Accuracy of OrthoPilot Image-Free Navigation in MIS TKA

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研究成果報告

Introduction

Correct alignment of the leg and positioning of the components are important factors in good long-term outcome of TKA.[1] Computer-assisted navigation systems were introduced to improve component alignment accuracies. Numerous cohort studies have shown improved prosthetic alignment in association with the use of computer-assisted navigation compared with standard instrumentation.[2] The use of computer-assisted surgery may reduce the risk of malalignment associated with MIS. We compared the accuracy of navigation systems with MIS. Our hypothesis was that computer-assisted navigation system would result in improved limb alignment in MIS TKA.

Patients and Methods

In this prospective study, 100 consecutive patients were allocated into two groups (MIS computer-navigated group or MIS jig-based group) according to the day of the week when the surgery was done. Between September 2007 and March 2009, 50 patients each underwent primary MIS TKA using either an image-free computer-assisted navigation system (Orthopilot, Aesculap, Tuttlingen, Germany) or a jig-based technique without navigation. No exclusion criteria were defined in terms of age, gender, or severity of the deformity. The MIS computer navigated group comprised 37 women and 13 men with a mean age of 73 years (53 to 88 years) and mean body mass index of 25.8 kg/m^2 (17.0 to 34.0 kg/m^2). The MIS jig-based group comprised 43 women and 7 men with a mean age of 74 years (52 to 86 years) and mean body mass index of 27.6 kg/m^2 (18.8 to 41.6 kg/m^2). Primary diagnoses in the MIS computer-navigated group included osteoarthritis in 46 patients and rheumatoid arthritis in 4 patients; primary diagnoses in the MIS jig-based group included osteoarthritis in 44 patients and rheumatoid arthritis in 6 patients. There were no significant differences in diagnoses demographic characteristics between groups. All implants used a posterior-stabilized design with a post-cam mechanism (Colombus, Aesculap), and all components were fixed with cement. The Orthopilot (Aesculap) navigation system is an image-free system that uses kinematic analysis of hip, ankle, and knee joints and anatomical mapping of the knee joint to build a working model of the patient’s knee. Clinical evaluations were performed using range of motion preoperatively and at 1 week, 3 weeks, 6

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weeks, 3 months, and 6 months postoperatively as well as ratings according to the system of the Knee Society preoperatively and at 6 months postoperatively. Full-length standing anteroposterior and lateral radiographs and CT scans of the knee were carried out 3 weeks after surgery to determine the alignment of the components after surgery. Radiographs were assessed by a single observer for measurement of angles; the observer was blinded to the surgical technique used. The coronal mechanical axis of the leg was measured (tibiofemoral angle between a line connecting the center of the hip with the center of the knee and the line connecting the center of the knee to the center of the ankle). Zero degrees was considered a straight mechanical axis; varus deviation was listed in negative values and valgus deviation in positive values. We assessed the coronal femoral component angle (the angle between the mechanical axis of the femur and the transcondylar line of the femoral component as measured on the lateral side of the midline; neutral=90°); the coronal tibial component angle (the angle between the mechanical axis of the tibia and the tibial base plate as measured on the lateral side of the midline; neutral=90°); the sagittal femoral component angle (the angle of femoral component flexion as measured on the posterior side of the midline; neutral=90°); and the sagittal tibial component angle (the posterior slope angle of the tibial component as measured posteroinferiorly from a line perpendicular to the midline; neutral=90°). The rotational alignment of the femoral and tibial components was evaluated on CT scans. The rotational femoral component angle was the angle between the surgical epicondylar axis and the posterior condylar line of the femoral component. The surgical epicondylar axis was measured from the sulcus of the medial epicondyle to the most prominent point of the lateral epicondyle. The rotational tibial component angle was defined as the angle between a line connecting the center of the stem of the tibial component and the medial third of the tibial tubercle and a line perpendicular to the posterior border of the tibial keel. A resulting coronal tibiofemoral angle of within ± 3° from the ideal is the maximum acceptable deviation to minimize early failure.

Statistical analysis was performed with Mann-Whitney's U test for continuous variables and Fisher's exact test for categorical data. $P<0.05$ was considered statistically significant.

Results

Patients in the MIS computer-navigated group had a significantly longer mean operative time (168 ± 18 minutes) than those in the MIS jig-based group (122 ± 16 minutes, $P<0.001$). The mean estimated blood loss was similar for the two groups (211 ± 122 ml in the MIS computer-navigated group vs 208 ± 99 ml in the jig-based group). MIS TKA in both groups was associated with satisfactory early clinical results. Range of motion was comparable in the two groups at all times (Fig. 1). Knee score and function score were improved in both groups after surgery ($P<0.001$). There were no significant differences between groups in terms of knee score and function score preoperatively or

6 months postoperatively.

In the MIS computer-navigated group, a coronal tibiofemoral angle of 0° was achieved in 14 patients. A deviation of 1° was achieved in 14, 2° in 6, and 3° in 13 patients. In the MIS jig-based group, a coronal tibiofemoral angle of 0° was seen in 14, 1° in 8, 2° in 7, and 3° in 10 patients (Fig. 2). The percentage of patients with a coronal tibiofemoral angle within ±3° of the ideal in the MIS computer-navigated group was significantly higher than in the MIS jig-based group (47 [94%] vs 39 [78%], respectively; P=0.041). No other significant differences were noted between groups in terms of implant alignment.

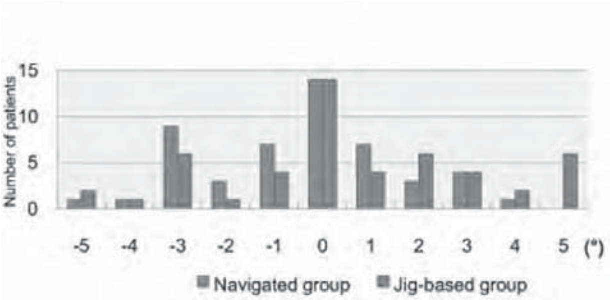

Fig. 1. Distribution of the postoperative mechanical leg axis in navigated group and jig-based group.

Discussion

Many studies have demonstrated that TKA with computer navigation leads to more accurate implantation,[2,3] but other reports have found no differences.[4,5] Recent meta-analyses noted fewer patients outside the critical ranges of 3° varus or valgus malalignment with navigated surgery.[6] However, we are not aware of any studies that have established whether these improvements in alignment accuracy with navigated surgery are associated with superior Knee Society knee scores and function scores or range of motion. We found that functional outcomes in MIS computer-navigated TKA were similar to MIS TKA without navigation soon after surgery. MIS TKA and computer-assisted navigation are both new techniques that have recently been used in combination. However, both represent new technologies that still have unproven benefits over conventional methods.

Several studies have compared MIS TKA using navigation with conventional TKA.[2,3] MIS TKA using navigation was shown to have fewer outlier (more than 3° of optimum) patients than the conventional TKA group.[2,3] However, Lüring et al.[7] demonstrated no difference between groups. In this current study of 100 patients, we found that patients in the MIS computer-navigated group had improved postoperative limb alignment compared with those in the MIS jig-based group. The coronal tibiofemoral alignment was reestablished to within ±3° of neutral in 94% of the patients in the MIS computer-navigated group compared with 78% of those in the MIS jig-based group. Our accuracy in achieving a neutral coronal tibiofemoral alignment with MIS in the jig-based group was comparable with the results of other reports, including conventional computer-navigated TKA (range, 68% to 98%).[2,3,7] To our knowledge, only three studies have compared the mechanical alignment between computer-navigated MIS TKA and jig-based MIS TKA.[7-9] Confalonieri et al.[8] demonstrated that the percentage of patients with a coronal mechanical axis of the leg within ±3° of the ideal was 100% for computer-navigated MIS TKA compared with 84% for conventional TKA. Bonutti et al.[9] showed the percentage of patients that deviated by more than 3° from the normal axis was similar in the two groups. Lüring et al.[7] showed no patients exceeding 3° from the normal axis in the computer-navigated MIS TKA.

Navigation systems have been associated with increased operation times, higher expenses, and higher complication rates, especially femur fractures. However, the intraoperative feedback with regard to resection, implant, and limb alignment provided by computer-navigated surgery offers surgeons an opportunity to improve their judgment with regard to the accuracy with which they perform and evaluate each step of the TKA procedure.

In conclusion, MIS computer-navigated TKA resulted in significantly more accurate limb alignment than that achieved by MIS jig-based TKA, and our hypothesis was proved. However, both coronal and sagittal alignments of each component were similar between groups. We believe that both the MIS and computer-navigated techniques have now been refined and can be used safely in combination. Additional experience with these techniques and longer follow-up periods may reveal further information about the usefulness of these procedures.

References

1. Lotke PA, Ecker ML. Influence of positioning of prosthesis in total knee replacement. J Bone Joint Surg [Am] 1977;59-A:77-9.

2. Bäthis H, Perlick L, Tingart M, et al. Alignment in total knee arthroplasty. A comparison of computer-assisted surgery with the conventional technique. J Bone Joint Surg [Br] 2004;86-B:682-7.

3. Dutton AQ, Yeo SJ, Yang KY, et al. Computer-assisted minimally invasive total knee arthroplasty compared with standard total knee arthroplasty. A prospective, randomized study. J Bone Joint Surg [Am] 2008;90-A:2-9.

4. Kim YH, Kim JS, Yoon SH. Alignment and orientation of the components in total knee replacement with and without navigation support: a prospective, randomised study. J Bone Joint Surg [Br] 2007;89-B:471-6.

5. Stulberg SD, Yaffe MA, Koo SS. Computer-assisted surgery versus manual total knee arthroplasty: a case-controlled study. J Bone Joint Surg [Am] 2006;88-A Suppl 4:47-54.

6. Mason JB, Fehring TK, Estok R, Banel D, Fahrbach K. Meta-analysis of alignment outcomes in computer-assisted total knee arthroplasty surgery. J Arthroplasty 2007;22:1097-106.

7. Lüring C, Beckmann J, Haiböck P, et al. Minimal invasive and computer assisted total knee replacement compared with the conventional technique: a prospective, randomised trial. Knee Surg Sports Traumatol Arthrosc. 2008;16:928-34.

9. Bonutti PM, Dethmers DA, McGrath MS, Ulrich SD, Mont MA. Navigation did not improve the precision of minimally invasive knee arthroplasty. Clin Orthop Relat Res 2008;466:2730-5.