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Original Article

A non-invasive biomechanical device to quantify knee rotational laxity: Verification of the device in human cadaveric specimens

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ABSTRACT

Background: Biomechanical measurement tools have been developed and widely used to precisely quantify knee anterior-posterior laxity after anterior cruciate ligament (ACL) injury. However, validated objective device to document knee rotational laxity, though being developed by different researchers, are not yet widely used in the daily clinical practice. A new biomechanical device was developed to quantify knee internal and external rotations.

Methods: The reliability of the new biomechanical device which measures knee rotations were tested. Different torques (1-10Nm) were applied by the device to internally and externally rotate human cadaveric knees, which were held in a flexion angle of 30°. The rotations were measured by the device in degrees. There were two independent testers, and each tester carried out three trials. Intra-rater and inter-rater reliability were quantified in terms of intraclass correlation (ICC) coefficient among trials and between testers. The device was verified by the comparison with a computer assisted navigation system. ICC was measured. Mean, standard deviation and 95% confident interval of the difference as well as the root mean square difference were calculated. The correlations were deemed to be reliable if the ICC was above 0.75.

Results: The intra-rater and inter-rater reliability achieved high correlation for both internal and external rotation, ranged from 0.959 to 0.992. ICC between the proposed meter and the navigation system for both internal and external rotation was 0.78. The mean differences were 2.3° and 2.5° for internal and external rotation respectively.

Conclusions: A new knee rotational laxity meter was proposed in this study. Its reliability was verified by showing high correlation among trials. It also showed good correlation to a gold standard of measurement. It might be used to document knee rotational laxity for various purposes, especially after ACL injury, after further validation of the device in human subjects.

Introduction

Among all sport-related knee injuries, around 45% are related to ligamentous injury.[1,2] Laxity of the knee is assessed clinically in order to diagnose ligament injury and to evaluate the restoration of knee rotation stability after reconstruction procedures. The pivot shift test and the dial test are often employed by clinicians to measure knee rotational stability before and after ACL reconstruction and to compare the outcomes between different surgical methods, for example between single-bundle and double-bundle ACL reconstruction,[3–5] and ACL reconstruction with or without lateral extra-articular tenodesis.[6] However, clinical examination has some potential limitations,[7] including variable grading from

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physician due to different experience and skills. For measuring anterior knee laxity, the KT-1000, which achieves a sensitivity of 0.93 and a specificity of 0.93 with maximal manual force in a recent meta-analysis,[8] is one of the most commonly used devices to measure anterior knee laxity.[9] However, rotational knee laxity measurements of the tibia with respect to the femur, though being developed by different researchers,[10–15] are not yet widely used in the daily clinical practice.[9] Furthermore, those devices were seldom verified with a comparative instrument like a navigation system. Therefore, the development of a simple, objective, verified and reliable tool that measures tibial rotation would be of great clinical value to document knee rotational laxity of healthy knees and injured knees.

The procedures for measuring knee laxity should be simple, easy and practical in clinical setting. It may be inaccurate to use skin markers because of significant skin movement during motion, although it has been utilized in previous research to quantify tibial rotation.[16–18] Motion sensors were employed by Musahl et al.,[12] in which three electromagnetic (EM) sensors were attached to the lower limb to measure knee rotational laxity. The device was proven to be reliable on cadaver and human subjects.[14] Moreover, computer assisted navigation systems have been used to measure intra-operative knee kinematics during ACL reconstruction.[19–22] Although it was reported that the system could achieve an accuracy of 1°,[23] the procedure is invasive to the patient as it involves rigid fixation of bone pin markers.

In this study, a new meter for measuring tibial rotation was presented. The meter consisted of an ankle orthosis, a torque sensor and one motion sensor. The orthosis was used to prevent any ankle motion when torque was applied. Torque and motion sensors were used to measure the applied torque and the corresponding tibial rotation. The objective of this study was to measure the inter-rater and intra-rater reliability of the proposed meter and to compare this device with a gold standard of measurement. It was hypothesized that the meter would reliably and accurately measure tibial rotation.

Materials and methods

We presented here the details of the knee rotational laxity meter, which aimed to measure external and internal tibial rotation. The meter consisted of an ankle orthosis, a torque sensor with a handle bar and one motion sensor at the bottom of the meter. The orthosis is a common orthotic device that is used to immobilize the ankle joint of patients suffering from ankle related injuries. Three sizes of orthosis that accommodated patients with different sizes of foot were fabricated in the Department of Prosthetics and Orthotics. Next, a torque sensor (FUTEK's TFF400, USA), which monitored the value of applied torque, was mounted at the bottom of each orthosis. A handle bar fixed on the torque sensor allowed tester to apply torques to the knee joint. One EM motion sensor with an accuracy of 1.4 mm Root Mean Square (RMS) and 0.5° RMS, as stated by the manufacturer (Trak STAR Ascension Technologies Corporation, USA) was further attached to the other side of the torque sensor such that its longitudinal axis was along the tibia's axis of rotation. The motion sensor provided six degrees of freedom of its orientation and position with high speed and accurate tracking data. The orientation data were outputted to a laptop computer. It was used to measure tibial rotation during the laxity test.

In this study, three cadaveric formalin preserved human lower extremities were used. The experiment was conducted in mortuary of Prince of Wales Hospital, Faculty of Medicine, The Chinese University of Hong Kong. The specimens were checked by inspection, palpation and physical examination to exclude any obvious bony deformity, previous fracture and ligamentous hyper-laxity.

For all the specimens, femurs were sawed at 15 cm above the joint line. Two 30 cm long bone pins were drilled through the femur from medial to lateral side. It was then fixed on an autopsy table using two custom-made clamps that allowed free movement of tibia for conducting biomechanical testing. Another two pairs of 4.5 mm pins were inserted into the anterior side of the distal femur and proximal tibia. These pins were used for anchoring trackers of the computer assisted navigation system.

An intra-operative navigation system (BrainLAB, Germany) with ACL Reconstruction System Version 2.0 was employed as a gold standard for measuring internal and external tibial rotation. It was also used to monitor the knee flexion angle throughout the experiment. Before the start of the experiment, two sets of infrared optical motion trackers were fixed to the pins that had been drilled into femur and tibia previously. The trackers were oriented such that they could be visualized within the full range of motion by the navigation system camera. The system was calibrated by using a specialized infrared pointer to register the required bony reference points over the distal femur and the tibia. A three-dimensional model of the knee and the kinematic details were calculated by the system that presented a real-time movement of the knee including flexion, extension, internal rotation and external rotation.

Two independent testers were included in the experiment for measuring knee laxity using the proposed meter. The orthosis was secured to the leg with a tourniquet and the leg was held at 30° of knee flexion and neutral position of rotation with no torque acting on the leg. The flexion angle was determined by the navigation system. Each tester progressively applied external torque to the handle bar until 10Nm torque was reached and then 10Nm torque of internal rotation was applied in the same way (Fig. 1). A maximum of 10Nm torque was applied because human comfortable limit was reported to be between 5 and 10Nm.[24] The measurements were repeated three times for each tester. Between each trial the handle was released to let the specimen return to the neutral position. The boot set-up was not removed or replaced between the tests of the same specimen. The first tester repeated the whole procedure for the rest of the knee specimens on the same day. The data from the navigation system was recorded by a technician while the EM sensor data were automatically recorded in the computer for further analysis.

For statistical analysis, single measurement intraclass correlation (ICC) with 95% confidence interval (CI) was used to gauge intra-

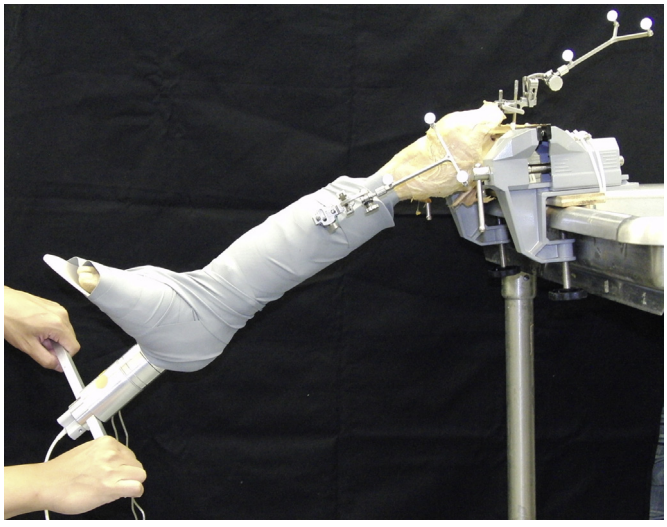

Fig. 1. Experimental setup for verifying knee rotational laxity meter.

rater and inter-rater reliability. Two-Way Random-Effects Model of ICC was employed. It was calculated in absolute agreement. For intra-rater reliability, the ICC across three trials was calculated for both testers. The average of the three trials for tester 1 would be compared to the average of the three trials for tester 2 to determine inter-rater reliability. Data from the proposed meter and the navigation system would be compared. ICC was measured. Mean, standard deviation and 95% CI of the difference as well as root mean square difference at different applied torques were calculated. All parameters were reported for internal and external rotations separately. An ICC value greater than 0.75 indicates good to excellent reliability as described by Koo et al.[25]

Results

The EM sensor at the bottom of the proposed meter measured tibial rotation relative to femur. The internal and external rotation angles increased with applied torque to the knee for both the proposed meter and the navigation system (Fig. 2). At 5Nm applied torque, the total range of rotation measured from the proposed meter (from the navigation system) was 38.0 ± 2.0 (34.0 ± 2.6) degrees with 21.3 ± 0.6 (19.7 ± 1.5) degrees internal rotation and 16.7 ± 2.5 (14.3 ± 1.2) degrees external rotation. The highest applied torque of 10Nm resulted in the total range of rotation of 59.3 ± 3.5 (43.3 ± 1.2) degrees with 32.7 ± 2.5 (24.0 ± 2.0) degrees internal rotation and 26.7 ± 3.2 (19.3 ± 1.2) degrees external rotation.

For reliability, intra-rater and inter-rater reliability achieved high correlation for both internal and external rotation, ranged from 0.959 to 0.992 (Table 1). When the proposed device was compared to the navigation system as a gold standard, ICC for both internal and external rotation was 0.78, which was regarded as a reliable correlation. The mean differences between the proposed meter and the navigation system were 2.3° and 2.5° for internal and external rotation respectively. The root mean square difference varied with the applied torque, which ranged from 1.0° to 8.8° (Table 2).

Discussion

In this study, a new biomechanical device for measuring knee rotational laxity was developed, and its reliability were tested in a cadaveric model. It was also verified with a navigation system. Results showed that the correlations between and within subjects were high, which supported our hypothesis that the proposed meter was a reliable measurement tool. Though the correlation between the proposed meter and the navigation system was not as high as the intra-rater and inter-rater measurement, its ICC was above the pre-set value. Moreover, the mean difference for internal and external rotation between the two measurement tools was below 2.5°. The side-to-side difference of the total rotational range of normal knees was reported to be 4.7–7.4°.[26] The results supported that the meter was an accurate device to measure tibial rotation for assessing knee rotational laxity.

The overall reliability of the proposed meter was high and comparable to other previous studies. The ICC coefficient was reported to be above 0.94 for all intra-tester and inter-tester reliability in a similar cadaveric study in which a device for measurement of rotational knee laxity was developed.[12] The same device was further applied on living human and revealed an ICC coefficient of 0.81–0.88 and 0.77 for inter-tester and test-retest reliability respectively.[14] Other studies reported the reliability from 0.86 to 0.98 depending on the value of applied torque, rotation direction and side of the knee.[13,27]

When checking validity of a measurement tool, a comparative instrument as a gold standard could be used and the correlation coefficient between the two measurement tools should preferably be above 0.70.[28] In this study, the navigation system was employed as a gold standard for measuring tibial rotation. Since the relative

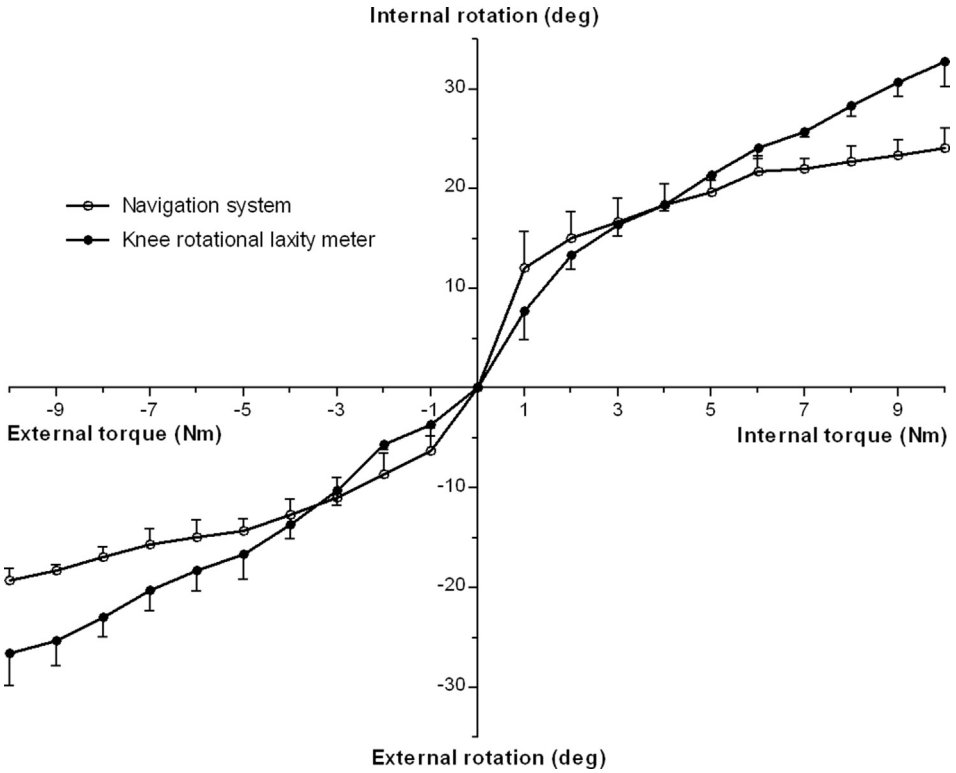

Fig. 2. Internal and external rotational angle under different applied rotational torque.

Table 1
Reliability of knee rotational laxity meter.

	Intra-rater reliability				Inter-rater reliability	
	Tester 1		Tester 2		Tester 1 and 2	
	ICC	95% CI	ICC	95% CI	ICC	95% CI
Internal rotation	0.983	0.885,0.996	0.992	0.977,0.998	0.989	0.896,0.998
External rotation	0.959	0.566,0.992	0.972	0.857,0.993	0.990	0.958,0.998

ICC: intraclass correlation CI: confidence interval.

Table 2
Comparison between knee rotational laxity meter and the navigation system.

	Torque (Nm)	Internal rotation	External rotation
ICC		0.78	0.78
95% CI of ICC		0.59,0.89	0.59,0.89
Mean difference (deg)		2.30	2.53
SD of difference (deg)		4.15	4.17
95% CI of mean difference (deg)		0.75,3.85	0.98,4.09
Root mean square difference (deg) at different torques	**1**	4.80	2.83
	2	2.08	3.42
	3	1.00	1.83
	4	1.41	2.83
	5	1.91	3.70
	6	2.52	4.16
	7	3.70	5.10
	8	5.69	6.16
	9	7.44	7.19
	10	8.83	7.53

ICC: intraclass correlation CI: confidence interval SD: standard deviation.

movement between femur and tibia was based on two sets of bone pin markers, the navigation system has been regarded as an accurate method.[29–31] However, because of its invasive procedure, such comparison could only be achieved in cadaveric model. That made our findings difficult to compare to other previous studies. Musahl and coworkers[12] tested in a best-case scenario for their new device, in which the EM sensors were directly fixed to the femur and tibia. In another cadaveric study,[11] a similar device was verified with a navigation system, and the correlation achieved was from 0.85 to 0.95. However, in this study, the tibial bone was fixed with screws to a metal bar which was cemented in a custom-made inside-boot. Therefore, the tibial fixation to the foot piece was not repeatable clinically in the mentioned two studies. In the current study, the ICC coefficient between our device and the navigation system was above the preferred value. Together with the low mean difference, we provided evidence of the validity of our proposed device.

In the present study, lower extremity specimens including knee and ankle joints, thigh, shank and foot segments were used to simulate a clinically relevant situation. To minimize ankle joint rotation and motion between the leg and the device when applying rotational torque, an orthosis was secured with a tourniquet such that the rotational torque was directly applied to the knee joint. The motion sensor was longitudinally placed at the bottom of the foot segment (attached to the device) such that its rotational axis was in line with tibia rotational axis. The assumption we made here was that the shank segment was cylindrical and therefore the motion sensor and the tibia rotated along the same axis. One advantage of this idea was to avoid placing the motion sensor directly on the skin, which would cause error up to 13° in measuring rotations,[32] especially in obese patients. From Fig. 2, the error increased during small and high applied torques though the two measurement values were highly correlated. It was possibly because pre-loading was necessary before the motion sensor value became stable. This finding was also comparable to the previous study[11] that the error at 10Nm applied torque was 8.4° and even up to 14.2° at 15Nm. It suggested that the motion between the leg and the device would not be completely avoided, especially at large applied torque. Moreover, 5Nm torque was commonly adopted in the previous studies for measuring knee rotational laxity.[10,15,33] All in all, torques ranged 4-6Nm were suggested in the future study employing our device because of its small error.

The proposed meter was designed to be clinically relevant. It would be a simple, easy operating and practical device for quantifying knee rotational laxity, especially for patients after ACL injuries in orthopaedic settings. In the present study, 30° of knee flexion was chosen. One of the reasons was that this particular knee flexion angle might be sensitive to detect knee rotational laxity for healthy, ACL deficient and reconstructed patients since the ACL has its maximum shortening peak at this flexion angle.[34] Moreover, biomechanical investigations demonstrated that ACL injuries mostly occur in slight flexion angles.[35] Furthermore, one should bear in mind that reproducibility should be verified again in human subjects before applying in clinical field. A standardized procedure for securing orthosis with different sizes to the leg should also be considered as the application of a tourniquet may not be comfortable or standardized when used in real human subjects.

This study was limited by the fact that it was a small-sized cadaveric experimental test although the device would hopefully be applied on living humans. However, as pointed out previously, it was not ethical to employ invasive procedures in human subjects. The only way to conduct such kind of research was to apply on human cadaveric specimens. Despite great efforts were made to simulate a clinically relevant situation, one limitation was that the femur was firmly attached to the autopsy table by bone pins and clamps, which was not possible when measuring laxity in real patients. Therefore, future studies were suggested to investigate a non-invasive way to stabilize the thigh. This would be important as minimizing the femur rotation would enhance accurate torque to

be applied to the knee joint.

Conclusion

A new knee rotational laxity meter was proposed in this study. Its reliability was verified in a cadaveric model by showing high correlation among trials. It also showed good correlation to a gold standard of measurement. It might be used to document knee rotational laxity for various purposes, especially after ACL injury, after further validation of the device in human subjects.

Conflict of interest

The authors have no conflict of interest relevant to this article.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.asmart.2018.11.005.

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