Long-term subjective outcomes of computer-assisted total knee arthroplasty

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Abstract

Purpose This study aimed to clarify the results of computer-assisted total knee arthroplasty (TKA) after ten years using patient-derived scores.

Methods Thirty posterior-stabilised total knee prostheses implanted using a computed tomography-free navigation system were compared with 30 matched total knee prostheses of the same type implanted using a conventional, manual technique. At an average of ten years after surgery, we investigated patient-reported outcomes using the Knee Society's new scoring system. The results of 27 patients (14 patients in the navigation group and 13 patients in the manual group) were assessed in this study.

Results There was no significant difference between the navigation and manual groups for any section of the questionnaire, which consisted of symptoms, patient satisfaction, patient expectation, walking/standing, standard activities, advanced activities, and discretionary activities.

Conclusion After long-term follow-up, we found no subjective advantages of using a navigation system for patients who undergo TKA though the absolute number of patients was very small. Additional extensive studies are required to validate our result.

Introduction

Total knee arthroplasty (TKA) is one of the most effective surgical procedures for improving physical function and relieving pain in patients with severe osteoarthritis (OA) or rheumatoid arthritis (RA) of the knee. Good results are achieved in most patients after TKA, and modern prosthesis design and advances in surgical techniques have improved the outcomes of this procedure. However, one of the most common causes of revision TKA is malpositioning of the components, i.e., surgical error, which leads to relatively poor outcomes after operation [6, 8, 21].

A computed tomography (CT)-free navigation system (Vector Vision; Brain LAB, Heimstetten, Germany) was introduced in October 2002, and the use of this system resulted in improved accuracy of the implantation in relation to the mechanical axis [14]. Additionally, early objective clinical outcomes measured using the conventional Knee Society scoring system (1989) after two years were similar between patients operated upon using the navigation system and conventionally operated patients [15]. In mid-term five-year clinical outcomes, a significantly better range of motion (ROM) and coronal mechanical axis were reported in the navigation group compared to the manual group [7]. Several authors have also reported slightly better radiographic and clinical outcomes for computer-assisted TKA (CA-TKA) over conventional TKA [3, 5, 9, 20, 22, 23].

Although these studies have demonstrated the benefits of CA-TKA from the doctor's viewpoint, such as ROM or radiographic outcomes, the benefits of this relatively new surgical technique from the patient's viewpoint, such as patient satisfaction, are unknown at present. Currently, patient satisfaction has been recognised as an important basis of evaluation in TKA [1, 2, 12]. Knee surgeons are paying increased attention to patient satisfaction after TKA. It is very difficult to evaluate patient satisfaction and subjective

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knee function after surgery. Quantifying the degree of patient satisfaction is challenging but necessary. There may be a poor correlation between physician-based scores and patient-reported scores [4]; therefore, the importance of patient-reported outcome scales is gaining increased recognition [16]. In 2012, the Knee Society created a new scoring system termed the new Knee Society knee scoring system (new KSKSS) to quantify the expectations, satisfaction, and physical activities of patients who had undergone TKA [18, 19].

In this report, the patient-reported clinical results of CA-TKA were examined after long-term follow-up of an average of ten years and compared with the patient outcomes of TKA performed using a manual, conventional surgical technique. We postulated that the objective benefits of CA-TKA at five years after surgery (ROM, coronal mechanical axis) may influence the subjective clinical outcomes measured by the new KSKSS at ten years.

Materials and methods

From October 2002 to May 2003, 36 posterior-stabilised TKAs (PFC Sigma; Depuy Inc., Warsaw, IN) using a CT-free navigation system (Vector Vision; Brain LAB, Heimstetten, Germany) were performed by the same senior author (N.T.). To fairly assess patient outcomes and minimise the influences of clinical variables, CA-TKA was not indicated for patients with valgus deformity, severe bony defects, and RA in this study. All patients were diagnosed with varus-type OA. Because the number of patients for whom the navigation system could be used was limited, a predetermined number of CA-TKAs were performed, and all other patients who required TKAs underwent the operation using conventional manual techniques.

After two years of clinical follow-up, six patients were excluded from the study because the radiographic quality of their findings was judged to be inadequate for accurate measurement, and the remaining 30 patients were compared with another 30 patients who were treated with total knee prostheses of the same type by the same surgeon using a conventional manual technique during the study period [15]. The selected patients in the manual group were matched to patients in the navigation group.

After five years of clinical follow-up, three patients in each group were excluded for various reasons (inability to contact, three patients; death, two patients; and inability to visit our hospital, one patient) [7]. Among the remaining 27 patients in each group, four patients in each group were excluded because of death. The remaining 46 patients (23 patients in each group) were mailed the new KSKSS questionnaire translated directly into Japanese at an average of ten years after surgery. Our institutional review board

approved this survey. All persons provided informed consent before their inclusion in the study. When compared to the conventional Knee Society scoring system (1989), which had only three patient-reported sections (pain, walking ability and ability to climb stairs), the new KSKSS consisted of seven patient-reported sections: symptoms, patient satisfaction, patient expectation, walking/standing, standard activities, advanced activities, and discretionary activities. Total numbers of points in each section are 25, 40, 15, 30, 30, 25 and 15, respectively.

We also reviewed the medical records including objective data collected before the operation and five years after surgery for patients who completed the questionnaire correctly. The details of the method for collecting objective data have been explained in a previous report [7]. In brief, for radiological measurements, weight-bearing radiographs (a 320-mA, 0.03-s exposure at 80–100 kV, depending on soft-tissue thickness) using the anteroposterior long-leg view were obtained and evaluated to measure the coronal mechanical axis of the long leg before the operation and at five years after surgery. This evaluation was performed at least three times in each patient by two authors (K. I. and T. M.) blinded to the clinical information. ROM was also evaluated and recorded by an independent observer before the operation and five years after surgery.

All statistical analyses were performed using Microsoft Excel (Microsoft Japan Inc, Tokyo, Japan). The differences in the two groups were analysed using F-test, followed by non-paired two-tailed Student's *t*-tests, which assumed equal dispersion. $P < 0.05$ indicated statistical significance.

Surgical procedure

The surgical techniques used for each group have been previously reported [15]. In brief, for the navigation group, surgery was performed as indicated by the manufacturer. Surgeons implanted two minimally invasive reference arrays on screws in the distal femur and distal tibia. The patient's orientation and position during the operation were defined, and the centre of the femoral head was calculated to identify the starting point of the mechanical axis. After point registration to define articular surfaces and the mechanical axis, the pointer was dragged along the structure of the bone surface by the surgeon to reconstruct the three-dimensional bone model. When the leg and the planned implant size and orientation were defined on the monitor screen, the surgeon adjusted the cutting block to the desired orientation as guided by the system, followed by osteotomy. For the manual group, knees were exposed by medial parapatellar arthrotomy, and osteotomy was performed using the measured resection technique. Tibial resection was performed using an extramedullary guiding rod, and femoral resection was performed using an intramedullary guiding rod. The

femoral component size was determined using posterior referencing. Proximal tibial osteotomy was performed perpendicular to the long axis in the coronal plane with a posterior slope of 3° in the sagittal plane. The tibial bony cut was made ten millimetres below the highest point of the articular cartilage on the lateral tibial plateau.

Results

We did not receive responses from nine patients in the navigation group and ten patients in the manual group for various reasons (inability to contact, nine patients; death, five patients; and inability to answer correctly, five patients). Finally, the remaining 27 patients (14 patients in the navigation group and 13 patients in the manual group) were included in this study (Table 1). There was no statistically significant difference between the two groups in age, gender, or the duration of follow-up. Because few patients regularly visited the office over time, we were unable to obtain current objective information such as radiographic data, ROM, and joint instability. No patients were recalled for this study; all data were obtained from the questionnaires.

The results of the questionnaire showed no statistically significant differences between the two groups for any of the seven sections of the new KSKSS (symptoms, patient satisfaction, patient expectation, walking/standing, standard activities, advanced activities, and discretionary activities) (Table 2).

Discussion

Currently, TKA is one of the most successful orthopaedic procedures. Younger and more active patients with OA tend to undergo TKA. Additionally, patients increasingly expect a more active and pain-free life after surgery. A poor correlation has been reported between physician-derived and patient-reported outcomes [4], and physicians tend to overestimate outcomes compared to patients [11]. A new scoring system to assess post-TKA patient satisfaction in detail was desired because the conventional Knee Society scoring system (1989) included only three subjective items: pain, walking

Table 1 Demographic data of the navigation and manual groups

Characteristics	Navigation group (n=14)	Manual group (n=13)
Mean age at operation ± SD (years)	72.1±6.2	71.1±9.0
Gender (% male)	7.1	15.4
Mean follow-up period ± SD (months)	118±2	119±2

Table 2 Subjective scores in the new KSKSS for the navigation and manual groups (mean ± SD). Differences of $P<0.05$ were considered statistically significant

Section (total number of points)	Navigation group (n=14)	Manual group (n=13)	P value
Symptoms (25)	15.6±6.2	18.0±8.8	n.s.
Patient satisfaction (40)	21.9±8.6	21.8±13.6	n.s.
Patient expectation (15)	11.0±3.0	10.1±3.5	n.s.
Walking / standing (30)	18.4±8.3	16.9±13.4	n.s.
Standard activities (30)	22.1±5.8	21.7±9.3	n.s.
Advanced activities (25)	8.9±7.1	12.3±7.9	n.s.
Discretionary activities (15)	9.0±4.5	9.7±5.9	n.s.

n.s. not significant, KSKSS Knee Society knee scoring system

ability, and ability to climb stairs. To solve this problem, the new KSKSS was developed. It focuses on the expectations, satisfaction, and physical activities of patients who undergo TKA. The new KSKSS also uses standard statistical and psychometric procedures for validation [18]. Matsuda et al. [13] reported that surgeons overestimated symptoms and function and that there was a weak relationship between the patient-derived and physician-derived scores for postoperative pain and function using the new KSKSS questionnaire. To our knowledge, this is the only report that has used the new KSKSS to evaluate patients' subjective outcomes. They also reported that postoperative varus alignment and restricted ROM result in lower patient satisfaction. It was difficult to compare our results with those of this previous study because we could not obtain data on objective outcomes at ten years after surgery.

A few reports have investigated the mid-term clinical outcome of CA-TKA [7, 10, 17]. These reports noted better objective outcomes including those for ROM and radiological

Table 3 Comparisons of the range of motion and coronal mechanical axis (mean ± SD). Differences of $P<0.05$ were considered statistically significant

Range of motion measurement	Navigation group (n=14)	Manual group (n=13)	P value
Preoperative extension (degrees)	-12.1±7.8	-8.8±7.9	n.s.
5-year extension (degrees)	-1.1±2.9	0	n.s.
Preoperative flexion (degrees)	111.8±10.7	112.3±18.9	n.s.
5-year flexion (degrees)	118.2±9.7	105.8±11.5	<0.05
Preoperative coronal mechanical axis ^a (degrees)	8.5±3.7	8.6±4.1	n.s.
5-year coronal mechanical axis ^a (degrees)	-0.3±2.3	2.2±3.9	<0.05

n.s. not significant

^a Positive values indicate varus alignment, and negative values indicate valgus alignment

assessment. Similar results were observed for the 27 patients in this study at five years after surgery. In this study, although preoperative ROM and coronal mechanical axis in the radiographic evaluations were not significantly different between the two groups, at five years after surgery, the navigation group exhibited a significantly better maximum flexion angle ($P<0.05$) and better alignment of the coronal mechanical axis in the radiographic evaluations ($P<0.05$) (Table 3). Although this study included half the number of patients as a previous report [7], statistically significant differences were identified between the two groups.

In a previous report [7], the pain and functional scores in the conventional Knee Society scoring system displayed no significant difference between patients who underwent CA-TKA and those who underwent conventional TKA at five-years after surgery. This finding indicates that there are no significant subjective benefits for patients undergoing CA-TKA up to five years after surgery. Though the absolute number of patients was very small, the most important finding of this study is that the subjective outcomes of patients who underwent CA-TKA and those of the patients who underwent conventional TKA are not significantly different, even at ten years after surgery. We believe that a ten-year follow-up period is sufficient to judge whether CA-TKA is subjectively better than conventional TKA. We think there are two reasons why no difference was found between the two groups. First, lack of the absolute number of patients (and many dropouts) might be the main reason. We need larger-scale studies in the future. Second, though the new KSKSS is suitable mainly for active or young patients, most patients with osteoarthritis of the knee are over 70 years of age in Japan. So, this new system could not currently be so useful to our patients. There are growing number of active patients who undergo TKA in the United States. We believe TKA will be performed for younger patients in Japan in the future, when the new KSKSS will become increasingly important as a means of evaluation for the knee patients in Japan.

We acknowledge several limitations in our study. First, this study is a paired matched study with a very limited number of patients and not a randomised controlled study. We should have increased the number of patients. Considering the statistical power analysis, we should have done this study with more than 64 patients in each group (with power=0.8, $\alpha=0.5$). Second, we did not have objective data at ten years after surgery. If patients who undergo TKA were able to visit the doctor's office more than ten years after surgery, physicians could obtain objective findings and compare the objective outcomes with the subjective outcomes. Third, we did not consider other factors, such as bone fractures, hip joint disorders, or neurological diseases that influence patient-reported clinical outcomes. These conditions should have been defined to eliminate them from the

study. Lastly, because the new KSKSS has been introduced since 2012, we could not obtain preoperative and short-term patient-reported outcomes using this scoring system. So, we could not compare the degree of improvement and change over time after TKA between the navigation and manual groups.

Conclusion

We did not find any significant subjective advantages of using The Vector Vision CT-free navigation system at an average of ten years of follow-up after TKA though the number of the patients in this study was very small. Further large-scale, prospective, and advanced studies are necessary to elucidate whether CA-TKA provides benefits to patients who undergo TKA.

Conflict of interest The authors declare that they have no conflict of interest.

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