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Comparison of clinical and biomechanical outcomes between the kinematic and mechanical alignment methods in total knee arthroplasty: Protocol for a multicenter randomized controlled trial

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ABSTRACT

Introduction: The concept of anatomic restoration has garnered considerable interest in the form of kinematically aligned total knee arthroplasty (KA-TKA). KA-TKAs have been reported to reproduce natural alignment and kinematics. However, few randomized controlled trials (RCTs) have compared the biomechanical outcomes and the long-term clinical outcomes of KA-TKA with those of mechanically aligned TKA (MA-TKA). We aim to investigate the long-term clinical and biomechanical effects of KA-TKA and to determine whether KA-TKA or MA-TKA is more appropriate for primary TKA.

Methods: This trial will compare clinical and biomechanical outcomes of KA-TKA to those of MA-TKA. Two hundred patients will be enrolled in the RCT and randomized into KA-TKA or MA-TKA groups. Both the groups will be evaluated 1 week before the operation, on the day of the operation, 6 months after the operation, and 1, 5, and 10 years after the operation. The primary outcome is the difference between preoperative and 1-year postoperative functional activity scores of the 2011 Knee Society Score (2011 KSS) in both groups as well as the differences between the scores of both groups. The secondary outcomes will include differences in symptom, satisfaction, and expectation scores of the 2011 KSS, intraoperative kinematics evaluation, postoperative clinical outcomes and complications, pre- and postoperative gait analyses and radiograph evaluations between both KA-TKA and MA-TKA.

1. Introduction

Total knee arthroplasty (TKA) is a standard therapy for patients with advanced knee osteoarthritis (OA) who were unsuccessful with conservative non-surgical treatment [1]. Other studies on primary knee OA have revealed a link between varus alignment and the subsequent progression of OA [2]. Therefore, restoring the overall alignment to a neutral mechanical axis, which is termed mechanically aligned TKA (MA-TKA), is considered to be an important factor for long-term implant survival and favorable postoperative clinical outcomes [1,3,4]. However, for the patients who had constitutional varus knees before the disease or damage occurred, the restoration of mechanical alignment to neutral may be unnatural and undesirable [5–7].

The concept of anatomic restoration has gained interest in the form of kinematically aligned TKA (KA-TKA). The goal of KA-TKA is to set the femoral and tibial components at the angles and levels of the distal and posterior femoral joint lines; the tibial joint lines are each restored to the patient's natural alignment and natural kinematics [8]. Dossett et al. reported that KA-TKA provides superior pain relief and restores greater function and range of motion (ROM) than MA-TKA [9]. Furthermore, we report that KA-TKA provided better patient satisfaction than MA-TKA [10]. However, only a few randomized controlled trials (RCTs) have directly compared the biomechanical outcomes including gait analysis and intraoperative kinematics, and the mid- and long-term clinical outcomes of KA-TKA with those of MA-TKA. Therefore, the purpose of our planned trial is to clarify the clinical and biomechanical

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long-term effects of KA-TKA and determine whether KA-TKA or MA-TKA provides more favorable outcomes.

2. Methods

2.1. Study design

We will undertake a multicenter RCT. This trial will be conducted in two hospitals from March 2018 to March 2030 and compare the clinical and biomechanical outcomes of KA-TKA and MA-TKA patients. The trial has been registered in the University Hospital Medical Network Clinical Trials Registry (UMIN-CTR) as UMIN #000026895. This trial was approved by the Ethical Review Committee of our institution (approval number: 1805–003).

2.2. Participants

A total of 200 patients with knee OA will be enrolled and investigated. Inclusion criteria are: diagnosis of varus knee OA, Kellgren-Lawrence classification grade ≥3, patients who have undergone cruciate-retaining (CR) TKA, ability to communicate, and particularly the ability to express and understand informed consent. Exclusion criteria are as follows: rheumatoid arthritis, valgus deformity, revision TKA, patients who had undergone primary posterior-stabilized (PS) TKA, severe varus deformities ≥ 20°, bony defect requiring bone graft or augmentation, active knee joint infection, or inability to walk. Written informed consent will be obtained from all patients preoperatively, and patients may withdraw consent at any time. Protocols of the RCT would adhere to the CONSORT guidelines. The duration of follow-up is 10 years, and both groups would be evaluated 1 week before the operation, the day of the operation, 6 months, 1, 5, and 10 years after the operation. All patients will undergo TKA within 30 days of randomization. A flow of the trial and the schedule of the trial assessments are summarized in Fig. 1 and Table 1, respectively.

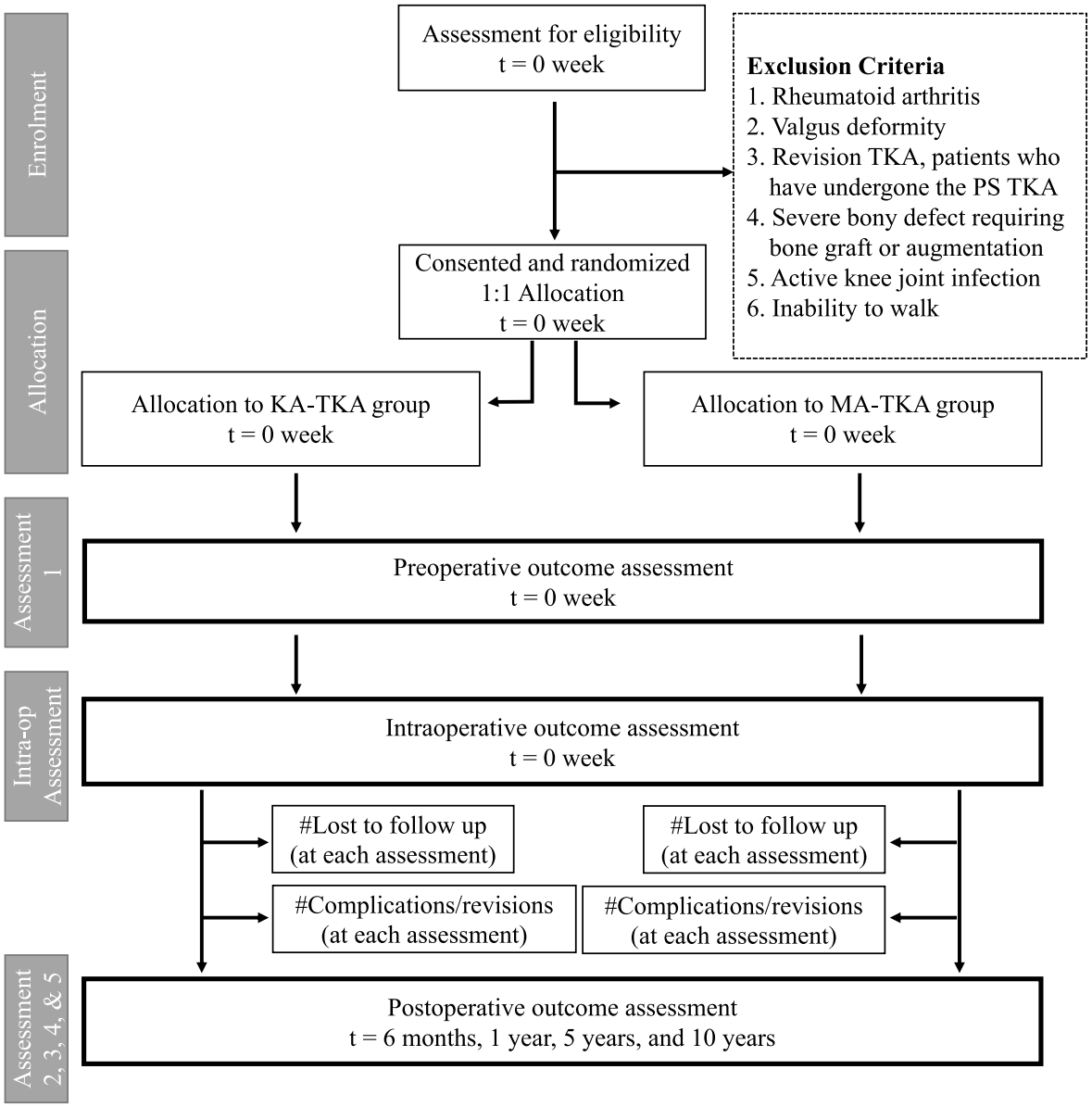

Fig. 1. Study protocol. TKA: Total knee arthroplasty; PS: Posterior-stabilized; #: Number; MA-TKA: mechanically aligned TKA; KA-TKA: kinematically aligned TKA; 2011 KSS: 2011 knee society score; t: time point.

Table 1
Schedule of study assessment.

	Preoperative	Intraoperative	Postoperative			
		0 week	6 month	1 year	5 year	10 year
Demographics	○					
Radiographs	○	○	○	○	○	○
Knee range of motion	○		○	○	○	○
Intraoperative kinematics		○				
2011 KSS	○		○	○	○	○
Gait analysis	○		○	○		
Adverse event reporting		○	○	○	○	○

2011 KSS: 2011 Knee Society Score.

2.3. Randomization and blinding

Patients who fulfill the entry criteria are randomly allocated in a 1:1 ratio to receive KA-TKA (KA-TKA group) or MA-TKA (MA-TKA group). Randomization will be implemented using a centralized telephone registration system. Stratification factors will include hospitals. The surgeon will be notified of the treatment allocation only after data have been independently recorded on the assessment of intraoperative knee kinematics and immediately prior to any knee osteotomy being undertaken. Although the surgeons will not be blinded to the allocation, the participants, assessors, and statisticians will be blinded to enable unbiased collection and analyses of outcomes. Independent data investigators will be employed to undertake randomized allocation and data recording and to ensure transparency, concealment, and integrity of blinding.

2.4. Intervention

TKA will be performed under general anesthesia using an air tourniquet during the surgery. All TKAs in this trial will be performed by four senior surgeons each with over 10 years of experience with TKA. We will undertake all TKA using the Persona® (Zimmer Biomet Inc, Warsaw, IN, USA) components, and perform the medial parapatellar arthrotomy assisted by a portable navigation system (iASSIST® Zimmer Biomet, Warsaw, IN, USA) [11] according to the manufacturer's instructions. Navigation data will be available to the surgeon for accurate bone resections. Preoperatively, coronal and sagittal long leg radiographs will be taken and used to select the appropriately sized femoral and tibial prostheses and to determine the appropriate level and angle of osteotomies in relation to the mechanical axes. Moreover, epicondylar view radiography and computed tomography (CT) will be performed to reference the original transepicondylar axes and posterior condylar axes. By using an epicondylar view radiograph and CT, osteophytes in the intercondylar notch will also be assessed preoperatively to enable selection of the type of CR component. Following the confirmation of functional posterior cruciate ligament (PCL) judged by the intraoperative findings and the preoperative epicondylar view radiograph and CT on intercondylar osteophytes, the insertion of the PCL will be preserved by a bony island. The tibial rotational axis is defined along the line from the medial border of the tibial tubercle to the middle of the PCL [12]. Postoperative care for all patients, including antibiotic administration, anticoagulation, and physiotherapy, will be based on the institutional protocols. The specific technical details of the two groups are outlined below.

2.4.1. Mechanically aligned TKA group (MA-TKA group)

In the MA-TKA group, prior to the femoral osteotomy, minimum medial release (osteophyte removal and release of the deep layer of the medial collateral ligament) will be performed to maintain medial stability [13]. The osteotomies will be performed perpendicular to the tibial and femoral mechanical axes. The femoral external rotation will be set at 3° to the femoral posterior condyles.

2.4.2. Kinematically aligned TKA (KA-TKA) group

In the KA-TKA group, tibial osteotomy will be performed with 3° of varus to the mechanical axis and a 7° posterior slope. Navigation system is used to apply a definitive 3° varus in order to avoid unexpected varus tibial osteotomy. This degree of varus was based on previous reports of a modified KA-TKA [14], where the tibial plateau inclination was about 3° in asymptomatic volunteers regardless of age, but progressed to approximately 10° in patients with OA progression [5]. Prior to the femoral osteotomy, minimum medial release will also be performed. Then, femoral osteotomy equal in thickness (9 mm) to the condyles of the femoral component will be performed after correcting for wear of the distal and posterior femur. With the use of the navigation system, distal and posterior resection with a consistent thickness of 9 mm will be performed at the lateral side, whereas distal and posterior resection with a thickness of 7 mm and 8–9 mm, respectively, will be performed at the medial side.

2.5. Outcomes

2.5.1. Primary outcome

The primary outcome is the difference between preoperative and 1-year postoperative functional activity scores using the 2011 Knee Society Score (2011 KSS) in both KA-TKA and MA-TKA patients as well as the differences between the scores of the MA-TKA group and those of the KA-TKA group. We predict that the difference in the score will be significantly greater in the KA-TKA group than in the MA-TKA group. The 2011 KSS is a validated and responsive questionnaire for assessing both objective and subjective clinical outcomes after TKA, including items such as functional activities, symptoms, satisfaction, and expectation [15].

2.5.2. Secondary outcomes

The secondary outcomes are: 1) the difference between preoperative and 6 month, 5 and 10 year postoperative functional activity scores of the 2011 KSS in both KA-TKA and MA-TKA groups; 2) the difference between preoperative and 6 month, and 1, 5 and 10 year postoperative symptoms, satisfaction, and expectation scores of the 2011 KSS in both KA-TKA and MA-TKA groups; 3) the intraoperative parameters; 4) clinical outcomes at 5 and 10 years following the operation; 5) the rate of major complications; 6) analysis of pre- and postoperative gait kinematics in both KA-TKA and MA-TKA groups at each time point; 7) evaluations of pre- and postoperative radiographs in both KA-TKA and MA-TKA groups at each time point.

2.6. Study procedures

2.6.1. Clinical parameters

Investigators will collect the following data: research identification code, date of birth, age, race, sex, height, body weight, body mass index (BMI), complications, medical and surgical history, the knee ROM, each item of the 2011 KSS at 1 week preoperatively, 6 months, and 1, 5, and 10 years postoperatively, and the rate of major complications including loosening, wear and breakage of the prosthetic components, patellar problems, fracture in the vicinity of the prosthesis, disruption of the extensor mechanism of the knee, and infection. The rate of these complications will be prospectively evaluated from the patients' records.

2.6.2. Intraoperative parameters

Intraoperative kinematics will be evaluated using an image-free navigation system. Investigators will collect the femoral and tibial component size, insert thickness, determine whether the patella was resur-

faced, and ROM. Investigators will also collect resected bone thickness of the medial and lateral tibia, distal femur, posterior femoral condyle, and patella.

2.6.3. Radiographic parameters

Preoperative and postoperative radiographs will include full-length single-leg and double-leg standing posteroanterior radiographs, knee anterior-posterior (AP) and lateral erect, and skyline radiographs as per the trial assessment timeline. The limb alignment will be evaluated with full-length leg standing posteroanterior radiograph, implant position, and implant loosening will be confirmed with knee AP erect radiograph. Radiographic data will include hip-knee-ankle (HKA) angle, the angle of orientation of the joint line in relation to the floor, conventional mechanical axis, and true mechanical axis (the line from the center of the hip to the lowest point of the calcaneum), femoral and tibial component angle in the coronal or sagittal plane.

2.6.4. Gait kinematics parameters

Gait analysis will be performed at 1 week preoperatively and 6 months and 1, 5, and 10 years postoperatively. After a few practice trials, all subjects will perform trials of 10 m level walking with shoes at a comfortable walking speed in a gait laboratory. Gait kinematics and ground reaction force (GRF) will be evaluated using the Microsoft Kinect developed as a video device to assess the spatiotemporal gait kinematics and the Kistler Force Plate (Kistler Instrument, AG, Winterthur, Switzerland), respectively. Gait kinematics parameters will include knee adduction and flexion angle, external knee adduction moment (KAM), GRF, walking speed, walking stride, and lateral thrust. KAM will be calculated using the Vicon bodybuilder® software (Oxford Metrics Ltd, Oxford, UK).

2.7. Sample size

The effect size was calculated by the means and standard deviation (SD) of the pilot study at our institution [14]. The primary outcomes in both KA-TKA and MA-TKA of the pilot study were 24.5 ± 17.1, and 17.5 ± 15.6, respectively. The effect size was detected as 0.427. A power analysis indicated that 88 patients in each group will be required in a two-sided Student's t-test using G* Power 3.1 [16] when alpha is set as 0.05, the effect size is set as 0.427 and power at 0.8.

2.8. Statistical analysis

The outcomes will be analyzed using Statview 5.0 (Abacus Concepts Inc., Berkeley, California). The clinical parameters, primary and secondary outcomes of the trial will be expressed as means ± SD. For continuous variables, the following values: 1) valid “n; ” 2) mean; 3) SD; 4) median; 5) minimum and maximum, will be calculated for each group and will compare the KA-TKA and MA-TKA groups using Student's t-test. Categorical variables will show the frequency and proportion of categories for each group and compare them using the χ^2-test or Fisher's exact test, as appropriate. A value of $p < 0.05$ will be considered statistically significant.

3. Discussion

The KA-TKA attempts to modify implant position to recreate the anatomy of the prearthritic articular surface for the individual patient and restore the patient's natural alignment [7] [[,17] [][][]. KA-TKA has generated interest for achieving better clinical outcomes than MA-TKA [8] [[,18] [][][] and meta-analyses comparing KA-TKA to MA-TKA reported that functional outcome as measured by the KSS favored KA-TKA in short-term follow-up [19–21]. However, since tibial plateau inclination might progress to ~10° in arthritic knees [5], it may be difficult to ascertain the natural tibial plateau inclination predicted from preoperative tibial plateau inclination. This difficulty may align the tibial component in outlier categories including severe varus that might predict compromised function and place the components at a higher risk for catastrophic failure in KA-TKA [22]. To prevent such a catastrophic failure, we developed the method of restricted KA-TKA in which the tibia osteotomy was set at 3° of varus assisted by navigation [5]. Despite favorable clinical outcomes reported at short-to mid-term follow-ups, surgeons should judge whether or not this method is useful and safe, and carefully assess the long-term clinical and biomechanical outcomes until KA-TKA becomes the recommended alternative procedure for MA-TKA. Therefore, we will perform a multicenter RCT to compare long-term clinical and biomechanical outcomes between KA-TKA and MA-TKA. We believe that this trial will provide evidence that KA-TKA not only achieves natural alignment but also produces superior clinical outcomes compared to MA-TKA, without severe complications.

There are several strengths in this trial. First, other reports on KA-TKA focused on short-to middle-term clinical outcomes [21]. Therefore, we set 10 years of follow-up for evaluating the long-term outcomes. Second, several studies mainly focused on clinical scores (KSS, Western Ontario, and McMaster Universities OA Index score et al.) and ROM. We will investigate not only the clinical parameters but also the biomechanical parameters including gait kinematics. Although varus component alignment has been assumed to increase external KAM and put patients at risk for premature loosening of the tibial component, Niki et al. reported the first peak of KAM during gait was greatly reduced in KA-TKA compared to that of MA-TKA [23]. Since few studies have reported gait kinematics after KA-TKA, more investigation in this arena is required. In contrast, there are several possible specific postoperative complications after KA-TKA. First, the femoral and tibial component loosening, instability, and insert wear as a result of varus alignment of the tibial component can occur after KA-TKA. Second, since KA-TKA sets the femoral component in an average of 2° more valgus, and 3° less external rotation than MA-TKA [9], the valgus and internal rotations of the femoral component result in a lateral shift of the patellar component and increase the lateral patellofemoral contact stresses, especially during early knee flexion [24]. Therefore, using a present femoral component in KA-TKA may increase the risk of patellar femoral instability. There are several limitations in this trial. First, the populations assessed will be limited to varus type OA and exclude valgus and severe varus deformities ≥20°. Therefore, before endorsing use of KA-TKA in the general population, we should carefully examine the patients with valgus and severe varus deformities. Second, the KA-TKA will not be performed by a single surgeon. However, as all the surgeons are experienced and familiar with KA-TKA, we assume that there will be no technical issues associated with performing the KA-TKA by the individual surgeons.

In summary, the outcomes of this trial should confirm that KA-TKA is a viable alternative to MA-TKA. The result will be instructive for knee surgeons as well as for patients in guiding informed choice for KA-TKA as a surgical option.

Ethics approval and consent to participate

This trial was approved by the Ethical Review Committee of Kobe University. The approval number is 1805–003.

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Nil.

Authors' contributions

Yoshinori Takashima: Writing - Original draft preparation. Yoshinori Takashima, Yuichi Kuroda and Tomoyuki Matsumoto: Conceptualization, Methodology and trial design. Naoki Nakano, Tomoyuki Mat-

sumoto, Toshihisa Maeda and Masanori Tsubosaka: Draft preparation of this article and will draft final report. Takaaki Chin: Contributed to trial design, Takao Inokuchi, Mitsunori Toda, Kenichi Kikuchi, Masahiro Fujita, Kemmei Ikuta and Kensuke Anjiki: Local conduct of the study at Central Hospital Hyogo Rehabilitation Center. Shinya Hayashi, Shingo Hashimoto and Ryosuke Kuroda: Contributed to the trial design. Naoki Nakano and Tomoyuki Matsumoto: Local conduct of the study at Kobe University Graduate School of Medicine. Tomoyuki Kamenaga: Statistical expertise. All authors read and approved the final manuscript.

Trial registration

University Hospital Medical Network Clinical Trials Registry, #000026895. Registered in March 2018.

Trial status

This trial started on March 1, 2018 and 10-years follow-up data collection is estimated to be completed by March 31, 2030.

Discussion

The outcomes of this trial should confirm that surgical KA-TKA is a viable alternative to surgical MA-TKA.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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