Comparison of Robotic-Assisted and Conventional Manual Implantation of a Primary Total Knee Arthroplasty

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Abstract: This study was aimed to compare robotic-assisted implantation of a total knee arthroplasty with conventional manual implantation. We controlled, randomized, and reviewed 72 patients for total knee arthroplasty assigned to undergo either conventional manual implantation (excluding navigation-assisted implantation cases) of a Zimmer LPS prosthesis (Zimmer, Warsaw, Ind) (30 patients: group 1) or robotic-assisted implantation of such a prosthesis (32 patients: group 2). The femoral flexion angle (γ angle) and tibial angle (δ angle) in the lateral x-ray of group 1 were $4.19 \pm 3.28^{\circ}$ and $89.7 \pm 1.7^{\circ}$, and those of group 2 were $0.17 \pm 0.65^{\circ}$ and $85.5 \pm$ 0.92°. The major complications were from improper small skin incision during a constraint attempt of minimally invasive surgery and during bulk fixation frame pins insertion. Robotic-assisted technology had definite advantages in terms of preoperative planning, accuracy of the intraoperative procedure, and postoperative follow-up, especially in the femoral flexion angle (γ angle) and tibial flexion angle (δ angle) in the lateral x-ray, and in the femoral flexion angle (α angle) in the anteroposterior x-ray. But a disadvantage was the high complication rate in early stage. Key words: total knee arthroplasty, robot, femoral flexion angle, γ and δ angle, post-cam impingement.

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Mechanical alignment systems in total knee arthroplasty (TKA) have fundamental problems that limit their ultimate accuracy. It is difficult to determine accurately, with standard instrumentation, the correct location of crucial alignment landmarks (eg, the center of the femoral head, the center of the ankle). Even the most elaborate mechanical

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© 2007 Elsevier Inc. All rights reserved. 0883-5403/07/1906-0004\$32.00/0 doi:10.1016/j.arth.2007.05.036 instrumentation systems rely on visual inspection to confirm the accuracy of limb and implant alignment and stability at the conclusion of the TKA procedure. So computer-based alignment systems have been developed to address the limitations inherent in mechanical instrumentation systems used for TKA, and computer-assisted orthopedic surgery is becoming increasingly popular recently. Two groups of systems-active and passive-are used. Passive systems are so-called navigation systems because they show the surgeon the position of the surgical tools or the implants within a patient's fixed reference system. The surgeon navigates within a virtual picture on a screen while handling the tools or implant [1-8]. On the other side, robotic systems are referred to as active systems. They serve as a delivery tool for a surgical procedure planned offline on a computer before the surgery. The surgeon positions the robot by means of a referencing

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procedure and then supervises the reaming process without the ability to modify (with the exception of interrupting) the procedure online. In industry, robotics is a well-established method for optimizing processes and increasing quality. The idea of using a robot in the field of orthopedic surgery, especially for total hip arthroplasty (THA), originated in the United States in the early 1990s [9,10]. American orthopedists thought that the long-term success of cementless THA may depend on bone ingrowth into the porous-fixation surfaces of the implant, and the ingrowth process is facilitated when the surgeon achieves a satisfactory fit for the prosthesis by more precise preparation of the femoral canal and selection of an appropriately fixed prosthesis [9,10]. Between 1992 and 1993, this robot (ROBODOC; Integrated Surgical Systems, Davis, Calif) was used on patients with authorization from the United States Food and Drug Administration. Fit and fill is determined by femoral component design, femoral canal geometry, and operative techniques. Especially, the more precise and accurate cavity-implant fit and fill in THA has been proved in many articles nowadays [1,3,4,7]. In Korea, this robot has been used in more than 2000 TKAs, beginning in as early as 2001. We are not aware of any published study demonstrating the clinical advantages or disadvantages of this particular procedure in comparison with those of conventional manual implantation of the same type of prosthesis. Robotic systems use machines that guide or replace the surgeon during portions of the TKA procedure. One of the reasons for this lack of data is that, in most centers, robotic and manual approaches are used to implant different types of prosthesis. This study aimed to compare robotic-assisted implantation of a TKA with conventional manual implantation.

Methods and Materials

The criterion for inclusion in the study was a diagnosis of osteoarthritis of the knee joint. We reviewed 72 patients who were scheduled for TKA using either conventional manual implantation of a Zimmer LPS prosthesis (30 patients: group 1) or robotic-assisted implantation of such a prosthesis (32 patients: group 2). The study design was approved by the institutional review board. Two surgeons (Park and Lee), both with experience in performing manual as well as robotic implantation of TKA, carried out the operation. Preoperatively as well as at final follow-up, the Knee Society score was determined. Each patient was randomly assigned to one of the groups. Before the first

surgical procedure in Korea, the robot was preassembled, calibrated according to the manufacturer's specifications in Germany, and imported to Korea securely. The robotic implantation was performed with ROBODOC along with the ORTHO-DOC planning computer. The patients were treated with pinless robotic implantation, which had a helical computed tomography (CT) scan (Siemens: Munich, Germany) which was carried out according to the manufacturer's specified protocol. After a CT scan of the femoral head, distal femur, proximal tibia, and ankle from a patient, the data were transferred to the ORTHODOC working station; ORTHODOC permits an optimal 3-dimensional preoperative accurate surgical planning of the correct axis, rotation, and implant size. In ORTHO-DOC, the mechanical axis (MA) alignment must be in one line on the anteroposterior (AP) view and lateral view as a hip-knee-ankle axis. The rotation axis (RA) of the femur was found by using the transepicondylar line and MA. For the tibial component, the RA of the tibia is set using the tibial tuberosity medial one third and the popliteal notch to MA (Fig. 1). After geometric identification on the scan data, the planning of the implantation of Zimmer LPS prosthesis was carried out. The implant was selected and positioned according to those landmarks. After the completion of the planning process, the data were transferred to the controlling computer of the ROBODOC. Then, ROBODOC performed intraoperative exact 3-dimensional cutting for the implant according to the preoperative planning in real time. In the registration algorithm, the ROBODOC registers the markers and pins and their angles. The data were matched with the CT data. After a successful registration, the high-speed cutter and irrigation system were installed. After referencing, the reaming was performed under constant irrigation with physiological saline solution. The specific cutting sleeve was powered by a pneumatic turbine (80000 resolutions per minute). First, the femoral part was cut by the robot, and then the tibial part was cut. After the cutting was finished, ROBODOC was moved away and the planned components were implanted by the surgeon manually. Soft tissue balancing so far was done the conventional way (Fig. 2). For the procedures to be performed with the conventional manual approach, a preoperative planning sketch was drafted with radiographic templates taken into account as well. In the group treated with the conventional manual approach, the implantation of Zimmer LPS prosthesis was performed according to the manufacturer's recommendation. Postoperatively, all patients were allowed to bear weight as tolerated. Physiotherapy

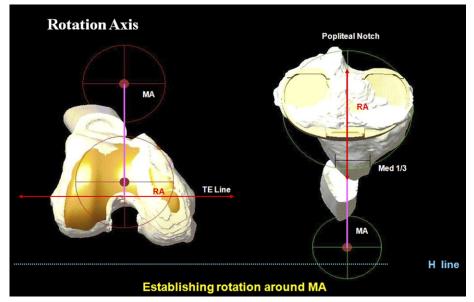


Fig. 1. In ORTHODOC, the RA of the femur is found by using the transepicondylar line and MA. For the tibial component, the RA of the tibia is set using the tibial tuberosity medial one third and the popliteal notch to MA. The implant is selected and positioned according to those landmarks.

was carried out for 3 weeks in the hospital, and then for another 3 weeks in the out-patient department. Radiographs made at these intervals using a picture archiving and communication system were analyzed for evidence of loosening, prosthetic alignment, and other complications by an independent bone radiologist blindly (Fig. 3) [11,12].

Statistical Methods

Independent *T* test or Mann-Whitney test was used for statistical analysis at a probability level of 95% using SPSS for Windows (version 12, Chicago, Ill).

Results

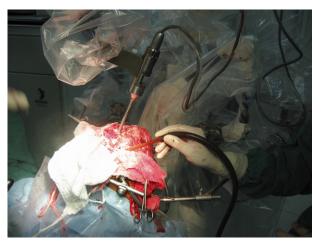


Fig. 2. In the registration algorithm, ROBODOC registers the markers and pins and their angles. The data are matched with the CT data. After a successful registration, the high-speed cutter and irrigation system are installed. First, the femoral part is cut by the robot, and then the tibial part is cut. After the cutting is finished, ROBODOC is moved away and the planned components are implanted by the surgeon manually. Soft tissue balancing so far is done the conventional way.

The age of group 1 (conventional) was 67.8 ± 6.44 and that of group 2 (robotic) was 62.7 ± 6.51 . The follow-up period of group 1 was 49.3 ± 3.47 months and that of group 2 was 45.0 ± 0.69 months. In clinical assessment, the final follow-up Knee Society score of group 1 was 90.9 \pm 4.88 points and that of group 2 was 91.6 \pm 2.94 points (Table 1). The final follow-up knee functional score of group 1 was 88.5 ± 3.70 points and that of group 2 was $87.9 \pm$ 4.99 points. The postoperative range of motion of group 1 was $122 \pm 16.9^{\circ}$ and that of group 2 was $118 \pm 9.02^{\circ}$. There was no statistical difference in clinical assessment. In radiological assessment, the postoperative tibiofemoral angle (Ω angle) of group 1 was $5.3 \pm 2.6^{\circ}$ and that of group 2 was $6.0 \pm 1.8^{\circ}$. There was no statistically significant difference (P =.19). The femoral flexion angle (α angle) and tibial angle (β angle) in the AP x-ray of group 1 were 95.6 ± 2.65° and $88.6 \pm 2.58^{\circ}$, and those of group 2 were $97.7 \pm 0.97^{\circ}$ and $88.8 \pm 1.59^{\circ}$; there was a statistically significant difference in femoral flexion angle (α angle) (P < .01) but no difference in tibial angle (β angle) in the AP x-ray (P = .74). The femoral



Fig. 3. Radiographs made at intervals using a picture archiving and communication system were analyzed for prosthetic alignment: femoral flexion angle (α angle) and tibial angle (β angle) in AP x-ray and femoral flexion angle (γ angle) and tibial angle (δ angle) in lateral X-ray, etc, by independent bone radiologists.

flexion angle (γ angle) and tibial angle (δ angle) in the lateral x-ray of group 1 were 4.19 ± 3.28° and 89.7 ± 1.7°, and those of group 2 were 0.17 ± 0.65° and 85.5 ± 0.92°. There was a statistically significant difference (P < .01). Complications observed in group 2 were as follows: 1 superficial infection, 1 patellar tendon rupture, 1 dislocation of the patella, 1 postoperative supracondylar fracture, 1 patellar fracture, and 1 peroneal injury in early cases.

Discussion

Roughly 70% of conventional TKA gives a MA alignment of less than $\pm 3^{\circ}$ as compared to more than 90% with navigation TKA [13-15]. Robotic surgery allows an exact intraoperative translation of the preoperative planning, whereas there is certain variability with the manual approach. This is illustrated by the higher accuracy with regard to the varus-valgus alignment of the prosthetic stem in the group treated with robotic implantation. The 24-month knee scores, however, were quite similar; per observed in the group treated with manual implantation is not of clinical relevance. The robot

provides a very accurate fit of the prosthesis in the bone [1-3,5,7]. The acceptable range for the postoperative leg alignment in a TKA is still controversial [11,12]. Recent studies have also emphasized that the most common cause for revision TKA is error in surgical technique [16-18]. Mechanical alignment guides including intramedullary and extramedullary femur and tibia guides have improved the accuracy with which implants can be inserted. Although mechanical alignment systems are continually being refined, errors in implant and limb alignment continue to occur, especially in the femur. Even excellent surgeons made flexion position of the femur implant postoperatively due to intramedullary femur guide inaccuracy [13-15]. This study found in the robotic (group 2) a significant improvement with regard to femur implant position in the AP plane, but with regard to the femorotibial angle (Ω angle) and tibial angle (β angle) in the AP plane, there was no difference between conventional manual (group 1) and robotic (group 2). It means that even though we achieved a more accurate and precise femur implant position in the AP plane, femoral flexion angle (α angle) in the AP x-ray in robotic (group 2) and soft tissue balancing in medial

Table 1. Comparison of Clinical Results Between Group 1 (Manual) and Group 2 (Robotic)

	Group 1 (conventional)	Group 2 (robotic)
The age	67.8 ± 6.44	62.7 ± 6.51
Knee Society score	90.9 ± 4.88	91.6 ± 2.94
Knee functional score	88.5 ± 3.70	87.9 ± 4.99
Postoperative range of motion	122 ± 16.9	118 ± 9.02
Postoperative tibiofemoral angles	5.3 ± 2.6	6.0 ± 1.8
α and β angles	95.6 ± 2.65, 88.6 ± 2.58	$97.7 \pm 0.97, 88.8 \pm 1.59$
γ and δ angles	$4.19 \pm 3.28, 89.7 \pm 1.7$	$0.17 \pm 0.65, 85.5 \pm 0.92$

structure such as medial collateral ligament determine the final femorotibial angle (Ω angle) and tibial angle (β angle) in the AP plane, and, furthermore, it could compensate for the rather inaccurate femur implant position in conventional (group 1) and decompensate for the rather accurate tibial position in robotic (group 2). This could explain that there was no difference in the final femorotibial angle and tibial angle (β angle) in the AP plane between the conventional and robotic group. So the soft tissue balancing technique is the most important one to make appropriate postoperative femorotibial angle in the AP plane. The data on the femoral flexion angle (α angle) in the AP plane in the robotic group (group 2) had less standard deviation than that of the conventional group (group 1). It means that robotic implantation is accurate and more precise; in other words, conventional implantation could be accurate depending on the surgeon's skill but less precise than robotic implantation [19]. As for the process capability index (C_p) , the data presented would be quite amenable to this analysis. For example, femoral α angle was 95.6 ± 2.65 for conventional and 97.7 \pm 0.97 for robotic. If one chooses an outlier of $\pm 3^{\circ}$ from the choice position, the $C_{\rm p}$ for this would be 6°/6 <sigma: standard deviation> or 6°/15.9° or $C_{\rm p}$ = 0.38 for conventional; $C_{\rm p}$ for robotic is 6°/ $6 < sigma > or 6^{\circ}/5.82^{\circ} or C_p = 1.03$. Motorola, GE, and Toyota Motors aim for a C_p of 1.3 in most industrial processes on the Internet. This is really an impressive precision [19]. On the other hand, there are many papers on the appropriate range of femoral flexion angle (γ angle) or tibial flexion angle (δ angle) [16-20]. Increased γ angle or δ angle may produce anterior post-cam impingement and promote polyethylene wear in the lateral plane [21]. But in actuality, the sum of femoral flexion angle (γ angle) and tibial flexion angle (δ angle) is more important because each knee implant has its own tibial inclination angle. The authors recommend that the sum of femoral flexion angle (γ angle) and tibial flexion angle (δ angle) should be less than 15° in the lateral x-ray postoperatively to prevent anterior post-cam impingement or to reduce polyethylene wear in the lateral plane in long-term follow-up. Robots are becoming a new tool for preventing anterior post-cam impingement or for reducing polyethylene wear in the lateral plane with their great precision. In early cases, there were a lot of complications, the most important of which was soft tissue injuries. Those were from improper small skin incision during a constraint attempt of minimally invasive surgery and during bulk fixation frame pins insertion. High-speed cutter ground and injured other soft tissue resulting in tendon rupture and peroneal nerve injury. After we switched to an ample and large enough incision for the robot to work properly and smaller fixation device pins, there were no soft tissue or fracture complications. A longer follow-up will be needed to determine whether this improvement in the accuracy of the alignment in the lower extremity and the robotic total knee operation will lead to an increased longterm knee implant survival rate, especially polyethylene wear or breakage in the lateral plane [21]. In conclusion, the robotic-assisted technology had definite advantages in terms of preoperative planning, accuracy of the intraoperative procedure, and postoperative follow-up, especially in the γ and δ angle. But a disadvantage was the high complication rate in early stage, which we believe was required for the more careful and experienced operative technique. As for the appropriate femoral flexion angle (γ angle) or the appropriate sum of femoral flexion angle (γ angle) and tibial angle (δ angle), less than 15° is recommended in lateral xray to prevent anterior post-cam impingement or to reduce polyethylene wear in the lateral plane in long-term follow-up. Further study on the kinematic importance of γ and δ angle in post-cam mechanism and polyethylene wear is needed before robotics use becomes popular in the United States.

References

- Nishihara S, Sugano N, Nishii T, et al. Comparison between hand rasping and robotic milling for stem implantation in cementless total hip arthroplasty. J Arthroplasty 2006;21:957.
- 2. Lee YS, Oh SH, Seon JK, et al. 3D femoral neck anteversion measurements based on the posterior femoral plane in ORTHODOC system. Med Biol Eng Comput 2006;44:895.
- 3. Nishihara S, Sugano N, Nishii T. Clinical accuracy evaluation of femoral canal preparation using the ROBODOC system. J Orthop Sci 2006;9:452.
- 4. Nogler M, Polikeit A, Wimmer C, et al. Primary stability of a ROBODOC implanted anatomical stem versus manual implantation. Clin Biomech (Bristol, Avon) 2004;19:123.
- Honl M, Dierk O, Gauck C, et al. Comparison of robotic-assisted and manual implantation of a primary total hip replacement. A prospective study. J Bone Joint Surg Am 2003;85-a:1470.
- 6. Sugano N. Computer-assisted orthopaedic surgery. J Orthop Sci 2003;8:442.
- 7. Nishihara S, Sugano N, Nishii T, et al. Comparison of the fit and fill between the anatomic hip femoral component and the VerSys taper femoral component using virtual implantation on the ORTHODOC workstation. J Orthop Sci 2003;8:352.

- 8. Nogler M, Wimmer C, Lass-Florl C, et al. Contamination risk of the surgical team through ROBO-DOC's high-speed cutter. Clin Orthop Relat Res 2001;387:225.
- 9. Paul AH, Bargar WL, Mittlestadt B, et al. Development of a surgical robot for cementless total hip arthroplasty. Clin Orthop Relat Res 1992;285:57.
- 10. Bargar WL, Bauer A, Boerner M. Primary and revision total hip replacement using the ROBODOC system. Clin Orthop Relat Res 1998;354:82.
- Ewald FC, Jacobs MA, Miegel RE, et al. Kinematic total knee replacement. J Bone Joint Surg Am 1984; 66-a:1032.
- 12. Ewald FC. The Knee Society total knee arthroplasty roentgenographic evaluation and scoring system. Clin Orthop Relat Res 1989;248:9.
- 13. Ensini A, Catani F, Leardini A, et al. Alignments and clinical results in conventional and navigated total knee arthroplasty. Clin Orthop Relat Res 2007; 457:156.
- 14. Zorman D, Etuin P, Jennart H, et al. Computerassisted total knee arthroplasty comparative results in a preliminary series of 72 cases. Acta Orthop Belg 2005;71:696.
- 15. Chin PL, Yang KY, Yeo SJ, et al. Randomized control trial comparing radiographic total knee

arthroplasty implant placement using computer navigation versus conventional technique. J Arthroplasty 2005;20:618.

- 16. Li G, Papannagari R, Most E, et al. Anterior tibial post impingement in a posterior stabilized total knee arthroplasty. J Orthop Res 2005:536.
- Banks SA, Harman MK, Hodge WA. Mechanism of anterior impingement damage in total knee arthroplasty. J Bone Joint Surg Am 2002;84-a(Suppl 2):37.
- Callaghan JJ, O'Rourke MR, Goetz DD, et al. Tibial post impingement in posterior-stabilized total knee arthroplasty. Clin Orthop Relat Res 2002; 404:83.
- Stiehl JB, Bach J, Heck DA. Chapter 9, Validation and metrology in CAOS. In: Stiehl JB, Konermann WH, Haaker R, editors. Navigation and MIS in Orthopaedic Surgery. Heidelberg: Springer Medizin Verlag; 2007. p. 68.
- Silva M, Kabbash CA, Tiberi III JV, et al. Surface damage on open box posterior-stabilized polyethylene tibial inserts. Clin Orthop Relat Res 2003;416: 135.
- 21. Dennis DA, Komistek RD, Colwell Jr CE, et al. In vivo anteroposterior femorotibial translation of total knee arthroplasty: a multicenter analysis. Clin Orthop Relat Res 1998;356:47.