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Coronal Alignment of Three Different Types of Implants in Kinematically Aligned Total Knee Arthroplasty: A Comparative Study

Yoshinori Soda[1*], Mitsuhiro Nakamura[1], Nobuo Adachi[2]

[1]Department of Orthopaedic Surgery, Hiroshima City Hiroshima Citizens Hospital, Hiroshima, Japan
[2]Department of Orthopaedic Surgery, Integrated Health Sciences, Institute of Biomedical and Health Sciences, Hiroshima University, Hiroshima, Japan
Email: *ysoda35@ybb.ne.jp, mitsuhiro@m3.dion.ne.jp, nadachi@hiroshima-u.jp

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Abstract

Background: The number of total knee arthroplasty (TKA) surgeries performed each year is increasing worldwide and mechanical alignment (MA) is currently seen as the gold standard procedure. However, taking neutral alignment as the universal goal may be mistaken. In our hospital, we currently conduct kinematically aligned TKA (KA-TKA). Three different types of implants are used: the cruciate-retaining (CR) type, cruciate-sacrificing (CS) type, or bi-cruciate-retained (BCR) type. We aimed to compare the coronal alignment observed following KA-TKA and MA-TKA and in normal knees, as well as that achieved with different types of implants. **Methods:** The study comprised 206 knees of Japanese patients who underwent KA-TKA using varying implants in our Hospital between May 2019 and April 2020. Measurements of pre- and postoperative coronal alignment were determined from weight-bearing full-leg standing radiographs. The postoperative results were compared to measurements taken from patients who underwent MA-TKA (N = 96) and normal knees (N = 60). **Results:** No significant differences between the KA-TKA group and normal knees were found for the medial proximal tibial angle (MPTA) (−4.2˚ ± 2.6˚ vs −3.8˚ ± 2.5˚) or joint line orientation angle (JLOA) (0.2˚ ± 1.9˚ vs 0.3˚ ± 1.4˚). However, when MA-TKA was compared to KA-TKA and normal knees, there were significant differences in both the MPTA and JLOA ($p < 0.01$). Furthermore, for the different implant types, MPTA exhibited significantly greater varus alignment when a CS-type was used than with the other two. **Conclusions:** Here, we demonstrated that following KA-TKA, the articular surface of the tibia exhibited a similar varus alignment as that of normal knees, meaning that the technique reproduces the native knee. Furthermore, KA is patient-specific, and does not have the same failures as MA-TKA. Therefore, we anticipate a paradigm shift from mechanical to kinematic alignment, which may help reduce the dissatisfaction rate of TKA patients.

Keywords

Total Knee Arthroplasty, Kinematic Alignment, Mechanical Alignment, Calipered Technique

1. Background

Total knee arthroplasty (TKA) is the established gold standard surgical treatment for osteoarthritis of the knee, and the number of procedures performed each year is gradually increasing [1]. Computer-assisted surgery (CAS) has been introduced in recent years, using methods such as navigation systems, patient-specific instruments (PSI), and robots to aid accurate implant placement. As yet, many studies have found that CAS use provides no clinical advantage [2] [3] [4] [5]. Therefore, it may be that taking neutral alignment as the universal goal is mistaken.

Most surgeons are aware that in many normal legs, the Mikulicz line does not pass through the center of the knee [6] [7], and therefore feel that this contradicts the goal of neutral alignment in surgery. This may be why the concept of constitutional varus reported by Bellemans *et al.* [8] has been accepted without resistance.

In our hospital, we currently conduct calipered kinematically aligned TKA (KA-TKA) following the method reported by Howell [9]. Our goal is to respect the soft tissues and replace the articular surfaces of both the femur and the tibia in order to return the joint to its native or pre-arthritic state while reproducing the patient's own joint line. We use one of three different types of implant: the cruciate-retaining (CR) type, cruciate-sacrificing (CS) type, or bi-cruciate-retaining (BCR) type.

The objective of this paper is to both describe our Simple Surgical Technique, double styluses procedure and cutting block adjusting method, and report and compare our measurements of postoperative coronal alignment from weight-bearing full-leg standing radiographs of Japanese patients, following surgery for osteoarthritis of the knee. These subjects tend to exhibit more pronounced varus and curvature than do Europeans and North Americans [10] [11]. This report is the first to evaluate the difference in coronal alignment achieved due to the different types of implant in KA-TKA. Also, we discuss our thoughts on KA-TKA compared to MA-TKA.

2. Methods

The study subjects were 206 knees (120 right and 86 left) of patients (40 men and

166 women of mean age 76 years) who underwent calipered KA-TKA in Hiroshima City Hiroshima Citizens Hospital between May 2019 and April 2020. KA-TKA was performed on all cases except for extra-articular deformity after fracture. The CR-type implants were used in 121 knees, CS-type implants in 49, and BCR-type implants in 36 (Table 1).

Weight-bearing full-leg standing radiographs were scanned preoperatively and 3 weeks after surgery. Patients were instructed to stand with their feet 10 - 15 cm apart with their knees pointing forward. As shown in Figure 1, the preoperative state was assessed by measuring the medial proximal tibial angle (MPTA) and the hip-knee-ankle angle (HKA). The MPTA is defined as the angle of inclination of the tibial axis with respect to the medial articular surface of the tibia (with a negative value denoting varus alignment), and the HKA is defined as the angle between a line joining the center of the femoral head and the distal femoral sulcus, and the tibial axis (with a negative value denoting varus alignment). The postoperative state was evaluated by measuring the MPTA, the joint line orientation angle (JLOA), defined as the angle of inclination of the articular surface of the tibia with respect to the floor (with a negative value denoting an inclination outward and downward), and the HKA.

Table 1. Implant models of KA-TKA (n = 206).

Type	Model	Maker	Number
CR-type	Persona CR	(Zimmer Biomet®, Warsaw, IN, USA)	9
	Vanguard ID	(Zimmer Biomet®, Warsaw, IN, USA)	35
	GMK Sphere CR	(Medacta®, Castel San Pietro, Switzerland)	19
	Triathlon CR	(Stryker®, Mahwah, NJ, USA)	43
	BKS TriMax CR	(Ortho Development®, Draper, UT, USA)	15
		Total	121
CS-type	GMK Sphere CS	(Medacta®, Castel San Pietro, Switzerland)	49
BCR-type	Vanguard XP	(Zimmer Biomet®, Warsaw, IN, USA)	36

CR, Cruciate retaining; CS, Cruciate sacrificing; BCR, Bi-cruciate retaining; KA, Kinematic alignment.

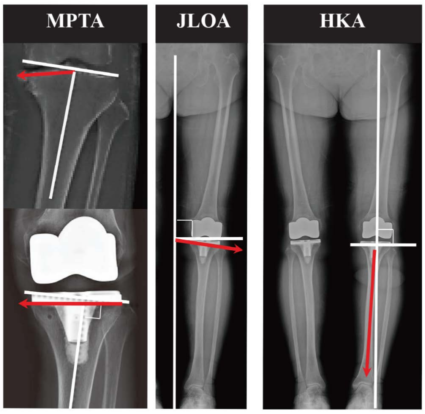

Figure 1. Measurements of coronal alignment from weight-bearing full-leg standing radiographs of Japanese patients. MPTA, medial proximal tibial angle; JLOA, joint line orientation angle; HKA, hip knee ankle angle.

Furthermore, 96 patients (17 men and 79 women of mean age 76 years) underwent mechanically aligned TKA (MA-TKA) in our hospital (68 CR-type, 10 CS-type, and 18 BCR-type) (**Table 2**), and the control group comprised 60 normal knees of patients with a ruptured anterior cruciate ligament (ACL) in the opposite knee (30 men and 30 women of mean age 26 years). We measured the MPTA, JLOA, and HKA of both groups, and compared their results with those of the KA-TKA group.

Statistical analysis was performed with unpaired Student's t-test using StatView software version 5.0 (SAS Institute, Cary, NC, USA), and $p < 0.05$ was considered statistically significant.

All study participants provided written informed consent, and this study was approved by the ethics committee of Hiroshima City Hiroshima Citizens Hospital (no. 2019-199).

Surgical Procedures

Firstly, the joint is exposed via a medial parapatellar approach. Any damaged cartilage is completely removed from both the distal femur and the posterior condyle, and a referencing guide to compensate for a 2-mm cartilage defect is set against the distal femur (**Figure 2**). An osteotomy of the same thickness as the distal and posterior parts of the component is performed. The thickness of the resected osteochondral fragment and the kerf of the bone saw are measured together, and the values are recorded on a data sheet. The remains of the meniscus and any osteophytes (particularly on the posterior condyle) are carefully removed.

Table 2. Implant models of MA-TKA (n = 96).

Type	Model	Maker	Number
CR-type	Vanguard ID	(Zimmer Biomet®, Warsaw, IN, USA)	38
	Triathlon CR	(Stryker®, Mahwah, NJ, USA)	22
	BKS TriMax CR	(Ortho Development®, Draper, UT, USA)	8
		Total	68
CS-type	GMK Sphere CS	(Medacta®, Castel San Pietro, Switzerland)	10
BCR-type	Vanguard XP	(Zimmer Biomet®, Warsaw, IN, USA)	18

CR, Cruciate retaining; CS, Cruciate sacrificing; BCR, Bi-cruciate retaining; MA, Mechanical alignment.

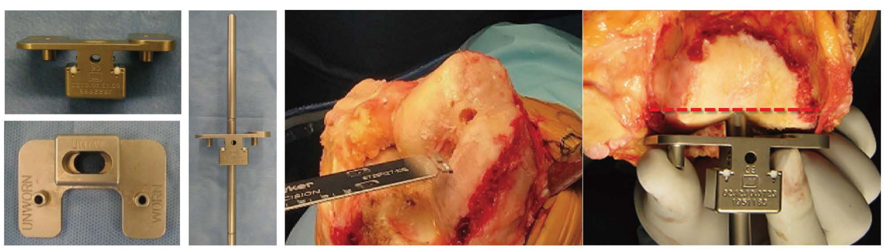

Figure 2. A referencing guide to compensate for a 2-mm cartilage defect is set against the distal femur after removing residual cartilage.

Next, a trial femoral component is fitted, the ankle is grasped in one hand, and the leg is manually drawn in the distal direction. While the leg is in traction, the distraction gap where the component protrudes furthest is measured; in general, this is in the medial joint in the case of varus deformity, and in the lateral joint in the case of valgus deformity. Because the proximal tibial osteotomy runs parallel to the distal femur, the distraction gap is the difference between the heights of the medial and lateral osteotomies.

For MA-TKA, in the case of varus knee deformity, the tibial axis can usually be measured by placing a tibial osteotomy guide from the lateral intercondylar eminence of the tibia pointing toward the center of the ankle. However, since KA-TKA can be completed in most patients with minimal adjustment, the tibial axis is initially set as a line joining the medial intercondylar eminence of the tibia and the distal tibiofibular joint.

The existence of various types of tibial osteotomy guides means that experience and adjustment are both required when fitting these. When using a cutting block fitted with only a single stylus, this stylus must be removed and adjusted several times, making the procedure more time-consuming. Types that can be fitted with a double variable stylus offer ease of use (**Figure 3**). The amounts of the medial and lateral osteotomy are determined simultaneously using the stylus, and the cutting block is secured with a pin. Its position is reviewed if it makes varus alignment more pronounced than the axis that was initially set (around 5˚ - 6˚ varus to the tibial axis). As some patients naturally have a more pronounced medial inclination, this can never be more than a reference axis.

When the tibial surface is uneven or the tibial slope is steep, the surgeon always cannot set the stylus correctly. In such cases, the double styluses procedure is difficult to do; Cutting Block Adjusting Method, as mentioned later, had better be employed. After tibial osteotomy, height is determined with a single stylus and tibial posterior slope is confirmed with "*angel wing*", after the lateral side of the cutting block is secured with a pin (**Figure 4(a)**), the tibial shaft alignment

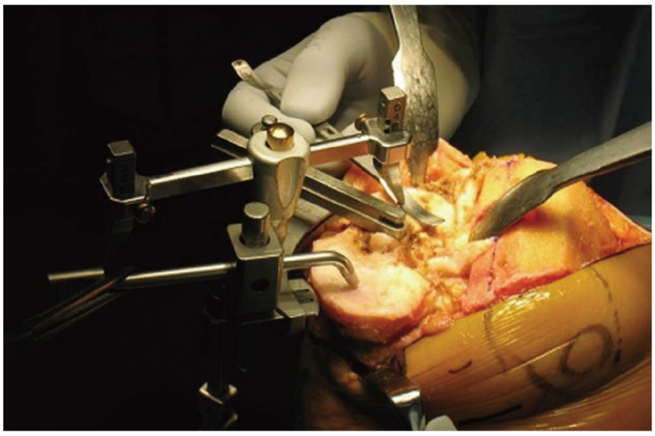

Figure 3. Osteotomy height is determined by setting the double variable styluses on both the medial and lateral tibial articular surface.

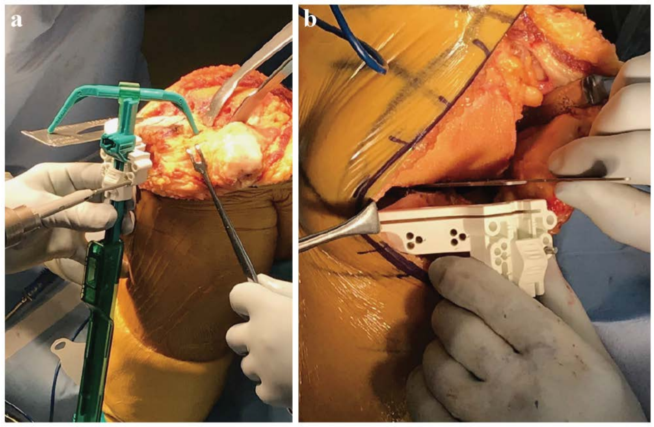

Figure 4. (a) The tibial cutting block is set by first securing with a pin. (b) The cutting block is adjusted parallel to the distal femoral cut surface under distraction of the leg in the knee extended position.

rod is removed. The osteotomy line can subsequently be adjusted, as required, by rotating the cutting block around the axis of the pin while it remains in position (**Figure 4(b)**). The leg is manually drawn in the distal direction, the pin is secured so that the slot in the cutting block is parallel to the cut surface of the distal femur, and the osteotomy height is reviewed using the stylus. The tibial shaft alignment rod is refitted to stabilize the cutting block during the osteotomy. In this case, too, its position is reviewed if the varus alignment is made more pronounced than the axis that was initially set.

If the posterior cruciate ligament (PCL) is removed (CS-type), the posterior inclination is made somewhat smaller (around 3˚ - 5˚) than the native slope, whereas if the PCL is spared (CR and BCR-types), it should be similar to the native slope, and in principle, the patella is not replaced.

3. Results

Socio-demographic characteristics of this study are summarized in **Table 3**.

In the patients who underwent KA-TKA (n = 206), preoperatively the MPTA was −11.1˚ ± 7.0˚ and the HKA was −9.9˚ ± 7.1˚, respectively. Postoperatively, the MPTA was −4.2˚ ± 2.6˚, the JLOA was 0.2˚ ± 1.9˚, and the HKA was −2.7˚ ± 3.5˚, respectively.

In the patients who underwent MA-TKA (n = 96), postoperatively the MPTA was −0.3˚ ± 1.2˚, the JLOA was −2.2˚ ± 1.7˚, and the HKA was −0.4˚ ± 2.3˚, respectively. The control group (n = 60) displayed an MPTA of −3.8˚ ± 2.5˚, JLOA of 0.3˚ ± 1.4˚, and an HKA of −1.2˚ ± 2.4˚, respectively.

A comparison of alignment in knees after KA-TKA and in the control group found that there were no significant differences in the MPTA or JLOA (p = 0.24 and p = 0.54, respectively), and their distributions were also equivalent. However, when alignment in the KA-TKA group was compared to that of the MA-TKA group, there were significant differences in both the MPTA and the JLOA (p <

0.01), and their distributions were also clearly different (Figure 5 and Figure 6). The HKA of knees aligned by KA-TKA differed significantly from that of both knees aligned by MA-TKA ($p < 0.01$) and the control group ($p < 0.01$). The HKA of knees aligned by KA-TKA was within ±3˚ in only 57% of patients (117/206).

Table 3. Socio-demographic characteristics of this study.

	N	Sex	Age
KA-TKA	206	M:F = 40:166	76 (55 - 94)
MA-TKA	96	M:F = 17:79	76 (50 - 94)
Control	60	M:F = 30:30	26 (13 - 55)

KA, Kinematic alignment; MA, Mechanical alignment; Control, Normal knees.

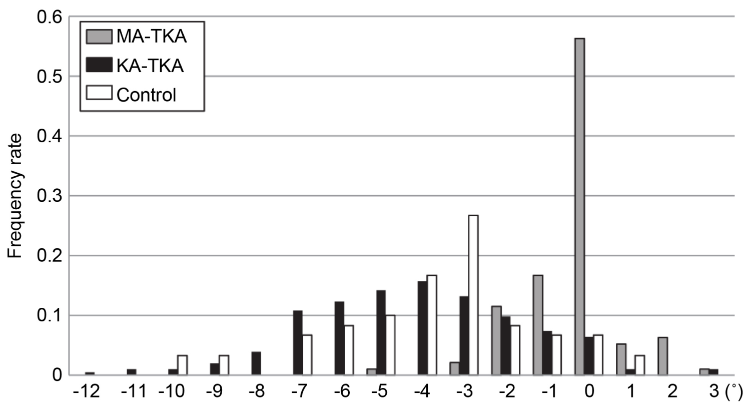

Figure 5. The distribution of MPTA in normal knees and knees following MA-TKA or KA-TKA. The graph shows that KA-TKA and Control group have a normal distribution centered on −3 to −4 degrees, while MA-TKA has a normal distribution centered on 0 degrees. MPTA, medial proximal tibial angle; MA-TKA, mechanically aligned total knee arthroplasty; KA-TKA, kinematically aligned total knee arthroplasty.

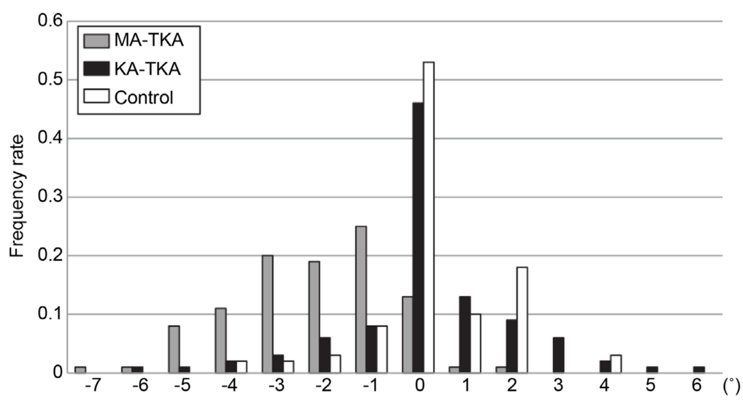

Figure 6. The distribution of JLOA in normal knees and knees following MA-TKA or KA-TKA. The graph shows that KA-TKA and the Control group have a normal distribution centered on 0 degrees, while MA-TKA has a normal distribution centered on −3 to −1 degrees. JLOA, joint line orientation angle; MA-TKA, mechanically aligned total knee arthroplasty; KA-TKA, kinematically aligned total knee arthroplasty.

Data on the different implants used in KA-TKA are shown in **Table 4**. There was no difference in either the JLOA or the HKA between different implants, but the MPTA exhibited significantly greater varus alignment when a CS-type implant was used than with either a CR-type ($p < 0.05$) or a BCR-type ($p < 0.01$).

For knees aligned by MA-TKA, there was no difference in any of the parameters between the different implants (**Table 5**).

Table 4. Radiographic measurements of KA-TKA.

	Pre-op.		Post-op.		
	MPTA	HKA	MPTA	JLOA	HKA
CR (N = 121)	−11.5 ± 8.0	−9.6 ± 8.2	−4.1 ± 2.7$^{\$}$	0.2 ± 2.1	−2.4 ± 3.6
CS (N = 49)	−11.7 ± 5.7	−11.8 ± 5.4	−4.9 ± 2.4$^{\$*}$	0.3 ± 1.9	−3.4 ± 3.1
BCR (N = 36)	−8.2 ± 4.4	−8.7 ± 4.5	−3.8 ± 2.2*	0.0 ± 1.5	−2.5 ± 3.4
Total (N = 206)	−11.1 ± 7.0	−9.9 ± 7.1	−4.2 ± 2.6	0.2 ± 1.9	−2.7 ± 3.5

$^{\$}P < 0.05$, $^{*}p < 0.01$, Unpaired student t-test. CR, Cruciate retaining; CS, Cruciate sacrificing; BCR, Bi-cruciate retaining; KA, Kinematic alignment; MPTA, medial proximal tibial angle; JLOA, joint line orientation angle; HKA, hip knee ankle angle. Valgus measurements are positive, varus measurements are negative.

Table 5. Post-operative radiographic measurements of MA-TKA.

	Pre-op.		Post-op.		
	MPTA	HKA	MPTA	JLOA	HKA
CR (N = 68)	−10.6 ± 7.4	−9.2 ± 8.5	−0.3 ± 1.3	−2.1 ± 1.7	−0.4 ± 2.3
CS (N = 10)	−13.4 ± 7.1	−13.5 ± 5.8	−0.2 ± 1.0	−2.1 ± 1.5	0.3 ± 2.5
BCR (N = 18)	−8.4 ± 5.2	−8.6 ± 4.5	−0.4 ± 0.8	−2.7 ± 1.6	0.9 ± 1.8
Total (N = 96)	−10.5 ± 7.0	−9.5 ± 7.5	−0.3 ± 1.2	−2.2 ± 1.7	−0.4 ± 2.3

CR, Cruciate retaining; CS, Cruciate sacrificing; BCR, Bi-cruciate retaining; MA, Mechanical alignment; MPTA, medial proximal tibial angle; JLOA, joint line orientation angle; HKA, hip knee ankle angle. Valgus measurements are positive, varus measurements are negative.

4. Discussion

Here, we demonstrated that following KA-TKA, the articular surface of the tibia exhibited a similar varus alignment as that of normal knees, meaning that the technique reproduces the native knee.

Total knee arthroplasty is an established surgical procedure for the treatment of advanced osteoarthritis that provides good long-term results. This technique boasts a 10-year postoperative survival rate exceeding 95% due to improvements in implant durability and design [12] [13]. Mechanical alignment is currently the gold standard procedure, focusing on the accuracy with which the implant can be placed. Although the use of CAS (such as navigation systems, PSI, or robots) may have improved the accuracy of implant placement [14] [15] [16], the clinical outcomes are no different from those of conventional methods that do not involve any extra costs, ironically [1] [2] [3] [4]. The use of these systems thus entails the waste of large amounts of money as well as time. Despite improvements to the accuracy of implant placement, around 20% of patients remain dissatisfied [17] [18] [19]. This may be because our current goal of neutral alignment is actually mistaken. Unless we break down the current situation, there may be no prospect of improving the outcomes of TKA 10 or even 20 years into the future.

Mechanical alignment was initially proposed by Freeman *et al.* [20] and Insall *et al.* [21]. In the knees in which the PCL is removed, an osteotomy is performed perpendicular to the line from the center of the femoral head to the center of the knee joint. In the lower leg, an osteotomy is performed perpendicular to the functional axis of the tibia, the soft tissues are denuded, and the alignment is finalized, with an under-correction of around 3˚ generally considered acceptable. To obtain the same rectangular gap [22], rotation of the femoral component is required. However, if it is rotated too far, reference must be made to anatomical landmarks. Although the context is understandable, the limitations and disadvantages of MA-TKA are now becoming exposed.

The goal of anatomical alignment, which was proposed by Hungerford & Krackow [23], is the maintenance of the joint line ("joint line theory"). However, this procedure involves a systematic 3˚ varus osteotomy of the tibia, and has been discontinued mainly due to issues with the durability of the polyethylene used at the time [24]. In addition, although in Westerners, the mean inclination of the tibial articular surface is 3˚ varus, data on healthy Japanese individuals shows that the mean value in this population is 3.8˚, and the standard deviation is 2.5˚. Therefore, it is dangerous to give all patients in this group a uniform varus inclination of 3˚; rather, osteotomy must be patient-specific. This is a limitation of both systemic alignment and anatomical alignment.

Although numerous studies have reported that obtaining neutral alignment results in good clinical outcomes [25] [26] [27] [28] [29], an even larger number have found that this is not the case [30]-[35]. However, as described by Rivière [36], kinematic alignment is patient-specific, and does not have the same failures as an anatomical alignment or MA-TKA, which involve systematic osteotomies.

Our results that after KA-TKA, the articular surface of the tibia exhibited a similar varus alignment with respect to the tibial axis as that of normal knees and was parallel to the floor are consistent with previous reports [37] [38]. The difference in the HKA between the KA-TKA group and the control was considered to be due to the age difference between the two groups (mean age 76 years and 26 years, respectively). Therefore, our KA-TKA technique reproduces the native & pre-arthritic knee condition.

The data on the comparison of JLOA in knees aligned by KA-TKA or MA-TKA and normal knees were almost entirely consistent with those reported by Ji *et al.* [38]. Although static and dynamic data are not necessarily associated [39], when the articular surface of the tibia is parallel with the floor in the same way as in normal knees, knee adduction movement (KAM) is smaller, as reported by Niki *et al.* [40]. This is believed to alleviate shear force during weight-bearing. Other studies have found that KA-TKA provides better gait function than does MA-TKA [41], and may contribute to improving not only the survival rate but also patient satisfaction.

Recent studies have also compared the short-term clinical outcomes of KA and MA-TKA, none of which have concluded that KA-TKA is inferior [42] [43] [44]. Although concerns about survivorship are one reason that many surgeons remain skeptical about KA-TKA, good 10-year postoperative outcomes have been reported by Howell *et al.* [45]. Further research should be done in the future to clarify these results.

Since osteotomy in MA-TKA is systematic, it produces no differences in alignment between different implants. However, following KA-TKA, the inclination of the tibial articular surface exhibited greater varus alignment when a CS-type implant was used compared with the other two types of implant, an extremely interesting result. We conjecture that this was because the procedure we used is a soft-tissue-respecting surgical technique that is dependent on the femoral component. Furthermore, we speculate that removing both cruciate ligaments causes the extension alignment under traction to become slightly more varus. Accordingly, when an implant that requires the resection of both cruciate ligaments is used, the tibial component is placed in an excessively varus alignment and may cause mechanical strain [46] [47]. Therefore, it may be better to combine the implant with a design such as a ball-in-socket shape or to use a CR-type or BCR-type implant, which preserves the posterior cruciate ligament.

Consideration must also be given to disorders for which KA-TKA is not indicated [48]. One of the guiding principles of KA is that it is a soft-tissue-respecting surgery. Contraindications thus include: 1) patients with contracture that cannot be corrected even after bone spur resection, 2) patients with joint instability due to soft tissue breakdown, and 3) patients with extra-articular deformity. However, as even severe deformity can be corrected by osteophyte removal in some patients, in principle, the decision on whether to perform KA-TKA is made intraoperatively. Another contraindication considered for KA-TKA is the difficult-to-correct fixed valgus knee, as it is not feasible to respect the soft tissue, although this condition is rare. However, it may still be necessary to reconsider the merits and demerits of aiming for neutral alignment to the point of unnecessarily destroying soft tissue in these patients. For the choice of an implant in these conditions, the best is the BCR-type or unicompartmental knee arthroplasty (UKA), which preserves the soft tissues involved in controlling knee movements (particularly the ACL and PCL). Given that the rotational axis of the knee is the medial joint, an implant that restricts the medial joint in the coronal section, such as a CR-type, is preferable. However, a medial pivot implant type that restricts the medial joint in both the coronal and sagittal sections, such as a posterior stabilizing (PS)-type, is favored over an implant with a post-cam structure in the center of the knee. Further studies are required to identify differences in outcomes when different types of implants are used.

A final consideration may be that we are being deceived by postoperative frontal X-rays after TKA. We have always thought that correct frontal X-rays of the knee are those in which the tibial axis is parallel to the vertical axis and the articular surface is parallel to the horizontal axis on short films. However, given that human frontal X-rays are scanned in line with the anatomical position, it is clear that the axis of the lower leg cannot run parallel to the vertical axis. Therefore, frontal knee X-rays should be scanned with the body in an inclined state.

The current study presented various limitations. Firstly, we assessed the validity of the surgical procedures purely in terms of X-ray measurements and included no descriptions of clinical outcomes. Secondly, the method and timing for capturing the standing X-rays of both legs were not strictly determined or applied for all patients. Finally, we carried out only a static assessment of the effect of the surgical procedure without indicating the association with dynamic assessment. Future studies should address these limitations to obtain a complete understanding of KA-TKA.

5. Conclusion

We are by no means decrying mechanical alignment, which has been the golden standard for many years. However, this paper has demonstrated that it may be possible to reduce the 20% dissatisfaction rate of TKA patients by fully grasping the concept of kinematic alignment and reproducing the joint lines of individual patients while maintaining the concepts of respecting soft tissue and resurfacing surgery. Since KA-TKA is a soft tissue respecting the procedure, the preserved ligaments (particularly the ACL and PCL) affect component placement. Therefore, it is important to remember that the placement of the tibial component may vary depending on the type of implant used. We anticipate that in the near future, there will be a paradigm shift in TKA from mechanical alignment, which systematically aims for neutral alignment, to kinematic alignment, which involves patient-specific, personalized alignment.

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Conflicts of Interest

All authors have completed the ICMJE uniform disclosure form. The authors have no conflicts of interest to declare.

Authors' Contributions

1) Conception and design: Yoshinori Soda.
2) Administrative support: Yoshinori Soda.
3) Provision of study materials or patients: Yoshinori Soda& Mitsuhiro Nakamura.
4) Collection and assembly of data: Yoshinori Soda.
5) Data analysis and interpretation: All authors.

6) Manuscript writing: All authors.
7) Final approval of manuscript: All authors.

Availability of Data and Materials

The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

Reporting Checklist Statement

The authors have completed the STROBE reporting checklist.

Ethical Statement

The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). The study was approved by the ethics committee of Hiroshima City Hiroshima Citizens Hospital (No. 2019-199) and written informed consent was taken from all individual participants.

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