

## BIOMEDICAL PAPER

# Comparison of robot-assisted and conventional total knee arthroplasty: A controlled cadaver study using multiparameter quantitative three-dimensional CT assessment of alignment

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### Abstract

**Introduction:** A functional total knee replacement has to be well aligned, which implies that it should lie along the mechanical axis and in the correct axial and rotational planes. Incorrect alignment will lead to abnormal wear, early mechanical loosening, and patellofemoral problems. There has been increased interest of late in total knee arthroplasty with robotic assistance. This study was conducted to determine whether robot-assisted total knee arthroplasty is superior to the conventional surgical method with regard to the precision of implant positioning.

**Materials and Methods:** Twenty knee replacements, comprising ten robot-assisted procedures and ten conventional operations, were performed on ten cadavers. Two experienced surgeons performed the surgeries. Both procedures on each cadaver were performed by the same surgeon. The choice of which procedure was to be performed first was randomized. Following implantation of the prosthesis, the mechanical axis deviation, femoral coronal angle, tibial coronal angle, femoral sagittal angle, tibial sagittal angle, and femoral rotational alignment were measured via 3D CT scanning. These variables were then compared with the preoperatively planned values.

**Results:** In the knees that underwent robot-assisted surgery, the mechanical axis deviation ranged from  $-1.94^{\circ}$  to  $2.13^{\circ}$  (mean:  $-0.21^{\circ}$ ), the femoral coronal angle from  $88.08^{\circ}$  to  $90.99^{\circ}$  (mean:  $89.81^{\circ}$ ), the tibial coronal angle from  $89.01^{\circ}$  to  $92.36^{\circ}$  (mean:  $90.42^{\circ}$ ), the tibial sagittal angle from  $81.72^{\circ}$  to  $86.24^{\circ}$  (mean:  $83.20^{\circ}$ ), and the femoral rotational alignment from  $0.02^{\circ}$  to  $1.15^{\circ}$  (mean:  $0.52^{\circ}$ ) in relation to the transepicondylar axis. In the knees that underwent conventional surgery, the mechanical axis deviation ranged from  $-3.19^{\circ}$  to  $3.84^{\circ}$  (mean:  $-0.48^{\circ}$ ), the femoral coronal angle from  $88.36^{\circ}$  to  $92.29^{\circ}$  (mean:  $90.50^{\circ}$ ), the tibial coronal angle from  $88.15^{\circ}$  to  $91.51^{\circ}$  (mean:  $89.83^{\circ}$ ), the tibial sagittal angle from  $80.06^{\circ}$  to  $87.34^{\circ}$  (mean:  $84.50^{\circ}$ ), and the femoral rotational alignment from  $0.32^{\circ}$  to  $4.13^{\circ}$  (mean:  $2.76^{\circ}$ ) in relation to the transepicondylar axis. In the conventional knee replacement group, there were two instances of outliers outside the range of  $3^{\circ}$  varus/valgus for the mechanical axis deviation. The robot-assisted knee replacements showed significantly superior femoral rotational alignment results compared with conventional surgery ( $p = 0.006$ ). There was no statistically significant difference between robot-assisted and conventional total knee arthroplasty with regard to the other variables. All the measurements showed high intra-observer and inter-observer reliability.

**Conclusion:** Robot-assisted total knee arthroplasty showed excellent precision in the sagittal and coronal planes of the 3D CT scan. In particular, the robot-assisted technique showed better accuracy in femoral rotational alignment compared to the conventional surgery, despite the fact that the surgeons who performed the operations were more experienced and familiar with the conventional method than with robot-assisted surgery. It can thus be concluded that robot-assisted total knee arthroplasty is superior to conventional total knee arthroplasty.

**Keywords:** *Total knee arthroplasty, robot-assisted surgery, conventional surgery, mechanical axis*

## Introduction

Accurate alignment of the components and soft tissue balancing have been cited as two of the most important factors in successful knee arthroplasty [1, 2]. Incorrect alignment can lead to abnormal wear [3, 4], early mechanical loosening of the components [5, 6], and patellofemoral problems [7, 8]. Deviations of greater than  $3^\circ$  varus/valgus will increase the rate of loosening in the coronal plane [5, 9], and the posterior tilting of the tibial component will affect the femoral rollback on the tibia, the tension of the posterior cruciate ligament, and the range of motion in the sagittal plane [4, 10, 11]. Anterior knee pain and patellar subluxation can be caused by the excessive internal rotation of the components in the transverse plane [12, 13].

Conventionally, alignment is facilitated using mechanical jigs, which consist of intramedullary or extramedullary devices or a combination of the two. Computer-assisted navigation systems have been designed to increase the precision of the implantation of the components [14, 15]. However, whether the conventional jig-based technique and the computer-assisted navigation system can achieve sufficient accuracy in the spatial positioning of an implant is a matter of debate [16]. Recently, a robot-assisted system was introduced which provides precise control of the operative instruments, but an evaluation of the effectiveness of robot-assisted total knee arthroplasty (TKA) compared with that of the conventional procedure performed on the same individuals was not conducted. Hence, the present study was undertaken to compare the robot-assisted TKA method with the conventional surgical method in a controlled cadaver study, using three-dimensional (3D) CT alignment assessment to evaluate the mechanical axis deviation and implant alignment.

## Materials and methods

Twenty knee replacements were performed on ten fresh cadavers. For each cadaver, one knee was replaced using the conventional operative technique, and the other was replaced using the robot-assisted technique. The choice of which procedure to perform first was randomized. Two surgeons performed the series of operations, but both procedures on a given cadaver were performed by the same surgeon. Both surgeons had considerable experience in conventional total knee replacement but were relatively unskilled at robot-assisted surgery.

The ROBODOC system (Curexo, Inc., Anyang City, South Korea) was used in the robot-assisted TKA procedures. The NexGen cruciate-retaining total knee prosthesis (Zimmer, Warsaw, IN) with a fixed bearing was applied to all the knees.

### *Radiographic evaluations*

The mechanical axis deviation, femoral coronal angle, tibial coronal angle, femoral sagittal angle, and tibial sagittal angle were measured preoperatively via 3D CT scanning. Following implantation of the prosthesis, these variables were measured again using the same method (Figure 1), and the rotational alignment of the femoral component was evaluated in relation to the transepicondylar axis (Figure 2). In each case, the mechanical axis of the knee was assessed preoperatively and postoperatively using the hip-knee-ankle (HKA) angle as determined using a true coronal view of the whole lower extremity in 3D CT. The hip, femoral notch, and ankle centers were assigned and connected, and the angle between these lines was defined as the mechanical axis angle of the knee. The femoral coronal angle is the medial angle between the mechanical axis of the femur and a line connecting the distal points of the medial and lateral condyles of the femoral component. The femoral sagittal angle is the angle between the perpendicular line running proximally from the distal femoral surface in contact with the femoral component and the mechanical axis of the femur in the sagittal plane. The tibial coronal angle is the medial angle between the undersurface of the tibial tray and the anatomical axis of the tibia in the coronal plane. The tibial sagittal angle is the medial angle between the undersurface of the tibial tray and the anatomical axis of the tibia in the sagittal plane. The tibial anatomical axis was defined as a straight line connecting the upper and lower midpoints of the tibial shaft, at 7 cm below the tibial tubercle and 7 cm above the plafond, respectively. This axis was used as a reference because it is the closest to the mechanical axis in the coronal and sagittal planes, and because the mechanical axis determined using a point in the plateau cannot be used after proximal tibial resection in TKA [17].

### *CT and preoperative planning*

Pre- and postoperative CT images of each cadaver were acquired with a BrightSpeed Edge WCT-440-140 eight-channel scanner (GE Healthcare, Milwaukee, WI). During CT scanning, the leg was fully extended. To obtain a 3D image, the whole leg was scanned from the femoral head through the knee joint to the ankle joint, but only

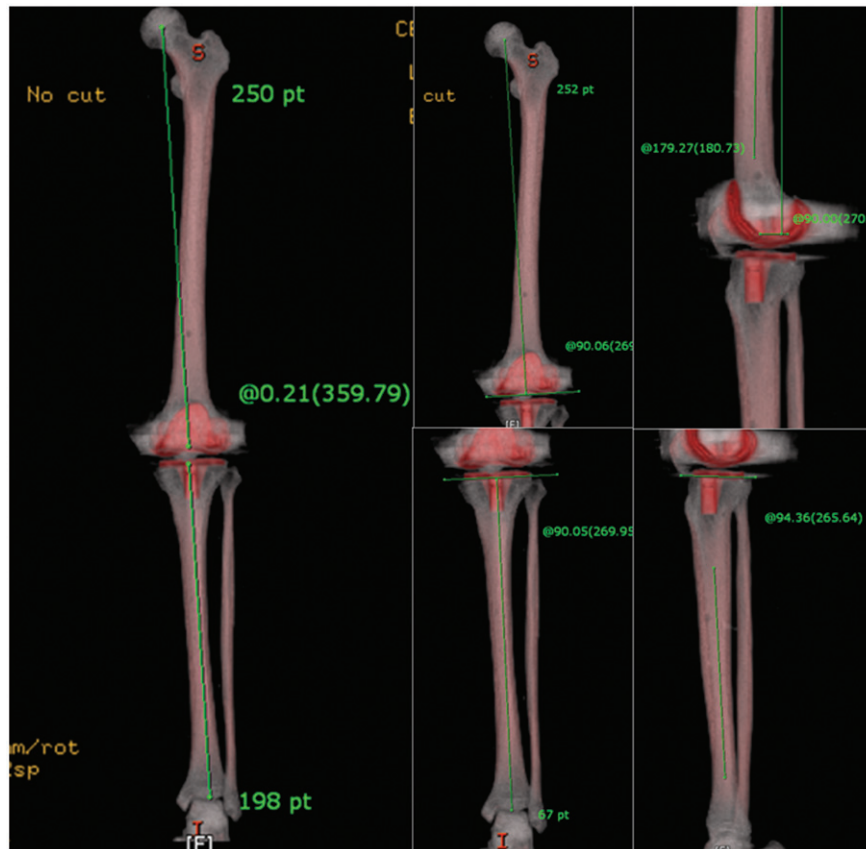


Figure 1. Preoperatively, the mechanical axis deviation, femoral coronal angle, tibial coronal angle, femoral sagittal angle, and tibial sagittal angle were measured by 3-dimensional CT scanning.

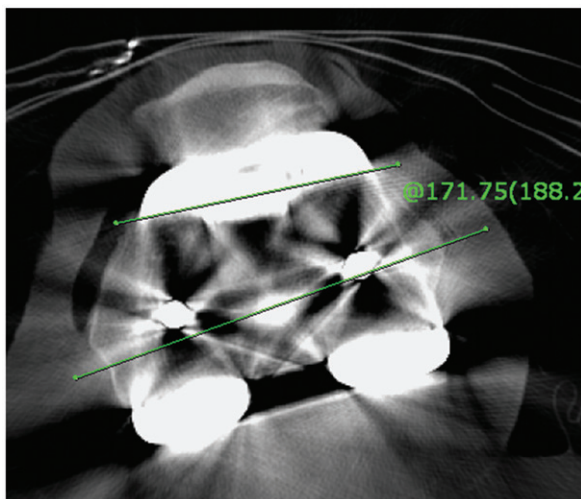


Figure 2. Rotational alignment of the femoral component was measured postoperatively using a transverse section of the CT scan.

three volumes were required for preoperative planning with ORTHODOC: the femoral head, knee joint, and ankle joint (Figure 3). The field of view was 250 mm for all scan slices, and the X/Y centers

were identical for all volumes. The scan parameters for the femoral head, knee joint, and ankle joint were 120 kV, 200 mAs, 0.9 mm pitch, and 1.25 mm slice thickness. The data were transferred to the preoperative planning software in ORTHODOC. CT data provide ORTHODOC with input regarding the patient's anatomy and the data required for building 3D images of the bone for computerized templating. The data must be obtained using the appropriate CT protocol provided in the ORTHODOC manual.

To properly position the milled implant surfaces, ROBODOC requires information about the spatial orientation of the planned surfaces. This information may be obtained by performing the DigiMatch surface registration procedures. The scan provides ORTHODOC with input to create 3D surface model images of the bone for computerized templating. The integrity of the data sets produced by axial and spiral (helical) scans results in a similar degree of placement accuracy. After transferring the CT data to ORTHODOC, the surgeon chose the type and size of the components and polyethylene from the menus and positioned them freely via

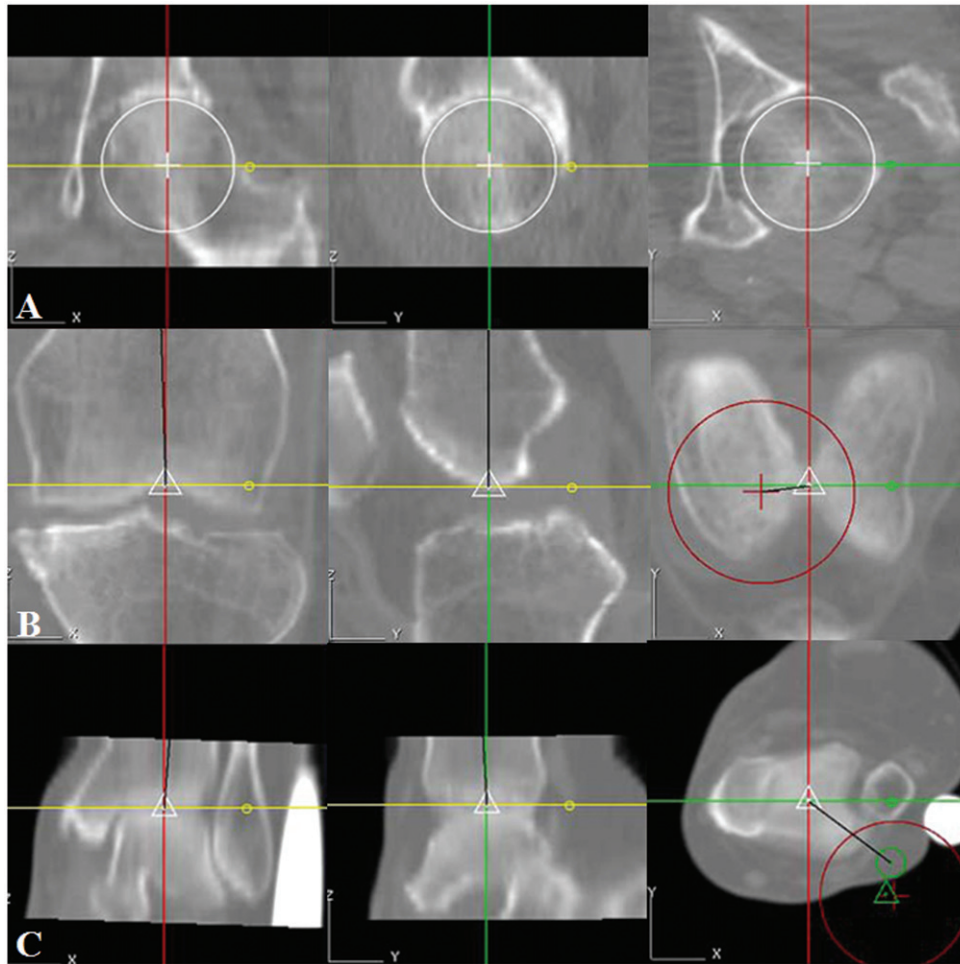


Figure 3. To obtain a 3D image, the whole leg was scanned from the femoral head through the knee joint to the ankle joint. However, preoperative planning with ORTHODOC requires only three volumes: the femoral head (A), the knee joint (B), and the ankle joint (C).

mouse control using the ORTHODOC software (Figure 4). The height of the joint line, the varus/valgus alignment of the components in the frontal plane, their slope in the sagittal plane, and their rotation in the transverse plane were set individually in increments as low as  $0.1^\circ$  or 0.1 mm, as desired. The final position of the virtual components was transferred to the control unit of the robot via a PC card.

#### *Robot-assisted TKA*

A conventional medial parapatellar approach to the knee joint was used. The knee was flexed and rigidly fixed (Figure 5). The surgeon oriented the robot by guiding the digitizing probe to specific locations on the bone surface. The ROBODOC robot probed the registration markers in the femur and tibia, thus matching the CT images to the reality. The robot-controlled computer compared the digitized

points to the coordinate locations contained in the ORTHODOC file to determine the position of the femur and tibia. When the surface registration was complete, the surgeon digitized the motion recovery posts to ensure that the procedure could be resumed in the event that bone motion occurred. The surgeon replaced the digitizing probe with a cutter, and a technician connected the gas and irrigation supply lines. The surgeon guided the milling cutter to a position near the distal femur, and the robot then milled the femoral volumes with a high-speed milling tool attached to its arm (Figure 6). While the robot was cutting the distal femur, the surgeon observed the procedure on the OR monitor to ensure there was continuous irrigation of the area around the cutter. The OR monitor showed the progress of the robot as it machined the bone preparation. The surgeon could pause or stop the bone preparation at any time by pressing a button on the pendant. The surgeon then guided the

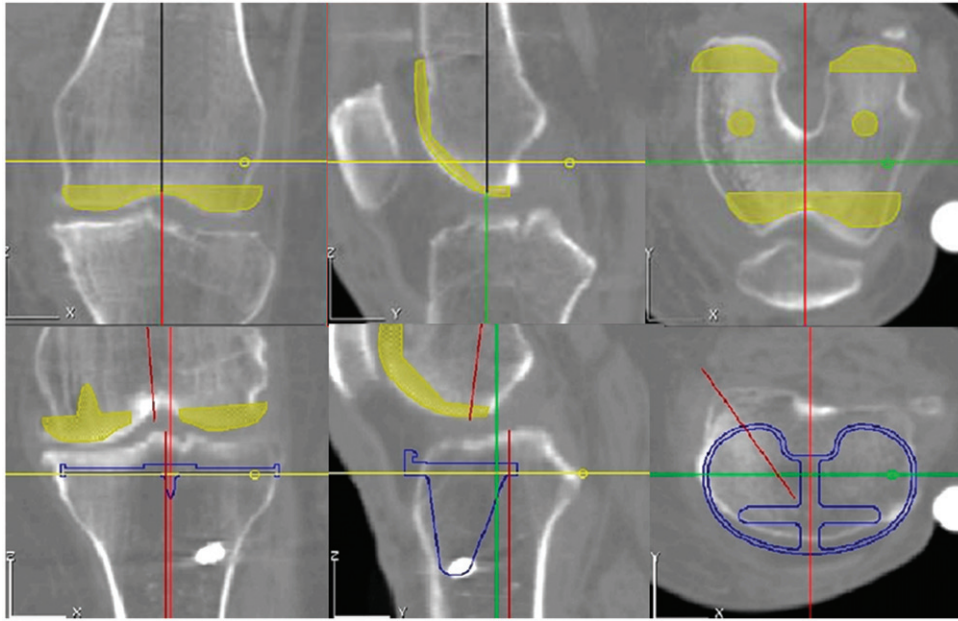


Figure 4. Transferring the CT data to ORTHODOC, the surgeon selected the type and size of component and the polyethylene from the menus and positioned them freely via mouse control with the ORTHODOC software.

milling cutter to a position near the proximal tibia and performed tibial cutting using the same method. When the bone preparation of the femur and tibia was complete, the robot arm was withdrawn from the operative field, the surgeon removed the femoral and tibial fixator and the bone motion monitor, and a technician moved the robot away from the OR table. Internal water cooling and irrigation was integrated into the milling tool, and different milling cutters ranging from 9 to 2.5 mm in diameter were used. The fixation frame and locator screws were removed after milling completion, the trial implants were placed, and the soft tissues were balanced as usual. The components were then inserted manually.

#### *Implants and alignment parameters*

In the planning software, the mechanical axis was set to  $0^\circ$ . The tibial and femoral components were aligned perpendicular to the mechanical axis in the coronal plane. A positive value for the measured mechanical axis deviation corresponds to varus, and a negative value means the opposite. In the sagittal plane, the posterior slope of the tibial components was set to  $7^\circ$ , and the slope of the femoral components was set on a case-by-case basis. In the transverse plane, the external rotation of the femoral components was set on a case-by-case basis in relation to the transepicondylar axis. The rotation of

the tibial components was then aligned with the rotation of the femoral component.

#### *Statistics*

The variables measured for the robot-assisted surgery were compared with those for the conventional surgery. Wilcoxon's signed rank test was applied to determine if the differences between outcomes with the two approaches were statistically significant.

Two observers measured the pre- and post-operative CT scans twice each at one-month intervals. The differences between the preoperatively planned and postoperatively achieved parameters were calculated based on these measurements. The inter-observer and intra-observer reliability were described by the intraclass correlation coefficients (ICCs).

## **Results**

#### *Mechanical axis deviation*

The mechanical axis deviation ranged from  $-1.94^\circ$  to  $2.13^\circ$  (mean:  $-0.21^\circ$ ) in the robot-assisted surgery group and from  $-3.19^\circ$  to  $3.84^\circ$  (mean:  $-0.48^\circ$ ) in the conventional surgery group. The difference between the two groups was not significant ( $p=1.000$ ). There were two instances of outliers outside the range of  $3^\circ$  varus/valgus for

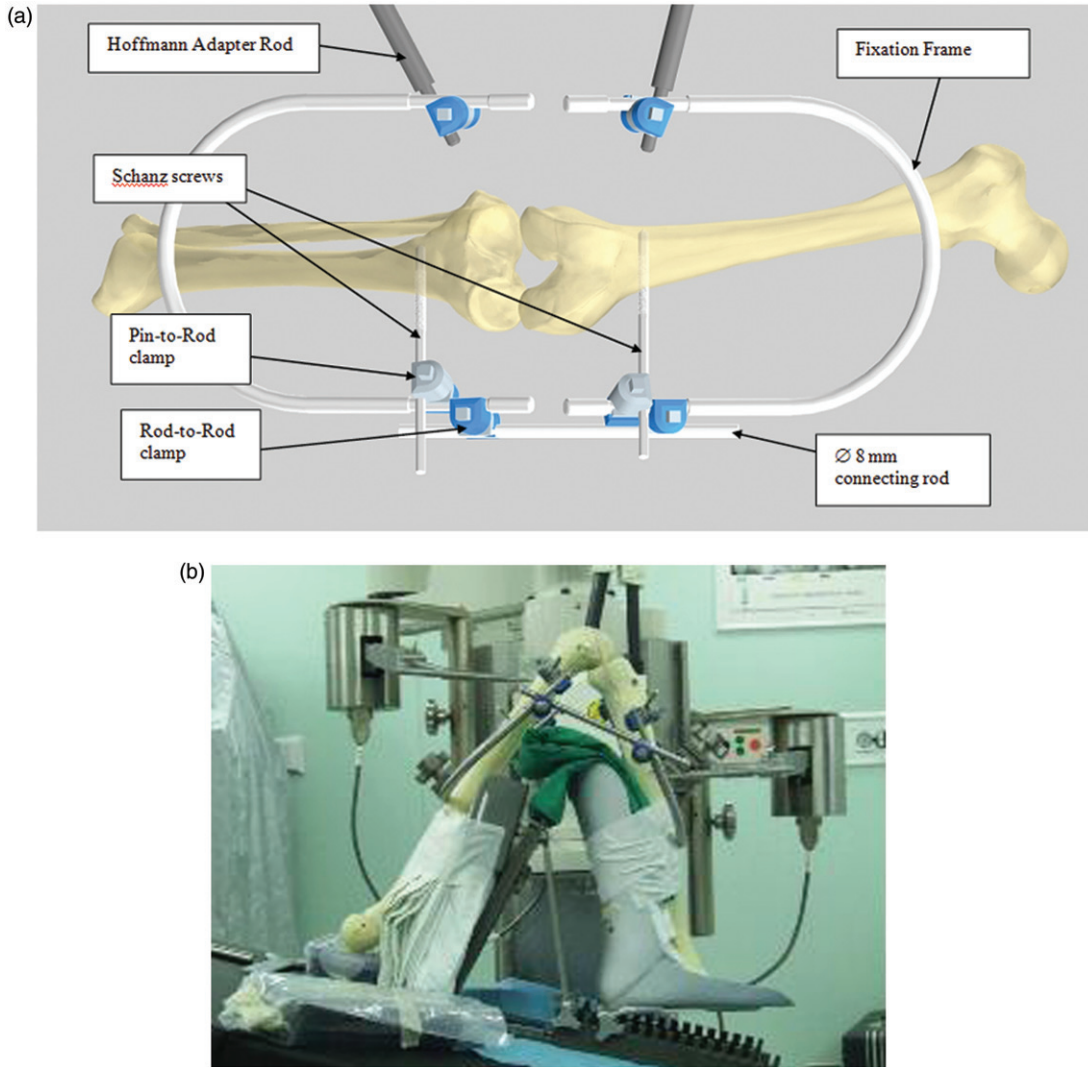


Figure 5. Robot-assisted TKA. The knee was flexed and rigidly fixed by two Schanz screws, fixation frames, connecting rods, pin-to-rod clamps, rod-to-rod clamps and Hoffmann adapter rods.

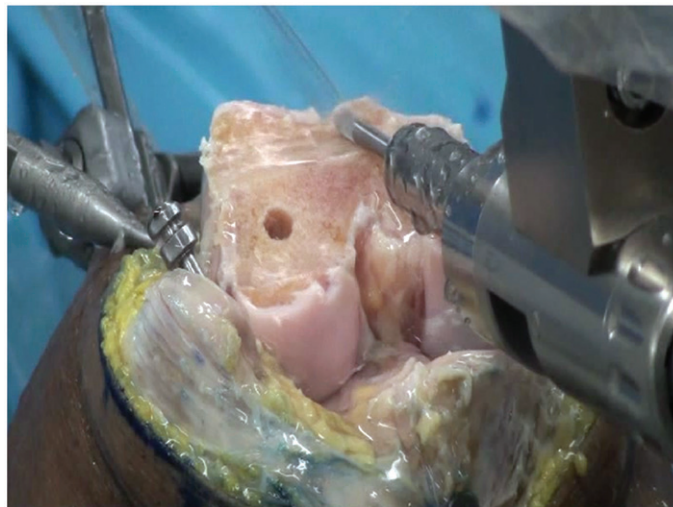


Figure 6. The robot milled the femoral volumes with a high-speed milling tool attached to its arm. Better surface quality of femoral or tibial bone cuts can be achieved using high-speed milling cutters attached to robotic arms than with oscillating saws.

mechanical axis deviation in for the conventional surgery group, but all values were within  $3^\circ$  of the optimum alignment for those that underwent robot-assisted surgery.

#### *Femoral alignment*

The femoral coronal alignment ranged from  $88.08^\circ$  to  $90.99^\circ$  (mean:  $89.81^\circ$ ) in the robot-assisted surgery group and from  $88.36^\circ$  to  $92.29^\circ$  (mean:  $90.50^\circ$ ) in the conventional surgery group. The difference between the two groups was not significant ( $p=0.323$ ). There were no cases of outliers outside the range of  $3^\circ$  varus/valgus for the femoral coronal alignment in either group.

In relation to the transepicondylar axis, the femoral rotational alignment ranged from  $0.02^\circ$  to  $1.15^\circ$  (mean:  $0.52^\circ$ ) in the robot-assisted surgery group and from  $0.32^\circ$  to  $4.13^\circ$  (mean:  $2.76^\circ$ ) in the conventional surgery group. The difference between the two groups was highly significant ( $p=0.006$ ). In the conventional surgery group, there were two instances of outliers outside the range of  $3^\circ$  for the femoral rotational alignment.

Femoral sagittal alignment in the robot-assisted surgery group ranged from  $0.2^\circ$  to  $3.51^\circ$  (mean:  $2.21^\circ$ ), and in the conventional surgery group from  $3.22$  to  $6.14^\circ$  (mean:  $4.60^\circ$ ).

#### *Tibial alignment*

In the robot-assisted surgery group the tibial coronal alignment ranged from  $89.01^\circ$  to  $92.36^\circ$  (mean:  $90.42^\circ$ ), and in the conventional surgery group from  $88.15^\circ$  to  $91.51^\circ$  (mean:  $89.83^\circ$ ). The difference between the two groups was not significant ( $p=0.106$ ). There were no outliers outside the range of  $3^\circ$  varus/valgus for the tibial coronal alignment in either group.

Tibial sagittal alignment in the robot-assisted surgery group ranged from  $81.72^\circ$  to  $86.24^\circ$  (mean:  $83.20^\circ$ ), and in the conventional surgery group from  $80.06^\circ$  to  $87.34^\circ$  (mean:  $84.50^\circ$ ). The difference between the two groups was not significant ( $p=0.323$ ). There was one outlier outside the range of  $3^\circ$  for the tibial sagittal alignment in the robot-assisted surgery group, while there were two such cases in the conventional surgery group.

### **Discussion**

The first surgical robot for total joint arthroplasty was developed in 1986 [18]. Since then, several robot models have been developed and tested [19, 20]. The robot-assisted system can enable sophisticated CT-based preoperative planning and

precise execution. These evident benefits have been proven in several clinical trials [19, 20]. However, although studies of this type have been performed *in vivo*, the clinical literature is limited. If a surgeon has no previous experience with robot-assisted TKA, it is not easy to perform this type of surgery from the beginning. We believe that a cadaveric study is necessary to give surgeons the appropriate training and to enable them to gain confidence with the system. This study can add valuable insights into the basic characteristics of this surgical technique and help in the subsequent performance of surgery *in vivo*. To our knowledge, although several studies have evaluated the outcomes of robotic-assisted TKA [19, 21–23], there have been few studies comparing the radiographic outcomes of simultaneous bilateral TKA using a robot-assisted and a conventional procedure. Accordingly, we designed this prospective randomized study using cadaveric models. Although the radiographic results obtained in this study are similar to those reported in other studies, these results were evaluated with 3D CT scans by two independent observers, and the results are therefore believed to be more reliable than those of other studies which used plain radiographs.

Proper implant positioning in TKA is sometimes difficult to achieve with the current conventional jig-based technique using oscillating saws [24]. Plaskos et al. [25] compared the planes determined by cutting blocks attached to a cadaver femur and tibia with the resulting planes after bone resection with oscillating saws. They concluded that the inaccuracy of the bone resection using oscillating saws contributes  $0.6$  to  $1.1^\circ$  (SD) in varus/valgus and  $1.8^\circ$  in flexion-extension to the overall variability in implant alignment. The optimal alignment would be difficult to achieve even if mechanical or navigated alignment guides could place the cutting blocks in the perfect positions. Thus, a better surface quality and tibial-cut angular accuracy can be achieved by high-speed milling cutters attached to robot-assisted arms than with oscillating saws [26, 27]. In a clinical and conventional radiographic follow-up of 70 patients, Siebert et al. [23] reported a mechanical axis of  $0.8 \pm 1^\circ$  (mean  $\pm$  SD) and an average operating time of 135 min with robot-assisted TKA. Robotic milling leads to a better surface quality than that obtained with the use of oscillating saws. In the present study, there was a statistically significant improvement in only one of the six radiological parameters for alignment of the component using robot-assisted surgery as compared to conventional surgery, but almost as important as improved accuracy is the reduction in the number of outliers for the various radiographic parameters. The reduction in the number of

outliers was greater in the robot-assisted TKA group, despite the fact that the surgeons were more experienced and familiar with the conventional surgery than with robot-assisted TKA.

A cadaver study was considered necessary by the surgeons concerned prior to the introduction of the technique into clinical practice. Working on a small number of fresh cadavers is clearly not the same as surgical practice on live patients, however, and several questions remain unanswered. Concerns regarding robot-assisted TKA include soft tissue balancing, relative morbidity, the additional time required by robotic surgery, pain due to implanted fiducials and fixation jigs, and ease of use and the learning curve. In addition, a cadaveric study cannot investigate clinical follow-up results such as knee scores.

In this robot-assisted TKA procedure, CT-based systems fail to incorporate soft tissue tension into the planning, and intraoperative tracking of ligament balance is still lacking. However, Song et al. [28] found that well-balanced flexion and extension gaps and routine medial soft tissue release were achieved in more than 90% of cruciate-retaining TKAs after the robotic milling process. These results are comparable to those reported by Griffin et al. [29]: 3 mm of flexion-extension mismatch was noted in 13.5% of TKAs laterally and in 10.6% medially. It is believed that these satisfactory results may be due to accurate femoral component rotation and the restoration of a normal tibial slope based on preoperative CT data. During surgical procedures, it is generally considered difficult to determine the surgical transepicondylar axis, but preoperative CT planning made it easy to find this axis and thereby enabled a balanced rectangular flexion and extension gap to be formed. Decking et al. [21] mentioned that accurate planning of the milling track and the velocity and power of the cutting device should reduce the risk of injury to ligaments, vessels, and nerves, which are undoubtedly endangered by manually directed oscillating saws. In addition, the precision of the robotic milling process contributes to minimal bone loss and optimal implantation, thereby improving the longevity of the TKA [19].

The operation time required by the robot-assisted TKA procedure was already known to be longer. Song et al. [28] reported that the mean operation time was 25 minutes longer for robot-assisted TKA compared to the conventional method, but that there was no increase in short-term complication rates. A high complication rate was reported in early

cases of robot-assisted surgery, including bone pain related to the implanted fiducials and the fixation jig [19, 22, 30]. Park and Lee [22] found that complaints about these problems seemed to be lessened after switching to smaller fixation markers and jigs, and no major adverse results have been observed following completion of the learning process.

Though it is generally accepted that robot-assisted surgery can achieve higher accuracy of implant orientation than conventional methods, these systems are often thought to be technically demanding and to involve a long learning curve. Song et al. [28] indicated that they had experience of more than 150 cases prior to their study, and after completion of the learning process major adverse results disappeared. Park and Lee [22] experienced no soft tissue or fracture complications in the latter half of a series of 30 knees. However, there is still controversy as to whether the learning period for robot-assisted surgery is longer than that for conventional surgery. Rees et al. [31] mentioned that one of benefits of the use of the robot is a shorter learning curve for surgeon, especially those in the earlier stages of the learning curve.

This study had several limitations. The first pertains to the cadavers themselves. There were no specific characteristics of osteoarthritis of the knee, such as cartilage denudation, subchondral sclerosis, osteophytes, bony deformity, and soft tissue contracture. Thus, the results of the analysis that was conducted are hardly applicable to the severely deformed knee of an osteoarthritis patient. Second, only the accuracy of bone cutting was evaluated in the robot-assisted TKA procedure, but other aspects should ideally have been analyzed because TKA can achieve success not only in terms of accurate alignment but also in terms of well-balanced soft tissue. Lastly, the tibial rotational alignment was not evaluated.

Further improvements to the system are in progress. Surface-based registration and the combination of a robot-assisted effector with navigational tools are being tested with a view to replacing the locator screws and eliminating the need for a second operation. The ability to track the ligament balance and change the implant size and position intraoperatively will improve the versatility of the system. In general, the system must become smaller, faster, and cheaper without compromising its accuracy. Stepwise technical improvements to the system must be evaluated in a specialized center. The robot-assisted system described herein executes the CT-based preoperative plan with unparalleled



accuracy, but further efforts and technical development are necessary to eliminate some of its evident shortcomings.

### Conclusion

Robot-assisted total knee arthroplasty showed excellent precision in the sagittal and coronal planes on three-dimensional CT scans. In particular, better accuracy in femoral rotational alignment was shown with robot-assisted surgery than with the conventional surgery, despite the fact that the surgeons who performed the operation were more experienced and familiar with the conventional method than with robot-assisted surgery. It can thus be concluded that robot-assisted total knee arthroplasty is superior to conventional total knee arthroplasty.

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