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An analysis of normative data on the knee rotatory profile and the usefulness of the Rotatometer, a new instrument for measuring tibiofemoral rotation: the reliability of the knee Rotatometer

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Abstract

Purpose This study proposes a simple and noninvasive instrument called the "Rotatometer" to measure tibiofemoral rotation and investigates its clinical applicability to the assessment of static rotational knee laxity.

Methods The degree of tibiofemoral rotation was measured for a sample of 94 healthy volunteers with 188 knees by using the Rotatometer. The measurement was made by two independent and blinded examiners in three sessions at one-month intervals. The normative rotational profile and its relationship with gender and age were evaluated, and inter-observer reliability and intra-observer reliability were calculated.

Results Males showed 62° ± 5° of external rotation, whereas females, 64° ± 5°. Males showed 44° ± 5° of internal rotation, whereas females, 49° ± 4°. Females showed significantly higher degrees of rotation than males. Tibiofemoral rotation was not correlated with age, and external rotation and internal rotation had a moderate positive relationship. Inter-observer reliability ranged from 0.84 to 0.91 for external rotation and 0.90 to 0.95 for internal rotation, and intra-observer reliability ranged from 0.69 to 0.89 for external rotation and 0.87 to 0.95 for internal rotation.

Conclusions The results suggest the Rotatometer to be a simple and noninvasive device with high inter- and intra-observer reliability. The device can provide a normative rotational profile for reference purposes and thus can be used to determine the preoperative and postoperative rotational status of knees with anterior cruciate ligament injuries and compare results from different reconstruction techniques.

Level of evidence Diagnostic study, Level III.

Keywords Rotatory profile · Tibiofemoral rotation · Pivot shift · Rotatory laxity · Measurement device

Introduction

Tibiofemoral rotation is known to be controlled by the anterior cruciate ligament (ACL), the joint capsule, the meniscus, the collateral ligament, and the iliotibial band. Among these, the ACL, particularly the posterolateral (PL) bundle, plays a key role in the kinematics of internal and

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external rotation [36]. An assessment of the rotational profile is necessary for knees with ACL injuries because abnormal kinematics from rotational laxity is responsible for the initiation and progression of knee osteoarthritis by shifting the load distribution to the cartilage [32]. The restoration of normal rotational knee kinematics is a main goal of various surgical ACL reconstruction procedures, and therefore appropriate assessment tools for rotational laxity and normative rotational profiles are required because they facilitate the identification of the preoperative and postoperative rotational status of the injured knee and a comparison of outcomes for different ACL reconstruction techniques (e.g. different tunnel placement and single-/double-bundle reconstruction procedures).

Currently, the pivot-shift test is the most widely used clinical technique for assessing knee rotational laxity. It is used not only for diagnosing a primary ACL injury but also for measuring outcomes of ACL reconstruction [3]. Its clinical applicability has been demonstrated by its positive correlation with patient-reported functional laxity, poor clinical outcomes, and late osteoarthritis [11, 12, 30]. However, it may not completely reflect the degree of rotational laxity and is not quantifiable. In addition, it depends on the examiner's subjective assessment, and the clinical grade is not consistently reproducible [10, 15, 22, 24]. Further, the test can cause pain or discomfort for the examinee, thereby reducing accuracy and reliability [24].

Various mechanical devices have been developed over the last decade to measure tibiofemoral rotation and assess static knee rotational laxity [2, 4–6, 8, 9, 15, 16, 20, 21, 23, 25, 29]. The KT-1000® Knee Ligament Arthrometer (MEDmetric, San Diego, CA, USA) [8], the GNRB® system (Genourob, Laval, France) [15], and the Genucom Knee Analysis System (FARO Technologies Inc., Lake Mary, FL, USA) [20] are some noninvasive tools that can be used for knees with ACL injuries. These devices provide better measurement accuracy and consistency than the pivot-shift test but focus more on the assessment of anterior–posterior laxity. The Rolimeter® (Aircast Europe, Neubeuern, Germany) [3, 9], the Rotameter [14, 16, 21], and the KneeKG™ system [18] are noninvasive and objective tools for assessing rotational laxity, and their clinical usefulness has been verified [3, 9, 14, 16, 18, 21]. However, they require uncomfortable patient positions and difficult measurement procedures. Robotics (41) and computer navigation systems [7, 13, 26, 35] have been introduced to assess tibiofemoral rotational laxity but cannot be used in clinical settings because they involve invasive procedures and difficult measurement methods. In addition, no study has provided a normative rotational profile for the measurement of tibiofemoral rotation.

This study (1) proposes a novel instrument called the "Rotatometer" (not yet commercially available) to assess static rotational knee laxity, (2) provides a normative rotational profile, (3) determines its relationship with gender and age, and (4) assesses the reliability of the proposed device.

Materials and methods

From March to June in 2012, 94 healthy volunteers with 188 knees were examined at two medical centres (KHU and CHA, hospitals of two of the authors). The examination was performed independently at KHU (33 males and 20 females for a total of 53) and CHA (21 males and 20 females for a total of 41). Physical examinations were performed for all subjects before the actual rotational measurement to identify and exclude knees with any laxity or hypermobility. No individual with any previous knee surgery or trauma was included. Mean ages of the subjects were 31 ± 9 and 31 ± 3 years for KHU and CHA, respectively, and mean BMI scores were 24 ± 2 and 24 ± 3, respectively.

The Rotatometer consists of the body, a footrest, a custom-made boot with straps, and a Velcro thigh strap. The body is connected to an electric power source and has a light-emitting diode window in front showing the degree of rotation of the footrest located on top of the body with a round rotating platform. The footrest has a parallel handlebar in front in line with the second toe, and the degree of rotation is recorded as zero when the bar is facing forward. The custom-made boot is connected to the footrest through a rugged surface and provides a tight fit, and it can be adjusted to different sizes of the lower leg to provide a tight fit from its U-shaped boot and three Velcro straps (one placed on the dorsum of the foot). A Velcro thigh strap is applied to keep it stationary as much as possible while measuring tibiofemoral rotation.

The examinee sat on an ordinary chair with armrests on both sides, and his or her hip, knees, and ankle joints were flexed to 90°. The examinee's lower extremity was secured and tightly fit inside the boot. To avoid unnecessary movements from the thigh, a large Velcro strap was applied to encircle the mid-thigh portion and anchored tight to the armrest. Then the manual maximal torque from the examiner was applied to the handlebar until the examinee's apprehension of end-feel as a displacing force. Then the degree shown on the light-emitting diode window was recorded. The rotational force was transmitted to the knee joint, causing tibiofemoral rotation. All subjects were under no anaesthesia or analgesia. The electronic torque key was not used because the application of some given torque consistently to every examinee without considering the size of each individual's leg or leg muscles may produce measurement bias. If the same amount of torque is applied to an obese patient with bulky leg muscles and a thin and slender patient but both have ideally the same knee rotational status, then the measurement provides very different degrees of tibiofemoral rotation for these two patients.

The measurement procedure was repeated over three sessions for each knee at one-month intervals. Two orthopaedic surgeons at each medical centre participated in the blinded measurement during each session. Each measurement for one leg took less than a minute, and there were no measurement errors. It took <5 min for the examiner to acquire the measurement technique. This study was approved by the institutional review board (IRB) of the institution (CHA, BD2013-025D).

Statistical analysis

All rotational variables were tested for normality by using the Shapiro–Wilk test, and the results show that they followed a normal distribution. The results for each measurement are shown as the mean ± standard deviation. Density plots and quantiles are expressed in each type of rotation. Student's *t* test was conducted to identify any significant difference between gender. A Pearson correlation analysis was conducted to determine the relationship between the degree of each rotation and patient age. Demographic data and measurements using the proposed device were compared between the two medical centres. Inter-observer reliability was assessed from two measurements by two blinded examiners within the same day. Intra-observer reliability was assessed using a test–retest method from three measurements at one-month intervals. JMP Statistical Discovery^{TM} (SAS Institute Inc, Cary, NC, USA) and R (Version 2.12; Comprehensive R Archive Network, Boston, MA, USA) were used in all statistical analyses, and significance was assumed at $p < 0.05$.

Results

External as well as internal tibiofemoral rotation followed a normal distribution. Under manually applied torque, 63° ± 5° were measured for external rotation, and 46° ± 5°, for internal rotation (Table 1). There was a significant gender difference for each type of rotation (Fig. 1). Males showed 62° ± 5° of external rotation, and females, 64° ± 5°. Males showed 44° ± 5° of internal rotation, and females, 49° ± 4°. Females showed significantly higher degrees of tibiofemoral rotation than males ($p = 0.021$ for external rotation and $p < 0.001$ for internal rotation). Table 2 shows the quantiles for each rotation type and gender.

Neither external nor internal tibiofemoral rotation was correlated with age regardless of gender (Fig. 2). In addition, external rotation and internal rotation had a moderately positive relationship ($p < 0.001$, $r = 0.56$), indicating that the higher the degree of external rotation, the higher the degree of internal rotation of the knee joint.

Table 1 The quantiles of normative tibiofemoral rotations using the "Rotatometer"

Quantiles	External rotation		Internal rotation	
	Men	Women	Men	Women
100.0 % max	70	74	59	58
99.5 %	70	74	59	58
97.5 %	70	54	53	58
90.0 %	68	50	47	54
75.0 %	66	47	47	51
50.0 % median	62	43	45	48
25.0 %	58	39	43	46
10.0 %	55	34	37	44
2.5 %	53	33	30	42
0.5 %	53	32	29	42
0.0 % min	53	32	29	42

Unit: degrees of angle

For inter-observer reliability, the ICC ranged from 0.84 to 0.91 for external rotation and from 0.90 to 0.95 for internal rotation. For intra-observer reliability, the ICC ranged from 0.69 to 0.89 for external rotation and from 0.87 to 0.95 for internal rotation. Inter-observer reliability in the third session was higher than that in the other two sessions for both rotation types. In addition, intra-observer reliability between the second and third sessions was higher than that between the first and second sessions.

Because there exists no gold standard for the exact tibiofemoral rotation, degrees of each type of rotation from the two medical centres were compared for an indirect analysis of accuracy. Both rotation types showed significant differences between the two centres (Table 2), casting some doubt on measuring under standard measurement protocol.

Discussion

The most important contribution of this study includes a normative rotational profile based on the Rotatometer, its relationship with gender and age, and an evaluation of the reliability of the proposed instrument. An assessment of a static knee rotational profile is crucial not only for understanding normal knee kinematics but also for preoperative and postoperative status of knees with ACL injuries. However, existing measurement tools lack objectivity or clinical usefulness and fail to provide a normative rotational profile, although the degree of tibiofemoral rotation of the injured knee should be considered in context.

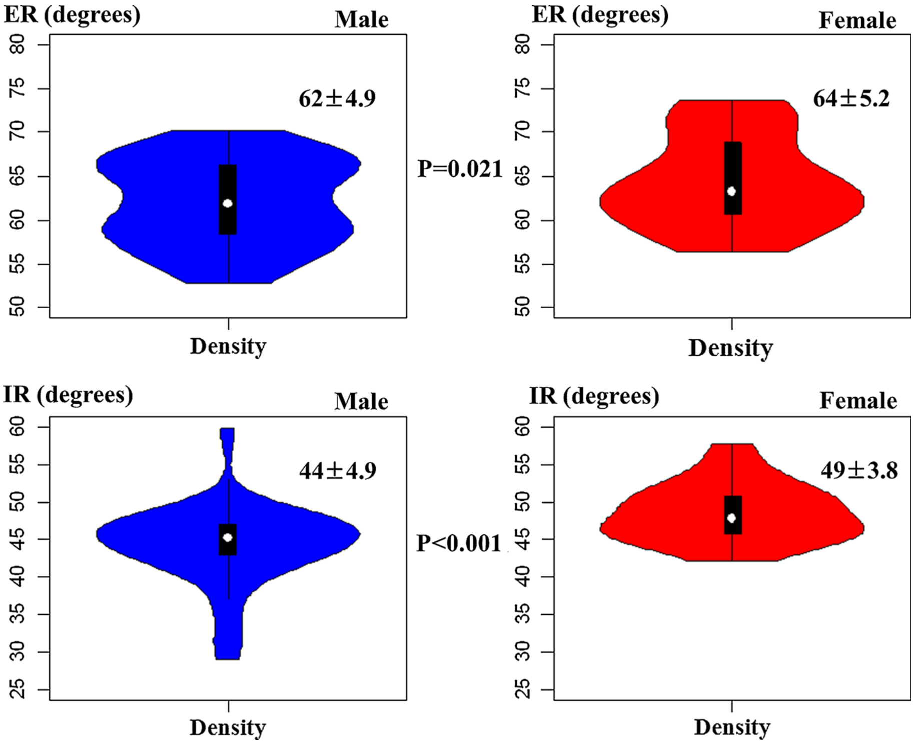

Fig. 1 Density plots showing the degree of external and internal tibiofemoral rotation. Women showed a significantly higher degree of tibiofemoral rotation than men ($p = 0.021$ for external rotation; $p < 0.001$ for internal rotation). All graphs are symmetric with the *box plot* (*black*) inside, and the *horizontal line* indicates the density of data such that the wider the horizontal area, the more the data. *ER* external rotation, *IR* internal rotation

Table 2 A comparison of tibiofemoral rotations and demographic status between the two independent centres

Two medical centres	KHU	CHA	*p* value
External rotation	63° ± 5°	53° ± 5°	<0.001
Internal rotation	46° ± 5°	38° ± 8°	<0.001
Age (years)	31 ± 9	31 ± 3	(n.s.)
Gender (M:F)	32:21	21:20	(n.s.)
Body mass index (kg/cm^2)	24 ± 2	24 ± 3	(n.s.)

This study has several limitations. First, the ACL condition is known to affect tibial rotation at about 30° of knee flexion. In this study, rotation was measured at 90° of knee flexion. It is easier for the patient to maintain a constant position throughout the measurement procedure for better reliability. Keeping the knee consistently at 30° of flexion for all measures is difficult for outpatients because such a measurement instrument requires some frame that can be adjusted to fit the patient's height or leg length, thereby requiring a bulky design, particularly if a prone position is necessary. The proposed instrument addresses this issue by measuring tibiofemoral rotation at 90° of knee flexion, allowing for a more comfortable and easier measurement procedure that can be used on an outpatient basis and providing more reliable clinical results. Second, it is unclear how simple and easy it would be to use the proposed device in reality. That is, no survey was administered from the perspective of examinees or examiners, although the short measurement time, no measurement error, and an easy measurement technique were described. Third, the accuracy of the device was not evaluated. Because there is no gold standard on the actual tibiofemoral rotation, no study can ensure the accuracy of the device. In the present study, although there were no demographic differences, there were significant differences in rotational values between the two medical centres, casting some doubt on the accuracy of the proposed device. However, these differences are likely due to examiner-dependent factors and thus may be minimized through a standardized measurement protocol. Most rotational devices, including the Rotatometer, are designed to be used by analysing side-to-side differences [1, 19, 22] and thus can be clinically useful for comparing the degree of rotation between two independent groups as quantiles if normative data are employed. Fourth, when a patient has some painful knee condition such as acute MCL, ACL, or meniscus injuries, the patient's guarding behaviour can underestimate the laxity of tibiofemoral rotation. In this regard, the guarding effect of injured knees should always be considered to prevent measurement bias.

Several measurement devices have been proposed to assess static knee rotational laxity (Table 3), and some make use of robotics (41), computer-aided navigation systems [7, 13, 26, 35], radiostereometric analysis methods [31], or stress radiography methods [27]. Such devices pursue objective and precise measurements but tend to be invasive or difficult to control. However, the Rotatometer

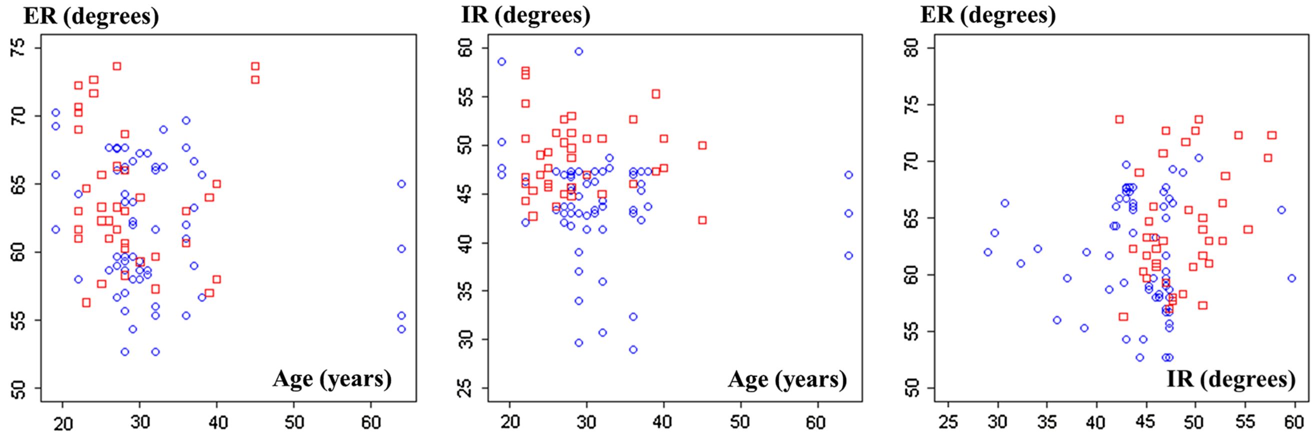

Fig. 2 *Scatter plots* showing the relationships between external (*left*) and internal (*middle*) tibiofemoral rotation and age and the relationship between external and internal tibiofemoral rotation (*right*). Neither external rotation nor internal rotation was correlated with age ($p = 0.072$ and $p = 0.065$, respectively), but their relationship was moderately positive ($p < 0.001$, $r = 0.56$). *Blue circles* indicate males, and *red rectangles*, females. *ER* external rotation, *IR* internal rotation

Table 3 Objective and noninvasive measurement devices for static knee rotational laxity

Author	Device	Force transmission	Angle measurement	Position & #Flexion (hip/knee)	Reliability
Almquist [2]	Rottometer	Manual to Foot	Manual	Seated 90°/90°	NR
Branch [5]	Robotic knee testing sys	Motorized to foot	Inclinometer	Supine NR/25°	Intra-ICC: >0.95 Inter-ICC: >0.77
Lorbach [15–17]	Rotameter	Manual to Foot	Electronic	Prone 0°/30°	Intra-ICC: 0.67–0.94 Inter-ICC: 0.88–0.98
Musahl-Tsai [24]	Knee laxity device	Manual to tibia	EM	Supine NR/NR	Intra-ICC: 0.67–0.94 Inter-ICC: 0.88–0.98
Park [26]	NR	Motorized to tibia	LED marker	Seated 85°/60°	NR
Shultz [28]	NR	Manual to tibia	EM	Supine 10°/20°	Intra-ICC: >0.86 Inter-ICC: NR
Current study	Rotatometer	Manual to foot	LED marker	Seated 90°/90°	Intra-ICC: 0.89–0.95 Inter-ICC: 0.91–0.95

NR not reported, *EM* electromagnetic

Flexion: hip and knee joints flexion. Ankles are flexed to about 90°

is noninvasive and easy to use. For example, it takes about a minute to measure the rotation of one knee and <5 min to teach its use to a clinician and is reliable. In addition, it can be used on an outpatient basis.

Recorded tibiofemoral rotation data should be considered in context with normative baseline data and can be expressed as quantiles, particularly when comparing two independent groups. To the authors' knowledge, this study is the first to report normative data on a static knee rotational profile depending only on the examinee's gender. The examinee's age had no effect on the degree of rotation.

For increased accuracy and reliability, several suggestions have been made concerning the amount of torque (2, 5, 10, and 15 Nm) and its location (the foot or tibia). Applied torque is partly absorbed by the foot, the ankle joint, and the instrument itself, and its amount remains to be investigated. Therefore, applying a given amount of torque to every examinee regardless of their demographic status (e.g. the BMI, the size of the knee or lower leg, and the presence of bulky muscles around the knee) may reduce measurement accuracy. In this study, manual torque was applied in all cases until the apprehension of end-feel causing the examinee's pain or discomfort based on the assumption of individual differences in the adjustment of soft tissue to applied torque. However, this raises a question about the subjectivity and individual variability of end-feel.

The location of torque application should also be considered. Applying it to the foot is known to be the best solution because of the anatomy of the lower leg. Applying it directly to the tibia accurately is technically difficult and may produce incorrect measurements because it may cause some skin movement in the lower leg [22].

Another important factor is the examinee's position when measuring tibiofemoral rotation [22]. Hip flexion is reported to influence tibiofemoral rotation, with lower values observed near hip flexion relative to hip extension (for a given knee flexed to 20°) because of the tightness of the hamstring [28]. Knee flexion about 20°–30° is known to be most appropriate for a pivot-shift test. However, it is easier to control unwanted femoral rotation at 90° of knee flexion than at full extension [1]. Therefore, an examinee's position (seated, supine, prone, or lateral decubitus with respective hip and knee joint flexion angles) has both pros and cons, and any fixed position cannot be the gold standard for the assessment of a rotational profile.

Another problem in measuring tibiofemoral rotation is the mobility of the thigh. In this study, a large Velcro strap was used to stabilize the mid-thigh for more reliable test results, and a seated position with hip and knee joints flexed to approximately 90° was adopted. This was assumed to be the most comfortable position for both examiners and examinees and for maximum reliability.

Producing consistent outcomes is the most important feature of any rotational device [22]. Reliability depends not only on the instrument itself but also on the measurement protocol. In this study, the inter-observer reliability was 0.91 for external rotation and 0.95 for internal rotation in the final session and showed an increasing trend over time. In addition, intra-observer reliability was 0.89 for external rotation and 0.95 for internal rotation between the second and third sessions, exceeding that between the first and second sessions. This may be due to the examiner's self-education and learning. These results are consistent with the findings of previous studies. The results suggest that the Rotatometer, a simple, easy, and comfortable device for assessing tibiofemoral rotation, can produce highly reliable outcomes and that it can be enhanced by appropriate measurement training for the examiner.

Conclusions

The Rotatometer is a simple, noninvasive, and easy-to-control measurement device that can be used to identify the preoperative and postoperative rotational status of knees with ACL injuries on an outpatient basis.

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