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Comparison of computer-assisted navigation and conventional instrumentation for bilateral total knee arthroplasty

The outcomes at mid-term follow-up

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Abstract

It remains unclear if computer-assisted surgery (CAS) technique actually improves the clinical outcomes of total knee arthroplasty (TKA) and decreases the failure rate. The purpose of this retrospective study was to compare the functional results of TKA in a series of patients who underwent staged bilateral TKAs with CAS TKA in 1 knee and conventional TKA in the contralateral knee.

From January 1997 to December 2010, we collected 60 patients who were randomly assigned to receive CAS TKA in 1 limb and conventional TKA in the other. The Brainlab Vector Vision navigation system was used for CAS TKA, and the DePuy press-fit condylar sigma guide system was used for conventional TKA. Patients were assessed before surgery, 3 months and 1 year after surgery, and annually thereafter. IKS criteria were used for radiographic evaluation. Clinical and functional evaluation using the scoring system of hospital for special surgery (HSS), international knee society (IKS), Western Ontario and McMaster University osteoarthritis index (WOMAC), and short form-36 (SF-36) were obtained on each knee, before surgery, and at each follow-up visit. Pertinent statistical methods were adopted for data analysis.

Fifty-six patients were available for analysis and 44 of the patients were female. The mean duration of follow-up was 8.1 years. Less blood loss ($P = .007$) and longer operation time were noted for CAS TKAs when compared with conventional TKAs. Precise alignment and fewer outliers of the lower limb and prosthetic component positions were found for CAS TKAs ($P < .001$). There were no differences between the 2 groups before surgery and at the latest follow-up with regard to scores for HSS, IKS, WOMAC, and SF-36 as well as active range of motion.

The clinical outcomes of CAS TKAs at the 8-year follow-up were similar to those of conventional TKAs despite the better radiographic alignment and fewer outliers achieved with navigation assistance.

Abbreviations: CAS = computer-assisted surgery, FF = femoral flexion angle, FV = femoral valgus, HSS = hospital for special surgery, IKS = international knee society, ORIF = open reduction and internal fixation, SF-36 = short form-36, TKA = total knee arthroplasty, WOMAC = Western Ontario and McMaster University osteoarthritis index.

Keywords: active ROM, computer-assisted surgery TKA, conventional TKA, IKA knee and functional score, IKS pain score

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RW-WH and W-HH contributed equally to this work.

W-HH, W-JS, W-BH, and S-HC are the co-authors.

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1. Introduction

Total knee arthroplasty (TKA) is a well-established procedure for treating advanced knee arthritis and is associated with good long-term outcomes.[1] Since postoperative malalignment is associated with unsatisfactory clinical outcomes and decreased long-term survival of the implant,[2–4] overall postoperative limb alignment corrected to within $0° \pm 3°$ of the mechanical axis is critical for the long-term success of TKA and survival of implants.[2–4] Computer-assisted surgery (CAS) was developed in an effort to achieve this goal.[3,4] It allows the surgeon to obtain real-time quantitative feedback, helps decrease surgical errors, and optimizes outcomes.[5,6] It was well accepted that CAS TKA could achieve accurate implantation with optimal alignment.[7] However, controversy existed whether the accuracy in implantation resulted in better clinical outcomes and overall rate of revision and revision for loosening/lysis following TKA in patients aged <65 years.[8–21] No differences in clinical outcome could result from, at least in part, the bias from person-related differences in the subjective reported score. The purpose of the present study was to compare the radiographic and functional outcomes between CAS and Convention TKA in the same patient who underwent staged bilateral TKAs (CAS TKA in 1 knee and conventional TKA in the other knee) at mid-term follow-up.

2. Methods

2.1. Participants

This study was approved by the institutional review board of our hospital (IRB: 201801373B0) and registered with the ClinicalTrials.gov database (ID: NCT03668756). We collected 60 patients who were randomly assigned to receive CAS TKA in one limb and conventional TKA in the other from January 1997 to December 2010. The procedure sequence was determined using the last digit of the patient's hospital registration number. If the last digit was odd, CAS TKA was performed first, followed by conventional TKA in the contralateral knee. If the last digit was even, the sequence was reversed. The inclusion criteria included

(1) a diagnosis of Ahlback stage III primary osteoarthritis with a genu varum deformity in both knee,
(2) staged bilateral TKA within 3 months,
(3) the same make and model of implant, and
(4) patients had complete radiographic analyses with long-leg weight-bearing split scanograms, as well as standard anteroposterior and lateral radiographs of the knees made preoperatively and postoperatively.

Moreover, patients who had an extraordinary deformity of the femoral tibia related to trauma or previous surgery or incomplete medical record or radiography were excluded.

All patients provided signed informed consent. Clinical data prospectively collected included age, sex, medical comorbidities, diagnosis at the time of the operation, preoperative assessment, make and model of the prosthesis, intraoperative procedures, perioperative findings, tourniquet time (the tourniquet was inflated before skin incision and was deflated after hardening of cement), total amount of blood loss (including intraoperative blood loss and blood accumulated in the drain used for 48 hours postoperatively), antibiotic prophylaxis, and radiographic assessments preoperatively and postoperatively.

2.2. Surgical technique

All patients received the same cruciate-retaining prosthesis (DePuy press-fit condylar sigma prosthesis; Depuy Orthopedics, Inc, Warsaw, IN) without patellar resurfacing, which were performed by the same experienced surgeon who was well-versed in both CAS and conventional procedures following the principle of mechanical aligned TKA with appropriate medial soft tissue release. In brief, the varus knee is exposed through a medial parapatellar arthrotomy. Subperiosteal stripping beneath the superficial medial collateral ligament was performed to expose the proximal tibia. If the deformity is fixed and medial release is required. The medial release is done in a sequential fashion and includes the removal of medial osteophytes and the elevation of a medial sleeve consisting of the periosteum, the deep medial collateral ligament, the superficial medial collateral ligament. Since cruciate retaining prosthesis was used in the present study, potential tethering effect of the posterior cruciate ligament was addressed during balancing. The target bone cut was planned preoperatively. The goal of alignment was to correct the postoperative mechanical axis to within 3° of neutral. A femoral component was positioned at a valgus angle of 97° in the coronal plane and at a flexion angle at 0° in the sagittal plane., while a tibial component was positioned at a valgus angle of 90° in the coronal plane and at a flexion angle of 87° in the sagittal plane (3° of posterior slope).[22] The femoral rotation was aligned with the transepicondylar axis. In CAS TKA, the image-free CAS navigation system VectorVision (Brainlab, Munich, Germany) was employed for CAS TKA. The other 60 TKAs were performed with the Sigma knee system (DePuy), which utilizes an intramedullary alignment jig for the femoral component and an extramedullary guide for the tibial side. The tourniquet was inflated before skin incision and deflated before skin closure.

2.3. Assessment

Perioperative and follow-up assessment data were recorded in our hospital arthroplasty registration database. Clinical and radiographic evaluations were performed by research assistants blinded to TKA technique at 3-month intervals until the 1-year point, and annually thereafter.

2.3.1. Radiographic evaluation. Standard anteroposterior, lateral radiographs of the knee and standing long-leg radiographs of the lower extremity were obtained pre- and postoperatively. The lower extremities were fully extended so that the tibial tuberosities were facing forward and the lateral malleoli were 15 cm apart to ensure that the tibia was vertical and facing forward with minimal rotation. The X-ray beam (20–25 mA/s; 80–85 kV) was centered at the knee joint level at a distance of 120 to 140 cm.

Radiographic data included the mechanical axis angle and the 4-component alignments described by Ewald et al[23] The measurements of 4 component alignment angles, specifically the femoral valgus angle (FV), tibial valgus angle, femoral flexion angle (FF), and tibial flexion angle, were based on anteroposterior and lateral radiographs of the knees made preoperatively and postoperatively[23] (Fig. 1). The mechanical axis of the knee was measured on full-length weight-bearing radiographs from the hip to the ankle of the lower limb. All measurements were done by a blinded observer using digital radiographs on a computer. Data were compared between the 2 groups. The percentage of ideal alignment achieved for all radiographic parameters was also compared. Malalignment >3° in the mechanical axis and component positions were considered to be outliers.

2.3.2. Clinical evaluation. Clinical data collected included tourniquet time, blood loss, length of hospital stay, and complications associated with operative techniques. The intraoperative blood loss was determined by weighing the gauze sponges and measuring the blood volume in the drains. The total blood loss was the sum of the intraoperative blood loss plus the volume of postoperative drainage in the Hemovac.

Preoperative and postoperative functional scores were obtained for all patients. On each follow-up visit, patients were assessed using the scores of hospital for special surgery (HSS),[24] international knee society (IKS),[32] and the Western Ontario and McMaster University osteoarthritis index (WOMAC),[25] and the short form-36 (SF-36) health survey[26] separately for each knee. The knee society score is based on pain, the range of movement and activities of daily living. A total score of 200 indicates full function. The WOMAC osteoarthritis index is a generalized scoring system for osteoarthritis, with a total score ranging from 0 to 96 (a low score indicates a better result), while the SF-36 assesses overall function, pain, and vitality, as well as emotional and physical well-being using 8 variables (physical functioning, role-physical, bodily pain, general health, vitality, social functioning, role emotional, mental health0, on a scale of 0 to 100 points. A higher score indicates better function.

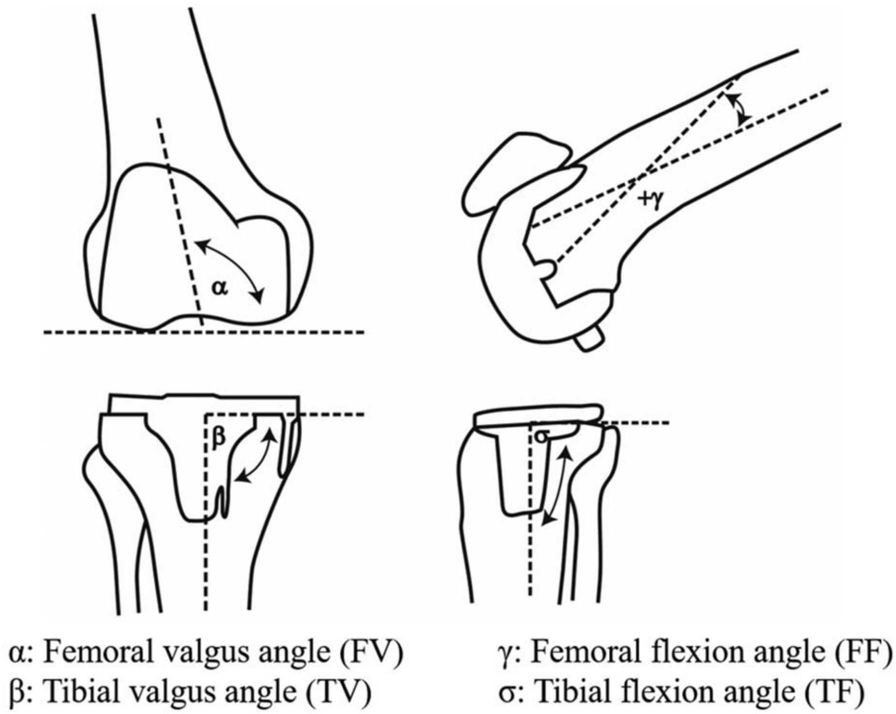

Figure 1. Schematic graph of 4 components angle.

Active knee motion was determined with the use of a goniometer preoperatively and postoperatively at follow-up.

2.4. Sample size

We calculated that at least 51 patients were required per group to achieve a power of 0.85 with 0.6 effect size and 5% significance level by using G power software version 3.1.9.2 (Heinrich Heine University Düsseldorf, Germany), and we estimated that 10% of the data would be outliers. Therefore, the proposed sample size is 56 patients in each group.

2.5. Statistical analysis

Pertinent statistic methods were applied to analyze the results. Independent *t* tests were used to detect the differences between 2 groups of clinical and radiographic data. Paired sample *t* tests were used to detect the differences between 2 groups of the processed data within 3° deviation and clinical outcomes. Statistical Package for the Social Sciences, Windows version 17.0 (SPSS, Chicago, IL) was used to analyze all data. All continuous data are presented as the mean (standard deviation). A P-value $< .05$ was considered significant.

3. Results

Four patients died from reasons unrelated to the TKA surgery. Fifty-six patients (112 TKAs) were available at the latest follow-up, of which 44 were female (Table 1). The mean follow-up duration was 8.1 ± 2.6 (4–13.6) years (Table 2). No significant difference was observed between the 2 groups regarding the length of hospital stay ($P > .05$). Conventional TKA was associated with greater operative blood loss (706 vs 565 mL, respectively; $P < .007$) and shorter operation time (65 vs 85 minutes, respectively; $P < .001$) than CAS TKA.

There was no difference in the preoperative mechanical axis angle between the 2 groups. The postoperative mechanical axis angle was closer to the target angle in the CAS TKAs when compared to conventional TKAs (180° vs 182°, $P < .001$). A closer angle to the target FV angle (97° vs 95°, $P < .001$) as well as a FF angle (2° vs 4°, $P < .001$) was observed in CAS TKAs (Table 3). There were fewer outliers in the mechanical axis angle as well as FF angles in CAS TKAs than conventional TKA ($P < .001$) (Table 4).

In 8-year follow up clinical assessment with HSS and IKS score (Table 5), the improvement was observed over both groups postoperatively, yet, was similar for both groups. The total WOMAC score also improved over 2 groups, but no significant difference existed between the groups ($P > .05$) (Fig. 2). The SF-36 scores showed no difference between the 2 groups in all parameters at the follow-up assessment ($P > .05$). The active range of motion also revealed no significant differences between the 2 groups ($P > .05$).

Table 1

Demographic characteristics of the study population.

	Navigation	Convention
N	56	
Age, yr	68.7 ± 5.8 (57–84)	
Sex	Female/Male: 44/12	
Body height, cm	154.9 ± 8.6 (137–173)	
Body weight, kg	69.2 ± 11.7 (45–96)	
BMI, kg/m^2	28.8 ± 4.1 (21.6–38.8)	

Data presented as mean ± SD (minimum-maximum).
BMI = body mass index.

Table 2

Perioperative data.

	Navigation (N=56)	Convention (N=56)	*P*
Follow up time, yr	8.1±2.6 (4–13.6)		None
Total blood loss, mL	565±223 (127–1040)	706±308 (230–1470)	**.007****
Tourniquet time, min	85±22 (42–142)	65±17 (40–120)	<.001***
LOS, d	6.2±1.2	6.5±1.5	.354

Data presented as mean±SD (minimum-maximum).
LOS=length of stay.
** *P*<.001, independent *t* test, compared between navigation and convention group.
*** *P*<.001.

Table 3

Radiographic data.

	Navigation (N=56)	Convention (N=56)	*P*
Mechanical axis			
Preoperative MA, °	193.3±7.3 (167°–214°)	193.6±7.3 (163°–209°)	.836
Postoperative MA, °	180.2±1.8 (175°–184°)	182.2±2.5 (177°–188°)	<**.001****
Component alignment			
Femoral valgus angle, °	97.0±2.0 (93°–102°)	95.4±2.1 (90°–100°)	<**.001****
Femoral flexion angle, °	2.0±1.7 (0°–10°)	4.1±3.0 (0°–11°)	<**.001****
Tibial valgus angle, °	90.1±1.4 (87°–96°)	90.1±2.3 (85°–98°)	.896
Tibial flexion angle, °	88.0±2.2 (82°–95°)	87.5±2.6 (80°–93°)	.387

Data presented as mean±SD (minimum-maximum).
MA=malalignment.
** *P*<.01, independent *t* test, compared between navigation and convention group.

Seven patients in the CAS TKA group developed complications (Table 6). Two patients developed a superficial infection, which was resolved with antibiotics. One patient developed a deep infection, which was successfully managed with arthroscopic debridement and antibiotics. One patient developed deep vein thrombosis and was managed with anticoagulant therapy. Two patients suffered from traumatic periprosthetic fracture and were successfully treated with open reduction and internal fixation (ORIF). Another patient sustained a patellar fracture in a car accident and was successfully treated with ORIF. Three patients in the conventional TKA group developed complications. Two patients sustained traumatic intertrochanteric and periprosthetic fractures of the femurs and were treated with ORIF. One patient suffered from a contusion with a laceration wound and was managed with conservative treatment. The incidence of periprosthetic fracture in CAS and conventional TKA are 4.46‰ and 2.23‰, respectively. After the Chi-square analysis, there is no

Table 4

Radiographic data within a 3° deviation of MA.

	Navigation (N=56)	Convention (N=56)	*P*
Mechanical axis (within 3° deviation)			
Postoperative MA	52 (92.9%)	36 (64.3%)	**.001****
Component positioning (within 3° deviation)			
Femoral valgus angle	49 (87.5%)	48 (85.7%)	>.999
Femoral flexion angle	46 (82.1%)	25 (44.6%)	<**.001****
Tibial valgus angle	54 (96.4%)	50 (89.3%)	.271
Tibial flexion angle	48 (85.7%)	44 (78.6%)	.459

Data presented as frequency (percentage).
MA=malalignment.
** *P*<.01, paired *t* test, compared between navigation and convention group.

Table 5

Clinical outcomes.

	Navigation (N=56)	Convention (N=56)	*P*
Preoperative function score			
IKS pain score	20.3±9.0	19.7±10.0	.729
IKS clinical knee score	54.4±15.7	55.8±14.3	.629
IKS functional knee score	41.4±12.5	39.4±14.6	.437
WOMAC	96.4±6.2	92.9±8.3	.074
HSS	77.5±9.5	78.0±12.1	.854
SF36-PCS	51.1±4.4	51.4±4.4	.815
SF36-MCS	52.1±4.1	52.1±4.1	.963
Active ROM	105.6±12.5	105.3±12.0	.895
Postoperative function score			
IKS pain score	49.4±1.9	48.5±5.0	.206
IKS clinical knee score	95.0±5.2	94.7±8.4	.847
IKS functional knee score	51.4±13.9	51.1±12.9	.914
WOMAC	93.4±5.8	93.9±5.0	.687
HSS	89.2±6.4*	91.7±3.5*	.302
SF36-PCS	43.6±7.5*	43.3±7.1*	.917
SF36-MCS	52.5±4.4	52.8±4.3	.899
Active ROM	126.3±7.8*	127.3±8.6*	.499

Data presented as mean±SD.
HSS=hospital for special surgery, IKS=international knee society, ROM=range of motion, SF-36=short form-36, WOMAC=Western Ontario and McMaster University osteoarthritis index.
P<.05, independent *t* test compared between navigation and convention group.
* *P*<.05, paired *t* test, significant difference between pre- and postoperation.

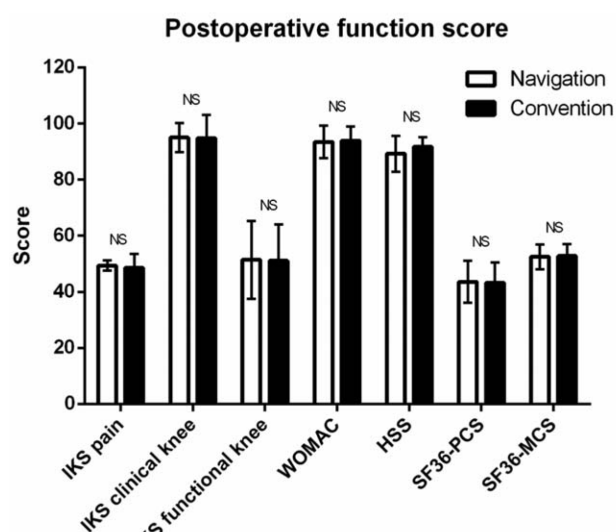

Figure 2. Comparison of postoperative clinical outcomes between navigation and convention group. *P*>.05. NS = no significant difference between 2 groups.

Table 6

Complications after surgery.

	Navigation (N=56)	Convention (N=56)
DVT	3	0
Re surgery	4	3
Revision	0	0

DVT=deep vein thrombosis.

difference between the groups ($P=.558$). No loosening of prosthesis was noted in the present study.

4. Discussion

The present study investigated and compared the results of TKA in patients who underwent staged bilateral TKAs with CAS TKA in 1 knee and conventional TKA in the other. This study design could decrease the bias from person-related differences in the subjective reported score. Further, the increased functional score may also reflect the preference of surgical technique by patients. Although closer angle to the target angle was observed in the CAS TKA group, similar subjective outcomes were observed at 8-year follow-up. No differences in clinical functional assessments such as IKDC and knee scores implied that the similar clinical results could be achieved within certain range of alignment. Meanwhile, no component loosening in both group also indicated that a certain range of deviation from the target alignment was not associated with mechanical failure at 8 years follow up. It was previously suggested that increased failure rate of TKA due to malalignment.[27] However, precise radiographic alignment of lower limbs and prosthetic component positions achieved with CAS, did not result in better clinical outcomes of TKA and decrease the failure rate in the present study.

Many studies have compared the outcomes of TKA performed with and without navigation assistance in different patients,[22,28–35] only a few have evaluated CAS TKA and conventional TKA performed in the same patient undergoing bilateral TKA.[11,18,20,22] In this study, we compared the outcomes of CAS and conventional TKA among patients undergoing staged bilateral TKA within the same surgical setting. The same TKA prostheses were implanted in the knees of the same patient by the same orthopedic surgeon to ensure that surgical technique was the main variable. The rehabilitation program was identical for each TKA. Each patient served as his/her own control, mitigating the effect of systemic comorbidity and adverse events.[18,22]

Previous studies have demonstrated that CAS TKA helps improve surgical accuracy and the alignment of lower limbs and prosthesis component positions compared to conventional TKA.[22,28–35] Some meta-analyses have also supported this conclusion.[36–41] However, only a few studies have investigated whether the radiographic improvement translates into improved clinical and functional scores, or implant survival in the medium to long-term. In our investigation, CAS TKA improved the alignment of lower limbs and prosthetic component positions and resulted in fewer outliers than conventional TKA. However, there was no significant difference between the 2 TKA types regarding clinical and functional score. Our results paralleled previous studies that no significant differences were demonstrated in clinical outcomes between CAS TKA and conventional TKA, despite the precise alignment achieved with computer-navigated surgery.[42–44]

We found no difference between CAS and conventional TKA regarding functional outcomes, implying that in the hands of an experienced orthopedic surgeon, the difference between CAS TKA and conventional TKA does not reach a level where it perturbs clinical knee function, regardless of the alignment of the lower limb and prosthesis component positions. CAS TKA is probably not advantageous for the typical patient with osteoarthritis [20,42] and maybe more beneficial in selected patients with severe deformity of the knee joint, extra-articular deformities, and severe femoral bowing.

There are limitations in our study. First, all patients were of Asian ethnicity. Second, this was a single-center study with a modest sample size. Third, the follow-up was mid-term only. A prospective, randomized multicenter study with a larger sample size and a long-term follow-up may yield different results.

5. Conclusions

The clinical outcomes at postoperative 8-year follow-up were not different between CAS TKA and conventional TKA, despite the precise radiographic alignment and fewer outliers of limb and prosthetic component positions achieved with CAS navigation assistance.

Author contributions

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Writing – original draft: Wen-Wei Robert Hsu.
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