Simultaneous Bilateral Total Knee Replacement with Robotic and Conventional Techniques
A prospective, Randomized, Comparative Study

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Abstract

Background: The purpose of this study was to analyze the outcomes of robotic-assisted versus conventional TKA in same patient simultaneously. We hypothesized that robotic-assisted procedure will lead to a better leg alignment and component orientation, and thereby might improve patient's satisfaction level, clinical and radiological outcome.

Methods: 30 patients were randomized to undergo bilateral sequential total knee replacement with a Zimmer NexGen prosthesis (Zimmer, Warsaw, Indiana), and one knee was replaced using a robotic-assisted implantation and the other conventionally manual implantation. The mean follow-up was 32.5 (28.6 to 46.9) months. The clinical parameters, radiological and functional assessment scores were evaluated and compared between two groups.

Results: There were more outliers of postoperative leg alignment in the conventional side than in the robotic side ($p<0.05$ in mechanical axis, coronal inclination of femoral prosthesis, and sagittal inclination of tibial prosthesis). Robotic side showed alight better postoperative knee score and ROM compared with conventional side, even though there was no statistically significant. Robotic side needed longer operation time (25min) and skin incision, however there was less postoperative bleeding in robotic side. More patients preferred robotic side to conventional. No major adverse events have been observed during follow up.

Conclusions: The Robotic-assisted TKA resulted in better leg alignment than conventional side with significant difference, and showed better clinical and radiographic results, however there was no significant difference. Overall, these good results in robotic TKA may influence patient's satisfaction level.

Key Words: Total knee arthroplasty, Surgical robot, Mechanical axis, Inclination of component, HSS score, WOMAC score

Level of Evidence: Therapeutic Level I. See Instructions to Authors for a complete description of levels of evidence

Introduction

Total Knee arthroplasty (TKA) is a reliable treatment for pain relief and restoration of joint function in arthritic knees with a satisfactory outcome in more than 90% of patients[1-3]. Several factors influence this satisfactory outcome of TKA such as patient characteristics, implant features, surgical technique, and restoration of alignment of the limb. Among them, mechanical alignment and soft tissue balance play a pivot role in their success and implant longevity[4-7]. To date, a mechanical limb axis within a range of 3° of varus/valgus alignment is reported to be associated with superior long term results[6,8,9]. In the conventional TKA only 72% of the patients showed deviation of the mechanical leg alignment of less than 3° varus/valgus, while in the computer-assisted group 92% of the patients had a comparable leg[10].

In terms of restoration of better mechanical alignment over conventional technique, two groups of computer-assisted system – passive and active – are utilized. Passive systems are so-called navigation systems, which show the surgeon the position of the surgical tools or the implant within a patient fixed reference system. The surgeon navigated within a virtual picture on a screen while handling the tools or implant. However, navigated TKA still depends on the use of cutting blocks and oscillating jigs which could result in inferior bone resection.[11] To further improve the accuracy of implant selection and position, and alignment as well as bone resection, robotic systems for TKA have been developed.[12,13,14,15] Robotic systems are referred to as active systems. They serve as a delivery tool for a surgical procedure planned offline on a computer prior to the surgery[16]. The surgeon positions the robot by means of a referencing procedure and then supervises the reaming process without the ability to modify the procedure online. Several studies have evaluated the outcomes of robotic-assisted TKA [12,13,15,17,18], however no study have been dealt with outcomes of simultaneous bilateral TKA in same patient. Therefore, the aim of our prospective study was to analyze the outcomes of robotic-assisted versus conventional TKA in same patient simultaneously. We hypothesized that robotic-assisted procedure will lead to a better leg alignment and component orientation, and thereby might improve patient's satisfaction level, clinical and radiological outcome.

Material and Methods

Thirty patients scheduled for both TKA were enrolled in this prospective study, after obtaining approval from our institutional review board and written informed consent from all participating patients (Table 1). In all patients, one knee was assigned to TKA by ROBODOC® system (Integrated Surgical Systems, Sacramento, CA, USA) and the other to conventional manual implantation randomly from August 2004 to March 2006 (Fig. 1). Both robotic and conventional TKA were performed by single surgeon who had robotic assisted TKA experience more than 150 cases previously. Intraoperatively, operative time, skin incision length, and flexion and extension gap just before prosthesis implantation were checked. Postoperative hemovac drainage amount was measured in both sides. The mean duration of follow-up was 32.5 (28.6 to 46.9) months. The study group consisted of 30 female patients, with an average of 67.8 years (range, 50 to 80) and their BMI was 27 kg/m^2 (17.4 to 32.1). The posterior cruciate ligament was retained and NexGen prostheses (Zimmer, Warsaw, Indiana) were implanted with cement for arthroplasty.

Clinical Assessment

Clinical evaluations were performed preoperatively, postoperative 3, 6 months, 1 year and last follow up. Clinical results analyzed included range of motion, Hospital for Special Surgery (HSS) score, Western Ontario and McMaster University (WOMAC) scores (for pain and function) and complications. In addition, the subjective preferences of patients were evaluated at preoperatively, postoperative 3 months, 1 year, and last follow up.

Radiographic Assessment

Radiographic measurements with regard to the change of mechanical axis, and the inclination of the femoral and tibial components (Fig. 2) were assessed. Coronal inclination of the femoral (θ, optimum, 90) and tibial prostheses (β, optimum, 90) on standing antero-posterior radiographs, and sagittal inclinations of femoral (γ, optimum, 0) and tibial prostheses (σ, optimum, 83) on lateral tibial radiographs, assessed at last follow up. Outcome was defined as "excellent" when values were within 2°, as "acceptable" when within 3°, and as "outliers" when > 3° of optimum.

Surgical Techniques

Robotic TKA was carried out in two steps, i.e., CT-based preoperative planning using ORTHODOC® and robot-assisted surgery using the ROBODOC Surgical Assistant (Fig.3). After creating a surface model of the tibia and femur, the first step in planning involves establishing femoral and tibial mechanical axes according to the anatomical centers of hip, knee, and ankle, and the bone is then aligned along these axes. The second step involves femoral component planning. Once the correct size, position, alignment, and rotation of the components have been individually set, the tibial component is added following a process similar to procedure in femoral component planning. After selecting the appropriately thick liner, the virtual surgery function was used to verify component alignment versus the established mechanical axis.

After flexing the patient's knee to 70-80 degrees using a special leg holder, a conventional medial parapatellar arthrotomy with patellar eversion was used to expose the knee joint. The leg was then fixed to the robot using two Steinmann and Hoffman fixation systems, 4 recovery markers and 2 bone motion monitors were installed. When surface registration and verification processes had been completed using the robot's DIGIMATCH™ ball probe, milling of the femur and tibia were started. Having completed the cutting, the robot was removed from the operative field. Soft tissue release was then performed using a tensor device (Stryker Howmedica Osteonics, Allendale, NJ). After completing soft tissue release, medial and lateral gaps were recorded in millimeters at full extension and 90° of flexion. Knee flexion-extension gap was considered "balanced" when the flexion gap was 0-3mm larger than the extension gap and medial and lateral gap difference was less than 3 mm in flexion and extension. After obtaining soft tissue balance, implants (Zimmer, Warsaw, Indiana) were inserted manually with cement.

On the contralateral side, conventional TKA was performed using a medial parapatellar arthrotomy, extending approximately 3-4cm into the quadriceps tendon, with patella eversion. Intramedullary instrumentation was used for femoral alignment (3° external rotation according to posterior condylar axis) and a 6° valgus cut was selected for all knees. The tibia cut was performed with extramedullary instrumentation, with the goal of making the cut perpendicular to the tibial shaft in the coronal with a 7° posterior slope in the sagittal palne. Alignment was checked with extramedullary rods referenced to the anterior superior iliac spine (ASIS) and placed 5-10 mm medially from the midpoint of both malleoli. After completing soft tissue release and checking the flexion and extension gap same as robotic side using the tension device, implants (Zimmer, Warsaw, Indiana) were inserted manually with cement.

Statistical Analysis

Descriptive statistics (arithmetic means, SDs, and ranges) were calculated using standard formulas. To test for significant differences between groups, independent t-tests were conducted. To test for intra-group differences in WOMAC, HSS, and ROM before and after surgery, paired t-tests were conducted. Associations between outliers and radiographic outcomes of both groups were analyzed with use of the chi-square test and the calculation of an odds ratio and 95% confidence intervals. Tested comparisons with $p < 0.05$ were considered to be significantly different. All statistical analyses were reviewed independently by a statistician.

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Results

Operative Results

The duration of the surgical procedures done with robotic implantation was about twenty-five minutes (mean 95 versus 70) longer than of the manual operations (p=0.057). The incision length was 15.2 cm (14.8 to 17.2) in robotic side and 13 cm (12.5 to 14.6) in conventional side (p=0.071). Blood loss was an average of 568.6 ml (200-1360) in robotic side and 816 ml (80 to 1800) in the other side (p=0.005).

In robotic side, mean intra-operative extension gap was 21.5mm and mean flexion gap 23.2mm. Flexion-extension gap balance could be achieved in 27 knees (92%). Flexion was loose in one knee (2%), and tight in two knees (6%). Mean medial and lateral gap asymmetry in extension and flexion gap was 0.6 mm and no case showed imbalance, i.e., >3 mm. On the other hand, mean intra-operative extension gap was 21.8 mm and mean flexion gap 22.9 mm in conventional side. Flexion-extension gap balance could be achieved in 23 knees (77%). Flexion was loose in two knees (5%), and tight in five knees (18%). Mean medial and lateral gap asymmetry in extension and flexion gap was 1 mm and no case showed imbalance, i.e., >3 mm in conventional side.

Clinical Results

As shown in Table II, preoperative ROM averaged 120° in robotic assisted group and 123° in conventional group, and were improved to 129° and 129° (p=0.006 and p-0.042), respectively at last follow up.

Preoperative HSS scores were 62.2 in robotic-assisted and 63.8 in conventional group, improved to 91.1 and 90.5 at 3 months, 93.4 and 93.5 at 6 months, 95.9 and 94.7 at 1 year, and 95.2 and 94.7 at the last follow up (p=0.000, preoperative and last follow-up HSS score in both group).

In terms of WOMAC scores, 77.8 in robotic-assisted and 75.2 in conventional scored in each group, these scores improved to 36.8 and 36.4 at 3 months, 28.1 and 27.9 at 6 months, 26.8 and 27.5 at 1 year, and 30 and 30 points at the last follow up (p=0.000, preoperative and last follow-up WOMAC score in both group).

Concerning about the preference side of TKA, patients showed different preference knee; preoperative (11 in robotic side versus 13 in conventional side), postoperative 3 months (10 versus 10), 1 year (10 versus 8), and last follow-up (12 versus 6). The other patients answered that both sides are same; 6 at preoperative, 10 at postoperative 3 months, 12 at 1 year, 12 at last follow up.

Radiographic Results

As shown in Table III, the mechanical axis improved from 9.1° varus and 10.9° varus to 0.2° varus and 1.2° varus (p=0.000, preoperative and postoperative mechanical axis in both group) in robotic group. 28 patients (93.3%) were classified as excellent outcome which mechanical axis was restored within 2°, however, 15 patients (50%) showed excellent in conventional, in addition, 7 patients (23.3%) were measured as outliers (fig. 4). Mean coronal inclination of the femoral and tibial component were 89.2° and 90.1° in robotic-assisted and 88° and 90.7° in conventional. An average sagittal inclination were 0.9° and 85.4° in robotic-assisted and 1.1° and 86.1° in conventional. In terms of outliers, there was only 2 (6.7%) outliers in sagittal inclination of tibial side in robotic-assisted TKA, on the other hand, in conventional side more outliers than opposite side were observed.

Complications

No major adverse events related to the use of the robotic system, such as deep infection or loosening requiring revision have been observed during the follow-up.

Discussion

Jeffery et al[8]. analyzed that the outcome after TKA in 115 patients and reported a rate of 24% of prosthetic loosening when the mechanical axis exceeded ±3° varus/valgus deviation, whereas it was only 3% in knees with an axis within 3° of neutral. Clearly, malalignment of the limb influences long-term survival. Mahaluxmivala et al[20]. found a varus/valgus deviation of the mechanical axis of more than 3° in 25% of 673 TKAs. Ritter et al[6]. analyzed 421 TKAs with regard to the femorotibial angle and concluded that the highest rate of aseptic loosening was seen in patients with a varus malalignment knee. Using conventional techniques, Peterson et al[19]. reported a postoperative deviation of the mechanical axis of the limb by more than 3° in 26% of patients. Likewise, In our study, the mechanical axis improved from 10.9° varus to 1.2° varus by conventional method. Even though intramedullary instrumentation was used for femoral alignment, the tibia cut was performed with extramedullary instrumentation, with the goal of making the cut perpendicular to the tibial shaft in the coronal with a 7° posterior slope in the sagittal plane, considerable numbers of patients (7 patients in mechanical axis, 8 coronal and 3 sagittal inclination in femoral side, 15 sagittal inclination in tibial side) were measured as outliers postoperatively.

In the conventional technique, extramedullary alignment guides or intramedullary rods were used for component orientation. Inherited to this technique are potential errors of component malalignment[21-24]. Therefore, navigation systems were developed to help surgeons improve alignment accuracies, and have since been shown to reduce some limb and component alignment errors. Encouraging results have been reported for navigated TKA by several groups.[25-28]. However, even if performing the computer-assisted technique, a deviation of the saw blade, particularly in dense bone stock, might be a reason for a deviation of the postoperative mechanical leg axis[11,29]. Bathis et al[29]. Reported cutting errors of up to 2° in the frontal and 4° in the sagittal plane.

Furthermore, current navigation systems rely on cutting blocks and oscillating saws, just as mechanical guides do. Plaskos et al[11]. concluded that the inaccuracy of the bone sawing procedure itself contributes 0.6°-1.1°(SD) in varus-valgus and 1.8° in flexion-extension to overall variability in implant alignment under experimental conditions. Thus the optimum alignment would be difficult to achieve even if navigated or mechanical alignment guides could place the cutting blocks in a perfect position. Therefore, robotic systems have been developed for TKA to further improve the accuracy of implant alignment and bone resection[12-15]. The robotic system allows the surgeon to choose freely among different strategies for placing the component, but only according to bony landmarks. Furthermore, this system executes the preoperative plan without any possibility of intraoperative changes. In our study, the mechanical axis improved from 9.1° varus to 0.2° varus in robotic side. Comparing to the conventional side, all knees were restored with ideal mechanical axis, coronal and sagittal inclination of both prosthesis, and there was only 2 outliers in sagittal inclination of tibia prosthesis. We believe that, in general, CT-based planning allows better implant position and intraoperative simulation of the implant overlap during complete knee movements. Consequently, it enables the surgeon to alter