Original Article

Accuracy of Advanced Active Robot for Total Knee Arthroplasty: A Cadaveric Study

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Abstract

Purpose Although the accuracy of other types of robotic systems for total knee arthroplasty (TKA) has been assessed in cadaveric studies, no investigations have been performed to evaluate this newly advanced active robotic system. Therefore, the authors aimed to analyze the accuracy of bone resection in terms of thickness and alignment in a cadaveric study.

Methods Three cadaveric specimens (six knees) and an active robotic system (CUVIS Joint, CUREXO) were used in the study. Three surgeons with different experiences in robotic TKAs performed this cadaveric study using the same robotic protocol with two different implant designs. The thickness and angle of bone resection planes obtained from the optical tracking system and the difference between resection planes and the planning data were assessed to determine accuracy.

Results With respect to the overall resection accuracy compared to the plan, the cutting depth accuracy was within 1.0 mm mean of root mean square (RMS), and the resection angle accuracy in terms of sagittal, coronal, and axial planes was within 1.0 degree mean RMS. In contrast, no significant differences were observed between the planned and measured values in terms of the resection angles and cutting thickness. The hip–knee–ankle angle at postoperative evaluation was 0.7 degrees ± 0.7 degrees (RMS 1.0 degrees).

Conclusion This in vivo study suggests that the use of this newly advanced active robotic system for TKA demonstrates a high degree of accuracy in terms of resection thickness and alignment. This finding supports the clinical application of this advanced robotic system.

Level of Evidence Cadaveric study, Level V.

Keyword
- Knee
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Total knee arthroplasty (TKA) has seen multiple advancements in terms of implant design, implant material, patient-specific implants, and computer navigation, as well as enhanced recovery programs, thromboembolic prophylaxis, and antibiotic prophylaxis.[1–5] Despite this, several studies have reported patient dissatisfaction of up to 20% following TKA, which may result from malalignment or soft tissue imbalance.[6–8]

Intraoperative factors performed by the surgeon such as accurate implant positioning, balanced flexion-extension gaps, proper mediolateral ligament balancing, and preservation of the surrounding soft tissue envelope during TKA could affect clinical outcomes and implant survivorship.[9,10] Theoretically, technology with greater accuracy and reproducibility may help to improve outcomes in TKA.

Various robotic systems have been developed to increase the accuracy of bone resections and decrease the outliers of alignment in TKA.[11–15] Compared to existing active robotic systems, the advanced active robotic system used in this study has the advantage of flexibility.[16,17] Intraoperative change in surgical plans is not possible in existing active robots, but the newly advanced active robotic system in this study enables surgeons to do such intraoperative changes through the evaluation of the patient's soft tissue condition. In addition, soft tissue envelopes can be protected by milling burr resection within safe boundaries. Some semiactive robots provide haptic boundaries, while some passive robots require direct control of the saw to protect the soft tissues.[18,19] Moreover, the newly advanced active robotic system used in this study is an open platform that enables the use of implants from different manufacturers according to the individual condition of the patients.

This study was designed to investigate the in vivo capabilities of this advanced active robotic system. Therefore, the authors aimed to determine the accuracy of bone cuts in terms of thickness and alignment using this newly advanced active robotic system for TKA.

Fig. 1 Composition of CUVIS-joint active robotic system. (**A**) Robotic arm. (**B**) Main console.

Methods

For this study, six fresh cadaveric knees (three specimens) were used. The mean age at the time of death was 76.7 ± 7.6 years. Three surgeons performed bilateral TKA (left and right knees), and two types of implant designs (EXULT, CORENTEC, Seoul, Republic of Korea; Luminus Flex, Cellumed, Seoul, Republic of Korea) were used to avoid implant selection bias. The same robotic system was used in each knee (CUVIS Joint, CUREXO, Seoul, Republic of Korea; ►**Fig. 1**). All surgeons participating in the study had professional knowledge and experience in conventional TKA. Experience in robotic-assisted surgery differs for each surgeon. To illustrate, one surgeon had approximately 50 surgical experiences with the CUVIS joint, another had about 120 surgical experiences with the Mako system (Stryker), while another had zero experience with robotic-assisted TKA.

Robotic Procedure

Preoperative computed tomography (CT) was performed on all knees. The surgical planning software reconstructed the patient's CT image data with stereoscopic images to provide information on optimal implant size and installation surface. Prior to surgery, the surgeon established preoperative planning for optimal implant size and positioning with the selected implant design. The planning information was stored on a removable storage device and transferred to the robot system. The measured resection technique with anterior referencing was applied, and the neutral alignment was determined for the mechanical axis of lower limb. The planning information was stored on a removable storage device and transferred to the robot system.

For each robotic TKA with a cadaveric knee, two trackers (one on the femur and one on the tibia) were rigidly fixed. After knee arthrotomy using the medial parapatellar approach, a probe was used to register the landmarks of the femur and tibia. Following registration, the agreement between the registered operated knee and the CT-reconstructed virtual knee was evaluated in terms of alignment and position. In the case of a discrepancy more than 1 mm, all points required repeat registration.

Two clamps (one on the femur and one on the tibia) were fixed for rigid docking of the active robot with the operated knee. The robot system was then moved to the operated knee considering a working space of 6 degrees of freedom of the active robotic arm. Rigid docking was performed by the surgeon (►**Fig. 2**). Prior to bone resection, the agreement of the operated knee with the virtual model developed from the CT images was reassessed. Bone resection from the femur to the tibia was performed using an active robotic arm with a milling burr of 6.2 mm thickness as dictated by the preoperative plan or revised intraoperative plan (►**Fig. 3**). During active milling bone resection, the resection process must be monitored by the surgeon at all times to protect the soft tissue envelope and to remove bone remnants that can decrease the efficiency of the milling tool. The robotic system provided the monitoring function of the cutting reference position and the force applied to the cutting tool assembly, and the monitoring results were presented through a graphical user interface. In addition, the robotic system

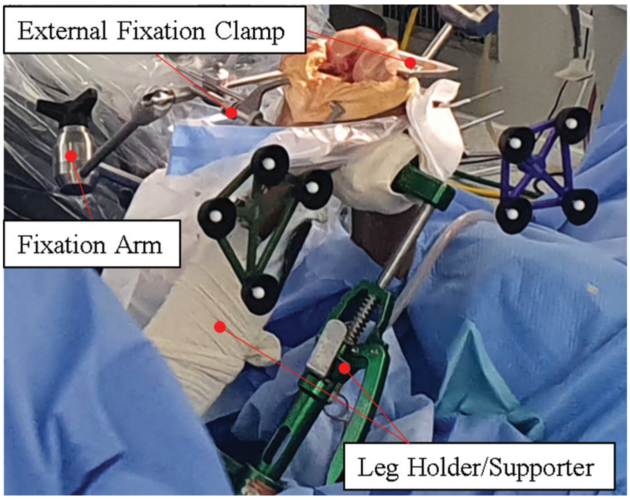

Fig. 2 The rigid docking of the operated knee with the active robotic system with stable fixation between clamps and fixation arm of robotic system.

provided a function to automatically stop cutting when data observed during monitoring exceeded the threshold value of 1 mm.

Measurement of Bone Resection

An optical tracking system (OTS) was utilized to measure the bone resection plane. The thickness and alignment of the bone resection on three planes (distal femoral plane, posterior femoral plane, and tibial plane) were measured using the verification tool (►**Fig. 4**). The verification tool was composed of a registration probe and a probe adapter, and it was placed on the resection surface to measure the thickness and alignment of each resection surface. The resection thickness was evaluated by measuring the distance from the reference position (medial and lateral) set in preoperative planning to the bone resection surface. The verification tool showed accuracy in thickness of 0.08 mm and alignment of 0.06 degree on the laboratory test. Alignment was measured in the coronal, sagittal, and axial planes. The varus/valgus and flexion/extension angles were measured in the distal femoral plane, while the internal/external angle was measured in the posterior femoral plane. On the tibial plane, the varus/valgus and flexion/extension angles were measured. To minimize human error, all measurements were performed three times by the surgeon who performed the surgery and two additional observers (a total of nine measurements). The average of the results was used for analysis.

After bone resection and proper ligament balancing, an implant trial was performed. The limb alignment (varus/valgus) was measured using the gap-checking function provided by the robotic system. Measurement of limb alignment was performed with the legs in extension and at 90 degrees of knee flexion.

Results

The target cutting thickness and measured cutting thickness for all six cadaveric knees are listed in ►**Table 1**. The mean values of the difference from the plan of each cutting thickness are all less than 1.1 mm, and the standard deviation is less than 0.7 mm. In addition, all root mean square (RMS) values are below 1.2 mm. Except for the femur posterior cutting thickness, all mean values are less than 0.5 mm and all RMS values are less than 0.7 mm.

The differences between the target angles and measured angles are shown in ►**Table 2**. The mean values of the difference from the plan of each resection angle were all less than 0.5 degree, and the standard deviation was less than 0.6 degree. Except for the femur posterior cut plane, all mean values were close to 0. All RMS values were below 0.7 degree.

►**Table 3** shows preoperative and postoperative coronal limb alignment. In terms of postoperative extension limb alignment, the mean value and the standard deviation were below 0.7 degree and the RMS was less than 1.0 degree.

Discussion

The advanced robotic system using an active robotic arm in this study achieved accurate bone resection in terms of

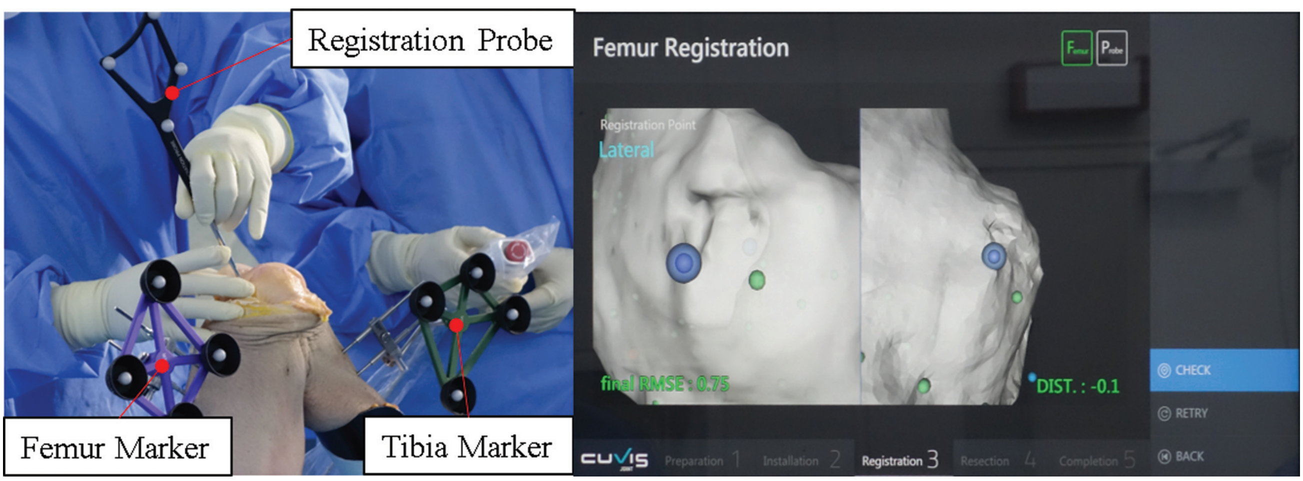

Fig. 3 The agreement of the operated knee with the virtual model developed from the CT images was assessed by probing. When a probe was placed on distal portion of medial femoral condyle, the difference between the operated knee and the virtual knee was presented on the main console.

Fig. 4 Bone resection measurement with a verification tool. (**A**) Distal femoral resection plane of depth, varus/valgus angle and flexion/extension angle, (**B**) Posterior femoral resection plane of depth and internal rotation/external rotation angle. (**C**) Tibial resection plane of depth, varus/valgus angle and flexion/extension angle.

thickness and alignment. Resection alignments of the coronal, sagittal, and axial planes revealed a high accuracy of less than 1 degree. In terms of the overall resection accuracy compared to the plan, the resection thickness was less than 1 mm, except for the medial posterior femoral resection of 1.1 mm. However, this was underresection of the femur during posterior resection, which could be managed through additional resection using an active robotic arm. The accuracy of the extension coronal limb alignment after surgery was 0.7 degree, and no cases of outliers greater than 3 degrees were observed.

The accuracy of this study was comparable to other types of robotic systems for TKA in previously reported cadaveric studies.[13,20,21] According to the results of previous studies of robotic-assisted TKA, one study reported that the mean hip–knee–ankle angle was −0.03 degree ± 0.87 degree and the

Table 1 Difference of resection thickness with plan (mm)

	Distal femoral plane		Posterior femoral plane		Tibia plane	
	Medial	Lateral	Medial	Lateral	Medial	Lateral
#1	0.2	0.3	−1.6	−1.2	0.5	0.6
#2	1.2	1.1	−0.7	−0.4	0.3	0.6
#3	−0.2	−0.1	−1.6	−1.6	0.3	0.8
#4	0.0	0.1	−0.8	−0.1	0.1	−0.1
#5	0.6	0.7	−0.8	0.5	0.6	−0.2
#6	0.0	0.1	−1.1	−0.9	0.2	1.1
Mean	0.3	0.4	−1.1	−0.6	0.4	0.5
SD	0.5	0.4	0.4	0.7	0.2	0.5
RMS	0.5	0.5	1.2	0.9	0.4	0.7

Abbreviations: RMS, root mean square; SD, standard deviation.
Note: The positive value means undercutting and the negative value means overcutting.

Table 2 Difference of resection angle with plan (degrees)

	Distal femoral plane		Posterior femoral plane		Tibia proximal	
	V/V	F/E	I/E	F/E	V/V	F/E
#1	0.2	−0.1	−0.5	−0.6	0.1	−0.8
#2	−0.1	−0.1	−0.3	−0.1	0.3	0.1
#3	0.1	0.3	0.0	−0.4	0.5	0.7
#4	0.0	0.0	−0.8	−0.3	−0.3	−0.8
#5	0.0	0.0	−1.3	−0.8	−0.9	−0.2
#6	0.3	−0.1	−0.3	−0.9	1.0	−0.1
Mean	0.1	0.0	−0.5	−0.5	0.1	−0.2
SD	0.1	0.2	0.4	0.3	0.6	0.5
RMS	0.1	0.2	0.7	0.6	0.6	0.6

Abbreviations: F/E, flexion or extension; I/E; internal rotation or external rotation; RMS, root mean square; SD, standard deviation; V/V, varus or valgus.
Note: The positive value means varus, flexion, or internal rotation alignment and the negative value means valgus, extension, or external rotation alignment.

mean difference in resection level was below 0.7 ± 1.1 mm.[20] Another study reported that the mean femoral flexion angle was −2.0 degrees ± 2.2 degrees, and the accuracy of bone resection level was below 1.0 mm.[13] In addition, another study reported that compared to the plan, the mean and RMS of bone resection were within 1 degree and 1 mm, respectively.[21] Taken together, previous cadaveric studies of other types of robotic systems showed high accuracy in terms of resection thickness and alignment. Based on these reliable results, the aforementioned robotic systems have been applied for knee arthroplasty in clinical practice. Therefore, the comparably high accuracy of this cadaveric study would enable the application of an active robotic system with an active arm for TKA.

The advanced robotic system in this study showed high accuracy compared to the advanced technology of patient-specific instrumentation (PSI).[22,23] A recent study on PSI reported that up to 80% of outliers were more than 2.5 mm of bone resection, which provides only fair to moderate accuracy.[22] Another study on PSI showed similar accuracy, with 37.7% of outliers more than 2.5-mm bone resection.[23] The exact reason for the low accuracy of PSI was difficult to determine, with human errors in block placement, resection errors due to saw blade deviation, and measurement errors considered as possible confounders. Therefore, an active robotic system with bone motion feedback and planned bone resection with safe boundaries and semiactive haptic system with additional haptic feedback would provide more accurate bone resection.

The accuracy of the active robotic system in this study was comparable or superior to that of a computer-assisted navigation system in a previously reported cadaveric study.[24,25] One cadaveric study reported mean values of differences in resection thickness and angle of approximately 1 mm and 1 degree, respectively, regardless of the type of computer-assisted navigation.[24] However, other cadaveric studies with computer navigation showed less accuracy in the sagittal plane, 2.8 degrees of flexion, and 3.4 degrees of anterior translation.[25] It was difficult to determine the reason behind the low accuracy of computer-assisted navigation systems, with manual resection and determination of implant position by the surgeon possibly contributing to this difference. Despite the few clinical studies comparing robotic systems and computer-assisted navigation TKA, superior control of surgical variables, including alignment, implant position, soft tissue balancing, and surgery time, was exhibited by robotic TKA.[26,27] For clear evidence of robotic systems in TKA, further randomized control studies with long-term follow-up are necessary.

The strength of this study was the direct measurement of the rotational alignment of the femoral components using the posterior femoral resection plane since most cadaveric studies on the accuracy of robotic systems for TKA have reported only coronal and sagittal alignment (►**Table 4**). Although the rotational alignment of the femoral component

Table 3 Measurement of coronal limb alignment (varus/valgus) (degree)

	Extension		Flexion	
	Preoperative	Postoperative	Preoperative	Postoperative
#1	4.0	0.0	1.0	1.0
#2	3.0	1.0	1.0	1.0
#3	0.0	1.0	5.0	2.0
#4	0.0	0.0	0.0	0.0
#5	5.0	0.0	1.0	1.0
#6	8.0	2.0	3.0	0.0
Mean	3.3	0.7	1.8	0.8
SD	2.8	0.7	1.7	0.7
RMS	4.4	1.0	2.5	1.1

Abbreviations: RMS, root mean square; SD, standard deviation.

Table 4 Measurement of accuracy of robotic systems for TKA in cadaveric studies

Study	Robot	Femur			Tibia	
		V/V	F/E	I/E	V/V	F/E
Seidenstein et al[29]	ROSA	V	V		V	V
Hampp et al[14]	MAKO	V	V		V	
Parratte et al[20]	ROSA	V	V		V	V
Casper et al[13]	NAVIO	V	V	V	V	V
Current study	CUVIS-Joint	V	V	V	V	V

Abbreviations: F/E, flexion or extension; I/E; internal rotation or external rotation; TKA, total knee arthroplasty; V/V, varus/valgus.

is important for successful TKA, the degree of rotational alignment is difficult to measure without a specific assessment tool. One cadaveric study utilized a 3-mm ball-point in the divot positions on the trial implant to assess femoral rotational alignment.[13] In this study, a validated verification tool was used to assess rotational alignment. The rotational error of −0.5 degree in this study was comparable to that of a previous cadaveric study with a semiactive robotic system (−0.5 degree). Therefore, the advanced active robotic system used in this study proves to be a reliable modality for successful TKA.

Some limitations of this study need to be addressed. First, this was a preclinical study using cadaveric specimens which typically have less osteoarthritis and deformities than clinical practices. However, this study focused on the surface to determine the accuracy of bone resections. Second, the number of cadaveric knees used was small. Regardless, the mean value of the difference in thickness between bone resection and plan was less than 1.1 mm in six parameters (►**Table 1**). In addition, the difference in resection angle was also less than 1 degree in six parameters. Therefore, the results of this study regarding accuracy are considered reliable. Third, an OTS was used to measure the accuracy in this study. The relative three-dimensional position and orientation are calculated by tracking a plurality of markers, so the error caused by the OTS itself can be increased by a factor of 2 or 3. In this study, the use of only two markers for individual measurements and a verification tool allowed minimization of error. Moreover, a recent study reported that intraoperative measured component alignment using optical navigation was comparable to CT-based measurements.[28] Fourth, this study did not include a control group for conventional techniques. However, other types of robotic systems have exhibited high accuracy compared to conventional techniques,[14,29] and the accuracy of this study was comparable to that of other robotic systems. Finally, three surgeons and two different implants were used in this study, which could increase the variability. Despite the use of multiple surgeons with different experiences of the robotic system, uniform results were obtained.

Conclusion

Based on the results of this cadaveric study, the use of this newly advanced robotic system for TKA demonstrated a high degree of accuracy in terms of resection thickness and alignment. These results support the clinical application of this active robotic system in the treatment of patients with end-stage knee osteoarthritis. Further studies will be necessary to investigate other potential advantages of the time efficiency and optimization of implant positioning and to evaluate the potential improvement of this new technology on patient-reported outcomes.

Ethical Approval

The study did not include research with animals or living human participants and was declared exempt by the local institutional review board.

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Conflict of interest

Y.-B.P. is paid consultants for CUREXO.
B.-O.K. is employed by CUREXO.

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