Brief communication

Radiographic assessment and clinical outcomes after total knee arthroplasty using an accelerometer-based portable navigation device

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A R T I C L E   I N F O

A B S T R A C T

It has been reported that an accelerometer-based portable navigation device can achieve accurate bone cuts, but there have been few studies of clinical outcomes after total knee arthroplasty (TKA) using such a device. The aim of this study was to evaluate lower limb alignment and clinical outcomes after TKA using an accelerometer-based portable navigation device. Thirty-five patients (40 knees) underwent primary TKAs using an accelerometer-based portable navigation device. Postoperative radiographic assessments included the hip-knee-ankle angle, femoral component angle (FCA), and tibial component angle (TCA) in the coronal plane and the sagittal FCA and sagittal TCA in the sagittal plane. Clinical outcomes were evaluated by the Japanese Orthopedic Association score for osteoarthritic knees, Japanese Knee Osteo-arthritis Measure, and the New Knee Society Score. The frequency of outliers (>3 degrees) was 10% for the hip-knee-ankle angle, 8% for FCA, 0% for TCA, 19% for sagittal FCA, and 9% for sagittal TCA. The Japanese Orthopedic Association score and Japanese Knee Osteoarthritis Measure were significantly improved postoperatively. The postoperative New Knee Society Score was 67.2% for symptoms, 50.3% for satisfaction, 58.6% for expectation, and 44.1% for function. TKA using an accelerometer-based portable navigation device achieved good results for both lower limb alignment and clinical outcomes.

Introduction

Accurate lower limb alignment is one of the most important factors for a successful total knee arthroplasty (TKA), and it has reportedly been associated with good postoperative clinical outcomes [1]. Recently, various devices have been used to achieve accurate lower limb alignment, such as computer-assisted surgery (CAS), an extramedullary alignment guide for femoral resection, and a patient-matched instrument (PMI) [2-4].

The KneeAlign 2 system (Orthalign Inc., Aliso Viejo, CA) is an accelerometer-based portable navigation device for TKA. This device can help achieve the correct angle of resection for the distal femur (flexion, varus/valgus) and the proximal tibia (posterior slope, varus/valgus). Although achievement of good lower limb alignment has been reported [5], little is known about the clinical outcomes using this device. The correlation between lower limb alignment after TKA and clinical outcomes is still controversial, but self-reported clinical outcomes may indicate the true clinical outcomes of TKA.

The aim of this study was to evaluate lower limb alignment and objective and self-reported clinical outcomes after TKA using an accelerometer-based portable navigation device.

Material and methods

This was a retrospective study approved by an institutional review board. Between March 2014 and November 2015, 35 patients (40 knees) underwent primary TKAs using the KneeAlign 2 system. These included 9 male patients with 9 knees and 26 female patients with 31 knees, with an average age of 75.5 years (range, 49-86 years). Overall, 36 knees had osteoarthritis, and 4 knees had

rheumatoid arthritis. The average follow-up period was 14.6 months (range 6-26 months). The implant type was the Vanguard Complete Knee System (Zimmer Biomet, Warsaw, IN), and the posterior-stabilized type implant was used in all knees.

The trivector-retaining approach or the medial parapatellar approach was used. Bone cuts were performed by the modified gap technique. The KneeAlign 2 system was used for distal femoral resection and proximal tibial resection. In the coronal plane, both the distal femur and the proximal tibia were cut perpendicular to the mechanical axis. In the sagittal plane, the femoral flexion angle was set as the angle between the mechanical axis and the anterior distal femoral cortex line. The tibial posterior slope was set to 2 degrees.

Postoperatively, anterior–posterior radiographs of the lower limb were obtained for evaluation of the hip-knee-ankle (HKA) angle, femoral component angle (FCA), and tibial component angle (TCA). Lateral radiographs of the lower limb were obtained for evaluation of sagittal FCA and sagittal TCA. The HKA angle was defined as the angle between the line connecting the center of the femoral head to the center of the knee joint (femoral mechanical axis) and the center of the knee joint to the center of the ankle joint (tibial mechanical axis). FCA was defined as the angle between the femoral mechanical axis and the joint surface line of the femoral implant. TCA was defined as the angle between the tibial mechanical axis and the base plate of the tibial implant (Fig. 1a). Sagittal FCA was defined as the angle between the femoral mechanical axis and the distal end of the femur. Sagittal TCA was defined as the angle between the tibial mechanical axis and the base plate of the tibial implant (Fig. 1b). Outliers were defined as follows: more than 180 ± 3 degrees for the HKA angle; more than 90 ± 3 degrees for the FCA and TCA; and femoral flexion set angle
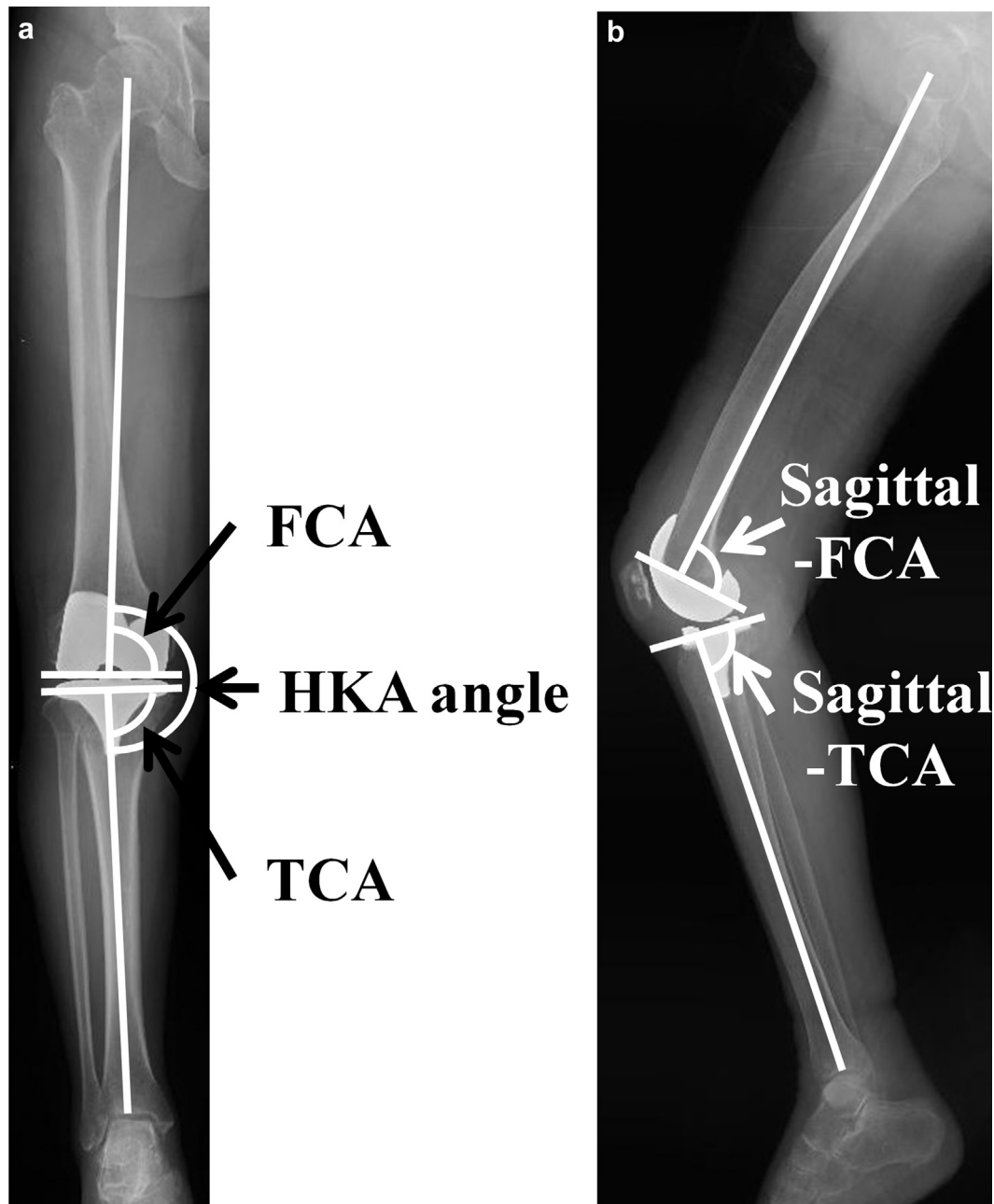

Figure 1. Postoperative lower limb alignment. (a) Coronal alignment. (b) Sagittal alignment.

Table 1
Postoperative coronal and sagittal lower limb alignment and outliers more than 3 degrees.

Measure	Value (mean ± SD, degrees)	Outliers (N, %)
HKA angle	179.3 ± 2.6	4, 10
FCA	88.6 ± 1.7	3, 8
TCA	89.4 ± 1.2	0, 0
Sagittal FCA	86.4 ± 2.7	6, 19
Sagittal TCA	85.9 ± 1.8	3, 9

SD, standard deviation.

more than ±3 degrees in sagittal FCA and more than 88 ± 3 degrees in sagittal TCA.

Clinical outcomes were evaluated by the preoperative and postoperative Japanese Orthopedic Association (JOA) score for osteoarthritic knees as an objective assessment. The JOA score consists of 4 subgroups: pain on walking (30-point scale), pain on ascending or descending stairs (25-point scale), range of motion (35-point scale), and joint effusion (10-point scale). The total score is on a 100-point scale, and a higher score means a good clinical outcome [6]. Also, the preoperative and postoperative Japanese Knee Osteoarthritis Measure (JKOM) and the postoperative New Knee Society Score (New KSS) were used as self-reported assessments. The JKOM consists of a visual analog scale (100-mm method) and the following 4 subgroups: pain and stiffness (32-point scale), daily life (40-point scale), general activities (20-point scale), and health conditions (8-point scale). The total score, excluding the visual analog scale, is a 100-point scale, and a lower score means a good clinical outcome [7]. The New KSS consists of 4 subgroups: symptoms (25-point scale), satisfaction (40-point scale), expectation (40-point scale), and function (100-point scale). A higher score means good clinical outcomes in each subgroup [8].

Statistical comparisons between preoperative and postoperative clinical scores (JOA score and JKOM) were performed using Mann–Whitney's U test. Significance was set at $P < .05$ for all analyses. All data were analyzed using EZR (Saitama Medical Center, Jichi Medical University, Saitama, Japan), which is a graphical user interface for R, version 2.13.0 (The R Foundation for Statistical Computing) [9].

Results

Anterior–posterior radiographs of the lower limbs and clinical outcomes were evaluated in all of the 40 enrolled knees, whereas lateral radiographs of the lower limbs were evaluated for 32 knees.

Postoperative lower limb alignment is presented in Table 1. The average HKA angle was 179.3 ± 2.6 degrees, and 10% were outliers. The frequency of outliers was the lowest for TCA (0%) and the highest for sagittal FCA (19%). For sagittal TCA, no cases were more extended than 88 degrees.

Table 2
Preoperative and postoperative JOA scores.

Subgroup	Preoperative (mean ± SD)	Postoperative (mean ± SD)	P-value
Walking	13.9 ± 5.4	27.5 ± 4.0	$P < .001$[a]
Stairs	5.1 ± 3.4	19.3 ± 7.1	$P < .001$[a]
Range of motion	24.0 ± 4.0	26.0 ± 4.0	$P = .21$
Swelling	8.1 ± 3.0	9.8 ± 1.1	$P = .007$[a]
Total	51.1 ± 9.7	82.3 ± 10.0	$P < .001$[a]

SD, standard deviation.
[a] A significant difference between preoperative and postoperative scores on Mann–Whitney's U test.

Table 3
Preoperative and postoperative JKOM.

Subgroup	Preoperative (mean ± SD)	Postoperative (mean ± SD)	P-value
VAS	67.2 ± 21.6	24.9 ± 27.3	$P < .001$[a]
Pain and stiffness	19.6 ± 6.0	9.0 ± 7.0	$P < .001$[a]
Daily life	22.6 ± 8.4	12.0 ± 8.1	$P < .001$[a]
General activities	13.9 ± 6.4	7.0 ± 5.8	$P < .001$[a]
Health conditions	5.0 ± 1.6	2.5 ± 1.7	$P < .001$[a]
Total	60.8 ± 19.7	30.1 ± 20.2	$P < .001$[a]

VAS, visual analog scale; SD, standard deviation.
[a] A significant difference between preoperative and postoperative scores on Mann–Whitney's U test.

Clinical outcomes are presented in Tables 2-4. The postoperative JOA score was significantly improved, except for range of motion. Postoperative JKOM was significantly improved in all subgroups. The New KSS percentages were 67.2% for symptoms, 50.3% for satisfaction, 58.6% for expectation, and 44.1% for function.

Discussion

For lower limb alignment after TKA using the KneeAlign 2 system, outliers were seen in 10% for the HKA angle, 8% for FCA, 0% for TCA, 19% for sagittal FCA, and 9% for sagittal TCA.

Jeffery et al. [10] reported that varus alignment more than 3 degrees for the HKA angle was a risk factor for poor long-term results after TKA. Previous studies reported that outliers more than 3 degrees for the HKA angle were seen in 21%-28% with the conventional method, 11%-14% with CAS, and 9% with PMI [11-13]. Nam et al. [13] compared coronal alignment after TKA using the KneeAlign 2 system and CAS. They reported that outliers more than 3 degrees were seen in 7.5/13.7% for the HKA angle, 1.3/5% for FCA, and 0/0% for TCA with KneeAlign 2 system/CAS; thus, KneeAlign 2 system showed significantly better alignment for the HKA angle and FCA. Compared with these studies, the present results showed good coronal lower limb alignment after TKA using the KneeAlign 2 system.

There have been a few studies of sagittal alignment after TKA. Nam et al.[14] reported that outliers more than 2 degrees in sagittal alignment of the tibial component were seen in 5% of the KneeAlign cohort and 28% of the conventional cohort, with the KneeAlign cohort showing significantly better sagittal alignment. Outliers more than 3 degrees for sagittal TCA were seen in 9% of the present study; these results show good sagittal alignment after TKA using the KneeAlign 2 system. Furthermore, no cases were more extended than 88 degrees in sagittal TCA. Some reports showed that an extended position of the tibial component caused loss of flexion angle, loosening, and dislocation of the polyethylene insert [15-18]. Because no cases showed an extended position of the tibial component in the present study, there was a low risk for such problems using the KneeAlign 2 system.

Outliers more than 3 degrees for sagittal FCA were seen in 19% of the present study, which was the highest percentage on

Table 4
Postoperative New KSS.

Subgroup	Score (mean ± SD)	Percentage (mean ± SD, %)
Symptoms	16.8 ± 6.3	67.2 ± 25.3
Satisfaction	20.1 ± 8.4	50.3 ± 21.0
Expectation	8.8 ± 2.7	58.6 ± 18.1
Function	44.1 ± 21.1	44.1 ± 21.1

SD, standard deviation.

Table 5
Postoperative clinical outcomes in previous studies and the present study.

| Authors | N | JOA score | JKOM | New KSS | | | |
		Total	Total	Symptoms	Satisfaction	Expectation	Function
Horikawa (2015)	50	81.1	21.7				
Sugita (2015)	40		37.0				
Kawahara (2014)	92			19.6	23.6	10.5	49.3
Nakahara (2015)	387				23.1	9.6	
This study	40	82.3	30.1	16.8	20.1	8.8	44.1

radiographic assessment. Two reasons may explain why this was the highest percentage: surgical technique and radiographic assessment. In surgical technique, there might be a risk of mismatch between the mechanical axis during operation and the assessment axis in radiographs after operation. The reason for this mismatch was variation of the distal femoral pin insertion in each case, bone-saw technique avoiding the anterior notch, and moving the center of the femoral head by motion of the pelvis when detecting the center of the femoral head. In radiographic assessment, there might be some inaccurate lateral radiographs; there have been few studies of sagittal alignment after TKA, and how to assess TKA sagittal alignment has not been well defined. To resolve these problems, assessment of the KneeAlign 2 system's accuracy, correct position when taking the radiograph, and 3-dimensional assessment using computed tomography are needed.

Postoperative clinical outcomes in TKA using the KneeAlign 2 system were significantly improved for both the JOA score and JKOM. Previous studies of clinical outcomes after TKA with conventional technique are shown in Table 5 [19-22]. The present results were good for the JOA score, JKOM, and New KSS compared with previous studies. Matsuda et al.[23] reported that varus lower limb alignment after TKA resulted in poor self-reported clinical outcomes using the New KSS. Gothesen et al.[24] reported that TKA using CAS achieved better alignment and clinical alignment than conventional technique. Iorio et al.[25] reported that using the KneeAlign 2 system for tibial cutting resulted in good tibial alignment and self-reported clinical outcomes postoperatively. In the present study, using the KneeAlign 2 system led to good lower limb alignment and good clinical outcomes both on objective and on self-reported assessments. Good lower limb alignment might prevent abnormal load distribution and lead to good clinical outcomes. Moreover, straight legs might satisfy patients and lead to good self-reported clinical outcomes.

There are some limitations in this study. First, there was no control group because all TKAs in this period were performed using the KneeAlign 2 system. A prospective study with other methods (conventional method, CAS, and PMI) should be performed to show the usefulness of the KneeAlign 2 system for TKA in the future. Second, sample size was small and the follow-up periods were short (14.6 months). Because the KneeAlign 2 system was released in 2014 in Japan, sample size must still be small and the follow-up period must still be short, so large sample size and long-term clinical results will need to be examined in the future. Third, the timing of clinical outcome assessment was not the same. However, in all cases, follow-up was for at least 6 months, and good results were achieved.

Conclusions

TKA using an accelerometer-based portable navigation device achieved good short-term results for both lower limb alignment and clinical outcomes. Both objective scores and self-reported clinical outcomes were good. An accelerometer-based portable navigation device was a useful tool for TKA.

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