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KNEE ARTHROPLASTY

Clinical outcomes in TKA are enhanced by both robotic assistance and patient specific alignment: a comparative trial in 120 patients

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Abstract

Introduction Robotically assisted surgery was introduced in total knee arthroplasty (TKA) to increase the precision of implant positioning and optimize clinical outcomes. However, the target implant position or alignment is debated. The aim of this study was twofold: to compare clinical outcomes of conventional TKA vs. robotically assisted TKA in an adjusted mechanically aligned (MA) TKA series, and to analyze the clinical effects of introducing patient-specific alignment (inverse kinematic alignment, iKA) in a robotically assisted TKA cohort.

Materials and methods A total of 120 patients with end stage osteoarthritis of the knee were enrolled. The first group ($n = 40$) received conventional adjusted MA TKA. The second group ($n = 40$) received robotically assisted adjusted MA TKA. The third group ($n = 40$) received robotically assisted iKA TKA. All patients received cruciate retaining Triathlon TKA with a uniform surgery protocol. The three groups were matched for age, sex, BMI and preoperative osteoarthritis. Preoperative and 1-year postoperative clinical outcomes were documented with the Oxford Knee Score (OKS).

Results Comparison of OKS between the MA groups indicated no significant difference ($p = 0.223$) between the conventional TKA (group 1; 40.2 ± 5.9) and robotically assisted TKA (group 2; 42.2 ± 6.3) 1 year postoperatively. Comparison of OKS between the robotically assisted groups indicated no significant difference ($p = 0.078$) between the MA TKA (group 2; 42.2 ± 6.3) and iKA TKA (group 3; 44.8 ± 3.5). Comparison of conventional MA TKA (group 1; 40.3 ± 6.0) with robotically assisted iKA TKA (group 3; 44.8 ± 3.5) indicated a significant difference ($p < 0.001$).

Conclusions The results of this study suggest that the introduction of both patient-specific alignment and robotically assisted surgery improve clinical outcomes in TKA surgery. When access to robotic assistance is available, performing patient-specific alignment should be the objective.

Keywords Knee · Arthroplasty · Patient-specific alignment · Robotically assisted surgery · Inverse kinematic alignment

Introduction

The current standard alignment philosophy in total knee arthroplasty (TKA) favors mechanical alignment (MA) [1]. However, MA does not restore the native knee alignment, thus potentially providing a partial explanation for patient dissatisfaction after TKA [1–3]. In the past decade, various innovations have been implemented, such as computer navigation systems with robotically assisted instruments, with a goal of achieving patient-specific alignment. These innovations have been hypothesized to improve clinical outcomes, patient satisfaction and implant survival [3–9].

New patient-specific alignment strategies have been introduced. Kinematic alignment (KA) aims to restore the native femoral anatomy and femoral joint line obliquity, without boundaries [2, 3, 10]. Outcomes of KA in varus knees have shown excellent results [2]; however, the results in valgus knees remain debated [11]. When performing KA, to balance a valgus knee in extension, the tibia resection generally removes more medial tibial bone than lateral tibial bone, thus potentially causing

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tibia-associated complications [12]. In addition, with the currently available implants, an excessive valgus cut on the femur can lead to patellofemoral tracking problems [13]. To bypass these potential issues, inverse KA (iKA) was introduced as an alternative to KA [14]. In iKA, equal medial and lateral tibial resections are performed, and the native tibial joint line obliquity is restored within boundaries. In iKA, in comparison to KA, over resection of the medial tibial bone stock is avoided. Balancing of the extension and flexion gaps is performed independently by adapting the distal and posterior femoral resection, respectively, and external rotation is allowed [14, 15].

The effects on the clinical outcomes of these innovations remain debated [16]. Several studies and meta-analyses have reported better clinical outcomes with robotically assisted TKA (ra-TKA) than conventional TKA [4, 7]. In addition, better clinical outcomes with patient-specific alignment than with MA in TKA, have been reported [3, 10, 14]. However, other studies and meta-analyses have reported no clinical benefits of ra-TKA or patient-specific alignment [5, 17–19].

Therefore, the aim of this study was to investigate the effects of robotics and patient-specific alignment on clinical outcomes. Our study compared the clinical outcomes of conventional adjusted MA (c-MA) TKA, robotically assisted MA (ra-MA) TKA and robotically assisted iKA (ra-iKA) TKA. We hypothesized that use of both robotics and patient-specific alignment (iKA) would lead to better clinical outcomes.

Materials and methods

Patients

A total of 120 patients receiving TKA after end-stage knee osteoarthritis were enrolled in this retrospective study. All data were collected prospectively. Three groups of 40 consecutive patients were compared. The first group received c-MA TKA (group 1, $n=40$, surgeon A and B). The second group received ra-MA TKA (group 2, $n=40$, surgeon A). The third group received ra-iKA TKA (group 3, $n=40$, surgeon B) (Fig. 1). All patients provided informed consent for the use of their data and images for research and publishing purposes. The study was approved by our institutional review board and complied with the Declaration of Helsinki (IRB: B117201630385 and B117201942336).

Preoperative evaluation

Preoperatively, clinical assessment was performed, and osteoarthritis was evaluated by grading of the weight-bearing radiographs according to the Kellgren–Lawrence score [20]. When the surgeons and patients agreed upon total knee replacement, written consent was obtained from the patients. Sex, age, weight, length, BMI, Kellgren–Lawrence score and preoperative Oxford Knee Score (OKS) were prospectively gathered.

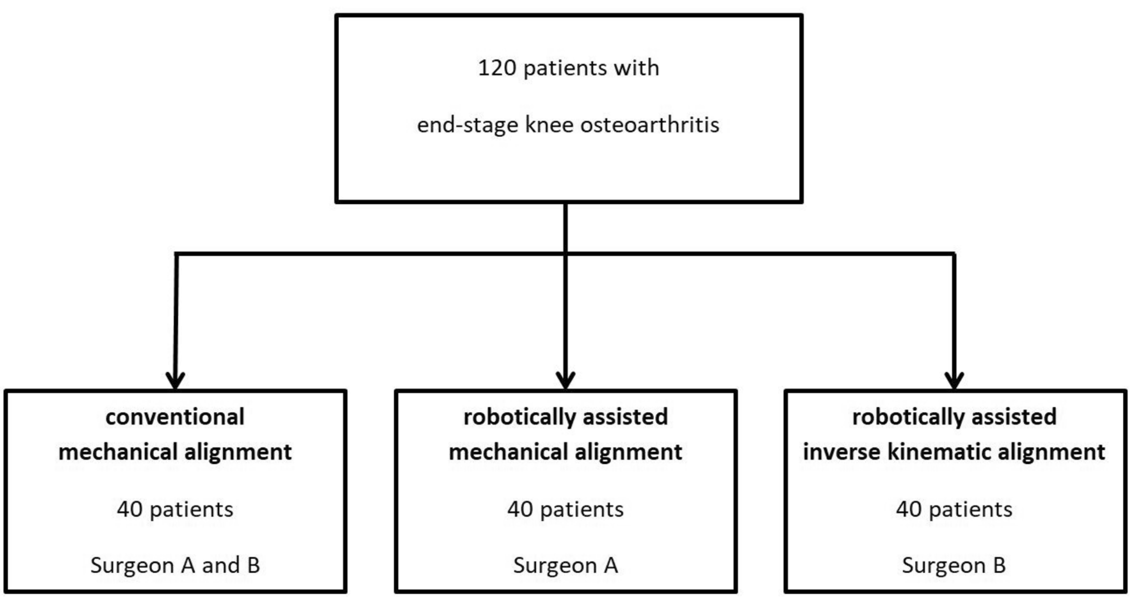

Fig. 1 Study flowchart

Surgical technique

All patients underwent general anesthesia with an additional ultrasound-guided adductor canal sensory nerve block. A far medial subvastus approach was used for all three TKA groups [21]. When the surgical approach was completed, the tourniquet was deflated for the remainder of the surgery. All patients received a cemented, cruciate retaining Triathlon TKA implant (Stryker, Kalamazoo, USA) placed with conventional instruments (group 1) or with Mako robotic assistance (group 2 and 3) (Stryker, USA) according to either MA (group 1 and 2) or iKA (group 3) principles. All patellae were resurfaced.

Mechanical alignment

By under-correcting the constitutional coronal deformity within a limit of ± 3° (hip-knee-ankle (HKA) angle safe zone of 177°–183°), adjusted MA was performed. First, tibial resection was performed perpendicularly to the tibial mechanical axis [22]. The tibial slope was positioned to be equal to the native medial tibial slope. Second, the femoral component position was determined by an adjusted resection preserving a mild constitutional frontal deformity. In conventional TKA, the valgus angle on the intramedullary femoral rod is typically set at 5° in a neutral knee, 4° in varus and 6° in valgus. Femoral rotation was adapted to balance the flexion gap. A residual laxity of 1–2 mm in both compartments in flexion and extension was the goal. Outside the safe zone of 3° from neutral, medial or lateral soft-tissue release was performed (Fig. 2).

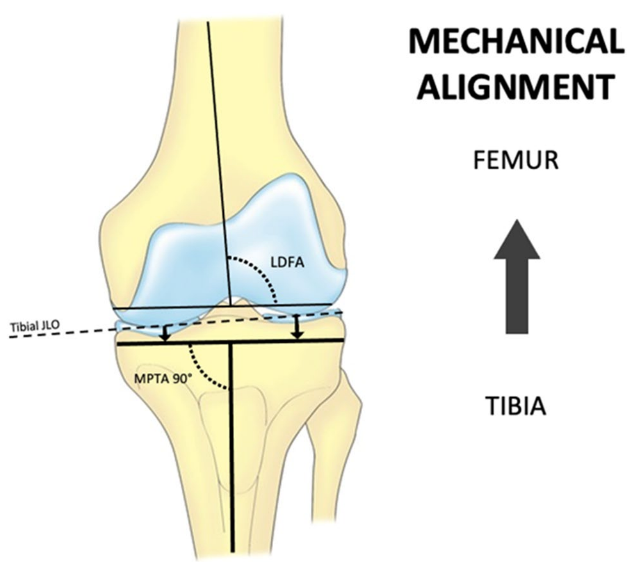

Fig. 2 Concept of mechanical alignment

Inverse kinematic alignment

iKA is a patient-specific alignment strategy wherein the resections are defined by the native knee anatomy and soft-tissue envelope. In iKA, the native tibial joint line obliquity is restored by resection of equal amounts of medial and lateral tibial bone [14]. Therefore, the native pre-arthritic medial proximal tibial angle is restored, limited by a safe zone of 84°–92°. If bony wear on the tibia is present, less bone is cut. The tibial slope was positioned to be equal to the native medial tibial slope. The position of the femoral component was adjusted to restore the medial joint line height in extension. In both flexion and extension, the goal of residual laxity was 1–2 mm. Lateral in flexion, a residual native laxity of 1–3 mm was accepted. These resections were limited by the safe zone to remain within an HKA angle of 174°–183°. Outside the safe zone, medial or lateral soft-tissue release was performed (Fig. 3).

Robotically assisted surgery

The robotic system used (Mako, Stryker, USA) combines computer navigation with an image-based planning tool and robotically assisted instruments with haptic control. After the robotic protocol, the robotic system was set up, calibrated and used. To use the robot, a precision level of less than 0.5 mm was required. During surgery, the overall alignment and the soft-tissue envelope were assessed in extension and 90° flexion, after removal of osteophytes. Subsequently, the knee was balanced virtually by adapting the resections according to the targeted alignment strategy (MA or iKA). After the knee was virtually balanced, the defined tibial and femoral resections were performed within the haptic boundaries.

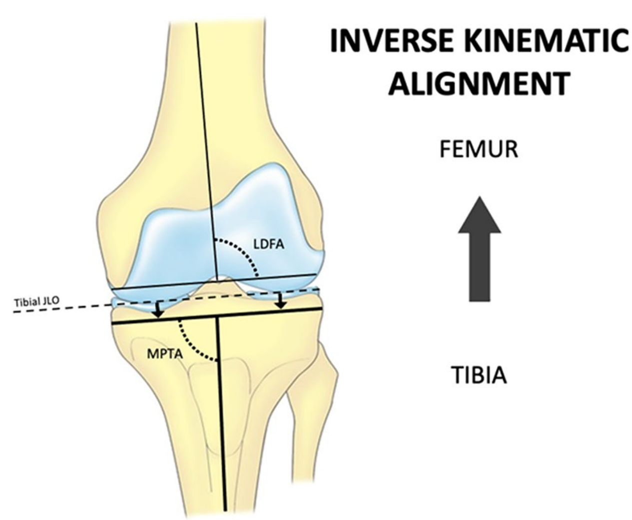

Fig. 3 Concept of inverse kinematic alignment

Postoperative

Postoperatively, direct mobilization and immediate full weight bearing protected by crutches during the first 2 weeks were recommended. Active flexion and extension exercises from the first day postoperatively were advised. Patients were expected to leave the hospital on the third postoperative day. Low-molecular weight heparin prophylaxis was routinely administered for 4 weeks postoperatively. Postoperative appointments were at 6 weeks, 3 months, and 12 months at the outpatient clinic.

Clinical outcomes

For assessment of the clinical performance of TKA, preoperative and 12-month postoperative OKS were collected. The postoperative OKS was analyzed through the mean OKS, patient acceptable symptom state (PASS) threshold (OKS > 36) and excellent OKS threshold (OKS > 41) [23]. Perioperative and postoperative complications were recorded during the follow-up. Results of groups 2 and 3 were partially reported in an earlier study [14]. However, this three-armed study setup with supplementary data and new statistical analysis reveals additional clinically relevant insights.

Statistical analysis

Sample size calculation was based on the minimal clinical important difference of the OKS. To detect a minimal clinical difference in five cases with a power of 0.80 and an alpha of 0.05, at least 33 patients were required in each arm [24]. Categorical data analysis was performed with the chi square test and Fishers' exact test if more than 25% of cells had fewer than five cases. Homogeneity of variances was evaluated with Levene's test. Normal distribution of continuous variables was tested with the Shapiro–Wilk test and visually verified with boxplots. Parametric data were analyzed with one-way ANOVA with post-hoc independent t-tests, corrected by the Holm–Bonferroni method. In the case of non-parametric data, a Kruskal–Wallis test was used with post-hoc Mann–Whitney U test. The statistical significance threshold was set at 0.05. SPSS 23.0 (IBM, New York, USA) was used to perform the statistical analysis.

Results

Preoperative demographics

The preoperative demographics of all three groups were similar. No significant differences were observed in age, BMI, sex, preoperative OKS and Kellgren–Lawrence classification among groups (Table 1). The mean OKS preoperatively was 23.7 in the c-MA group, compared with 27.2 in the ra-MA group and 26.3 in the ra-iKA group ($p = 0.061$). Of the 120 patients, two exceeded the OKS PASS threshold preoperatively.

Complications

During the 1-year follow-up period, in the c-MA group, one closed mobilization for a stiff knee was performed; and one early infection requiring debridement, antibiotics and implant retention, as well as one deep venous thrombosis occurred. In the ra-MA group, one mobilization with arthroscopic release for arthrofibrosis was performed. In the ra-iKA group, a superficial wound infection requiring antibiotics occurred. No other complications requiring minor or major revision surgery were observed.

Oxford Knee Score

All three groups showed an increase in 1-year mean postoperative OKS (Table 2). The 1-year mean postoperative OKS in the c-MA group increased to 40.2 with 16.5 points. A 1-year mean postoperative OKS of 42.2 was observed in the ra-MA group, with an increase in 15.0 points, which was not significantly better than that in the c-MA group ($p = 0.223$). The 1-year mean postoperative OKS of the ra-iKA group increased from 18.5 points to 44.8, an improvement significantly better than that in the c-MA group ($p < 0.001$) but not significantly different from that in the ra-MA group ($p = 0.078$).

Satisfaction

In the c-MA group, ten patients did not meet the PASS threshold (OKS > 36) 1 year postoperatively, whereas an excellent postoperative OKS (OKS > 41) was observed in 22 patients. These findings did not significantly differ from those in the ra-MA group, in which 33 patients met the PASS threshold ($p = 0.586$) 1 year postoperatively, and 28 patients had excellent OKS 1 year postoperatively ($p = 0.248$). In the ra-iKA group, all patients except one met the postoperative PASS threshold, a result significantly better than that in the c-MA group ($p = 0.007$) but not the ra-MA group ($p = 0.057$). The ra-iKA group had 38 patients with excellent OKS, a result significantly better than those in the c-MA group ($p < 0.001$) and the ra-MA group ($p = 0.006$) (Table 2, Fig. 4).

Discussion

The main result of this study is that the combination of robotic assistance with patient-specific alignment in TKA led to superior clinical outcomes with c-MA TKA

Table 1 Patient demographics

	c-MA ($n=40$)			ra-MA ($n=40$)			ra-iKA ($n=40$)			*p* value
	Mean *n*	±SD (%)	(min–max)	mean *n*	±SD (%)	(min– max)	mean *n*	±SD (%)	(min–max)	
Age (years)	69.1	±9.5	(49–88)	66.8	±9.7	(49–88)	69.7	±9.1	(53–87)	0.300
BMI (kg/m^2)	30.3	±5.0	(21.8–40.8)	30.0	±5.3	(21.3–45.1)	29.2	±4.8	(21–42.6)	0.848
Women	28	(70%)		23	(58%)		25	(63%)		0.542
Preoperative OKS	23.7	±7.9	(13–41)	27.2	±5.2	(13–35)	26.3	±6.4	(12–35)	0.061
Kellgren-Lawrence classification										
Medial compartment										0.083
≤2	7			8			7			
3	12			11			8			
4	21			21			25			
Lateral compartment										0.873
≤2	22			19			22			
3	10			11			9			
4	8			10			9			
Patellofemoral compartment										0.172
≤2	13			3			8			
3	14			17			14			
4	13			20			18			

c-MA, conventional mechanical alignment; ra-MA, robotically assisted mechanical alignment; ra-iKA, robotically assisted inverse kinematic alignment; SD, standard deviation; BMI, body mass index; OKS, Oxford Knee Score

Table 2 Clinical outcomes

	c-MA (n=40)	ra-MA (n=40)	ra-iKA (n=40)	
	mean±SD n (%)	mean±SD n (%)	mean±SD n (%)	*p-value*
Clinical scores				
OKS (worst, 0; best, 48)				
Preoperative	23,7 ±7,9	27,2 ±5,2	26,3 ±6,4	*0,061*
Postoperative	40,2 ±5,9	42,2 ±6,3	44,8 ±3,5	*<0,001*
				0,223
				0,078
				<0,001
Satisfaction				
PASS threshold (OKS >36)	30 75,0%	33 82,5%	39 97,5%	*0,012*
				0,586
				0,057
				0,007
Excellent OKS (OKS >41)	22 55,0%	28 70,0%	38 95,0%	*<0,001*
				0,248
				0,006
				<0,001

c-MA, conventional mechanical alignment; ra-MA, robotically assisted mechanical alignment; ra-iKA, robotically assisted inverse kinematic alignment; n, number of patients; SD, standard deviation; OKS, Oxford Knee Score; PASS, patient acceptable symptom state

(OKS 44.8 vs. 40,2; $p < 0.001$). No significant differences were observed when the individual effects of implementing robotic assistance (OKS 42.2 vs. 40.2; $p = 0.223$) or patient-specific alignment (OKS 44.8 vs. 42.2; $p = 0.078$) were assessed. These results suggested that the combination of robotic assistance with a patient-specific alignment strategy potentially outperforms c-MA TKA. Therefore, the real added value of robotically assisted surgery is the ability to perform patient-specific alignment in a controlled manner.

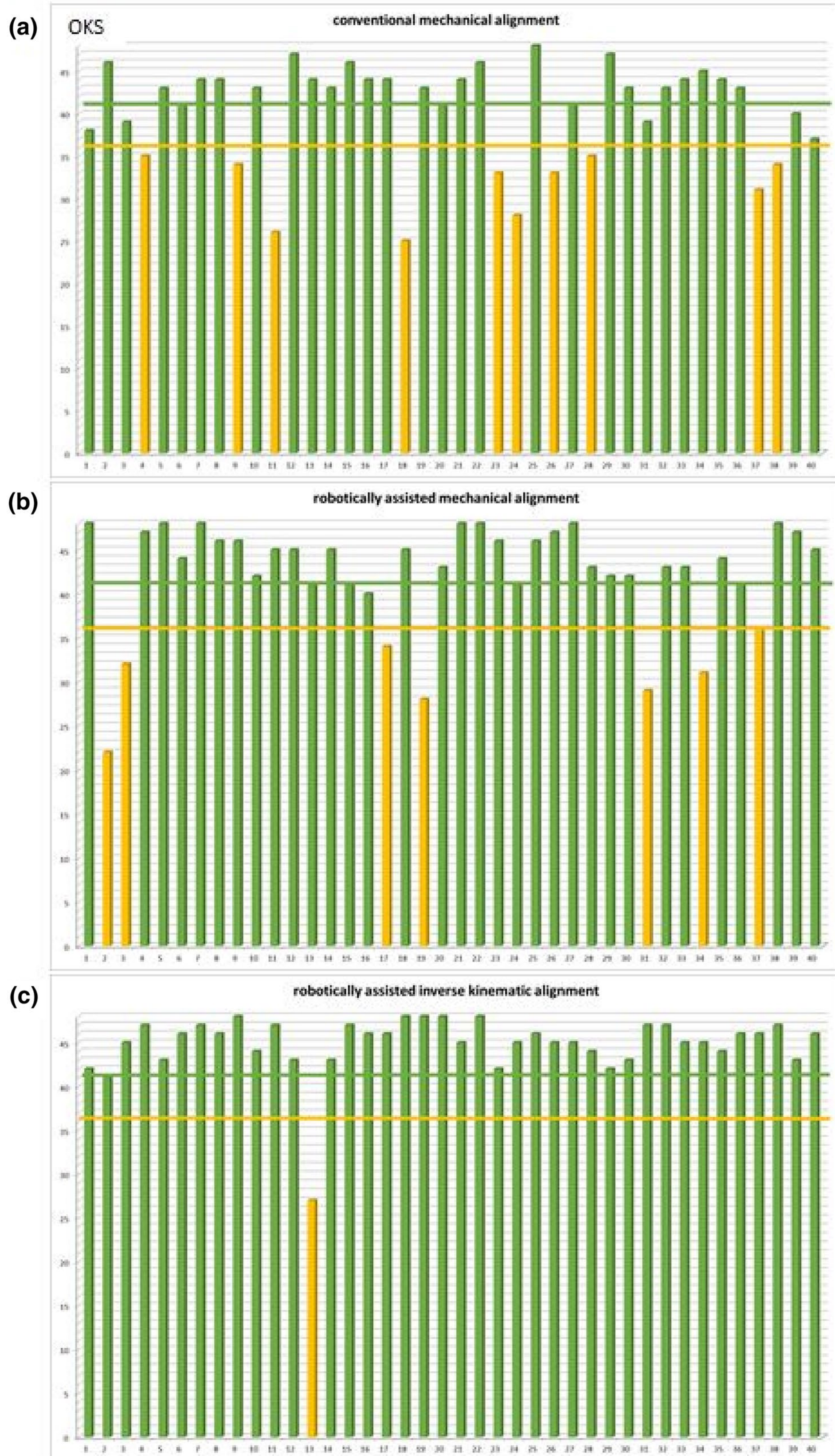

Fig. 4 One-year postoperative OKS with PASS (> 36/48) and excellent (> 41/48) OKS thresholds. **A** conventional mechanical alignment. **B** Robotically assisted mechanical alignment. **C** Robotically assisted inverse kinematic alignment

Comparison of ra-MA TKA with c-MATKA indicated no significant difference in total OKS at 1 year postoperatively (42.2 vs. 40.2; $p = 0.066$), in agreement with findings from Abdel. et al. [25] indicating that using robotics without performing patient-specific alignment does not lead to significantly better clinical outcomes. Meta-analysis of the effects of robotically assisted TKA has been inconclusive regarding clinical outcomes [5]. Yet, notably, in the meta-analysis, data on different types of robots, including first-generation designs, were pooled, thus introducing bias. The newest generation robotic TKA systems provide real-time intra-operative measurements on soft-tissue tension and/or gap-sizes, and implant position and alignment, and enable efficient execution with haptic feedback [26]. Moreover, current robotic TKA systems can assist surgeons precisely during TKA balancing, thus potentially improving clinical outcomes, patient satisfaction and implant survival [6, 9, 27].

Comparison of a patient-specific alignment strategy (ra-iKA) with adjusted MA (ra-MA), both operated with robotic assistance, indicated no significant differences in total OKS 1 year postoperatively (44.8 vs. 42.2; $p = 0.066$). However, when excellent outcomes were compared (95% vs. 70%; $p = 0.006$), we observed a significant difference favoring patient-specific alignment (ra-iKA). In addition, in the literature, the benefits of patient-specific alignment in clinical outcomes remain debated [19, 28]. Nevertheless, a substantial fraction of the population has a constitutional alignment that is not neutral [29–31]. MA (90° tibial cut and 180° HKA) has been suggested to lead to the best implant survival [22, 32]. More recently, however, Abdel et al. [25], in a concise 20-year follow-up study and concomitant review of the literature, have reported no effect of component "malalignment" (varus and valgus outliers) on implant survival. Consequently, positioning implants outside the safe zones determined by Ritter et al. should be safe [32]. iKA is a tibia-first, patient-specific alignment technique involving equal medial and lateral resections on the tibia, within boundaries. By restoring the joint line obliquity to the pre-osteoarthritis native knee joint line obliquity, the adduction moment is lower than that in MA TKA [33]. To date, with patient-specific alignment strategies, the debate regarding the balance between better functional outcomes and higher patient satisfaction vs. possible lower implant survival continues. Therefore, although patient-specific TKA may potentially outperform MA TKA in short- and moderate-term follow-up, longer follow-up is needed to assess the long-term clinical outcomes and implant survival.

Emerging technologies in TKA surgery empower surgeons to identify the three-dimensional knee- and limb alignment and soft-tissue envelope specific to each patient [34]. Consequently, surgeons are able to identify patient-specific targets [4, 6]. Despite good results regarding patient reported outcome measures with patient-specific alignment, performance-based outcome measures evaluating kinetics and kinematics have scarcely been reported. Further biomechanical studies investigating gait and functional movement are needed to demonstrate that patient-specific alignment is superior to MA.

Several limitations to this study should be acknowledged. First, the data were prospectively collected in this retrospective study design. Second, the follow-up time was short, at 12 months. Longer follow-up is needed to confirm the current findings. Third, two different surgeons recruited and performed the TKAs, thus making the results susceptible to bias. However, both were experienced surgeons who routinely perform high-volumes of procedures, and both followed identical surgical protocols. In addition, the preoperative demographics between groups did not significantly differ.

Conclusion

This study evaluated the effects of robotic assistance and patient-specific alignment in TKA. The combination of robotic assistance with patient-specific alignment (iKA), compared with conventional mechanical aligned TKA, resulted in significantly better clinical outcomes and patient satisfaction 1 year postoperatively (OKS 44.8 vs. 40.2; $p < 0.001$). Therefore, the real added value of robotically assisted surgery is the ability to perform patient-specific alignment in a controlled manner. Moreover, in the setting of robotic surgery, patient-specific alignment should be the goal.

Author contributions PWDG: study design, recruiting, data collection, literature review, data interpretation, manuscript writing. JK: data collection, literature review, manuscript writing. TT: manuscript editing, HV: statistical analysis. TL: manuscript editing. KC: manuscript editing.

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Availability of data and materials The manuscript has no associated data, and the data will not be deposited. Nevertheless, data can be shared at the explicit request of the editors or reviewers.

Declarations

Conflict of interest The authors declare no competing interests relevant to the content of this article.

Ethical approval The study was approved by the institutional review board according to the Helsinki guidelines (IRB: B117201630385 and B117201942336). Documents with the favourable advice of the ethical committee are attached to the submission.

Consent to participate Informed consent of patients was obtained to participate in this study and use of data and images for research.

Consent to publish Informed consent of patients was obtained to publish their data and images.

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