

Conventional versus Smart Wireless Navigation in Total Knee Replacement: Similar Outcomes in a Randomized Prospective Study

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Abstract

Purpose The development of new computer-assisted navigation technologies in total knee arthroplasty (TKA) has attracted great interest; however, the debate remains open as to the real reliability of these systems. We compared conventional TKA with last generation computer-navigated TKA to find out if navigation can reach better radiographic and clinical outcomes.

Methods Twenty patients with tricompartmental knee osteoarthritis were prospectively selected for conventional TKA ($n = 10$) or last generation computer-navigated TKA ($n = 10$). Data regarding age, gender, operated side, and previous surgery were collected. All 20 patients received the same cemented posterior-stabilized TKA. The same surgical instrumentation, including alignment and cutting guides, was used for both the techniques. A single radiologist assessed mechanical alignment and tibial slope before and after surgery. A single orthopaedic surgeon performed clinical evaluation at 1 year after the surgery. Wilcoxon's test was used to compare the outcomes of the two groups. Statistical significance was set at $p < 0.05$.

Results No significant differences in mechanical axis or tibial slope was found between the two groups. The clinical outcome was equally good with both techniques. At a mean follow-up of 15.5 months (range, 13–25 months), all patients from both groups were generally satisfied with a full return to daily activities and without a significance difference between them.

Conclusion Our data showed that clinical and radiological outcomes of TKA were not improved by the use of computer-assisted instruments, and that the elevated costs of the system are not warranted.

Level of Evidence This is a Level II, randomized clinical trial.

Keywords

- total knee arthroplasty
- navigation
- smart wireless
- limb alignment
- computer-assisted

Introduction

Over the past years, the effect of limb alignment on implant survival, component loosening, and clinical outcomes of total knee arthroplasty (TKA) has been widely reported.^{1–6}

Navigation in TKA can improve accuracy of bone resection, clinical function, and blood loss. Since its introduction, navigation has taken various forms: image-based navigation, imageless navigation, fluoroscopy-based navigation, optical navigation,^{7–10} and electromagnetic navigation.^{11–15}

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Recently, navigation systems have developed the use of gyroscopes,^{16,17} which can be attached to conventional resection instrumentation and can capture data during the procedure and exchange information using a secure local wireless (WiFi) channel, to guide the bone resections and validate component placement. This system simplifies the tracking process and provides alignment information directly on the surgical field, deserving the name of “smart wireless navigation.” One of these new navigation systems is iAssist (Zimmer, Inc., Warsaw, Indiana, United States), which is an alignment system designed with the user interface built into disposable electronic pods that attach onto the femoral and tibial resection instruments. This should assist the surgeon in the evaluation of the limb alignment, guiding bone resections and the position of the components. However, there is no clear evidence whether this new system can give such an advantage to the surgeons in their daily practice, which can justify its elevated costs.

The purpose of this study was to compare the outcome of conventional and computer-assisted knee replacement, using this new “smart wireless navigation.” Our hypothesis was that there would be no significant differences in mechanical limb alignment and tibial slope between conventional and computer-assisted TKA.

Methods

Participants

Twenty patients were randomly assigned (using a sealed envelope method) to two groups who underwent TKA either via the conventional technique ($n = 10$) or with the smart wireless navigation ($n = 10$). Inclusion criteria were unilateral pain and function impairment of the knee with bi- or tricompartmental knee osteoarthritis (OA) confirmed on preoperative standing X-rays. The Institutional Review Board approved the study and written informed consent was obtained from all subjects. Patients who refused to enter the study were excluded.

Interventions

All the patients were operated by a single orthopaedic surgeon (MD) using a limited medial parapatellar approach and received the same cemented posterior-stabilized TKA (Persona Knee; Zimmer Inc). The same surgical instrumentation, including alignment and cutting guides, was used for both the techniques. In the conventional technique, alignment guides (extramedullary for the tibia and intramedullary for the femur) were set according to a preoperative planning on anteroposterior standing and lateral X-rays, aimed to reproduce or restore the mechanical alignment of the lower limb.

For the wireless navigation technique, the surgical workflow follows the classic method of femoral and tibia bone resection with each bone resected independently along the mechanical axis (►Fig. 1). Before the resection, the electronic pods, mounted on a tibial extramedullary guide (for the tibia) and on a femoral intramedullary guide (for the femur), are activated through several movements (abduction, adduc-



Fig. 1 In the navigated total knee arthroplasty, a bone spike is impacted into the distal femoral sulcus ~10 mm anterior to the posterior cruciate ligament, in the anatomic location of the distal femoral mechanical axis, to provide a reference for the cutting guide.

tion, internal, and external rotation) of the leg (►Fig. 2). The inertial system creates and registers the coordinate system required for the navigation (femoral and tibial mechanical axes and tibial slope). Other electronic pods are placed on the cutting guides, and receiving wireless information from the other pods guides the surgeon in the correction of axis and assists the surgeon with incremental cues, including red lights when out of alignment and green lights when the cutting guide is within the desired alignment (►Fig. 3). After the resection, the cutting surface can be checked and validated with the same pods (►Fig. 4).

Outcome Measures

Data regarding age, gender, operated side, and previous surgery to the same knee were collected. Before and after surgery, anteroposterior standing and lateral X-rays views were obtained and a single radiologist, who was blinded to the surgery performed, assessed mechanical alignment, tibial slope, and fit of the implant. A single orthopaedic surgeon (F.S.) performed the clinical assessment at least 1 year after the surgery, evaluating knee range of motion (ROM), residual pain on a visual analog scale, capability of



Fig. 2 A sleeve with an electronic pod is inserted over the spike and the mechanical axis of the femur is then registered through multiple stop-and-go movements by the surgeon. The information will be then wirelessly registered and transferred to the second pod on the cutting guide.

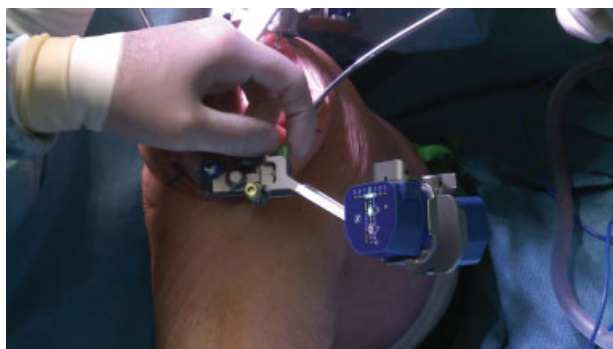


Fig. 3 Other electronic pods are placed on the cutting guides, and receiving information wirelessly from the other pods guides the surgeon in the correction of axis and assists the surgeon with incremental cues, including red lights when out of alignment and green lights when the cutting guide is within the desired alignment. Here tibial alignment and slope can both be checked.

walking without crutches, limitations in daily living activities, and general satisfaction.

Data Analysis

Outcomes were described as means \pm standard deviation (SD). Differences between the two groups according to baseline characteristics, preoperative and postoperative mechanical alignment, tibial slope, and clinical outcomes were explored using Wilcoxon's test. Statistical significance was set at $p < 0.05$.



Fig. 4 After the resection, both (A) femoral and (B) tibial cutting surfaces can be checked and validated using the electronic pods, before placing the trial components, with the same sequence of multiple movements.

Results

There was no statistically significant difference in side of operated knee, sex, age, and previous surgical history. The mean age of the two cohorts was 71 (SD 5 years) for the conventional group and 69 (SD 14 years) for the navigation group; with three male patients in the first group and four in the second group; six and four left side, respectively. Seven patients in each group had had previous surgery; all partial meniscectomy in the conventional group, while five with meniscectomy, and one with a corrective osteotomy and one who had undergone autologous chondrocyte implantation plus ACL reconstruction plus partial meniscectomy in the navigated group (**►Table 1**).

Preoperative axial alignment and tibial slope were similar in the two groups (**►Table 2**).

The femoral size of the prosthesis was from C to G in the conventional group and from D to G in the navigation group, with no significant difference ($p = 0.42$). All female patients (seven for each group) received a narrow femoral implant, as this model is more appropriate in such patients.

The tibial size was from 4 to 9 in the conventional group and from 3 to 10 in the navigation group, with no significant difference ($p = 0.35$). The polyethylene insert was from 10 to 11 in the conventional group and from 10 to 12 in the navigation group ($p = 0.58$). In seven patients for each group, we replace the patella, due to important patella OA. Coronal and sagittal images showed perfect implant fit between femur and tibia.

There were no significant differences in postoperative mechanical axis and tibial slope between the two groups (**►Table 3**).

We had no patients lost at follow-up. At a mean follow-up of 15.5 months (range, 13–25 months), all patients from both groups were generally satisfied with a full return to daily activities without any limitations. They were able to walk without crutches, and had a nearly complete ROM without a significance difference between them ($p = 0.692$). In both groups, we had one knee with occasional pain (**►Table 4**).

Discussion

Current literature has not cleared out yet whether computer-assisted navigation can provide surgeons a useful tool to have more reliable outcomes, specifically in terms of accuracy and

Table 1 Patients data

	Conventional (N = 10)	Navigation (N = 10)	p-Value
Mean age (\pm SD) (y)	71 \pm 5	69 \pm 14	ns
Gender (male)	3	3	ns
Side (left)	6	4	ns
Previous surgery	7	7	ns

Abbreviations: ns, nonsignificant; SD, standard deviation.

Table 2 Preoperative assessment

	Conventional (N = 10)			Navigation (N = 10)			p-Value
	Mean	SD	Range	Mean	SD	Range	
Preoperative MA	1.97	1.47	−0.71–4.23	1.30	2.15	−3.62–3.71	ns
Preoperative TS	2.69	1.66	0.01–4.82	2.83	2.23	0.45–7.95	ns

Abbreviations: MA, mechanical axis; ns, nonsignificant; SD, standard deviation; TS, tibial slope.

Table 3 Postoperative MA and TS

	Conventional			Navigation			p-Value
	Mean	SD	Range	Mean	SD	Range	
Postoperative MA	2.03	1.15	0.33–3.72	2.44	2.01	0.56–7.10	ns
Postoperative TS	3.04	2.00	0.91–8.12	1.94	1.50	0.36–4.68	ns

Abbreviations: MA, mechanical axis; ns, nonsignificant; SD, standard deviation; TS, tibial slope.

Table 4 Clinical outcomes

	Conventional	Navigation	p-Value
Full ROM	8	9	ns
Flexed knee	2 (1 deg)	1 (2 deg)	ns
Occasional pain	1	1	ns

Abbreviations: ns, nonsignificant; ROM, range of motion.

reproducibility of the preoperative planning. Prenavigation, introduced in 2006, had the drawback that it did not allow for evaluation of bone resection and prosthetic alignment during surgery.^{1–6} Further developments included computer-assisted TKA with optical systems,^{7–10} electromagnetic navigation, and more recently smart wireless navigation system.

Studies on computer-assisted navigation have produced inconsistent results.^{13,14,16,18} Carli et al¹⁹ reported that navigation is system dependent and not all instruments could be considered equivalent. Catani et al²⁰ found that alignment errors occur when navigation is not used for bone resection and prosthesis implantation. Benavente et al²¹ reported that navigation could be useful in correcting varus deformity between 10 and 15 degrees, whereas Shao et al²² found that it could be useful in correcting more severe deformities even in cases of valgus knee deformity. In contrast, Huang et al²³ found no major differences or benefits with navigation in correcting severe valgus knee deformity. In their review of 30 studies, Thienpont et al⁶ concluded that it is unclear whether navigated TKA provides clinical benefits because many of them were methodologically flawed.

In this still controversial scenario, we wanted to understand if computer-assisted navigation could provide surgeons a useful tool to have more accurate and reproducible radiographic results in respect to preoperative planning. However, our hypothesis was there would be no significant difference in mechanical alignment of the limb and tibial

slope between conventional and computer-assisted TKA. On this purpose, we prospectively analyzed two randomly selected groups of patients who, respectively, underwent a conventional or navigated knee replacement. The two groups showed to be homogeneous as for their demographic characteristics and for the knee preoperative mechanical alignment and tibial slope. The same surgeon performed the procedures with the same surgical technique, and the type and size of the implants were not significantly different in both groups.

The results showed no significant differences between the two groups for mechanical alignment and tibial slope. Neither had we found out a real advantage in reaching preoperative planned component alignments. Clinically, patients from both groups were generally satisfied with no significant limitations in ROM and daily activities at more than 1 year after the surgery, thus no differences were underlined between the two techniques.

Smart wireless navigation for TKA offers some advantages over other navigation systems or prenavigation and as compared with prenavigation, it does not require imaging studies (magnetic resonance imaging or computer tomography). In addition, the hardware is less invasive because it obviates the need for placing large pins in bony segments.²² The surgeon can focus his complete attention on the operating field, obtain immediate control, and verify axial alignment.^{23–25}

As with other navigation systems, these advantages come at a price: more expensive than conventional TKA and more attention must be paid to guide positioning.¹³ Furthermore, operating time is slightly longer and an assistant must be present to direct the navigation.^{13–15}

Nonetheless, as with other navigation systems, different results may be obtained particularly in difficult knees (valgus or varus–flexion deformities) and there is no way to adequately control the femoral rotation.

The study has major limitations. First, the small sample size implies a risk of type-II error. Second, the short-term

follow-up does not provide information on survivorship of the implants.

In conclusion, the data from this prospective, randomized study showed no substantial difference in outcomes between conventional and smart wireless navigation TKA, nor a major advantage of the latter method in achieving mechanical alignment and tibial slope planned values. Smart wireless navigation does not provide more information on knee rotation, particularly as concerns femoral rotation. Given the higher cost of computer-assisted navigation, there is no real benefit for patients.

Conflict of Interest
None.

References

- 1 Ensini A, Timoncini A, Cenni F, et al. Intra- and post-operative accuracy assessments of two different patient-specific instrumentation systems for total knee replacement. *Knee Surg Sports Traumatol Arthrosc* 2014;22(03):621–629
- 2 Liu Z, Pan X, Zhang X. Total knee arthroplasty using navigation system for severe osteoarthritis with extra-articular deformity. *Eur J Orthop Surg Traumatol* 2013;23(01):93–96
- 3 Mannan A, Smith TO, Sagar C, London NJ, Molitor PJ. No demonstrable benefit for coronal alignment outcomes in PSI knee arthroplasty: a systematic review and meta-analysis. *Orthop Traumatol Surg Res* 2015;101(04):461–468
- 4 Ng VY, DeClaire JH, Berend KR, Gulick BC, Lombardi AV Jr. Improved accuracy of alignment with patient-specific positioning guides compared with manual instrumentation in TKA. *Clin Orthop Relat Res* 2012;470(01):99–107
- 5 Sassoon A, Nam D, Nunley R, Barrack R. Systematic review of patient-specific instrumentation in total knee arthroplasty: new but not improved. *Clin Orthop Relat Res* 2015;473(01):151–158
- 6 Thienpont E, Fennema P, Price A. Can technology improve alignment during knee arthroplasty. *Knee* 2013;20(Suppl 1):S21–S28
- 7 Cheng T, Zhao S, Peng X, Zhang X. Does computer-assisted surgery improve postoperative leg alignment and implant positioning following total knee arthroplasty? A meta-analysis of randomized controlled trials?. *Knee Surg Sports Traumatol Arthrosc* 2012;20(07):1307–1322
- 8 Confalonieri N, Chemello C, Cerveri P, Manzotti A. Is computer-assisted total knee replacement for beginners or experts? Prospective study among three groups of patients treated by surgeons with different levels of experience. *J Orthop Traumatol* 2012;13(04):203–210
- 9 Fu Y, Wang M, Liu Y, Fu Q. Alignment outcomes in navigated total knee arthroplasty: a meta-analysis. *Knee Surg Sports Traumatol Arthrosc* 2012;20(06):1075–1082
- 10 Schlatterer B, Linares JM, Chabrand P, Sprauel JM, Argenson JN. Influence of the optical system and anatomic points on computer-assisted total knee arthroplasty. *Orthop Traumatol Surg Res* 2014;100(04):395–402
- 11 Blyth MJ, Smith JR, Anthony IC, Strict NE, Rowe PJ, Jones BG. Electromagnetic navigation in total knee arthroplasty—a single center, randomized, single-blind study comparing the results with conventional techniques. *J Arthroplasty* 2015;30(02):199–205
- 12 Rhee SJ, Seo CH, Suh JT. Navigation-assisted total knee arthroplasty for patients with extra-articular deformity. *Knee Surg Relat Res* 2013;25(04):194–201
- 13 Smith JR, Rowe PJ, Blyth M, Jones B. The effect of electromagnetic navigation in total knee arthroplasty on knee kinematics during functional activities using flexible electrogoniometry. *Clin Biomech (Bristol, Avon)* 2013;28(01):23–28
- 14 Thiengwittayaporn S, Kanjanapiboonwong A, Junsee D. Midterm outcomes of electromagnetic computer-assisted navigation in minimally invasive total knee arthroplasty. *J Orthop Surg* 2013;8:37
- 15 Thiengwittayaporn S, Junsee D, Tanavalee A. A comparison of blood loss in minimally invasive surgery with and without electromagnetic computer navigation in total knee arthroplasty. *J Med Assoc Thai* 2009;92(Suppl 6):S27–S32
- 16 Nam D, Weeks KD, Reinhardt KR, Nawabi DH, Cross MB, Mayman DJ. Accelerometer-based, portable navigation vs imageless, large-console computer-assisted navigation in total knee arthroplasty: a comparison of radiographic results. *J Arthroplasty* 2013;28(02):255–261
- 17 Khan H, Walker PS, Zuckerman JD, et al. The potential of accelerometers in the evaluation of stability of total knee arthroplasty. *J Arthroplasty* 2013;28(03):459–462
- 18 Clayton AW, Cherian JJ, Banerjee S, et al. Does the use of navigation in total knee arthroplasty affect outcomes? *J Knee Surg* 2014;27(03):171–175
- 19 Carli A, Aoude A, Reuven A, Matache B, Antoniou J, Zukor DJ. Inconsistencies between navigation data and radiographs in total knee arthroplasty are system-dependent and affect coronal alignment. *Can J Surg* 2014;57(05):305–313
- 20 Catani F, Biasca N, Ensini A, et al. Alignment deviation between bone resection and final implant positioning in computer-navigated total knee arthroplasty. *J Bone Joint Surg Am* 2008;90(04):765–771
- 21 Benavente P, López Orosa C, Oteo Maldonado JA, Orois Codesal A, García Lázaro FJ. Computer assisted surgery. Its usefulness in different levels of pre-operative deformities. *Rev Esp Cir Ortop Traumatol* 2015;59(04):245–253
- 22 Shao JJ, Zhang XL, Wang Q, Chen YS, Shen H, Jiang Y. Total knee arthroplasty using computer assisted navigation in patients with severe valgus deformity of the knee. *Chin Med J (Engl)* 2010;123(19):2666–2670
- 23 Huang TW, Kuo LT, Peng KT, Lee MS, Hsu RW. Computed tomography evaluation in total knee arthroplasty: computer-assisted navigation versus conventional instrumentation in patients with advanced valgus arthritic knees. *J Arthroplasty* 2014;29(12):2363–2368
- 24 Manzotti A, Confalonieri N, Pullen C. Intra-operative tibial fracture during computer assisted total knee replacement: a case report. *Knee Surg Sports Traumatol Arthrosc* 2008;16(05):493–496
- 25 Tigani D, Busacca M, Moio A, Rimondi E, Del Piccolo N, Sabbioni G. Preliminary experience with electromagnetic navigation system in TKA. *Knee* 2009;16(01):33–38