BMC Surgery

RESEARCH

Open Access

A new gap balancing technique with functional alignment in total knee arthroplasty using the MAKO robotic arm system: a preliminary study

Hung-Kang Tsai[1,2†], Zhengyuan Bao[1,2†], Dengxian Wu[1,2], Jing Han[3], Qing Jiang[1,2*] and Zhihong Xu[1,2*]

Abstract

Background Gap tension is an important factor influencing the clinical outcomes of total knee arthroplasty (TKA). Traditional mechanical alignment (MA) places importance on neutral alignment and often requires additional soft tissue releases, which may be related to patient dissatisfaction. Conversely, the functional alignment requires less soft tissue release to achieve gap balance. Conventional gap tension instruments present several shortcomings in practice. The aim of this study is to introduce a new gap balancing technique with FA using the modified spacer-based gap tool and the MAKO robotic arm system.

Methods A total of 22 consecutive patients underwent primary TKA using the MAKO robotic arm system. The gap tension was assessed and adjusted with the modified spacer-based gap tool during the operation. Patient satisfaction was evaluated post-operatively with a 5-point Likert scale. Clinical outcomes including lower limb alignment, Knee Society Score (KSS) and Western Ontario and McMaster Universities Arthritis Index (WOMAC) were recorded before surgery, 3 months and 1 year after surgery.

Results The range of motion (ROM) was significantly increased ($p < 0.001$) and no patients presented flexion contracture after the surgery. KSS and WOMAC score were significantly improved at 3 months and 1 year follow-up ($p < 0.001$ for all). During the surgery, the adjusted tibial cut showed more varus than planned and the adjusted femoral cut presented more external rotation than planned ($p < 0.05$ for both). The final hip-knee-ankle angle (HKA) was also more varus than planned ($p < 0.05$).

Conclusions This kind of spacer-based gap balancing technique accompanied with the MAKO robotic arm system could promise controlled lower limb alignment and improved functional outcomes after TKA.

Keywords Total knee arthroplasty, Robotic arm system, Functional alignment, Gap balancing

†Hung-Kang Tsai and Zhengyuan Bao contributed equally to this work.

*Correspondence:
Qing Jiang
qingj@nju.edu.cn
Zhihong Xu
xuzhihong@njglyy.com

Full list of author information is available at the end of the article

Backgrounds

Traditional mechanical alignment (MA) in total knee arthroplasty (TKA) aims to achieve a neutral alignment by adjusting the bone resection perpendicular to femoral and tibial mechanical axes [1]. This technology presents convincing implant survivorship, but the patient satisfaction rate remains relatively low, which may be contributed to the additional soft tissue release when adjusting the gap balance [2, 3]. To achieve gap balancing, the concept of alignment in TKA is continuously evolving. Howell et al. proposed the kinematic alignment (KA) technique, which aims to perform symmetric anatomic resection on tibia and femur to replicate the individual's native limb alignment and joint line of pre-arthritic status [4]. KA features preserve individual anatomical structure and potentially improve clinical outcomes, although a concern with KA is that unrestricted alignment may increase the risk of aseptic loosening. Functional alignment (FA) is another new technique that refers to the approach of positioning components in a manner that minimally impacts the soft-tissue envelope of the knee, thereby restoring the plane and obliquity of the joint as dictated by the soft tissue [5]. FA achieves balanced extension-flexion gaps and soft tissue tension by adjusting bone resections, fine-tuning component positioning, and less soft tissue release with robotic arm system [6, 7]. Up to now, several robotic arm systems have emerged, which elevate the precision of bone resection and are outstanding in evaluating the gap size in real time during the operation [8–12]. Although current studies have not yet shown that robotic systems can obtain better medium to long-term functional outcomes [13, 14].

Gap balancing technique aims to obtain equal and balanced gaps by adjusting soft tissue tension. The Mako robotic arm system provides two kinds of devices for the ligament tension evaluation. One is like a lamina spreader that produce symmetrically distracted force (Fig. 1A). But this kind of spreader cannot reproduce the physiologic varus laxity of the natural knee in flexion, consequently placing the femoral prosthesis with more external rotation [15]. Furthermore, the appropriate gap tension is still undefined, so another issue is the uncertain force to be applied [16, 17]. Another tension device is the spoon-shaped spacer block, which can be inserted into extension and flexion gaps (Fig. 1B). The spacer block has the advantage of reproducing native gap properties and allowing the surgeon to adjust the knee laxity with more fineness [18]. But this kind of device is not convenient in practice. Because the straight-designed handle is likely to contact the patellar tendon when inserted into the lateral gap, which may lead to inaccurate tension evaluation. Besides, the curved surface makes it difficult to be fixed in the target site during the tension assessment considering the oblique joint surface.

The purpose of this study is to describe a new spacer-based gap balancing technique with FA using the MAKO robotic arm system (Fig. 2).

Methods

Subjects

Twenty-two consecutive patients (7 males, 15 females, 22 knees) who underwent primary TKA using the MAKO robotic arm system (Stryker, Mahwah, NJ, USA) from June to December in 2021 were included in this study. All surgeries were performed by a single experienced orthopaedic surgeon. The modified spacer-based gap tool (Jiangsu Bazheng Medical Technology Co., Ltd) has been patented (Publication: CN213249800U) and was used under the supervision of the MAKO product specialist. The mean age of subjects was 61.3±6.1 years old (51–72 years). All subjects were diagnosed with knee osteoarthritis and graded III-IV by Kellgren-Lawrence (K-L) classification (11 grade III, 11 grade IV), with 17 cases of varus knee and 5 cases of valgus knee. Patients with a history of trauma or surgery on the operative knee were excluded. The implant used included posterior-stabilized (PS) and

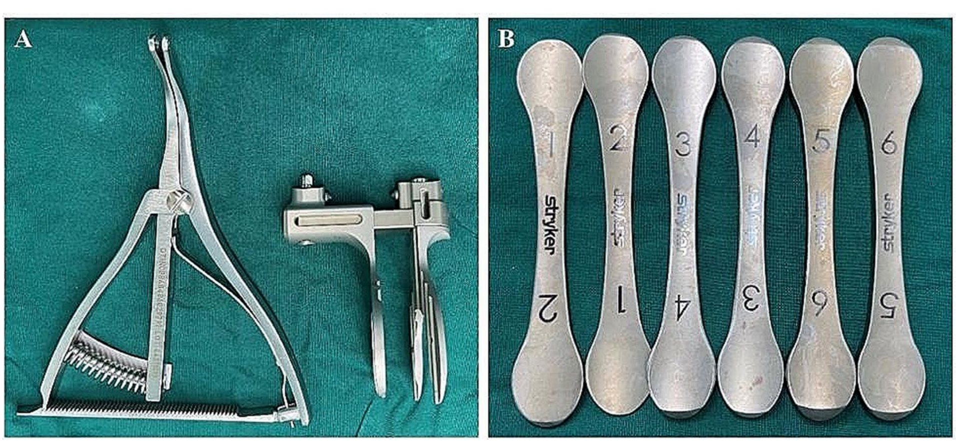

Fig. 1 **(A)** The lamina spreader like tension device. **(B)** The spoon-shaped spacer block with different thickness

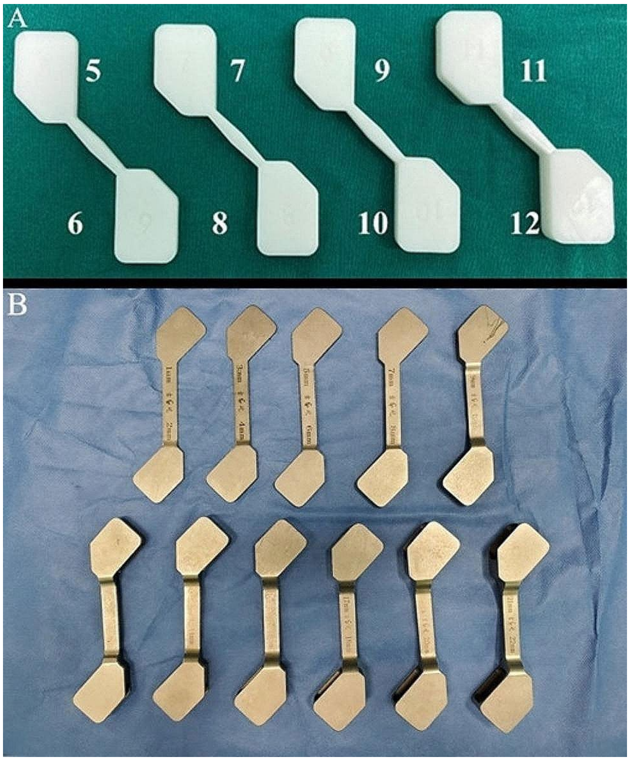

Fig. 2 The modified spacer-based gap tool is comprised of two plates with flat surface connected by a handle with an offset lever. **(A)** The thickness of plates ranges from 5–12 mm with 1 mm interval **(B)** The latest version has increased the thickness range: 1–22 mm with 1 mm interval)

Table 1 Patient demographic

Patient demographic	Total (*N* = 22)
Age (y)	
Mean (SD)	61.3 (6.1)
Range	51–72
Gender	
Male	7
Female	15
Side	
Right	12
Left	10
Preoperative K-L classification	
III	11
IV	11
Preoperative HKA (°)	
Mean (SD)	175.2 (6.7)
Range	165–187
LDFA (°)	
Mean (SD)	87.4 (3.4)
Range	80–95
MPTA (°)	
Mean (SD)	85.4 (3.0)
Range	77–90
JLCA (°)	
Mean (SD)	3.9 (2.3)
Range	0–8
Implant type	
PS	16
CR	6
Weight (kg)	
Mean (SD)	69.9 (8.9)
Range	54–84
Height (cm)	
Mean (SD)	161.3 (8.1)
Range	149–173
BMI (kg/m^2)	
Mean (SD)	26.9 (2.7)
Range	20.3–30.3

SD: standard deviation; BMI: body mass index; HKA: hip-knee-ankle angle (measured medially); LDFA: lateral distal femoral angle; MPTA: medial proximal tibial angle; JLCA: joint line convergence angle

cruciate-retaining (CR) types (16 PS, 6 CR) (Table 1). The surgeons who measured and evaluated clinical outcomes were blinded. Written informed consent was obtained from all patients for the use of their data and images in research. This study was conducted after approval by the Institutional Review Board of Nanjing Drum Tower Hospital (2022−668).

Pre-operative management

Pre-operatively, the hip-knee-ankle angle (HKA) was measured from standard long-standing anteroposterior radiographs. Knee function was recorded using Knee Society Score (KSS) and Western Ontario and McMaster Universities Arthritis Index (WOMAC).

Operative procedures

All MAKO robotic arm-assisted TKA surgeries were performed by a single surgeon. After exposing the knee joint with the medial parapatellar approach, reflective array insertion and landmark registration were performed following the MAKO TKA Surgical Guide. Then intra-operative ligament balancing adjustment was conducted as below:

Step 1: pre-evaluation of maximal extension and flexion gaps

Complete removal of osteophytes could raise the accuracy of gap measurement and ligament tension assessment, as osteophytes may misestimate both gaps and tension. After removal of osteophytes, native ligament tension was pre-assessed using the varus and valgus test at extension (-3°~20° of knee flexion) and 90° of flexion (85°~95° of knee flexion). The medial/lateral gap size under the valgus/varus test indicated the maximal gap distance under the current resection planning.

Step 2: tibial resection adjustments to obtain equal extension and flexion gaps

The aim of this step was to obtain equal extension and 90° of flexion gaps of around 19 mm. The values of gap encompassed the distance between the proximal tibial cut surface and the distal and posterior femoral cuts surface in extension and flexion, respectively, while also accounting for the combined thickness of the implants and polyethylene insertion (9 mm) as recommended by the MAKO guideline. In patients with severe tibial bone defect, the surgeon can change the gap target to 21–23 mm for 11–13 mm insertion. One or more of the following methods could be applied to achieve equal extension and flexion gaps, but the overall limb alignment on the coronal plane should be limited between 3° of valgus and 3° of varus [19]:

- If extension and flexion gaps were not balanced with less than 19 mm, the surgeon could increase more tibial resection medially or laterally.
- If extension and flexion gaps were balanced but not equal to 19 mm, the surgeon could lower or raise the resection level to manipulate medial and lateral gaps simultaneously, and could also adjust the posterior slope of the tibia to increase or decrease flexion gaps (within 0°-3° for PS prosthesis and 5° for CR prosthesis).

When the medial and lateral gaps were around 19 mm with difference within 1 mm, tibial resection was proceeded first. But in practice, most cases cannot receive appropriate flexion gaps at this step, which can be further adjusted at the next step.

Step 3: ligament tension assessment with modified gap plate instrument

All osteophytes were carefully removed after completing the tibial cut. The aim of this step was to apply modified gap plate to obtain equal extension and flexion gaps of around 19 mm with appropriate ligament tension. Gap plates with different thickness were inserted into the medial and lateral gap together. Suitable thickness was determined by the surgeon's experience, which could refer to the two standards as below [20, 21].

- After inserting gap plates, the surgeon could apply varus and valgus test, if the increase of medial/lateral gap distance under valgus/varus test was less than 2 mm, the corresponding ligament tension could be considered suitable.
- After inserting gap plates, the medial and lateral collateral ligaments were a little tight but still elastic. And when pulling out gap plates, the surgeon could feel the resistance. The medial gap was allowed to be a little tighter than the lateral gap.

If the gap was not balanced to 19 mm, one or more of the following methods could be applied. The coronal alignment should be limited to 6° varus to 3° valgus for tibia component, 6° valgus to 3° varus for femoral component, and 3° varus to 3° valgus for HKA [22]. If not, soft tissue release would be performed till the alignment was controlled in the safe range.

- If only flexion or extension gap needed to be balanced, the surgeon can adjust the rotation or varus/valgus alignment of the femoral component.
- If flexion gap was balanced but not equal to 19 mm, the surgeon could position the femoral component more anterior or posterior to manipulate the flexion gap, while avoiding anterior femoral notching and femoral component overhanging.
- If extension gap was balanced but not equal to 19 mm, the surgeon could position the femoral component more distal or proximal to manipulate the extension gap.

Step 4: final assessment of gap balance

When the medial and lateral gaps were around 19 mm with difference within 1 mm and optimal ligament tension was obtained, femoral resection was proceeded. After trial and final implants were placed, gap balance could be reassessed with the method described at Step 3.

Post-operative management

Post-operative analgesia was applied routinely in patients without renal insufficiency, including intravenous parecoxib and buprenorphine transdermal patch. Each patient was encouraged to walk with a walker frame under the guidance of rehabilitation physicians within 3 days after surgery. Lower limb alignment was evaluated at 3 months after surgery and knee function was evaluated at 3 months and 1 year of follow-up. A 5-point Likert scale (very satisfied, satisfied, neutral, dissatisfied, very dissatisfied) was used to evaluate patient satisfaction at 1 year of follow-up.

Statistical analysis

Statistical analysis was conducted using the SPSS 25 (IBM Corp., Armonk, NY, USA). Shapiro-Wilk test was used to assess data normality. Wilcoxon signed-rank test and two-tailed paired t-test analyzed non-normal and normal data, respectively, for bone resection parameters. The statistical difference between pre and postoperative HKA was analyzed using Wilcoxon signed-rank test. One-way ANOVA and Bonferroni method were used for

Table 2 Pre-operative and post-operative clinical outcome measures

Clinical outcomes	Pre-operative		3-month follow up		1-year follow-up		*p*-value		
	Mean (SD)	Range	Mean (SD)	Range	Mean (SD)	Range	*p*1	*p*2	*p*3
HKA (°)	175.2 (6.7)	165–187	179.4 (2.9)	177–183			< 0.001	N/A	N/A
ROM (°)									
Extension	7.6 (4.6)	0–15	0.0 (0.0)	0–0	0.0 (0.0)	0–0	< 0.001	NS	< 0.001
Flexion	88.6 (4.1)	80–95	109.1 (7.3)	100–125	116.6 (7.3)	105–130	< 0.001	< 0.001	< 0.001
WOMAC									
Pain	8.7 (1.6)	6–11	2.8 (1.2)	1–5	0.7 (0.8)	0–2	< 0.001	< 0.001	< 0.001
Stiffness	2.5 (1.1)	1–4	0.6 (0.5)	0–1	0.0 (0.0)	0–0	< 0.001	< 0.001	< 0.001
Physical function	35.9 (6.4)	21–45	7.5 (1.9)	4–11	3.9 (1.5)	2–6	< 0.001	< 0.001	< 0.001
Total	47.1 (7.6)	32–58	11.0 (3.1)	6–16	4.5 (2.0)	2–8	< 0.001	< 0.001	< 0.001
KSS									
Clinical score	51.0 (10.7)	29–67	84.1 (3.8)	80–90	91.0 (4.3)	82–95	< 0.001	< 0.001	< 0.001
Functional score	34.5 (15.9)	10–60	78.4 (4.7)	70–85	87.5(5.7)	80–95	< 0.001	< 0.001	< 0.001

SD: standard deviation; HKA: hip-knee-ankle angle (measured medially); ROM: range of motion; WOMAC: Western Ontario and McMaster Universities Arthritis Index; KSS: Knee Society Score; *p*1: comparison between pre-operation and 3-month follow-up; *p*2: comparison between 3-month and 1-year follow-up; *p*3: comparison between pre-operation and 1-year follow-up

Table 3 Parameters for planned and adjusted bone resection in robotic arm system

	Planned		Adjusted		*p*-value
	Mean (SD)	Range	Mean (SD)	Range	
HKA (°)	179.7 (0.8)	177–180	178.2 (1.9)	175–182	< 0.05
Tibia					
Varus cut (°)	0.4 (1.2)	0–5	1.1 (1.5)	-1-5	< 0.05
Posterior slope (°)	2.8 (1.6)	1–5	3.0 (1.5)	1–5	= 0.18
Femur					
Varus cut (°)	-0.1 (0.4)	-2-0	0.1 (1.4)	-3-3	= 0.475
External rotation cut (°)	1.6 (2.4)	-3-6	2.7 (2.5)	-1-8	< 0.05
Implant flexion (°)	2.2 (1.9)	0–5	2.0 (2.1)	-1-5	= 0.458

SD: standard deviation; HKA: hip-knee-ankle angle (measured medially)

clinical outcome measures and multiple comparison correction. A *p*-value of <0.05 was considered statistically significant.

Results

During the surgery, the final gap distance was 18.6±0.7 mm (18–20 mm) medially and 19.0±1.0 mm (18–21 mm) laterally at extension and 18.6±0.7 mm (17–20 mm) medially and 18.6±0.5 mm (18–19 mm) laterally at 90° of flexion. All 22 patients were followed up at 3 months and 1 year after surgery. Lower limb presented more neutral alignment after surgery (175.2° ± 6.7° vs. 179.4° ± 2.9°) based on standard long-standing anteroposterior radiographs. The mean preoperative knee extension was 7.6° ± 4.6° (0°-15°) and flexion was 88.6° ± 4.1° (80°-95°). Among the 22 patients, 9 were recorded as 'very satisfied', 11 as 'satisfied', and 2 as 'neutral'. No patients presented knee flexion contracture after surgery. The post-operative flexion was significantly improved at 3-months follow-up (109.1° ± 7.3° (100°-125°) vs. 88.6° ± 4.1° (80°-95°), $p<0.001$) and at 1-year follow-up compared to 3-months follow-up (116.6° ± 7.3° (105°-130°) vs. 109.1° ± 7.3° (100°-125°), $p<0.001$) (Table 2).

The intra-operative bone resection parameters were shown in Table 3. The planned and adjusted tibial cut varus angle were 0.4° ± 1.2° and 1.1° ± 1.2°, respectively ($p<0.05$). There was a statistical difference of the external rotation angle of femoral cut (with respect to trans-epicondylar axis (TEA)) between the planned and adjusted measures (1.6° ± 2.4° vs. 2.7° ± 2.5°, $p<0.05$). The adjusted HKA was significantly more varus than planned (178.2° ± 1.9° vs. 179.7° ± 0.8°, $p<0.05$).

WOMAC score was significantly improved at 3-months follow-up and at 1-year follow-up compared to 3-months follow-up, including pain (8.7±1.6 vs. 2.8±1.2 and 2.8±1.2 vs. 0.7±0.8, $p<0.001$ for both), stiffness (2.5±1.1 vs. 0.6±0.5 and 0.6±0.5 vs. 0.0±0.0, $p<0.001$ for both), physical function (35.9±6.4 vs. 7.5±1.9 and 7.5±1.9 vs. 3.9±1.5, $p<0.001$ for both), and total (47.1±7.6 vs. 11.0±3.1 and 11.0±3.1 vs. 4.5±2.0, $p<0.001$ for both). KSS score was also significantly improved at 3-months follow-up and at 1-year follow-up compared to 3-months follow-up, including clinical score (51.0±10.7 vs. 84.1±3.8 and 84.1±3.8 vs. 91.0±4.3, $p<0.001$) and functional score (34.5±15.9 vs. 78.4±4.7 and 78.4±4.7 vs. 87.5±5.7, $p<0.001$) (Table 2).

Case demonstration

Pre-operative management

A 58-year-old male underwent MAKO robotic arm-assisted TKA for the right knee with osteoarthritis. Pre-operative HKA was 172° (Fig. 3). The pre-operative range of motion (ROM) of the right knee was 10°-85°. The pre-operative WOMAC score was 8 for pain, 1 for stiffness, 40 for physical function, and 49 for total. The

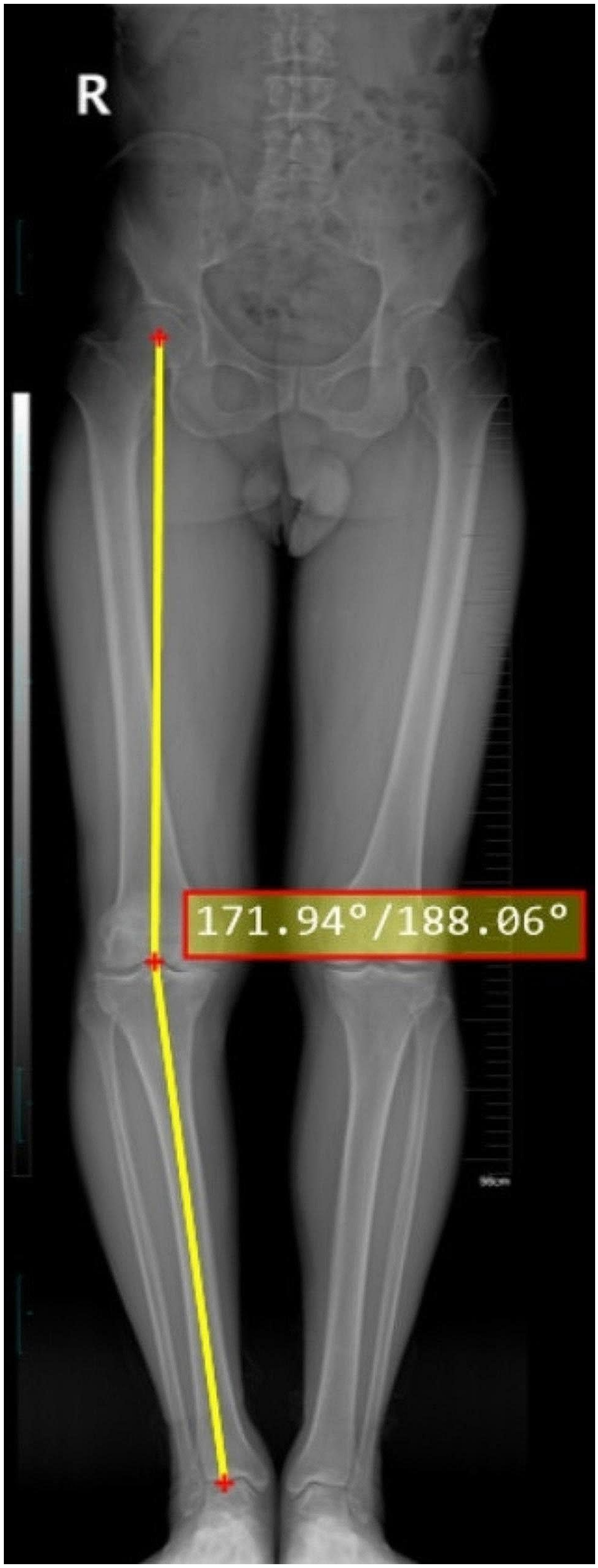

Fig. 3 Pre-operative HKA was 172° measured medially from the standard long-standing anteroposterior radiograph

pre-operative KSS score was 48 for clinical score and 30 for functional score. PS implant was used in the surgery.

Surgical procedure

Step 1 After removing visible osteophytes, native knee ligament tension was pre-assessed using varus-valgus test at extension and 90° of flexion. The maximum medial and lateral gap was 15 and 17 mm at extension (Fig. 4A and B) and the maximum medial and lateral gap was 11 and 19 mm at 90° of flexion (Fig. 4C and D).

Step 2 In this case, the medial gaps were smaller than 19 mm at extension and 90° of flexion, so the surgeon locked the tibial cut laterally and applied 1° of varus on the coronal plane and increased 1° of posterior slope on the sagittal plane. Then the surgeon obtained a balanced extension gap of 19 mm, but the flexion gap was still not balanced limited to the safe zone of alignment (Fig. 5A and B).

Step 3 After completing the tibial resection, the residual osteophytes surrounding the femoral posterior condyles were then removed to obtain more accurate ligament tension. Gap plates with suitable thickness were inserted into medial and lateral gaps at extension first. No additional adjustments of the femoral distal resection were required because the extension gap was balanced with the gap distance of 19 mm (Fig. 6A and B). Then gap plates with suitable thickness were inserted into medial and lateral gaps at 90° of flexion. Because the flexion gap was not balanced (Fig. 5B), the surgeon placed the femoral component more anterior and applied 4° more external rotation relative to the trans-epicondylar axis (TEA) to equalize gaps to 19 mm (Fig. 6C and D).

Step 4 After the femoral resection was accomplished, trial and final implants were placed and the gap balance was reassessed again using the method described before. In this case, the surgeon chose size 5 for femoral implant, size 5 for tibial implant, and 9 mm for polyethylene insert. Well balanced gaps of 19 mm with appropriate ligament tension were obtained after placing final components (Fig. 7A and B).

Post-operative outcomes

The post-operative HKA measured from the standard long-standing anteroposterior radiograph was 178° (Fig. 8). The ROM of the right knee was 0°-105° and 0°-115° at 3-months and 1-year follow-up. The level of patient satisfaction was recorded as 'very satisfied' after surgery. WOMAC score at 3-months and 1-year follow-up was 1 and 0 for pain, 0 and 0 for stiffness, 8 and 4 for physical function, and 9 and 4 for total score. KSS score at

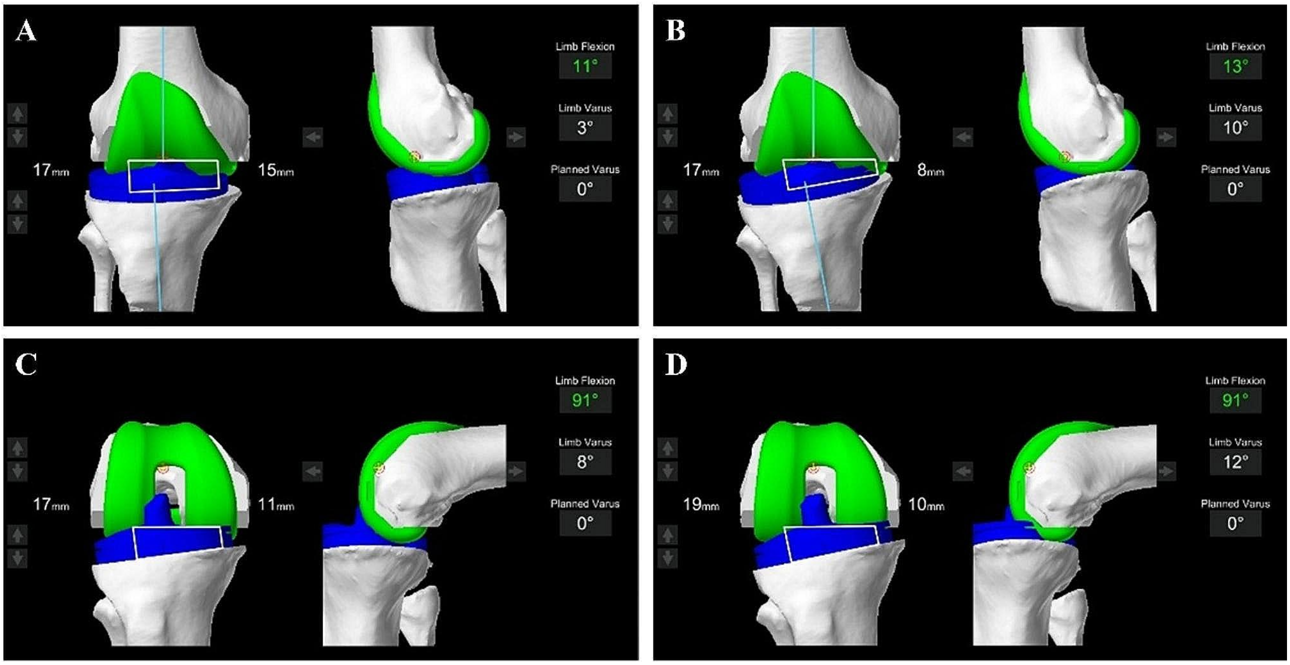

Fig. 4 **(A)** The maximum medial gap under valgus test was 15 mm at extension; **(B)** The maximal lateral gap under varus test was 17 mm at extension; **(C)** The maximum medial gap under valgus test was 11 mm at 90° of flexion; **(D)** The maximal lateral gap under varus test was 19 mm at 90° of flexion

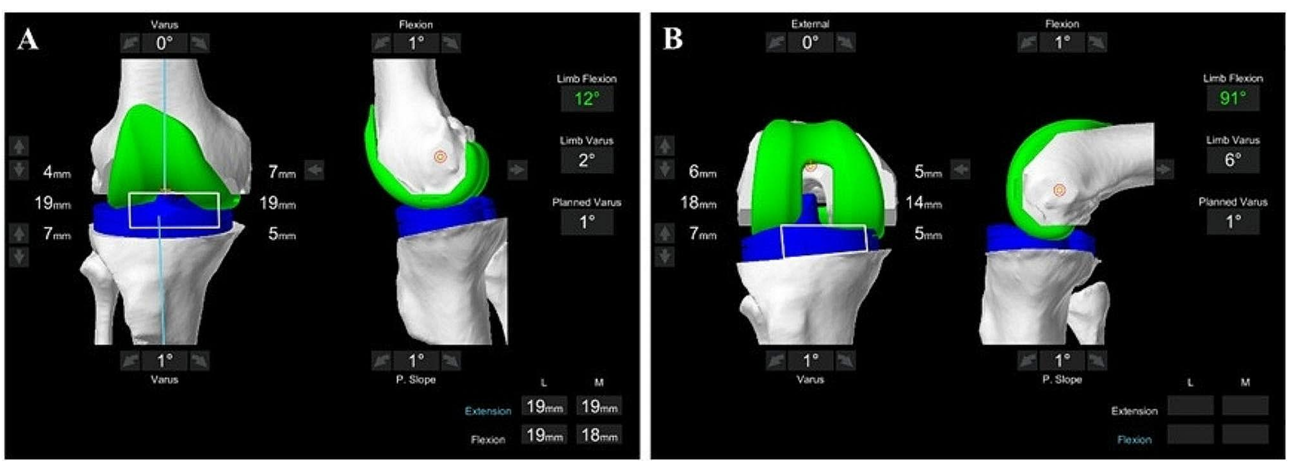

Fig. 5 After applying 1° more varus on the coronal plane and 1° more posterior slope on the sagittal plane of the tibial resection, **(A)** a balanced extension gap of 19 mm was obtained, **(B)** but the flexion gap was still not balanced and the medial gap distance was much smaller than 19 mm

3-months and 1-year follow-up was 86 and 93 for clinical score, and 75 and 90 for functional score.

Discussion

Limb alignment, flexion-extension gap balancing, and soft tissue tension are important roles in impacting patient satisfaction, functional outcomes, and component survivorship after TKA [19, 20]. In this study, a new gap balancing technique with FA using the MAKO robotic arm system was described, which presented controlled limb alignment and satisfied clinical outcomes.

There are some individuals have constitutional varus knee and obliquity of native knee joint line in the general population [23]. Classical MA technique is designed to achieve a neutral alignment. But for cases with serious varus or valgus deformity, soft tissue release is always necessary to obtain balanced gap tension, which is considered as one important factor contributing pain and patient dissatisfaction after TKA [2, 24]. KA technique involves performing parallel bone resections to reconstruct the joint surface with the purpose of restoring the original anatomical structure and kinematics [4]. To promote better kinematics, some KA techniques utilize

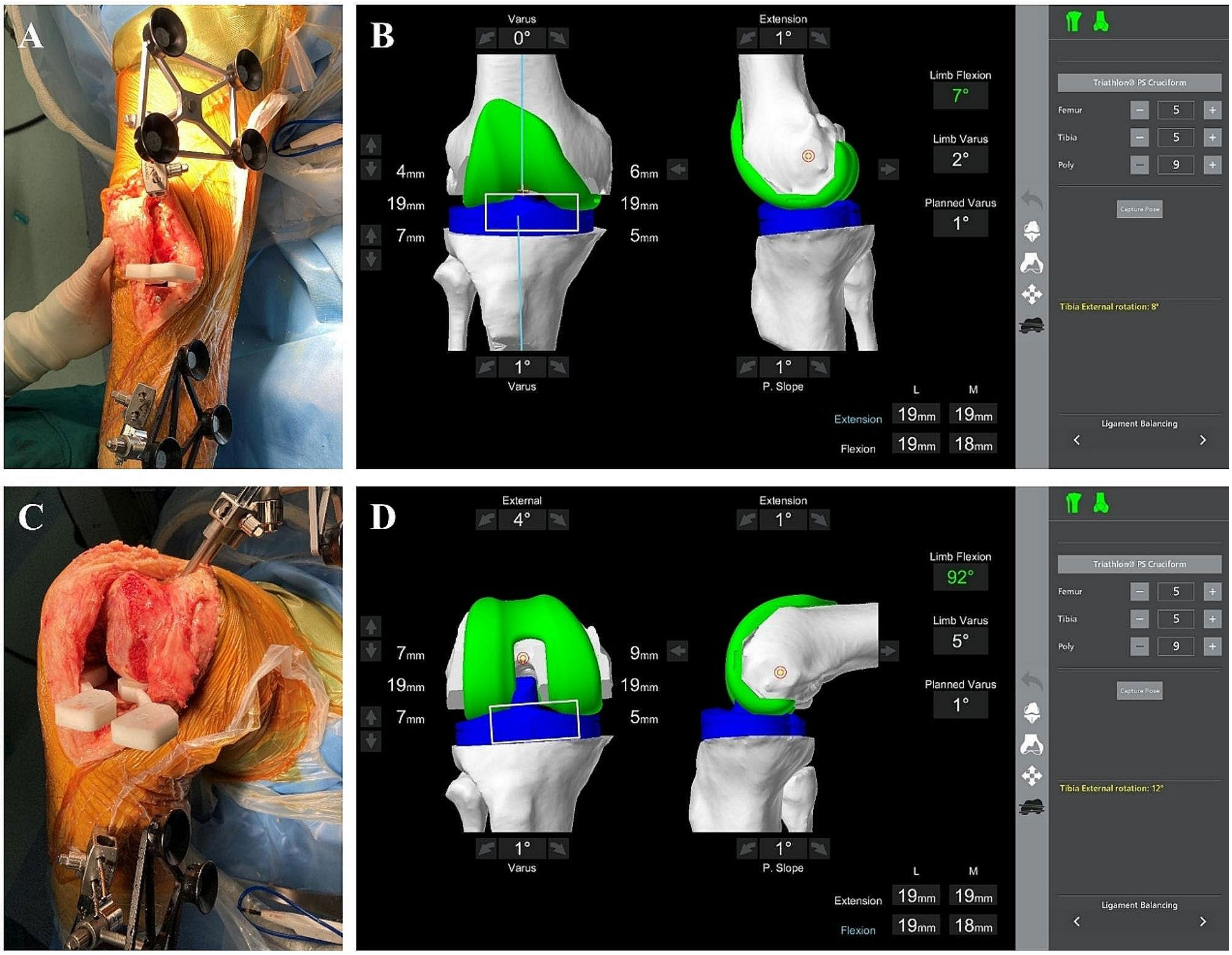

Fig. 6 **(A)** and **(B)** No additional adjustments of femoral resection on the coronal plane were required. **(C)** and **(D)** The femoral component was placed more anterior and 4° of external rotation to obtain balanced gaps of 19 mm

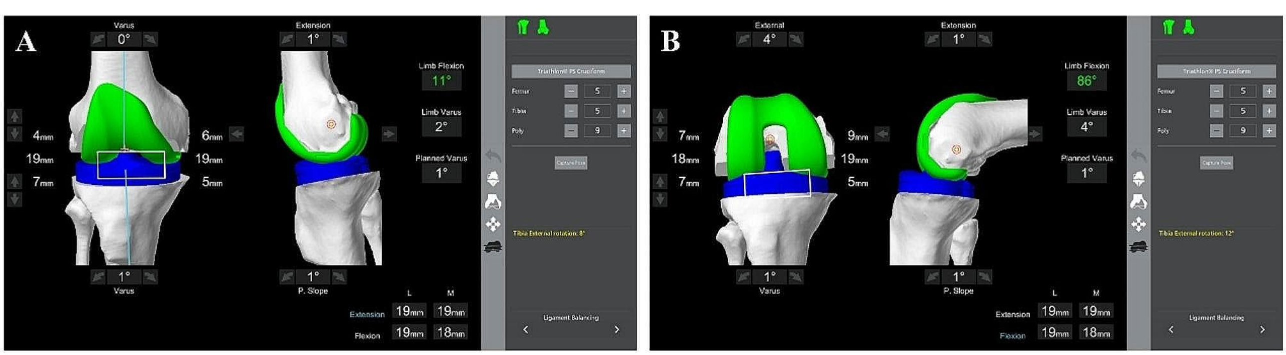

Fig. 7 After placing final implants, balanced gaps of 19 mm with appropriate ligament tension were obtained at **(A)** extension and **(B)** 90° of flexion

asymmetric polyethylene inserts. Further reaserch is needed to explore the relationship between polyethylene inserts, kinematics, and outcomes [25–27]. Additionally, there were some studies indicated that KA improved early functional outcomes, while other studies suggested no difference compared to traditional MA [4, 28, 29]. Another concern is the higher rate of outliers for KA [30]. Although there is research that this does not reduce components survivorship, concerns persist about the potential increased risk of early revisions due to positioning components outside the safe zone [31]. In this study, all cases were aligned within define range through

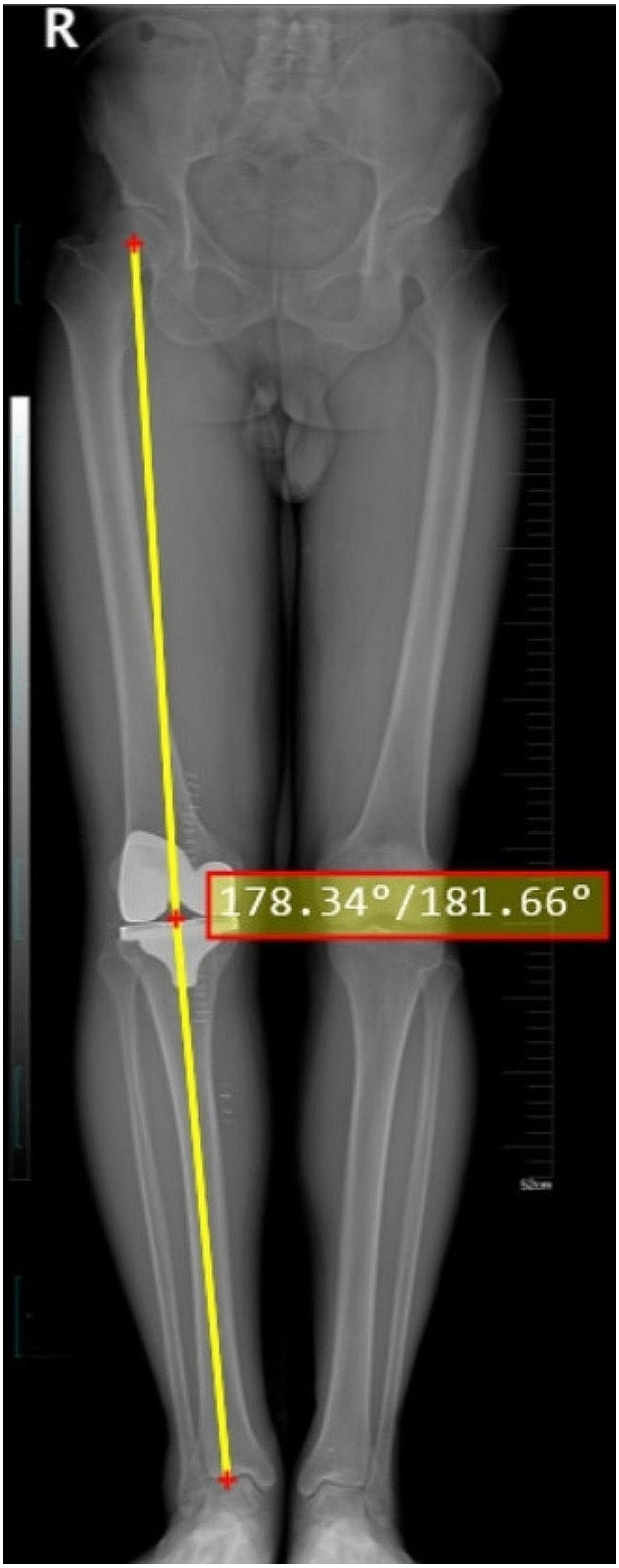

Fig. 8 Post-operative HKA was 178° measured medially from the standard long-standing anteroposterior radiograph

adjusting bone resections, and soft tissue releases were not required. But for patients with severe deformity, soft tissue release can be attempted until safe alignment is achieved.

The mean post-operative HKA was 179.4° ± 2.9° ranging from 177° to 183° (n=22). When compared with the alignment using the kinematic technique reported by McEwen et al., which was 179.0° ± 2.4°ranging from 174.0° to 183.9° (n=41) [32], the method of this study showed a more controlled HKA. The mean MPTA was 85.4°, which could explain the more varus of the tibial cut. The increased external rotation of the femoral resection was associated with changes in the flexion gap after cutting the cruciate ligament. This adjustment could reduce medial soft tissue release while achieving medial gap balance. Innocenti et al.'s study indicated the tibial component malalignment on the coronal plane was associated with increased stress between the bone and polyethylene [33], while another study proposed that tibial component malalignment would not increase the pressure of medial or lateral compartments compared with those in-range alignment (87° ≤ MPTA≤93°) [30]. In this study, the bone resection was tended to be adjusted to receive balanced gap, instead of using the soft tissue release technique, so the actual tibial cut was more varus and the femoral resection was more external rotation and as a result, the final HKA was more varus than planned during the surgery.

Gap tension is another critical factor affecting clinical outcomes after TKA. Research indicated that asymmetric flexion gap could also improve early clinical outcomes [34]. Each alignment technique has its proponents, and in this study, FA technique was utilized to achieve symmetric extension and flexion gaps with minimized soft tissue release. To obtain approximately controlled extension and flexion gaps before ligament tension assessment, complete tibial resection was presented first. Conventional tensioner-based gap balancing technique is designed to distract the medial and lateral gap with the target force by a torque driver and adjust the gap balance referring to the gap obliquity. But considering the gap tension and differences between medial and lateral gap would both change constantly during the arc of flexion in native knees, so this kind of device is hard to reproduce the physiologic tension of native knees [35]. Tension sensor device has also been developed to quantitate the gap tension, but the current technique is more usually applied to describe the tension profiles of native and replaced knees. And considering the individual difference, the target tension is still not unified. Furthermore, extended operative time and higher cost also limited the application of the tension sensor [36–38]. The modified gap tool is like a bisected spacer block. The surgeon could finetune the gap tension by adjusting the medial and lateral plate thickness separately, allowing to reproduce the gap properties of native knees. In this study, well balanced gap with appropriate ligament tension was obtained in all 22 patients, with 18.6±0.7 mm / 19.0±1.0 mm of medial / lateral gap at extension and 18.6±0.7 mm / 18.6±0.5 mm of medial / lateral gap at 90° of flexion.

This study has some limitations. First, a larger population and longer follow-up would be required to verify the effectiveness and reliability of this technique. Second, no control group was included for comparison. This decision was taken for two reasons. First, some studies comparing FA with other techniques have shown that FA achieved better early outcomes. [39–41]. This study only proposed a modified method using the spacer-based gap tool accompanied with the MAKO robotic arm system for the conduction of FA technique. Then this is a preliminary study and limited to the few patients choosing the robotic-assisted TKA, it is hard to conduct a prospective randomized controlled trial with other FA technique also using the robotic arm system as the control group. Third, the ligament tension assessment is still subjective, so this kind of gap plates would be further developed to quantify the gap tension and help more beginners conduct gap balancing during TKA. Additionally, all surgeries were performed by a single surgeon, which could introduce bias, as the results may be influenced by the specific skills and techniques of this surgeon. Future studies should take this into consideration and provide a more comprehensive assessment of the instrument's effectiveness.

Conclusions

This kind of spacer-based gap balancing technique with FA using the MAKO robotic arm system could promise controlled limb alignment, balanced flexion-extension gap, and suitable soft tissue tension, thus improving patient satisfaction and functional outcomes after TKA.

Acknowledgements

The authors appreciate all colleagues who provided support and assistance in the Division of Sports Medicine and Adult Reconstructive Surgery of Nanjing Drum Tower Hospital.

Author contributions

All authors were engaged in the study design. JH, QJ, and ZX were involved in data collection. ZX contributed to performing surgery. HKT, ZB, and DW participated the data analysis and interpretation. HKT, ZB, QJ, and ZX participated in manuscript writing and revision.

Funding

This work was supported by the National Key Research and Development Project (2021YFA1201404), Major Project of NSFC (81991514), Jiangsu Province Medical Innovation Center of Orthopedic Surgery (CXZX202214), Jiangsu Provincial Key Medical Center Foundation, Jiangsu Provincial Medical Outstanding Talent Foundation, Jiangsu Provincial Medical Youth Talent Foundation and Jiangsu Provincial Key Medical Talent Foundation, the Fundamental Research Funds for the Central Universities (14380493, 14380494), National Natural Science Foundation of China (81871832, 82272492).

Data availability

The datasets generated and/or analyzed during the current study are not publicly available due [part of another research has not been completed yet] but are available from the corresponding author on reasonable request.

Declarations

Ethics approval and consent to participate

This study was conducted after approval by the institutional ethics committee of Nanjing Drum Tower Hospital (2022 – 668). Informed consent was obtained from all patients.

Consent for publication

Each author has seen the manuscript and approved it to submit to your journal. Informed consent for publication of identifiable data was obtained from all patients.

Competing interests

The authors declare no competing interests.

Author details

[1]State Key Laboratory of Pharmaceutical Biotechnology, Division of Sports Medicine and Adult Reconstructive Surgery, Department of Orthopedic Surgery, Nanjing Drum Tower Hospital, The Affiliated Hospital of Nanjing University Medical School, 321 Zhongshan Road, Nanjing 210008, Jiangsu, PR China
[2]Branch of National Clinical Research Center for Orthopedics, Sports Medicine and Rehabilitation, Nanjing, Jiangsu, PR China
[3]Department of Anesthesiology, Nanjing Drum Tower Hospital, The Affiliated Hospital of Nanjing University Medical School, 321 Zhongshan Road, Nanjing 210008, Jiangsu, PR China

Received: 6 January 2024 / Accepted: 6 August 2024
Published online: 14 August 2024

References

1. Insall JN, Binazzi R, Soudry M, Mestriner LA. Total knee arthroplasty. Clin Orthop Relat Res. 1985(192):13–22.
2. Vigdorchik JM, Wakelin EA, Koenig JA, Ponder CE, Plaskos C, DeClaire JH et al. Impact of Component Alignment and Soft Tissue Release on 2-Year Outcomes in Total Knee Arthroplasty. J Arthroplasty. 2022;37(10):2035-40.e5.
3. Bourne RB, Chesworth BM, Davis AM, Mahomed NN, Charron KD. Patient satisfaction after total knee arthroplasty: who is satisfied and who is not? Clin Orthop Relat Res. 2010;468(1):57–63.
4. Howell SM, Howell SJ, Kuznik KT, Cohen J, Hull ML. Does a kinematically aligned total knee arthroplasty restore function without failure regardless of alignment category? Clin Orthop Relat Res. 2013;471(3):1000–7.
5. Oussedik S, Abdel MP, Victor J, Pagnano MW, Haddad FS. Alignment in total knee arthroplasty. Bone Joint J. 2020;102–b(3):276–9.
6. Clark GW, Esposito CI, Wood D. Individualized functional knee alignment in total knee arthroplasty: a robotic-assisted technique. Techniques Orthop. 2022;37(3):185–91.
7. Shatrov J, Battelier C, Sappey-Marinier E, Gunst S, Servien E, Lustig S. Functional alignment philosophy in total knee arthroplasty - rationale and technique for the varus morphotype using a CT based robotic platform and individualized planning. Sicot j. 2022;8:11.
8. Deckey DG, Rosenow CS, Verhey JT, Brinkman JC, Mayfield CK, Clarke HD et al. Robotic-assisted total knee arthroplasty improves accuracy and precision compared to conventional techniques. Bone Joint J. 2021;103-b(6 Supple A):74–80.
9. Rossi SMP, Benazzo F. Individualized alignment and ligament balancing technique with the ROSA® robotic system for total knee arthroplasty. Int Orthop. 2023;47(3):755–62.
10. Murphy GT, Shatrov J, Duong J, Fritsch BA. How does the use of quantified gap-balancing affect component positioning and limb alignment in robotic total knee arthroplasty using functional alignment philosophy? A comparison of two robotic platforms. Int Orthop. 2023;47(5):1221–32.
11. Mancino F, Rossi SMP, Sangaletti R, Caredda M, Terragnoli F, Benazzo F. Increased accuracy in component positioning using an image-less robotic

arm system in primary total knee arthroplasty: a retrospective study. Arch Orthop Trauma Surg. 2024;144(1):393–404.
12. Bollars P, Meshram P, Al Thani S, Schotanus MGM, Albelooshi A. Achieving functional alignment in total knee arthroplasty: early experience using a second-generation imageless semi-autonomous handheld robotic sculpting system. Int Orthop. 2023;47(2):585–93.
13. Cho KJ, Seon JK, Jang WY, Park CG, Song EK. Robotic versus conventional primary total knee arthroplasty: clinical and radiological long-term results with a minimum follow-up of ten years. Int Orthop. 2019;43(6):1345–54.
14. Kim YH, Yoon SH, Park JW. Does robotic-assisted TKA result in Better Outcome scores or Long-Term Survivorship Than Conventional TKA? A Randomized, Controlled Trial. Clin Orthop Relat Res. 2020;478(2):266–75.
15. Heesterbeek PJ, Jacobs WC, Wymenga AB. Effects of the balanced gap technique on femoral component rotation in TKA. Clin Orthop Relat Res. 2009;467(4):1015–22.
16. Walker L, Clement N, Ghosh K, Deehan D. What is a balanced knee replacement? EFORT Open Rev. 2018;3:614–9.
17. Nowakowski A, Majewski M, Müller-Gerbl M, Valderrabano V. Development of a force-determining tensor to measure 'physiologic knee ligament gaps' without bone resection using a total knee arthroplasty approach. J Orthop Sci. 2011;16:56–63.
18. Lavoie F. Spacer-based gap balancing in total knee arthroplasty: clinical success with a reproducible technique. J Knee Surg. 2017;30(8):798–806.
19. Almaawi AM, Hutt JRB, Masse V, Lavigne M, Vendittoli PA. The impact of mechanical and restricted kinematic alignment on knee anatomy in total knee arthroplasty. J Arthroplasty. 2017;32(7):2133–40.
20. Aunan E, Kibsgård TJ, Diep LM, Röhrl SM. Intraoperative ligament laxity influences functional outcome 1 year after total knee arthroplasty. Knee Surg Sports Traumatol Arthrosc. 2015;23(6):1684–92.
21. Ghosh KM, Merican AM, Iranpour F, Deehan DJ, Amis AA. Length-change patterns of the collateral ligaments after total knee arthroplasty. Knee Surg Sports Traumatol Arthrosc. 2012;20(7):1349–56.
22. Clark GW, Steer RA, Khan RN, Collopy DM, Wood D. Maintaining Joint Line Obliquity optimizes outcomes of functional alignment in total knee arthroplasty in patients with constitutionally Varus Knees. J Arthroplasty. 2023;38(7 Suppl 2):S239–44.
23. Bellemans J, Colyn W, Vandenneucker H, Victor J. The Chitranjan Ranawat award: is neutral mechanical alignment normal for all patients? The concept of constitutional varus. Clin Orthop Relat Res. 2012;470(1):45–53.
24. Matsumoto T, Muratsu H, Kubo S, Matsushita T, Kurosaka M, Kuroda R. The influence of preoperative deformity on intraoperative soft tissue balance in posterior-stabilized total knee arthroplasty. J Arthroplasty. 2011;26(8):1291–8.
25. Castellarin G, Pianigiani S, Innocenti B. Asymmetric polyethylene inserts promote favorable kinematics and better clinical outcome compared to symmetric inserts in a mobile bearing total knee arthroplasty. Knee Surg Sports Traumatol Arthrosc. 2019;27(4):1096–105.
26. Nakamura S, Kuriyama S, Ito H, Nishitani K, Song YD, Ikebe S, et al. Kinematic comparison between asymmetrical and symmetrical polyethylene inserts during deep knee bend activity. J Orthop Sci. 2022;27(4):810–4.
27. Koster LA, van Kaptein BL, der Linden-van, der Zwaag E, Nelissen R. Knee kinematics are not different between asymmetrical and symmetrical tibial baseplates in total knee arthroplasty: a fluoroscopic analysis of step-up and lunge motions. Knee Surg Sports Traumatol Arthrosc. 2024;32(5):1253–63.
28. Dossett HG, Arthur JR, Makovicka JL, Mara KC, Bingham JS, Clarke HD, et al. A Randomized Controlled Trial of Kinematically and mechanically aligned total knee arthroplasties: long-term Follow-Up. J Arthroplasty. 2023;38(6s):S209–14.
29. Waterson HB, Clement ND, Eyres KS, Mandalia VI, Toms AD. The early outcome of kinematic versus mechanical alignment in total knee arthroplasty: a prospective randomised control trial. Bone Joint J. 2016;98–b(10):1360–8.
30. Shelton TJ, Nedopil AJ, Howell SM, Hull ML. Do varus or valgus outliers have higher forces in the medial or lateral compartments than those which are in-range after a kinematically aligned total knee arthroplasty? Limb and joint line alignment after kinematically aligned total knee arthroplasty. Bone Joint J. 2017;99–b(10):1319–28.
31. Howell SM, Shelton TJ, Hull ML. Implant survival and function ten years after kinematically aligned total knee arthroplasty. J Arthroplasty. 2018;33(12):3678–84.
32. McEwen PJ, Dlaska CE, Jovanovic IA, Doma K, Brandon BJ. Computer-assisted Kinematic and Mechanical Axis total knee arthroplasty: a prospective randomized controlled trial of bilateral simultaneous surgery. J Arthroplasty. 2020;35(2):443–50.
33. Innocenti B, Bellemans J, Catani F. Deviations from optimal alignment in TKA: is there a Biomechanical Difference between femoral or tibial component alignment? J Arthroplasty. 2016;31(1):295–301.
34. Parratte S, Van Overschelde P, Bandi M, Ozturk BY, Batailler C. An anatomo-functional implant positioning technique with robotic assistance for primary TKA allows the restoration of the native knee alignment and a natural functional ligament pattern, with a faster recovery at 6 months compared to an adjusted mechanical technique. Knee Surg Sports Traumatol Arthrosc. 2023;31(4):1334–46.
35. Roth JD, Howell SM, Hull ML. Native Knee Laxities at 0°, 45°, and 90° of Flexion and their relationship to the goal of the Gap-Balancing Alignment Method of Total Knee Arthroplasty. J Bone Joint Surg Am. 2015;97(20):1678–84.
36. Kim JK, Lee DW, Ro DH, Han HS, Lee MC. Variability between the trial and final implant measurements during the sensor-guided total knee arthroplasty. Knee Surg Sports Traumatol Arthrosc. 2022;30(8):2846–53.
37. Shah DS, Taylan O, Verstraete M, Berger P, Vandenneucker H, Scheys L. Can intraoperative intra-articular loads predict postoperative knee Joint Laxity following total knee arthroplasty? A Cadaver Study with Smart Tibial trays. Sens (Basel). 2021;21(15).
38. Bardou-Jacquet J, Murgier J, Laudet F, Fabre T. Combining load sensor and robotic technologies for ligament balance in total knee arthroplasty. Orthop Traumatol Surg Res. 2022;108(5):102889.
39. Clark G, Steer R, Wood D. Functional alignment achieves a more balanced total knee arthroplasty than either mechanical alignment or kinematic alignment prior to soft tissue releases. Knee Surg Sports Traumatol Arthrosc. 2023;31(4):1420–6.
40. Van de Graaf VA, Chen DB, Allom RJ, Wood JA, MacDessi SJ. Functional alignment in total knee arthroplasty best achieves balanced gaps and minimal bone resections: an analysis comparing mechanical, kinematic and functional alignment strategies. Knee Surg Sports Traumatol Arthrosc; 2023.
41. Choi BS, Kim SE, Yang M, Ro DH, Han H-S. Functional alignment with robotic–arm assisted total knee arthroplasty demonstrated better patient-reported outcomes than mechanical alignment with manual total knee arthroplasty. Knee Surg Sports Traumatol Arthrosc. 2023;31(3):1072–80.

Publisher's Note