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Reproducibility of a New Device for Robotic Assisted TKA Surgery

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Abstract

Background: Achieving optimal implant placement and gap balance is critical in total knee arthroplasty (TKA). Due to the limited precision of traditional instrumentation, technologies like computer-assisted surgery and robotic-assisted TKA have been developed. This experimental cadaveric study aimed to evaluate the accuracy and reproducibility of the Robin robotic system, a collaborative image-free technology, to support its clinical application.

Methods: Fifteen cadaveric specimens were treated by eight experienced TKA surgeons, all proficient in computer-assisted TKA but new to the Robin system. After receiving the same standardized training, surgeons used the robotic system, which positions and holds a universal cutting jig while they perform osteotomies. Registration repeatability was assessed by the alignment of cutting block positions with pre-existing pin placements. Bone resections, angles, and axes were analyzed by comparing preoperative planning values with the outcomes measured using a validated navigation system.

Results: There were no statistically significant differences between planned and measured resection angles, except for femoral and tibial orientation on the sagittal plane (0.6±0.8° and 0.6±1.0°). Similarly, resection thickness showed minimal deviations, with only the distal medial femoral cut differing by 0.8±0.7 mm. These results were consistent across all first-time users.

Conclusions: The Robin robotic system demonstrated high accuracy and reproducibility, closely matching preoperative plans for TKA. Its intuitive design allows surgeons to achieve their planned targets without altering surgical techniques, potentially improving efficiency and outcomes, even in complex cases.

1 Introduction

Achieving precise implant placement and optimal gap balance is fundamental in total knee arthroplasty (TKA). Traditional instrumentation often leads to alignment errors, with up to 40% of cases deviating from the intended outcome [8,10]. While neutral limb alignment has long been the goal, there is growing interest in preserving a more anatomical alignment, which may reduce the need for extensive ligament releases and improve functional outcomes [4, 19]. The limitations of conventional mechanical instrumentation have spurred the adoption of advanced technologies, including computer-assisted surgery and robotic systems [1, 2, 13]. Over the past two decades, robotic-assisted TKA has undergone significant advancements, incorporating preoperative CT scans and tools such as burrs and haptic saws. These technologies offer potential advantages but come with trade-offs, including longer setup times and increased costs. The Robin robotic system represents a novel approach to robotic TKA. It is a collaborative, image free system that uses a robotic arm to position cutting jigs while the surgeon retains full control of the osteotomies preserving the tactile feedback and workflow of conventional instrumentation. This system doesn’t need preoperative imaging, and allows surgeons to use their preferred prosthetic implant. During the procedure, rigid body trackers are attached to the femur and tibia, allowing the surgeon to register key anatomical landmarks manually. After registration, intraoperative planning is performed to define optimal resection planes. The robotic arm then autonomously positions the cutting jigs according to this plan. Therefore, its precision depends heavily on the accuracy of manual landmark registration, which introduces variability [5, 6, 16,18]. This study aims to evaluate the accuracy of the Robin robotic system in bone resections and the reproducibility of landmark registration among users. The primary endpoint is to assess resection accuracy, while the secondary endpoint focuses on surgical time efficiency and inter-operator consistency.

2 Materials and Methods

2.1 Study Design

Fifteen cadaveric specimens were used in this study, and eight experienced TKA surgeons performed the procedures. All surgeons were proficient in computer-assisted TKA but had no prior experience with the Robin robotic system. Each surgeon completed three to four procedures, with two surgeons operating on the same specimen to evaluate inter-operator repeatability. All surgeons received the same standardized training

2.2 Robotic Workflow

The robotic arm of the Robin system was calibrated before each procedure. Rigid body trackers were attached to the femur and tibia to facilitate registration of anatomical landmarks. After registration, intraoperative planning was conducted to determine the optimal resection thickness and angles. The robotic arm positioned the cutting blocks, which were pinned in place by the surgeon. The registration process involved identifying standard bony landmarks, including the medial and lateral epicondyles, the tibial tuberosity, the center of hip rotation, and the malleoli. These were manually digitized by the surgeon using a pointer tracked by the optical system. Registration was repeated independently by a second surgeon to assess reproducibility. The navigation system (BLU-IGS, Orthokey Italia) served as a control, offering real-time feedback and enabling intraoperative confirmation that the robotic resection planes aligned with the navigation protocol previously validated in the literature.. To assess inter-operator reproducibility, the second surgeon repeated the registration process and re positioned the cutting blocks. Alignment of the blocks with previously placed pins was used as an indicator of reproducibility. Osteotomies were performed following the completion of the registration phase. Bone resections were measured using a caliper and compared to the preoperative plan. In addition, the navigation system (BLU-IGS, Orthokey Italia) was used also post-resection to re-assess final alignment and resection thickness, serving as an independent verification tool and reference standard.

2.3 Statistical Analysis

The study recorded resection angles, thicknesses, and registration times. Paired t-tests were used to compare planned and executed values, with significance set at $P<0.05$. Descriptive statistics, including means, standard deviations, and prediction intervals, were computed to evaluate reproducibility. The sample size was calculated to achieve a statistical power greater than 0.8 for detecting differences exceeding 1° or 1 mm.

3 Results

3.1 Resection Accuracy

The differences between planned and executed resections followed a normal distribution. Deviations in resection angles on the frontal and sagittal planes were less than 1°, with no values exceeding 2°. Thickness measurements showed minimal discrepancies, with the largest deviation observed in the distal medial femoral cut (0.8 ± 0.7 mm). These results demonstrate the system's high level of accuracy.

3.2 Registration Time

The average time required for registration was 81 ± 14 seconds, with a range of 58 to 120 seconds. There were no statistically significant differences in registration times between surgeons, indicating that the system's workflow is consistent and efficient.

3.3 Inter-Operator Reproducibility

The ability of the second operator to align cutting blocks with previously placed pins was consistently successful. This suggests that the system's reproducibility is robust, even among users with no prior experience with the Robin robotic system.

Rotation	mean ± st.dev (°)		Range (°)	within 1°	within 2°	95% CI
Fem frontal	0.2	± 0.8	-1.5~ 1.5	93%	100%	-0.17~ 0.59
Fem sagittal*	-0.6	± 0.8	-1.5~1.5	73%	100%	-1.09~ -0.13
Tib frontal	-0.3	± 0.8	-2.0~1.5	73%	100%	-0.84~ 0.17
Tib sagittal*	-0.6	± 1	-1.8~1.0	67%	100%	-1.02~ -0.18

Table 1. Mean difference in orientation between planned resection with robotic system and verified resection with navigation system on distal femoral and tibial cut. *p<0.05

Osteotomy	mean ± st.dev (mm)		Range (mm)		within 1mm	within 2mm	95% CI	
Medial condyle*	0.8	± 0.7	-0.4	~ 1.9	67%	100%	0.41	~ 1.11
Lateral condyle	0.6	± 0.9	-1.0	~ 1.8	60%	100%	0.11	~ 1.06
Medial plateau	0.3	± 0.6	-0.5	~ 1.2	80%	100%	-0.04	~ 0.54
Lateral plateau	0.6	± 0.8	-1.0	~ 1.8	60%	100%	0.22	~ 1.02

Table 2. Mean difference between planned resection with robotic system and resection measured with caliper. *=p

4 Discussion

The study's findings highlight the Robin robotic system's ability to achieve accurate bone resections, even among first-time users. Differences between planned and executed cuts were minimal, with resection angles and thicknesses well within clinically acceptable ranges. These results align with previous studies on robotic-assisted TKA, which have demonstrated improved accuracy compared to traditional instrumentation [17]. While inter-operator reproducibility was evaluated by repeating the registration and verifying the alignment of cutting blocks with pre-positioned pins, we acknowledge that the same navigation system (BLU-IGS) was used for both intraoperative guidance and postoperative measurement. This may introduce a potential measurement bias, as the lack of an independent assessment tool could overestimate system accuracy. Future studies should include external measurement methods, such as CT or fluoroscopy, to further validate these findings.

The collaborative design of the Robin system offers several advantages. By eliminating the need for preoperative imaging, the system reduces setup time and associated costs. Its open-platform nature allows compatibility with a wide range of implant designs, providing surgeons with greater flexibility to tailor procedures to individual patient needs. Additionally, the tactile control retained by the surgeon during osteotomies helps maintain familiarity with traditional surgical workflows. The accuracy of the Robin system is comparable to other robotic platforms. For example, Parratte et al. (2019) reported similar accuracy levels after a short learning curve [17]. However, unlike many studies that focus on experienced users, this investigation demonstrated high accuracy and reproducibility even among first-time users. This highlights the system's intuitive design and minimal learning curve.

While the study provides valuable insights, several limitations should be acknowledged. First, the use of cadaveric specimens may not fully replicate clinical conditions, where factors such as patient anatomy and soft tissue constraints can impact outcomes. Second, the small sample size limits the generalizability of the findings. Finally, although the system's accuracy is promising, further research is needed to establish whether this translates into improved clinical outcomes. Another limitation is the use of the same navigation system for both guiding the robotic arm and validating resection accuracy. Although BLU-IGS is a validated system, relying on it for both steps may result in a confirmation bias. Independent validation tools are recommended for future investigations.

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