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Early experiences with robot-assisted total knee arthroplasty using the DigiMatch™ ROBODOC® surgical system

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INTRODUCTION The use of robotics in total knee arthroplasty (TKA) has been shown to minimise human error, as well as improve the accuracy and precision of component implantation and mechanical axis alignment. The present study aimed to demonstrate that robot-assisted TKA using ROBODOC® is safe and capable of producing a consistent and accurate postoperative mechanical axis.
METHODS We prospectively recruited 27 consecutive patients who underwent robot-assisted TKA between May and December 2012. Two patients were excluded from the study due to intraoperative technical problems with the robot. Long-leg radiography and computed tomography were performed prior to surgery, and used for mechanical axis measurements and component sizing. DigiMatch™ ROBODOC® Surgical System software version 4.3.6 (Curexo Technology Corp, Fremont, CA, USA) was used in all cases to perform bone cuts in accordance with the preoperative plan.
RESULTS The postoperative coronal mechanical alignment was within 3 degrees, with a mean alignment of −0.4 ± 1.7 degrees, confirming the accuracy of the preoperative surgical plan and bone cuts. The mean operating time was 96 ± 15 min, and preoperative planning yielded 100% implant sizing accuracy.
CONCLUSION Robotics has the potential to enable surgeons to consistently attain ideal postoperative alignment. The use of bone movement monitors and an integrated navigation system enhances the safety profile of ROBODOC® by minimising errors. However, the role of the surgeon in TKA is still vital, as the surgeon is ultimately in charge of planning the surgery, its execution and ensuring soft tissue balance during TKA.

Keywords: coronal mechanical axis alignment, ROBODOC®, robot-assisted, robotic surgery, total knee arthroplasty

INTRODUCTION

The use of robotics in orthopaedic surgery was employed in the 1980s to circumvent the high complication rates associated with the use of cementless total hip replacement implants.[1] Robotics in arthroplasty has always been of interest to orthopaedic surgeons because it is able to minimise human error, and improve the accuracy and precision of implantations.[2] A study on conventional total knee arthroplasty (TKA) revealed that conventional TKA was associated with a mechanical axis deviation of 9 degrees in 7% of patients, and > 5 degrees in 34% of cases.[3] In contrast, robot-assisted TKA promises excellent implant positioning and alignment, with errors within 1–3 degrees of neutral alignment.[4-5]

Other than excellent implant positioning and alignment, robot-assisted TKA has also been shown to consistently yield: (a) ideal postoperative mechanical alignment through individualisation of the distal femoral resection angle; (b) accurate rotational alignment of the femoral component; (c) accurate machining of bone surfaces with a milling device; and (d) good maintenance of bone temperature during machining, preventing bone injury. These characteristics may lead to reduced implant wear rates, and thus, longer prostheses survivorship.

We herein share our early experience with robotic surgery in our institution, with the aim of the present study being to demonstrate that robot-assisted TKA using ROBODOC® is safe and capable of producing a consistent and accurate postoperative mechanical axis.

METHODS

This prospective clinical study was carried out from May to December 2012. It was approved by our institution's Centralised Institutional Review Board and Ethics committee. A total of 27 consecutive patients who underwent robot-assisted TKA during the aforementioned period were enrolled in the study. The DigiMatch™ ROBODOC® Surgical System software version 4.3.6 (Curexo Technology Corp, Fremont, CA, USA) was used in all cases. Patients were recruited based on the diagnosis of primary knee osteoarthritis with genu varum deformity and a fixed flexion deformity < 15 degrees. All patients were informed of the benefits and risks of robot-assisted TKA and were aware of the increased operating time and costs. Patients with post-traumatic osteoarthritis, inflammatory arthropathy, ligamentous laxity, valgus knee deformities, pre-existing hip pathology or previous hip replacements were excluded from the study.

All patients underwent preoperative radiography (anteroposterior, lateral, skyline, long-leg films) and computed tomography (CT) of the affected lower limb. The CT images were used by the surgeons to perform virtual surgery using the ORTHODOC® software version 4.6.2 (Curexo Technology Corp, Fremont, CA, USA), 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 implants of the desired sizes (Fig. 1) and virtual hip-knee-ankle axis of zero degrees were generated for each

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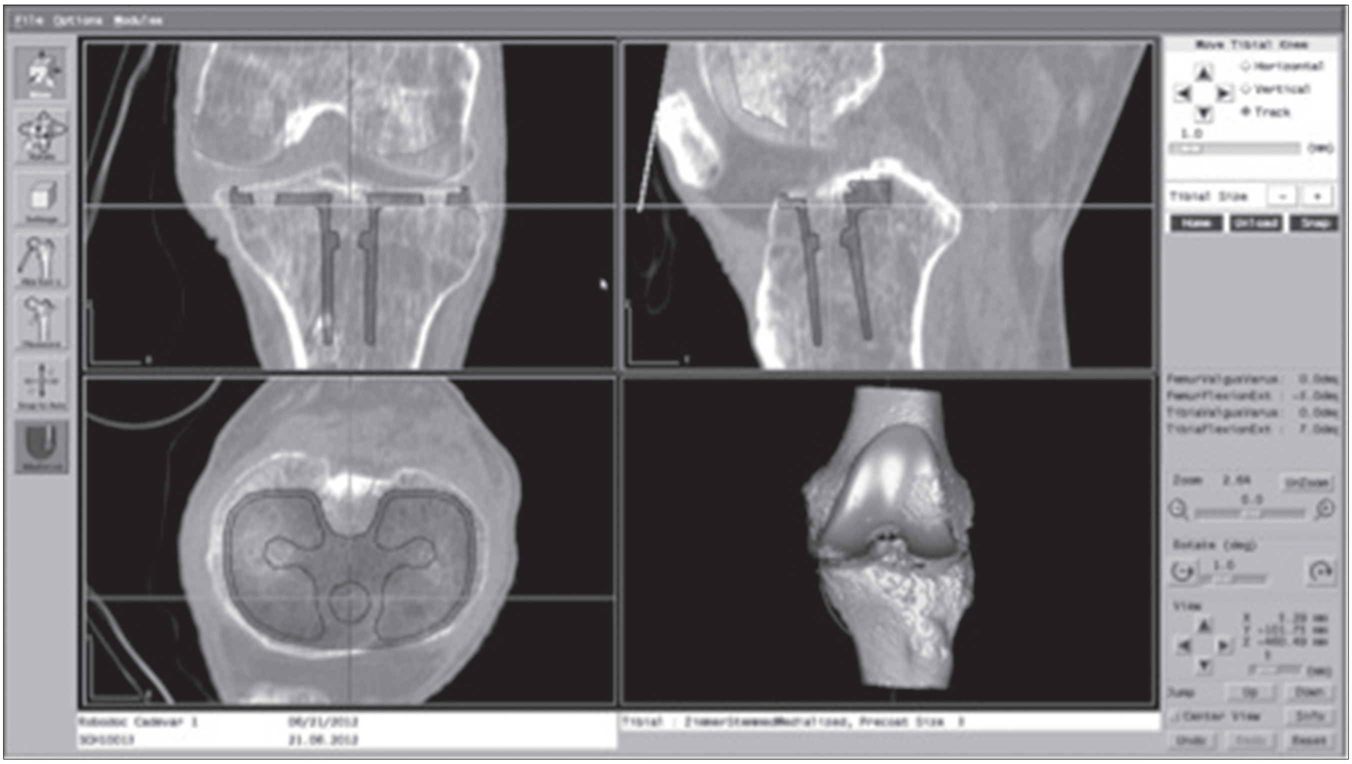

Fig. 1 Screenshot shows virtual implantation during ORTHODOC® preoperative virtual surgical planning.

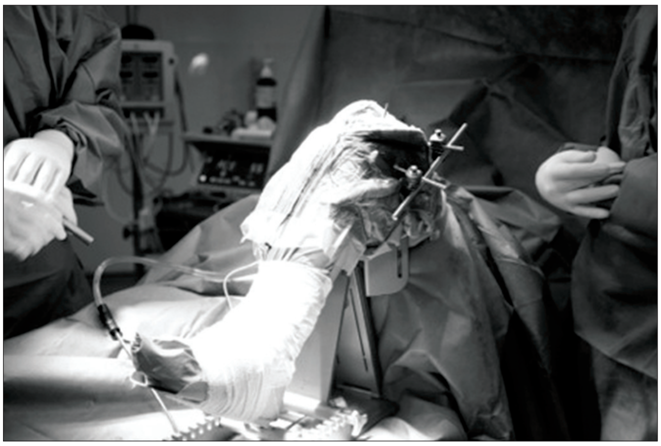

Fig. 2 Photograph shows the transverse stabilisation pins on the lateral side of the knee.

patient and saved onto a compact disc. This information was uploaded to ROBODOC® prior to surgery. For each patient, the time taken for the virtual surgery was about 15–20 min.

All surgeries were performed by two surgeons at a single institution. In all cases, a standard medial parapatellar approach, with patella eversion and patelloplasty, was performed. Stabilisation pins, navigation markers and bone movement monitors were put in place and workspace checks conducted prior to the rigid mating of the patient to ROBODOC® (Fig. 2). The patient was rigidly connected to ROBODOC® via two transverse stabilisation pins in the distal femur and proximal tibia. These two pins were connected to a frame that was coupled to ROBODOC® (Fig. 3).

The surgeon identified anatomic landmarks on the femur and the tibia (Fig. 4) as part of the registration process. Once registration was complete, the surgeon activated ROBODOC®, which used a milling cutter to complete all femoral and tibia bone cuts (Fig. 5). This process is aided by constant water irrigation for cooling and the removal of milling debris. Soft tissue balancing and a trial of the predetermined femur and tibia components were performed after the milling process. Finalised components were implanted, and stability, patellar tracking and range of motion were assessed. All patients were implanted with predetermined Zimmer NexGen®

Fig. 3 Photograph shows a patient rigidly mated to ROBODOC®.

Fig. 4 Photograph shows a surgeon going through the integrated navigation and registration process.

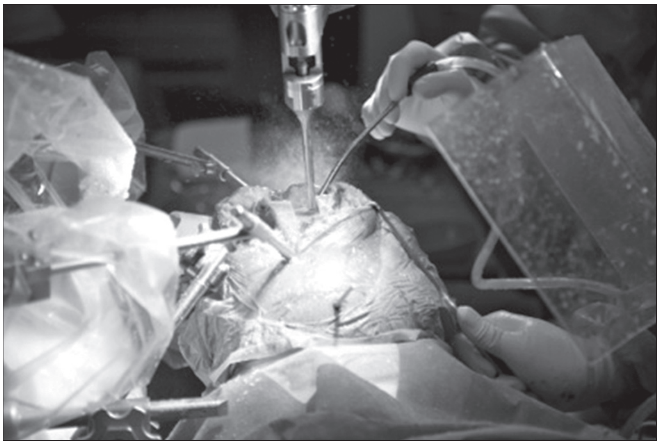

Fig. 5 Photograph shows ROBODOC® milling the femur.

LPS-Flex posterior-stabilised implants. An intrasynovial and intramuscular injection comprising bupivacaine/adrenaline and ketorolac was given if there were no contraindications.

Postoperatively, all patients received low-molecular-weight heparin and mechanical calf pumps for thromboprophylaxis. Rehabilitation in accordance with the integrated care pathway was prescribed. Weight-bearing radiographies (anteroposterior, lateral, skyline, long- leg films) were performed at the specialist outpatient clinic at one-month follow-up. Coronal plane mechanical axis measurements, using the angle between the mechanical femoral axis (i.e. the line connecting the centre of femoral head and the centre of intercondylar notch) and the mechanical axis of the tibia (i.e. the line connecting the centre of tibia plateau and the centre of ankle) on weight-bearing long-leg films, were calculated by two independent clinicians not involved in the surgical procedures.

RESULTS

Our study prospectively recruited a total of 27 consecutive patients who underwent robot-assisted unilateral TKA during the study period. However, 2 of these 27 patients were excluded from the study due to intraoperative technical problems with the robot. In the first case, the problem was due to a workspace software error that could not be rectified, while for the second case, the problem was due to a faulty motor that required replacement. In both cases, the robot-assisted TKAs were converted into conventional total knee replacements, with no complications encountered. None of our patients were lost to follow-up. The demographics of the 25 patients enrolled in the present study are listed in Table I.

Table I. Patient demographics (n = 25).

Parameter	No. (%)
Gender	
Male	6* (24.0)
Female	19† (76.0)
Mean age‡ (yr)	67.4 ± 8.5
Body mass index‡ (kg/m²)	28.1 ± 3.9
Length of stay‡ (days)	4.4 ± 1.1
Diagnosis of osteoarthritis	25 (100.0)
Zimmer NexGen® LPS FLEX prosthesis	25 (100.0)

*Of the 6, 2 were left-sided and 4 were right-sided. †Of the 19, 10 were left-sided and 9 were right-sided. ‡Data is presented as mean ± standard deviation.

Table II. Pre- and postoperative range of motion and function scores.

Parameter	Mean ± standard deviation	
	Pre-op	Post-op*
Range of motion (degrees)		
Extension	6.3 ± 5.7	4.4 ± 4.6
Flexion	120 ± 16.1	117.2 ± 14.4
Function score		
Oxford knee score	33.4 ± 8.1	68.9 ± 5.5
Knee function score	50.8 ± 19.2	82.3 ± 17.3
Knee society score	34.5 ± 14.2	18.8 ± 16.4

*Postoperative follow-up was conducted 6 months after surgery.

Two independent clinicians separately reviewed the long-leg radiographs of the 25 patients. The preoperative mean lower limb mechanical axis was 9.8 ± 4.1 degrees and the postoperative mean lower limb mechanical axis was –0.4 ± 1.7 degrees (negative values denote valgus alignment, while positive values denote varus alignment). The first few cases had longer operating times due to initial familiarisation with the new robot-assisted surgical technique. Once they were familiar with the technique, operating time was reduced. The mean operating time was 96 ± 15 min. The mean surgical incision length was 13.8 ± 1.0 cm. Preoperative planning yielded 100% femoral and tibial component sizing accuracy. The pre- and postoperative (at follow-up six months after surgery) range of motion and function scores are detailed in Table II.

No early complications arose from the use of stabilisation markers and pins. No superficial or deep joint infections, deep vein thrombosis, loosening of prosthesis or perioperative mortality occurred in the present study. The pre- and postoperative long-leg radiographs of a patient who underwent robot-assisted TKA using ROBODOC® are shown in Fig. 6.

DISCUSSION

Robot-assisted TKA has been shown to produce consistent and accurate postoperative mechanical alignment, which may result in longer implant survivorship.[4-9] Its ability to achieve precise component implantation can be attributed to four factors. First, unlike conventional surgery where a fixed resection angle

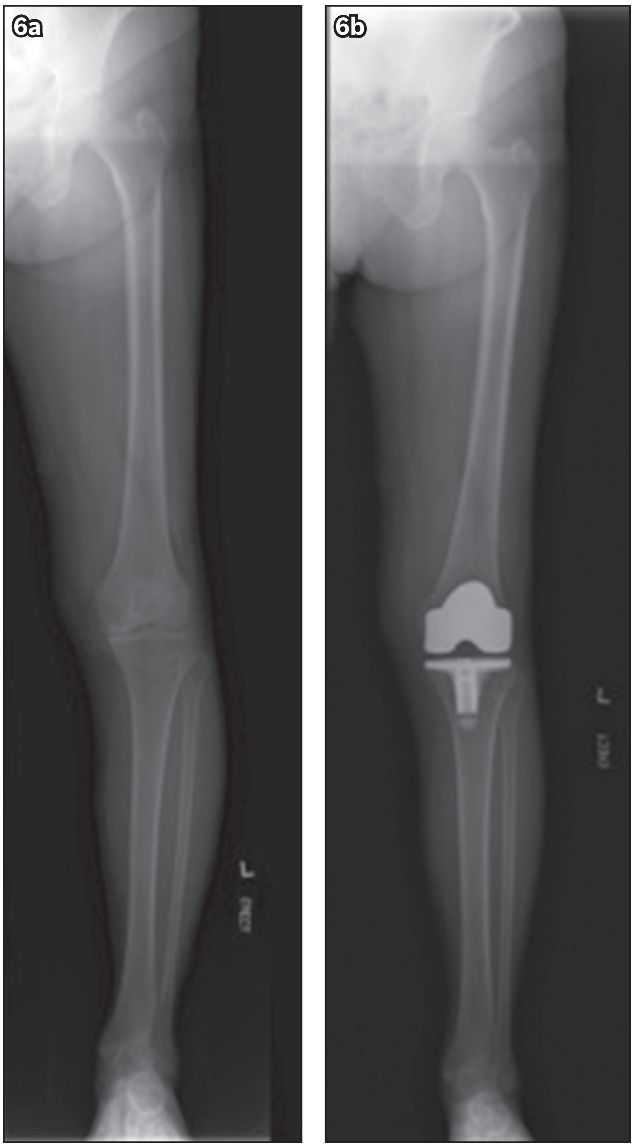

Fig. 6 Long-leg radiographs show the leg of a patient (a) before and (b) after robot-assisted total knee arthroplasty using ROBODOC®.

(i.e. 5–6 degrees) is used, the distal femoral resection angle for each patient is customised and preoperatively determined in robot-assisted TKA. A fixed resection angle has been associated with coronal plane mechanical axis deviation.[6,7] Second, compared to conventional surgery, we found that robot-assisted TKA was able to achieve accurate preoperative determination of the rotational alignment of the femoral component. Studies have shown that estimation using either the transepicondylar axis, Whiteside's line or posterior condylar axis has an accuracy of only 65%–80%.[8-15] Third, the accurate machining of bone surfaces via robot-assisted TKA using a milling tool ranges from 0.15 mm to 0.29 mm, while that of a conventional procedure using an oscillating saw ranges from 0.16 mm to 0.42 mm.[4] Accurate machining of the bone surfaces is important, as bony ingrowth can only occur with a maximum distance of 0.3–0.5 mm between the bone and the implant.[16,17] Fourth, in robot-assisted TKA, the temperature of the bone is maintained within the threshold of 44°C–47°C, with constant irrigation and control of the robotic milling speed. Temperatures going beyond this threshold are frequently encountered during

Table III. The percentages of coronal plane mechanical axis outliers (i.e. malalignment > 3 degrees) in conventional, navigation-assisted and robot-assisted TKA.

Study	Mechanical axis outliers (%)		
	Robot-assisted	Navigation-assisted	Conventional
Present study	0	-	-
Bellemans et al[4]	0	-	-
Song et al[5]	0	-	24
Decking et al[8]	0	-	-
Song et al[23]	0	-	23
Siebert et al[24]	2	-	-
Chauhan et al[25]	-	15	33
Bathis et al[26]	-	4	23
Chin et al[27]	-	20	37
Confalonieri et al[28]	-	13	27
Sparmann et al[29]	-	0	13
Oberst et al[30]	-	0	38
Saragaglia et al[31]	-	16	24

the use of an oscillating saw in conventional surgery, resulting in potential bony injury and compromised implant fixation.[17,18]

The factors listed in the previous paragraph contribute to the reduction in mechanical axis outliers in robot-assisted procedures, as compared to conventional and navigation-assisted procedures (Table III). As numerous studies have indicated that a coronal mechanical alignment of greater than 3 degrees results in poorer patient outcomes and decreased prosthetic survivorship, obtaining a consistent and accurate coronal plane mechanical axis may result in improved patient outcomes and longer implant survivorship.[19-22]

The use of ROBODOC®, an autonomous robot, is safe and reliable for the following reasons: (a) multiple verification points are required to confirm the exact spatial orientation of the bone in relation to the robot; (b) the robot is programmed to automatically shut down if bone movement exceeds a certain threshold during surgery; and (c) the surgeon is able to intervene and stop the robot at any time, if required.

Some studies have reported femur shaft fractures,[32,33] patella tendon abrasions and pin site seroma formation in navigation-assisted TKA procedures.[5,34] Fortunately, no fracture- or soft tissue-related complications arose from the use of stabilisation pins in the present study. Peersman et al have shown that an increased risk of infection is associated with a prolonged operating time.[35] The mean operating time in the present study (i.e. 96 min) was similar to those noted in Song et al's and Borner et al's studies (i.e. 90–100 min).[5,6] Although the initial few robot-assisted procedures in the present study took more than 120 min, our surgeons subsequently managed to reduce the operating time, and no superficial or deep infections were encountered.

However, there are several disadvantages to robot-assisted procedures. First, there is a need for additional radiation (e.g. preoperative CT) that is not required in conventional procedures. Second, there is a lack of intraoperative versatility with robot-assisted procedures. This may result in abandonment of the robotic procedure and conversion to a conventional procedure, incurring additional costs (i.e. monetary and time) to both the patient and surgeon. The reported rates of aborted robot-assisted procedures range from 1% to 22%.[4,6,7,34] In the present study, the rate of abortion was 7.4% (2 out of 27; one was aborted due to an error in workspace recognition, while another was aborted due to a hardware motor failure). Third, robotic systems do not possess the technological ability to appreciate the nuances of soft tissue balancing and are thus unable to balance the knee, which is paramount in TKA. However, Song et al showed that 94% of ROBODOC®-treated knees attained well-balanced rectangular flexion/extension gaps, as compared to 80% in conventionally treated knees.[5] The authors reasoned that this paradoxical result was due to the precise implant positioning in robot-assisted procedures, which promotes good restoration of the premorbid joint line and normal tibial slope, facilitating the process of soft tissue balancing. Fourth, a high startup cost is required to operate a robotic surgical system, and patients are required to bear the cost of CT and the operation performed in our institution (SGD 1,600). In Europe in 2007, the cost of a robotic system was €400,000 (~ USD 545,000) and the operating cost per case was €1,000 (~ USD 1,360).[4] Cost and other regulatory hurdles (e.g. government and insurance company policies) 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.

Furthermore, the present study was a prospective, small group, safety audit of the ROBODOC® system during its initial implementation at our institution. A limitation of the present study is that it was a purely descriptive study that lacked a control group. However, a follow-up, randomised prospective study comparing between robot-assisted and conventional TKA is currently underway.

In conclusion, we echo the sentiments of Dr William Bargar, who believes that we are currently in the 'preindustrial' phase of surgical evolution.[36] In time, the use of robotics will become widespread, allowing surgeons to attain reproducible and accurate results that will eliminate undesirable patient outcomes. The results of the present study provide evidence that robot-assisted TKA using the ROBODOC® system is safe and capable of producing a consistent postoperative coronal mechanical alignment (within 3 degrees), with minimal complications.

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