More accurate component alignment in navigated total knee arthroplasty has no clinical benefit at 5-year follow-up

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Submitted 12-04-06. Accepted 12-09-03

Background and purpose **Computer navigation in total knee arthroplasty is somewhat controversial. We have previously shown that femoral component positioning is more accurate with computed navigation than with conventional implantation techniques, but the clinical impact of this is unknown. We now report the 5-year outcome of our previously reported 2-year outcome study.**

Methods **78 of initially 84 patients (80 of 86 knees) were clinically and radiographically reassessed 5 (5.1–5.9) years after conventional, image-based, and image-free total knee arthroplasty. The methodology was identical to that used preoperatively and at 2 years, including the Knee Society score (KSS) and the functional score (FS), and AP and true lateral standard radiographs.**

Results **Although a more accurate femoral component positioning in the navigated groups was obtained, clinical outcome, number of reoperations, KSS, FS, and range of motion were similar between the groups.**

Interpretation **The increased costs and time for navigated techniques did not translate into better functional and subjective medium-term outcome compared to conventional techniques.**

Abnormal wear patterns and component loosening are mainly results of component malalignment and complications of the extensor mechanism, the most common reasons for early failure of TKA (Ritter et al. 1994, Rand et al. 2003, Vince 2003, Bathis et al. 2004). It has been suggested that a varus or valgus malalignment of more the 3° leads to faster wear and debris, followed by early failure of TKA (Ecker et al. 1987, Archibeck and White 2003, Nizard et al. 2004).

Several surgical navigation systems for TKA have been introduced to optimize component positioning (Delp et al. 1998, DiGioia et al. 1998, Krackow et al. 1999). It has been shown that navigation provides a more precise component positioning and fewer outliers (Bathis et al. 2004, Nabeyama et al. 2004, Stockl et al. 2004, Victor and Hoste 2004, Anderson et al. 2005, Zumstein et al. 2006). Nevertheless, comparing computer-navigated total knee arthroplasty with conventional implantation techniques, there is no evidence in the current literature of any significant improvement in clinical outcome and in component loosening (Bathis et al. 2004, Jenny et al. 2005, Yau et al. 2005, Bonutti et al. 2008, Molfetta and Caldo 2008).

In a prospective study involving 86 patients in 3 different groups (image-based navigation, image-free navigation, and conventional), we showed that femoral component positioning was more accurate with navigation than with conventional implantation techniques, but tibial positioning showed similar results (Zumstein et al. 2006).

Although other medium-term data on navigated total knee arthroplasty have already been reported (Ishida et al. 2011, Schmitt et al. 2011), there has been no prospective cohort series with reporting of the clinical, functional, and radiographic outcome with all 3 techniques: image-based navigated, image-free navigated, or conventional TKA. We therefore determined the clinical, functional, and radiographic 5-year results after each of the 3 techniques.

Patients and methods

78 of the 84 patients (80 of 86 knees) described in our previous study (Zumstein et al. 2006) returned for re-examination using the same (i.e. identical) clinical and radiographic imaging methodology as used at the follow-up evaluation done at a mean of 2 years. Thus, 6 patients (6 knees) were lost to follow-up between the 2-year evaluation and the 5-year evaluation. 5 of them had died of unrelated causes and 1 was unable to attend the follow-up examination because of medical conditions unrelated to the involved knee.

DOI 10.3109/17453674.2012.747923

Table 1. Demographics preoperatively and postoperatively, including reoperations. Ages are mean (SD)

	Preoperatively knees	age	5 years postop. knees	age	Lost	Reoperation
Image-based	26	69 (9)	24	76 (9)	2/26	4/26
p-value [a]		0.2 [e]		0.2 [e]	0.6 [d]	0.1 [d]
Image-free	29	73 (7)	28	77 (7)	1/29	1/29
p-value [b]		0.7[e]		0.2 [e]	0.5 [d]	0.5 [d]
Conventional	31	74 (7)	28	77 (8)	3/31	2/31
p-value [c]		0.1 [e]		0.2 [e]	0.5 [d]	0.1 [d]
Total	86		80		6/86	7/86

[a] Comparison between the image-based group and the image free-group.
[b] Comparison between the image-free group and the conventional group.
[c] Comparison between the image-based group and the conventional group.
[d] Fisher's test.
[e] Mann-Whitney U test.

At the time of total knee arthroplasty, the average age of the 78 patients in this study was 74 (50–91) years. Patients with inflammatory joint diseases or rheumatoid arthritis were not included. The study population had been divided into 3 groups sequentially according to the availability of the navigation techniques used. 26 knees were operated with an imaged-based navigation device (the image-based group), 29 were operated with an image-free device (the image-free group), and 31 knees were operated with the conventional technique (the conventional group) (Table 1). All patients were planned for a 2-year and a 5-year follow-up. Preoperative age, sex, Knee Society score, and varus/valgus malalignment were similar between the groups.

Surgical technique

All operations were performed by 2 experienced knee surgeons as described in the previous report. A standard medial parapatellar approach was used in cases with an valgus/varus malalignment of less then 10°. In the 11 knees with a greater valgus deformity, a lateral approach with an osteotomy of the tibial tuberosity was used.

As described in our previous study (Zumstein et al. 2006), the the Navitrack surgical navigation system (Zimmer, Warsaw, IN), which is based on a infrared reflex camera system, was used. For the image-based navigation, we used a computer program (Navitrack TKR 1.2; Orthosoft, Montreal, Canada) using preoperative CT scans to create a 3D model including bony landmarks. The image-free navigation was performed without preoperative CT scans. The conventional technique was performed with intra- and extramedullary standard instruments for the femur and the tibia. For planning purposes, all patients got standard long standing radiographs. The difference in mechanical and anatomical axis was assessed for planning the cuts.

All patients received an Innex UCOR TKA (Zimmer) with a rotating platform. The femoral component was either cemented or press-fitted due to the femoral bone stock; the tibial component was always cemented. Patellar resurfacing was not used in any cases.

Clinical assessment

Patients were examined 2 and 5 years after the index operation by two investigators (MAZ and LF; SH and JDM) who were not the operating surgeons (PMB/RH). For measurement of outcome, we used the "Knee Society outcome measurement tool" (also known as Knee Society score) including the "knee score" and the "functional score". Infections, reoperations, and persistent pain were registered separately.

Radiographic assessment

AP and true lateral standard radiographs were obtained. Changes in the mechanical axis and in the orientation of the femoral and tibial component were assessed by comparison with the 2-year follow-up radiographs (including long standing radiographs) by 2 surgeons in consensus. Signs of component loosening according to the Knee Society Total Knee Arthroplasty Roentgenographic Evaluation and Scoring System (Ewald 1989) and loss of alignment were registered.

Statistics

Differences between groups were analyzed using Fisher's test and the Mann-Whitney U-test. A Bonfferoni correction was done in multiple group comparisons. Post hoc power analysis was performed for Knee Society knee score and functional score. Statistical analyses were performed using SPSS statistical software version 11.

Results

Clinical results

7 patients were reoperated due to complications between the 2-year and the 5-year follow-up examinations (image-based: 4; image-free: 1; conventional: 2). In the image-based group, 2 patients needed change of the prosthesis due to late-onset infection 3 and 4 years after primary surgery. In 1 patient, we changed the femoral component 3 years after primary operation due to persistent lateral joint pain with arthroscopically confirmed lateral overstuffing. 1 patient was reoperated in another hospital because of persistent pain that we could not attribute to clinical or radiolographic pathology.

In the image-free navigated group, we made an arthroscopic debridement for postoperative arthrofibrosis 1.5 years after primary surgery. In the conventional group, 1 patient needed a change of prosthesis due to component malalignment and resulting malrotation of the inlay 1 year after implantation. Another patient had persistent pain in the region of the the tractus iliotibialis 1 year after primary surgery. We changed

Table 2. Knee Society score, functional score and active range of motion preoperatively, and 2 years and 5 years postoperatively. Scores and angles are mean (SD)

	Preoperatively	p-value [d]	2 years postop.	p-value [e]	5 years postop.	p-value [f]
Knee score (points)						
Image-based	33 (14)	0.03	81 (12)	0.7	90 (13)	0.03
p-value [a]	0.4		0.5		0.6	
Image-free	34 (15)	0.02	88 (4)	0.5	94 (6)	0.02
p-value [b]	0.8		0.8		0.6	
Conventional	29 (14)	0.04	88 (11)	0.3	94 (12)	0.03
p-value [c]	0.3		0.5		0.2	
Functional score (points)						
Image-based	44 (15)	0.03	80 (16)	0.7	82 (15)	0.02
p-value [a]	0.4		0.5		0.6	
Image-free	52 (16)	0.01	81 (19)	0.7	84 (14)	0.01
p-value [b]	0.5		0.4		0.6	
Conventional	39 (16)	0.02	82 (22)	0.2	84 (16)	0.02
p-value [c]	0.9		0.8		0.3	
Range of motion						
Image-based	96° (16°)	0.1	107° (10°)	0.5	113° (8°)	0.1
range	75°–120°		85°–125°		100°–120°	
p-value [a]	0.3		0.4		0.4	
Image-free	100° (14°)	0.3	108° (11°)	0.5	110° (9°)	0.3
range	70–115		100°–125°		90°–120°	
p-value [b]	0.3		0.6		0.2	
Conventional	102° (16°)	0.3	116° (11°)	0.4	117° (7°)	0.3
range	75°–125°		95°–130°		105°–125°	
p-value [c]	0.5		0.5		0.4	

[a] Comparison between the image-based group and the image free-group.
[b] Comparison between the image-free group and the conventional group.
[c] Comparison between the image-based group and the conventional group.
[d] Comparison between preoperatively and 2 years postoperatively.
[e] Comparison between 2 years and 5.3 years postoperatively.
[f] Comparison between preoperatively and 5.3 years postoperatively.
[a–f] Mann-Whitney U-test.

the inlay to a smaller size and the pain was relieved for 1 year, but it returned.

Comparing both navigated groups with the conventional group alone, there was a significantly higher occurrence of mechanical problems causing reoperation in the conventional group (2 of 28) than in both other groups (1 of 52) (p = 0.02).

67 of the 78 patients were very satisfied or satisfied at the 5-year follow-up. 20 of 24 patients in the image-based group and 23 of 28 patients in the image-free group had to pain. In the conventional group, 22 of 28 patients had no pain. Of these patients, 6 had some minor pain mainly during longer periods of activity. No radiographic or clinical explanation could be found.

In all 3 groups, the average knee score (KSS), the average functional score (FS), and the range of motion had increased at the 2-year follow-up and remained similar at the 5-year follow-up (Table 2). A post hoc power analysis for comparison of KSS and FS revealed enough power to detect differences of 10 points in each score (power = 0.85; alpha = 0.05; sample size = 22).

Radiographic results

2 patients in the conventional group showed lysis on the lateral (zone 3 according the the Knee Society Total Knee Arthroplasty Roentgenographic Evaluation and Scoring System) and medial (zone 1) tibia plateau of < 1 mm without any clinical significance. There was no need for reintervention. There were no signs of loosening in the image-based group and image-free group. Comparing all 3 treatment groups, there was no statistical difference according radiological signs of component loosening. Compared to both navigated groups (0 of 54), there was a higher rate of radiolucent lines in the conventional group (2 of 28; p = 0.05), but without any clinical relevance.

Preoperative varus/valgus alignment of > 10°

14 knees (image-based: 5; image-free: 4; conventional: 5) had a preoperative varus and 11 knees (image-based: 4; image-free: 3; conventional: 4) had a preoperative valgus alignment of more then 10° (Table 3). 1 knee in the image-based group had to be reoperated because of an infection. Otherwise, there were not more complications in this subgroup (varus and valgus > 10°). There was no statistically significant difference in outcome for patients with a preoperative alignment of > 10° varus/valgus and for those without—in terms of KSS, FS, and ROM (data not shown).

Table 3. Preoperative varus/valgus alignment of > 10°. Angles are mean (SD)

	Varus n	Varus angle	Valgus n	Valgus angle	Reoperations
Image-based	5	17.0° (9.6°)	4	16.3° (5.5°)	1/9
p-value [a]		0.2 [e]		0.1 [e]	0.4 [d]
Image-free	4	17.8° (4.3°)	3	18.7° (5.5°)	0/7
p-value [b]		0.4 [e]		0.1 [e]	0.2 [d]
Conventional	5	19.0° (9.6°)	4	15.3° (1.5°)	0/9
p-value [c]		0.2 [e]		0.2 [e]	0.9 [d]
Total	14		11		1/25

[a] Comparison between the image-based and the image free-group.
[b] Comparison between the image-free and the conventional group.
[c] Comparison between the image-based and the conventional group.
[d] Fisher's exact test.
[e] Mann-Whitney U-test.

Discussion

We have not found any studies showing better clinical outcome, longer implant survival, or superior postoperative function with computed-assisted TKA at medium-term follow-up. Most studies have been short-term (2 years), with no differences in clinical outcome despite the better component alignment achieved with navigation techniques (Ensini et al. 2007, Spencer et al. 2007). In a medium-term follow-up (5 years), a retrospective case-control study by Molfetta et al. found significantly better alignment in the coronal plane (but not in the sagittal plane) with navigation, but the outcomes were similar between computer-assisted surgery and conventional surgery (Molfetta and Caldo 2008). Evaluating the short-term outcome of computer-navigated knee replacement with the Norwegian Arthroplasty Register, Gothesen et al. (2011) found a higher risk of revision than with the conventional technique.

In our patients, we obtained better femoral component positioning in the 2 navigated groups then in the conventional group whereas the tibial positioning was the same. The mean surgical time was longer in the image-based group (132 min) than in the image-free group (114 min) and the conventional group (91 min) (Zumstein et al. 2006). However, we could not find any differences concerning the clinical outcome parameters shown by the KSS and the FS. Preoperative varus/valgus alignment of more than 10° did not, however, affect the postoperative outcome in any of the groups. Comparing all 3 groups, there were no differences in the numbers of reoperations and survival rates 5 years postoperatively. The more accurate femoral component positioning could be one reason for the slightly lower rate of mechanical complications and radiographic signs of loosening in the navigated groups compared to the conventional group.

We followed our patients for 5 years. It is known that the KSS and the FS increases during the first 5 years after TKA and starts to decrease around the seventh postoperative year, perhaps due to progression of arthritis at other sites (hip, not operated leg) or generally limited functional capacity (Benjamin et al. 2003). Perhaps a longer follow-up period would show the differences between our groups. In a meta-analysis of the outcome of 37 publications between 2000 and 2006, Mason et al. showed a reduction in outliers and alignment by computer-navigated TKA. Even so, they found no improvement in implant survivorship and clinical outcome by the use of navigation (Mason et al. 2007). Longer surgical times in TKA may increase the infection rates (de Boer et al. 2001). In our study we could not find any correlation between infection rate and longer operation times.

Our study has some limitations. We did not randomize our patients. However, to limit selection bias they were assessed prospectively and consecutively. Moreover, the equal differences between variances and equal means of radiographic parameters and knee scores between the groups indicate that there was no systematic selection bias between techniques. The learning curve may have been affected by the order of the procedures (image-based before image-free). Because the surgeons were familiar with the conventional technique, the learning curve may have had less influence on the operating time in the image-free group than in the image-based group. A major limitation is that we did not use CT scans to determine axial alignment and malrotation. However, there were no intraoperative or postoperative patella complications and no insufficiencies of the knee extensor mechanism, which is why we did not suspect that there was any major femoral malrotation.

In summary, the increased costs and time for navigated techniques did not result in a better medium-term outcome compared to the conventional technique.

Study design: SH, MAZ, and LF. Clinical evaluation: SH, JDM, MAZ, and LF. Surgical procedures: PMB and RH. Statistics: SH, MAZ, and JDM. Preparation of the manuscript: SH and MAZ.

No competing interests declared.

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