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Robot-Assisted Total Knee Arthroplasty Accurately Restores the Joint Line and Mechanical Axis. A Prospective Randomised Study

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ABSTRACT

Robot-assisted Total Knee Arthroplasty (TKA) improves the accuracy and precision of component implantation and mechanical axis (MA) alignment. Joint-line restoration in robot-assisted TKA is not widely described and joint-line deviation of > 5 mm results in mid-flexion instability and poor outcomes. We prospectively randomised 60 patients into two groups: 31 patients (robot-assisted), 29 patients (conventional). No MA outliers (> ± 3° from neutral) or notching was noted in the robot-assisted group as compared with 19.4% ($P = 0.049$) and 10.3% ($P = 0.238$) respectively in the conventional group. The robot-assisted group had 3.23% joint-line outliers (>5 mm) as compared to 20.6% in the conventional group ($P = 0.049$). Robot-assisted TKA produces similar short-term clinical outcomes when compared to conventional methods with reduction of MA alignment and joint-line deviation outliers.

The use of robotics in orthopaedic surgery started in 1980s to circumvent the high complication rates faced with the use of uncemented total hip arthroplasties [1]. Satisfaction rates of patients undergoing TKA are generally good at 82% to 89% [2–4] with 10–15 years implant survival rates being reported as more than 90%. [5–7] Surgical technique errors have been identified as the most prevalent cause of failure of TKAs [7] and Orthopaedic surgeons continue to look for novel techniques, including robot-assisted procedures to aid them in their pursuit for surgical perfection and patient satisfaction.

A conventional total knee arthroplasty study revealed a mechanical axis deviation of 9° in 7% of patients and over 5° in 34% of cases [8]. In contrast, robotic surgery promises excellent implant positioning and alignment with errors within one to three degrees of neutral alignment [9–13]. Of note, restoration of joint line in robot-assisted TKA has not been widely described and a joint line elevation of > 5° may result in patella baja, impingement of the patellar button component and anterior knee pain. Other potential problems affect collateral ligament and quadriceps function, leading to mid-flexion/hyperextension instability and patient dissatisfaction [14,15].

To date, robot-assisted TKA has not been shown to improve clinical outcomes. Patients undergoing robot-assisted TKA are subjected to unnecessary radiation and there is a higher operating cost involved with robotic procedures. However, it has been shown to consistently yield an ideal post-operative mechanical alignment with individualisation of the distal femoral resection angle, accurate rotational alignment of the femoral component, accurate machining of bone surfaces with a milling device and maintenance of bone temperature during machining to prevent bone injury. These factors may translate into longer prostheses survivorship due to reduced implant wear rates.

Our study aims to verify if robot-assisted TKA (1) reduces coronal plane mechanical axis alignment outliers; (2) provides accurate restoration of joint line; (3) improves clinical outcomes; (4) reduces length of stay, post-operative complications and operative time when compared to conventional TKA over a 6-month follow-up period.

Materials and Methods

We prospectively recruited 60 patients who were randomised into two groups: 31 patients underwent robot-assisted TKA and 29 patients underwent conventional TKA from May 2012 to December 2012. The Centralised Institutional Review Board and Ethics committee approved this study and all patients were informed of the benefits and risks of robot-assisted TKA and were aware of the potential increased operating time and additional costs. A power analysis was conducted with type-I error set at 0.05 ($\alpha < 0.05$) and the type-II

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error at 0.15 (85% power). A minimum sample size of 29 knees was needed to detect a significant difference between the two groups based on two-sample test of proportions and a two-sided test hypothesis using SPSS software (SPSS Inc, Chicago, Illinois).

Patients were recruited based on the diagnosis of primary knee osteoarthritis with genu varus deformity and a fixed flexion deformity of less than 15°. Patients with post-traumatic osteoarthritis, inflammatory arthropathy, ligamentous laxity, valgus knee deformities, pre-existing hip pathology and previous hip arthroplasties were excluded from the study.

All patients had preoperative radiographs (anteroposterior, lateral, skyline, long-leg films) of the affected lower limb. A CT scan of the affected lower extremity was performed for patients in the group undergoing robot-assisted TKA. The CT scans were used by the surgeons to perform virtual surgery using ORTHODOC version 4.6.2 (Curexo Technology Corp planning workstation) which determined the desired mechanical axis and implant sizes (NexGen LPS-Flex; Zimmer, Inc, Warsaw, IN, USA) for the femur and tibia separately. The virtual implantation of desired implant sizes and virtual hip–knee–ankle (HKA) axis of zero degree was generated for each patient and saved into a compact disc. This information was uploaded to ROBODOC prior to surgery. This procedure required 15 to 20 min for each patient.

All operations were performed at our institution by a single experienced surgeon for the robot-assisted and conventional groups respectively. Digimatch, ROBODOC Surgical System with software version 4.3.6 was used in all robot-assisted cases (Curexo Technology Corp, Fremont, CA, USA). All patients received Zimmer NexGen LPS-Flex posterior-stabilised implants.

A standard medial parapatellar approach with patellar eversion and patelloplasty was performed in all cases. For the robot-assisted group, stabilization pins, navigation markers and bone movement monitors were placed and workspace checks conducted prior to the rigid mating of the patient to ROBODOC. The patient was rigidly connected to ROBODOC via two transverse stabilization pins in the distal femur and proximal tibia. These two pins are connected to a frame that is coupled to ROBODOC. A meticulous registration process ensues with the surgeon identifying 4 types of landmarks on the femur and the tibia detailed in Table 1.

Once registration is complete, the surgeon activates ROBODOC which uses a milling cutter to complete all femoral and tibia bone cuts. The surface angle cuts were pre-determined using the ORTHODOC workstation to obtain a mechanical axis of zero degrees. The femur and tibia surface resection planes were perpendicular to the desired mechanical axis in the AP and lateral planes. Therefore, the surface angle cuts for the tibia and femur were customised and different for every patient. The surface resection thickness was planned using ORTHODOC CT images and was based on the thickness of the selected implant (Zimmer NexGen LPS-Flex posterior-stabilised implant) and was set at 8 mm for the distal femoral resection and 9 mm for the proximal tibia as recommended by the manufacturer. This process is aided by constant water irrigation for cooling and the removal of milling debris. Soft tissue balancing and a trial of pre-determined femur and tibia components are performed. Finalised components are implanted and stability, patellar tracking and range of motion are assessed.

All of the conventional TKAs adhered by the principles of the measured resection technique and followed the manufacturer's instrumentation guide. The tibia was cut orthogonal to the tibial anatomical axis by using an extramedullary guide with a posterior slope of 5 and a resection height of 10 mm. The femur was cut with intramedullary instruments and the external rotation was based on the transepicondylar axis.

For both groups, intra-synovial and intra-muscular injection comprising of Marcaine/Adrenaline and Ketorolac was given if there were no contraindications. Standard wound closure in layers was performed for both groups. Postoperatively, all patients received low molecular weight heparin and mechanical calf pumps for thromboprophylaxis. Rehabilitation is in accordance with the integrated care pathway.

Weight bearing radiographs (anteroposterior, lateral, skyline, long-leg films) were performed in the specialist outpatient clinic at one-month follow up. All measurements were performed using the institution's integrated radiology information (IRIS) and picture archiving and communication solution systems (PACS). Knee Society TKA Roentgenographic Evaluation and Scoring System [16], joint line position (We used the modified Kawamura and Bourne AP method [17]. This involved drawing a line from the superior aspect of the fibular head perpendicular to the long axis of the tibia and measuring the perpendicular distance from this line to the inferior aspect of the femoral condyles or femoral component. Measurements were made to the medial and lateral femoral condyles as well as to the midpoint between the condyles. We took the mean value of these readings pre-operatively and post-operatively and recorded it as the "joint line". The difference in millimetres between pre-operative and post-operative values was noted as deviations to the joint line.) and coronal plane mechanical axis measurements using the angle between the mechanical femoral axis (line connecting centre of femoral head and centre of intercondylar notch) and the mechanical axis of the tibia (line connecting the centre of tibia plateau with the centre of the ankle) on weight-bearing long-leg films were calculated by 2 independent clinicians who were not involved in the surgical procedures. The interobserver reliability was 0.863 for coronal mechanical axis measurements, 0.785 and 0.841 for the AP femoral flexion and tibia slope angles respectively, 0.822 and 0.806 for the Lateral femoral flexion and tibia slope angles respectively, and 0.772 and 0.817 for the pre-op and post-op joint line measurements.

We also examined clinical outcome markers including post-operative Knee Society score, Knee Society function score, Oxford knee score, SF-36 score, range of motion (flexion/extension) at six-month follow-up. Operative times, length of stay and any perioperative complications were also recorded.

Results

There were no significant differences between the robot-assisted and conventional groups for the pre-operative variables including age, body mass index (BMI), Oxford Knee Score, Knee Society Score and

Table 1
Registration Landmarks for ROBODOC TKA.

Type of Landmark	Landmark/Points Used for Registration
Anatomic points (Single surface points at specific locations)	Femur: Distal femoral condyle, anterior trochlea surface, medial epicondyle and lateral epicondyle Tibia: Proximal plateau, anterior condyle, medial condyle and Gerdy's tubercle
Band points (Single surface points in a longitudinal band on the long bone)	Femur: Proximal and distal femoral shaft Tibia: Proximal and distal tibial shaft
Region points (Multiple surface points collected within a specified bony region)	Femur: Anterior trochlea surface, medial and lateral epicondylar regions, medial and lateral femoral condyle regions Tibia: Articular surface, anterior–superior, anterior–medial and inferior–medial regions along tibial shaft
Cluster points (Multiple surface points collected in close vicinity to a specific bony landmark)	Femur: Medial epicondyle and medial and lateral posterior condyles Tibia: Medial to tibial tuberosity and medial condyle

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SF-36 scores. There was also no significant difference in length of stay (Table 2). The mean operating time for the robot-assisted group was 91 ± 10 min and 93 ± 15 for the conventional group ($P = 0.432$). Pre-operative planning yielded 100% femoral and tibial component sizing accuracy for the robot-assisted group.

At 6-month follow-up, there was no overall difference in terms of clinical outcome measures, except in SF-36 vitality scores, where the robot-assisted group reported higher vitality scores (Table 3).

There was no statistical difference noted in terms of absolute mechanical axis numbers, however, there were 19.4% ($P = 0.049$) coronal plane mechanical axis outliers (defined as malalignment > 3°) and 10.3% cases ($P = 0.238$) which had anterior femoral notching in the conventional group (Tables 4 and 5). None of the notches were clinically significant and resulted in complications. Our study also found a statistical difference in the AP femoral flexion angle between the robot-assisted and conventional groups ($P = 0.001$) (Table 4).

Our study showed that the robot-assisted group managed to restore the joint line more accurately than the conventional group (Table 4). Our study noted 3.2% joint line shift outliers in the robot-assisted group as compared to 20.6% in the conventional group ($P = 0.049$) (Table 5).

We did a subgroup analysis of the clinical outcome scores of the joint line shift outliers (>5 mm deviation) versus the non-outliers of the conventional group. There was no overall difference in terms of clinical outcome measures, except in SF-36 physical function scores, where the conventional group reported higher scores (Table 6).

The robot-assisted group had two local complications with one case of deep vein thrombosis (soleal vein) and one case of superficial wound site infection. The conventional group had one patient who suffered from post-operative delirium (systemic complication) and another patient with deep vein thrombosis (peroneal vein). All complications were managed non-surgically with no difference in complication rates between the two groups.

Discussion

Patients desire a durable TKA that is stable, provides pain relief and improves their function. To date, robot-assisted TKA has not been shown to improve clinical outcomes as compared to conventional methods in short-term follow-up studies. It also subjects patients to avoidable radiation risks and has not been shown to be cost-effectiveness since its inception. However, it has been shown to produce consistent and accurate post-operative mechanical alignment, which may prolong implant longevity [9–13]. This precise component implantation can be attributed to the following factors. First, a customised distal femoral resection angle for each patient as compared to a fixed resection angle (five to six degrees) used in conventional surgery is pre-operatively determined. A fixed resection angle has been associated with coronal plane mechanical axis deviation [18,19]. Second, accurate pre-operative determination of the rotational alignment of the femoral component was achieved when compared with conventional surgery. Studies have shown that estimation using either the transepicondylar axis, Whiteside's line or posterior condylar axis has only 65% to 80% accuracy [20–23]. Third, the accurate machining of bone surfaces by a robot-assisted procedure using a milling tool ranges from 0.15 to 0.29 mm versus 0.16 to 0.42 mm in a conventional procedure using an oscillating saw [9]. This is important as bony ingrowth can only occur with a maximum distance of 0.3 to 0.5 mm between bone and the implant [24,25]. The inaccuracies in bone sawing also result in the variability of implant alignment by up to 1.1° (standard deviation) of varus/valgus and 1.8° of flexion/extension [26] and this will occur even if the cutting guides are placed perfectly. The other advantages of robotic milling over conventional sawing are the reduced risk of neurovascular and ligamentous injuries, better prosthesis fitting with a theoretical advantage to be able to use cementless implants, circumventing complications related to cementation; and bony preservation to simplify future revision surgery [27]. Fourth, temperature of bone is maintained within the threshold of 44 °C to 47 °C with constant irrigation and control of the robotic milling speed. Temperatures beyond this threshold result in bony injury and compromised implant fixation and are frequently encountered during the use of an oscillating saw in conventional surgery [25,28].

Table 2
Patient Demographics, Pre-Operative Clinical Parameters and Length of Stay.

		Robot-Assisted	Conventional	*P* Value
Mean age in years		67.5 ± 8.6	68.3 ± 7.7	.709
Mean BMI in kg/m^2		27.5 ± 3.8	27.2 ± 4.9	.788
Mean LOS in days		5.2 ± 2.3	5.8 ± 3.8	.457
Mean operating duration in min		91 ± 10	93 ± 14	.432
Range of motion in degrees	Extension	6.8 ± 6.4	7.9 ± 7.1	.508
	Flexion	121.0 ± 17.4	119.8 ± 17.9	.792
Oxford knee score		34.4 ± 7.8	37.4 ± 8.7	.322
Knee society score	Function score	55.9 ± 16.9	51.0 ± 20.4	.360
	Knee score	34.2 ± 14.6	34.0 ± 17.1	.943
SF-36	Physical function	41.8 ± 21.6	33.1 ± 23.7	.144
	Role physical	21.8 ± 36.4	10.3 ± 24.6	.157
	Bodily pain	33.4 ± 16.6	28.0 ± 15.4	.192
	General health	75.7 ± 16.1	67.9 ± 25.1	.163
	Vitality	71.5 ± 20.3	66.0 ± 22.1	.326
	Social function	55.2 ± 36.5	48.7 ± 35.6	.486
	Role emotional	88.2 ± 31.7	77.0 ± 41.9	.252
	Mental health	81.3 ± 14.9	74.5 ± 21.3	.155

Table 3
Clinical Outcomes at Six-Month Follow-Up.

		Robot-Assisted	Conventional	*P* Value
Range of motion in degrees	Extension	5.3 ± 4.8	4.5 ± 4.0	.499
	Flexion	116.0 ± 17.8	122.4 ± 10.7	.112
Oxford knee score		18.8 ± 5.7	19.6 ± 6.8	.619
Knee society score	Function score	71.3 ± 18.5	70.0 ± 15.6	.791
	Knee score	80.8 ± 17.1	82.6 ± 14.7	.684
SF-36	Physical function	69.2 ± 22.6	60.0 ± 23.8	.160
	Role physical	80.2 ± 37.6	68.1 ± 39.5	.261
	Bodily pain	65.0 ± 27.1	64.8 ± 25.4	.986
	General health	76.9 ± 17.2	66.5 ± 21.6	.062
	Vitality	80.6 ± 16.1	67.6 ± 18.6	*.010*
	Social function	87.0 ± 26.2	87.1 ± 22.5	.989
	Role emotional	100 ± 0.0	92.0 ± 26.2	.109
	Mental health	89.5 ± 10.7	81.9 ± 16.1	.054

Table 4
Radiographic Results.

		Robot-Assisted	Conventional	*P* Value
Mechanical Axis	Pre-op	8.8 ± 4.6	8.6 ± 6.3	.892
	Post-op	1.3 ± 0.9	1.8 ± 1.2	.095
Knee Society Roentgenographic Evaluation and Scoring System	AP Femoral Flexion	95.5 ± 1.3	97.0 ± 1.9	*.001*
	AP Tibia Angle	89.7 ± 1.1	89.1 ± 1.8	.179
	LAT Femoral Flexion	2.2 ± 1.9	2.3 ± 2.4	.841
	LAT Tibia Angle	84.9 ± 2.0	85.0 ± 3.5	.893
Joint line measurements (Modified method of Kawamura et al)	Pre-op	11.7 ± 3.3	12.6 ± 3.6	.327
	Post-op	10.8 ± 2.9	14.6 ± 3.0	*.000*
	Difference	1.9 ± 1.1	3.5 ± 2.8	*.010*

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Table 5
Coronal Plane Mechanical Axis Outliers, Joint Line Shift Outliers and Cases With Notching in Both Groups.

	Robot-Assisted	Conventional	*P* Value
Coronal plane MA outliers (mal-alignment > 3°)	0/31	4/29 (19.4%)	*.049*
Joint line shift outliers (> 5 mm deviation)	1/31 (3.2%)	6/29 (20.6%)	*.049*
Cases with anterior femoral notching	0/31	3/29 (10.3%)	.238

The factors listed above contribute to the reduction in mechanical axis outliers in robot-assisted procedures as compared to conventional and navigation-assisted procedures (Table 7). Our study results resonate with current literature, demonstrating a zero percentage of mechanical axis outliers. With numerous studies indicating that a coronal mechanical alignment greater than 3° results in poorer patient outcome and decreased prosthetic survivorship, obtaining a consistent and accurate coronal plane mechanical axis may result in longer implant longevity and improved patient outcomes [29–32].

Joint line restoration in primary TKA has been well documented, contributing to range of motion, mid-flexion stability, patellofemoral joint mechanics and functional outcomes [41]. Restoring the native joint line is important and an alteration of 2 mm can reduce flexion [42]. Instability, particularly mid-flexion instability can occur with as little as 5 mm deviation of the joint line [43]. Elevation of the joint line can lead to increased patellofemoral contact forces and patella impingement [44]. The landmark study by Figgie et al highlighted the importance of preserving the joint line within 8 mm to avoid complications of anterior knee pain, stiffness and revision surgery [45]. Navigation has not been shown to improve joint line restoration [46]. Our study shows that robot-assisted TKA accurately restores the joint line, with only 3.2% outliers (defined as > 5 mm deviation) as compared to 20.6% in the conventional group. This may lead to a reduced incidence of knee instability and improved clinical outcomes for patients undergoing robot-assisted TKA. However, we did not detect any significant differences in clinical outcomes between the groups. Subgroup analysis of the conventional group revealed improved physical function in the non-outlier group at 6 months (67.0 ± 21.5 vs 45.0 ± 29.0, $P = 0.019$).

Although robot-assisted TKA improves mechanical alignment, however, no significant differences have been demonstrated in short-term and mid-term follow-up studies [10,33]. Our study did

Table 6
Subgroup Analysis of Joint-Line Outliers Versus Non-Outliers in the Conventional Group.

		Non-Outlier (< 5 mm) (n = 23)	Outlier (>5 mm) (n = 6)	*P* Value
Range of motion in degrees	Extension	5.2 ± 4.4	3.1 ± 3.8	.256
	Flexion	119.2 ± 15.1	121.4 ± 11.8	.713
Oxford knee score		19.1 ± 6.4	20.0 ± 5.3	.730
Knee society score	Function score	71.9 ± 16.4	62.1 ± 18.7	.157
	Knee score	82.2 ± 14.9	79.4 ± 21.6	.670
SF-36	Physical function	67.0 ± 21.5	45.0 ± 29.0	*.019*
	Role physical	73.9 ± 37.6	71.4 ± 48.8	.876
	Bodily pain	65.9 ± 26.3	58.4 ± 24.4	.485
	General health	72.2 ± 18.1	64.0 ± 31.8	.525
	Vitality	74.5 ± 17.9	67.1 ± 22.9	.336
	Social function	87.2 ± 23.6	85.7 ± 28.3	.878
	Role emotional	97.1 ± 15.4	85.7 ± 37.8	.460
	Mental health	85.4 ± 15.0	85.1 ± 8.9	.966

Table 7
Coronal Plane Mechanical Axis Outliers (Mal-Alignment > 3°) in Conventional, Navigation-Assisted and Robot-Assisted TKA.

Study	Robot-Assisted (%)	Navigation-Assisted (%)	Conventional (%)
Our study	0		19
Song et al [10]	0		24
Song et al [33]	0		23
Bellemans et al [9]	0		
Decking et al [13]	0		
Siebert et al [27]	2		
Chauhan et al [34]		15	33
Bathis et al [35]		4	23
Chin et al [36]		20	37
Confalonieri et al [37]		13	27
Sparmann et al [38]		0	13
Oberst et al [39]		0	38
Saragaglia et al [40]		16	24

not show any significant differences in terms of clinical outcomes at 6-month early follow-up.

There are several disadvantages to robot-assisted procedures. First, there is a need for additional avoidable radiation (pre-operative CT) that is not required in conventional procedures. Second, the lack of versatility intra-operatively results in abandonment of the robotic procedure and conversion to a conventional procedure. The reported rates are from 1% to 22% and this results in a waste of time and money to the patient and surgeon [9,11,12,47]. Third, robotic systems do not possess the technology to appreciate the nuances of soft tissue balancing and are unable to balance the knee, which, unfortunately, is paramount in TKA. However, Song et al showed that 94% of ROBODOC knees attained well-balanced rectangular flexion/extension gaps as compared to 80% in conventional knees [10]. They reasoned that this paradoxical result was due to precise implant positioning accompanied by the restoration of a premorbid joint line and normal tibial slope. This facilitated the process of soft tissue balancing. Fourth, a high start-up cost is required to operate a robotic surgical system (up to USD 800,000) and patients are required to bear the CT scan and operating costs for the operation in our institution (SGD 1600). In Europe, the cost of a robotic system was 400,000 Euros (approx. USD 545,000) and operating cost per case was 1000 Euros (approx. USD 1360) in 2007 [9,47,48]. Cost and other regulatory hurdles (government, insurance companies) will result in resistance to the acceptance of this new technology. The inception of robotic surgery into mainstream orthopaedics can only be advised after its clinical benefits and cost-effectiveness have been proven in controlled studies.

There was no significant difference between the complication rates of the robot-assisted and conventional groups in our study. In our study, the mean operating time of 91 min was similar to Song et al's and Borner et al's study (90 to 100 min) [10,11]. Limitations of our study were that it was not blinded as patients undergoing robot-assisted procedure had to bear the extra costs and the procedures were performed by 2 surgeons. There was no soft tissue balancing gap data, which would have been helpful to examine.

Robotics augment Orthopaedic surgeon's ability to execute his pre-operative plan with precision and accuracy. This is essential in knee arthroplasty as outcomes are influenced by precise component placement and our study has shown that robot-assisted TKA is capable of reducing mechanical axis outliers and accurately restoring the joint line. However, surgeons should remain cautious in adopting this new technology, as it is not a bed of roses. Current literature indicates that although robot-assisted TKA improves overall mechanical alignment, there has been no definite improvements in short-term clinical outcomes. Until the day that robotic surgery demonstrates a definite intermediate or long-term benefit, conventional TKA remains more cost-effective and provides better value to patients

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undergoing this procedure (due to similar clinical outcomes) and surgeons should be cautious about adopting this technology (or any other technology that produces similar results).

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