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Functional comparison of total knee arthroplasty performed with and without a navigation system

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Abstract This study was undertaken to compare the clinical and radiological outcomes achieved using total knee arthroplasty (TKA) with and without a navigation system. This study included 43 TKAs performed with a navigation system and 42 TKAs without a navigation system with a minimum two-year follow-up. We compared clinical outcomes including range of motion, Hospital for Special Surgery (HSS) and Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) scores at the final follow-up. For radiological comparisons, we evaluated radiological alignment on standing radiographs of knees. HSS and WOMAC scores showed significant improvements at final follow-ups in both groups, but showed no significant inter-group differences (p > 0.05). Similarly, no significant differences were observed in range of motion (p=0.962). TKAs performed with navigation showed significantly better outcomes in terms of mechanical angle and prosthetic alignment outliers than TKAs performed without navigation. However, we could not find any differences in functional outcomes between TKAs performed with or without a navigation system.

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K. B. Lee Department of Orthopedics, Chonnam National University Hospital, Gwang-Ju, Republic of Korea Résumé: Cette étude a pour but de comparer le devenir clinique et radiologique de prothèses totales du genou avec ou sans utilisation d'un système de navigation. 43 prothèses ont été réalisées avec navigation et 42 sans navigation. Le suivi minimum a été de deux ans. Nous avons comparé les résultats cliniques incluant la mobilité, le score HSS, le score WOMAC. Sur le plan radiologique nous avons évalué les axes en position debout. Les scores HSS et WOMAC montraient une très nette amélioration au suivi final dans les deux groupes mais, sans différence significative entreeux (p>0,5). De la même façon nous n'avons pas trouvé de différence significative au niveau de la mobilité (p=0.962). Par contre, la réalisation d'une prothèse totale du genou avec un système de navigation permet d'améliorer de façon significative l'axe mécanique angulaire de la prothèse en évitant un certain nombre d'anomalies axiales extrêmes que l'on peut rencontrer lorsque l'on réalise ces prothèses sans navigation. Cependant, il n'est pas possible de trouver une différence sur le plan fonctionnel entre les prothèses totales du genou réalisées avec ou sans système de navigation.

Introduction

The success of total knee arthroplasty (TKA) depends on several factors, such as patient selection and prosthesis design. The correct alignment of implanted components and anatomical structures are considered important factors that can be controlled by surgery. In an eight-year follow-up study the loosening rate was only 3% in those patients with correctly aligned leg alignment, but 24% in those with malalignment [9]. Moreover, conventional total knee arthroplasty is limited in terms of its scope for improving alignment accuracy. Computer-assisted navigation systems were introduced to improve component alignment accuracy. A number of studies have concluded that leg and

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component alignment are improved when TKA is performed with navigation [1, 3–5, 7, 8, 10, 12, 13, 15, 16, 18–20]. However, there are few reports showing that accurate radiological alignment of TKA using a navigation system influences short-term clinical results [2, 6].

We hypothesised that good TKA alignment achieved using a navigation system (NA-TKA) would provide better short-term clinical outcomes than conventional TKA without navigation (CON-TKA). To test this hypothesis, the short-term clinical results and the alignment accuracy of NA-TKA and CON-TKA components were compared after a minimum two-year follow-up.

Materials and methods

Ninety-two consecutive patients awaiting unilateral primary TKA were enrolled into this trial and the Institutional Review Board approved this study. During preoperative assessments (performed 7-14 days before surgery), patients were randomised into TKA with navigation (the NA-TKA group) or TKA without navigation (the CON-TKA group) groups. Randomisation was achieved using sealed envelopes. Written informed consent was obtained from all patients. Exclusion criteria included patients that had undergone prior open knee surgery and those with a severe deformity (>20° varus or >30° flexion contracture). Three knees (two knees due to registration failure of the navigation system and one knee due to loss to follow-up) in the NA-TKA group and four knees (all due to loss to follow-up) in the CON-TKA group were excluded, which left 85 knees available for this study. The NA-TKA group consisted of two men and 41 women with an average age of 67.2 years at the time of surgery (range: 56-84 years) and the CON-TKA group consisted of four men and 38 women with an average age of 67.6 years (range: 52-83 years). All patients had primary osteoarthritis.

The senior author who had performed over 100 CON-TKAs and 50 NA-TKAs before this trial was initiated performed all TKAs. NA-TKAs were performed using a standard medial parapatellar approach using the OrthoPilot[®] (version 4.08, Aesculap, Tuttlingen, Germany) navigation system, which is an image-free system that analyses the kinematics of hip, knee and ankle joints and performs anatomical mapping of knee joints to build a working model of the knee. After removing all osteophytes, we fixed the tibial and femoral cutting jigs to bone using a freehand technique under navigational control. After proximal tibial cutting at 0° in the coronal and sagittal planes, adequate medial soft tissue releases were obtained to achieve collateral balancing. The distal femoral cutting block was then placed for a perpendicular cut in the coronal and sagittal planes and the cut was completed. A 4-in-1 cutting block was then placed for a chamfer cut. After completing bony resections and soft tissue balances, components were inserted with cement.

CON-TKAs were performed using the same approach as that described above. Tibial cuts were performed using extramedullary instrumentation, with the goal of achieving a cut perpendicular to the tibial shaft in both coronal and sagittal planes. Intramedullary instrumentation was used to achieve femoral alignment, and 4- to 6-° valgus cuts were selected according to differences between anatomical and mechanical femoral axes. Bone resection was performed after positioning the anteroposterior and chamfer cutting blocks. After trial insertion, component alignment was checked using extramedullary rods using the anterior superior iliac spine (ASIS) and both malleoli as points of reference. Components were then inserted with cement. In both surgical groups, the posterior cruciate ligament was retained and the patella was not resurfaced, and e.motion® (Aesculap, Tuttlingen, Germany) prostheses were implanted with cement for arthroplasties. The patients in both groups underwent the same postoperative rehabilitation protocol, and active range of motion (ROM) exercises was started within the first few hours. Weight-bearing with a walker or crutch and active and passive ROM exercises were started on the first postoperative day and then progressed according to patient tolerance.

Clinical evaluations were performed preoperatively and at final follow-up. Clinical outcomes included ROM and Hospital for Special Surgery (HSS) and Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) scores. Mean preoperative ROM, HSS scores and deformities of the operated knees were similar in the two groups (Table 1).

The radiological indices measured included mechanical femorotibial angles (optimum, 0°), coronal inclinations of the femoral (optimum, 90°) and tibial prostheses (optimum, 90°) on standing anteroposterior radiographs of whole legs

p value

0.216

0.338

0.733

0.568

Table 1Comparison of thepreoperative demographic dataof the NA-TKA andCON-TKA groups

signifies varus

Table 2Comparisons of theclinical results between the twogroups

	NA-TKA group	CON-TKA group	p value
HSS score (points)			
Total	91.6 (83-100)	90.6 (81-100)	0.289
Pain	28.7 (25-50)	29.2 (25–45)	0.624
WOMAC score (points)			
Total	31.3 (24-59)	32.2 (24–59)	0.563
Pain	6.1 (4–9)	6.3 (4–13)	0.606
Range of motion (°)	129.0 (90–145)	129.2 (100–145)	0.962

taken at final follow-up. Two investigators, who were unaware of the surgical technique and clinical outcome, carried out these measurements twice on two different occasions. Radiographic outcomes were defined as "satisfactory" when within $\pm 3^{\circ}$ of optimum and as "outliers" when $> \pm 3^{\circ}$ from optimum.

Statistical analyses were performed using SPSS for Windows Release 11.0 (SPSS Inc., Chicago, IL, USA). Normality and distribution were tested using a Kolmogorov-Smirnov test. A Student's *t*-test was used to analyse parametric data and a Mann-Whitney U test to analyse non-parametric data, using a confidence interval of 95%.

Results

HSS and WOMAC total knee scores were similar in the NA-TKA and CON-TKA groups preoperatively (p=0.216 and p=0.338, respectively) and at final follow-up (p=0.289 and p=0.563, respectively) (Tables 1 and 2). In the NA-TKA group, mean final total knee scores were 91.6 (range: 83–100) and 31.3 (range: 24–59) according to the HSS and WOMAC systems, and in the CON-TKA group these were 90.6 (range: 81–100) and 32.2 (range: 24–59), respectively (Table 2).

HSS and WOMAC pain scores at final follow-up were also similar in the two groups (p=0.624 and p=0.606, respectively). In the NA-TKA group, mean final follow-up knee scores were 28.7±4.1 and 6.1±1.2 according to the HSS and WOMAC systems, and in the CON-TKA group these were 29.2±4.3 and 6.3±1.8, respectively (Table 2).

No differences were observed with respect to ROM. Preoperatively, ROM averaged $121.4\pm16.8^{\circ}$ and $120.2\pm18.8^{\circ}$ in the NA-TKA and CON-TKA groups, respectively (p=0.733) (Table 1), and at final follow-up these were $129.0\pm12.2^{\circ}$ and $129.2\pm10.8^{\circ}$, respectively (p=0.962) (Table 2).

In terms of radiological alignment, mean femorotibial mechanical axes were similar $(0.4\pm1.5^{\circ}$ varus in the NA-TKA group and $0.7\pm2.6^{\circ}$ varus in the CON-TKA group, P=0.531). However, there were significantly more outliers in the CON-TKA group (9) than in the NA-TKA group (2) (p=0.026). With regards to femoral component coronal alignment, the CON-TKA group (8) also had more outliers

than the NA-TKA (2) group, showing a significant difference (p=0.049). However, mean femoral component coronal alignment showed no significant difference between the two groups ($90.0\pm1.7^{\circ}$ in the NA-TKA group and $89.5\pm2.2^{\circ}$ in the CON-TKA group, p=0.146). No significant differences in coronal tibial alignment were observed between the two groups in terms of means (p=0.713) or outliers (p=0.676) (Table 3).

Discussion

Computer-assisted navigation systems were introduced to improve component alignment accuracy [18], and a number of studies have reported that leg and component alignment are improved when a navigation system is used in TKA [1, 3–5, 7, 8, 10, 12, 13, 15, 16, 18–20]. The results of this study confirm that the use of a navigation technique reduces the number of radiographic alignment outliers as compared with conventional TKA (Table 3), particularly with respect to femorotibial mechanical axis and femoral component alignment. However, although our tibial coronal inclination results tended to favour TKA with computer navigation, there was no significance. This result was similar to others' results [16, 17] and suggests that the use of conventional extramedullary guides is adequate for surgeons to achieve correct tibial alignments.

 Table 3
 Comparisons of radiological outlier results between the two groups

	NA-TKA group	CON-TKA group	p value
Mechanical axis ang	gle		
Average value	-0.4 ± 1.5	-0.7 ± 2.6	0.531
Outliers' number	2	9	0.026
Coronal inclination	of femoral prosthes	sis	
Average value	90.0±1.7	89.4±2.2	0.146
Outliers' number	2	8	0.049
Coronal inclination	of tibial prosthesis		
Average value	90.1±1.9	90.2±1.4	0.713
Outliers' number	2	3	0.676

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To date, comparative assessments of TKA with and without navigation have only been studied by comparing radiological results on postoperative radiographs, though a small number of studies have addressed the functional results of NA-TKA [2, 16]. Therefore, we undertook this study to compare the short-term functional results of NA-TKA and CON-TKA. Our findings indicate that the NA-TKA and CON-TKA groups were similar in terms of HSS and WOMAC total and pain scores and ROM after a minimum follow-up of two years, which it should be said is comparatively short for a NA-TKA versus CON-TKA comparison. Nevertheless, our data suggest that improving prosthesis component alignment does not necessarily result in an early functional improvement, although it is possible that better alignment will reduce implant wear and improve long-term functional outcome.

Several limitations of this study should be considered. First, radiographs were used to determine alignment and not computed tomography (CT) scans, and CT scans have been shown to be more sensitive and effective at determining alignment measurements [11, 14]. However, two investigators obtained the radiographic measurements twice on different days, and inter-observer variability for radiological indices and inter-observer variability for radiological indices and inter-observer variations were not significant. Therefore, the radiographic alignment data were deemed reliable and suitable for this comparative study. Second, the follow-up was short and the number of subjects was relatively small. However, despite the small numbers involved, this study is a randomised prospective comparative study undertaken to evaluate the clinical and radiological results of NA-TKA.

In conclusion, NA-TKA was found to provide significant improvements in terms of achieving desired mechanical axes and reducing prosthetic alignment outlier numbers as compared with CON-TKA. However, no significant differences were found between any functional parameters in the two study groups at two-year follow-up. We suggest that a study be undertaken on a larger patient cohort with a longer follow-up period to determine the influence that the observed radiographic alignment improvements have on clinical results and survival rates.

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