Computer Navigation Systems in Unicompartmental Knee Arthroplasty: A Systematic Review

Rajesh Nair, BSc, MD, Gayatri Tripathy, MD, and Gaston R. Deysine, MD

Abstract

We conducted a systematic review to consolidate the body of knowledge about use of computer navigation systems in unicompartmental knee arthroplasty (UKA), to determine whether these systems are useful in UKA, and to discuss the financial costs involved. We searched Medline (2002 to 2013) for articles in which results of navigated and conventional techniques were compared.

In the navigated group, implant alignment was optimal in the desired angular range more often, and there were fewer outliers. However, the groups did not differ with respect to clinical knee scores, survival rates, or range of motion. Longer surgery in the navigation group could result in an increase in navigation-related complications. The lack of clear evidence of the usefulness of computer-assisted navigation systems in UKA has impeded universal acceptance of this technology in the orthopedic community. Definitive evidence can be generated only with large randomized studies with long-term follow-up.

Treatment of isolated medial compartmental arthritis is a significant challenge for orthopedic surgeons. Evidence suggests that unicompartmental knee arthroplasty (UKA) may be effective in providing long-term pain relief and functional improvements.[1-3] However, the success of UKAs is influenced by several factors, including patient selection, implant design, alignment, and fixation.[1] Failure can result from malposition or malalignment (> 3° malalignment of the tibial component, > 7° posterior tibial slope, or varus malalignment of the mechanical axis).[1,3-6] Such malalignment can occur in 40% to 60% of all components that are implanted using conventional manual instrumentation techniques.[1,7] The assumption regarding mechanical alignment is that any variance beyond a certain safety range can lead to aseptic component loosening.[1,2,7] There is, however, considerable debate about what constitutes the optimal safety range.

The catalyst for developing navigation systems was the desire to improve postoperative limb alignment and component positioning. The main goal of the navigation system is to produce a digital image that can be used as a road map by the operating surgeon.[8] Surgical instruments are incorporated into the map and controlled so that their position, attitude, and progress are accurately monitored.[8] There are 3 different ways to produce this digital image. The first method involves performing preoperative computed tomography (CT) or magnetic resonance imaging to collect anatomical information that is then transferred in an appropriate format to the system computer. A second method uses perioperative imaging through a modified fluoroscopy unit that is maneuvered during the surgery, and data are transferred directly to the system computer through a hardwired connection. These 2 methods are called *image-based systems*.[8] The third method is image-free, and the anatomical model predetermined in the software is upgraded through a registration process. Image-free systems use infrared cameras, metal body markers fixed to femur, tibia, and pelvis, and a detector that determines implant position and defines the mechanical limb axis. Registration involves identifying key anatomical landmarks for the computer and is required in all 3 methods.[8] Registration accuracy is important in successful postoperative limb alignment.

The authors of a prospective randomized study comparing navigated versus conventional techniques noted that navigated UKA was not as well validated as navigated total knee arthroplasty (TKA).[9] Despite the lack of randomized trials, however, individual studies have tried to explore characteristics of navigation systems, such as their radiographic and clinical results. Our aims in this systematic review were to consolidate the body of knowledge about use of computer navigation systems in UKA, to determine whether computer navigation systems are useful in UKA, and to discuss the financial costs of using this technology.

Materials and Methods

We searched Medline (2002 to 2013) for articles in which clinical results of navigated and conventional techniques were compared with respect to UKA. All randomized controlled trials, meta-analysis, and retrospective studies were included.

Authors' Disclosure Statement: The authors report no actual or potential conflict of interest in relation to this article.

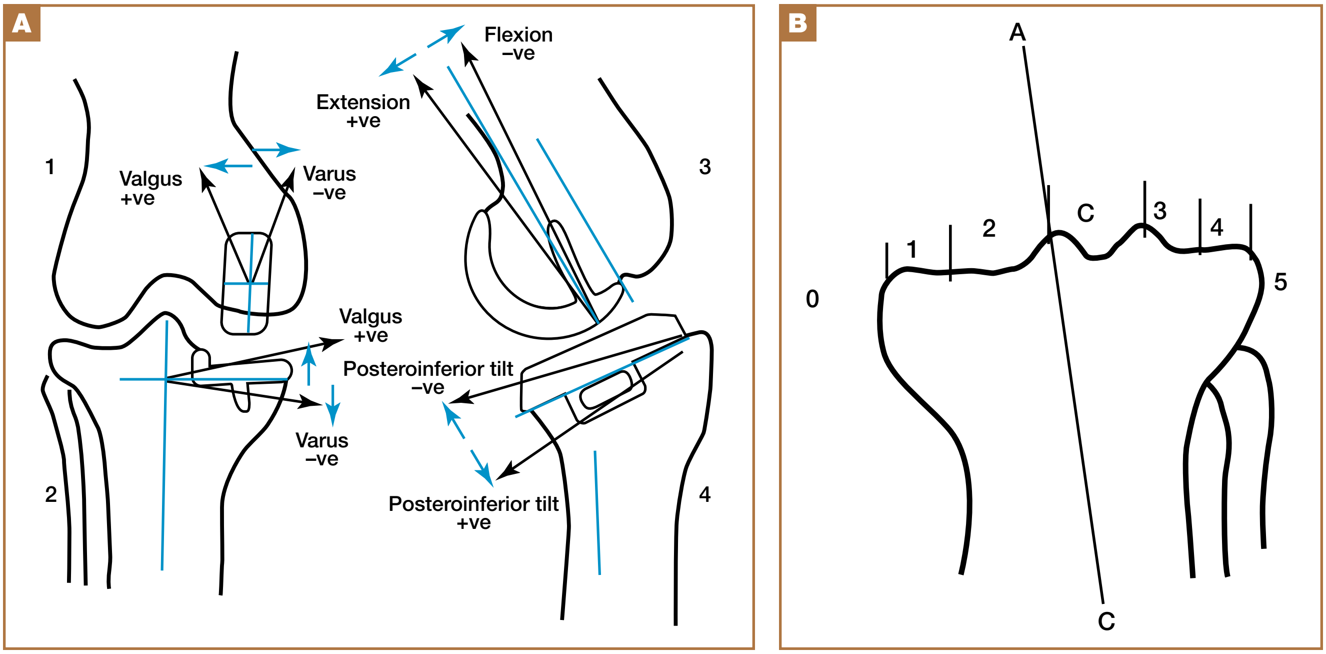

Figure. General radiographic criteria used in the literature for component alignment. (A) 1. Femoral component varus/valgus; 2. Tibial component varus/valgus; 3. Femoral flexion/extension; 4. Tibial posteroinferior tilt. (B) Kennedy and White zones (A-C, mechanical axis).

Abbreviations: +ve, positive counter-clockwise direction; –ve, negative clockwise direction.

Key search terms were *unicompartmental knee arthroplasty* and *computer navigation*. There were no language restrictions. Variables of interest were coronal alignment, clinical outcome, range of motion (ROM), cost, and survival rates. We did not perform a meta-analysis because of the small number of randomized prospective studies that compared UKA with navigation and UKA without navigation.

Results

Current investigations of the role of navigation systems in UKA have had inconsistent results (**Table**).

In a prospective randomized study, Lim and colleagues[9] did not find any improvement in postoperative axial limb alignment measurement with use of a computer navigation system compared with conventional non-navigation techniques. Their study, conducted over a 12-month period, involved 30 navigated UKAs and 21 cases with non-navigation techniques. Generally, most studies used radiographic criteria similar to the ones shown in the **Figure**.

In the conventional group, measurement of the limb mechanical axis on CT scanogram revealed a mean (SD) axis of –2.8° (2.0°; range, –5.8° to 3.1°). Four CT measurements (19%) were within the desired postoperative limb alignment assessed with the alignment rod. According to the Kennedy protocol, 95% of the cases had the mechanical axis passing through desired tibial zones 2 and C. Measurement of the frontal alignment of the tibial component on the CT scanogram revealed a mean (SD) alignment of 87.2° (1.5°).

In the navigated group, measurement of the limb mechanical axis on CT scanogram revealed a mean (SD) axis of –3.3° (2.4°; range, –9.5° to 0.9°). Three CT measurements (10%) were within the desired postoperative limb alignment based on the navigation system readings. According to the Kennedy protocol, 90% of the cases had the mechanical axis passing through desired tibial zones 2 and C. Measurement of the frontal alignment of the tibial component on CT scanogram revealed a mean (SD) alignment of 87.0° (2.1°).

The overall mechanical limb alignment for the study cohort was –3.1° ± 2.2°. Analysis of the difference in the mean mechanical alignment measurement using the *t* test revealed no statistical significance (*P* = .2) between the mean differences in alignment between the 2 groups at 95% confidence level. The navigation-assisted group was found to have a wider range and increased outliers. Analysis of the difference in the frontal alignment of the tibial component revealed no statistical significance (*P* = .4) for the mean differences in alignment between the 2 groups (95% confidence interval [CI]).

In a prospective randomized matched-pair trial involving 20 patients with simultaneous bilateral UKA, Keene and colleagues[10] found at 6 weeks that navigation UKA improved lower limb alignment. In the navigated knees, actual mean (SD) correction achieved was to 1.3° (2.1°) of varus (range, 5.5° varus to 2° valgus), including varus and valgus alignments. Mean (SD) variation between preoperative planned alignment and actual achieved alignment was 0.9° (1.1°; range, 0° to 4°).

In the non-navigated knees, actual mean (SD) correction achieved was to 0.5° (2.9°) of varus (range, 6° varus to 5° valgus), including varus and valgus alignments. Mean (SD) variation between preoperative planned alignment and actual achieved alignment was 2.8° (1.4°; range, 1° to 7°).

These differences in planned versus achieved alignment (1.9°) between the groups were found to be statistically highly significant ($P < .001$). Assessment of lower limb alignment in the non-navigated group revealed that only 12 cases (60%) were within plus or minus 2° of the preoperative plan, compared with 17 (87%) of the navigated cases; 5 patients (27%) therefore had limb alignment improved with use of the navigation system.

We further evaluated a recent meta-analysis by Weber and colleagues,[11] who compared radiologic positioning of the implant between navigated UKA and conventional techniques. One important limitation of their study is the level of evidence included (level II and III studies) because of the low num-

Table. **Prospective and Retrospective Studies Comparing Conventional (C) and Navigated (N) UKAs**

Study	Year	C/N, n	Study Design	Follow-Up	C/N Implant	Navigation System	Findings
Weber et al[17]	2011	20/20	Prospective	1.5 y	Same for both—Univation[a]	OrthoPilot[a]	No difference in positioning; KSS was similar
Konyves et al[18]	2010	15/15	Retrospective	6.9 y	Allegretto[b]/EIUS[c]	Stryker[d]	No difference in radiologic alignment, OKS, or survivorship
Jung et al[19]	2010	25/17	Retrospective	2 y	Same—Oxford Phase III[e]	Stryker[d]	Improved accuracy in sagittal alignment for N
Seon et al[15]	2009	33/31	Prospective	2 y	Same—Miller-Galante[f]	OrthoPilot[a]	Improved mechanical axis and lower % of outliers for N; no difference in HSS scores, WOMAC, or ROM
Ma et al[14]	2009	45/53	Prospective	2 y	Same—Oxford Phase III[e]	FluoroGuide[g] (image-based system)	Improvements in coronal alignment precision of tibial component and sagittal alignment precision of femoral component for N; no difference in SF-36 or WOMAC
Lim et al[9]	2009	21/30	Prospective randomized	1 y	Same—Freedom[h]	OrthoPilot[a]	More neutral mechanical axis with narrower range for C than for N; no difference in mechanical axis
Rosenberger et al[24]	2008	20/20	Prospective	Immediate postoperative period	Same—Oxford Phase III[e]	Medtronic Treon Plus[i]	Optimal implant alignment higher in N narrowed range of outliers in all planes of component orientation
Jenny[23]	2008	30/30	Retrospective	3 mo	Search/Search[a], Univation[a]	OrthoPilot[a]	N improved accuracy of radiologic implantation
Jenny et al[13]	2007	60/60	Prospective	1 y	Same—Search[a]	OrthoPilot[a]	No difference in alignment outcomes between minimally invasive surgery–N and C
Keene et al[10]	2006	20/20	Prospective randomized matched-pair	6 wk	Same—Preservation[j]	Ci[k]	Postoperative alignment significantly improved for N than for C
Jenny et al[22]	2006	87/49	Retrospective	6 mo	Oxford Phase III[e]/Univation[a]	OrthoPilot[a]	Implantation results better for N than for C
Cossey & Spriggins[16]	2005	15/15	Prospective	8 mo	Allegretto[b]/EIUS[c]	Stryker[d]	Limb alignment more accurate and reproducible for N than for C; OKS was similar
Jenny[21]	2005	30/30	Retrospective	3 mo	Same—Search[a]	OrthoPilot[a]	Implant positioning more improved for N than for C
Perlick et al[12]	2004	20/20	Prospective	5 mo	Same—Preservation[j]	Ci[k]	Component orientation more precise for N than for C
Jenny & Boeri[20]	2003	30/30	Retrospective	3 mo	Same—Search[a]	OrthoPilot[a]	For N, significant increase in rate of prostheses implanted in desired angular range for all criteria, except coronal mechanical femorotibial angle

Abbreviations: HSS, Hospital for Special Surgery; KSS, Knee Society Score; OKS, Oxford Knee Score; ROM, range of motion; SF-36, Short Form–36; WOMAC, Western Ontario and McMaster Osteoarthritis Index.

[a]Aesculap, Tuttlingen, Germany; [b]Sulzer, Wintherthur, Switzerland; [c]Stryker-Howmedica, Allendale, NJ; [d]Stryker Navigation, Kalamazoo, MI; [e]Biomet, Warsaw, IN; [f]Zimmer, Warsaw, IN; [g]iGO Technologies, Grundy, VA; [h]Maxx Orthopedics, Plymouth Meeting, PA; [i]Medtronic Inc., Minneapolis, MN; [j]DePuy, Warsaw, IN; [k]DePuy/Brainlab, Warsaw, IN.

ber of randomized trials. Their analysis of 10 studies (258 navigated UKAs, 295 conventional UKAs) revealed a reduced risk for outliers with navigation systems. Regarding femoral anteroposterior (AP) alignment, the studies reported a total of 9/173 outliers (5%) in the navigated group and 38/219 (17%) in the conventional group. Regarding femoral lateral alignment, there were 32/173 outliers (18%) in the navigated group and 91/219 (41%) in the conventional group. Regarding tibial AP alignment, there were 13/173 outliers (8%) in the navigated groups and 30/219 (14%) in the conventional group. Regarding tibial lateral alignment (tibial slope), there were 15/173 outliers (9%) in the navigated group and 48/219 (22%) in the conventional group. Weber and colleagues[11] concluded that use of navigation systems in UKA leads to more precise component positioning. Whether more accurate position in UKA leads to a better clinical outcome or long-term survival is yet unknown.

Various prospective[12-17] and retrospective[18-24] studies have also analyzed the accuracy of postoperative leg alignment and component orientation of navigated and conventional UKA. Typical findings were published by Rosenberger and colleagues,[24] who examined the immediate short-term effect of image-free computer navigation technology on implant accuracy. Optimal implant alignment, including all measurements in the desired angular range, was significantly ($P = .041$) higher in the navigated cohort. Navigation eliminated outliers in frontal mechanical alignment and coronal orientation of the femoral component totally and significantly ($P < .02$). Furthermore, navigation narrowed the range of outliers in all other planes of component orientation. The authors concluded that navigation immediately improves accuracy of bone cuts and reduces the number of outliers with implementation in UKA.

In a recently published mid-term study with 7-year follow-up, Konyves and colleagues[18] found that a larger proportion of navigated knees was well aligned with a more reproducible position. However, they also found no statistically significant difference in radiologic alignment between navigated and conventional groups. Their study followed up on a 2005 study by Cossey and Spriggins[16] and is one of the few published studies that have examined implant survivorship. Of 28 original patients (30 knees), 3 patients (3 knees) underwent revision to TKA. All 3 were in the navigated group. Two were revised after 1 year because of continuing pain, and 1 was revised after 5 years because of disease progression. Comparison of survival curves between the navigated group (78.6%) and the non-navigated group (100%) showed the difference was not statistically significant ($P = .0625$).

Only 5 studies have used clinical knee scores for navigation UKA and conventional techniques.[14-18] No differences were reported. Weber and colleagues[17] found Knee Society Scores (KSS) improved significantly in both groups 1.5 years after surgery but did not differ between the 2 groups. Seon and colleagues[15] found no significant differences in Hospital for Special Surgery (HSS) and Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) total, pain, and function knee scores between the groups. Similarly, there were no significant differences in preoperative and postoperative ROM. Cossey and Spriggins[16] found no differences in Oxford Knee Scores (OKS) between navigated UKAs at a mean follow-up of 8 months (range, 1 to 13 months) and UKAs with conventional techniques at a mean follow-up of 17 months (range, 15 to 23 months). Konyves and colleagues[18] also found no differences between the 2 groups in terms of OKS or ROM. Ma and colleagues[14] found no significant differences between the conventional group and an imaged-based system group in terms of WOMAC and Short Form–36 (SF-36) scores at 1- and 2-year follow-up.

These results are difficult to interpret clinically, as there are differences in study design (retrospective, prospective), types of knee scoring systems used, and small sample sizes. Some of the major complications listed for navigated UKA include deep vein thrombosis,[16] revision to TKA for pain and disease progression,[18] tibia-side pin-site infection for tracker attachment,[19] and periprosthetic stress fractures in the medial tibial plateau.[15,17] Fractures have also occurred around pin sites used in navigated TKA, according to Burnett and Barrack.[25] Pin-site fractures were unique to the procedure and occurred about 1% of the time, commonly in the distal femoral diaphysis or supracondylar region. These fractures had a complicated course involving retrograde nailing or locking-plate fixation. The authors indicated that other nonfracture pin-site minor complications include multiple pin-insertion attempts, navigated TKA aborted because of pin loosening, inability to insert other pins, and nerve injury.

> Use of navigation systems in UKA leads to more precise component positioning. Whether more accurate position in UKA leads to a better clinical outcome or long-term survival is yet unknown.

There is also a reported time difference between navigated and conventional groups in terms of operating time. According to the meta-analysis by Weber and colleagues,[11] mean duration of surgery was 15.4 minutes longer for navigated UKA (95% CI, 10.19 to 20.61) than for conventional methods. There were no differences in terms of infection rates or mortality. During the postoperative course, there were fewer cardiologic events in the navigation group. The difference was attributed to use of intramedullary rods in the conventional group, as these rods were not used in the navigation group and possibly reduced the incidence of fat emboli.

Discussion

Our review found that, compared with conventional methods, navigated UKA improved component alignment and position and reduced radiographic outliers. However, there were no differences in short- and mid-term clinical outcome related to implant survivorship, knee function scores, or ROM. In addition, using the navigation system increased duration of surgery by about 15 minutes. Advocates of navigated UKA have proposed that an improvement in postoperative limb alignment would lead to better long-term patient outcomes.

Weber and colleagues[11] identified all trials involving imageless navigation of UKA and pooled them in a meta-analysis. Our systematic review was different: we included the 1 study with an image-based navigation system[14] and various retrospective studies[13,18,20-23] that Weber and colleagues[11] excluded. In addition, we examined implant survivorship and the financial cost of using this technology. Any review of the literature is limited by the quality of its reports. Studies of navigated UKA were mainly retrospective and nonrandomized and had small sample sizes and weak methodology (level II and III). This can lead to biases. Therefore, we used a systematic search strategy to identify publications and screened with predetermined criteria to reduce bias. We included retrospective studies because of the small number of randomized trials. Our rationale was that improvement in postoperative limb alignment could lead to improved long-term knee function and implant survivorship.

Our findings were similar to those of Burnett and Barrack[25] in their systematic review for navigated TKA. Those authors hypothesized that, though navigated TKA improves coronal plane alignment and may reduce outliers, clinical outcomes will not yet be improved. They also found improved alignment in navigated TKA in the coronal plane and fewer radiographic outliers. Previous studies of short-, medium-, and long-term follow-up did not find any improvement in clinical function scores, revision rates, or implant survivorship.

We identified other issues with the literature. Data on mid- to long-term results are limited. Studying long-term outcomes of navigation technology may require follow-up of at least 10 years. Konyves and colleagues[18] reported a study with a mean 7-year follow-up for the navigated group, but the sample size was small, and there was a loss of statistical power. The difference in survival between the 2 groups was not statistically significant ($P = .06$); with longer follow-up, however, it may become significant in favor of the non-navigated group. The study by Konyves and colleagues[18] represented the initial part of the surgeon's learning curve with the navigation system, which has unfavorably affected their results. Higher revision rates have also been reported with respect to the EIUS implant,[26] and that finding may have been a factor in their survival analysis. Consequently, results are difficult to interpret. Another issue is that many surgeons who favor navigated UKA work at university hospitals and conducted their research there. To get a wider spectrum of results, more nonacademic community hospitals need to conduct their own trials. Arguably, this can be a challenge because of the costs involved.

Perhaps one of the most important factors in determining the usefulness of new technology is cost. There have been no formal assessments of use of this technology, but current estimates of incorporating a new system into the operating room range from $135,000 to $300,000.[27,28] Studies describing the financial impact of using navigation systems have found it can be cost-effective if the revision rates are lowered to a specific level and the longevity of the implant is extended.[27,28] However, there is a lack of cost-effectiveness data comparing UKA with navigation systems and UKA without. One issue to consider is whether market size warrants the expenditure.[27,28] Primary UKAs in the United States translate to a market potential of about 600,000 knees per year.[27,28] Current advantages of navigation systems are theoretical. The costs involved in buying specific types of hardware are significant.[8] The surgery also involves additional steps that would require extra resources and training. In addition, the software is specific to each brand of hardware.[8] Some systems are even closed systems, in which a procedure can demand different software packages for different implants.[8] Changes in implant designs can also require buying software upgrades.[8] Despite these cost-related questions, there are no published prospective studies on cost-effectiveness data.

Unfortunately, the discrepancy in study types, the small sample sizes, and the lack of long-term results make meaningful comparisons of navigated and conventional techniques difficult. To date, the literature includes little evidence that surgeons can use to guide modification of clinical practice. Theoretically, computer-assisted navigation systems were designed to improve implant alignment and component positioning. Given the current indeterminacy in their outcomes, however, universal acceptance of this technology is lacking. The challenge for proponents of navigation technology in UKA is to provide clinical data showing better patient outcomes. In addition, the technology should improve surgeon productivity, be cost-effective, increase implant longevity, and give a return on investment. This can be accomplished only with large randomized trials. As yet, clear evidence of the usefulness of this technology in UKA does not exist.

Conclusion

The current literature demonstrates that using computer navigation for UKA results in better limb alignment and component positioning. However, the different methodologies combined in these studies—retrospective and prospective—impair the translatability of the results. Most of the studies referenced are underpowered and poorly controlled. Even mid-term clinical results are lacking. There is no clear evidence demonstrating the usefulness of navigation systems in UKA thus impeding universal acceptance of this technology by surgeons. Definitive evidence can only be generated with large, randomized, prospective studies.

Dr. Nair is Research Associate, Vancouver Island Health Authority, Victoria, Canada. Dr. Tripathy is Foundation Year 2 Resident, Royal Lancaster Infirmary, Lancaster, United Kingdom. Dr. Deysine is Orthopedic Surgeon, Section of Orthopedics, Virginia Mason Federal Way Medical Center, Federal Way, Washington.

Address correspondence to: Rajesh Nair, BSc, MD, Vancouver Island Health Authority, #2-1521 Belcher Avenue, Victoria, BC, V8R 4N2, Canada (tel, 914-595-2699; fax, 250-721-8146; e-mail, nairra@gmail.com).

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