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The diagnostic reliability of the quantitative pivot-shift evaluation using an electromagnetic measurement system for anterior cruciate ligament deficiency was superior to those of the accelerometer and iPad image analysis

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Abstract:	<p>Purpose: Several non-invasive devices have been developed to obtain quantitative assessment of the pivot-shift test in clinical setting using similar but diverse measurement parameters. However, the clinical usability of those measurements has yet to be closely investigated and compared. The purpose of this study was to compare the diagnostic accuracy of three non-invasive measurement devices for the pivot-shift test.</p> <p>Methods: Thirty patients with unilateral anterior cruciate ligament (ACL) injury were enrolled. The pivot-shift test was performed under general anaesthesia. Three devices, an accelerometer system (KiRA), an image analysis iPad application (iPad), and electromagnetic measurement system (EMS), were used simultaneously to provide two parameters, namely tibial acceleration monitored using KiRA and EMS, and tibial translation recorded using iPad and EMS. Side-to-side differences in each parameter and correlation between the measurements were tested, and a receiver operating characteristic (ROC) curve analysis was conducted to compare their measurement accuracy.</p> <p>Results: Significant side-to-side differences were successfully detected using any of</p>

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Abstract

Purpose: Several non-invasive devices have been developed to obtain quantitative assessment of the pivot-shift test in clinical setting using similar but diverse measurement parameters. However, the clinical usability of those measurements has yet to be closely investigated and compared. The purpose of this study was to compare the diagnostic accuracy of three non-invasive measurement devices for the pivot-shift test.

Methods: Thirty patients with unilateral anterior cruciate ligament (ACL) injury were enrolled. The pivot-shift test was performed under general anaesthesia. Three devices, an accelerometer system (KiRA), an image analysis iPad application (iPad), and electromagnetic measurement system (EMS), were used simultaneously to provide two parameters, namely tibial acceleration monitored using KiRA and EMS, and tibial translation recorded using iPad and EMS. Side-to-side differences in each parameter and correlation between the measurements were tested, and a receiver operating characteristic (ROC) curve analysis was conducted to compare their measurement accuracy.

Results: Significant side-to-side differences were successfully detected using any of the measurements (all $p < 0.01$). KiRA demonstrated moderate correlation with the EMS for tibial acceleration ($r = 0.54$; $p < 0.01$), while poor correlation was observed between iPad and the EMS for the translation ($r = 0.28$; $p < 0.01$). The ROC curve analysis demonstrated better accuracy for detection of ACL insufficiency in the EMS than KiRA and iPad for tibial acceleration and translation, respectively.

Conclusions: Although all three measurements were similarly capable of detecting ACL deficiency, the EMS has the advantage of comprehensive evaluation of the pivot-shift test by evaluating both tibial acceleration and translation with higher accuracy than those of KiRA and iPad. It could be suggested that any of those measurement tools might improve

29 the clinical diagnosis of ACL insufficiency.

30

31 **Keywords:** anterior cruciate ligament, pivot-shift test, quantitative evaluation,
32 acceleration, anterior tibial translation

33

Introduction

The pivot-shift test is commonly used for clinical evaluation of knee rotational laxity in patients who have anterior cruciate ligament (ACL) deficiency and have undergone ACL reconstruction, and the results are related to the subjective function [14] and long-term degenerative change of the knee [13]. However, this clinical manual test is difficult to compare between different surgeons and institutions because of the wide variation of testing techniques and judgements [16, 29, 32]. In addition, only four levels of descriptive grading are provided by the clinical pivot-shift test [12].

In an attempt to achieve comparable and meticulous evaluation of the pivot-shift test, several measurement systems have been developed [5, 11, 18, 23, 28]. Some of them can be operated in a non-invasive manner and, thus, are clinically applicable [9, 11, 20, 24, 25]. However, the clinical usability of such measurement systems has not been fully examined and compared.

The purpose of this study was to compare the diagnostic accuracy of three different non-invasive measurement devices for the pivot-shift test. It was hypothesized that all three measurements would have similar clinical accuracy to detect ACL deficiency.

Materials and Methods

Thirty patients with unilateral ACL injury (23 ± 10 years old, 12 men and 18 women) who underwent ACL reconstruction at our institution between January 2013 and December 2014 were included. The inclusion criteria were age from 14 to 50 years, within 12 months from injury, and no damage on the contralateral knee. The exclusion criteria were history of a previous knee surgery, combination of collateral ligament injuries of grade III or higher, posterior cruciate ligament tear, and osteoarthritic knee. The study

protocol was approved by the institutional review board in Kobe University, and informed consent was obtained from all the patients.

The pivot-shift test was performed prior to the planned ACL reconstruction under general anaesthesia while quantitative evaluations were conducted using three non-invasive measurement systems simultaneously, namely the electromagnetic measurement system (EMS) [11, 31], triaxial accelerometer system of KiRA (KiRA) [20, 24], and the iPad app for simple image analysis (iPad) [9] (Figure 1). The measurement data were collected on site electronically, and the data were analysed to provide measurement values. The detailed measurement methods using each device are described below.

Electromagnetic measurement system: The electromagnetic sensors (Liberty, Polhemus, Colchester, VT, USA) were attached on the thigh and shank by means of plastic braces. The third sensor was used to input the three-dimensional (3-D) positions of anatomic bony landmarks for the femur and tibia in relation to the sensors attached to the thigh and shank, respectively. The anatomical landmarks on the femur are the major trochanter, medial epicondyle, and lateral epicondyle. Those on the tibia are at the intersection of the medial collateral ligament and knee joint line, fibula head, and medial and lateral malleoli of the ankle. Once the anatomic coordinate system of the knee according to Grood and Suntay [8] is set up in a virtual space based on the 3-D position data of the femur and tibia, the 6-degree-of-freedom knee kinematics can be monitored in real time during the pivot-shift test. Relative tibial anterior translation and its acceleration can be calculated from the data of the tibial anteroposterior translation [11, 15, 34].

Triaxial accelerometer system: The accelerometer, KiRA (Kinematic Rapid

Assessment, Orthokey LLC, Lewes, DE, USA), was attached to the lateral aspect of the shank between the tibial tuberosity and Gerdy's tubercle with a wrapping band. It was wirelessly connected to a computer with Bluetooth, where the instant acceleration of the knee movement was recorded using the original software as described in a previous study [20, 24].

Simple image analysis using iPad: Three round yellow stickers, 3/4 inch in diameter (Color Coding Labels, Avery Dennison Corporation, Pasadena, CA, USA), were attached to the skin over specific bony landmarks, including the lateral epicondyle, Gerdy's tubercle, and fibular head for the image analysis of the pivot-shift [10]. Movie capturing the lateral aspect of the knee joint was completed during the pivot-shift test with the video function (resolution of 1080p and frame rate of 30 fps) of the iPad (Apple, Cupertino, CA, USA), not to miss the three stickers. The iPad was held within 2 m, perpendicular to the lateral aspect of the knee as much as possible. The specially programmed iPad application (PIVOT, Impellia, Pittsburgh, PA, USA) for the image analysis was used to provide the lateral translation of the knee joint based on the relative movement of the three stickers during the testing.

Eventually, two measurement parameters were provided by the three devices, namely tibial acceleration and translation. The tibial acceleration of the pivot-shift was measured using KiRA and the EMS, whereas the anteroposterior tibial translation was provided using iPad and the EMS. For each testing procedure, the pivot-shift test was performed five times, and the maximum and minimum of the five measured values were excluded. The average of the remaining three values were then used for further analysis.

Institutional review board approval was obtained from the ethics committee of Kobe University Graduate School of Medicine (Approval No. 341).

Statistical analysis

An a priori power analysis revealed that 27 subjects were required to detect a 0.5-m/sec² difference in tibial acceleration, assuming a two-sided Student *t* test, a power of 0.80, a significance level of 0.05, and a common variance of 0.5 m/sec² based on the data from the previous reports [11]. All values assessed were expressed as mean \pm standard deviation (SD). A dependent *t* test was used to test the side-to-side difference of each measurements, and the Pearson correlation coefficient was calculated to evaluate the correlation between the two tibial accelerations measured using KiRA and the EMS, and the two tibial translations measure using iPad and the EMS. In addition, the receiver-operating characteristic (ROC) curve was plotted, and the area under the curve (AUC), sensitivity, and specificity of each evaluation parameters were determined. The results were analysed statistically by using a statistical software package (StatView 5.0, Abacus Concepts Inc, Berkeley, CA, USA). Statistical significance was set at a *p* value of 0.05.

Results

The knees with ACL injury had significantly larger tibial acceleration than the contralateral intact knees, detected using either KiRA or EMS (both *p* < 0.01; Table 1). The accelerations measured using KIRA and the EMS moderately correlated (*r* = 0.54; *p* < 0.01; Figure 4). In the ROC curve analysis, the EMS had a slightly better AUC and sensitivity than KiRA when the cutoff levels to detect ACL injury were set at 1.5 m/s² for the EMS and 3.0 m/s² for KiRA (Figure 2, Table 2).

Tibial translation was also significantly different between the knees with ACL injury and the contralateral knees on the basis of the iPad and EMS measurements (both *p* <

0.01; Table 1). Only a poor correlation was observed between the iPad and EMS measurements of tibial translation ($r = 0.28$; $p < 0.01$; Figure 5). In the ROC curve analysis, the EMS demonstrated better AUC, sensitivity, and specificity for measurement of tibial translation than iPad when the cutoff levels for detection of ACL injury were 9.0 mm for EMS and 0.73 mm for iPad (Figure 3, Table 3).

Discussion

The most important finding of this study was that the diagnostic accuracy of EMS was superior to those of KiRA and iPad using either tibial acceleration or translation, respectively, although all three measurements could detect the side-to-side difference in the patients with unilateral ACL injury. Tibial acceleration and translation are two major parameters for the quantitative evaluation of knee rotational laxity [17, 22], and either KiRA or iPad provides one of those quantitative parameters without any laborious procedure required for EMS measurement, which includes attaching the sensors and inputting the 3-D positions of the bony landmarks. However, EMS may have the advantage of evaluating two parameters simultaneously, especially in some cases whose pivot-shift does not have a significant increase in tibial translation but has a substantial surge of tibial acceleration, or vice versa. As the pivot-shift is not a simple movement [7], this complex abnormal knee laxity should be better evaluated by using more than one parameter, if possible.

The relationships between three measurement systems such as the EMS, KiRA, and the image analysis iPad application were previously tested in a cadaveric study [2]. Similar to the present study, a significant correlation was observed between the EMS and KiRA measurements of tibial acceleration, and between the EMS and the image analysis

measurements of tibial translation [2]. However, the clinical diagnostic values such as the sensitivity and specificity for diagnosing ACL insufficiency were not examined in the previous cadaver experiment.

In this study, the sensitivities of KiRA and the EMS for detecting ACL insufficiency by tibial acceleration were 59% and 77%, respectively. These results were higher than those of the previously reported manual tests [6, 19, 33]. In addition, the sensitivity of >70% by the tibial translation was also satisfactory for either iPad or the EMS. Thus, we could suggest that any of those measurement tools might improve the clinical diagnosis of ACL insufficiency.

There are technical differences between the tibial accelerations evaluated with the EMS and that with KiRA, and between the tibial translations measured using the EMS and iPad. The tibial acceleration during pivot-shift measured using the EMS was calculated on the basis of the tibial anteroposterior translation data by capturing the relative motion between the tibia and the femur [11], whereas the KiRA system directly measures the instant acceleration of the tibial movement without clearly identifying the direction of the acceleration [20, 23]. Therefore, the EMS might underestimate the acceleration of the pivot-shift by overlooking the axial rotation movement, while the KiRA could overestimate the acceleration by including the global lower leg movement in addition to the knee joint movement. Thus, the acceleration measured with KiRA was larger than that measured using the EMS, about two times on average. However, it is interesting that moderate correlation was observed between the two measurements. On the other hand, the difference between the tibial translations measured with the EMS and that measured using iPad stems from the evaluated locations. The EMS provides the tibial anteroposterior translation from the 6 degree-of-freedom knee kinematics according to

the standard knee coordinate system [8], whereas the tibial translation using the iPad is reflected in the lateral compartment translation [9]. From the biomechanical viewpoint, the lateral compartment translation measured using iPad is influenced by both tibial AP translation and tibial rotation, whereas the EMS measures only tibial AP translation while intentionally ignoring tibial rotation. As tibial rotation during the pivot-shift test is widely varied according to the knees and examiners [16, 29, 32], focusing on tibial AP translation might provide a more stable evaluation of pivot-shift. However, tibial rotation could have additional value for the evaluation of knee joint laxity as a whole, including the function of the anterolateral capsule [30]. So far, it is still undetermined if the tibial rotation should be included in the quantitative measurement of pivot-shift. Although lateral compartment translation during the pivot-shift test should be larger than the tibial translation measured in the centre of the knee joint [5], the tibial translation evaluated using iPad must have a significant buffering effect on skin movement, resulting in a smaller amount of translation than that evaluated using the EMS. In comparison with our reported correlation, Arilla et al reported better correlation between iPad and EMS measurements [3]. The relatively poor consistency between the two measurements in our study could be mainly due to lack of strict control of the iPad data acquisition, such as the distance and angle between the iPad camera and the lateral aspect of the knee. Considering the accuracy of the iPad measurement reported by Muller et al, [27], the relationship between the iPad and EMS measurements can be improved with more-controlled testing situations.

The limitations of this research are as follows: First, the number of cases was as small as 30 cases. A significant side-to-side difference was successfully observed between the knees with ACL injury and the contralateral knees by any of the three tested devices, but the number was not sufficient for detailed analysis of rotational laxity to diagnose partial

202 tear of the ACL [1], concomitant meniscus, and other secondary restraint injuries [30].
203 Second, although diagnostic accuracy was evaluated in this study, the clinical usability of
204 some measurement devices should include other factors such as portability, cost, and
205 operability. Obvious drawbacks of the EMS should be its large size and expensive cost in
206 comparison with the other two systems, although the price of the EMS is currently
207 undetermined. In addition, the EMS requires additional procedure to set up the knee
208 coordinate system in the PC prior to testing, which normally takes approximately 5
209 minutes, while KiRA and iPad do not require any system preparation but just a few
210 minutes to place the stickers or the accelerometer on the knee.

211 The clinical relevance of this study is that use of non-invasive measurement devices for
212 the pivot-shift test can provide more accurate detection of ACL deficiency.

214 Conclusions

215 Although all three measurements could detect ACL deficiency, the diagnostic reliability
216 of the quantitative pivot-shift measurement using the EMS for ACL deficiency was
217 superior to those using KiRA and iPad. It is to be noted that the commercial availability
218 of the EMS is quite limited for the moment.

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Figure Legends

Figure 1. Three measurement devices for the pivot-shift test: 1) an electromagnetic measurement system (EMS) consisting of two sensors on the thigh and shank (1-a) and an electromagnetic transmitter (1-b), 2) an accelerometer (KiRA), 3) an image analysis iPad application (iPad) which provides lateral translation based on relative movement between three yellow markers on the lateral aspect of the knee.

Figure 2.

The receiver-operating characteristic (ROC) curves for detecting the threshold value. The AUC of acceleration was 0.76 in KiRA and 0.84 in the electromagnetic measurement system.

Figure 3.

The receiver-operating characteristic (ROC) curves for detecting the threshold value. The AUC of translation was 0.77 in iPad and 0.96 in the electromagnetic measurement system.

Figure 4.

The accelerations measured using KiRA and that using the electromagnetic measurement system moderately correlated.

Figure 5.

The tibial translation measured using iPad and that using the electromagnetic measurement system poorly correlated.

1 **Table 1.**

2 Tibial acceleration and translation during the pivot-shift test

		ACL injured	Contralateral	P-value
		side	healthy side	
Acceleration (m/s ²)	EMS	2.2 ± 1.3	0.93 ± 0.58	< 0.01
	KiRA	4.4 ± 2.9	2.0 ± 1.3	< 0.01
Translation (mm)	EMS	13.0 ± 5.0	3.0 ± 2.0	< 0.01
	iPad	1.7 ± 1.5	0.7 ± 0.6	< 0.01

3 (Mean ± SD)

4

5 **Table 2.**

6 AUC, Cut-off value, sensitivity and specificity of acceleration in the pivot-shift test
7 measured by KiRA and EMS

	KiRA	EMS
AUC	0.76	0.84
Cut-off (m/s ²)	3.0	1.5
Sensitivity (%)	59	77
Specificity (%)	82	82

8 AUC: area under the curve

9

Table 3.

AUC, Cut-off value, sensitivity and specificity of tibial translation in the pivot-shift test
measured by iPad and EMS

	iPad	EMS
AUC	0.77	0.96
Cut-off (m/s ²)	0.73	9
Sensitivity (%)	71	79
Specificity (%)	71	91

AUC: area under the curve

2) KiRA accelerometer

1) Electromagnetic Sensors
Attached to the Skin

1-b) Electromagnetic transmitter

3) Yellow stickers for iPad image analysis









