

Clinical outcome using a ligament referencing technique in CAS versus conventional technique

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Abstract

Purpose Computer-assisted surgery (CAS) for total knee arthroplasty (TKA) has become increasingly common over the last decade. There are several reports including meta-analyses that show improved alignment, but the clinical results do not differ. Most of these studies have used a bone referencing technique to size and position the prosthesis. The question arises whether CAS has a more pronounced effect on strict ligamentous referencing TKAs.

Methods We performed a prospective cohort study comparing clinical outcome of navigated TKA (43 patients) with that of conventional TKA (122 patients). Patients were assessed preoperatively, and 2 and 12 months postoperatively by an independent study nurse using validated patient-reported outcome tools as well as clinical examination.

Results At 2 months, there was no difference between the two groups. However, after 12 months, CAS was associated with significantly less pain and stiffness, both at rest and during activities of daily living, as well as greater overall patient satisfaction.

Conclusion The present study demonstrated that computer-navigated TKA significantly improves patient outcome scores such as WOMAC score ($P = 0.002$) and Knee Society score ($P = 0.040$) 1 year after surgery in using a ligament referencing technique. Furthermore, 91% were

extremely or very satisfied in the CAS TKA group versus 70% after conventional TKA ($P = 0.007$).

Keywords Knee arthroplasty · TKA · Computer navigation · CAS · Patient outcome · Ligament referencing technique

Introduction

Despite excellent long-term results of total knee arthroplasties (TKA) [27, 37], premature failure still occurs and early loosening due to prosthesis mal-alignment remains a major factor [40]. Almost one-third of all early revisions are potentially avoidable with more accurate component positioning and ligament balancing [40]. Even though computer-assisted surgery (CAS) has been shown to improve implant positioning of the femoral and tibial component and to restore more precisely the mechanical axis in TKA [1–3, 16, 17], long-term results are lacking and there is no evidence yet that CAS also improves patient satisfaction [43]. Most prospective studies did concentrate on the radiological evaluation [2, 12, 17, 23, 32, 34, 42, 47], and only few included self-reported questionnaires such as WOMAC score or others [10, 16, 30, 31].

Two different approaches have emerged to establish the exact component position (bone referencing versus ligament referencing). Most CAS programs use bony landmarks to establish size, rotation and position of the components. Ligamentous releases are performed at the end of the procedure to fine-tune the ligament balancing. The ligament referencing technique on the other hand uses a flexion-gap-first technique, and the ligament tension at 90 deg of knee flexion determines rotation, exact position and size of the femoral component. Hence, the ligament

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referencing technique might profit more from CAS than bone referencing techniques. It was the aim of the present study to determine whether CAS improves patient satisfaction and function two and 12 months postoperatively using a strict ligament referencing technique.

Materials and methods

A prospective non-randomized cohort study was conducted. All patients undergoing a primary LCS TKA between 2006 and 2007 were included in the study. Patients with previous knee surgery (except arthroscopy) were excluded from the study. The choice whether CAS or a conventional technique was applied depended on the availability of the navigation system as well as the convenience of the theater list.

All patients gave informed consent to participate in the study, and ethical approval was attained from the Cantonal Review Board of St. Gallen.

Surgical technique

All procedures were performed with a tourniquet. A medial parapatellar approach was the standard approach. In cases of valgus deformity, patella baja or preoperative patella subluxation, a lateral subvastus approach with tuberosity osteotomy was used [20]. All patients received an LCS mobile-bearing prosthesis (DePuy Low Contact Stress Complete Knee System, Leeds, UK). A tibia-first and flexion-gap-first technique was used for both groups. The PCL was resected in all cases.

For patients in the non-navigated group, an intramedullary femoral and an extramedullary tibial alignment guide was used. Ligament tension in flexion determined femoral component size and femoral rotation. The flexion gap was routinely left 2–3 mm looser than the extension gap to improve postoperative ROM [22]. The patella was not routinely resurfaced. All knees were cemented. All

knees underwent the same standard post-TKA rehabilitation program.

For patients in the navigated group, the Vector Vision navigation system (CT-free, optoelectronic, passive marker navigation system (BrainLab, Munich, Germany)) was used. After the tibial cut had been made, the flexion gap and extension gap were measured using a spring-loaded sensor tensor (Fig. 1). The femoral component size, antero-posterior position and femoral rotation were determined to fill the flexion gap. As with the conventional technique, the flexion gap was created 2–3 mm looser than the extension gap. Using navigation, in combination with the spring-loaded sensor tensor, the position and size of the femur component could be determined precisely to obtain a slightly looser flexion gap.

Outcome assessment

The WOMAC score and Knee Society score (KSS) were used to measure clinical outcome. The Western Ontario and McMaster University Arthritis Index (WOMAC) has been validated for both preoperative and postoperative use in TKA [18]. The Knee Society score (KSS) consists of a knee referring subscale, based on clinical parameters, and a patient function score during specific activities, such as climbing stairs and walking [38].

Prior to admission, all patients were posted the WOMAC score to fill in. The Knee Society score was completed on the day of admission. All patients were reviewed at 2 and 12 months postoperatively by the same research nurse.

At the 1-year follow-up, all patients were asked how satisfied they were with the operation (“extremely”, “very”, “moderately”, “slightly” or “not at all”) and whether they would undergo the operation again (“yes” or “no”).

Statistical analysis

Student’s *t* test and analysis of variance were performed for continuous variables (age, BMI, hospital stay, operation time).



Fig. 1 Spring-loaded sensor tensor

Two-sided significance tests were used throughout. Proportions were compared by using chi-squared tests with continuity correction or Fisher's exact test when appropriate for categorical variables (complication rate, outcome scores, subjective outcome measurement).

Confirmatory analysis of knee scores was done using *t*-tests with adjustment for multiplicity by the Bonferroni–Holm procedure [21]. Statistical analysis was performed using SPSS 14.0 for Windows (SPSS Inc, Chicago, IL). The level for statistical significance was set a priori to <0.05 for all tests.

The scores were adjusted for BMI and preoperative values by an analysis of covariance.

A priori sample size determination was based on 80% power ($P = 0.05$, two-sided) to detect a difference of 10 points in WOMAC total score with a standard deviation of 20 points [43] revealed that 168 patients were needed when the ratio of navigated to non-navigated patients was 1:3.

Results

A cohort of 166 patients was included in this study. One patient was not available for follow-up because he relocated from the hospital service area (navigated group). There were no adverse events reported for this patient, and the data were excluded from the analysis. Of the remaining 165 patients, 43 had a CAS TKA (navigated group) and 122 patients had a conventional TKA (non-navigated group). A lateral approach was used in 25% of patients in the navigated and non-navigated group. All other patients had a standard medial parapatellar approach. The patella was resurfaced in one patient (navigated group).

The two groups were similar with regard to age and sex distribution (Table 1). BMI was significantly lower ($P = 0.037$) in the navigated group. This difference was adjusted for in the statistical analysis of the outcome scores. Knee flexion–extension range of motion was similar for the navigated and non-navigated groups and did not

Table 1 Demographic data for patients in the navigated and the non-navigated groups

	Navigated (<i>n</i> = 43)	Non-navigated (<i>n</i> = 122)	<i>P</i> -value
Female	23 (54%)	83 (68%)	n.s.
Male	20 (47%)	39 (32%)	
BMI [kg/m ²]	28 ± 5	30 ± 6	0.037
Age [years]	68 ± 8	70 ± 10	n.s.
Hospital stay [days]	13 ± 4	12 ± 5	n.s.
Operation time [min]	102 ± 14	95 ± 19	0.030

Table 2 Knee flexion–extension range of motion in degrees (mean ± 1SD) for the navigated and non-navigated groups preoperatively, and at 2 months and 12 months postoperatively

	Navigated	Non-navigated	<i>P</i> -value
Preoperatively	114° ± 18°	110° ± 17°	0.188
Postoperatively			
2 months	104° ± 18°	103° ± 16°	n.s.
12 months	116° ± 12°	114° ± 12°	n.s.

change from preoperatively up to 12 months postoperatively in either group (Table 2).

The navigated and non-navigated groups had similar KSS scores preoperatively and 2 months postoperatively (Table 3). However, at 12 months, the navigated group had higher scores than the non-navigated group (Table 3). In addition, 12 months postoperatively, the navigated group showed less pain during walking ($P = 0.002$), at rest ($P = 0.023$) and while climbing stairs ($P = 0.034$). Also, the total WOMAC score was significantly lower 12 months postoperatively in the navigated group compared to the non-navigated group (Table 3). The difference was also significant for all WOMAC subscales (pain, stiffness and physical function).

Twelve months postoperatively, patients in the navigated group were more satisfied with their knee replacement compared to patients in the non-navigated group (Table 4).

Overall, there were 14 postoperative complications (Table 5). The number of incidences was too small for meaningful statistical analysis. Nevertheless, it is noteworthy that no DVT occurred in the navigated group. One complication that is unique to the CAS was a fracture of the tip of a Schanz pin. The tip of the pin was left in situ. The other complication was a fissural fracture in one patient in the navigated group who presented with an undisplaced incomplete fissure of the cortex after tibial tuberosity osteotomy at the site of the pin insertion for the surgical block. The fracture was fixed with two interfragmentary screws as a prophylactic measure.

Discussion

In contrast to recent literature [1, 3–6, 8, 9, 12–14, 16, 17, 21, 25, 28, 33, 35, 39, 41–43, 45, 47], the results of the present study showed a clear benefit of CAS regarding WOMAC and KSS compared to a non-navigated technique. The disparate results raise the question of what could have caused these different findings. We believe the operating technique might be a reason. Most studies used a bone referencing technique [12, 33, 43]. The present study

Table 3 Clinical outcome assessment scores (mean \pm 1SD) adjusted for multiplicity with Bonferroni–Holm [21]

Scores	Preoperative data				12-months follow-up			
	<i>n</i>	Navigated	Non-navigated	<i>P</i> -value	<i>n</i>	Navigated	Non-navigated	<i>P</i> -value
<i>Knee Society score (KSS)</i>								
Total (0–200)	164	111 \pm 32	97 \pm 29	0.373	162	177 \pm 21	159 \pm 30	0.043
Function score	166	65 \pm 19	57 \pm 19	0.353	164	90 \pm 15	80 \pm 18	0.025
Knee score	164	47 \pm 18	40 \pm 17	0.168	162	87 \pm 10	80 \pm 17	0.018
<i>WOMAC</i>								
Total score (0–96)	154	50 \pm 18	55 \pm 17	1.000	166	9 \pm 10	21 \pm 19	0.001
Pain (0–20)	154	11 \pm 4	12 \pm 4	0.828	166	1 \pm 2	4 \pm 4	0.000
Stiffness (0–8)	154	4 \pm 2	5 \pm 2	1.000	166	1 \pm 1	2 \pm 2	0.003
Physical function (0–68)	154	35 \pm 13	39 \pm 13	1.000	166	7 \pm 9	15 \pm 14	0.004

Table 4 Subjective outcome measurement after 1 year (*n* (%))

	CAS (<i>n</i> = 43)	Conventional (<i>n</i> = 120/121)	<i>P</i> -value
Are you satisfied with your prosthesis? (extremely/very satisfied with TKA)	39 (91%)	85/121 (70%)	0.007
Would you undergo the operation again?	42 (98%)	102/120 (85%)	0.026

Table 5 Intraoperative complication and complications at 2 months postoperatively (*n* (%))

	<i>n</i>	CAS	Conventional	<i>P</i> -value
<i>Intraoperatively</i>	165	<i>n</i> = 43	<i>n</i> = 122	
Local complications	11 (7%)	2 (5%)	9 (7%)	n.s.
Fissural fracture		1 (2%)	1 (1%)	
Lesion of popliteal tendon		1 (2%)	4 (3%)	
Fracture		0	1 (1%)	
Other local complications		0	3 (3%)	
<i>2 months postoperatively</i>	165	<i>n</i> = 43	<i>n</i> = 122	
Overall complications	21 (12.7%)	1 (2%)	20 (16%)	n.s.
Transient lesion of peroneal nerve		0	1 (1%)	
Deep infection		0	1 (1%)	
Superficial wound healing problems		0	4 (3%)	
Clinical DVT		0	7 (6%)	
Subcutaneous hematoma		0	4 (3%)	
Intraarticular hematoma		1 (2%)	0	
Other local complication		0	3 (3%)	

applied a strict ligament referencing technique in flexion and extension, which might be more sensitive to cumulative errors than a bone referencing technique. In the ligament referencing technique, femoral size and rotation are established with a distraction device such as the spring-loaded tensioning device (Fig. 1) to fill and obtain a rectangular flexion gap. This strongly depends on an accurate tibial cut and correct tensioning of the medial and lateral collateral ligaments. Also in extension, the femoral bone cut is influenced by the tibial cut. Because of the strong dependency of each bone cut from the previous cut, small errors add up in the ligament referencing technique.

Longstaff et al. [29] showed in a prospective study that patients with a low cumulative error ($<6^\circ$) showed faster rehabilitation and a significantly better functional outcome. There are further studies [10, 15] supporting the present results. Choong et al. [10] demonstrated in a prospective randomized study that patients with a coronal alignment of $\leq 3^\circ$ showed a better functional outcome and higher quality of life scores. And in a retrospective case matched study of 50 patients per group, Ek et al. [15] found significantly better SF12 quality of life and International Knee Society scores (KSS) when CAS was used. Kelley et al. showed that ligament referencing CAS in combination with the

same spring-loaded tensioning device (Fig. 1) significantly reduced the postoperative manipulation rate from 16 to 7% [26]. This spring-loaded sensor tensor was also used in the CAS group, but was not used in the conventional group. Hence, it is impossible to determine whether the spring-loaded device alone, CAS alone or the combination of both CAS and sensor tensor caused our significant findings.

The CAS group did show a significantly longer operation time of 7 min. This time difference might seem small considering the necessary registration of the knee joint in the CAS group. We also did measure independently the time necessary for the pin insertion and the registration of the computer. It was well possible to perform these measures within 6 to 9 min. This time difference is also in agreement with the literature. Kalairajah et al. [24] showed a mean difference of 13 min, Lützner et al. [30] 9 min and Stulberg et al. [46] 7–10 min using the latest hardware and software.

Interestingly, no clinically relevant thromboembolic complications occurred in the navigated group compared to seven deep venous thromboses in the non-navigated group suggesting that thromboembolic complications may be reduced by CAS [11, 24]. Computer-aided surgery obviates the need for an intramedullary device at the femur. Church et al. [11] performed a double-blind randomized study to compare the incidence of fat embolic phenomena between navigated and non-navigated knee prosthesis and demonstrated a significantly reduced embolic burden in the CAS group. Fat and bone marrow is a potential activator of the clotting system and is thought an important factor for deep venous thrombosis in major orthopedic procedures. In a prospective randomized study after total hip arthroplasty, Pitto et al. [36] found a lower incidence of deep venous thrombosis in cases where an intraoperative prophylaxis against fat and bone marrow embolism was performed. It seems feasible that CAS reduces the intraoperative embolization of potential activators of the clotting cascade and thereby lowers the rate of DVTs.

A real limitation of this study was the lack of randomization. However, the study reported results on a large number of patients with complete follow-up of all but one patient. In addition, an independent study nurse performed all clinical preoperative and postoperative investigations.

The two patient groups were comparable with regard to age, sex and co-morbidities. The navigated group had a lower BMI than the non-navigated group, and this could also be a potentially confounding factor. The significant improvements also remained after adjustments for the BMI by an analysis of covariance. Also, in the literature, BMI does not appear to be a strong predictor of postoperative pain or patient satisfaction following arthroplasty [7, 19, 44].

Conclusion

The results of this 12-month follow-up study demonstrated that CAS produced better clinical outcome compared to traditional surgery in ligament referencing TKA after one year. Further refinements of computer navigation systems might not only advance radiological alignment but also pain and stiffness after TKA, which are both very influential parameters for patient satisfaction and mobility.

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