Reliability and validity of quantitative ultrasound for evaluating patellar alignment: A
 pilot study

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- 4 Abstract

Background: Patellar malalignment is a risk factor of patellofemoral pain. Evaluation of the
patellar alignment have mostly used magnetic resonance imaging (MRI). Ultrasound (US) is a
non-invasive instrument that can quickly evaluate patellar alignment. However, the method for
evaluating patellar alignment via US has not been established. This study aimed to investigate
the reliability and validity of evaluating patellar alignment via US.
Methods: The sixteen right knees were imaged via US and MRI. US images were obtained at
two sites of the knee to measure US-tilt as the index of patellar tilt. Using a single US image,

12 we measured US-lateral distance and US-angle as the index of patellar shift. All US images

13 were obtained three times each by two observers to evaluate reliabilities. Lateral patellar angle

14 (LPA), as the indicators of patellar tilt, and lateral patella distance (LPD) and bisect offset (BO),

15 as the indicators of patellar shift, were measured via MRI.

16 **Results:** US measurements provided high intra- (within-day and between days) and 17 interobserver reliabilities with exception of interobserver reliability of US-lateral distance. 18 Pearson correlation coefficient indicated that US-tilt is significantly positively correlated with 19 LPA (r = 0.79), and US-angle is significantly positively correlated with LPD (r = 0.71) and BO (r = 0.63).

21	Conclusion: Evaluating patellar alignment via US showed high reliabilities. US-tilt and US-
22	angle showed moderate to strong correlation with MRI indices of patellar tilt and shift via MRI,
23	respectively. US methods are useful for evaluating accurate and objective indices of patellar
24	alignment.
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26	Keywords: Ultrasonography; magnetic resonance imaging; patellar shift; patellar tilt

28 Introduction

29	Patellar malalignment is a potential risk factor of patellofemoral pain (PFP) [1–4]
30	and many studies have investigated the association between patellar malalignment and PFP
31	[5–8]. Excessive lateral alignment of the patella, a typical patellar malalignment, can lead to
32	an increase in contact pressure in the patellofemoral joint [9,10], resulting in PFP and early
33	degeneration of the patellofemoral joint [10]. Patellar tilt and shift are proxies for the lateral
34	patellar alignment, and both are potentially related to PFP [5,6,11–14]. Thus, a quantitative
35	evaluation of the patellar tilt and shift is necessary to evaluate knee condition [12,15–17].
36	PPatellar alignment is generally evaluated using X-ray, computed tomography, and
37	magnetic resonance imaging (MRI) [5,18,19]. Although these instruments can accurately
38	evaluate patellar alignment, they are disadvantageous because of factors such as radiation
39	exposure and taking long time. In contrast, ultrasound (US) is a non-invasive instrument and
40	can quickly obtain images. However, the method for evaluating patellar alignment via US has
41	been challenging.
42	No study has reported the US method for the patellar tilt evaluation. The lateral
43	patellar angle (LPA), which has been evaluated using the MRI, is used as the indicator of
44	patellar tilt [20]. LPA is calculated from the patellar tilt with respect to the anterior condyle of
45	the femur. Because US images at the anterior knee allow us to simultaneously capture both

46	the patella and the anterior condyle of the femur, the US method equivalent to MRI measured
47	LPA may be developed with two US images at the anterior knee.
48	A US method has been developed to determine patellar shift [21,22]. The distance
49	between the lateral edge of the patella and anterior lateral condyle of the femur in a single US
50	image (US-lateral distance), obtained at the anterior-lateral knee, was defined as the indicator
51	of patellar shift. Herrington et al. [23] reported that the US-lateral distance shows high
52	intraobserver reliability and a moderate correlation with lateral patella displacement (LPD1),
53	as an indicator of patellar shift, measured via MRI at 20° knee flexion. Several previous
54	studies investigated the association between patellar shift and soft tissue using this method
55	(i.e. US-lateral distance) [24-26]. However, it has been unclear as to whether the method is
56	valid at other knee angles (e.g., at 0° knee flexion). As per a recent systematic review, patellar
57	alignment that is most related to PFP was patellar shift at 0° knee flexion [11]. Therefore, it is
58	necessary to investigate whether the method can be applied at 0° knee flexion. Additionally,
59	lateral patella displacement (LPD2) and bisect offset (BO), in addition to LPD1, are
60	commonly used for evaluating the patellar shift [27,28]. However, it remains unclear whether
61	US-lateral distance can correlate with these indicators (LPD2 and BO). Hence, it is crucial to
62	explore the relations of LPD2 and BO with US-lateral distance and to establish the US
63	method to evaluate the accurate patellar shift at 0° knee flexion.

64	This study aimed to investigate the reliability and validity of evaluating patellar tilt
65	and shift using US images. We hypothesized that measuring the patellar tilt and shift with US
66	images show correlations with the MRI measurements. In addition, we also hypothesized that
67	the US measurement methods which most corelated to MRI indices of patellar shift are
68	different for 0° and 20° knee flexions.
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71	Materials and Methods
72	Participants
73	Sixteen young adults ($n = 16$, 8 males; 16 right knees) participated in this study. The
74	mean age, height, and weight of the participants were 25.9 ± 3.3 years, 163.8 ± 6.4 cm, $56.9 \pm$
75	7.0 kg, respectively. All participants were more than 20 years old. Two out of 16 participants
76	had knee pain. Furthermore, individuals that had a history of fractures or surgeries of the right
77	leg and contraindications to undergoing MRI were excluded. The sample size was calculated
78	using G*Power 3.1 (Heinrich Heine University, Düsseldorf, Germany) for correlation analysis
79	(effect size: $r = 0.64$, α error: 0.05, power: 0.8), which showed that 14 participants were
80	required. The effect size was determined based on a previous study in which correlation
81	analysis was performed between patellar alignments that were evaluated using US and MRI
82	[23]. Therefore, 16 participants were recruited in this study considering the measurement errors

83	and omissions. Prior to this study, the procedures and goals of the study were verbally explained
84	to the participants, and all the subjects provided written informed consent in accordance with
85	the ethical standards of the 1964 Declaration of Helsinki. All procedures were approved by the
86	Ethics Committee of our institution.
87	
88	Protocol
89	The participants visited our laboratory on three separate days. MRI measurements
90	were obtained on the first day and US measurements were obtained on the other two days. On
91	the second day, US images were obtained by two observers (observer1 and observer2) to test
92	interobserver reliability. One week later, similar US images were obtained by observer1 to test
93	intraobserver reliability (between days). The measurements were performed while ensuring
94	that the participants were relaxed. The two observers analyzed each of the US and MRI
95	measurements respectively.
96	
97	Ultrasound measurements
98	Patellar alignment was evaluated using US (Aixplorer; SuperSonic Imagine, Axi-en-
99	Provence, France) with a linear probe (SL15-4, 4-15MHz, SuperSonic Imaging, Aix-en-
100	Provence, France).
101	The participants were asked to lay in the supine position with their right knee at 0°
	4

102	flexion. US images were obtained at two sites of the anterior surface of the knee (Fig. 1). One
103	US image was obtained in such a way to satisfy two requirements: both superior-lateral edge
104	of the patella and lateral condyle of the femur were captured, and the surface of the lateral
105	condyle of the femur was put in a horizontal direction (US1, Fig. 2a), and the other was
106	obtained in such a way to satisfy a requirement: superior-medial edge of the patella and medial
107	condyle of the femur were captured (US2, Fig. 2b). The probe was placed softly on the skin to
108	prevent any displacement of the patella as a result of the pressure of the probe. In addition,
109	water-soluble transmission gel was applied on the scanning head to eliminate any gaps between
110	the probe and skin. The participants were instructed to relax as much as possible during the
111	ultrasound measurements. US images at each of the two sites were obtained three times.
112	By using the US1, we measured US-lateral distance [23] (Fig. 3a), and the angle
113	between a line from the lateral edge of the patella to the most anterior of the anterior lateral
114	condyle of the femur and the horizontal line of the anterior lateral condyle of the femur (US-
115	angle) (Fig. 3b) as the indicator of patellar shift. In addition, by using the US2, we measured
116	the distance between the medial edge of the patella and the most anterior of the anterior medial
117	condyle of the femur (US-medial distance) (Fig. 3c), and calculated the ratio of US-medial
118	distance and US-lateral distance (US-tilt) as the indicator of patellar tilt. US-tilt was calculated
119	using the following equation:

US-tilt = US-medial distance / US-lateral distance

For further statistical analysis, we computed the average US-lateral distance, US-angle, and
US-tilt across three US1 and US2 images, separately.

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124 MRI measurements

Patellar alignment was evaluated from a proton density-weighted image (PD), which 125126was obtained from a 3.0 T MRI scanner (Magnetom Verio, SIEMENS, Germany). The MRI sequence corresponded to 3D SPACE with PD variable contrast using a body matrix coil and 127a spine coil, and the parameters were set as follows: slice thickness: 0.7 mm, repetition time: 1281000 ms, echo time: 35 ms, field of view: 150 mm × 150 mm, flip angle: 120°, voxel size: 0.59 129mm \times 0.59 mm \times 0.7 mm. The images were evaluated using an image analysis software 130131(version 9.0; Osirix, Geneva, Switzerland). LPA was used as the indicator of patellar tilt [28] (Fig. 4a), and LPD1 [23] (Fig. 4b), LPD2 [28] (Fig. 4c), and BO [28] (Fig. 4d) were used as 132the indicators of patellar shift. Measurements were performed as follows: 133134

135 LPA

The angle formed between the line parallel to the lateral patella facet (line AB) and the line
tangent to both the anterior femoral condyle was measured (line CD). A positive value indicated
lateral tilt.

140 LPD1

141	A line was drawn tangent to both the anterior femoral condyles as a baseline (line AB). A
142	perpendicular line was drawn passing through the highest point of the anterior lateral condyle
143	of the femur (line CD). Then, the perpendicular distance from the lateral edge of the patella to
144	the perpendicular line was measured (line EF). A positive value indicated that the lateral edge
145	of the patella is lateral to the perpendicular line.
146	
147	LPD2
148	A line was drawn tangent to both the posterior femoral condyles as a baseline (line AB). A
149	perpendicular line was drawn passing through the highest point of the anterior medial condyle
150	of the femur (line CD). Then, the perpendicular distance from the medial edge of the patella to
151	the perpendicular line was measured (line EF). A negative value indicated that the medial edge
152	of the patella is medial to the perpendicular line.

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154 BO

A line was drawn tangent to both the posterior femoral condyles as a baseline (line AB). A perpendicular line was drawn passing through the deepest point of the trochlear groove (line CD). Then, the ratio of medial to lateral displacement of the patella relative to the perpendicular line was measured (length FG / length EF ×100%). A high ratio indicated that patella is 159 displaced laterally.

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161	Statistical	anal	vsis
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- 162 Statistical analysis was performed using IBM SPSS statistic software (version 22; 163 IBM, Armonk, NY, USA). Shapiro–Wilk test confirmed that the data exhibit a normal 164 distribution.
- The intraobserver (within-day), interobserver, and intraobserver (between days) 165reliability were evaluated using intraclass correlation coefficient (ICC) (1,1), ICC (2,1), and 166ICC (1,1), respectively. Additionally, the standard error of measurement (SEM) and minimal 167detectable change (MDC95) were calculated for evaluating the measurement error. SEM and 168MDC₉₅ were calculated as follows: SEM = SD_d / $\sqrt{2}$, and MDC₉₅ = 1.96×SD_d, where SD_d 169denotes the standard deviation (SD) of the difference in scores. 170Pearson correlation coefficient was used to evaluate the validity between US and MRI. 171A confidence level of 0.05 was set in all statistical tests. Reliability thresholds for ICC values 172were defined as almost perfect (> 0.81) [29]. 173174175Results 176

177 Figure. 5 showed the MR and ultrasound image of the same participant. Table 1 shows

the results with respect to the evaluation of patellar alignment using US and MRI. Noparticipant had patellar malalignment [30,31].

- Intraobserver (within-day), interobserver, and intraobserver (between days) 180 reliabilities of US-lateral distance were 0.93 (95% CI: 0.85–0.97), 0.58 (95% CI: 0.11–0.84), 181and 0.88 (95% CI: 0.69-0.95), respectively. Thus, reliabilities of US-lateral distance were 182183almost perfect with the exception of interobserver reliability. With respect to interobserver, SEM was 1.1 mm and MDC₉₅ was 3.0 mm, and for intraobserver (between days), SEM was 1840.7 mm and MDC95 was 1.9 mm. 185Intraobserver (within-day), interobserver, and intraobserver (between days) 186 reliabilities of US-angle were 0.86 (95% CI: 0.71-0.95), 0.89 (95% CI: 0.72-0.96), and 0.88 187(95% CI: 0.69–0.96), respectively. Thus, reliabilities of the US-angle were almost perfect. With 188respect to interobserver, SEM was 3.6° and MDC₉₅ was 10.1°, and for intraobserver (between 189days), SEM was 4.2° and MDC95 was 11.6°. 190
- Intraobserver (within-day), interobserver, and intraobserver (between days)
 reliabilities of US-tilt were 0.84 (95% CI: 0.66–0.94), 0.79 (95% CI: 0.51–0.92), and 0.89 (95%
 CI: 0.70–0.96), respectively. Thus, reliabilities of the US-tilt were almost perfect. With respect
 to interobserver, SEM was 0.14 and MDC₉₅ was 0.32, and for intraobserver (between days),
 SEM was 0.12 and MDC₉₅ was 0.35.

196 The Pearson correlation coefficient showed that US-tilt exhibits a significant positive

197	correlation with LPA ($r = 0.79$, p < 0.01). The US-angle exhibits a significant positive
198	correlation with LPD1 ($r = 0.65$, p < 0.01), LPD2 ($r = 0.71$, p < 0.01), and BO ($r = 0.63$, p =
199	0.01) (Table 2; Fig. 6). The US-lateral distance was not significantly correlated with all indices
200	of patellar alignment, which was measured via MRI.
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203	Discussion
204	This study aimed to investigate the reliability and validity of evaluating patellar tilt
205	and shift using US images. US-tilt measured from two US images showed high reliability and
206	a strong correlation with LPA, an indicator of patellar tilt via MRI. To the best of our knowledge,
207	this is the first study to establish an original US method for evaluating patellar tilt. Additionally,
208	US-angle measured from a single US image showed high reliability and a significant
209	correlation with the patellar shift, which was measured via MRI. However, the US-lateral
210	distance that was used in a previous study [23] did not exhibit a significant correlation with the
211	patellar shift. These findings indicated that the novel US methods (US-tilt and US-angle) are
212	useful in evaluating accurate and objective indices for patellar alignment.
213	We hypothesized that measuring the patellar tilt and shift with US images show
214	correlations with MRI. Our results indicated a strong correlation between US-tilt and patellar

tilt measured via MRI (i.e. LPA), and indicated moderate to strong correlation between US-

216	angle and patellar shift measured via MRI (i.e. LPD1, LPD2, and BO). These results was
217	consistent with our hypothesis. The association between the LPA and US-tilt can be explained
218	by the change in patellar and femoral position with patellar tilt. For example, a greater lateral
219	tilt results in a greater distance between the medial patella and medial femoral condyle, or a
220	smaller distance between the lateral patella and lateral femoral condyle. A greater medial tilt
221	results in an inverse change to the lateral tilt. These relative positions between the patella and
222	femur resulting from patellar tilt can be accurately captured by the equation for US tilt;
223	therefore, we consider it rational that the US tilt is associated with LPA, the gold standard for
224	patellar tilt.

US-tilt and US-angle can be measured quickly and conveniently, therefore, these methods are useful in clinical and sports settings.

In addition, we also hypothesized that the US measurement methods which were most 227corelated to MRI indices of patellar shift are different for 0° and 20° knee flexions. At 0° knee 228flexion, US-angle show high reliability and a significant correlation with the patellar shift 229measured via MRI. Conversely, the US-lateral distance exhibited low interobserver reliability 230and no significant correlation with LPD1, unlike that in a previous study [23]. These results 231were consistent with our hypothesis. The difference of the results of this study and the previous 232study can be due to the knee angle. The measurement was performed at 20° knee flexion in the 233previous study, while it was performed at 0° knee flexion in this study. In other words, the US-234

235	angle can be evaluate patellar shift at 0° knee flexion, the US-lateral distance can be evaluate
236	patellar shift at 20° knee flexion. A recent systematic review reported that patellar alignment
237	that is most related to PFP was patellar shift at 0° knee flexion [11]. Therefore, the evaluation
238	of patellar shift at 0° knee flexion can be clinically important. The patellar shift at 0° knee
239	flexion exhibited a higher correlation with US-angle than with US-lateral distance. These
240	results indicated that US-angle is useful to evaluate patellar shift at 0° knee flexion which is
241	most related to PFP.
242	This study established US methods for evaluating patellar alignment. By using these
243	methods, the patellar tilt and shift can be evaluated simultaneously and non-invasively. Given
244	that patellar tilt and shift can be related to PFP [5,6,11,12], our original methods can potentially
245	be applied to reveal the characteristics of PFP patients during muscle activity or loading in
246	future studies. In particular, using these methods, it is possible to simultaneously evaluate the
247	patellar alignment and muscle activity using electromyography, which is not possible with X-
248	ray or MRI. In addition, these methods can be used multiple times for one participant (e.g. to
249	evaluate the patellar alignment at different quadriceps contraction conditions), without
250	radiation exposure unlike X-ray. Moreover, in clinical setting, these US methods can be used
251	to evaluate the immediate and/or long-term effects of conservative treatment. Frequent
252	measurements of patellar alignment using X-ray and MRI are not feasible due to their high cost
253	and unnecessary radiation exposure. In sports settings, these US methods can be used to easily

254evaluate patellar alignment in athletes who have little to no pain, and if the athletes have abnormal patellar alignment, appropriate interventions (e.g., exercise and movement guidance) 255can be provided. This may be useful in preventing the onset and/or exacerbation of PFP. 256There are a few limitations of this study. First, this study involved only young adults. 257It is unclear whether the results of this study can be applied to older patients or patients with 258259knee osteoarthritis, and thus, further investigation is required for generalizing the methods to broader populations. Second, although patients with patellar malalignment often have 260abnormal patellar and condylar morphologies, no participants in this study had such issues. It 261is unclear whether the results of this study can be applied to the patients who have abnormal 262patellar and condylar morphologies. Third, although patellar malalignment and patellofemoral 263pain are common in women, half of the participants in this study were men. Further research 264is required to examine the differences across sexes. 265266267Conclusion 268269In this study, we investigated the reliability and validity of evaluating patellar alignment via US. US-tilt measured from two US images and the US-angle measured from a 270single US image showed high reliabilities, and showed moderate to strong correlation with the 271patellar tilt and patellar shift measured via MRI, respectively. These US methods provide 272

accurate and objective indicators for evaluating patellar alignment.

276 Ethical statement

- 277 The participants were informed that data from the research would be submitted for
- 278 publication, and gave their consent.

- **Conflict of interest**
- 281 None.

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Table

		US	MRI		
	Da	ly1	Day2		
	Observer1	Observer2	Observer1		
US-tilt	2.0 ± 0.3	2.2 ± 0.4	2.0 ± 0.4	_	
US-lateral distance (cm)	1.1 ± 0.2	0.9 ± 0.2	1.1 ± 0.2	_	
US-angle ($^{\circ}$)	$40.0~\pm~9.9$	$40.8~\pm~9.4$	$40.6~\pm~9.8$	_	
LPA				-0.5 ± 4.1	
LPD1 (mm)	—	—	_	5.3 ± 2.6	
LPD2 (mm)	—	_	_	$-6.6~\pm~2.8$	
BO (%)	_	_	_	51.0 ± 6.9	

Table 1. Patella alignment as measured using US and MRI.

393 Values are expressed as mean \pm standard deviation.

394 US = ultrasound; MRI = magnetic resonance imaging; LPA = lateral patellar angle; LPD =

395 lateral patella displacement; BO = bisect offset.

		MRI				
		LPA	LPD1	LPD2	BO	
US	Tilt	0.79*	0.13	0.17	0.43	
	Lateral distance	-0.13	0.49	0.24	0.26	
	Angle	0.31	0.65*	0.71*	0.63*	

Table 2. Pearson correlation (*r*) of US-tilt, lateral distance, and angle versus LPA, LPD1,

399 LPD2, and BO.

400 * Significant correlation between US and MRI (p < 0.05).

401 US = ultrasound; MRI = magnetic resonance imaging; LPA = lateral patellar angle; LPD =

402 lateral patella displacement; BO = bisect offset.

403

404

Figure

Figure. 1



- 409 Position of the ultrasound probe to obtain the two ultrasound images.

Figure. 2



- 413 Ultrasound (US) images obtained at the two sites of the knee. **a**, The lateral edge of the
- 414 patella and lateral condyle of the femur. **b**, The medial edge of the patella and medial
- 415 condyle of the femur. US = ultrasound.

Figure. 3



- 420 Methods for measuring US-lateral distance (a), US-angle (b), and US-medial distance (c).
- US = ultrasound.

Figure. 4







426 angle; LPD = lateral patella displacement; BO = bisect offset.



430 Representative images of MRI (a) and lateral (b) and medial (c) US images of the same

431 participant. **a** Axial image of the right knee at the point of superior-lateral edge of the

432 patella.







and LPD2. **d** US-angle and BO. LPA = lateral patellar angle; LPD = lateral patella

