

Dissertation

**Kinematic versus mechanical Alignment in Medial Pivot
Total Knee Arthroplasty**

submitted by

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Declaration of Academic Integrity

I hereby declare that this thesis is my own original work and that I have fully acknowledged by name all of those individuals and organizations that have contributed to the research for this thesis. Due acknowledgement has been made in the text to all other material used. Throughout this thesis and in all related publications I followed the guidelines of “Good Scientific Practice and Ombuds Committee at the Medical University of Graz”.

Furthermore, I hereby declare that if artificial intelligence (AI) tools were used for the generation and/or correction of certain text passages in the creation of this work, such employment was conducted in compliance with ethical principles, academic integrity, and the regulations of my university. Additionally, it was ensured that this usage was transparently disclosed and appropriately attributed.

Graz, July 21, 2025

Amir Koutp

Disclosures

The current cumulative dissertation is based on the following peer-reviewed publications:

1. Koutp A, Clar C, Leitner L, Fischerauer S, Reinbacher P, Leithner A, Sadoghi P.

Accuracy of Conventional Instrumentation is Dependent on Alignment Philosophy Using the Identical Surgical Technique in Total Knee Arthroplasty.

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2. Koutp A, Schroedter R, Leitner L, Vielgut I, Leithner A, Sadoghi P.

Unrestricted kinematic alignment offers limited functional benefit over mechanical alignment in medial pivot total knee arthroplasty: A randomized controlled trial using conventional instrumentation.

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3. Koutp A, Hauer G, Leitner L, Kaltenecker L, Fischerauer S, Clar C, Sadoghi P.

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Referring Publications

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2. Koutp A, Schroedter R, Leitner L, Vielgut I, Leithner A, Sadoghi P. *Unrestricted kinematic alignment offers limited functional benefit over mechanical alignment in medial pivot total knee arthroplasty: A randomized controlled trial using conventional instrumentation*. Knee Surg Sports Traumatol Arthrosc. 2025.
3. Koutp A, Hauer G, Leitner L, Kaltenegger L, Fischerauer SF, Clar C, Sadoghi P. *Less Induction Time and Postoperative Pain Using Spinal Anesthesia Versus General Anesthesia With or Without the Use of Peripheral Nerve Blocks in Total Knee Arthroplasty*. J Arthroplasty. 2024.

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Abbreviations and Definitions

Abbreviation Definition

ASA	American Society of Anesthesiologists
BMI	Body Mass Index
CI	Conventional Instrumentation
FJS-12	Forgotten Joint Score – 12
GA	General Anesthesia
HKA	Hip-Knee-Ankle Angle
ICC	Intraclass Correlation Coefficient
KA	Kinematic Alignment
KSS	Knee Society Score
MA	Mechanical Alignment
MCID	Minimal Clinically Important Difference
MP	Medial Pivot (prosthesis)
MPTA	Medial Proximal Tibial Angle
OA	Osteoarthritis
OR	Operating Room
PNB	Peripheral Nerve Block
ROM	Range of Motion
SA	Spinal Anesthesia
SD	Standard Deviation
TKA	Total Knee Arthroplasty
WOMAC	Western Ontario and McMaster Universities Osteoarthritis Index
3D	Three-Dimensional
RCT	Randomized Controlled Trial

Abbreviation Definition

ERAS	Enhanced Recovery After Surgery
THA	Total Hip Arthroplasty
CT	Computed Tomography
MRI	Magnetic Resonance Imaging

Zusammenfassung

Die vorliegende kumulative Dissertation befasst sich mit dem Einfluss unterschiedlicher Alignmentsphilosophien in der totalen Knieendoprothetik (TKA) auf radiologische Genauigkeit, funktionelles Outcome und patientenzentrierte Parameter. Besonderes Augenmerk wird dabei auf den Vergleich zwischen mechanischer (MA) und kinematischer (KA) Ausrichtung bei Verwendung einer medial-pivotierenden Prothese unter konventioneller Instrumentierung gelegt.

Im Sinne einer personalisierten Medizin stellt die Wahl der Ausrichtungstechnik zunehmend einen entscheidenden Faktor dar, um das anatomische Profil des Patienten optimal zu berücksichtigen. Während die mechanische Ausrichtung weiterhin als Goldstandard gilt, zielt die kinematische Ausrichtung auf die Rekonstruktion der präarthrotischen Gelenkanatomie ab mit dem Ziel, die natürliche Kinematik des Knies wiederherzustellen.

Diese Arbeit umfasst drei Originalpublikationen. Die erste Studie analysiert die Genauigkeit der Wiederherstellung der tibialen Obliquität unter MA und KA mithilfe von standardisierten Röntgenmessungen. Die zweite Arbeit präsentiert die Ergebnisse einer randomisierten kontrollierten Studie, in der klinische und funktionelle Parameter (z. B. WOMAC, KSS, FJS-12) zwischen MA und KA verglichen wurden. Die dritte Studie fokussiert auf das perioperative Management und untersucht die Rolle unterschiedlicher Anästhesieverfahren (Spinalanästhesie versus Allgemeinanästhesie) im Hinblick auf Induktionszeiten und postoperativen Opioidbedarf, ebenfalls als Beitrag zur personalisierten Therapieentscheidung in der Knieendoprothetik.

Die Ergebnisse zeigen, dass KA unter Einsatz konventioneller Instrumente zwar eine tendenziell individuellere Rekonstruktion ermöglicht, jedoch in Bezug auf Genauigkeit limitiert sein kann. Funktionell konnten zwar Unterschiede zugunsten der KA in bestimmten Subgruppen beobachtet werden (insbesondere bei varus-konfigurierten Knien), jedoch erreichten diese teils nicht die klinisch relevante Schwelle. Die Anästhesiestudie unterstreicht ergänzend, dass die individualisierte Auswahl des Anästhesieverfahrens ebenfalls einen entscheidenden Beitrag zur postoperativen Genesung leisten kann.

Abstract

This cumulative thesis investigates the impact of alignment strategy in total knee arthroplasty (TKA) on radiological precision, functional outcome, and patient-centered perioperative factors. It focuses on the comparison between mechanical alignment (MA) and kinematic alignment (KA) using a medial pivot (MP) prosthesis and conventional instrumentation.

Within the scope of personalized medicine, surgical alignment philosophy represents a growing field of interest. While MA aims to achieve neutral limb alignment, KA strives to restore the patient's pre-arthritic joint anatomy, thereby promoting more natural joint kinematics and individualized reconstruction.

This work includes three original studies. The first study assesses the accuracy of tibial obliquity restoration under MA and KA using radiographic measurements. The second study presents the results of a randomized controlled trial comparing clinical outcomes (e.g., WOMAC, KSS, FJS-12) between MA and KA in patients receiving an MP TKA. The third study evaluates the effect of different anesthesia techniques (spinal vs. general anesthesia, with or without peripheral nerve blocks) on induction times and postoperative opioid demand, as a broader contribution to the personalization of perioperative care.

The results suggest that while KA enables a more individualized alignment, its precision using conventional tools may be inferior to MA. Functional advantages for KA were observed particularly in patients with varus alignment, though often not exceeding minimal clinically important difference thresholds. The anesthesia study additionally highlights the value of personalized anesthetic strategies in enhancing recovery and pain management after TKA.

Introduction

In recent years, personalized medicine has increasingly shaped clinical decision-making across multiple medical disciplines [1]. With the aim to tailor diagnostic, therapeutic, and perioperative strategies to the individual characteristics of each patient, the paradigm of a “one-size-fits-all” approach is progressively being replaced [2,3]. In the context of total knee arthroplasty (TKA), such personalization extends from preoperative anesthesia selection to the alignment philosophy applied during implant positioning.

Personalized approaches in perioperative management have already demonstrated substantial benefits, as shown in our previous work on anesthesia strategies in TKA[4]. In that study, we found that spinal anesthesia significantly reduced opioid consumption and postoperative pain levels compared to general anesthesia, particularly when combined with peripheral nerve blocks, which aligns with current literature on multimodal analgesia and enhanced recovery after surgery [5,6]. These findings emphasized the importance of tailoring perioperative protocols to individual patient profiles, be it based on comorbidities, expected pain response, or functional goals.

A similar evolution is underway in the surgical alignment strategies for TKA.

Traditionally, mechanical alignment (MA) has been considered the gold standard. It aims to position the prosthetic components perpendicular to the mechanical axes of the femur and tibia, thereby achieving a neutral hip-knee-ankle (HKA) angle [7,8]. Theoretical advantages include even load distribution across the tibiofemoral compartments, reduced polyethylene wear, and lower risk of early implant loosening[9,10].. However, large-scale anatomical studies have shown that truly neutral alignment is rare in asymptomatic individuals—only 0.1% have an anatomically neutral axis—while constitutional varus occurs in up to 32% of males and 17% of females [11]. In such patients, enforcing a

neutral mechanical axis could represent an overcorrection, potentially leading to altered joint mechanics and dissatisfaction [11,12].

Kinematic alignment (KA), introduced by Howell et al., offers an alternative philosophy. Rather than imposing uniform geometry, KA aims to restore the patient's native pre-arthritis anatomy by respecting individual joint line orientation and soft tissue balance [13]. Several randomized studies have reported improved early functional outcomes and joint awareness in patients treated with KA, particularly in those with varus-type coronal alignment [14,15]. However, many of these differences remain below the minimal clinically important difference (MCID) threshold, and the reproducibility of KA, especially when using conventional instrumentation, remains a matter of ongoing debate [14,16].

This cumulative dissertation seeks to explore surgical and anesthetic personalization in TKA by investigating the implications of alignment strategy (KA vs. MA) and anesthesia method in medial pivot (MP) TKA. MP designs aim to replicate more natural knee kinematics through a medially stabilized ball-and-socket articulation, making them particularly suitable for evaluating KA effects in isolation from implant design variability [17]

Three clinical studies form the basis of this thesis:

1. A prospective cohort study assessing the radiographic accuracy of tibial obliquity restoration under KA and MA using conventional instruments [7]
2. A randomized controlled trial evaluating clinical and functional outcomes between KA and MA in MP-TKA at two years of follow-up [14].
3. A retrospective cohort study analyzing anesthetic induction time and postoperative pain under spinal versus general anesthesia, with or without PNBs [4]

Together, these studies aim to provide a comprehensive view of how personalization—in both surgical technique and perioperative care—can contribute to optimizing outcomes in total knee arthroplasty.

Results

This cumulative dissertation includes three original studies, each addressing distinct aspects of personalization in total knee arthroplasty (TKA):

1. Koutp et al. Accuracy of Conventional Instrumentation is Dependent on Alignment Philosophy Using the Identical Surgical Technique in Total Knee Arthroplasty. J

Knee Surg. 2023.[7]

(Original Article)

This prospective study evaluated 260 patients undergoing either mechanically aligned (MA, n = 139) or kinematically aligned (KA, n = 121) TKA using conventional instrumentation. The primary endpoint was the restoration accuracy of tibial obliquity, assessed via the medial proximal tibial angle (MPTA). MA achieved significantly higher accuracy compared to KA ($p = 0.005$). A neutral MPTA of 90° was obtained in 84% of MA cases, while 69% of KA cases achieved restoration of the preoperative obliquity. Inter- and intra-observer reliability was high ($ICC > 0.90$).

2. Koutp et al. Unrestricted Kinematic Alignment Offers Limited Functional Benefit Over Mechanical Alignment in Medial Pivot Total Knee Arthroplasty: A

Randomized Controlled Trial. Knee Surg Sports Traumatol Arthrosc. 2025.

(Randomized Controlled Trial)[14]

In this randomized controlled trial, 100 patients with medial pivot (MP) TKA and conventional instrumentation were assigned to receive either KA or MA. At two-year follow-up, KA patients showed statistically significantly better results in FJS-12 ($p = 0.001$), WOMAC ($p = 0.003$), and KSS Pain ($p = 0.024$). Range of motion did not differ significantly ($p = 0.201$). Subgroup analyses indicated clinically meaningful

improvement for varus-aligned knees treated with KA. However, most outcome differences remained below minimal clinically important difference (MCID) thresholds.

**3. Koutp et al. Less Induction Time and Postoperative Pain Using Spinal Anesthesia Versus General Anesthesia With or Without the Use of Peripheral Nerve Blocks in Total Knee Arthroplasty. J Arthroplasty. 2024.[4]
(Retrospective Cohort Study)**

This retrospective cohort study analyzed 559 patients undergoing primary TKA under one of four anesthetic strategies: general anesthesia (GA) with or without peripheral nerve block (PNB) and spinal anesthesia (SA) with or without PNB. SA was associated with significantly shorter induction time (-7.0 minutes; $p < 0.05$) and reduced postoperative opioid consumption (-2.08 mg IV morphine equivalent; $p < 0.05$). The use of PNB further decreased opioid use (-3.59 mg; $p < 0.05$) but extended induction time significantly.

Discussion

The present cumulative dissertation addresses current developments in personalization strategies within total knee arthroplasty (TKA), focusing on both surgical alignment philosophy and anesthetic management. The three included clinical studies explore how individualized approaches, ranging from joint line restoration to anesthetic technique, may impact radiological accuracy, functional outcome, and postoperative recovery.

The first study demonstrated that the accuracy of restoring tibial obliquity is significantly influenced by the chosen alignment strategy, even when the surgical technique and instrumentation remain constant. Specifically, mechanically aligned TKA achieved a neutral medial proximal tibial angle (MPTA = 90°) in 84% of cases, while restoration of native tibial obliquity in kinematic alignment (KA) was achieved in 69% of patients.. This aligns with previous findings suggesting that MA allows for easier reproducibility of target alignment due to its reliance on standard references [7]. Howell et al., who originally described the calipered KA technique, emphasized that restoring individual tibial joint line obliquity can be technically demanding, especially when using conventional instrumentation [13,18]. Furthermore, anatomical studies have shown that a neutral mechanical axis is rare in asymptomatic individuals, with constitutional varus alignment found in up to 32% of adult males, questioning whether MA truly represents an ideal universal target [11].

The second study, a randomized controlled trial, evaluated functional outcomes between KA and MA using a medial pivot (MP) prosthesis. At two-year follow-up, statistically significant differences in the WOMAC score, KSS Pain score, and FJS-12 were observed in favor of KA. These findings are in line with earlier studies reporting enhanced joint awareness and satisfaction with KA in selected patient groups[19–23]. Of particular note,

subgroup analyses revealed that patients with varus-type coronal alignment (CPAK Types I–III) appeared to benefit more from KA [14]. This supports Bellemans’ hypothesis of constitutional varus and indicates that restoring the native joint line may improve outcomes in patients with non-neutral anatomy [11]. Nevertheless, the magnitude of observed functional differences often remained below minimal clinically important difference (MCID) thresholds, as also noted in several meta-analyses [15]. Additionally, most comparative trials investigating KA versus MA suffer from heterogeneity in implant design and alignment definitions, as emphasized by Nucci et al. and others [24]. In the present study, the use of an MP design intended to replicate native medial ball-and-socket kinematics might have mitigated differences in kinematic performance between KA and MA [14].

The third study contributed a broader view on personalization by investigating anesthetic strategies in TKA. In this large retrospective cohort, spinal anesthesia (SA) was associated with shorter induction times and reduced opioid consumption in the first 48 hours compared to general anesthesia (GA)[4]. These results are consistent with earlier reports demonstrating lower pain scores, less nausea, and faster recovery under SA[5,6].

Furthermore, the addition of peripheral nerve blocks (PNBs) further reduced postoperative opioid use, in line with previous investigations supporting multimodal analgesia strategies to enhance early functional recovery. However, the trade-off of longer induction time for PNBs highlights the need to balance analgesic efficacy against operating room efficiency. Given the rising importance of enhanced recovery protocols, these findings support a patient-centered selection of anesthetic technique, based on comorbidities, pain thresholds, and mobilization targets.

Collectively, the findings of this dissertation underscore the evolving importance of personalization in both the surgical and anesthetic domains of TKA. While mechanical alignment remains highly reproducible and standardized, kinematic alignment offers a potentially superior functional outcome in specific anatomical subtypes—though its precision is more dependent on surgeon experience and instrumentation. The inclusion of a medial pivot prosthesis in all cases minimized implant-related confounders, providing a focused evaluation of alignment effect. From a perioperative standpoint, the demonstrated benefits of spinal anesthesia and PNBs further highlight that individualization should extend beyond surgical technique alone.

Future research should investigate whether advanced technologies such as computer-assisted navigation, robotics, or patient-specific instrumentation can enhance the reproducibility and outcome of KA. Additionally, large-scale phenotype-based registries may help clarify which patient groups truly benefit from KA and whether these benefits justify the potential technical complexity.

In conclusion, this thesis supports the principle that TKA can and should be individualized across both surgical and perioperative dimensions. Kinematic alignment, when accurately performed, offers selective advantages in medial pivot TKA, especially in patients with varus anatomy. In parallel, the choice of anesthesia influences short-term recovery, underscoring the multifactorial nature of personalization in modern joint arthroplasty.

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Appendix

The following publications are appended (in order of appearance):

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Accuracy of Conventional Instrumentation is Dependent on Alignment Philosophy Using the Identical Surgical Technique in Total Knee Arthroplasty

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Abstract

The objective of this prospective study was to assess the precision of restoring the anatomical tibial obliquity, as measured by the medial proximal tibial angle (MPTA) on conventional X-rays, in relation to the surgical technique employed. Specifically, the study aimed to compare the accuracy of tibial obliquity restoration between kinematic alignment (KA) and conventional mechanical alignment (MA) in total knee arthroplasty (TKA). Two-hundred-and-sixty patients underwent either mechanically aligned TKA ($n = 139$) or kinematically aligned TKA ($n = 121$) using conventional instrumentation (CI). Pre- and postoperative X-rays were measured twice by two observers, with a 2-week interval. Inter- and intraclass correlations were calculated, and postoperative tibial obliquity was compared to the preoperative anatomy. In the group of 139 patients with mechanically aligned TKA, no cases with an MPTA deviation greater than 1 degree from 90 degrees were observed. Sixteen percent of the cases ($n = 22$) had a deviation of 0 to 1 degree. The remaining 84% of the cases ($n = 117$) had their MPTA of 90 degrees achieved. In the group of 121 patients with kinematically aligned TKA, no cases had a deviation greater than 1 degree compared with the preoperative MPTA. Thirty-one percent of the cases ($n = 37$) had a deviation of 0 to 1 degree with respect to preoperative MPTA. The remaining 69% of the cases ($n = 84$) had their tibial obliquity restored. Mechanically aligned TKA revealed statistically significant smaller deviations of accuracy compared to kinematically aligned TKA ($p = 0.005$). The inter- and intraclass correlations indicated substantial agreement of all measurements (intraclass correlation coefficient [ICC] < 0.90). Both mechanically aligned and kinematically aligned TKA demonstrated satisfactory outcomes in terms of restoring tibial obliquity or a neutral MPTA of 90 degrees using CI. However, MA showed superior results regarding precision compared to KA. When starting with kinematical alignment using CI, the surgeons should be aware that the learning curve according to accuracy differs to MA. It was a Prospective Level II study.

Keywords

- ▶ total knee arthroplasty
- ▶ tibial obliquity
- ▶ MPTA
- ▶ kinematic alignment
- ▶ mechanical alignment

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Mechanical alignment (MA) has been the gold standard in total knee arthroplasty (TKA) for decades, with orthopaedic surgeons aiming for a neutral tibial alignment with a medial proximal tibial angle (MPTA) of 90 degrees.^{1–3} However, with the introduction of kinematic alignment (KA) and the focus on restoring the patient's preexisting individual anatomy, the perspective has shifted. Some surgeons are now adapting to align the tibia based on its physiological MPTA, which has a mean of 2.9 degrees and a range from 20.5 degrees of valgus to 20.5 degrees of varus.^{4,5} This adjustment allows for a more personalized and anatomically aligned approach in TKA.⁶ Neutral MA in TKA offers the theoretical advantage of achieving even load distribution between the medial and lateral femorotibial compartments. This balanced distribution reduces the risk of implant loosening and wear. By aligning the knee in a neutral position, the forces exerted on the implant are evenly distributed, minimizing stress concentration, and potential complications associated with uneven loading. This has been a primary reason for considering MA as the standard approach in knee replacement surgery.^{1,7–9} However, this is controversially discussed in the current literature.¹⁰ MA does not accurately represent the individual knee anatomy of most patients. Only a minimal percentage, approximately 0.1%, of patients exhibit a completely neutral alignment of the femoral and tibial mechanical axes. Most patients present with some degree of variation in their knee anatomy.^{11,12} Moreover, a study conducted by Bellemans et al revealed that a constitutional varus knee, characterized by a natural MA of at least 3 degrees varus, is present in approximately 17% of asymptomatic adult females and 32% of asymptomatic adult males.⁷ In such cases, achieving neutral MA during TKA would result in overcorrection of the preexisting varus alignment. These findings led to the development of the KA approach, which was initially introduced by Howell et al. The concept of KA focuses on achieving a more personalized reconstruction of the mechanical axis in accordance with

each patient's individual anatomy by restoring tibial obliquity.^{12,13} However, using conventional instrumentation (CI), it is not clear how accurate this obliquity can be restored, as aiming for an MPTA of 90 degrees in MA might be easier than aiming for an MPTA of 83 degrees in KA.

The current study aimed, therefore, to assess the accuracy of restoring anatomic tibial obliquity using the MPTA measured on conventional X-rays in relation to the chosen surgical technique (MA vs. KA). It was hypothesized that achieving a neutral tibial alignment in mechanically aligned TKA is more accurate than restoring the preoperative tibial obliquity in kinematically aligned TKA using the identical instrumentation.

Patients and Methods

This study was approved by the institutional review board (31-176 ex 18/19). The study included 260 patients with end-stage osteoarthritis in two out of three compartments of the knee joint. The patients were prospectively included and pseudorandomized into two groups: MA ($n = 139$) and KA ($n = 121$) as illustrated in **Fig. 1**.

The mean age of the entire cohort was 68 ± 5.1 years, with 63% female. All surgeries were performed by a single experienced senior knee surgeon. The inclusion criteria included patients above 40 years of age with primary knee osteoarthritis requiring TKA. Patients with a tibial or femoral fracture, osteotomy, septic arthritis, rheumatoid arthritis, or previous (partial) knee replacement at the side of osteoarthritis were excluded from the study. Written informed consent was obtained prior to study participation.

Surgical Technique

All patients underwent surgery using the Medacta medial pivot cemented GMK Sphere system from Castel San Pietro, Switzerland. MA was performed in 139 cases using a tibia first extension gap first gap balanced technique using CI, as

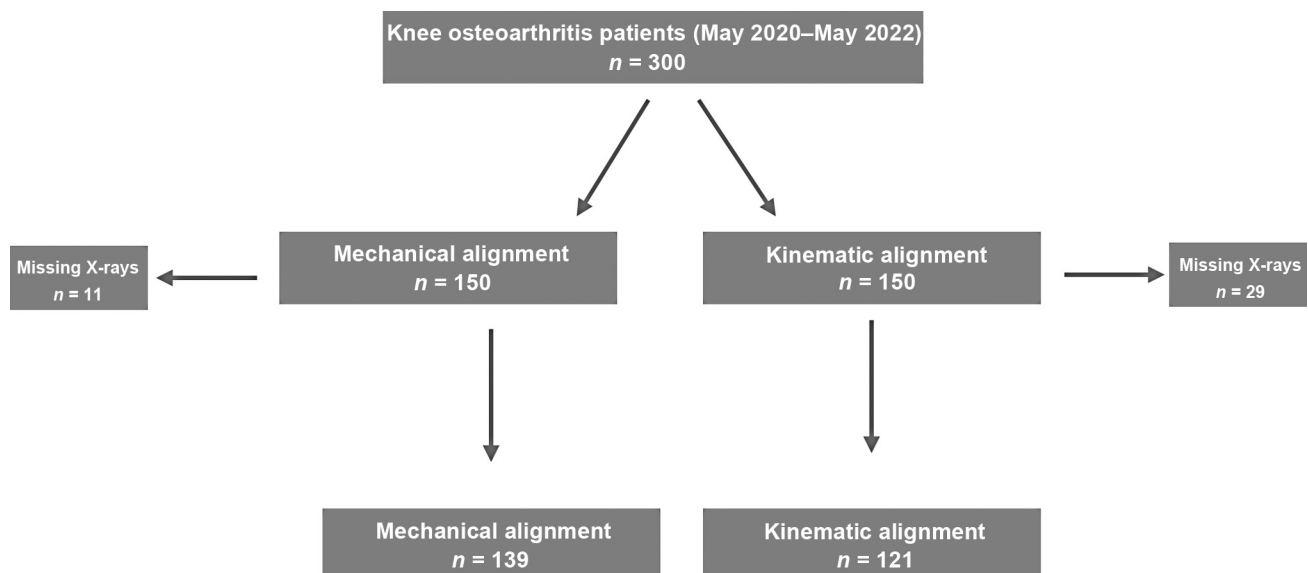


Fig. 1 Flow chart for patient selection.

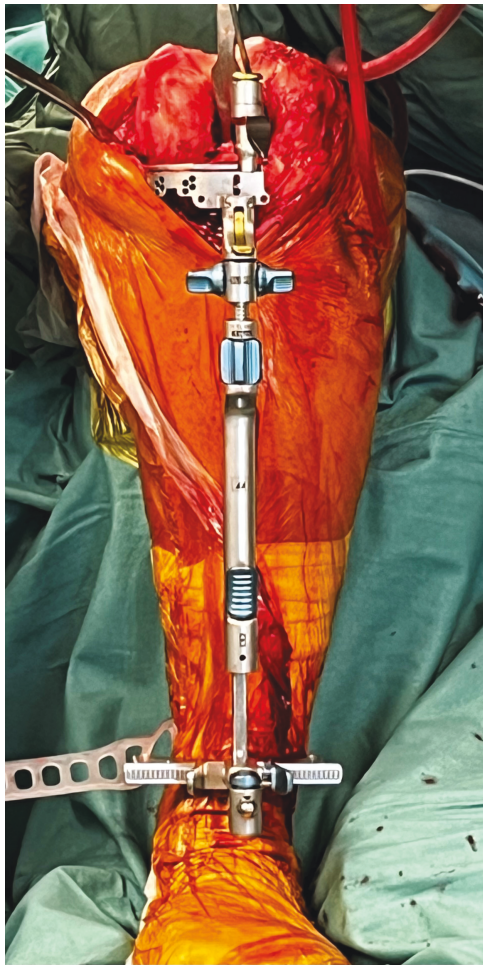


Fig. 2 Surgical technique for mechanical alignment using conventional instrumentation aiming for a medial proximal tibial angle of 90 degrees, representing the center of the ankle joint in this case.

illustrated in **Fig. 2**.^{14,15} KA was performed in 121 cases following the calipered technique developed by Howell using the same instrumentation (extramedullary tibial guide) as illustrated in **Fig. 3**.¹⁶ Prior to the surgery, tibial obliquity was measured using X-ray imaging and the MPTA as a reference. Following the completion of the femoral component using the calipered technique, tibial obliquity was established using two tibial stylus measuring 8 mm, referencing the medial and lateral sides of the tibial spine where no cartilage wear was observed. This approach aimed to restore the pre-arthritic anatomy. Intraoperatively, the plausibility of tibial obliquity was assessed using a tibial alignment rod aligned with the preoperative X-ray of the tibia. If the extension or flexion gaps were deemed inadequate, tibial recuts were performed.¹⁶

Radiological Measurements

Radiological measurements were conducted by two independent investigators using mediCAD 2D® software. The MPTA, defined as the angle between the tangent to the tibial plateau line and the tibial mechanical axis, were measured on pre- and postoperative X-rays of the entire limb, as illustrated on **Fig. 4**. Two investigators performed measure-

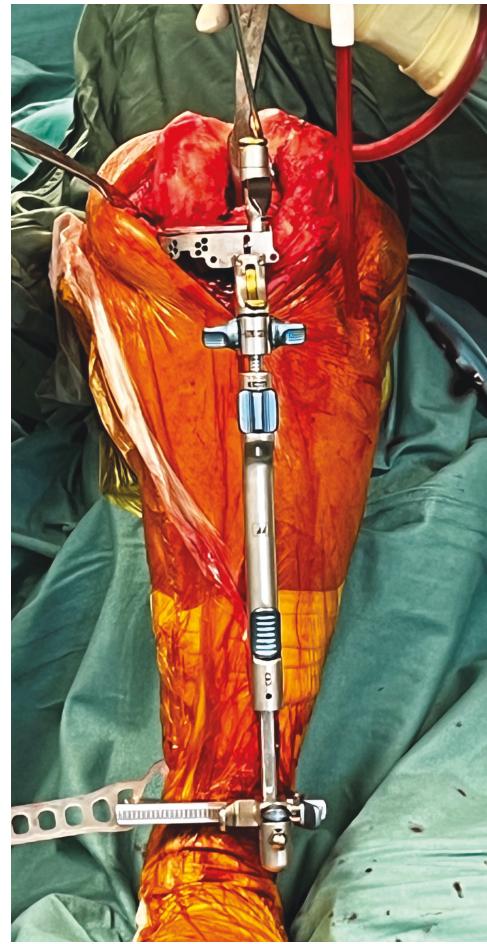


Fig. 3 Surgical technique for kinematic alignment using conventional instrumentation aiming for a medial proximal tibial angle corresponding to the preoperative tibial obliquity, representing the center of the lateral malleolus in this case.

ments twice, and a minimum interval of 2 weeks separated the two rounds of measurements. There were no dropouts in the study.

Statistical Analysis

Mean values with standard deviations were calculated for continuous variables that followed a parametric distribution, while medians with interquartile ranges were calculated for variables with a nonparametric distribution. The definite values of pre- and postoperative tibial obliquity were determined by averaging the two mean measurements obtained by the two investigators. The *t*-tests were used to compare differences in continuous variables between groups. For assessing changes in continuous variables among more than two groups, Kruskal–Wallis tests were employed. Changes in tibial obliquity, based on the MPTA, from pre- to postoperative were categorized into two groups: (1.) restoration of tibial obliquity and (2.) change of 0 to 1 degree.

Chi-square tests were used to compare differences in tibial obliquity based on the treatment group. ICCs were calculated to assess the agreement between the two reviewers for the tibial obliquity measurements. A prestudy sample size calculation was performed with a significance

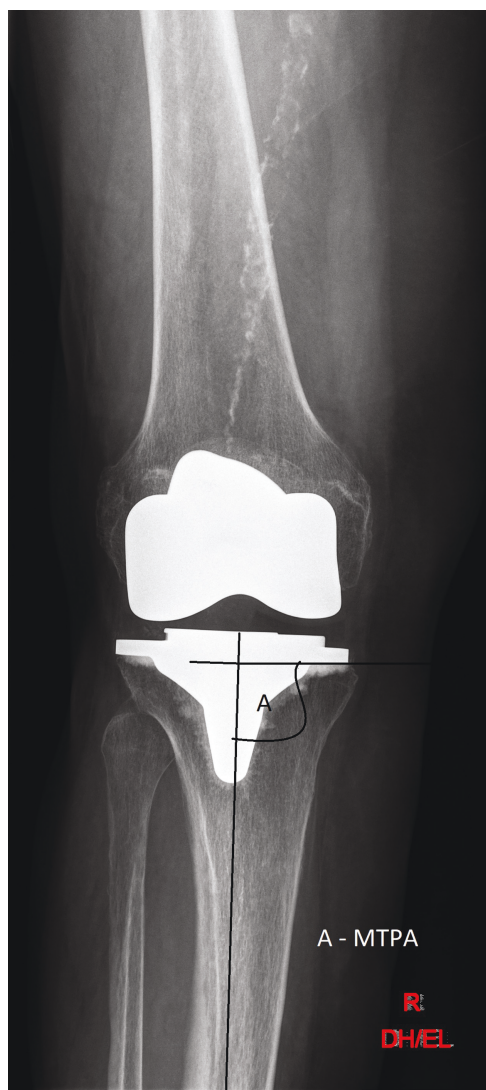


Fig. 4 X-ray of the measurements of the MPTA. MPTA, medial proximal tibial angle.

level (p -value) of less than 0.05 and a statistical power of greater than 80%. The calculation indicated that a total of $n = 50$ cases per group would be sufficient to detect a clinically relevant difference of 10% deviation within the range of 0 to 1 degree or higher. A p -value of less than 0.05 was considered statistically significant.

Results

No statistically significant differences were observed between the two treatment groups in terms of gender distribution ($p = 0.114$), age at surgery ($p = 0.004$), or body mass index ($p = 0.322$) according to **Table 1**.

The mean preoperative tibial obliquity was 89 ± 1.4 degrees (range: 86–93 degrees). There was a significant difference in tibial obliquity depending on the treatment group, with the MA group having greater varus tibial obliquity (mean: 89.6 degrees [range: 86–93 degrees]) compared to the KA group (mean: 90.6 degrees [range: 88–92 degrees]; $p < 0.001$).

In the group of 139 patients with mechanically aligned TKA, no cases with an MPTA deviation greater than 1 degree from 90 degrees were observed. Sixteen percent of the cases ($n = 22$) had a deviation of 0 to 1 degree. The remaining 84% of the cases ($n = 117$) had an MPTA of 90 degrees achieved.

In the group of 121 patients with kinematically aligned TKA, no cases had a deviation greater than 1 degree compared with the preoperative MPTA. Thirty-one percent of the cases ($n = 37$) had a deviation of 0 to 1 degree with respect to preoperative MPTA. The remaining 69% of the cases ($n = 84$) had their tibial obliquity restored. Mechanically aligned TKA revealed statistically significantly smaller deviations of accuracy compared to kinematically aligned TKA ($p = 0.005$). While in the MA group, only 16% percent of the cases deviated from the targeted MPTA of 90 degrees, in the KA group 31% of the cases failed to restore the exact preoperative tibial obliquity. However, it should be emphasized that the mentioned deviation only amounts between 0 and 1 degree, as shown in **Table 2**.

The ICCs between the reviewers for the preoperative measurements demonstrated excellent agreement, with an ICC of 0.996. Similarly, for the postoperative measurements, the ICC between reviewers was 0.986, indicating excellent agreement as well.

Discussion

The aim of this study was to assess the accuracy of restoring anatomic tibial obliquity using the MPTA measured on conventional X-rays in relation to the chosen surgical technique (MA vs. KA). It was hypothesized that achieving a neutral tibial alignment in mechanically aligned TKA is more accurate than restoring the preoperative tibial obliquity in kinematically aligned TKA using the identical instrumentation.

We found that both, MA and KA TKA demonstrated satisfactory outcomes in terms of achieving neutral tibial alignment and restoring preoperative tibial obliquity, respectively. However, MA revealed superior results compared to KA in terms of precision.

To date, no published studies have directly compared MA and KA TKA using CI in terms of change of tibial obliquity.^{17–19} However, some studies have investigated the change in tibial obliquity comparing patient specific instrumentation (PSI)-based KA with conventional MA using different systems.¹⁸ Waterson et al conducted a prospective randomized controlled trial comparing KA with PSI ($n = 71$) and conventional MA ($n = 71$) using the Stryker Triathlon system.¹⁸ They reported that 78 and 77% of kinematically and mechanically aligned TKAs, respectively, were within 3 degrees of preoperative alignment. However, statistical tests were not provided in their study. It is worth noting that Waterson et al used preoperative MRI scans for alignment measurements in the PSI group, while the present study relied on X-ray-based radiological alignment measurements.¹⁸

In comparison to the findings of Waterson et al, the present study observed better results in terms of tibial obliquity preservation, as no change in tibial obliquity greater than 2 degrees was found. However, it should be noted that the patient cohorts

Table 1 Characteristics of the study population split by type of surgery (mechanical alignment vs. kinematic alignment in total knee arthroplasty using conventional instrumentation)

	Total (N = 260)	Conventional (n = 139)	Kinematic (n = 121)	p-Value in bivariate analysis
Age (years) ^a	68 ± 5.1 (43–90)	67 ± 9.4 (43–89)	70 ± 9.4 (44–90)	0.004
Gender				0.114
Female	163 (63%)	81 (58%)	82 (68%)	–
Male	97 (37%)	58 (42%)	39 (32%)	–
BMI ^a	30 ± 5.3 (18–48)	30 ± 5.7 (28–48)	30 ± 4.8 (20–44)	0.322
ASA score				0.509 ^b
1	11 (4.2%)	8 (5.8%)	3 (2.5%)	–
2	98 (38%)	53 (38%)	45 (37%)	–
3	145 (56%)	74 (53%)	71 (59%)	–
4	6 (2.3%)	4 (2.9%)	2 (1.7%)	–
Preoperative tibial slope ^a	–	–	89 ± 1.4 (86–93)	–

Abbreviation: BMI, body mass index; ASA, American Society of Anesthesiologists.

^aValues are expressed as mean ± standard deviation, with range in parentheses.

^bFisher's exact test.

Table 2 Accuracy of the endoprosthetic component restoration in mechanical alignment versus kinematic alignment in total knee arthroplasty using conventional instrumentation

	Total (N = 260)	Conventional (n = 139)	Kinematic (n = 121)	p-Value in bivariate analysis
Postoperative tibial slope ^a	–	–	89 ± 1.4 (85–93)	–
Tibial slope restoration				0.005
I (0 degree)	201 (77%)	117 (84%)	84 (69%)	–
II (0–1 degrees)	59 (23%)	22 (16%)	37 (31%)	–
III (1–2 degrees)	–	–	–	–
IV (>2 degrees)	–	–	–	–

^aValues are expressed as mean ± standard deviation, with range in parentheses.

and surgical techniques may differ between the studies, which could contribute to the variations in results.¹⁸

Overall, while no direct comparisons between MA and KA using CI have been published regarding tibial obliquity change, the present study suggests favorable outcomes in tibial obliquity restoration compared to previous studies that examined PSI-based KA versus conventional MA using different systems.

The study by Calliess et al conducted a similar prospective randomized controlled trial involving 100 patients who underwent TKA with PSI and conventional mechanical instrumentation.¹⁹ Their findings were indicating larger deviations in postoperative limb alignment following PSI compared to conventional mechanical instrumentation. However, it is important to note that Calliess et al did not provide statistical tests to assess the significance of these differences.¹⁹

The parallel findings between the present study and the study by Calliess et al suggest a trend towards greater accuracy in achieving desired limb alignment with conven-

tional mechanical instrumentation.¹⁹ However, further studies with larger sample sizes and rigorous statistical analysis are needed to establish the significance and generalizability of these findings.

The study by Dossett et al conducted a prospective randomized controlled trial comparing KA TKA with PSI and conventional MA using the Vanguard system.¹⁷ In their study, they found that knee and limb alignment were comparable between the groups. However, they observed that the knee joint alignment in the kinematic group was significantly more valgus by 1.9 degrees, the tibial component was significantly more varus by 2.1 degrees, and the femoral component was significantly more valgus by 2.2 degrees compared to the mechanically aligned group.¹⁷ These findings showed that PSI resulted in tibial obliquity in a more valgus position compared to CI, despite the use of CI with KA instead of MA.

The similarities in findings between the present study and the study by Dossett et al support the notion that PSI-based KA can lead to different tibial obliquity outcomes compared

to conventional MA.¹⁷ However, it is important to note that the specific techniques and systems used in the two studies may differ, and further research is needed to fully understand the implications of these differences on clinical outcomes and long-term implant survivorship.

The most recent study regarding restoring tibial obliquity was conducted by Smolle et al. Their results showed excellent results for both TKA with CI and PSI with no deviation postoperatively greater than 2 degrees in tibial obliquity. Slightly better results were observed in the CI group. However, no distinction was made between kinematic and MA in the CI group. According to this study, excellent results were obtained restoring tibial obliquity using CI.⁵

The current study acknowledges several limitations. Firstly, it lacks clinical outcome data such as Western Ontario and McMaster Universities Osteoarthritis Index or Knee Society Score to correlate with the radiographic findings. These clinical outcome measures provide valuable information regarding the functional and symptomatic improvement following TKA. Including such data would have strengthened the study's findings by providing a more comprehensive assessment of the patients' outcomes. Additionally, the measurement of tibial obliquity in the current study was limited to anteroposterior X-rays. This means that the sagittal alignment, specifically the tibial slope, was not taken into consideration. The tibial slope has been shown to have an influence on knee biomechanics and can impact clinical outcomes.

Conclusion

Both mechanically aligned and kinematically aligned TKA demonstrated satisfactory outcomes in terms of restoring tibial obliquity or a neutral MPTA of 90 degrees using CI. However, MA showed superior results regarding precision compared to KA. When starting with kinematic alignment using CI, the surgeons should be aware that the learning curve according to accuracy differs from MA.

Authors' Contributions

All authors have made substantial contributions by acquisition, analysis, and interpretation of data as well as drafting and revising the article. Results were discussed and all authors approved the submission of the manuscript.

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Conflict of Interest

None declared.

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Unrestricted kinematic alignment offers limited functional benefit over mechanical alignment in medial pivot total knee arthroplasty: A randomized controlled trial using conventional instrumentation

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Abstract

Purpose: The aim of this randomized controlled trial was to compare clinical outcomes between kinematic alignment (KA) and mechanical alignment (MA) in total knee arthroplasty (TKA) using a medial-pivot (MP) prosthesis and conventional instrumentation. The primary hypothesis was that KA would result in improved joint awareness at 2 years postoperatively.

Methods: One hundred patients with end-stage knee osteoarthritis were enrolled between October 2020 and December 2024 and randomized to receive either KA or MA. All surgeries were performed by a single surgeon using the same MP prosthesis. Clinical scores (OKS, WOMAC, KSS, FJS-12) and radiographic measurements were collected preoperatively and at a 2-year follow-up. Subgroup analysis was performed based on coronal knee alignment (Coronal Plane Alignment of the Knee classification).

Results: At 2 years, KA demonstrated statistically significant differences in KSS Pain ($p=0.024$), WOMAC total ($p=0.003$) and FJS-12 ($p=0.001$) compared to MA. The range of motion did not differ significantly between groups ($p=0.201$). In subgroup analyses, patients with varus alignment showed a statistically significant and clinically meaningful improvement in WOMAC scores. However, most between-group differences did not exceed established minimal clinically important difference thresholds.

Conclusion: KA with an MP TKA design was associated with statistically higher functional scores and joint awareness compared to MA, particularly in patients with varus alignment. However, the observed differences were modest, and further studies are warranted to clarify the clinical relevance of KA across phenotypes-specific subgroups.

Level of Evidence: Level II (randomized controlled trial).

Abbreviations: BMI, body mass index; CI, conventional instrumentation; CPAK, Coronal Plane Alignment of the Knee; FJS-12, Forgotten Joint Score; HKA, hip-knee-ankle angle; KA, kinematic alignment; KSS, Knee Society Score; LDFA, lateral distal femoral angle; MA, mechanical alignment; MCID, minimal clinically important difference; MP, medial pivot (prosthesis design); MPTA, medial proximal tibial angle; OKS, Oxford Knee Score; PS, posterior-stabilized (prosthesis design); RCT, randomized controlled trial; ROM, range of motion; SD, standard deviation; TKA, total knee arthroplasty; WOMAC, Western Ontario and McMaster Universities Arthritis Index.

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KEYWORDS

CPAK classification, joint awareness, mechanical alignment, patient-reported outcome measures, randomized controlled trial

INTRODUCTION

Kinematic alignment (KA) is a resurfacing-based technique in total knee arthroplasty (TKA) that aims to restore the patient's pre-arthritic knee anatomy by aligning the prosthetic components with the individual's natural anatomical axes of motion. While not a new approach, KA has gained renewed interest due to its focus on replicating native joint kinematics by respecting the unique geometry and soft tissue balance of each knee [16]. Historically, its wider adoption has been limited by concerns regarding outlier limb alignment, patellar maltracking and potential risk of aseptic loosening. However, these concerns are increasingly being addressed in recent studies, and KA continues to be evaluated as a promising alternative to mechanical alignment (MA) [12, 14, 30].

Several randomized studies have explored the comparison between mechanical and KA, with some reporting clinically and functionally favourable outcomes for KA [5, 8], whereas other studies have found no significant difference in outcomes between the two approaches [10, 33]. While meta-analyses generally report no significant differences in clinical and functional outcomes between mechanical and KA, they often group various alignment strategies, such as unrestricted, restricted and inverse KA, under a single umbrella term [24, 31, 32]. This methodological limitation, as highlighted by recent systematic appraisals [27], contributes to conflicting results and hinders a clear interpretation of the true efficacy of unrestricted KA. Furthermore, most included studies use cruciate-retaining or posterior-stabilized (PS) implant designs and encompass a wide range of alignment phenotypes, which adds further heterogeneity to the pooled analyses. Limited evidence exists regarding the use of medial pivot (MP) designs, which aim to replicate more natural knee kinematics through a medially stabilized ball-and-socket mechanism [29]. However, one randomized study employing an MP design with patient-specific instrumentation (PSI) and restricted KA reported superior patient satisfaction, self-reported function and joint awareness for KA compared to MA in the early postoperative period [11].

The aim of this study was to compare clinical and functional outcomes of unrestricted KA versus MA TKA using an MP design and conventional instrumentation (CI).

Our hypothesis was that KA would lead to superior joint awareness compared to MA, as measured by the

Forgotten Joint Score-12 (FJS-12) at 2 years post-operatively, and that secondary differences would be observed in functional outcomes and patient-reported scores depending on Coronal Plane Alignment of the Knee (CPAK) phenotype.

METHODS

Trial design and setting

This monocentric, prospective, randomized controlled, open-label trial was conducted from October 2020 to December 2024. Ethical approval was obtained from the institutional review board, and the study was prospectively registered at [ClinicalTrials.gov](https://clinicaltrials.gov) (Identifier: NCT04436211).

Changes to trial protocol

Important amendments to the trial protocol were made prior to data analysis and were approved by the institutional review board. Initially, KA was planned using patient-specific cutting blocks from computed tomography scans. This technique was later replaced by the use of CI based on Howell's caliper technique [13], which was ultimately used in all patients included in this analysis. The primary outcome was also changed from knee range of motion (ROM), and functional outcomes as Oxford Knee Score (OKS), Western Ontario and McMaster Universities Arthritis Index (WOMAC) and Knee Society Score (KSS) at intervals of 3, 6 and 12 months to the FJS-12 at 2 years postoperatively. ROM and functional scores remained as secondary outcomes.

Participants

Patients aged ≥ 50 years scheduled for unilateral primary TKA for end-stage knee osteoarthritis (Kellgren–Lawrence grade IV) were eligible. Exclusions included age < 50 years, previous fractures of the femur or tibia, septic arthritis, osteotomy, previous partial or total knee arthroplasty, inflammatory arthritis, indication for bilateral TKA and preoperative malalignment exceeding 5° varus or any valgus deformity, as well as clinically relevant joint instability. All patients provided explicit informed consent for study participation.

Randomization, stratification and allocation concealment

In the broader randomized trial, a total of 433 patients were randomized in a 1:1 ratio to receive either MA or KA total knee arthroplasty. Randomization was conducted using block randomization with randomly varying block sizes of four and six, stratified by age and gender. The sequence was generated using an online platform (www.randomizer.at), and allocation concealment was maintained using sequentially numbered, opaque sealed envelopes handled independently by research personnel uninvolved in patient care.

The current study analyzes a predefined subgroup of patients treated with CI who completed a minimum of 2 years of follow-up. From the 379 patients treated with CI (171 KA, 208 MA), 50 randomized patients from each group were included in this analysis. No post hoc matching was performed.

Blinding

The surgeon was unblinded due to the nature of interventions. However, outcome assessors, including clinical examiners and radiographic evaluators, were blinded to group allocation. Patients were also not informed about their alignment group.

Interventions

All patients underwent implantation of an MP TKA system (GMK Sphere, Medacta). All TKAs in both groups were implanted using antibiotic-loaded bone cement (PALACOS fast R + G, Heraeus). MA was achieved in using a tibia-first and extension-gap-first technique with CIs and an external rotation of the femoral component of 3°. A detailed description was delivered by our study group in previous studies [19, 20]. Unrestricted KA was performed using the calipered technique described by Howell, employing the same extramedullary tibial guide [13].

Postoperative rehabilitation

Postoperative care followed the standardized rehabilitation protocol as previously described in our prior study [22]. All patients underwent early mobilization on the day of surgery, with structured inpatient physical therapy beginning within 24 h postoperatively. The rehabilitation regimen included ROM exercises, progressive weight-bearing as tolerated, quadriceps and gait training, and outpatient continuation of therapy after discharge. Progress was monitored through standardized clinical milestones to ensure consistent rehabilitation across both groups.

Outcome measures

The primary outcome measure was the FJS-12, assessed 2 years postoperatively. The FJS-12 evaluates joint awareness during activities of daily living on a scale from 0 to 100; higher scores indicate less joint awareness, reflecting better outcomes [3].

Secondary outcomes included the OKS, WOMAC, KSS and knee ROM, measured by a blinded examiner. The OKS evaluates knee pain and function (scores 0–48, higher scores better) [7], WOMAC measures pain, stiffness and function (total scores 0–96, higher scores worse) [4], and the KSS assesses knee condition and function (scores 0–100, higher scores better) [17].

Radiographic measurements

All patients underwent skyline view, anterior-posterior and lateral view of the knee, and long leg X-rays, preoperatively as part of the preoperative planning. A single experienced observer not involved in the surgical procedures measured the lateral distal femoral angle (LDFA) and the medial proximal tibial angle (MPTA) on these radiographs. LDFA was measured as the lateral angle subtended by a line from the centre of the femoral head to the centre of the intercondylar notch and the other line tangential to the femoral condyles. MPTA was measured as the medial angle subtended by a line from the centre of the tibial spines to the centre of the ankle joint and the other line tangential to the tibial articular surface. Preoperative arithmetic hip-knee-ankle angle (aHKA) was calculated by the formula $MPTA - LDFA$ and JLO was the sum of MPTA and LDFA. Each knee was classified preoperatively according to the CPAK system [25]. While CPAK-specific reliability was not assessed in this study, excellent inter- and intraobserver agreement for frontal plane alignment parameters was previously demonstrated in a prospective analysis from the same cohort, where two observers independently measured pre- and postoperative tibial angles with high precision (intraclass correlations > 0.90) [21].

Sample size calculation

The initial sample size calculation was based on detecting a 5° difference in postoperative knee flexion ROM ($SD \pm 10^\circ$), with $\alpha = 0.05$ and power = 0.80, requiring at least 44 patients per group. To account for attrition, 50 patients per group were enrolled. A priori sample size calculation was based on detecting a clinically meaningful difference in knee flexion of 7° with a standard deviation (SD) of 10°, requiring 45 patients per group ($\alpha = 0.05$, power = 0.80). To account for potential dropouts, we included 50 patients per group.

A post hoc power analysis was conducted for the primary outcome FJS-12. With an observed between-group difference of 8.4 points and a pooled SD of 11.65, the resulting effect size (Cohen's d) was 0.72. Given the final sample size of 50 patients per group, the post hoc power was 94.6%, indicating that the study was adequately powered to detect the observed difference in FJS-12 between the kinematic and MA groups.

Statistical analysis

The mean and SD were determined for each measure in each group. Differences in the means of primary outcome measures between groups were analyzed using the non-parametric Mann–Whitney U -test for non-normally distributed data, an unpaired t -test for normally distributed data, and chi-squared tests for categorical data. For each group, we calculated the change from preoperative to 2-year postoperative scores for OKS, WOMAC and KSS to assess clinical improvement. These change scores were compared between the MA and KA groups. Minimal clinically important differences (MCIDs) were used to interpret the clinical relevance of statistically significant findings.

Based on existing literature, MCID thresholds were defined as follows: 4 points for the OKS [2], 10–12 points for the WOMAC [9], 14–16.6 points for the FJS-12 [6] and 6.3–10.3 points for the KSS [23]. All analyses were performed using statistical software (SPSS Inc. v29, IBM Corp., and JMP v11, SAS). Statistical significance was set at $p < 0.05$.

RESULTS

Participant flow and recruitment

From October 2020 to December 2024, a total of 379 patients with end-stage knee osteoarthritis (Kellgren–Lawrence grade IV) were randomized to receive either KA ($n = 171$) or MA ($n = 208$) using CI. Patients who received PSI were excluded from this analysis.

After exclusions for insufficient 2-year follow-up (KA: $n = 121$; MA: $n = 158$), 50 patients from each group who had undergone surgery as randomized and completed the full 2-year follow-up were included in the final intention-to-treat analysis. All 100 patients included in the present analysis were randomized and received CI TKA. The full participant flow is illustrated in Figure 1.

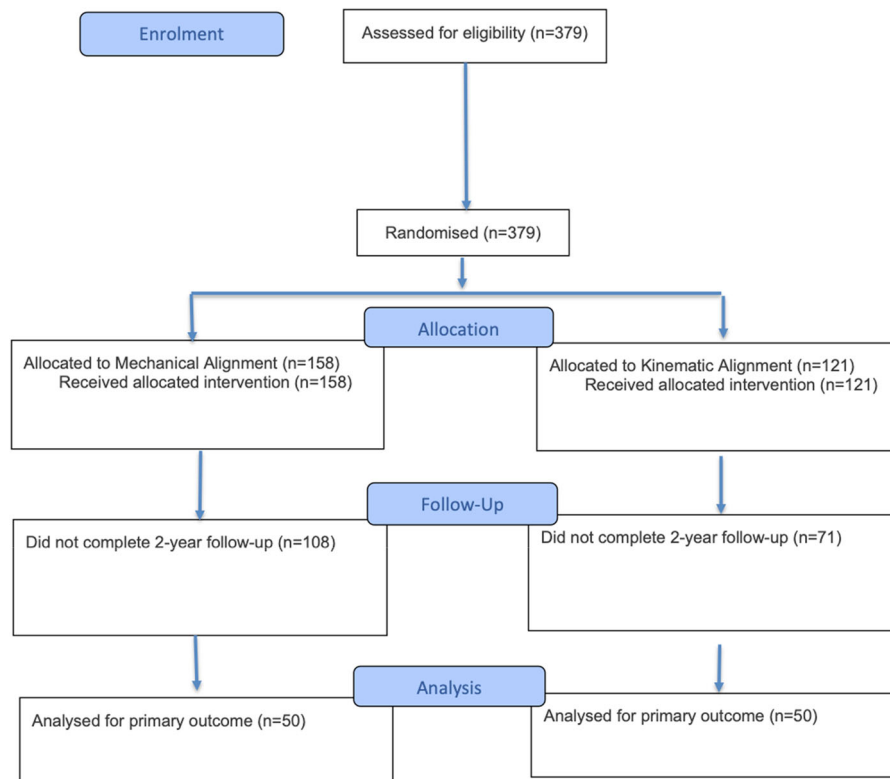


FIGURE 1 CONSORT flow diagram of patient 208 enrolment, allocation, follow-up and analysis. A total of 379 patients were assessed for eligibility and randomized to receive either mechanical alignment (MA) or kinematic alignment (KA) total knee arthroplasty. Of the 158 patients allocated to MA, 50 completed the 2-year follow-up and were included in the final analysis. Similarly, 50 of the 121 patients in the KA group completed the 2-year follow-up and were analyzed for the primary outcome.

TABLE 1 Baseline demographic and anatomical characteristics of patients in the mechanical alignment (MA) and kinematic alignment (KA) groups.

Variable	MA	KA	p-value
Age	69.60 ± 9.30	72.52 ± 8.57	0.106
Sex (female, %)	60.0%	58.0%	1.0000
BMI	31.55 ± 6.22	30.00 ± 4.72	0.188
aHKA	0.48 ± 5.40	-0.60 ± 4.44	0.2778
MPTA	88.40 ± 3.85	87.44 ± 2.89	0.1621
LDFA	87.92 ± 2.93	88.04 ± 2.73	0.8326
CPAK			
Varus			
Type I	10 (20%)	13 (26%)	0.634
Type IV	6 (12%)	5 (10%)	1.000
Type VII	0	0	-
Neutral			
Type II	9 (18%)	11 (22%)	0.797
Type V	7 (14%)	7 (14%)	1.000
Type VIII	0	0	-
Valgus			
Type III	8 (16%)	7 (14%)	1.000
Type VI	9 (18%)	7 (14%)	0.774
Type IX	1 (2%)	0	1.000

Note: Values are presented as mean ± standard deviation or percentage unless otherwise noted. No statistically significant differences were observed between groups across any variable.

Abbreviations: aHKA, arithmetic hip-knee-ankle angle; BMI, body mass index; CPAK, Coronal Plane Alignment of the Knee classification; LDFA, lateral distal femoral angle; MPTA, medial proximal tibial angle.

Baseline characteristics

Baseline demographic, radiographic and clinical characteristics were similar between groups. The mean age was 72.52 ± 8.57 years in the KA group and 69.60 ± 9.30 years in the MA group ($p = 0.106$). The proportion of female patients was 58% in the KA group and 60% in the MA group ($p = 1.000$). The body mass index (BMI) was 30.00 ± 4.72 in the KA group and 31.55 ± 6.22 in the MA group ($p = 0.188$). Radiographic alignment values showed no significant group differences: aHKA was -0.60 ± 4.44 in KA versus 0.48 ± 5.40 in MA ($p = 0.2778$); MPTA was 87.44 ± 2.89 versus 88.40 ± 3.85 ($p = 0.1621$); and LDFA was 88.04 ± 2.73 versus 87.92 ± 2.93 ($p = 0.8326$). CPAK phenotype distributions were also comparable (Table 1).

Comparison of preoperative characteristics of the two groups showed no significant differences in age, gender, BMI, alignment parameters, OKS, WOMAC

scores or KSS components (pain, function, combined) (Table 2).

Numbers analyzed

All 100 randomized patients who met the eligibility criteria and completed the required 2-year follow-up were included in the final analysis. There were no protocol deviations, crossovers or exclusions after allocation. The analysis followed an intention-to-treat principle.

Primary outcome

At the 2-year follow-up, joint awareness measured by the FJS-12 was significantly higher in the KA group (65.64 ± 13.28) than in the MA group (57.24 ± 10.01), with a between-group difference of 8.4 points ($p = 0.001$). Although statistically significant, this difference did not reach the MCID of 16.6 points, suggesting that the improvement in joint perception may not be clinically meaningful.

Secondary outcomes

At 2 years, the OKS was 42.4 ± 4.3 in the KA group and 40.1 ± 5.7 in the MA group ($p = 0.048$). The total WOMAC score was significantly lower (better) in the KA group (22.82 ± 11.65) compared to the MA group (26.53 ± 10.15, $p = 0.003$). Subscale analysis showed statistical differences in WOMAC symptoms (11.48 ± 5.73 vs. 13.88 ± 5.56, $p = 0.005$) and activity (38.40 ± 20.14 vs. 44.12 ± 18.28, $p = 0.036$), while WOMAC stiffness did not differ significantly ($p = 0.110$). However, none of these differences exceeded the commonly cited MCID thresholds of 10–12 points, indicating they may not be clinically perceptible.

The KSS pain subscore was statistically significantly better in the KA group (47.90 ± 6.23) versus the MA group (45.90 ± 8.12; $p = 0.024$), while the KSS functional score ($p = 0.081$) and combined score ($p = 0.067$) showed non-significant trends favouring KA.

Knee ROM at 2 years was slightly higher in the KA group (119° ± 10°) compared to the MA group (117° ± 11°), though this was not statistically significant ($p = 0.201$).

At the 1-year follow-up, differences between groups in most outcomes were not statistically significant, except for WOMAC symptoms ($p = 0.015$), which again did not exceed MCID.

A detailed listing of the results of the primary outcome and secondary outcomes is illustrated in Table 3 and Figure 2.

TABLE 2 Preoperative clinical scores comparing mechanical alignment (MA) and kinematic alignment (KA) groups.

Parameter	MA (mean ± SD)	KA (mean ± SD)	p-value	Cohen's <i>d</i>
ROM	110.8° ± 21.27°	113.5° ± 14.19°	0.457	0.15
KSS Combined Preoperative	107.48 ± 28.94	118.44 ± 19.69	0.532	0.06
KSS ROM Preoperative	22.56 ± 4.25	23.10 ± 2.84	0.997	0.15
KSS Pain Preoperative	17.20 ± 10.89	19.60 ± 13.40	0.370	0.20
KSS Function Preoperative	46.90 ± 22.70	51.00 ± 10.25	0.084	0.23
OKS Preoperative	22.88 ± 7.79	22.44 ± 7.62	0.634	-0.06
WOMAC combined Preoperative	63.37 ± 13.09	61.85 ± 7.35	0.081	-0.14
WOMAC Symptoms Preoperative	29.32 ± 8.25	27.00 ± 6.76	0.220	-0.31
WOMAC Stiffness Preoperative	14.56 ± 3.75	14.08 ± 2.52	0.336	-0.15
WOMAC Activity Preoperative	108.20 ± 24.6	107.36 ± 13.81	0.184	-0.04

Note: Values are presented as mean ± standard deviation. No statistically significant differences were found across any parameter. Cohen's *d* is provided as a measure of effect size.

Abbreviations: KSS, Knee Society Score; OKS, Oxford Knee Score; ROM, range of motion; SD, standard deviation; WOMAC, Western Ontario and McMaster Universities Osteoarthritis Index.

TABLE 3 Postoperative clinical scores at 1- and 2-year follow-up comparing mechanical alignment (MA) and kinematic alignment (KA) groups.

Parameter	Follow-up	MA (mean ± SD)	KA (mean ± SD)	p-value	Cohen's <i>d</i>
ROM	Postoperative 2 years	117° ± 11°	119° ± 10°	0.201	0.19
KSS combined	Postoperative 1 year	188.56 ± 13.87	187.76 ± 16.12	0.328	-0.05
	Postoperative 2 years	193.12 ± 13.71	196.38 ± 8.24	0.07	0.29
KSS ROM	Postoperative 1 year	23.56 ± 1.86	23.56 ± 2.02	0.936	0.00
	Postoperative 2 years	23.82 ± 1.87	24.48 ± 1.42	0.078	0.40
KSS Pain	Postoperative 1 year	45.60 ± 6.12	44.40 ± 9.18	0.595	-0.15
	Postoperative 2 years	45.90 ± 8.12	47.90 ± 6.23	0.024	0.28
KSS Function	Postoperative 1 year	94.40 ± 9.72	94.80 ± 8.14	0.884	0.04
	Postoperative 2 years	98.40 ± 5.48	99.00 ± 3.62	0.930	0.13
OKS	Postoperative 1 year	37.88 ± 6.77	38.52 ± 6.78	0.559	0.09
	Postoperative 2 years	36.64 ± 8.34	36.68 ± 8.11	0.874	0.00
WOMAC combined	Postoperative 1 year	26.22 ± 9.81	26.13 ± 8.59	0.654	-0.01
	Postoperative 2 years	26.53 ± 10.15	22.82 ± 11.65	0.003	-0.34
WOMAC Symptoms	Postoperative 1 year	13.80 ± 4.73	11.84 ± 2.55	0.015	-0.52
	Postoperative 2 years	13.88 ± 5.56	11.48 ± 5.73	0.005	-0.43
WOMAC Stiffness	Postoperative 1 year	6.48 ± 3.20	6.36 ± 2.27	0.623	-0.04
	Postoperative 2 years	5.68 ± 2.84	4.88 ± 2.53	0.103	-0.04
WOMAC Activity	Postoperative 1 year	42.64 ± 17.39	44.52 ± 17.22	0.311	0.11
	Postoperative 2 years	44.12 ± 18.28	38.40 ± 20.14	0.036	-0.30
FJS	Postoperative 1 year	47.56 ± 12.21	55.48 ± 9.70	0.009	0.72
	Postoperative 2 years	57.24 ± 10.01	65.64 ± 13.28	<0.001	0.71

Note: Values are presented as mean ± standard deviation (SD). Statistical significance ($p < 0.05$) and effect sizes (Cohen's *d*) are reported to indicate the magnitude and direction of between-group differences. Positive Cohen's *d* values indicate higher scores in the KA group, and negative values indicate higher scores in the MA group. For the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC), lower scores indicate better outcomes (less pain, stiffness and functional impairment), in contrast to the Knee Society Score (KSS), Oxford Knee Score (OKS) and Forgotten Joint Score (FJS), where higher scores reflect better clinical status. Range of motion (ROM) is reported in degrees.

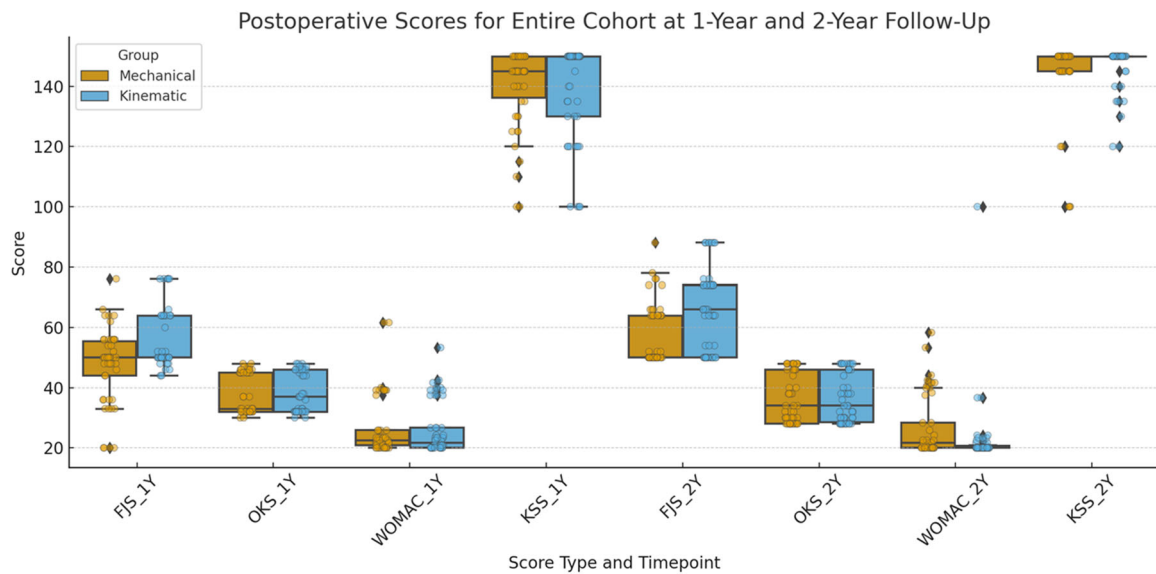


FIGURE 2 Boxplots of postoperative clinical outcome scores at 1- and 2-year follow-up for the entire cohort, comparing mechanical alignment (MA) and kinematic alignment (KA) groups. Outcomes include the Forgotten Joint Score (FJS), Oxford Knee Score (OKS), Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) and the Knee Society Score (KSS). Boxes represent the interquartile range; whiskers extend to 1.5× IQR. Individual data points are overlaid.

TABLE 4 Improvement in clinical outcomes from preoperative baseline to 2-year postoperative follow-up in the mechanical alignment (MA) and kinematic alignment (KA) groups.

Outcome measure	Follow-up	MA improvement (mean ± SD)	KA improvement (mean ± SD)	p-value	Cohen's <i>d</i>
Combined KSS	Postoperative 2 years	85.64 ± 13.4	87.42 ± 15.9	0.744	0.12
Combined WOMAC	Postoperative 2 years	-36.83 ± 15.2	-39.03 ± 14.8	0.500	-0.15
OKS	Postoperative 2 years	13.76 ± 8.3	14.24 ± 8.1	0.841	0.06
ROM	Postoperative 2 years	6.2 ± 21.3	5.5 ± 14.2	0.847	-0.04

Note: Values are presented as mean ± standard deviation (SD). Cohen's *d* is reported to quantify the effect size of between-group differences. Positive values indicate greater improvement in the KA group. For the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC), more negative values reflect greater clinical improvement (as lower WOMAC scores indicate better outcomes). Outcome measures include the Knee Society Score (KSS), Oxford Knee Score (OKS), WOMAC and range of motion (ROM, in degrees).

In an additional analysis comparing changes from baseline to 2 years, the mean improvement in combined KSS was 87.42 ± 15.87 in the KA group and 85.64 ± 13.43 in the MA group ($p = 0.744$). The mean improvement in WOMAC was -27.13 ± 15.41 in the KA group and -25.72 ± 14.51 in the MA group ($p = 0.500$), and the OKS improvement was 17.94 ± 8.17 versus 16.56 ± 7.99 ($p = 0.841$), respectively. These differences were not statistically significant. As illustrated in Table 4 and Figure 3.

Subgroup analysis

Exploratory subgroup analyses were performed based on CPAK phenotypes, grouped into varus (Types I, IV, VII), neutral (Types II, V, VIII) and valgus (Types III, VI, IX) morphotypes.

Among patients with varus phenotypes, those in the KA group demonstrated significantly better outcomes in the total WOMAC score at 2 years (20.92 ± 1.5 vs. 30.63 ± 13.12 in the MA group, $p = 0.039$). Additionally, FJS-12 scores favoured KA both at 1 year (60.33 ± 12.12 vs. 49.63 ± 14.09 , $p = 0.017$) and 2 years (69.89 ± 15.59 vs. 58.50 ± 10.72 , $p = 0.046$). However, the observed FJS-12 difference of 11.4 points, while statistically significant, did not exceed the established MCID of 16.6, suggesting limited clinical relevance. The results are illustrated in Table 5 and Figure 4.

In patients with valgus phenotypes, KA was also associated with a statistically significantly higher FJS-12 score at 2 years (61.14 ± 9.11 vs. 55.78 ± 7.48 , $p = 0.049$). As with the varus group, the difference did not surpass the MCID threshold, and no other clinical outcomes showed significant differences between

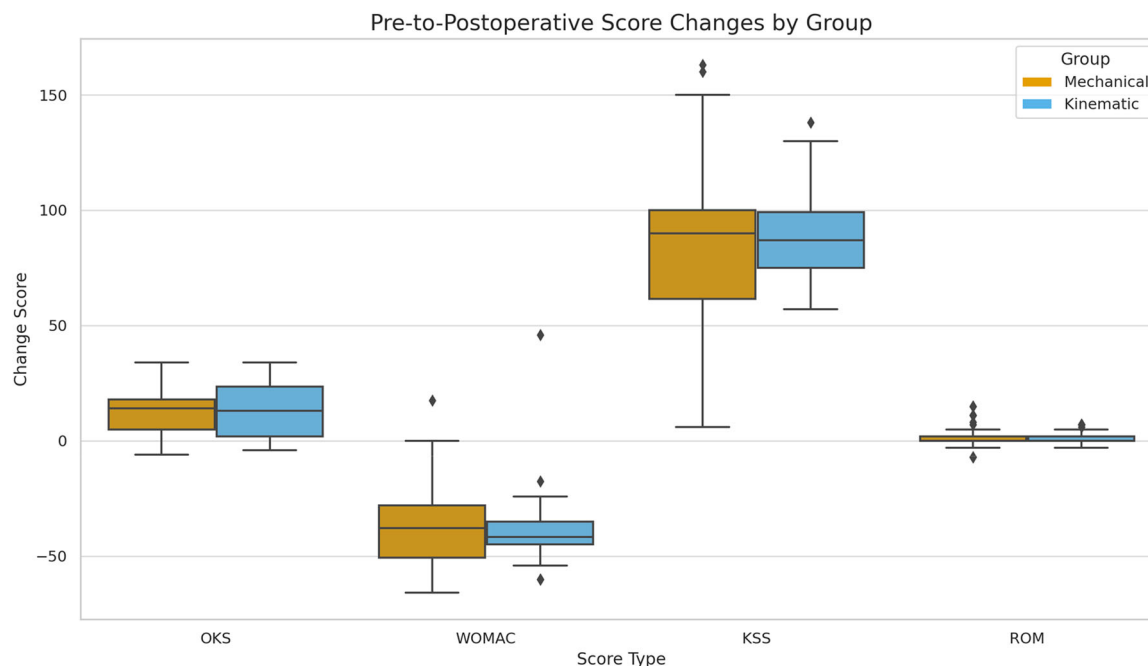


FIGURE 3 Pre-to-postoperative change scores in the Oxford Knee Score (OKS), Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC), Knee Society Score (KSS) and range of motion (ROM) for mechanical alignment (MA) and kinematic alignment (KA) groups. Positive values indicate improvement for OKS, KSS and ROM, while more negative values indicate greater improvement for WOMAC, as lower WOMAC scores reflect better outcomes. Boxplots show the median, interquartile range and outliers ($1.5 \times$ IQR).

TABLE 5 Postoperative clinical scores at 1- and 2-year follow-up in patients with a varus phenotype, comparing mechanical alignment (MA) and kinematic alignment (KA).

Parameter	Follow-up	Varus phenotype		p-value	Cohen's <i>d</i>
		MA (mean \pm SD)	KA (mean \pm SD)		
KSS	Postoperative 1 year	177.44 \pm 15.21	186.89 \pm 17.53	0.055	0.57
	Postoperative 2 years	193.25 \pm 13.91	197.00 \pm 5.90	0.237	0.36
OKS	Postoperative 1 year	39.25 \pm 6.73	40.89 \pm 7.01	0.365	0.24
	Postoperative 2 years	36.38 \pm 8.43	35.78 \pm 8.20	0.959	-0.07
WOMAC	Postoperative 1 year	26.56 \pm 11.17	28.52 \pm 10.32	0.574	0.18
	Postoperative 2 years	30.63 \pm 13.12	20.92 \pm 1.51	0.039	-1.07
FJS	Postoperative 1 year	49.63 \pm 14.09	60.33 \pm 12.12	0.017	0.82
	Postoperative 2 years	58.50 \pm 10.72	69.89 \pm 15.59	0.046	0.84

Note: Values are presented as mean \pm standard deviation (SD). Effect sizes are reported as Cohen's *d*, with positive values indicating better outcomes in the KA group and negative values indicating better outcomes in the MA group. For the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC), lower scores represent better outcomes (i.e., less pain and functional limitation). Higher scores reflect better outcomes for the Knee Society Score (KSS), Oxford Knee Score (OKS) and Forgotten Joint Score (FJS).

alignment strategies in this subgroup. The results are illustrated in Table 6 and Figure 5.

For patients with neutral phenotypes, no statistically significant differences were observed between KA and MA in any of the outcome measures at either follow-up timepoint, as illustrated in Table 7 and Figure 6.

These subgroup analyses suggest a possible trend toward improved joint perception and function in varus and valgus morphotypes following KA. However, none

of the observed between-group differences met the threshold for minimal clinical importance.

Harms and adverse events

Two patients in the KA group experienced complications requiring revision surgery. One case involved an acute postoperative infection, and the other resulted

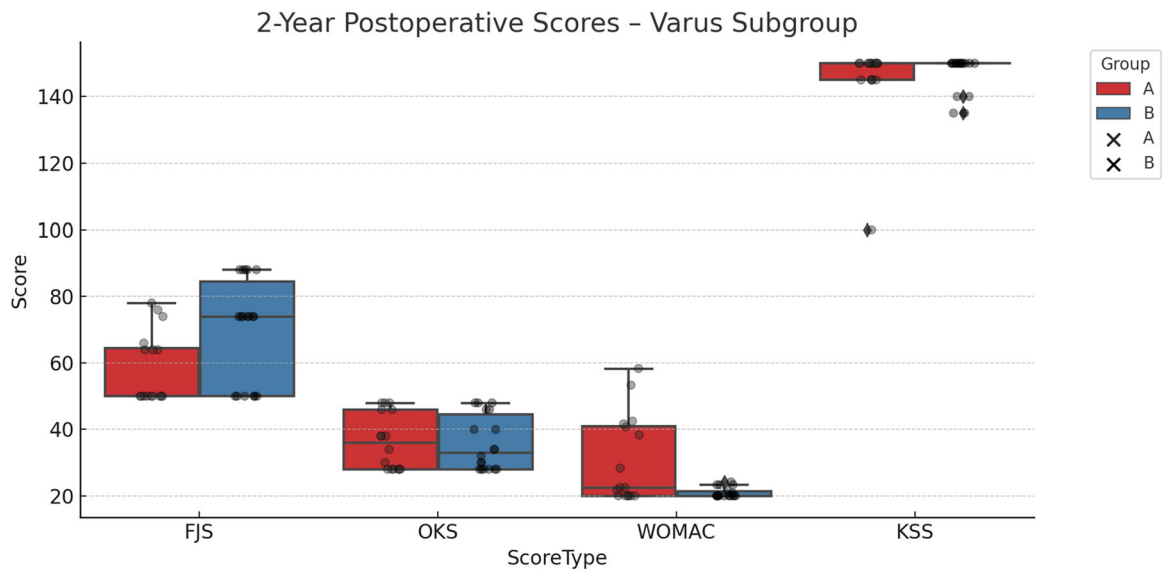


FIGURE 4 Two-year postoperative outcome scores for the varus phenotype subgroup, comparing mechanical alignment (MA, red) and kinematic alignment (KA, blue) groups. Boxplots display score distributions for the Forgotten Joint Score (FJS), Oxford Knee Score (OKS), Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) and Knee Society Score (KSS). Higher scores indicate better outcomes for FJS, OKS and KSS, while lower scores indicate better outcomes for WOMAC. Individual data points are overlaid to show distribution and variation within each group.

TABLE 6 Postoperative clinical scores at 1- and 2-year follow-up in patients with a valgus phenotype, comparing mechanical alignment (MA) and kinematic alignment (KA) groups.

Parameter	Follow-up	Valgus phenotype		<i>p</i> -value	Cohen's <i>d</i>
		MA (mean ± SD)	KA (mean ± SD)		
KSS	Postoperative 1 year	192.50 ± 12.25	189.36 ± 15.44	0.613	-0.22
	Postoperative 2 years	193.11 ± 14.38	197.64 ± 8.82	0.054	0.39
OKS	Postoperative 1 year	37.17 ± 6.68	37.29 ± 6.81	1.000	0.02
	Postoperative 2 years	37.22 ± 7.98	33.29 ± 5.79	0.168	-0.57
WOMAC	Postoperative 1 year	28.10 ± 11.22	24.94 ± 8.13	0.135	-0.33
	Postoperative 2 years	25.42 ± 8.94	21.30 ± 4.44	0.071	-0.60
FJS	Postoperative 1 year	45.33 ± 12.50	51.71 ± 6.79	0.377	0.65
	Postoperative 2 years	55.78 ± 7.48	61.14 ± 9.11	0.049	0.64

Note: Values are presented as mean ± standard deviation (SD). Cohen's *d* effect sizes are included to quantify the magnitude and direction of group differences, with positive values indicating better outcomes in the KA group and negative values indicating better outcomes in the MA group. Note that for the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC), lower scores indicate better clinical status, whereas higher scores denote improvement for the Knee Society Score (KSS), Oxford Knee Score (OKS) and Forgotten Joint Score (FJS).

from a traumatic patellar dislocation. No complications or revisions were reported in the MA group. No intraoperative complications were observed in either group.

DISCUSSION

This randomized controlled trial compared the clinical outcomes of KA and MA in total knee TKA using an MP prosthesis and CI. The primary hypothesis was that KA would improve joint awareness, measured by the FJS-12,

and enhance functional outcomes, with variation based on coronal alignment phenotype defined by the CPAK classification.

At the 2-year follow-up, the KA group showed higher FJS-12 scores compared to the MA group; however, the mean difference of 8.4 points did not exceed the established MCID of 16.6. Thus, while the trend favoured KA, the clinical relevance remains uncertain. Similar modest or non-significant differences have been reported by Shelton et al. [28] and Young et al. [33], reflecting ongoing variability in the literature regarding the impact of alignment strategy on joint awareness.

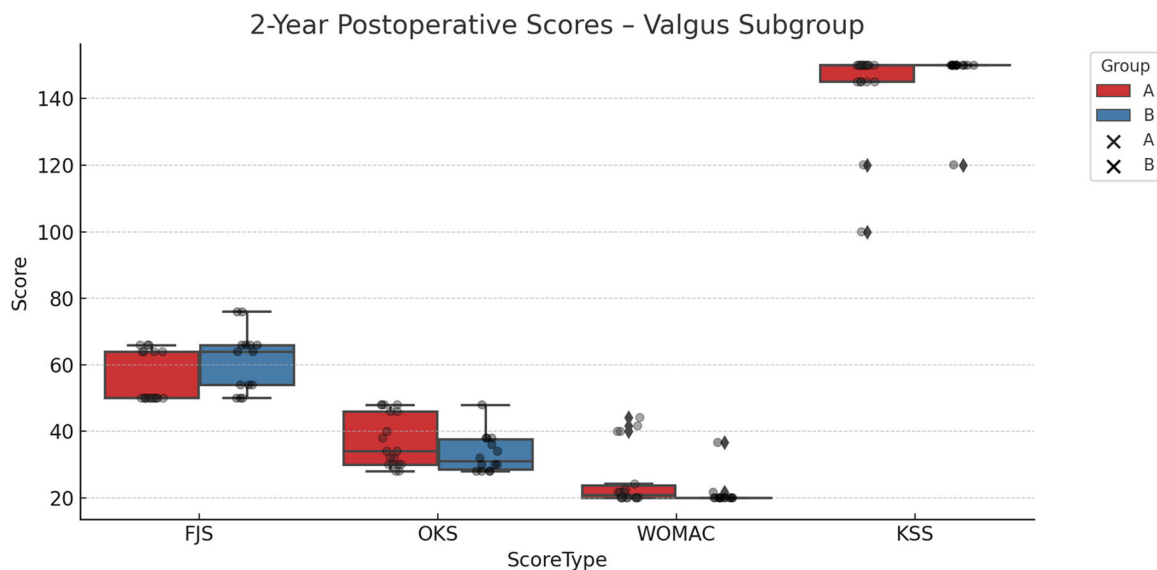


FIGURE 5 Two-year postoperative outcome scores for the valgus phenotype subgroup, comparing mechanical alignment (MA, red) and kinematic alignment (KA, blue) groups. Boxplots represent group distributions for the Forgotten Joint Score (FJS), Oxford Knee Score (OKS), Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) and Knee Society Score (KSS). Higher scores reflect better outcomes for FJS, OKS and KSS, whereas lower scores indicate better outcomes for WOMAC. Data points are overlaid to visualize individual variation within each group.

TABLE 7 Postoperative clinical scores at 1- and 2-year follow-up in patients with a neutral phenotype, comparing mechanical alignment (MA) and kinematic alignment (KA) groups.

Parameter	Follow-up	Neutral phenotype		<i>p</i> -value	Cohen's <i>d</i>
		MA (mean ± SD)	KA (mean ± SD)		
KSS	Postoperative 1 year	195.25 ± 5.40	187.39 ± 16.01	0.403	−0.64
	Postoperative 2 years	193.00 ± 13.64	194.78 ± 9.85	0.347	0.15
OKS	Postoperative 1 year	37.31 ± 7.13	37.11 ± 6.20	0.851	−0.03
	Postoperative 2 years	36.25 ± 9.14	40.22 ± 8.54	0.175	0.45
WOMAC	Postoperative 1 year	23.75 ± 6.00	24.67 ± 6.79	0.825	0.14
	Postoperative 2 years	23.70 ± 6.68	25.88 ± 18.92	0.384	0.15
FJS	Postoperative 1 year	48.00 ± 10.03	53.56 ± 6.81	0.251	0.66
	Postoperative 2 years	57.63 ± 12.03	64.89 ± 12.87	0.175	0.58

Note: Values are reported as mean ± standard deviation (SD). Cohen's *d* effect sizes quantify the magnitude and direction of between-group differences, where positive values indicate better outcomes in the KA group and negative values indicate better outcomes in the MA group. For the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC), lower scores reflect better outcomes, whereas higher scores reflect better clinical status for the Knee Society Score (KSS), Oxford Knee Score (OKS) and Forgotten Joint Score (FJS).

We also assessed improvements from baseline to 2 years in secondary outcome measures. Although KA showed greater mean improvements in the KSS, OKS and WOMAC, none of these changes reached statistical significance, and most did not surpass MCID thresholds. These results suggest that the alignment strategy may have limited overall influence on perceived recovery in the general cohort.

Subgroup analysis according to CPAK phenotype suggested that patients with varus alignment may benefit more from KA, particularly in WOMAC scores; however, it did not exceed the MCID threshold of

10–12 points in this group. FJS-12 improvements in the varus subgroup fell short of the MCID. These observations may indicate phenotype-specific benefits of KA, though subgroup analyses were exploratory and underpowered.

The influence of prosthetic design should also be considered. The MP design is intended to reproduce native knee kinematics, particularly in the medial compartment. Bauer et al. demonstrated in cadaveric studies that KA with MP TKA restored more physiologic motion than MA [1]. However, meta-analyses by Kakoulidis et al. and van Essen et al. found no

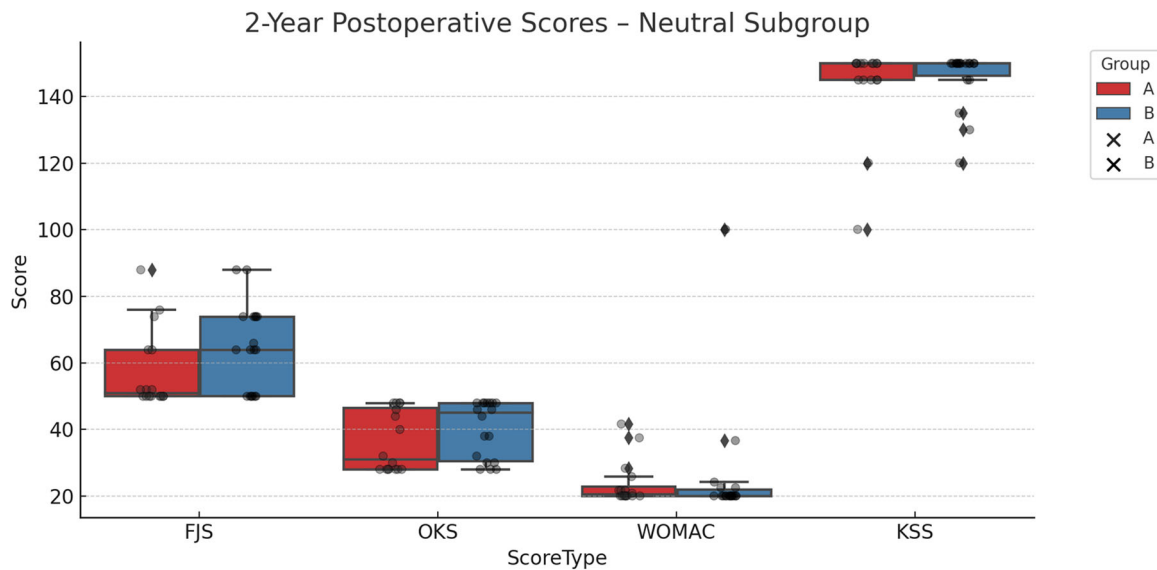


FIGURE 6 Two-year postoperative outcome scores for the neutral phenotype subgroup, comparing mechanical alignment (MA, red) and kinematic alignment (KA, blue) groups. Boxplots show the distribution of scores for the Forgotten Joint Score (FJS), Oxford Knee Score (OKS), Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) and Knee Society Score (KSS). Higher scores indicate better outcomes for FJS, OKS and KSS. In contrast, lower scores reflect better outcomes for WOMAC. Individual patient scores are overlaid as scatter points to illustrate variation within each group.

consistent superiority of MP implants or KA over conventional techniques in terms of satisfaction or outcomes, underscoring the need for a nuanced view of alignment-implant interactions [10, 18].

In terms of complications, two revisions occurred in the KA group (one for infection, one for traumatic patellar dislocation), neither of which was related to alignment. No revisions were required in the MA group. While reassuring, the low number of events precludes definitive conclusions about safety or durability.

These findings are consistent with previous studies reporting low and comparable revision rates between mechanical and KA techniques [refs]. For example, a systematic review by Roussot et al. [26] found no significant difference in revision risk between the two alignment philosophies. Similarly, Howell et al. [15] reported a 6-year implant survival rate of over 97% for KA without an increased risk of complications. Our results support the growing body of evidence suggesting that KA does not increase early postoperative risk, although larger and longer-term studies are needed to confirm long-term safety.

Clinical implications

Our findings suggest that while routine use of KA cannot be broadly recommended based on the current evidence, there may be potential benefits in selected phenotypes, particularly varus-aligned patients. These preliminary findings may inform individualized surgical planning but require confirmation in larger trials.

Limitations

This study has several limitations. First, the sample size was adequate for the primary outcome but limited for subgroup comparisons. Second, radiographic assessments were performed by a single observer, although previous data from this cohort showed high inter- and intraobserver reliability. Third, domains related to patient expectations and satisfaction (KSS subscales) were not recorded. Fourth, only a single implant type (MP design) was evaluated, which limits generalizability. Fifth, although operative time was documented, it was not included in the original outcomes and thus not analyzed. Finally, a notable proportion of patients lacked complete 2-year follow-up due to the timing of enrolment relative to the database lock. This may introduce a degree of attrition bias despite an intention-to-treat design. While the original protocol specified a minimum follow-up of 12 months, the primary outcome was later revised to the FJS at 24 months to better reflect long-term joint awareness. This amendment was made before data analysis and was approved by the institutional review board.

CONCLUSION

KA using an MP TKA design was associated with statistically significant improvements in selected outcomes compared to MA, though most differences did not reach MCID thresholds. In varus-aligned patients, WOMAC improvements approached MCID, suggesting possible

phenotype-specific benefits. These findings emphasize the need for further high-quality RCTs to clarify the role of alignment.

AUTHOR CONTRIBUTIONS

Study design, data collection, statistical analysis, manuscript writing: Amir Koutp. *Data analysis, statistical consultation, manuscript editing:* Lukas Leitner. *Data acquisition, radiographic analysis, manuscript editing:* Rene Schroedter. *Data analysis, interpretation, manuscript review:* Ines Vielgut. *Conceptualization, critical manuscript revision:* Andreas Leithner. *Principal investigator, study conception, supervision, final manuscript approval:* Patrick Sadoghi.

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CONFLICTS OF INTEREST STATEMENT

Andreas Leithner received industry grants from DePuy Synthes, Johnson & Johnson, Alphamed and Medacta. Patrick Sadoghi received industry grants from DePuy Synthes, Johnson & Johnson, Alphamed and Medacta; Editorial Board Member for JOA, KSSTA and Arthroscopy. The remaining authors declare no conflicts of interest.

DATA AVAILABILITY STATEMENT

Data are available from the corresponding author upon reasonable request.

ETHICS STATEMENT

This study was approved by the Ethics Committee of the Medical University of Graz (31-176 ex 18/19). All patients provided informed consent.

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Primary Knee

Less Induction Time and Postoperative Pain Using Spinal Anesthesia Versus General Anesthesia With or Without the Use of Peripheral Nerve Blocks in Total Knee Arthroplasty



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ABSTRACT

Background: Our aim was to analyze anesthetic induction time and postoperative pain using spinal anesthesia versus general anesthesia with or without the use of peripheral nerve blocks (PNBs) in total knee arthroplasty. The hypothesis was that spinal anesthesia would be beneficial with respect to induction time and postoperative pain and that PNBs would complement this effect.

Methods: Patients were stratified according to demographics, American Society of Anesthesiologists physical status classification system (ASA), and opioid intake and divided into: (A) general anesthesia without PNB; (B) general anesthesia with PNB; (C) spinal anesthesia without PNB; and (D) spinal anesthesia with PNB. Endpoints were anesthetic induction time, opioid consumption, and pain. Of 559 patients, 348 (62.3%) received general anesthesia (consisting of group A with 46 and group B with 302 patients), and 211 (37.7%) spinal anesthesia (consisting of group C with 117 and group D with 94 patients).

Results: We observed significantly lower total opioid intake 48 hours postoperative when applying spinal anesthesia by 2.08 mg ($P < .05$) of intravenous morphine-equivalent, and a reduction of 7.0 minutes ($P < .05$) until skin incision. The application of a PNB achieved a reduction of piritramide intake of 3.59 mg ($P < .05$) 48 hours postoperative and lengthened induction time by 8.5 minutes ($P < .05$).

Conclusions: Statistically shorter anesthetic induction times without clinical relevance, but lower postoperative opioid dosages with clinical relevance were observed for patients undergoing total knee arthroplasty with spinal anesthesia. The additional application of PNBs led to a lower need for opioids and lower pain levels in the early postoperative phase.

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While postoperative pain management is still evolving [1,2], it is essential for successful recovery, rehabilitation [3,4], satisfaction, and perioperative patient well-being [5–10]. Currently, there is no ideal analgesic protocol that performs best on all outcome measures, including well-being for primary total knee arthroplasty (TKA).

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Previous investigations have demonstrated a major connection between postoperative pain, early recovery, and functionality and an optimized analgesia in patients who underwent TKA [11]. Recovery and early rehabilitation can be affected and compromised by postoperative pain [3,12]. Early rehabilitation should be possible immediately after surgery; therefore, pain management for TKA should allow adequate movement of the knee with minimal pain and without motor block to promote early mobilization [13] and improve postoperative functionality of the affected knee [13].

The use of multimodal analgesic regimens that target multiple pain pathways in order to reduce opioid consumption has become more common [14–16]. These multimodal pain treatments include local infiltration analgesia and peripheral nerve block (PNB) to treat surgical pain and allow early postoperative mobilization [14–16].

Among PNBs, femoral nerve block (FNB) and sciatic nerve block are applied most frequently for analgesia after TKA [17], with both performed in combination to contribute to additional improved pain relief [18].

The aim of this study was to analyze anesthetic induction time and postoperative pain using spinal anesthesia (SA) versus general anesthesia (GA) with or without the use of PNBs in TKA. The hypothesis was that SA would be beneficial with respect to induction time and postoperative pain and that PNBs would complement this effect.

Patients and Methods

After obtaining ethical approval (EK 30-253 ex 17/18), we included 559 patients who underwent primary TKA in a single center by or under the supervision of one single surgeon from January 1, 2018 until February 28, 2019. Patients who had severe varus or valgus deformity greater than 10 degrees were excluded from the study in order to eliminate for additional bias due to excessive pain after soft tissue releases. Patients were stratified according to age, sex, body mass index, American Society of Anesthesiologists physical status classification system (ASA), preoperative opioid intake, and preoperative hemoglobin values and retrospectively analyzed and divided into 4 groups according to their anesthesia: (A) GA without PNB; (B) GA with PNB; (C) SA without PNB; and (D) SA with PNB. Outcome was retrospectively analyzed until 24 months of follow-up. Primary endpoints were anesthetic induction time, opioid consumption, and pain perception. Secondary endpoints were mortality, complication rate, and hospitalization time. The characteristics of the study population are shown in Table 1.

Surgical Technique

A medial parapatellar approach in a mechanically aligned extension gap first technique was applied in all cases. The tibial cut was performed with a posterior slope of 5° [19]. The femoral cut was planned according to the flexion balancing technique. The tibial and the femoral parts were cemented in all cases. A detailed description of the surgical technique was published previously [19–21].

The patients were allowed full weight bearing postoperatively. Continuous passive motion machines were provided for each single patient on the first postoperative day after the procedure twice a day for 30 minutes until discharge from hospital.

Anesthesiology Protocols

All subjects were anesthetized according to standardized protocols, regardless of the method performed [22]. Induction was performed in the operation theater. There were 62.3% (348) of the patients who received GA, while 37.7% (211) of the patients received SA. As SA and nerve blocks are both dependent on the years of experience of the anesthesiologist, so only those who had 2 years of experience or more in these interventions participated in this study. For SA, bupivacaine (isobaric and hyperbaric) was applied. Ultrasound-guided regional anesthesia was performed with 0.5% ropivacaine.

A PNB was applied for 396 patients (70.8%) whereby the FNB combined with the sciatic block was mostly performed with 58.4%, followed by the FNB with 33.3%. Of all the patients, 18.2% received dexamethasone (4 mg intravenously). Adjuvants were applied in 12% of the patients. Complications were classified according to Goslings and Gouma [23].

Data Analyses

We performed a descriptive and exploratory data analysis. Independent *t*-tests were used to compare demographic parameters between groups. An *a priori* sample size was estimated according to the main endpoints anesthetic induction time and pain perception with a power greater than 80% and a *P* value less than .05 at a clinically relevant difference of 30 minutes per case and 3 mg piritramide intravenous unit opioid dosage according to a previously published level 2 study [A]. This opioid dosage is equivalent to a clinically relevant difference in visual analog scale [A]. In addition, a *post hoc* power was calculated according to Hoenig and Heisey [24]. Stratification of *n* = 50 patients per group was performed according to age, height, and weight. All calculations were performed using Statistical Package for the Social Sciences 24.0 (SPSS Inc., Chicago, IL).

Demographic Data

In total, 559 consecutive patients underwent primary TKA in the investigated period. 365 (65.3%) were women and 194 (34.7%) were men. The average age of patients undergoing TKA was 71 years (range, 63 to 79). The Attune TKA system (DePuy Synthes, Warsaw, Indiana) was used for 405 (72.4%) patients, the ACS (Implantcast, Buxtehude, Delaware) for 81 (14.5%), the LCS (DePuy Synthes) for 18 (3.2%), and the PFC (DePuy Synthes) for 55 (9.9%) patients. The overall percentage distribution of ASA classifications was ASA1 in 4.4%, ASA2 in 44.9%, ASA3 in 44.6%, and ASA4 in 6.1% of cases. Among the 4 groups with the different anesthetic approaches, there were no relevant significant differences regarding age, body mass index, sex, and ASA physical status.

Results

Complications and Delirium

The results showed that 538 (96.2%) patients did not sustain any surgery-related complication. One patient sustained an infection and required a two-stage exchange, followed by amputation after persistent infection. There were 5 patients who consequently needed a reoperation, including 3 revisions after implant infection, one displaced polyethylene component, and one avulsion fracture of the tibial tuberosity within the first year after the procedure. There were 17 temporary complications without the necessity of a reoperation: 4 deep vein thromboses; 6 peripheral nerve-related problems (5 after PNB) (odds ratio [OR] 2.302, 95% confidence interval [CI] 0.267 to 19.834, *P* > .05), one superficial surgical site infection, and 2 postoperative soft tissues hematomas. In total, 20 falls were documented within the first 5 postoperative days, whereby 16 included patients who had a PNB, which resulted in an OR of 1.86 (95% CI 0.61 to 5.64, *P* < .05). Concerning the anesthetic method, 13 of the patients who fell had received GA. Accordingly, an OR of 0.822 (95% CI 0.32 to 2.09, *P* > .05) was calculated for the use of SA regarding the occurrence of falls. Most falls were observed in group B followed by group D. Delirium and behavioral changes were noticeable in ten cases, whereby 6 patients were from group B and 4 from the SA group with an OR for GA of 1.028 (95% CI 0.29 to 3.68, *P* > .05) and for the use of a PNB of 0.684 (95% CI 0.19 to 2.45, *P* > .05).

Pain Medication and Pain Intensity

The significantly highest total opioid consumption (mean 25.6 mg morphine equivalence [ME]) was observed in group A, while group D got along with the fewest number of opioid consumptions (mean 13.4 mg ME) *P* < .05.

When comparing the differences between general and SA regardless of the administration of PNB, the total opioid

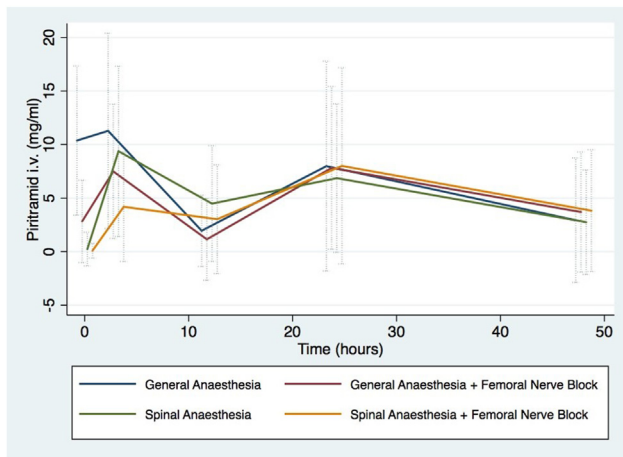


Fig. 1. Postoperative piritramide intake after implantation of primary total knee arthroplasty (TKA) using general anesthesia, spinal anesthesia, general anesthesia with femoral nerve block, and spinal anesthesia with femoral nerve block.

consumption was significantly reduced with SA, with a mean difference of 2.1 mg ME (95% CI 0.1 to 4.1, $P < .05$). The use of a PNB reached a significantly reduction of total opioid intake of averagely 3.6 mg ME (95% CI 1.5 to 5.7, $P < .05$). A hierarchical regression analysis for variables predicting intravenous piritramide application was performed, the results are shown in Table 2.

Regarding the postoperative course, the total postoperative use of opioids in the 4 groups had the same pattern as the total opioid intake, without any significant difference ($P > .05$). On postoperative day 0, both groups with PNB, group B (5.9 mg ME) and group D (5.2 mg ME), showed significantly lower need of opioids than the groups without PNB ($P < .05$). On postoperative days 1 and 2, no significant differences were observed among the 4 groups.

When comparing the administration of a PNB versus no PNB, the use of a PNB saved a mean of 3.8 mg ME (95% CI 2.76 to 4.81, $P < .05$) on day 0. No significant differences were observed on postoperative days 1 and 2 with the application of a PNB. There were no significant differences comparing GA with SA in the postoperative course observed. Concerning pain management, a patient-controlled analgesia was applied for 14.4% of all patients, which was stopped on the second (26.1%) or third (38.6%) postoperative day or thereafter. For analyzing the postoperative pain levels during the inpatient course, the maximal pain values were explored for each day separately. Furthermore, pain peaks were defined as a numeric rating scale ≤ 5 and then compared within the 4 groups. Group C showed significantly higher pain levels ($P < .05$) compared to the other 3 groups on day 0. On the following days, day 1 and day 2, no significant differences were observed.

The highest pain peaks were noted on the first postoperative day in all groups. Thereby, group B had the highest relative frequency for pain peaks with 10.4%, followed by group A with 9.8%, group C with 6.9%, and group D with 4.6%. A linear mixed effects model on the course of intravenous piritramide application was calculated and is shown in Table 3.

The postoperative piritramide intake after implantation of primary TKA using GA, SA, GA with FNB, and SA with FNB is illustrated in Figure 1.

Time to Incision

The overall mean duration until incision was 52 minutes (range, 40 to 64, 95% CI 51.4 to 53.2). Time to incision with GA was in average 55 minutes (range, 43 to 67, 95% CI 53.9 to 56.3) and with

SA 48 minutes (range, 38 to 58, 95% CI 46.9 to 49.4) regardless of the use of a PNB. That difference between GA and SA is statistically significant but not clinically relevant, with a mean difference of 6.95 minutes (95% CI 5.17 to 8.72, $P < .05$).

Evaluating the additional time of a regional anesthesia revealed a mean of 8 minutes (95% CI 6.63 to 10.36, $P < .05$). In these cases, the average time to incision (with a PNB) was 55 minutes (range 43 to 67, 95% CI 53.9 to 56.1) versus 47 minutes (range 37 to 58, 95% CI 45.2 to 47.8) without PNB.

The longest time to incision was required in the group B (56 minutes), followed by the group D (52 minutes). The fastest groups were C (46 minutes), followed by group A (49 minutes), both without the use of a PNB. All groups had a significant advantage over group B $P < .05$. Group C had slightly but not significantly decreased time to incision compared to group A $P > .05$. A regression analysis for variables predicting anesthesia time was performed, the results are shown in Table 4.

Postoperative Parameters: Length of Stay, Urinary Catheter, Gait Training, Range of Motion

On average, patients stayed in the hospital for 9 days (range, 7 to 11) before being discharged. There were no significant differences among the 4 groups.

The majority of patients were able to stand up and start gait training on the second postoperative day (± 1.01 days). In detail, 33.4% commenced gait training on the first postoperative day, 47.9% on the second, and 10.2% on the third. In total, 469 patients had a urinary catheter inserted, which was removed on the second postoperative day (± 1.17 days) with an incidence rate of 45.2%. Preoperative and six-week postoperative range of motion was available in 250 cases. There were no significant differences between GA and SA and the use of a PNB observed regarding the preoperative and postoperative range of motion, the duration of catheter attachment, and the duration till gait training commenced ($P > .05$).

Discussion

The aim of this study was to analyze induction time and postoperative pain using SA versus GA with or without the use of PNBs in TKA. The hypothesis was that SA would be beneficial with respect to induction time and postoperative pain and that PNBs would complement this analgesic effect. We found less induction time and postoperative pain using SA versus GA and less pain using PNBs in TKA.

Of note, no differences with respect to postoperative pain could be noted between different implant designs.

Numerous studies have shown significant differences in patients' outcome regarding the choice of anesthetic method [25,26]. The obtained results were analyzed and compared with relevant studies comparing differences in GA versus SA for TKA. Overall, this study confirmed that SA was either equivalent or superior to GA in some endpoints.

Only a few studies investigated the time to incision before, and none were investigating it specifically for TKA [27]. Sasano et al [27] showed an average duration of 49 minutes (range, 37 to 61) from entrance to incision for 172 orthopedic surgeries. In the current study, a mean of 52 minutes time from wound closure to incision of the next case were measured. However, Sasano et al included all orthopedic interventions and did not differentiate from the anesthetic methods. The use of SA was able to undercut the time to incision of GA by 7.0 minutes, which is not clinically relevant with respect to one operating day, as no additional case can be scheduled. Two other studies additionally showed such superiority of SA,

Table 1
Characteristics of the Study Population

Variable	All Patients (N = 559)	Peripheral Nerve Block		P Value
		Yes (n = 396)	No (n = 163)	
Patient characteristics				
Age, mean (range)	71 (63 to 79)	71 (63 to 79)	72 (64 to 80)	.397
Sex, n (%)				.502
Women	365 (65)	262 (66)	103 (63)	
Men	194 (35)	134 (34)	60 (37)	
Mean BMI (range)	30 (25 to 35)	29 (24 to 34)	30 (24 to 36)	.228
ASA, n (%)				.407
1	24 (4.3)	17 (4.3)	7 (4.3)	
2	254 (45)	188 (47)	66 (40)	
3	252 (45)	173 (44)	79 (48)	
4	29 (5.2)	18 (4.6)	11 (6.8)	
Preoperative opioid intake, n (%)	49 (8.8)	33 (8.3)	16 (9.8)	.573
Preoperative hemoglobin, mean ± SD	14 (13 to 15)	14 (13 to 15)	13 (12 to 14)	.079
Intraoperative characteristics				
Anesthesia, n (%)				<.001
General	348 (62)	302 (76)	46 (28)	
Spinal	211 (38)	94 (24)	117 (72)	
Adjuvant dexamethasone, n (%)	108 (19)	100 (25)	8 (4.9)	<.001
Intraoperative fentanyl mg, median (IQR)	0 (100)	0 (100)	0 (20)	.010^a
Anesthesia time, mean ± SD	51 (11)	54 (11)	47 (9)	<.001
Postoperative characteristics				
Piritramide IV (mg/mL), mean ± SD	23 ± 16	22 ± 15	27 ± 17	.002
NRS peak (within 3 d postoperative), median (IQR)	4 (2)	4 (2)	4 (2)	.313^a
NRS (within 3 d postoperative), mean ± SD	1.5 ± 0.90	1.4 ± 0.85	1.7 ± 1.0	.007
NRS ≥4 (within 3 d postoperative), n (%)	299 (53)	210 (53)	89 (55)	.735
Hemoglobin loss <24 h, mean ± SD	−3.0 ± 1.2	−3.0 ± 1.3	−3.1 ± 1.1	.832
Erythrocyte concentrate, n (%)	72 (13)	50 (13)	22 (14)	.780
Delirium, n (%)	8 (1.4)	3 (0.76)	5 (3.1)	.050
Complications				
Non	540 (97)	381 (96)	159 (98)	.601^b
With temporary disadvantage	14 (2.5)	11 (2.8)	3 (1.8)	
With recovery after (re-)operation	3 (0.54)	3 (0.76)	0	
With (probably) permanent harm	2 (0.36)	1 (0.25)	1 (0.61)	

Statistically significant results are in bold.

BMI, body mass index; ASA, American Society of Anesthesiologists physical status classification; IV, intravenous; IQR, interquartile range; NRS, numeric rating scale.

^a Two-sample Wilcoxon rank-sum (Mann-Whitney) test.

^b Fisher's exact test.

but specifically for surgeries on the spine. Pierce et al [28] presented a significantly shorter time period till incision for SA with 39 minutes compared to GA with 47 minutes. In the study of Singeisen et al [29], a reduction of 19 minutes was achieved when using SA instead of GA.

Piritramide values had to be put into equivalence to morphine for standardization and better comparison with other studies. According to the systemic review of Hinrichs et al, the analgesic potency of piritramide in morphine is 0.7 to 0.75:1 for IV application [30]. For the statistical calculation of pain medication with opioids

Table 2
Hierarchical Regression Analysis for Variables Predicting Intravenous Piritramide Application.

Variable	b	(SE)	t	P Value	95% Confidence Interval	Step		
						ΔR ²	ΔF(df)	P Value
Step 1 (anesthesia)								
Spinal (versus general)	−5.6	1.6	−3.7	<.001	[−8.6; −2.6]	0.008	4.233 (1,557)	.008
Step 2 (adjuvants)								
Dexamethasone	−0.36	1.7	−0.21	.832	[−3.7; 3.0]	0.006	1.789 (2,551)	.168
Intraoperative fentanyl	0.01	0.01	0.83	.405	[−0.01; 0.02]			
Step 3 (peripheral nerve block)								
Peripheral nerve block	−7.2	1.6	−4.4	<.001	[−10; −4.0]	0.035	20.07 (1,550)	<.001
Step 4 (demographics)								
Age	−0.31	0.09	−3.6	<.001	[−0.48; −0.14]	0.047	5.616 (5,545)	<.001
Men (versus women)	0.82	1.4	0.60	.549	[−1.9; 3.5]			
BMI	0.18	0.14	1.3	.181	[−0.08; 0.45]			
ASA 3/4 (versus 1/2)	3.8	1.5	2.6	.009	[0.96; 6.7]			
Preoperative opioid intake	−0.07	2.3	−0.03	.976	[−4.6; 4.5]			
Constant (full model)	45	8.6	5.2	<.001	[28; 62]			

Statistically significant results are in bold.

BMI, body mass index; SE, standard error.

Table 3
Linear Mixed Effects on the Course of Intravenous Piritramid Application.

Variables	b	(SE)	z	P Value	95% Confidence Interval
Anesthesia and peripheral nerve block (reference: general anesthesia)					
Spinal	-4.0	0.72	-5.6	<.001	[-5.4; -2.6]
General + block	-4.5	0.64	-7.1	<.001	[-5.8; -3.3]
Spinal + block	-6.3	0.73	-8.6	<.001	[-7.7; -4.9]
Age	-0.05	0.02	-2.17	.030	[-0.09; <0.01]
ASA 3/4 (versus 1/2)	0.63	0.35	1.83	.068	[-0.05; 1.3]
Dexamethasone	-0.37	0.44	-0.84	.403	[-1.2; 0.49]
Intraoperative fentanyl	<-0.01	<-0.01	-0.11	.916	[<-0.01; <0.01]
Time # anesthesia and peripheral nerve block (reference: general anesthesia)					
Spinal	0.12	0.03	4.1	<.001	[0.06; 0.18]
General + block	0.14	0.03	5.3	<.001	[0.09; 0.19]
Spinal + block	0.20	0.03	6.6	<.001	[0.14; 0.26]
Time # age	<-0.01	<-0.01	-1.7	.084	[<-0.01; <0.01]
Time # ASA 3/4 (versus 1/2)	0.01	0.01	0.94	.345	[-0.01; 0.04]
Time	-0.04	0.07	-0.64	.522	[-0.17; 0.09]
Constant	72.6	7.46	9.74	<.001	[58.0; 87.2]

Statistically significant results are in bold.

and pain intensity in the postoperative course, all patients receiving patient-controlled analgesia and patients who have chronic preoperative opioid therapy had to be excluded. Consequently, only 508 patients out of 559 were analyzed for those parameters. The reason was because patients who have chronic opioid therapy need higher doses of morphine due to their higher tolerance against the effects of opioids [31]. It is important to mention that before applying strong opioids World Health Organization level 3, standard medication of level one and level 2 against pain were exploited.

The total opioid consumption was defined as the intraoperative opioid administration and the postoperative opioid intake until the second postoperative day.

The total opioid consumption was significantly higher with GA by a mean of 2.1 mg ME compared to SA. Besides that, a block of a peripheral nerve was able to reduce the total intake of ME by a mean of 3.6 mg with significance. Thereby, the use of a PNB significantly saved a mean of 3.8 mg ME on day 0 but did not show significant differences on postoperative day 1 and day 2. However, the clinical relevance of such low opioid consumption differences is questionable for clinical practice. Donauer et al [32] analyzed 2,346 cases of knee arthroplasty and associated regional anesthesia with lower opioid consumption (OR 0.20 [95% CI 0.13 to 0.30], $P < .05$) and pain levels (OR 0.53 [95% CI 0.36 to 0.78], $P < .05$) on the first postoperative day. However, regional anesthesia included neuraxial as well as peripheral nerve blockade and did not differentiate among them for their analysis. Furthermore, Donauer et al [32] used different opioids, including sufentanil, morphine, and fentanyl, and converted them into ME, whereby in our study, only piritramide was administered eliminating for this potential bias. In the systemic review by Chan et al [33], 29 randomized-controlled studies were analyzed, and they observed that PNB comes along with less pain at rest and on movement in the first 72 hours after

surgery. In contrast to the current study, they observed a significantly lower total opioid consumption with a PNB, although it is not clear if the intraoperative opioid administration was considered. Another study about the effects of PNB in TKA was published by Jenstrup et al [34], where authors measured reduced opioid consumption in the early postoperative phase. Furthermore, patients reported lower pain during movement but not when resting. The potential benefits of PNB have to be evaluated with potential harms and complications, such as the higher rate of postoperative falls due to quadriceps weakness or reversible or permanent nerve damage [35–37].

Unfortunately, there is no systematic documentation of the duration of peripheral nerve blockade in our hospital. Due to logistical reasons, we record only during nurses' rounds whether the blockade is still affecting motor or sensoric function as well as pain scores. However, it has already been described elsewhere, that a duration from 10 to 12 hours with 0.5% ropivacaine is to be expected [38].

There are potential limitations of this manuscript. Fentanyl was not only used for analgesia but mainly for induction of anesthesia; thus exact evaluation of how much it influenced postoperative pain, when also taking context-sensitive half-time into account, is impossible in this retrospective study setting. Systematic measurements of length of peripheral nerve blockade were not recorded in all patients. Due to its retrospective design, the level of evidence is naturally low in the presented manuscript and a prospective design would be favorable.

Conclusion

Spinal anesthesia for patients undergoing TKA led to statistically shorter anesthetic induction times without clinical relevance, but with lower postoperative opioid dosages with clinical relevance. The

Table 4
Regression Analysis for Variables Predicting Anesthesia Time.

Variable	b	(SE)	t	P Value	95% Confidence Interval
Peripheral nerve block	4.6	1.1	4.2	<.001	[2.5; 6.8]
Spinal anesthesia (versus. general anesthesia)	-5.4	1.0	-5.3	<.001	[-7.4; -3.4]
ASA score (reference: ASA 1)					
ASA 2	1.3	2.2	0.58	.561	[-3.1; 5.7]
ASA 3	3.0	2.2	1.3	.183	[-1.4; 7.4]
ASA 4	6.1	2.9	2.1	.035	[0.44; 12]
Constant	48	2.4	20	<.001	[43; 53]

F(5, 553) $P = <.001$ $r^2 = 0.1402$.

Statistically significant results are in bold.

additional implementation of PNBs led to a lower need for opioids and lower pain levels in the early postoperative phase at the cost of more frequent falls and a higher potential for nerve damages.

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