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RESEARCH ARTICLE

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# Enhancing total knee arthroplasty outcomes: the role of individualized femoral sagittal alignment in robotic-assisted surgery - A randomized controlled trial

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## Abstract

**Background** Optimal sagittal alignment of the femoral prosthesis is critical to the success of total knee arthroplasty (TKA). While robotic-assisted TKA can improve alignment accuracy, the efficacy of default femoral alignment versus individualized alignment remains under scrutiny. This study aimed to compare the differences in prosthetic alignment, anatomical restoration, and clinical outcomes between individualized femoral sagittal alignment and default sagittal alignment in robotic-assisted TKA.

**Methods** In a prospective randomised controlled trial, 113 patients (120 knees) underwent robotic-assisted TKA were divided into two groups: 61 with individualized femoral flexion (individualized alignment group) and 59 with default 3–5° flexion (default alignment group). The individualized alignment was based on the distal femoral sagittal anteverted angle (DFSAA), defined as the angle between the mechanical and distal anatomical axes of the femur. The radiographic and clinical outcomes were compared.

**Results** Despite similar postoperative femoral flexion angles between groups ($P=0.748$), the individualized alignment group exhibited significantly lower incidences of femoral prosthesis extension and higher rates of optimal 0–3° prosthesis flexion (9.8% vs. 27.1%, $P=0.014$,78.7% vs. 55.9%, $p=0.008$, respectively). The individualized alignment group also demonstrated more favourable changes in sagittal anatomy, with higher maintenance of postoperative anterior femoral offset within 1 mm (54.1% vs. 33.9%, $P=0.026$) and posterior condylar offset within 1 mm and 2 mm (44.3% vs. 25.4%, $p=0.031$,73.8% vs. 50.8%, $p=0.010$, respectively). Although slight improvement in the Hospital for Special Surgery Knee Score (HSS) at three months was observed ($P=0.045$), it did not reach a minimal clinically important difference.

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**Conclusion** Individualized tailoring of femoral sagittal alignment in robotic-assisted total knee arthroplasty (TKA) enhances prosthetic alignment and anatomical restoration, suggesting potential improvements in postoperative outcomes.

**Keywords** Total knee arthroplasty, Femoral alignment, Robot, Offset, Anatomy

## Introduction

The sagittal alignment of the femoral prosthesis is crucial for both function and the long-term survival of total knee arthroplasty (TKA) [1–3]. Femoral prosthesis extension increases patellofemoral forces, potentially leading to postoperative anterior knee pain [4]. Hyperflexion of the femoral prosthesis, conversely, significantly heightens the risk of subsequent failure [5]. Therefore, most surgeons recommend a femoral prosthesis with mild flexion of 0°-3° [1, 6, 7]. Femoral flexion varies greatly in conventional TKA [8], but robotic-assisted TKA offers a means to precisely achieve the desired sagittal alignment.

In robotic-assisted TKA, the femoral mechanical axis (from the femoral head centre to the intercondylar notch apex) serves as a common reference for sagittal alignment, however, this may not align with the postoperative anatomical assessment, which utilizes the femur's distal anatomical axis [9–12]. The distal femoral sagittal anteverted angle (DFSAA), the angle between the mechanical and distal anatomical axes in the sagittal plane, reconciles these differences and serves as a sagittal alignment reference [13, 14]. Notably, the DFSAA varies considerably amongst individuals due to differences in femoral morphology and ethnicity, with values ranging from 1.72° extension to 8.5° flexion within the general population [15, 16], challenging the one-size-fits-all approach of setting femoral flexion between 3–5° [17, 18]. Emerging evidence suggests that default femoral flexion significantly raises the incidence of femoral prosthesis extension and notching [9, 17, 19, 20]. On the contrary, aligning femoral flexion to account for individual anatomy can optimize joint gap balance and sagittal diameter restoration [21].

The restoration of femoral anatomy, including anterior femoral offset (AFO) and posterior condylar offset (PCO), is crucial for replicating native joint mechanics and enhancing patient satisfaction [22–24]. Although the relationship between femoral flexion and changes in AFO and PCO is established [4], the efficacy of individualized sagittal alignment in bettering the restoration of femoral anatomy and improving patient outcomes warrants further investigation.

The prospective randomized controlled trial aimed to compare individualized and default femoral sagittal alignment in robotic-assisted TKA. The primary objective was to assess the distribution of DFSAA in patients with knee osteoarthritis and explore potential postoperative sagittal alignment differences between individualized and default alignment groups. The secondary objective was to compare sagittal anatomy restoration and short-term postoperative clinical outcomes between the two groups.

## Methods and materials

This study represents a partial data analysis from a prospective randomised controlled trial conducted on robotic-assisted TKA. Ethical approval was obtained from the Ethics Committee of the First Affiliated Hospital of Chongqing Medical University (Approval No. 2022−176), and the trial was registered with the Chinese Clinical Trial Register (Registration number. ChiCTR2200063223). Informed consent was obtained from all participants. Enrolment spanned from November 2022 to June 2023, involving patients scheduled for TKA. Inclusion criteria included age 21–80 years, suitability for surgery, ability to attend follow-up visits and no vascular or neurological injury. Exclusion criteria encompassed previous hip arthroplasty on the same side, significant deformities (>15° valgus or varus), knee infection, tumours, or ankylosing deformities of the hip or ankle.

A total of 155 patients were initially assessed, with 121 qualifying for the study and were subsequently randomly grouped using a random number table method. The patient flow is detailed in Fig. 1. Finally, data from 58 patients (61 TKAs) in the individualized alignment group and 55 patients (59 TKAs) in the default alignment group were subjected to analysis. Baseline characteristics, including demographics, DFSAA measurements, and preoperative functional scores showed no significant difference between groups (Table 1).

All patients underwent full-length CT scanning of both lower extremities (scanning protocol: 200 mA, 130KV, slice spacing of 0.6 mm), facilitating the bilateral assessment of DFSAA in all cases (comprising 211 femurs). Utilizing these scans, three-dimensional models of the femur were reconstructed by trained orthopaedic surgeons using Mimics 21.0 (Materialise, Leuven, Belgium). The surgical transepicondylar axis (sTEA) was defined as the line between the medial epicondylar sulcus and the lateral epicondylar prominence. The sagittal plane of the femur was defined as the plane through the centre of the femoral head and perpendicular to the sTEA (Fig. 2a). Additionally, the mechanical axis of the femur was defined as the line connecting the centre of the femoral head to the apex of the intercondylar notch. The anatomical axis of the femur was defined as the line connecting

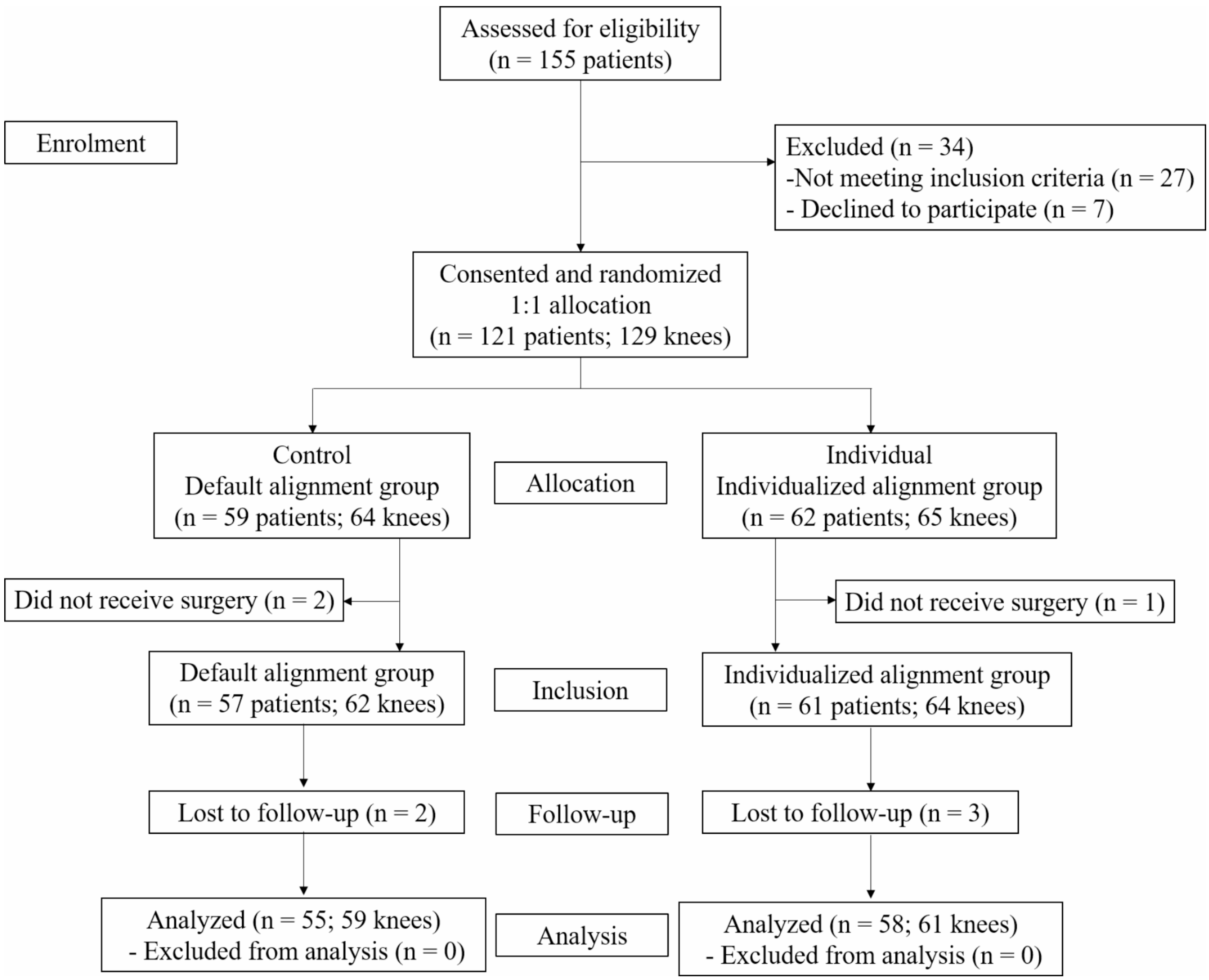


**Fig. 1** Flow diagram showing recruitment and allocation of patients

**Table 1** Details of the patients in the study

| Parameters | Individualized alignment group | Default alignment group | *p* |
|---|---|---|---|
| No. of knee | 61 | 59 | N/A |
| Mean age, years | 69.2 ± 8.0 | 69.3 ± 6.4 | 0.965* |
| Gender, female/male | 49/12 | 48/11 | 0.931† |
| Side, left/right | 24/37 | 27/32 | 0.477† |
| Mean height, cm | 156.4 ± 8.3 | 155.3 ± 6.9 | 0.401* |
| Mean weight, kg | 63.2 ± 10.6 | 62.2 ± 10.3 | 0.580* |
| Mean BMI, kg/m2 | 25.8 ± 3.2 | 25.8 ± 3.7 | 0.997* |
| Mean DFSAA, ° | 4.1 ± 1.7 | 4.2 ± 1.6 | 0.787* |
| Mean VAS | 6.0 ± 0.9 | 5.7 ± 1.0 | 0.131* |
| Mean HSS | 63.9 ± 8.4 | 66.4 ± 8.8 | 0.120* |
| Mean WOMAC | 42.2 ± 5.4 | 40.1 ± 7.9 | 0.093* |

BMI, Body Mass Index; DFSAA, distal femoral sagittal anteverted angle; VAS, Visual Analogue Score; HSS, Hospital for Special Surgery Knee Score; WOMAC, Western Ontario and McMaster Universities Osteoarthritis Index, SD, standard deviation; N/A, not applicable.

*Independent-samples t-test. †Chi-squared test.

the geometric centres of the femoral medullary cavity at 5 cm and 10 cm from the knee joint line. Subsequently, the femoral mechanical and anatomical axes were projected onto its sagittal plane to measure their intersecting angle, known as the DFSAA (Fig. 2b).

All operations were performed by a unified team led by a senior orthopaedic surgeon (W.H) using the KUNWU-TKA (Yuanhua Intelligent Technology, Shenzhen, China). This system, proven effective in previous studies [25, 26], employs functional alignment with a fixed-platform posterior cruciate ligament sacrificing prosthesis (Unique knee, Zhengtian, Tianjin, China). Preoperative plans were based on Shatrov et al.'s procedure [27]. Prosthesis size was determined based on matching the prosthesis model to the bone model, avoiding anterior notching and patellofemoral joint overfilling. Prosthesis adjustments in the coronal plane were made according to the lateral angle of the distal femur and medial angle of the proximal tibia, targeting a final limb alignment between 3° valgus

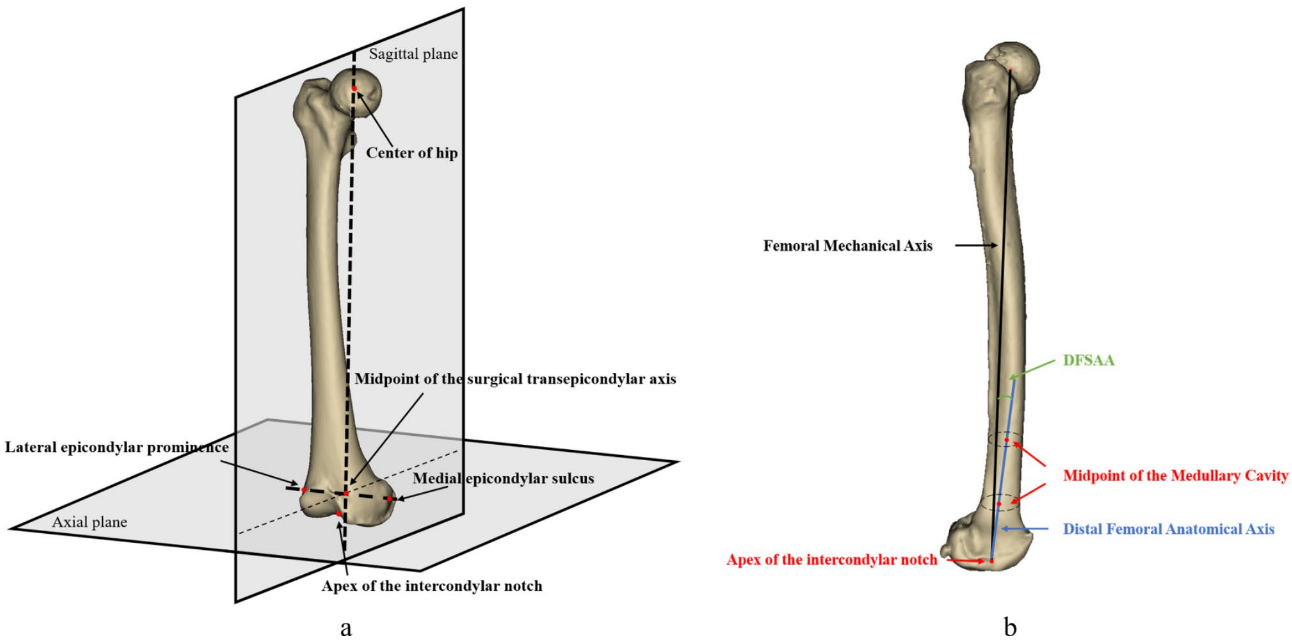


**Fig. 2** Establishment of the coordinate system and definition of the femoral axis and angle. Figure 2a. Establishment of the coordinate system and projection plane. The sagittal plane was defined as the plane perpendicular to the surgical transepicondylar axis and passing through the centre of the femoral head. Figure 2b. Definition of the femoral axis and angle. The femoral mechanical axis is determined by connecting the centre of the femoral head to the apex of the intercondylar notch. The anatomical axis of the femur is determined by connecting the midpoint of the femoral medullary cavity. Both the femoral mechanical axis and the distal femoral anatomical axis are projected onto the femur's sagittal plane. The angle formed between these two axes is identified as the distal femoral sagittal anteverted angle (DFSAA). If the femoral mechanical axis was extended relative to the distal femoral anatomical axis, the value of DFSAA was assigned a positive value. DFSAA, distal femoral sagittal anteverted angle

and 6° varus. In the axial plane, the femoral prosthesis was aligned parallel to the sTEA with up to a 3° adjustment, while the tibial prosthesis followed the Akagi line. In the sagittal plane, the individualized alignment group matched the distal anatomical axis and allowed 0–3° of flexion according to the DFSAA; the default alignment group set 3–5° of flexion relative to the mechanical axis, and the tibial prosthesis was set to match the patient's native posterior tibial slope.

Operations were conducted using a medial parapatellar approach with a tourniquet. Adjustments occurred at 0° of extension and 90° of flexion to balance the medial-lateral knee gap. The individualized alignment group aligned with the distal anatomical axis, permitting 0–3° of flexion, while the default alignment group adjusted femoral flexion as directed by the system prompts to prevent anterior notching. Appropriate flexion and extension gaps were obtained by fine-tuning the position of the femoral and tibial prostheses, and subsequent osteotomies were performed according to the intraoperative plan without the need to loosen the soft tissues. Postoperatively, all patients received antibiotics and anticoagulation therapy, without drain placement, and began passive and active knee exercises immediately.

Anterior-posterior and lateral knee radiographic imaging were performed pre-surgery and during the final postoperative evaluation. Following the technique described by Pierson et al [28], two authors (DHW and KL) independently evaluated, basing their analyses on the average of both sets of measurements. The femoral flexion angle was defined as the angle between the anatomic axis of the distal femur and the anterior flange of the femoral prosthesis, minus a 3° adjustment for the prosthesis's design-induced tilt (Fig. 3a). The AFO was defined as the distance between the anterior edge of the femoral cortex and the anterior aspect of the femoral condyle, corrected for magnification differences using a scale and standardized to a radiographic distance of 1.5 m. The change in AFO was calculated as the preoperative AFO minus the postoperative AFO. Similar measurements were made for PCO as shown in Fig. 3b and c. As previous studies indicate the cartilage thickness of the distal femur averages 2.0±0.4 mm [29], the cartilage thickness was standardized at 2 mm for all patients.

Clinical outcomes were evaluated preoperatively, 6 weeks and 3 months postoperatively by a trained orthopaedic surgeon using the Visual Analogue Scale (VAS) for pain, the Hospital for Special Surgery Knee Score (HSS) and the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) for overall joint assessment. In order to comprehensively assess the postoperative knee range of motion (ROM) in both groups, ROM was collected at 6 weeks and 3 months postoperatively. Measurements were taken with the patients prone

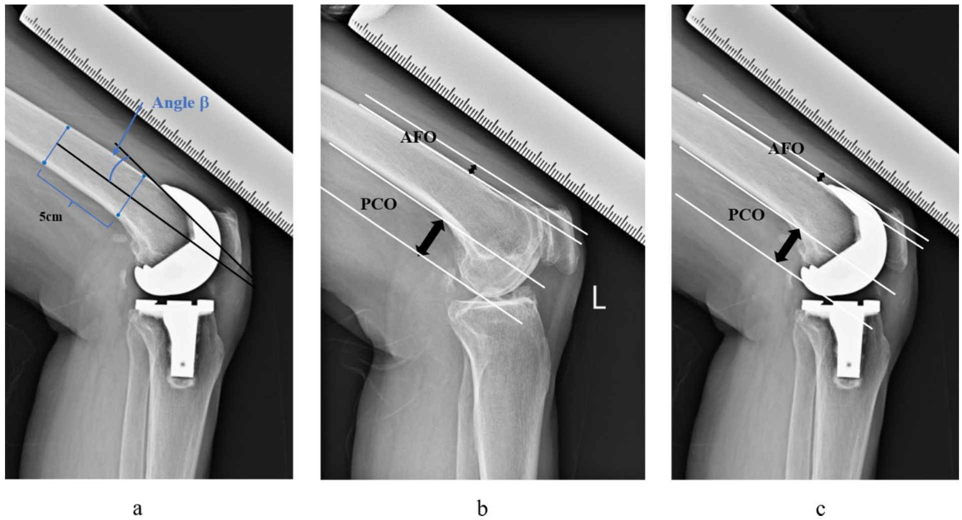


**Fig. 3** Radiographic analysis. Figure 3a Measurement of femoral prosthesis flexion angle. According to the design of the prosthesis, the femoral prosthesis flexion angle = β -3°. (+): flexion, (–): extension. Figure 3b and c Measurement of AFO and PCO. The preoperative(b) and postoperative(c) measurements on lateral radiographs. A cartilage thickness of 2 mm was considered when evaluating the preoperative AFO and PCO. AFO anterior femoral offset; PCO posterior condylar offset

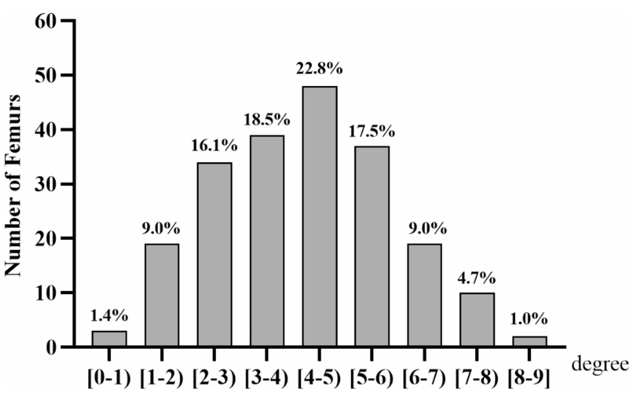


**Fig. 4** The distribution of DFSAAs in study patients. *n* = 211 knees

on a rigid bed, the knee extended to its maximum angle of flexion, and the angle between the longitudinal axis of the femur and the longitudinal axis of the tibia was measured in the sagittal plane.

**Statistical analysis.** Data analysis was performed using GraphPad Prism 9 version 9.4.0 (GraphPad Software, USA). Descriptive statistics were presented as mean ± standard deviation. The Kolmogorov-Smirnov test was employed to assess the normal distribution of data. Differences between groups were compared using the independent samples t-test. Count data were described as rates, and the chi-square test was used for comparisons between groups. $p<0.05$ was considered statistically significant. With a power of 95%, α level of 0.05, and 95% confidence level, the number of subjects needed was calculated as 37 per group.

## Results

The analysis of the 211 knees revealed the mean DFSAA was found to be 4.2° ± 1.7°, ranging from 0.7° to 8.7°. Notably, only 41.3% of cases fell within the traditionally targeted DFSAA range of 3° to 5° (Fig. 4).

While the mean postoperative femoral flexion angles did not significantly differ between the Individualized and Default alignment groups (1.9 ± 1.7° vs. 1.6 ± 2.7°, $p=0.748$), the Individualized alignment group presented a significantly lower incidence of femoral extension (9.8% vs. 27.1%, $p=0.014$). Moreover, within the Individualized alignment group, there was a substantial increase in the occurrence of the femoral component within the desired mild flexion range of 0° to 3° (78.7% vs. 55.9%, $p=0.008$), as detailed in Fig. 5.

Analysis of AFO and PCO showed no significant difference in preoperative values between the groups. Postoperatively, the Individualized alignment group achieved better AFO restoration, with 54.1% maintaining an offset within 1 mm of preoperative measurements, significantly higher than the Default alignment group's 33.9% ($p=0.026$). In terms of PCO, an improvement was also observed in the Individualized alignment group, where postoperative measurements within 1 mm and 2 mm of preoperative values were seen in 44.3% and 73.8% of patients, respectively, compared to 25.4% and 50.8% in the Default alignment group ($p=0.031$ for 1 mm, $p=0.010$ for 2 mm), as reported in Table 2.

After 3 months, an analysis of functional outcomes revealed a marginal but statistically significant increase in the HSS in the Individualized alignment group in comparison to the Default alignment group ($p=0.045$). This finding, though notable, did not achieve the threshold of

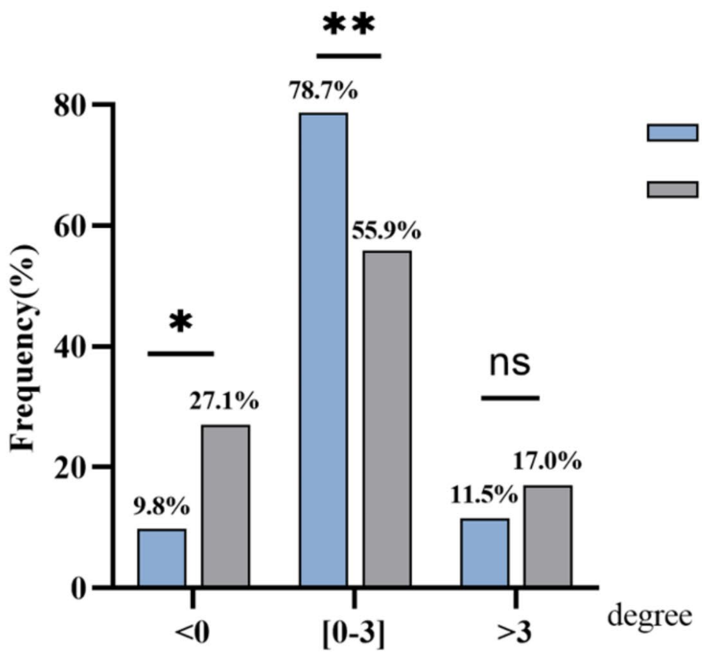


**Fig. 5** The distribution of femoral prosthesis flexion angle between the two groups. *$P<0.05$. ** $P<0.01$

**Table 2** Comparison of offset between the two groups

| Parameters | Individualized alignment group | Default alignment group | *p* |
|---|---|---|---|
| Pre AFO, mm | 7.7 ± 1.1 | 7.5 ± 1.5 | 0.341* |
| Post AFO, mm | 6.7 ± 1.2 | 6.8 ± 1.5 | 0.698* |
| Pre PCO, mm | 26.4 ± 3.3 | 27.0 ± 4.6 | 0.235* |
| Post PCO, mm | 25.9 ± 2.7 | 25.9 ± 3.1 | 0.951* |
| Change in AFO within ± 1 mm, n (%) | 33(54.1%) | 20(33.9%) | **0.026**† |
| Change in AFO within ± 2 mm, n (%) | 47(77.0%) | 42(71.2%) | 0.463† |
| Change in PCO within ± 1 mm, n (%) | 27(44.3%) | 15(25.4%) | **0.031**† |
| Change in PCO within ± 2 mm, n (%) | 45(73.8%) | 30(50.8%) | **0.010**† |

Pre AFO, preoperative anterior femoral offset; Post AFO, postoperative anterior femoral offset; Pre PCO, preoperative posterior condylar offset; Post PCO, postoperative posterior condylar offset;

*Independent-samples t-test. †Chi-squared test

a minimal clinically important difference [30]. The two groups did not exhibit significant differences in other clinical measures at the 6-week and 3-month follow-up points (Table 3). There was no significant difference in ROM between the individualized alignment group and the default alignment group at 6 weeks and 3 months postoperatively. At 6 weeks postoperatively, the mean

**Table 3** Comparison of clinical outcomes between the two groups

| Parameters | Individualized alignment group | Default alignment group | *p* |
|---|---|---|---|
| 6 weeks outcome | mean ± SD | mean ± SD | |
| VAS | 1.9 ± 0.7 | 2.0 ± 0.7 | 0.196 |
| HSS | 77.4 ± 4.4 | 78.9 ± 5.0 | 0.069 |
| WOMAC | 20.8 ± 4.0 | 20.4 ± 4.4 | 0.561 |
| 3 months outcome | mean ± SD | mean ± SD | |
| VAS | 1.1 ± 0.6 | 1.1 ± 0.6 | 0.783 |
| HSS | 89.2 ± 4.7 | 87.4 ± 4.8 | **0.045** |
| WOMAC | 12.1 ± 4.5 | 12.4 ± 4.1 | 0.792 |

VAS, Visual Analogue Score; HSS, Hospital for Special Surgery Knee Score; WOMAC, Western Ontario and McMaster Universities Osteoarthritis Index, SD, standard deviation.

ROM was 104.7±7.4° in the individualized alignment group compared with 104.1±8.2° in the default alignment group. At 3 months postoperatively, the ROMs were 118.2±6.8° and 117.5±7.5° in the two groups, respectively, $p>0.05$.

## Discussion

This study presents pioneering insights into the high variability of DFSAA in patients with knee osteoarthritis and underscores the potential advantages of individualized sagittal femoral alignment in robotic-assisted TKA.

Alignment of femoral flexion to each patient's unique anatomy, alignment with the femoral axis and anatomical restoration are markedly improved.

Recent advancements in robotic-assisted TKA have demonstrated improved accuracy in component placement and alignment. Studies have shown that individualized alignment strategies can lead to better anatomical and functional outcomes compared to conventional methods. For example, Mancino et al. and Rossi et al. highlighted the enhanced accuracy of robotic-arm knee arthroplasty systems, which significantly improve prosthetic alignment and patient outcomes [31, 32]. Similarly, studies by Rossi et al. and Mancino et al. have demonstrated that accounting for individual anatomical variations can optimize joint mechanics and reduce postoperative complications [33, 34].

The risks associated with extension of femoral prostheses in robotic-assisted TKA have received increasing attention [9]. Such risks can be mitigated by individualized alignment strategies during surgery. To counteract this issue and ensure alignment with the anatomic axis, distal femoral resection is typically executed at 3–5° of flexion [1, 17, 18]. The findings resonate with those reported by Chung et al., who observed a broad DFSAA range [15], and Hood et al., who noted a minority of healthy individuals conforming to the conventional 3°-5° DFSAA range [16]. This mirrors the observation that only 41.3% of osteoarthritis knees lay within this range, suggesting the necessity of individualized alignment adjustments to achieve more accurate reconstruction.

Given the sagittal alignment of the femoral prosthesis depends on the variable distal femoral anatomy, adjusting this alignment to match the distal femoral anatomy during computer-assisted TKA may be crucial for improved clinical outcomes. Roßkopf et al. found that intentional flexion of the femoral prosthesis during navigated TKA improved the restoration of the sagittal diameter and was critical in establishing flexion-extension balance [21]. Similarly, Kuriyama et al. reported that aligning the sagittal of the femoral prosthesis with the anatomical axis during navigated TKA enhanced bone-to-prosthesis matching [18]. Numerous studies have demonstrated that 0–3° flexion of the femoral prosthesis leads to improved postoperative function [35, 36]. The data from this study adds to this narrative by showcasing a higher frequency of femoral prosthesis alignments within the optimal mild flexion range when using individualized settings.

Alterations in AFO after TKA can influence the biomechanical integrity of the knee joint, potentially leading to complications such as patellar malalignment and anterior knee pain [37]. Postoperative changes in AFO are common in conventional TKA. Matz et al. reported that only 13.4% of 970 patients maintained an AFO change within 1 mm in postoperative lateral X-ray analysis [38]. Similarly, Chloe et al. identified femoral prosthesis extension leading to anterior femoral overfilling as a significant cause of postoperative anterior patellofemoral pain [4]. These findings suggest that individualized femoral alignment more effectively preserves AFO, thus potentially minimizing these postoperative challenges.

Similarly, restoring the PCO is crucial for promoting stability and range of motion after TKA. Matziolis et al. analyzed intraoperative data from 42 patients undergoing navigated TKA and found that variations in PCO exceeding 2 mm were associated with midflexion instability [39]. Van et al. analysed 98 cases of TKA and found that maintaining PCO resulted in improved postoperative flexion angles and functionality [36]. However, restoring the posterior femoral condylar anatomy remains challenging, even with the posterior reference technique [40]. In line with Popat et al., who championed the precision of robotic-assisted TKA for PCO [41], the data affirms that individualized alignment approaches can optimize PCO restoration and potentially enhance overall postoperative function.

Individualized sagittal alignment of the femur provides better restoration of the femoral anatomy, potentially due to the effects of sagittal osteotomies on prosthesis sizing [42]. Flexing the femoral prosthesis by a few degrees can effectively reduce its size while preventing an excessive increase in the flexion gap [21].

The significance of sagittal femoral alignment in enhancing postoperative functionality is well-supported in the literature. For instance, Nishitani et al. observed that patients with mildly flexed femoral prostheses achieved higher scores in functional assessments one year after TKA compared to those with extended or hyperflexed prostheses [6]. Similarly, Hassan et al., after a two-year follow-up, reported that femoral prosthesis flexion of 0–3° was associated with a knee that felt 'always normal' [1]. Although the data indicate enhanced functionality with individualized alignment, as suggested by increased HSS scores, the observed differences did not reach the threshold of minimal clinically important differences after TKA. Despite the theoretical benefits of individualized alignment, the results did not demonstrate a significant improvement in postoperative ROM. This stands in contrast to Zhou et al.'s findings, where the ROM in the mildly flexed group was significantly better than that in the extended or hyperflexed groups after one year. This may indicate that the measurement of ROM in the early postoperative period fails to adequately reflect long-term functional recovery and the effectiveness of alignment strategies. Given these observations, subsequent long-term assessments are essential to more fully understand these effects.

However, it is crucial to acknowledge certain limitations. Firstly, the follow-up period duration of only 3 months, restricting the ability to evaluate sustained clinical outcomes consequent to individualized femoral alignment. Therefore, it is intended that prospective patient follow-ups continue, with plans to publish longer-term data in the future. Secondly, the use of lateral radiographs and standardization of 2 mm cartilage thickness for assessing the AFO and PCO may not fully capture cartilage thickness. Future studies need to measure cartilage thickness more accurately. Lastly, although employing a single knee design enhanced the study's internal validity, it may limit the generalizability of the findings to other prosthesis designs.

## Conclusion

In conclusion, the study demonstrates that robotic-assisted TKA employing individualized femoral sagittal alignment can significantly reduce the occurrence of femoral prosthesis extension. Furthermore, it markedly enhances the precision in postoperative prosthetic alignment and anatomical restoration. These findings suggest the utility of an individualized approach to femoral prosthesis alignment in TKA, which may have implications for refining surgical techniques and guiding future orthopaedic research.

**Abbreviations**

| | |
|---|---|
| TKA | Total knee arthroplasty |
| DFSAA | Distal femoral sagittal anteverted angle |
| AFO | Anterior femoral offset |
| PCO | Posterior condylar offset |
| BMI | Body Mass Index |
| VAS | Visual Analogue Score |
| HSS | Hospital for Special Surgery Knee Score |
| WOMAC | Western Ontario and McMaster Universities Osteoarthritis Index |
| sTEA | surgical transepicondylar axis |
| ROM | range of motion |
| SD | Standard deviation |

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None.

**Author contributions**
DHW, YY, LX, KL and WHcontributed to the study conception and design. DHW and YY performed material preparation, data collection and analysis. The first draft of the manuscript was written by DHW and all authors commented on previous versions of the manuscript. All authors read and approved the final manuscript.

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**Data availability**
No datasets were generated or analysed during the current study.

## Declarations

**Ethics approval and consent to participate**
The First Affiliated Hospital of Chongqing Medical University (IRB approval number: 2022 – 176) approved this study. Informed consent was obtained from all participants.

**Consent for publication**
Not applicable.

**Competing interests**
The authors declare no competing interests.

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