Influence of limb alignment and prosthetic orientation on patient-reported clinical outcomes in total knee arthroplasty

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Conflict of Interest: None

Abstract

Background: The relationship between postoperative limb alignment and clinical outcomes in primary total knee arthroplasty (TKA) is well reported, but the instruments used to evaluate clinical outcomes of TKA are mainly scoring systems from the physician's viewpoint, not patient-reported outcomes. The purpose of this study was to investigate retrospectively the relationship between postoperative limb alignment and patient-reported clinical outcomes using the 2011 Knee Society Knee Scoring System (2011 KSS).

Methods: The present study included 155 knees of patients (median age, 74 years) who underwent primary TKA for varus osteoarthritis, with a mean follow-up period of 46 months. The subjects were divided into three groups based on postoperative limb alignment and femoral and tibial component positioning angle (varus, neutral, and valgus). The 2011 KSS scores were compared among the groups.

Results: For limb alignment, the postoperative objective knee indicator score was significantly lower in the valgus group than in the varus and neutral groups, whereas no significant differences were observed in any subjective categories of the 2011 KSS. However, for the femoral component angle, functional activity scores were significantly lower in the valgus group than in the varus and neutral groups.

Conclusions: The subjective patient-reported score was not affected by the postoperative limb alignment. However, the valgus femoral component angle resulted in lower subjective functional scores. For clinical relevance, postoperative valgus positioning of femoral component should be avoided from patient-reported functional aspects during TKA.

1. Introduction

Restoration of neutral limb alignment has been generally considered a prerequisite for successful total knee arthroplasty (TKA). Previous reports demonstrated that obtaining a hip-knee-ankle (HKA) angle of 0° in the coronal plane is an ideal target for primary TKA [1,2]. Deviations greater than 2° or 3° from HKA angle, particularly in varus, have been associated with lower clinical scores and higher risk of implant failure in the medium or long term [3,4].

A study showed that a relevant proportion of the physiologically normal human population has a natural limb alignment of ≥3° varus, termed constitutional varus, and demonstrated that its incidence is approximately 32% in men and 17% in women [5]. Furthermore, the incidence of constitutional varus was reported to be higher in Asian than in Western nations (40% in men and 28% in women) [6]. Some authors reported that patients with excessive varus alignment require more complex bone cuts or larger soft tissue release during TKA [7]. As for clinical outcomes, Vanlommel et al. [8] reported that patients with preoperative varus had better clinical and functional outcome scores when the alignment was left in mild varus than when the alignment was adjusted to neutral position. Furthermore, for Asian patients with varus osteoarthritis, Nishida et al. [9] showed that postoperative mild varus and neutral mechanical alignments of the lower limb led to excellent functional outcomes. However, these assessments, used to evaluate clinical outcomes, are mainly scoring systems that rely on physicians' viewpoint, and the relationship between postoperative alignment and clinical outcomes from patients' viewpoint is currently unknown. Regarding patient-reported outcomes, patient satisfaction has been recognized as an important basis of TKA evaluation, and the Knee Society developed a new knee scoring system, the 2011 Knee Society Knee Scoring System (2011 KSS), to quantify patient satisfaction, expectations, and physical activities after TKA [10,11].

Therefore, this study aimed to investigate retrospectively the relationship between postoperative limb alignment and patient-reported clinical outcomes for primary TKA using the 2011 KSS for Asian populations. We hypothesized that Asian patients with varus osteoarthritis might obtain superior patient-reported outcomes after TKA, including patient satisfaction, if the knee was left in mild varus alignment instead of being corrected to neutral position.

2. Materials and methods

Between 2009 and 2012, 232 consecutive computer navigation–assisted primary TKA procedures for 212 patients were performed (Vector Vision; DePuy-Brainlab, Germany; Orthopilot 4.2; B. Braun Aesculap, Germany). Patients with neutral or valgus alignment, a history of surgery on the index knee other than meniscectomy, arthritis from other etiologies (e.g., posttraumatic, rheumatoid, or inflammatory arthritis), severe bony defects needing bone grafting or augmentation, revision TKA, or postoperative flexion contracture >5° were excluded to ensure fair assessment and minimize the influence of clinical variables. The remaining 203 patients (220 TKAs) were included in the survey. We mailed 2011 KSS questionnaires to the included patients, of whom 143 (155 TKAs) returned completed questionnaires.

Therefore, 155 TKAs for 143 patients (119 women and 24 men) with a median age of 75 years (range, 43–89 years) who met the inclusion criteria were included in this study. Patients underwent TKA using posterior-stabilizing prostheses (PFC Sigma, n = 54; DePuy Synthes, USA; e-motion PS, n = 43; B. Braun Aesculap) and cruciate-retaining (CR) implants (e-motion CR; n = 58). Patients had a preoperative coronal alignment of 12.7° ± 6.0° in HKA angle. The minimum follow-up period was 2 years, and the median follow-up period was 46.5 months (range, 24–120 months). The surgeries were performed by the two senior authors, both of whom have more than 10 years of experience with TKA.

Radiological assessment

All preoperative and postoperative anteroposterior long-leg weight-bearing radiographs were taken according to a previously described standardized protocol [12]. The preoperative radiographs were taken within 1 month before surgery, and the postoperative radiographs were taken 1 month after surgery. HKA angle between a line connecting hip center and knee center and another line connecting knee center and ankle center was measured (Fig. 1). The hip center was designated as the center of a circle fitted into the contour of the femoral head. Preoperatively, the knee center was determined as the intersection of the midline between the tibial spines and the midline between the femoral condyles and the tip of the tibia. Postoperatively, the center was determined as the intersection of the midline in the middle of the polyethylene inlay and the midline between the condyles of the femoral component and the tip of the tibial component. The ankle center was considered as the middle of the talus roll at the level of the joint gap. Furthermore, the lateral distal femoral angle (LDFA) and medial proximal tibial angle (MPTA) were measured to evaluate the varus/valgus position of the components [13] (Fig. 1). The LDFA was measured

between the line parallel to the femoral component and the mechanical axis of the femur. The MPTA was calculated between the line parallel to the tibial baseplate and the mechanical axis of the tibia.

All 155 knees included in this study were divided into three groups according to postoperative HKA angle: varus (HKA angle >3°, *n* = 55), neutral (HKA angle 0° ± 3°, *n* = 89), and valgus (HKA angle <-3°, *n* = 11). No significant differences were found in patient demographic data, including follow-up period, preoperative Knee Society Knee Score (KSKS) or Knee Society Functional Score (KSFS), and preoperative alignment among the three groups (Table 1). Regarding the postoperative component positioning angle, the 155 knees were also divided into three groups according to postoperative LDFA and MPTA: varus (LDFA >92°/ MPTA <88°, *n* = 53 and 32, respectively), neutral (LDFA/MPTA 90° ± 2°, *n* = 83 and 108, respectively), and valgus (LDFA <88°/MPTA >92°, *n* = 19 and 15, respectively). No significant differences were found in patient demographic data among the three groups (Table 1).

Clinical outcome measure

KSKS and KSFS were evaluated preoperatively [14]. The 2011 KSS scores were used as postoperative clinical scores at the last follow-up (minimum 2 years). The patient-reported score of the 2011 KSS has four categories: symptoms, patient satisfaction, patient expectations, and functional activities. The objective knee indicator score of the 2011 KSS, completed by the surgeon, includes alignment, instability, and joint motion [10,11]. The HKA angle was measured as an alignment included in objective knee indicators category at the last follow-up. This research has been approved by the IRB of the authors' affiliated institutions.

Statistical analysis

All values were expressed as means ± standard deviations. All angles were evaluated at least three times in each patient by three different investigators and then averaged. Ekuseru-Toukei 2015 (Social Survey Research Information Co., Ltd., Tokyo, Japan) was used for statistical analysis. To determine the intraobserver and interobserver reliabilities of the radiographic assessment, the two investigators assessed 20 randomly selected radiographs twice. The intraobserver and interobserver reliabilities of all radiographic measurements were evaluated using intraclass correlation coefficients (ICCs). Based on postoperative limb alignment and component positioning angle, the preoperative KSKS/KSFS and

postoperative 2011 KSS scores were compared among the groups using the Kruskal-Wallis test. The comparisons between the two groups were performed using the Steel-Dwass test. *P* values <0.05 were considered statistically significant.

3. Results

Intra- and inter-rater reliability

The ICCs for intraobserver and interobserver reliability were >0.85 (range, 0.88–0.99) for all measurements (Table2).

Limb alignment

Postoperatively, no statistically significant differences were observed among any of the subjective categories of the 2011 KSS (Table 2). On the contrary, the postoperative objective knee indicator scores were significantly lower in the valgus groups than in the varus and neutral groups ($P < 0.001$; Fig. 2 and Table 3).

Component angle

In case of LDFA, the postoperative functional activity scores were significantly lower in the valgus group than in the varus and neutral groups ($P = 0.032$, respectively; Fig. 3 and Table 4). In case of MPTA, no significant differences were observed in the postoperative 2011 KSS scores among the three groups (Table 4).

4. Discussion

The present study revealed two important findings regarding the relationship between postoperative limb alignment and patient-reported clinical outcomes using the 2011 KSS. First, no significant differences were found in the 2011 KSS subjective scores among the groups categorized using postoperative limb alignment in the mid-term postoperative period. Second, as compared with neutral and varus positioning, valgus positioning of the femoral component resulted in a lower patient-reported functional score.

Vanlommel et al. [8] reported that postoperative mild varus alignment resulted in better clinical and functional outcomes and suggested this as a possible reason for less soft tissue release. Bellemans et al. [5] defined the knee with varus alignment that the patients have had since the end of their growth as

158 constitutional varus knee and reported that 32% of men and 17% of women had constitutional varus knees
159 with a natural mechanical alignment ≥3° varus. They concluded that the restoration of mechanical
160 alignment to neutral position in these cases may not be desirable and would be unusual for them.
161 Furthermore, Shetty et al. [6] reported that the incidence of constitutional varus in Asian population was
162 higher than that in a Western population. In a Japanese population, Matsumoto et al. [15] demonstrated that
163 the average femorotibial angle showed a slight varus alignment in healthy subjects. Nishida et al. [9]
164 showed that postoperative mild varus and neutral mechanical alignments of the lower limb led to excellent
165 clinical outcomes in the Japanese population. Matsumoto et al. [16] reported that the mean 2011 KSS
166 objective knee indicator score in the kinematically aligned TKA with slightly varus mechanical alignment
167 were significantly better than mechanical aligned TKA. In the present study, the objective knee indicator
168 score categorized as a physician-derived score in the 2011 KSS showed no significant difference between
169 the varus and neutral mechanical alignment groups, and the clinical scores were adequately high in both
170 groups. When considering our findings and those of previous studies, postoperative mild varus alignment
171 of the lower limb may be acceptable for better physician-derived clinical outcomes.
172 Regarding the clinical outcome from patients' viewpoint, several authors have reported the
173 relationship between patient-reported clinical score and postoperative alignment after TKA [17,18].
174 Huang et al. [17] reported that a coronal alignment >3° was associated with a significant decline in the
175 12-Item Short Form Survey (SF-12) mental health scores. In contrast, Matziolis et al. [18] reported that
176 the Western Ontario and McMaster Universities Index (WOMAC) and 36-Item Short Form Survey (SF-
177 36) did not reveal any significant differences between the varus malalignment knee group (3.9°–10.7°
178 varus) and the neutral group (2.6° valgus to 2.1° varus) after TKA. According to the authors, coronal
179 alignment may play a subordinate role at most for the patient-reported clinical mid-term outcome after
180 TKA. However, patient satisfaction and knee function after TKA are difficult to evaluate specifically
181 using previous instruments such as SF-12, SF-36, and WOMAC. The 2011 KSS was developed based on
182 the conventional Knee Society scoring system (1989), but only included three subjective items, namely
183 pain, walking ability, and ability to climb stairs [14], to better characterize the expectation, satisfaction,
184 and physical activities of patients who underwent TKA [10,11]. The 2011 KSS was reported to be a
185 reliable, internally consistent, and responsive questionnaire with construct validity when used to assess
186 the outcomes of TKA patients [19]. Recently, Kamenaga et al. [20] showed that lateral laxity at extension

after CR TKA was significantly correlated with the better patient satisfaction in the 2011 KSS [20]. Regarding the relationship with alignment, Matsuda et al. [21] reported that postoperative varus alignment resulted in lower patient satisfaction and fewer expectations but was not related to functional activities in the 2011 KSS in the mid-term follow-up. In the present study, the scores in all the categories of 2011 KSS in the varus alignment knee group were not significantly lower than those in the neutral group. This previous report and our findings suggest that varus alignment does not affect patient-reported knee function, and whether varus postoperative alignment is related to patient satisfaction in the mid-term postoperative period is controversial. Based on the present results, although there was no statistical difference, valgus alignment groups universally demonstrated worse functional results, which was compatible with the data of objective score indicated in Figure 2.

As for coronal alignment of the femoral component, valgus femoral component alignment resulted in lower 2011 KSS functional activity scores in the present study. Longstaff et al. [4] reported that patients with neutral femoral alignment had better KSKS at 1-year follow-up. In addition, femoral valgus alignment resulted in lower international knee society scores in a study by Magnussen et al. [22] and lower KSFS values in a study by Nishida et al. [9]. According to these authors, lower clinical scores may be associated with a more oblique cut and subsequently with more difficult ligament balancing required to achieve femoral valgus in many patients with a preoperative varus deformity [9,22]. On the contrary, in kinematically aligned TKA, it has been advocated that the distal femoral cut was made valgus to the mechanical axis. Previous randomized controlled study showed a more valgus alignment of the femoral component in kinematically aligned TKA compared to that in mechanically aligned TKA, but the mean postoperative LDFA was less than 2° [23]. Therefore, more than 2 ° valgus alignment of femoral component may not be recommended in not only mechanically aligned TKA, even in kinematically aligned TKA.

Regarding implant durability, Ritter et al. [2] reported that a femoral component alignment >8° of valgus with respect to the femoral anatomical axis (FAA) resulted in a five times higher rate of failure. Kim et al. [24] reported a 1.7% failure rate in the knees with a femoral valgus alignment >8° with respect to FAA, which is higher than the 0.7% failure rate in knees with femoral neutral alignment. In this study, valgus positioning of the femoral component resulted in a lower patient-reported functional score than that in neutral and varus positioning. Based on the results of the current study and those of previous

reports, not only objective clinical outcomes, but also patient-reported outcomes should be avoided in postoperative femoral valgus alignment during TKA.

As for coronal alignment of the tibial component, no significant differences were observed between the tibial component angle and the patient-reported clinical scores in the present study. Malalignment of the tibial component alters the distribution of tibial loading, which can lead to increased shear forces at the tibiofemoral interface and increased wear [25]. Berend et al. [26] reported that tibial malalignment >3° of varus increased the risk of medial bone collapse. Kim et al. [24] showed an increased failure rate of 3.4% in TKAs with a tibial component alignment other than neutral, in comparison with the 0% failure rate in neutral tibia alignment. Magnussen et al. [22] reported that postoperative tibial varus alignment was associated with a lower KSS. On the contrary, Nishida et al. [9] reported no significant differences in KSS or KSFS among the groups divided according to the tibial component alignment. Furthermore, Dossett et al. [23] reported that kinematically aligned TKAs had a tibial component placed 2.3° more varus than that in mechanically aligned TKAs, which resulted in improved patient-reported outcomes at 6 months postoperatively. In this study, the tibial varus alignment was not related to the lower patient-reported outcomes during the mid-term follow-up using the 2011 KSS. Thus, regarding the relationship between clinical outcome and tibial component alignment, further long-term follow-up will be necessary to make a firm conclusion, but mild varus positioning may be an acceptable target for TKA.

Our study had several limitations. First, only a small number of cases were included in each group, especially in the group of valgus limb alignment. Future studies should include a larger sample size with enough statistical power to confirm the finding of our study. Second, this study included patients who underwent PS and CR TKAs. Differences may exist between the two surgical techniques considering from soft tissue balance. However, Matsumoto et al. [27] reported that superiority of CR TKA in achieving equalised rectangular gaps at extension and flexion compare to PS TKA does not directly reflect postoperative clinical outcomes. Thus, the difference in clinical outcome between these two procedures may be less. Furthermore, there was no significant difference between the ratio of PS and CR in the three groups. Therefore, we believed that the findings are not affected much by the difference between the PS and CR techniques. Third, LDFA, MPTA influence HKA angle, which may affect the current results. Therefore, in order to minimize this bias, future study should be evaluated considering confounding factors. Finally, we could not assess the long-term postoperative outcomes using the 2011

KSS. A longer follow-up time will be needed to clarify our findings.

Conclusions

The relationship between postoperative limb alignment and patient-reported clinical outcomes were evaluated using the 2011 KSS. Although the postoperative objective score was significantly lower in the valgus groups compared with that of the varus and neutral groups, the patient-reported subjective score did not affect limb alignment. Meanwhile, the valgus femoral component angle resulted in lower subjective functional scores. For clinical relevance, postoperative valgus positioning of femoral component should be avoided from patient-reported functional aspects during TKA.

Conflict of interest

No funding or external support was received by any of the authors in support of or in any relationship to the study. The authors have no conflict of interests to declare.

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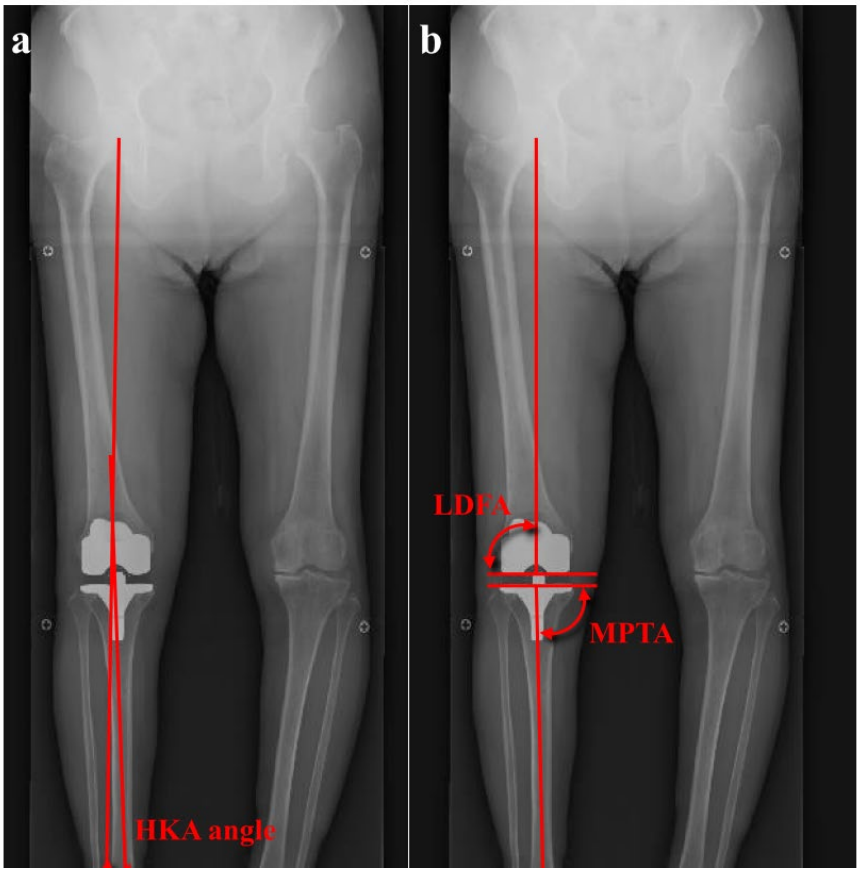
329 7.

Figure Legends

Fig.1.

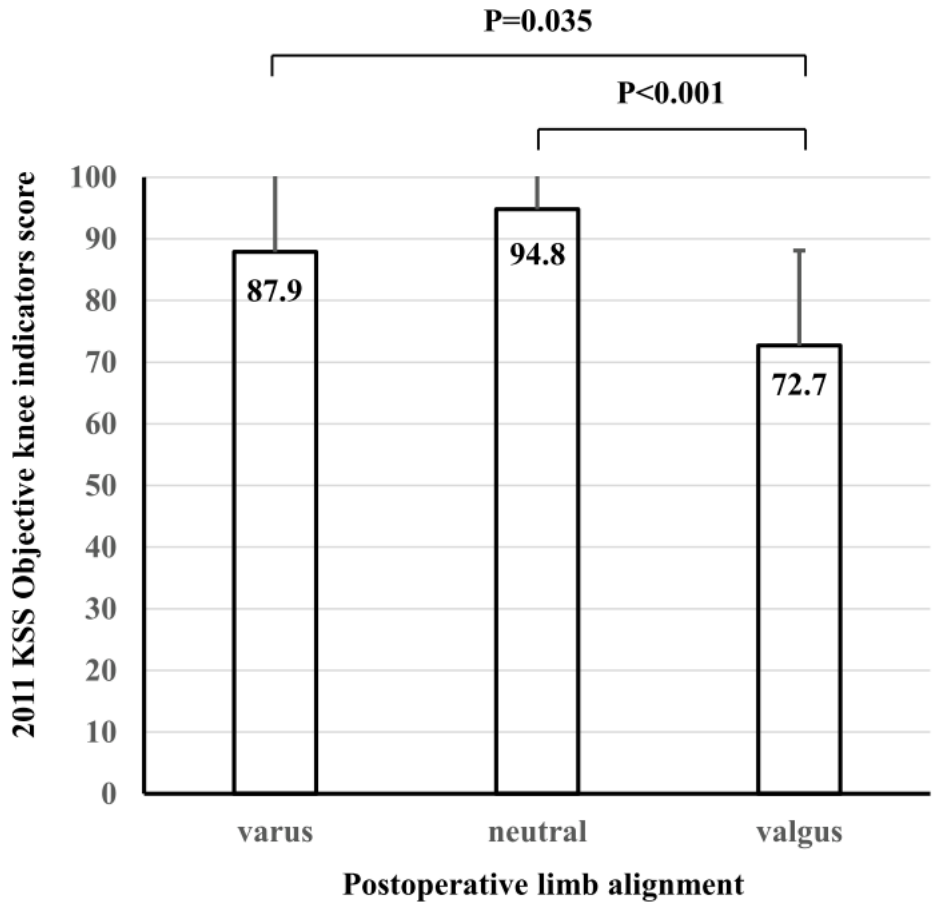


a Radiographs showing the measurements of hip-knee-ankle (HKA) angle.

b lateral distal femoral angle (LDFA) and medial proximal tibial angle (MPTA).

336 **Fig.2.**

Fig.2.



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338 Graphs showing differences in postoperative 2011 KSS objective knee indicators scores between the three

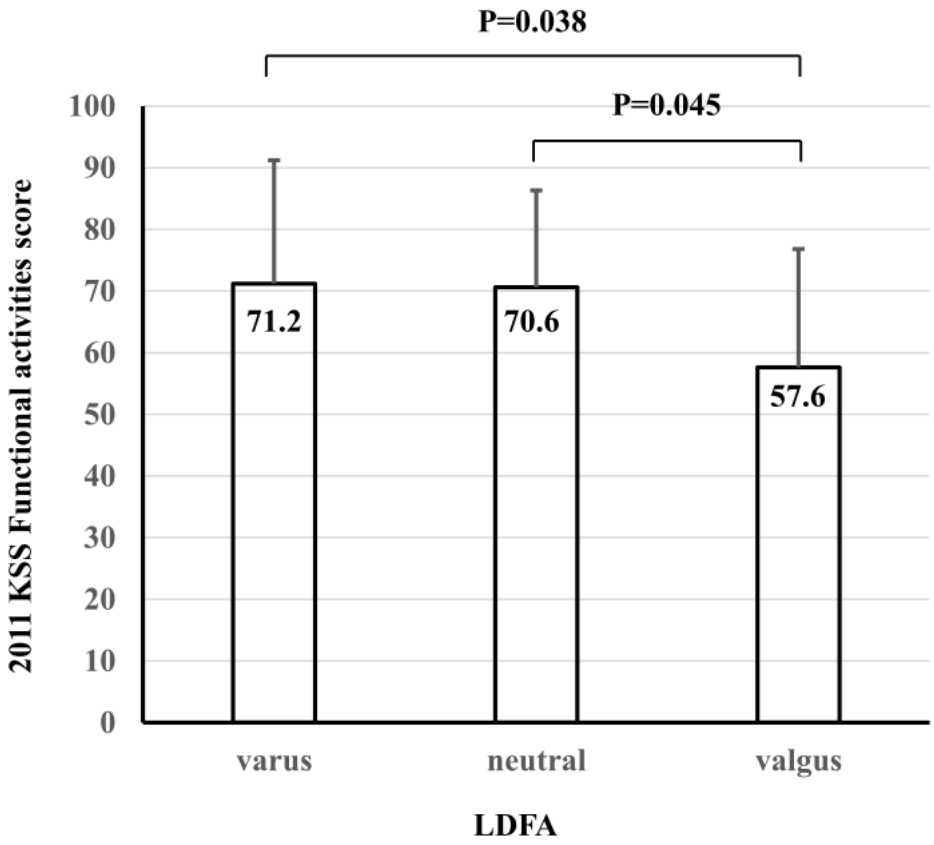
339 groups categorized HKA angle. The postoperative objective knee indicator scores were significantly

340 lower in the valgus groups than in the varus and neutral groups.

341

342 **Fig.3.**

Fig.3.



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344 Graphs showing differences in postoperative 2011 KSS functional activities scores between the three

345 groups categorized LDFA.

346 The postoperative functional activity scores was significantly lower in the valgus groups than in the varus

347 and neutral groups.

348

Table 1. Preoperative demographic data for all patients based on the three limb alignment and component angle groups

Variable	varus	neutral	valgus	*P* value
HKA angle				
Gender (female: male)	49:6	74:15	8:3	0.337
Age (years)	74.5 ± 6.8	74.0 ± 7.4	76.8 ± 3.0	0.516
CR: PS	17:38	36:53	5:6	0.439
Follow-up period (month)	45.4 ± 16.0	47.4 ± 20.9	44.4 ± 16.0	0.998
Preoperative KSKS	56.9 ± 12.3	59.9 ± 15.0	56.5 ± 12.6	0.611
Preoperative KSFS	57.9 ± 17.6	62.4 ± 15.4	64.4 ± 7.5	0.266
Preoperative HKA angle (°)	13.3 ± 5.2	11.9 ± 6.2	10.2 ± 2.9	0.103
	(1.3-25.0)	(2.2-27.4)	(7.0-13.8)	
Postoperative HKA angle(°)	5.1 ± 2.1	0.7 ± 1.5	-4.8 ± 1.2	<0.001
	(3.2-9.2)	(-2.5-3.0)	(-6.5--3.2)	
LDFA				
Gender (female: male)	47:6	69:14	15:4	0.529
Age (years)	73.6 ± 6.7	74.9 ± 7.5	73.9 ± 5.8	0.289
CR: PS	25:28	26:57	7:12	0.176
Follow-up period (month)	47.0 ± 16.2	42.7 ± 15.8	47.7 ± 18.2	0.174
Preoperative KSKS	57.6 ± 14.3	59.2 ± 14.1	55.1 ± 15.0	0.853
Preoperative KSFS	61.1 ± 16.3	60.4 ± 16.7	59.9 ± 17.7	0.991
Preoperative HKA angle (°)	12.6 ± 4.3	10.5 ± 6.4	11.6 ± 6.1	0.09
	(2.9-22.2)	(1.3-27.4)	(3.6-22.3)	

Postoperative LDFA (°)	93.8 ± 1.3	90.5 ± 1.0	86.7 ± 1.0	<0.001
	(92.2-97.3)	(88.0-92.0)	(85.0-87.9)	
MPTA				
Gender (female: male)	24:8	93:15	14:1	0.768
Age (years)	74.2 ± 6.9	74.2 ± 7.4	75.5 ± 4.3	0.753
CR: PS	13:19	41:67	4:11	0.639
Follow-up period (month)	47.3 ± 23.3	47.1 ± 18.0	40.6 ± 14.4	0.463
Preoperative KSKS	52.1 ± 13.9	59.2 ± 14.3	62.4 ± 15.0	0.296
Preoperative KSFS	57.5 ± 16.7	61.1 ± 16.3	64.2 ± 17.4	0.661
Preoperative HKA angle (°)	12.7 ± 4.9	11.8 ± 6.0	10.9 ± 6.3	0.297
	(1.3-20.8)	(1.6-27.4)	(1.5-25.5)	
Postoperative MPTA (°)	86.3 ± 2.0	89.9 ± 1.1	93.6 ± 1.4	<0.001
	(79.3-87.9)	(88.0-92.0)	(92.2-97.8)	

The data are expressed as mean ± SD values (range).

HKA angle: hip-knee-ankle angle, +: varus alignment -: valgus alignment

The preoperative HKA angle was measured within 1 month before surgery, and the postoperative HKA angle was measured 1 month after surgery.

CR: cruciate-retaining, PS: posterior-stabilizing, KSKS: the Knee Society Knee score, KSFS: the Knee Society Functional score

LDFA: lateral distal femoral angle, MPTA: medial proximal tibial angle

Table 2. Measurement of intra- and inter-rater reliability

Measurement	Intra-rater reliability	Inter-rater reliability
HKA angle	0.92	0.88
LDFA	0.99	0.94
MPTA	0.99	0.96

HKA angle: hip-knee-ankle angle, LDFA: lateral distal femoral angle, MPTA: medial proximal tibial angle

Table 3. Postoperative 2011 KSS scores between three groups categorized by limb alignment

The 2011 KSS categories	varus (*n*=55)	Neutral (*n*=89)	Valgus (*n*=11)	*P* value
Objective knee indicators	87.9 ± 14.8	94.8 ± 7.7	72.7 ± 15.4	<0.001
Postoperative HKA angle at last follow-up	5.2 ± 2.2	0.7 ± 1.6	-4.2 ± 1.9	<0.001
Symptoms	19.6 ± 5.8	19.8 ± 4.9	19.6 ± 4.5	0.431
Satisfaction	28.5 ± 9.0	27.1 ± 7.9	26.2 ± 6.6	0.431
Expectations	11.3 ± 4.2	10.9 ± 2.8	11.4 ± 2.4	0.648
Functional activities	71.2 ± 20.6	67.3 ± 17.5	63.3 ± 19.0	0.263

The data are expressed as mean ± SD values.

HKA angle: hip-knee-ankle angle, +: varus alignment -: valgus alignment

The postoperative HKA angle was measured as an alignment included in objective knee indicators category at the last follow-up.

372 **Table 4. Postoperative 2011 KSS scores between three groups categorized by femoral**

373 **and tibial component angle**

The 2011 KSS categories	varus	neutral	valgus	*P* value
LDFA	(*n*=53)	(*n*=83)	(*n*=19)	
Objective knee indicators	89.3 ± 14.1	93.0 ± 10.4	87.2 ± 14.7	0.260
Postoperative HKA angle at last follow-up	4.1 ± 2.6	1.1 ± 2.6	-1.2 ± 3.2	<0.001
Symptoms	19.1 ± 5.9	20.4 ± 4.6	18.8 ± 4.9	0.343
Satisfaction	27.5 ± 8.7	28.0 ± 8.0	25.9 ± 8.0	0.633
Expectations	11.3 ± 3.9	11.4 ± 2.9	9.8 ± 2.7	0.141
Functional activities	71.3 ± 20.0	70.6 ± 15.7	57.6 ± 19.2	0.032
MPTA	(*n*=32)	(*n*=108)	(*n*=15)	
Objective knee indicators	89.5 ± 13.8	92.4 ± 11.6	83.8 ± 14.3	0.088
Postoperative HKA angle at last follow-up	3.8 ± 2.8	1.9 ± 2.9	-1.4 ± 3.7	<0.001
Symptoms	20.0 ± 4.9	20.0 ± 5.3	17.5 ± 4.0	0.066
Satisfaction	28.6 ± 9.0	27.6 ± 8.3	25.2 ± 5.3	0.251
Expectations	10.4 ± 3.7	11.4 ± 3.3	10.7 ± 2.9	0.340
Functional activities	68.7 ± 21.9	70.3 ± 16.8	59.0 ± 20.3	0.142

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375 The data are expressed as mean ± SD values.

376 The postoperative HKA angle was measured as an alignment included in objective knee
377 indicators category at the last follow-up.
378 LDFA: lateral distal femoral angle, MPTA: medial proximal tibial angle
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