two training sessions).

Table 1. Inter-series study results for each parameter. Translation (TR), rotation (ROT), or both were performed. Intervals show the extent of difference with the reference, varying the parameters.

Parameters	Tests	Interval for Δm	Ref.
P1	TR	[-0.24mm; -0.07mm]	90°
P2	TR	[-0.33mm; 0.46mm]	C
P3	ROT	[-0.35°; -0.21°]	0°
P4	TR	[-0.02mm; 1.47mm]	C
P5	ROT	[-0.67°; 0.7°]	C
P6	TR	[0.51mm; 4.97mm]	80N
	ROT	[-0.4°; 6.11°]	
P7	ROT	[-1.32°; -0.36°]	Tight

Each operator performed 10 series of measures on the leg, where a series is composed of 1x134N, 1x150N and 3x200N for translations and 1x3N.m, 1x5N.m and 3x8N.m for internal and external rotations, according to the DYNEELAX[®] user guide. Only data at 200N and 8N.m were presented here. 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. For positioning, we recorded the same parameters as in the first part of the study, with only the time in addition. Some results could be obtained: intra-series studies per operator (computing means, standard deviations and variation coefficients), inter-series studies per operator, intra-group comparison and inter-group comparison.

3. Results and discussion

Repeatability part showed excellent results for intra-series studies. For all parameters, whatever the change of configuration, on each series of measurements, on average $STD = 0.035\text{mm} \pm 0.021\text{mm}$ (CI95% [0.03mm;0.039mm]), and $CV = 0.77\% \pm 0.3\%$ (CI95% [0.7%;0.83%]) for translations and $STD = 0.09^\circ \pm 0.15^\circ$ (CI95% [0.06°;0.13°]), and $CV = 1.77\% \pm 1.57\%$ (CI95% [1.44%;2.11%]) for rotations.

Table 1 shows sensitivity results of the DYNEELAX[®] according to positioning configurations. The device is a little bit sensitive to the change of angle (P1) and position of the displacement sensor (P2), as well as to the change of angle of the rotation sensor (P3) and the position of the ankle support (P5). The DYNEELAX[®] is a bit more sensitive to the change of position of the patella support (P4), especially for low positions because it prevents tibial translations, and the tightening of the ankle support (P7). Finally, it is very sensitive to the tightening of the patella support (P6). Table 2 shows the mean laximetry results obtained by each operator at 200N and 8N.m. STD are a bit higher than in the

Table 2. Intra-operator laximetry results for reproducibility study for translations (TR) at 200N, internal and external rotations (RI and RE) at 8N.m.

	Test	MEAN \pm STD	CI95%
OP1	TR-200N	6.07mm \pm 0.71mm	[5.75mm;6.38mm]
	RI-8N.m	3.02° \pm 0.43°	[2.82°;3.21°]
	RE-8N.m	3.05° \pm 0.22°	[2.95°;3.15°]
OP2	TR-200N	5.57mm \pm 0.26mm	[5.46mm;5.69mm]
	RI-8N.m	3.29° \pm 0.44°	[3.09°;3.49°]
	RE-8N.m	3.24° \pm 0.3°	[3.1°;3.37°]
OP3	TR-200N	5.24mm \pm 0.35mm	[5.09mm;5.4mm]
	RI-8N.m	2.43° \pm 0.29°	[2.3°;2.55°]
	RE-8N.m	2.8° \pm 0.39°	[2.63°;2.97°]
OP4	TR-200N	5.19mm \pm 0.5mm	[4.96mm;5.41mm]
	RI-8N.m	2.56° \pm 0.24°	[2.45°;2.66°]
	RE-8N.m	3.2° \pm 0.34°	[3.05°;3.34°]

repeatability study. This probably comes from each positioning changes between series, or the change in tightening. But results are not very different between the two groups, especially for rotations. The main difference is the time, in general experimented operators carried out the measurement session in 5min \pm 1min against 8min \pm 2min. The rest was pretty close thanks to information provided by the DYNEELAX[®] software to guide the user.

The main limit of this study is the use of a prototype leg, because it is not completely realistic in terms of biomechanical behaviour. A further study has to be performed with patients and real knees. Moreover, it could be interesting to hire more operators and use different DYNEELAX[®] devices for the reproducibility.

4. Conclusions

The new arthrometer DYNEELAX[®] presented good results with a good accuracy and a good reliability. However, operators must be careful about positioning, as DYNEELAX[®] results are pretty sensitive, especially for the tightening of the ankle and patella support, as well as the position of the patella support.

Disclosure statement

No potential conflict of interest was reported by the authors.

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KEYWORDS DYNEELAX®; reliability; arthrometer; ACL

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