

副論文

平成 20 年度学位申請論文

Concurrent Criterion-Related Validity and Reliability of a Clinical
Device Used to Assess Lateral Patellar Displacement

(膝蓋骨外側可動距離を計測する装置の妥当性と再現性について)

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INTRODUCTION

Patellofemoral pain is a common condition seen in orthopedic practice.^{2,3,10} A frequently cited factor thought to contribute to patellofemoral pain and/or pathology is excessive lateral displacement of the patella.^{5,12,25} Repetitive lateral displacement or subluxation of the patella is thought to lead to articular cartilage wear and subsequent pain.^{6,8,9} Evidence in support of this theory has been provided by Moller et al.¹⁵ who demonstrated that surgically induced lateralization of the patella resulted in degenerative changes in the patellofemoral joint cartilage of rabbits.

Identification of excessive lateral displacement of the patella is an important aspect of the clinical examination of persons with patellofemoral pain as treatment decisions are based on this finding.⁷ However, assessment of lateral patellar displacement in the clinic is difficult given the fact that the relationship between the patella and the trochlear groove of the femur can not be visualized. Instead, various imaging methods have been developed to determine the presence of this condition.^{11,17,22}

To date, only one clinical method to assess lateral patellar displacement has been described in the literature. According to McConnell,¹⁴ lateral displacement of the patella can be determined by the use of a soft tape measure, with the femoral epicondyles and midpoint of the patella as landmarks. If the distance between the medial femoral epicondyle and the midpoint of the patella is greater than the distance from the lateral epicondyle and midpoint of the patella, it is assumed that the patella is laterally displaced.¹⁴ McConnell advocates the use of this method with the patient supine and the knee flexed to 20°. In addition, McConnell states that this assessment should be performed with the quadriceps relaxed.¹³ Although widely used clinically, the reliability of this method has been shown to be poor,^{4,21,24} and the validity of this technique has been questioned.¹⁸

Given the need for objective measures of patellofemoral joint impairments, we have developed a clinical device (patellofemoral joint arthrometer [PFA]) to quantify lateral patellar displacement. Since maximum lateral patellar displacement has been shown to occur with the knee in the extended position with the quadriceps contracted,¹⁹ the device described in the current investigation was designed to assess lateral patellar displacement under these conditions. The purpose of this study was to describe the PFA, and

to assess the concurrent, criterion related validity, as well as the intertester and intratester reliability of this device.

METHODS

Subjects

A total of 36 individuals volunteered for this study. Subjects were recruited from local orthopaedic clinics and the student population at the University of Southern California. Prior to participation, all participants were informed as to the nature of the study, and informed consent was obtained as approved by the Institutional Review Board of the University of Southern California.

Twenty six of the subjects, consisting of 24 females and 2 males (26 knees) participated in the validity portion of this study. The average \pm SD age, height and body mass of the participants was 27 ± 4 years, 164 ± 5 cm, and 59 ± 8 kg, respectively. Twelve of the participants had a current history of patellofemoral pain at the time of testing, while 14 were asymptomatic. The presence of patellofemoral pain was determined through physical exam as well as the reproduction of retropatellar and/or peripatellar symptoms with tasks such as squatting, lunging and descending stairs.

For the reliability portion of this study, a sample of convenience consisting of 10 pain-free individuals (9 females and 1 male; 10 knees) was used. The average \pm SD age, height and body mass of these participants was 28 ± 5 years, 166 ± 7 cm, and 65 ± 11 kg, respectively.

Subjects in either portion of this study were excluded if they demonstrated gross knee joint effusion, or were unable to achieve full knee extension. In addition, individuals were excluded if they reported previous patellofemoral surgery or traumatic patellar dislocation.

Instrumentation

A custom designed PFA was used to assess the amount of lateral patellar displacement. The PFA was fabricated from low molecular weight polyethylene and was comprised of 4 components: 1) a fixed ruler, 2) an adjustable arm, 3) a clamping mechanism, and 4) a thigh strap (Fig. 1a). The clamping mechanism secured the PFA to the femoral condyles, while the strap stabilized the device around the posterior thigh after clamping (Fig. 1b). The adjustable arm allowed the medial border of the patella to be localized in the frontal plane with respect to the fixed ruler (Fig. 1b). The precision of the fixed ruler was 0.5 mm.

Magnetic resonance imaging (MRI) of the patellofemoral joint was conducted using a 1.5X-T Signa scanner (GE Medical Systems, P.O. BOX 414, Milwaukee, WI 53201-0414). Axial images of the patellofemoral joint were obtained using a fat suppressed FSPGR pulse sequence (TR 8.2 msec, TE 1.5 msec, NEX 1, spectral inversion for fat suppression, FOV 20 cm X 20 cm, matrix 512 X 512, slice thickness 2 mm, two 12.7 cm receive only coils).

Validity Study

Participants in the validity portion of the study underwent two phases of data collection: 1) assessment of lateral patellar displacement using the PFA and 2) assessment of lateral patellar displacement using MRI. Typically these measures were obtained on the same day. PFA measurements were performed at the Musculoskeletal Biomechanics Research Laboratory at the University of Southern California, while imaging was performed at the Los Angeles County Hospital (LAC) + USC Imaging Sciences Center.

Assessment of lateral patellar displacement using the PFA was measured with the participant supine on a plinth. The knee was positioned in 0° of flexion (measured with a standard goniometer), and the lower extremity was maintained in neutral rotation (i.e. hip in neutral rotation with patella facing upwards toward the ceiling). Rolled towels were placed under the thigh and ankle to support this position.

With the quadriceps relaxed, the PFA was aligned perpendicular to the long axis of the thigh in the frontal plane (Fig. 2a), and parallel to the long axis of the thigh in the sagittal plane (Fig. 2b). Following appropriate positioning, the PFA was clamped to the femoral epicondyles and the strap was tightened to secure the PFA to the thigh. Next, the adjustable arm of the PFA was moved to a position where it approximated the medial border of the patella (Fig. 3). The position of the adjustable arm with respect to the fixed ruler was then recorded.

Following this initial measurement, the towel support under the ankle was removed, thereby requiring the subjects to perform an isometric quadriceps contraction to hold the knee in the extended position (Fig. 4a-b). A second measurement of patellar position was made by moving the adjustable arm to remain flush with the medial border of the patella. The amount of lateral patellar displacement was defined as the difference between the initial measurement with the quadriceps relaxed and the final position with

the quadriceps contracted. Each subject was measured 3 times with the average value used for statistical analysis. All PFA measures of lateral patellar displacement were reported to the nearest 0.5 mm and were obtained by a physical therapist that was experienced in the use of this device.

Following assessment of lateral patellar displacement using the PFA, participants underwent MRI of the patellofemoral joint. Axial images were acquired with the knee in 0° of knee flexion and the lower extremity in neutral rotation. Using rolled towels, every effort was made to reproduce the relaxed and contracted positions as described for the clinical measurement of lateral patellar displacement using the PFA. Two series of images were obtained, one with the quadriceps relaxed and the other with the quadriceps contracted.

Computer-generated measurements of lateral patellar displacement for the relaxed and contracted conditions were made from the images containing the maximum midsection of the patella using a modification of the bisect offset index as described by Powers et al.¹⁷ The bisect offset index was measured by drawing a line connecting the posterior femoral condyles and then projecting a perpendicular line anteriorly through the deepest aspect of the trochlear groove. This line intersected the patellar width line, which connected the widest points of the patella (Fig. 5a). The bisect offset index represented the amount of the patella lateral to the projected perpendicular line and were reported to the nearest 0.5 mm.

To account for the confounding effects of patellar tilt on the bisect offset measurement, a correction factor was employed. This was accomplished by measuring the patellar tilt angle (the angle formed by lines joining the maximum width of the patella and the posterior condyle lines; Fig 5b), taking the cosine of this angle, and multiplying it by the bisect offset measurement. This correction factor gave the true amount of lateral patellar displacement in the frontal plane. As with the PFA measurement, the amount of lateral patellar displacement was calculated as the difference between the initial measurement with the quadriceps relaxed and the final position with the quadriceps contracted.

A second investigator made all MRI measurements. This individual, demonstrated excellent repeatability in a previously published study,²³ and was blinded to the results of the clinical measurements with the PFA. MRI measurements were made 3 times and averaged for statistical analysis. A custom

macro written for NIH Image Software (National Institutes of Health, Bethesda, MD) was used for all MRI measurements.

Reliability study

To assess the intratester and intertester reliability of quantifying lateral patellar displacement using the PFA, repeated measurements were obtained by two additional physical therapists who were trained in the use of the device. To prevent measurement recall, data were obtained on 2 separate days at least 1 week apart. In all instances, measurements were taken 3 times and averaged for final analysis. Both investigators were blinded to each other's PFA readings.

Statistical Analysis

To assess the level of agreement between measurements of lateral patellar displacement using the PFA and MRI, the intraclass correlation coefficient (ICC 2,3) was used. Intratester and intertester reliability of measurements obtained with the PFA was assessed using the ICC (2,3) and the standard error of measurement ($SEM = SD \times \sqrt{1-ICC}$). All statistical analyses were performed with SPSS statistical software (SPSS Inc., 233 S Wacker Dr, Chicago, IL 60606).

RESULTS

Validity

The average \pm SD amount of lateral patellar displacement as measured using the PFA was 3.60 ± 1.51 mm, while the average amount of lateral patellar displacement as assessed using MRI was 3.35 ± 1.95 mm (Table). The ICC assessing the level agreement between the 2 methods was 0.86 (95% CI: 0.69-0.94).

Reliability

The ICCs assessing intratester reliability of the PFA for examiner #1 and examiner #2 were 0.96 (95% CI: 0.85 to 0.99; SEM: 0.37 mm) and 0.97 (95% CI: 0.89 to 0.99; SEM: 0.38 mm) respectively. The ICC assessing intertester reliability was found to be 0.92 (95% CI: 0.69 to 0.94; SEM: 0.64 mm).

DISCUSSION

In this study, we report on a device designed to quantify lateral patellar displacement in the clinic. However, to be considered a viable clinical tool, acceptable validity and repeatability must be demonstrated. The results of this study indicate that measurements using the PFA were similar to those obtained from a recognized gold standard (MRI) and were highly repeatable.

In validity portion of this study, the ICC comparing the level of agreement between the 2 methods of quantifying lateral patellar displacement was good (0.86).¹⁶ This result represents an improvement in validity over other clinical methods that have been described to estimate lateral patellar displacement. For example, Powers et al.¹⁸ reported that the agreement of the McConnell method¹⁵ with MRI measurements was poor (ICC=0.44), with lateral patellar position being overestimated approximately 2.4 times.

Despite the high ICC value in the current investigation, quite a bit of variation in the difference scores was observed across subjects (Table). Although the average difference score was only 0.25 mm, the maximal difference scores ranged from 0 mm to 2.8 mm. Taken together, 58% of the measurements of lateral patellar displacement using the PFA were overestimated when compared to the MRI, while 38% of the measurements of lateral patellar displacement using the PFA were underestimated when compared to MRI.

The most likely reason for the inconsistent difference scores among subjects was the variable degree of soft tissue between the patella and the adjustable arm of the PFA. As shown in Figure 6, the amount of soft tissue at the medial border of the patella would prevent the adjustable arm of the PFA from contacting the patella. As assessment of lateral patellar displacement using MRI was based on bony landmarks, such measurements would not be influenced by soft tissue. Obviously, greater degrees of soft tissue also could lead to difficulties in aligning the PFA, thereby causing erroneous measurements in certain individuals. Another possible explanation for the variation in the difference scores between subjects may be related to the fact that concurrent motions such as patellar tilt and rotation could have influenced PFA measurements. Although patellar tilt was taken into consideration for the MRI measures, the PFA was not capable of accounting for patellar motion in other planes.

In the reliability portion of this study, excellent intratester (ICC's of 0.96 and 0.97) and intertester reliability (ICC 0.92) was demonstrated. The high intertester reliability demonstrated with the PFA is relevant in that when re-examining a patient or conducting clinical research, the same clinician would not have to obtain all measurements. Our reliability results using the PFA are better than previously described clinical measurements of lateral patellar displacement. For example, Tomsich et al.²¹ reported that the intratester and intertester (ICC) reliability using the McConnell method was 0.70 and 0.14 respectively.

To further investigate the sensitivity of the PFA in assessing lateral patellar displacement, the smallest real difference (SRD) was used to indicate the magnitude of change (or differences between populations) that would exceed the expected trial to trial variability. Based on the average SEM for both the intratester and intertester reliability portions of this study (0.46), the SRD was calculated as follows: $SRD = SEM \times \sqrt{2} \times 2.26 = 1.5 \text{ mm}$, where 2.26 represents the value of the t-distribution for a 95% confidence interval ($df=9$).¹ This value indicates that one would be 95% confident that any difference between populations or differences within an individual (i.e. a treatment effect) would reflect a true difference or change. Given that the difference in lateral patellar displacement between persons with and without patellofemoral pain at 0 degrees of knee flexion has been reported to be approximately 4.4 mm,¹⁸ it would appear that the PFA would be sensitive enough to discern between normal and abnormal lateral patellar displacement. However, further research would have to be conducted to establish normative values for lateral patellar displacement using the PFA so that pathological motion can be identified.

There are several limitations with the PFA that need to be acknowledged. First, this device only measures relative displacement of the patella (initial position minus final position) and does not take into consideration the fact that the starting position of the patella would likely have an influence on how a given displacement value was interpreted. For example, 4.0 mm of lateral displacement would not have the same consequence in a patient whose patella started in the middle of the trochlear groove as compared to a patient whose patella started in a more lateral position. Future iterations of the PFA (or other devices) should consider the relative starting position of the patella (i.e. relative to the femoral condyles) so that displacement values can be better interpreted.

A second limitation of the PFA is that this device only measures lateral patellar displacement under a specific testing condition (i.e. supine with knee extended). While the functional relevance of this testing position could be questioned, previous work comparing lateral patellar displacement between weightbearing and non-weightbearing tasks has shown that the magnitude of lateral displacement is similar between conditions.²⁰ Therefore, an argument could be made that the amount of lateral displacement observed in a non-weightbearing condition may be related to the amount of lateral patellar displacement that would be present under more functional weightbearing tasks. However, additional research would have to be performed to substantiate this assertion. Until such data are available, care must be taken when interpreting lateral displacement values obtained using the specific procedures described for the PFA.

CONCLUSION

A clinical device to quantify lateral patellar displacement has been described and shown to exhibit excellent reliability and good agreement when compared to MRI measurements. These findings suggest that reasonable estimations of lateral patellar displacement can be obtained in the clinic, and appear to be an improvement over previously described methods to assess the lateral patellar displacement. However, it should be noticed that the clinical device used in this study only would be capable of detecting changes in lateral patellar displacement or differences between populations that were greater than 1.5 mm.

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TABLE

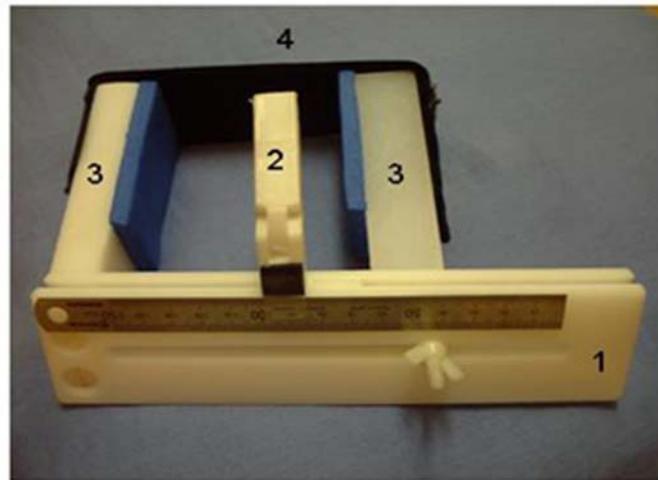
Agreement between the Patellofemoral Arthrometer (PFA) and MRI
Method of
Measuring Lateral Patellar Displacement
(values represent the average of 3 measurements; expressed in mm)

Subject	PFA	MRI	Difference
1*	8.8	8.5	+0.3
2*	4.8	6.1	-1.3
3*	4.0	5.3	-1.3
4*	5.0	7.8	-2.8
5	3.2	2.1	+1.1
6*	3.0	3.1	-0.1
7*	3.7	4.4	-0.7
8	3.5	1.7	+1.8
9	1.2	1.5	-0.3
10*	2.8	3.5	-0.7
11	3.3	2.9	+0.4
12*	1.3	2.3	-1.0
13*	5.3	4.0	+1.3
14	1.8	1.0	+0.8
15	4.0	3.5	+0.5
16	3.0	0.9	+2.1
17	3.2	3.1	+0.1
18*	4.3	5.4	-1.1
19	3.5	2.4	+1.1
20	4.5	2.6	+1.9
21*	2.3	3.2	-0.9
22	1.8	0.7	+1.1
23	4.2	3.0	+1.2
24*	3.5	2.4	+1.1
25	3.5	3.5	0.0
26	4.3	2.4	+1.9
Mean	3.60	3.35	0.25
SD	1.51	1.95	1.23

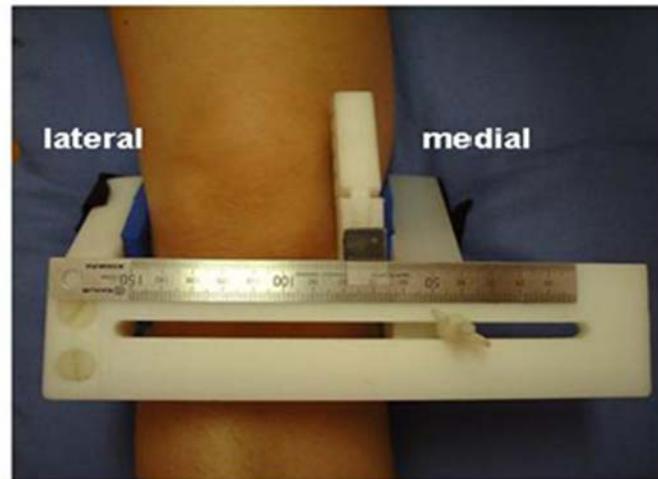
+ Difference Score = PFA > MRI

− Difference Score = PFA < MRI

* indicates subject with patellofemoral pain



A



B

Figure 1. The patellofemoral arthrometer consisted of 4 components: 1) a fixed ruler, 2) an adjustable arm 3) a clamping mechanism , and 4) a thigh strap (A). The clamping mechanism secured the arthrometer to the femoral condyles, while the strap stabilized the device around the posterior thigh (B).

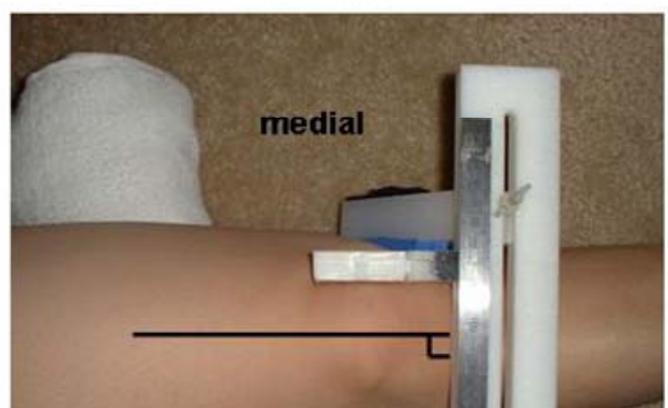


Figure 2. Fitting of patellofemoral arthrometer. With the quadriceps relaxed, the arthrometer was aligned perpendicular to the long axis of the thigh in the frontal plane (A), and parallel to the long axis of the thigh in the sagittal plane (B).

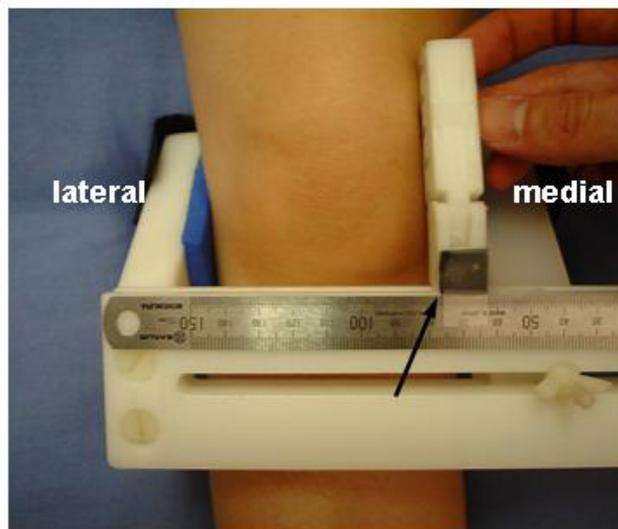


Figure 3. The adjustable arm of the patellofemoral arthrometer allowed the medial border of

the

patella to be

the

localized in

frontal plane

with

respect to the

fixed

ruler.



A



B

Figure 4. For both the patellofemoral arthrometer and MRI assessments, rolled towels were used to maintain subjects in 0° knee flexion and neutral rotation (A). To force quadriceps contraction, the rolled towel under the ankle was removed (B).

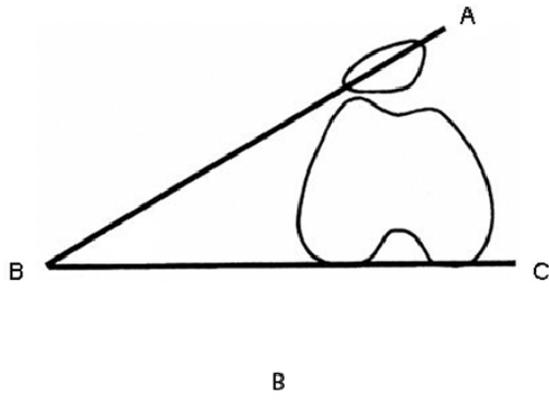
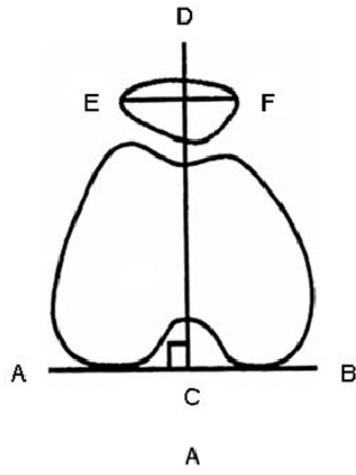
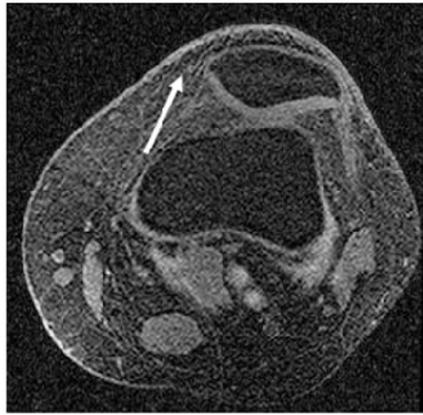
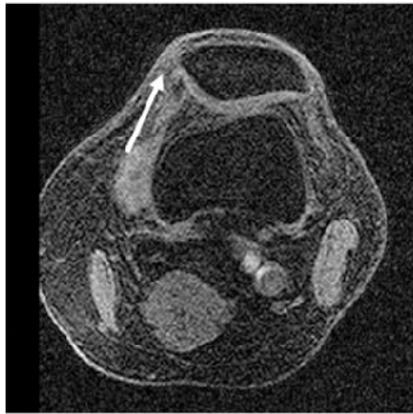


Figure 5. MRI method used to measure bisect offset index and patellar tilt. (A) The bisect offset index was measured by drawing a line connecting the posterior femoral condyles (A-B) and then projecting a perpendicular line anteriorly through the deepest portion of the trochlear groove (C-D) to a point at which it bisected the patellar width line (E-F). The bisect offset index represents the amount of the patella lateral to the projected midline and was reported as a percentage of patellar width. (B) Patellar tilt was defined as the angle formed by lines jointing the maximum width of the patella (A-B) and the posterior femoral condyles (B-C). Reproduced with permission from Powers CM, et al., Quantification of patellar tracking using kinematic MRI. *J Magn Reson Imaging*. 1998;8(3):724-732



A



B

Figure 6. The degree of soft tissue medial to the patella can influence the patellofemoral arthrometer measures. The individual in (A) has a greater degree of soft tissue medial to the patella when compare to the individual in (B).

和文抄録

Concurrent Criterion-Related Validity and Reliability of a Clinical Device Used to Assess Lateral Patellar Displacement

(膝蓋骨外側可動距離を計測する装置の妥当性と再現性について)

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【目的】 定量的に膝蓋骨外側可動距離を計測する装置の妥当性と再現性を検証すること

【背景】 過剰な膝蓋骨外側可動性は膝蓋大腿関節痛やその病態に深く関連している。しかしながら現在、妥当性及び再現性のある臨床的な膝蓋骨外側可動距離の測定方法は報告されていない。

【方法】 妥当性研究では、26名(14名:健常者、12名:膝蓋大腿関節痛症例)、再現性研究では10名の健常者を対象とした。膝蓋骨外側可動距離は、我々の開発した Patellofemoral arthrometer (PFA) を用い、MRIによる測定と比較した。両方の測定は膝伸展位において、大腿四頭筋の弛緩時と収縮時による膝蓋骨の外側移動距離を計測した。PFAとMRIによる比較及び検者内・検者間再現性には級内相関係数を用いた。

【結果】 PFAとMRIによる膝蓋骨外側可動距離の一致性は級内相関係数0.86であり、検者内再現性は0.96と0.97であり、検者間再現性は0.92であった。

【結語】 本研究の結果より、PFAにより膝蓋骨外側可動距離は、臨床応用するに際し適切に得られることが示唆された。