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ORIGINAL RESEARCH

Predictive Accuracy Analysis of a Novel Robotic-Assisted System for Total Knee Arthroplasty:A Prospective Observational Study

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Background: Robotic-assisted total knee arthroplasty (RATKA) has been reported to enhance operative decision-making. The purpose of this study was intended to assess the predictive accuracy of bone cuts, lower limb alignment, and component size of a novel system for RATKA preoperatively and intraoperatively.

Methods: Preoperatively planned bone cuts, limb alignment, and component size were projected using a reconstructed 3D model. Intraoperative bone cuts and postoperative limb alignment were measured. Errors between planned and real bone cuts, limb alignment, and component size were compared.

Results: The mean absolute errors for bone cuts and alignment were within 1.40mm/1.30° with a standard deviation (SD) of 0.96mm/1.12°. For all errors of bone cuts and alignment compared with the plan, there were no statistically significant differences except for the lateral distal of femoral cuts (P=0.004). The accuracy for predicting the femoral, tibial, and polyethylene component sizes was 100% (48/48), 90% (43/48), and 88% (42/48), respectively. Regarding all mean absolute errors of bone cuts and alignments, no significant differences were observed among surgeons.

Conclusion: The novel robotically-assisted system for RATKA donated reliable operative decision-making based on the predictive accuracy regardless of the surgeon's level of experience.

Keywords: robotic surgery, total knee arthroplasty, resection, implant, level of experience

Introduction

Total knee arthroplasty (TKA) is a widely recognized and successful intervention for end-stage osteoarthritis with favorable clinical outcomes.[1] However, studies have reported a survival rate of only 80%[2–5] with a satisfaction rate of only 20%.[6,7]

Procedures during operation such as bone cuts, component position, and lower limb alignment are key factors for a successful TKA.[8,9] Deviation in bone cuts and component positions can lead to malalignment, thereby increasing the risk of pain, instability, and aseptic loosening.[10–12] Optimal replacement and advantageous alignment are crucial prognostic factors that significantly impact patient satisfaction and component survival.[9–12] It can be challenging for surgeons to achieve optimal outcomes in each TKA, as surgical errors are inherent in the process.

RATKA techniques were first introduced in the 1980s,[13–15] it was designed to eliminate surgical errors and thus enhance the accuracy of bone cuts and component position,[16,17] thereby improving component survival and early functional benefits of patients.[18] However, the utilization of RATKA faces certain limitations, including extended operation time, elevated usage costs, and a lack of clear advantages in mid-term and long-term clinical outcomes compared to traditional TKA.[14,15,19–21] These limits the application of orthopedic robots in TKA still somewhat controversial.[16,17] Notably, RATKA offers distinct advantages such as haptic feedback, which enhances the protection

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of periarticular soft tissues[22] and reduces iatrogenic damage to bone and periarticular soft tissues compared with conventional TKA.[23,24] RATKA may be a possible trend in the growth of joint surgery.[25,26]

Most recently, a novel real-time robotic-assisted system for RATKA named HURWA has been developed.[27] The system is semi-active, employing a computer platform and a robotic arm with a power system. It operates by utilizing computed tomography (CT) data to generate a three-dimensional (3D) model, which is used to execute a pre-operative plan. Additionally, the system delivers haptic feedback in real-time. Previous studies have partially provided evidence on the accuracy of bone cuts on both sheep and saw bone models.[28]

In the present study, we aim to evaluate the predictive accuracy of bone cuts, limb alignment and component size achieved using the HURWA robotic system for RATKA, which is primary outcome of this study. The accuracy among surgeons with different levels of experience was also evaluated to be secondary outcomes.

Materials and Methods

Patient Selection

Prospective data of 45 consecutive patients between December 2021 and June 2022 who underwent primary RATKA was collected at a single medical center. Patients meeting the criteria for a diagnosis of osteoarthritis were included. The inclusion criteria were symptomatic end-stage osteoarthritis; failure of conservative treatment; varus/valgus deformity within 20°; and no signs of knee infection. The exclusion criteria for patients were signs of infection; neurological disease; and inflammatory arthropathies. All patients signed informed consent. The study was assessed by the hospital review board, and approval was granted by the Ethics Committee of People's Hospital of Liaoning Province (IRB202112-17-61). To detect a minimal difference of 0.5 mm/°(SD 1 mm/°) with a power of 0.80 and a two-sided alpha error of 0.05, a minimum sample size of 34 cases would be needed.

Surgeons' Level of Experience

All procedures were performed by three surgeons at a single medical center. One experienced surgeon (Surgeon 1) with 20 years in practice (>100 TKA cases/year) and two surgeons (Surgeon 2 and Surgeon 3) with 5 years in practice (50–100 TKA cases/year).[29] None of them had prior experience with RATKA or computer-assisted surgery (CAS) for TKA. All surgeons completed theoretical training and saw bone model training for eight hours.

Surgical Technique

The HURWA (BEIJING HURWA-ROBOT Medical Technology Co. Ltd. in Beijing, China) semi-active robotic system was utilized. The system generates a virtual 3D skeletal model using patients' preoperative 3D CT scans (Figure 1). The engineer collaborates with the surgeons to strategize the optimal bone cuts, component position, and limb alignment preoperatively. Mechanical alignment was performed in every case. An anteromedial skin incision with a medial parapatellar approach was performed. Then femoral and tibial frames were installed on the femur and tibia for intra-operative dynamic tracking. A tracking pin was inserted for femoral and tibial bone registration. After registration (Figure 2A) and adjustment of the preoperative plan, the operator performs the resection using the robotic arm with a cutting blade within a virtual haptic boundary (Figure 2B). In the coronal plane, the limb alignment was initially set to neutral. After the resection, the medial and lateral gaps were assessed in both flexion and extension. The component and polyethylene sizes were installed according to the intra-operative flexion/extension gap and range of motion (Figure 2C–D). The cemented Vanguard (Zimmer Biomet, Warsaw, IND, USA) and Persona (Zimmer Biomet) posterior stabilized (PS) prosthesis were installed.

Outcome Measurements

The thickness of intraoperative bone cuts, postoperatively coronal lower limb alignments, and surgically recorded component size were evaluated. (1) Preoperative planned and intraoperative real bone cuts were recorded, including distal and posterior femoral cuts (medial and lateral), as well as tibial cuts (medial and lateral) measured with Vernier calipers (Figure 3). The thickness of the cartilage at the central locations of the cuts was measured. The real thickness of bone cuts was equal to the thickness of measured bone cuts plus the thickness of the cutting blade, minus the thickness of

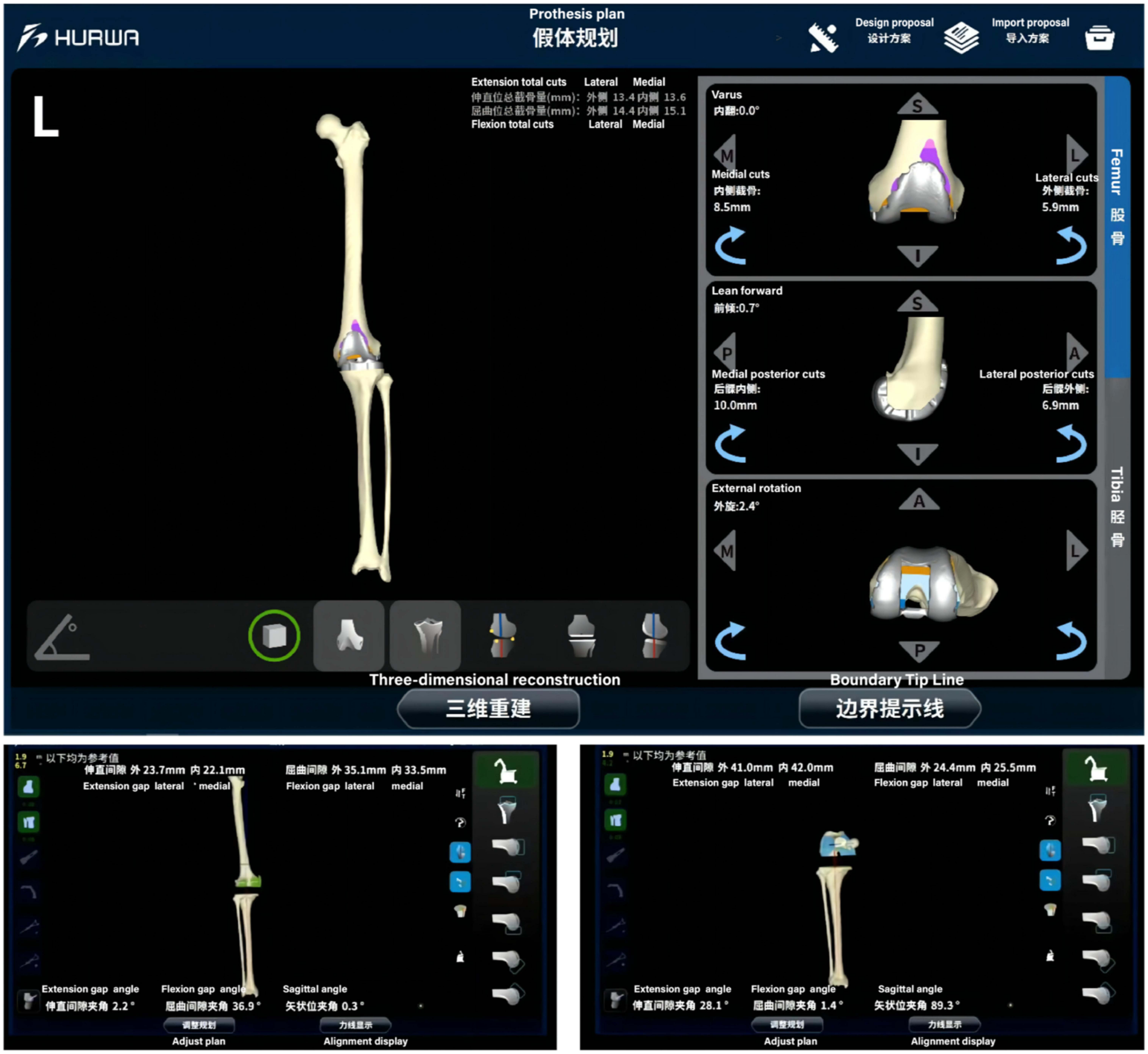

Figure 1 Preoperative computer images of planning for RATKA based on a 3D reconstructed model.

the cartilage. Errors were calculated between the real and planned parameters. (2) A standard full-leg, standing weight-bearing radiograph was obtained for coronal component varus/valgus position and limb alignment (Figure 4). The hip-knee-ankle angle (HKA) axis was defined as the angle between the mechanical axis of the femur, which is the line from the center of the femoral head to the intercondylar fossa, and the mechanical axis of the tibia, which is the line from the center of the tibial plateau to the center of the talus. A negative value was defined as varus. Femoral coronal alignment was measured as the lateral distal femoral angle (LDFA), which is the angle between the mechanical axis of the femur and the horizontal plane of the femoral component. Tibial coronal alignment was measured as the medial proximal tibial angle (MPTA), which is the angle between the mechanical axis of the tibia and the horizontal plane of the tibial component. The implant was assessed by the criteria used by Peek et al.[30] The percentages within 1, 2, and 3 mm/° of bone cuts and alignment errors were recorded. The outliers were defined as varus/valgus>3mm/° compared with the preoperative planning. (3) The predictive accuracy of component size was also recorded. The planned and measured bone cuts data, radiographs and operative records of all patients were reviewed by the principal author. Bone cuts and alignments were assessed by two other independent experienced surgeons who were unaware of each other's records, and

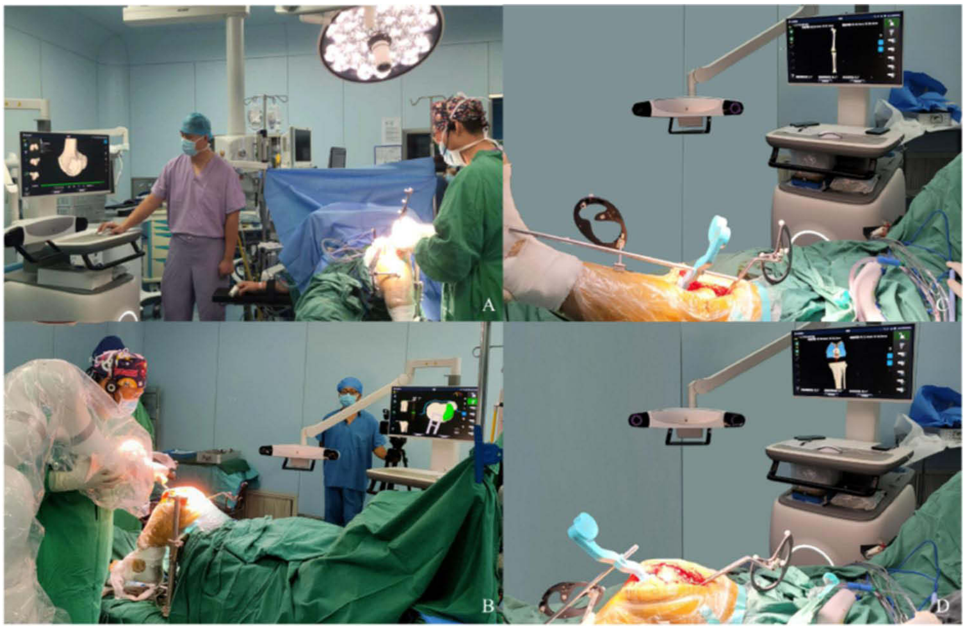

Figure 2 Intraoperative operation for RATKA. (**A**) Robotic bone preparation registration; (**B**) Robotic intraoperative bone cuts. (**C**) Measurement of the extension gap after bone cuts; (**D**) Measurement of the flexion gap after bone cuts.

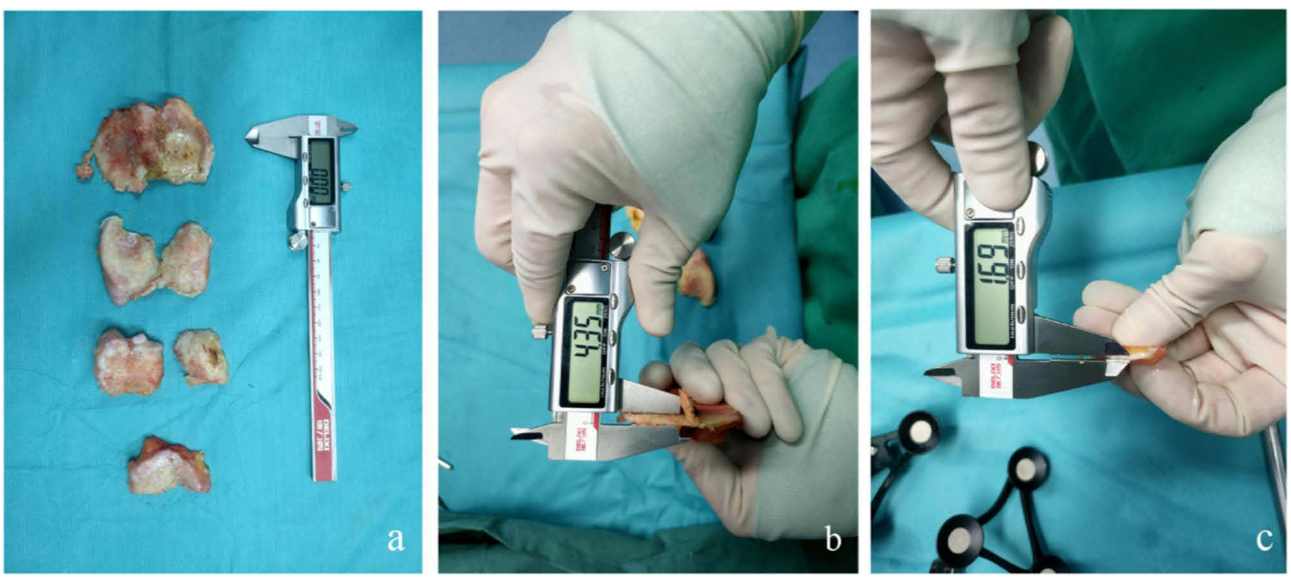

Figure 3 Postoperative measurement of the thickness of real bone cuts and cartilage from each position. (**a**) Distal femoral cuts, posterior femoral cuts, tibial cuts, front of femoral cuts (up to down). (**b**) Measurements of the thickness of bone cuts. (**c**) Measurement of the thickness of cartilage.

not involved in surgical planning, procedures. Interobserver correlation coefficient was used to assess the variation between observers.

Statistical Analysis

Data were analyzed with IBM SPSS Statistics (Version 26.0; IBM, Armonk, NY, USA). Continuous variables were expressed with means and standard deviations (SD). Categorical variables were expressed using frequencies and percentages. The paired *t*-test was used to compare the differences preoperatively and intraoperatively. The mean

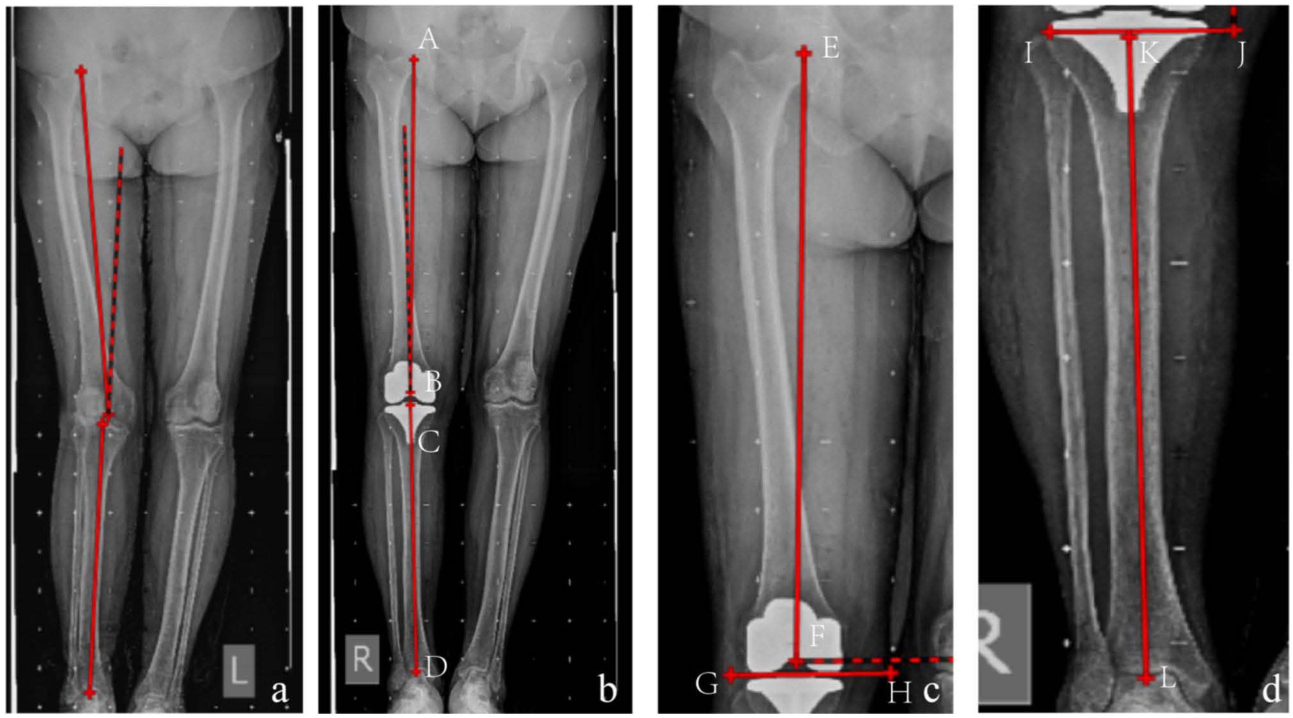

Figure 4 Postoperative measurement of component and limb alignment for RATKA. (**a**) Preoperative radiographs of limb alignment of patients. (**b**) Postoperative HKA angle: the angle between line AB and line CD. (**c**) Postoperative LDFA Angle: the angle between line EF and line GH. (**d**) Postoperative MPTA Angle: the angle between line IJ and line KL.

absolute errors of bone cuts and alignments were compared among surgeons. A *p-value* <0.05 was considered statistically significant.

Results

There were no statistically significant differences compared with the planning except for the lateral distal of femoral cuts (P = 0.004). The mean absolute errors of cuts for the distal femur (medial and lateral) and posterior femur (medial and lateral) were 0.96±0.66 mm, 0.86±0.79 mm, 0.87±0.65 mm, and 0.88±1.00 mm, respectively. The mean absolute errors of tibial cuts (medial and lateral) were 1.40±0.96mm and 1.14±1.50 mm. For 288 bone cuts for femoral and tibial cuts, 170 (59.03%) were ≤1 mm. (Table 1).

The mean absolute errors for coronal limb alignment were 1.30±1.12°. The mean absolute errors for LDFA and MPTA from the plan were 0.89±0.08° and 0.64±0.75°, respectively. No outliers were noted (Table 2).

The accuracy for predicting the femoral, tibial, and polyethylene component sizes was 100% (48/48), 90% (43/48), and 88% (42/48), respectively (Table 3).

Table 1 Comparison of Bone Cuts Errors for RATKA

Parameters	Mean real errors (SD)	*P value*	Mean absolute errors (SD)	Range (mm)
Medial distal femoral	−0.29 (1.14)	0.079	0.96(0.66)	−2.7, 2.6
Lateral distal femoral	−0.47 (1.08)	0.004*	0.86(0.79)	−2.7, 2.3
Medial posterior femoral	−0.16 (1.08)	0.297	0.87(0.65)	−1.9, 2.6
Lateral posterior femoral	−0.17 (1.14)	0.931	0.88(1.00)	−2.7, 2.6
Medial tibial	0.02 (1.74)	0.839	1.40(0.96)	−4.4, 3.6
Lateral tibial	0.04 (1.50)	0.306	1.14(1.50)	−4.2, 3.0

Table 2 Comparison of Alignment Errors for RATKA

Parameters	Mean real errors (SD)	*P value*	Mean absolute errors (SD)	Range (°)
HKA	−0.28 (1.51)	0.177	1.30(1.12)	−3.0, 2.9
LDFA	0.53 (0.93)	0.001*	0.89(0.08)	−2.0, 1.8
MPTA	−0.11 (0.82)	0.34	0.64(0.75)	−1.9, 1.8

Table 3 Component Size, Real versus RATKA Planned

Size differential (Component)	0	1
Femoral component	48(100%)	0(0%)
Tibial component	43(90%)	5(10%)
Polyethylene component	42(88%)	6(12%)

Variables for each patient were recorded and analyzed (Supplementary Table 1A-Supplementary Table 1B). There were no significant differences in patients' baseline data (Supplementary Table 1B). Regarding all mean absolute errors of bone cuts and alignments, no significant differences were observed among surgeons (Supplementary Figure 1).

Discussion

In the present study, the HURWA RATKA system demonstrated reliable bone cuts, limb alignment, and component size prediction. Furthermore, a noteworthy finding is that the outcomes above are not influenced by the surgeon's experience based on subgroup analysis. As far as we know, this is the first report on the accuracy of bone cuts for the system.

In this study, we have several findings, firstly, RATKA provides accurate and reliable accuracy of bone cuts. The mean absolute errors of resection for each position did not exceed 1.40 mm, with an overall SD of 1.50mm. This result is consistent with those of Parratte et al,[31] who found that of all resections in 30 cadaveric knees, the mean differences were below 0.7 mm and standard deviations below 1.1mm using the ROSA robot. In our study, the percentage of mean absolute errors of resection for each position within 1 mm ranged from 40–69%, within 2 mm ranged from 77–96%, and 92–100% within 3 mm (Figure 5), which are in line with those of Wan et al,[32] who found that mean absolute errors within 1 mm from the plan were 71% of all cuts using the YUANHUA robot. The results of this study reinforce the potential for RATKA in achieving accurate bone resections. The reason for the small differences from previous studies may be due to measurement errors. Even though not statistically significant, we also note a minimal difference in that the mean absolute errors of femur cuts are better than tibial cuts, and there are cases with errors over 3 mm in tibial cuts. It could be explained that in the process of end-stage osteoarthritis, the tibial plateau almost loses cartilage, which leads to osteophyte and osteoporosis of subchondral bone, thereby causing the operator's grip to be unstable, which leads to the drifting of the cutting blade intraoperatively. A statistically significant difference ($P<0.05$) was observed in the distal lateral of the femur, it may be due to the inability to visualize the cartilage on CT. During actual measurements, the measurement points on the actual bone surface do not coincide with the cutting points of the preoperative plan.[33]

Long-held beliefs about optimal alignment are being challenged by new ideas.[34,35] However, returning the HKA to 0 ± 3° is generally considered standard.[12,36] Ritter et al[12] reported that poor alignment significantly increased the rate of surgical failure, while Deckey et al[20] reported a higher precision of RATKA mechanical alignment compared with conventional TKA. In our study, regarding all 48 knees, the percentage of alignments in the 1° range from 52–79% and those within the 2° range from 75–100% (Figure 5). Although whether improved alignment leads to better outcomes and survival is still in controversial,[37,38] many studies report poor alignment, especially outliers to be a risk factor for mechanical problems and negative patient outcomes.[39–41]

Furthermore, our study suggested that HURWA can provide accurate cuts and alignments independent of the surgeon's level of experience. The surgeon's experience plays a crucial role in conventional TKA, and the optimal bone cuts and alignments are determined by the surgeon through pre-operative radiographs, intra-operative anatomical

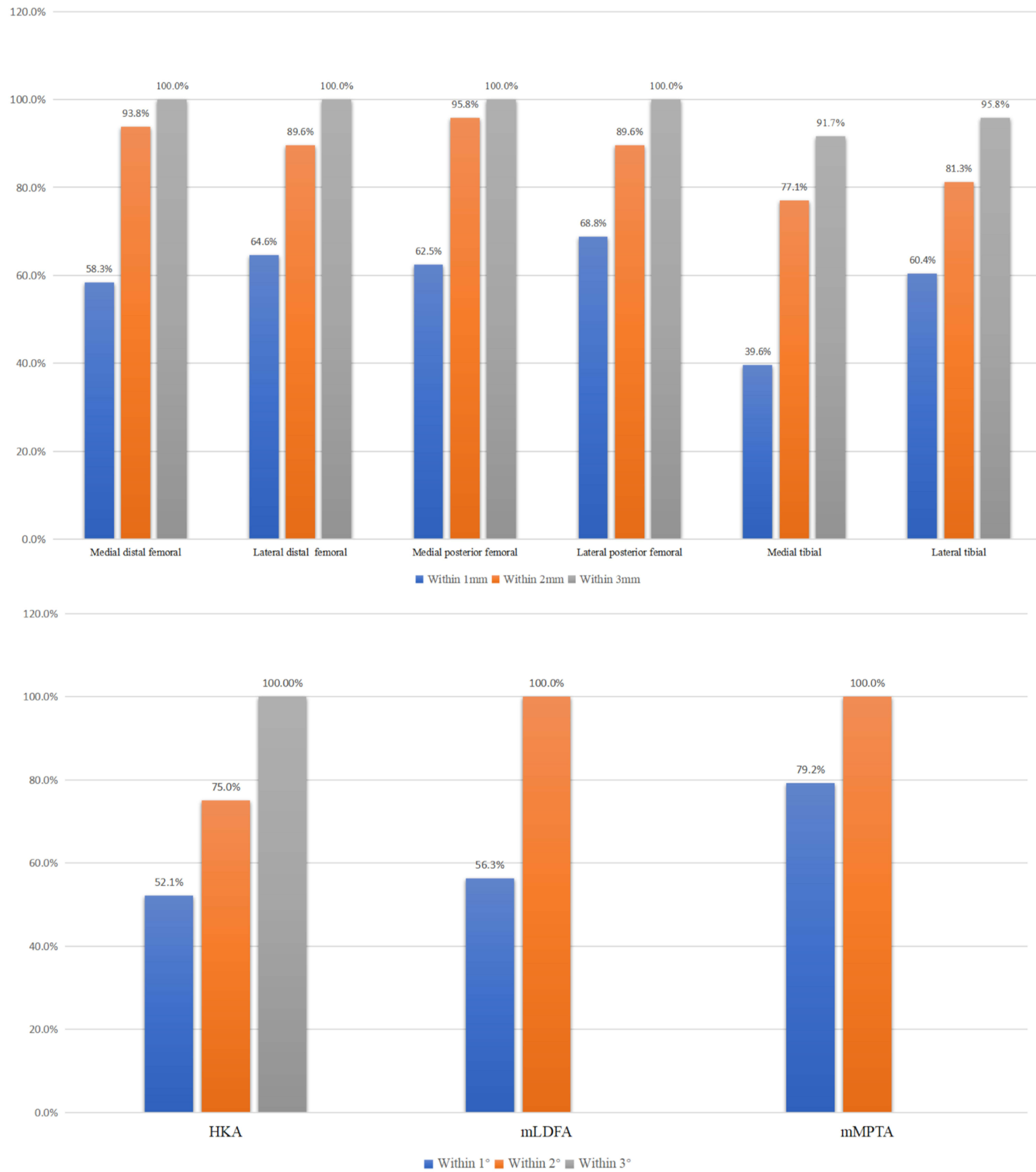

Figure 5 The percentages of mean absolute errors of bone cuts and alignments within 1, 2, and 3mm/°.

landmarks, and jigs. A radiographic analysis of 1570 primary TKAs performed at 4 private academic and state-funded centers, comparing high volume, low volume, trainee or non-trainee surgeons, showed that low surgical volume and trainee status were risk factors for outlier malalignment of implants in primary TKA.[42] The subjective assessment of surgeons may increase the discrepancy of bone cuts and malalignment, which ultimately affects the survival and clinical outcomes of patients.[4,5] Robotic technology attempts to minimize the impact of these factors by providing surgeons with optimal and accurate execution of their plans.

In our study, regarding all the mean absolute errors of cuts and alignment between surgeons, no significant difference was observed, which means the bone cuts and alignment did not rely on surgeons' experience. Our study was consistent with those of Consendey et al[43] and Antoniadis et al.[44] Nevertheless, our study focused on real patients and real-life situations. This finding has important meaning for today's increasing demand for TKA, especially for young surgeons with relatively little experience. Robotic systems may be appropriate for young surgeons to help them face a shorter learning curve for optimal resections and alignment.

Moreover, the system for RATKA accurately predicted component size, resulting from accurate bone cuts and alignments. According to earlier reports, variations in the distal femur's size and form might lead to inaccurate TKA alignment.[45] It has been investigated how to predict prosthetic size utilizing conventional templates, computer navigation, patient-specific equipment, and robotic-assisted arthroplasty methods. Numerous techniques have demonstrated a lack of high accuracy.[46] Template-based methods have shown low accuracy in predicting the size of femoral and tibial components, ranging from 28% to 48% and 37% to 55%, respectively.[46] Iorio et al[47] reported higher accuracy for the femoral component (93%) and similar accuracy for the tibial component (54%) when using CT instead of 2D digital templates. Our exact sizing matched the RA-TKA technique's high accuracy of predicting femoral and tibial component sizes as shown by Marchand et al's[48] and Londhe SB et al's findings.[49] Reliable prosthesis size prediction can reduce the quantity of surgical trays required, thereby saving preparation time and surgical resources, as well as decreasing surgical time and cost, which is critical for large academic and community centers allowing for quality control and more accurate inventory management.

This study has some limitations. The sample of more knees and surgeons would add reliability to this study. Furthermore, the clinical outcomes could better show the results of the study. Moreover, the pre-operative flexion deformities and surrounding soft tissue of the patients were not recorded. On the other hand, the alignment of the component was only evaluated on the coronal plane due to the limitations of radiographs, and 3D CT of the post-operative component and lower limb may improve the reliability of the results. Furthermore, the results of this robotic system may not be generalizable to others.

In conclusion, the present study contributes that RATKA donated reliable operative decision-making on the accuracy of bone cuts, alignment, and component size prediction, regardless of the surgeon's level of experience. Increased precision and repeatability in RATKA could be crucial when more patient-specific and precise new goals for component positioning are devised.

Abbreviations

RATKA, Robotic-assisted total knee arthroplasty; **mHKA**, mechanical Hip-knee-ankle angle; **mLDFA** mechanical Lateral distal femoral angle; **mMPTA**, mechanical Medial proximal tibial angle; **TKA**, Total knee arthroplasty; **BMI**, Body mass index; **CT**, Computed tomography; **3D**, three-dimensional; **PS**, posterior stabilized; **OA**, osteoarthritis; **SD**, Standard deviation.

Data Sharing Statement

The final data sets generated and/or analyzed are available from the corresponding author upon reasonable request.

Ethics Approval

This study was performed in line with the principles of the Declaration of Helsinki. Approval was granted by the Ethics Committee of The People's Hospital of Liaoning Province (IRB 202112-17-61).

Consent for Publication

All authors have stated consent for publications.

Patient Consent Statement

Informed consent was obtained from all participants in the study.

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Disclosure

The authors have no relevant financial or non-financial competing interest to disclose in this work.

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