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Computer-assisted Total Knee Arthroplasty Is Currently of No Proven Clinical Benefit: A Systematic Review

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Abstract

Background Navigated total knee arthroplasty (TKA) may improve coronal alignment outliers; however, it is unclear whether navigated TKA improves the long-term clinical results of TKA.

Questions/Purposes Does the literature contain evidence of better long-term function and lower revision rates with navigated TKA compared with conventional TKA?

Methods A systematic literature review was conducted of navigated TKA reviewing articles related to coronal alignment, clinical knee and function scores, cost, patient satisfaction, component rotation, anteroposterior and mediolateral stability, complications, and longer-term reports.

Results Coronal plane alignment is improved with navigated TKA with fewer radiographic outliers. We found limited evidence of improvements in any other variable, and function was not improved. The duration of surgery is increased and there are unique complications related to navigated TKA. The long-term benefits of additional increase in accuracy of alignment are not supported by any current evidence.

Conclusions The findings in reports of navigated TKA should be interpreted with caution. There are few short- and medium- and no long-term studies demonstrating improved clinical outcomes using navigated TKA. Despite substantial research, contradictory findings coupled with reservations about the cost and efficacy of the technology have contributed to the failure of computer navigation to become the accepted standard in TKA. Longer-term studies demonstrating improved function, lower revision rates, and acceptable costs are required before navigated TKA may be widely adopted. In the future, with improvements in study design, methodology, imaging, navigation technology, newer functional outcome tools, and longer-term followup studies, we suspect that navigated TKA may demonstrate yet unrecognized benefits.

Introduction

TKA is a common surgical procedure for knee arthritis, effective in relieving pain and improving function [102]. Adequate alignment and proper component positioning at the time of TKA improve the survivorship of TKA [5, 15], whereas implant malalignment and malposition are

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This study was performed at the Washington University Department of Orthopedic Surgery (St Louis, MO, USA) and the University of Victoria/University of British Columbia (Victoria, BC, Canada) Division of Orthopaedic Surgery.

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associated with decreased function and/or higher revision rates [14, 101]. In one study, more than 50% of TKA revisions were performed within 2 years postoperatively, and component malposition was a common reason [108]. In addition, when TKA is performed in lower volume hospitals (hospital volume of < 25–50 TKAs/year), a higher TKA revision rate at 5 to 8 years has been reported [58, 74, 92] along with increased complications. Thus, solutions to improve revision rates and to reduce component malposition have been the focus of current research.

The use of conventional alignment guides in TKA reportedly achieves a neutral mechanical axis (± 3°) in approximately 75% of cases [7] and has been described as the best case scenario [73] for conventional TKA using standard guides. Early TKA failure if not within 3° of neutral mechanical axis has been reported [14, 51] and is the basis for selecting this degree of alignment for current TKA research [29, 65, 69, 98, 101, 121, 127] and for computer-assisted TKA.

Navigated TKA was first performed in 1997 [34] and its use and technology have evolved rapidly. Navigated TKA has been recognized as a useful technique in patients undergoing TKA with extraarticular deformity [22, 64] with applications now evolving for use in knees with less deformity (< 10°) in routine TKA [46]. Navigated TKA is gaining popularity [2, 40, 42, 87] and combines the technology of computer-assisted orthopaedic surgery with conventional TKA in an attempt to improve the clinical, radiographic, and functional scores in patients undergoing TKA by reducing radiographic outliers.

Navigated (computer-assisted) TKA reduces the number of outliers in the coronal mechanical axis [9, 11, 36, 41, 52, 57, 72, 79, 80, 97, 112, 116, 128] and has indirectly associated reduced outliers with improved long-term function and perhaps lower revision rates and/or survival, although this is not substantiated with data. However, recently reported Mayo Clinic data [95] at 15 years after conventional TKA question the validity aiming for a mechanical axis within 3° of neutral. A postoperative mechanical axis alignment in the coronal plane within 0° to 3° did not improve the implant survival rate with modern conventional TKA techniques.

Proponents of navigated TKA have argued that these techniques may improve the functional scores, alignment, revision rates, and survival in TKA. The arguments in favor of navigated TKA over conventional TKA include decreasing the percentage of radiographic outliers in coronal and sagittal plane alignment, improved accuracy in component axial rotation, improved flexion-extension gap and ligament balancing, comparable operative times once experience is gained, acceptable costs, low complication rates, reasonable learning curves, equal or improved functional scores, and the potential for improved survival of TKA implants as a result of improved surgical technique. Many of the reports supporting these arguments include small cohorts and low levels of evidence. In addition, although many of these navigated TKA studies do show improvement in radiographic outliers, they correctly suggest these improvements have not translated, as yet, to improved knee function, quality of life, and survival of the implant [50]. In addition, the unique complications associated with navigated TKA and the added expense and operative time further bring into question the cost-benefit of navigated TKA.

The purpose of this review is to provide a balanced view of navigated TKA and to discuss the current literature and controversies surrounding navigated TKA regarding coronal alignment, axial alignment, long-term durability, and patient-specific instrumentation. In addition, we discuss operating room times, costs, and the complications unique to navigated TKA.

Materials and Methods

We undertook a systematic review of the current literature of navigated TKA to determine if any clinical functional or radiographic parameters are improved with navigated TKA compared with conventional TKA. This is not a meta-analysis, because recent meta-analyses have been reported and focus on alignment primarily in the coronal plane. Using the MEDLINE database, with a focus on randomized clinical trials, meta-analyses, and registry data, we performed a review of the evidence for navigated TKA. Publications within the last 10 years in the English literature were evaluated using the search headings: total knee arthroplasty, navigation, computer assisted, and complications. In addition to TKA coronal alignment (which is the primary variable studied in most reports), we reviewed other factors including clinical scores, cost, patient satisfaction, component axial rotation, AP and mediolateral stability, complications, and longer-term durability of navigated TKA compared with conventional TKA.

Results

Recent studies examining the effect of navigation on TKA alignment have produced contradictory findings. Although most studies report more accurate mechanical axis and component alignment with fewer outliers using navigation [9, 18, 36, 41, 60, 66, 123], others have shown no major differences [61, 63, 71, 117] between navigated TKA and conventional TKA comparing clinical, functional, and imaging results. To evaluate this further, we have reviewed recent meta-analyses and randomized clinical trials (RCTs) with an emphasis on recently reported RCTs with longer followup. Meta-analyses have been used to evaluate the findings in studies with small numbers and often inadequate power analysis to make adequate conclusions themselves. Unfortunately, meta-analyses are limited by many factors including level of evidence, patient selection biases, surgeon experience with the studied intervention, and most notably statistical variability. Studies comparing navigated TKA versus conventional TKA have been recently evaluated in five meta-analyses [10, 23, 25, 78, 89] with two published within the last year [23, 25]. Interestingly, there is disagreement among these studies. In 2007 Bauwens et al. [10] reported on 33 studies combining 3423 patients comparing navigated TKA with conventional TKA. The main conclusions included no difference in infection, thromboembolic events, or the overall mechanical axis alignment between the two groups with a 23% increase in operating room time for navigated TKA. There was inconclusive evidence to assess functional improvement and complications. However, navigated TKA did demonstrate a lower risk of malalignment at the 3° and 2° thresholds for mechanical axis outliers. In addition, as the mechanical axis outlier degree was increased from 0° up to 6°, the authors demonstrated the decreasing advantage of navigated TKA. Strong statistical heterogeneity and differences were noted, and the conclusion was that there are few advantages over conventional TKA on the basis of radiographic end points. Later the same year a second meta-analysis was reported by Mason et al. [78] with conflicting results despite including similar studies. Navigated TKA showed improvements in mechanical axis (within 3° in 9% of navigated TKA versus 31.8% of conventional TKA), frontal tibial and femoral component alignments within 3°, and tibial slope and femoral flexion angles within 2°. This study included comparative cohort studies and did indicate that doing so may have inherent selection bias. The authors were critical of and indicated there may have been an analytic and design error in the study by Bauwens et al. [10], explaining the differences. In 2010, Novicoff et al. [89] reported a meta-analysis spanning 1990 to 2008 reviewing studies comparing conventional and computer-assisted techniques in TKA. Analysis of 22 randomized controlled studies showed a clear advantage in terms of alignment for computer-assisted surgery; however, no studies evaluated the associations between patient characteristics and function beyond the degree of malalignment within a short period after the surgery. The authors concluded there is a need for studies that examine knee function at more than 1 year postoperatively using standardized assessment tools, especially because malalignment is an intermediate measure that cannot be linked causally in all cases of eventual implant failure. In 2011, two meta-analyses were reported. Cheng et al. [25] analyzed six studies [17, 83, 91, 97, 120, 129] published before 2008, again noting improved coronal alignment within 3° for navigated TKA (95%) compared with conventional TKA (66%) with an increased operative time of 18 minutes in navigated TKA. However, no differences in knee function or complications were found, and they concluded there was no benefit in short-term clinical functional benefit using navigated TKA. Brin et al. [23] used a Bayesian meta-analysis compiling 20 studies demonstrating an 80% reduction in mechanical axis and similar coronal tibial and femoral component outliers when navigated TKA was used. There was no evaluation of sagittal alignment. In 2011, the Norwegian Arthroplasty Register [38, 39] reported a higher rate of revision at 2 years in navigated TKA (using a mobile-bearing implant) compared with a conventional technique. They attributed these findings to the learning curve and technical aspects of navigated TKA, which was the new variable introduced. In summary, the findings of these five meta-analyses and the Registry data are inconclusive to support routine use of navigated TKA based on their conclusions. Registry data and longer-term, well-designed RCTs may provide more useful information.

Several RCTs comparing navigated TKA with conventional TKA have now been reported [3, 7, 11, 14, 15, 18, 20, 21, 28, 29, 32, 33, 35, 38, 49–51, 55, 56, 61, 65, 127] (Table 1). One of these recently reported by Harvie et al. [42] is an example of the findings that have been reported by other studies yet with longer followup than any other RCT. This study is a 5-year followup (and update of two previous reports by the same authors [24, 113]) of a RCT comparing navigated TKA and conventional TKA. Improvement in coronal, sagittal, and axial alignment on CT scans was observed with navigated TKA. Despite achieving better alignment with navigated TKA, no improvement in clinical or functional knee scores, quality of life, or patient satisfaction has been demonstrated compared with conventional TKA. A recently reported 5-year randomized trial (nonblinded) [48] comparing the functional knee scores of computer-assisted and conventional TKA demonstrated no difference in the frequency of malalignment between navigated and conventional TKA. Compared with conventional surgery, navigated TKA resulted in a better mean Knee Society score. However, the difference in mean Knee Society scores over time between the two groups was not constant. Unfortunately, nearly 40% of the patients did not have complete clinical scores; thus, the data must be interpreted with caution. The majority of these studies have a common theme: fewer outliers in coronal plane alignment/mechanical axis deviation from 3° [11, 14, 18, 20, 35, 38, 49, 50, 55, 56, 61, 65, 127], some demonstrating improved sagittal plane alignment [14, 18, 20, 35, 55, 65, 127] and no or not studied

Table 1. Recent randomized clinical and radiographic studies comparing navigated TKA with conventional TKA

Authors	Year	Journal	Study design	Number	Followup duration	Results
Harvie et al. [42]	2011	J Arthroplasty	Alignment, rotation, function, satisfaction	71	5 years	Improved coronal, sagittal, axial alignment; no clinical, functional or satisfaction difference
Blakeney et al. [16]	2011	J Bone Joint Surg Am	Alignment, rotation, complications, function	107	3 months	Improved coronal, sagittal alignment; no axial rotation, clinical, functional or satisfaction differences
Schmitt et al. [103]	2011	BMC Musculoskelet Disord	Clinical, alignment, CT scan	90	3 years	worse clinical results (KSS); improved femoral coronal alignment only
Zhang et al. [127]	2011	J Bone Joint Surg Am	Simultaneous bilateral TKA, alignment, rotation, function	64	6 months	Improved coronal, sagittal alignment; no axial rotation, clinical, functional differences
Choi et al. [28]	2011	J Arthroplasty	Radiographic alignment in frontal plane	160	6 months	improved frontal femoral alignment; mechanical axis and frontal tibial alignment similar; 20% outliers on postoperative radiographs despite no intraoperative outliers
Barrett et al. [6]	2011	J Arthroplasty	Multicenter, radiographic coronal and sagittal, clinical (KSS, WOMAC)	208	1 year	Only improved coronal tibial alignment
Hiscox et al. [47]	2011	J Arthroplasty	Alignment, rotation, function, satisfaction	141	1.2 year	No improvement in any study variable
Lutzner et al. [70]	2010	Knee Surg Sports Trauma Arthrosc	Functional outcomes (KSS, EQ5D) and rotation	73	20 months	Improvement in knee society *knee* score only; no other differences
Kim et al. [61]	2009	J Bone Joint Surg Am	Simultaneous bilateral TKA, alignment, rotation, function	320	3.4 years	No improvement in any variable
Lutzner et al. [71]	2008	J Bone Joint Surg Br	CT and radiographic alignment and rotation	80	1 year	No difference in axial, sagittal, or coronal alignment
Matziolis et al. [80]	2007	J Bone Joint Surg Am	Three-dimensional CT alignment, rotation, ROM, KSS	60	6 month	Improved coronal and sagittal alignment; no rotation or clinical difference (KSS, WOMAC)
Mombert et al. [85]	2007	Acta Orthop Belg	CT coronal, sagittal, rotational	42	3 months	Improved range of outliers but no significant differences
Seon et al. [106]	2007	Comput Aided Surg	Bilateral TKA comparing navigation versus conventional; alignment, clinical	42	1 year	No differences at 1 year
Kim et al. [63]	2007	J Bone Joint Surg Br	Simultaneous bilateral TKA, alignment, function	200	2.3 years	No improvement in alignment or function
Seon and Song [105]	2006	J Arthroplasty	MIS-TKA with navigation versus conventional TKA, pain scores, ROM	102	2 weeks	No differences in clinical or alignment outcomes

Table 1. continued

Authors	Year	Journal	Study design	Number	Followup duration	Results
Victor and Hoste [120]	2004	Clin Orthop Relat Res	Alignment in the coronal, sagittal plane, patella, clinical	100	3 months	Improved alignment in the coronal plane not sagittal; no differences clinical or patella tracking
Chin et al. [27]	2005	J Arthroplasty	Alignment coronal and sagittal	90	Immediate postoperative	Improved alignment coronal and sagittal; no clinical results
Decking et al. [33]	2005	J Arthroplasty	Alignment coronal and sagittal, function,	50	3 months	Improved coronal and sagittal alignment, no clinical difference (KSS, WOMAC)
Sparmann et al. [112]	2003	J Bone Joint Surg Br	alignment sagittal and coronal; no functional outcomes	240	2 months	Improved mechanical axis and frontal femoral and tibial axes; no clinical outcomes reported

KSS = Knee Society score; MIS = minimally invasive surgery.

clinical, functional, or survival improvement associated with navigated TKA compared with conventional TKA [3, 7, 11, 18, 20, 21, 35, 50, 51, 55, 56, 65, 127], and all studies demonstrated a substantially increased operating room time and associated added cost to the procedure. Worse functional knee scores have been reported with navigated TKA in one study [103] at 3 years. Three recent studies [15, 21, 32] demonstrated no improvement in coronal, sagittal, or axial alignment. Despite no outliers intraoperatively, up to 20% outliers [28] on plain radiographs have been reported, questioning the use of plain radiographs to assess frontal plane alignment [1, 46, 64, 99, 125]. In several recent studies [3, 21, 28, 29, 38, 51], there was no difference in limb alignment, component rotation using both radiographs and/or CT imaging, and no difference in function. In one study, there was more varus limb alignment [47] in the navigated TKA group with no improvement in alignment precision. The authors hypothesized that small but consistent errors in navigation landmarking may be responsible and that the costs of navigated TKA are not warranted. In another study [6], improvement in coronal tibial alignment only occurred and femoral sagittal flexion was worse with navigation. Navigation may not take into account the bow of the femur, and the authors recommend distinct dissection of the anterior femoral area to improve navigated TKA registration. Unfortunately, many of these series typically do not include functional or knee scoring despite large study designs [112].

It would be expected that longer-term studies with improved followup and larger numbers would deliver the proposed results in favor of navigated TKA that the proponents of this technology have emphasized. However, that is not necessarily the case. Kamat et al. [57] analyzed 637 primary TKAs comparing navigated TKA with conventional TKA in two cohorts (nonrandomized) with 1 to 5 years followup. There was no difference in clinical knee score measures; however, a higher number of mechanical axis outliers in conventional TKA were noted, suggesting longer followup is required. Similarly, in 777 navigated TKAs evaluated retrospectively [42] at 5 years, no differences in clinical or functional knee scores were noted. Other 5-year comparative cohort studies [84] have demonstrated improved mechanical axis and component rotation but no improvement in function or clinical knee scores measures. Ishida et al. [50] reported a prospective comparative study of 60 knees (30 navigated TKAs) at a minimum of 5 years and found improved coronal mechanical axis alignment, less femoral component internal malrotation, improved ROM, and better Knee Society knee scores but not function scores. Other non-RCTs demonstrate no advantage to navigated TKA [21, 45] at 8 years (functional and clinical scores, revision rates, and mechanical axis the same) [45] or show improved alignment and mechanical axis only but without evidence for improved knee function [9, 84].

The importance of correct axial rotational component alignment in TKA has been reported, and the effect and association with extensor mechanism maltracking have been recognized [5, 15]. Although the proponents of navigated TKA argue the benefits of improved coronal alignment, the use of navigated TKA studying component rotation has been less well reported [24, 32, 47, 80, 91, 100, 103, 115, 119], requiring more complex CT scan analysis. In addition, the virtual position of the femoral component during navigated TKA differs from the CT scan femoral component rotation postoperatively, and intraoperative navigated TKA rotation may be subject to variations during the procedure such as pin movement, component insertion, bone loss, and difficulty locating and registering epicondylar landmarks and may not reflect final component position [119]. Although there have been reports of reducing the percentage of outliers (ideal within 3° of epicondylar or tibial tubercle axis; outliers defined as $> 6°$ outside of the axis [52, 103] of acceptable axial component rotation [24, 103, 115] for both the femoral and tibial components in both mean and percentage of outliers [103]), others (including RCTs) have demonstrated no improvement in mean and percentage of outliers for component rotation [21, 35, 42, 47], we found no study demonstrating improvement in mean or outlier numbers for tibial component rotational alignment. One cohort study compared component malalignment and postoperative pain in navigated TKA [32] and found no difference between chronic pain using WOMAC pain score with navigated TKA compared with conventional TKA. In one study [32], postoperative pain correlated with CT axial malalignment of $> 3°$ of rotation for both navigated and conventional TKA, and the authors concluded there was no clinical benefit to navigated TKA but that a statistical relationship between axial malalignment and pain may exist regardless of a navigation or conventional TKA technique.

The effects of changes in the joint line in TKA are well documented in conventional TKA [37, 96] affecting stability, ROM, patellofemoral joint mechanics, and functional knee scores. Few studies have evaluated joint line position in navigated TKA compared with conventional TKA [3, 126]. In a recent RCT [3] comparing navigated TKA with conventional TKA, the authors found no difference in joint line position between the two techniques and no difference in ROM or SF-12 with respect to joint line change. However, TKAs in which the joint line was depressed postoperatively improved the least in terms of functional scores, whereas changes in alignment also affected Knee Society scores. Song et al. [111] have studied the relationship between AP and mediolateral stability comparing navigated TKA with conventional TKA in cruciate-retaining TKAs using fluoroscopic stress view techniques and found no difference in knee scores at 1 year in stability, ROM, or Hospital for Special Surgery knee scores.

The costs associated with navigated TKA, without a clear long-term benefit, continue to be debated. Startup costs, training, software, maintenance and upgrade, additional operating room time, learning curves, complications, imaging (CT or other), and the costs associated with each of these may be important and are clearly recognized [9, 19, 40], even by proponents of navigated TKA. In all studies comparing navigated TKA with conventional TKA, the cost of using a navigated TKA system is a factor that is well recognized yet difficult to quantify. Cost is often addressed indirectly with an increase in operative and procedure time for navigated TKA [47]. An increase in operating room time for navigated TKA is required as a result of the additional computer processing, pin and tracker placement, array registering of data points, and analysis of intraoperative data. This increase in operating room time is variable and ranges [3–5, 9, 12, 13, 19, 28, 59, 61, 65, 66, 127] between an increase of 8 to 63 minutes and may be nearly double [62] or more than double [10] the procedure time with a higher incidence of complications [9] compared with conventional TKA. However, it has been suggested that time efficiency in navigated TKA may be gained by customizing the navigation protocol to eliminate certain steps and by not resurfacing the patella [114]. In one study by Bonutti et al. [21] comparing minimally invasive TKA in navigated versus nonnavigated knees, "no advantage for navigation" was reported in the article and abstract, yet the mean operating room time for navigation (112 minutes) versus nonnavigation (54 minutes) was more than two times longer. We identified no studies that demonstrate a cost savings or equality in the long or short term comparing navigated TKA with conventional TKA. Using a decision model to evaluate the cost-effectiveness of navigated TKA, Novak et al. [88] determined that a cost savings might be achieved if the navigated TKA cost is $629 US or less (compared with conventional TKA per procedure). This analysis considered revision TKA rates at 15 years and achieving a coronal plane alignment within 3° of the mechanical axis. Notably, cost-effectiveness with this model will become more favorable when applied to younger patients undergoing TKA with longer life expectancies. Using a different model to assess costs associated with navigated TKA, Dong and Buxton [35] also believe there may be a savings in the long term with an additional charge of $430 US per case. The potential for reduced revision rates and lower complications through more accurate and precise alignment in navigated TKA is predicted. When image-based navigated TKA (preoperative CT scan or fluoroscopy) with the additional preoperative image planning is compared with image-free navigated TKA, no improved accuracy can be demonstrated [129], and there is an increase in preoperative planning costs combined with preoperative radiation associated with the additional imaging. These analyses presume that a lower revision rate will be achieved with navigated TKA, a hypothesis that has never been proven.

With the development of patient-specific TKA techniques, there has been an interest in comparing the costs of this technique with navigated TKA and conventional TKA procedures. Patient-specific TKA, in which preoperative imaging provides the surgeon with custom cutting jigs for optimal component alignment, has been recently developed. This technique avoids the expense of computer hardware, software, and maintenance costs that prevents computer navigation from being cost-effective at low-volume centers. Watters et al. [122] recently reported that using this technique and guides compared with navigated TKA (and conventional TKA) produced an operating room time savings of 67 minutes compared with navigated TKA and overall lower total procedure-related cost compared with navigated TKA at their institution. The authors concluded that this time savings is likely to provide a greater economic impact to the healthcare system than implant-related cost savings and navigation.

Complications unique to navigated TKA have been reported, are typically increased [19–21], and may occur in up to 17% [20] compared with conventional TKA. Studies are conflicting with data from the NSQUIP survey reported in 2005 (identified 1156 navigated TKAs from 101,596 TKAs) showing no difference in mortality, a lower rate of cardiac complications, shorter lengths of hospital stay, and a trend toward fewer hematomas in the navigated TKA group.

Proponents of navigated TKA favor this technique as a result of the potential for reducing or eliminating intramedullary (IM) canal instrumentation and secondarily reducing fat and marrow embolization [31, 56]. However, differences in methodology measuring emboli exist between studies, making comparisons difficult. Transesophageal (TE) and transcranial ultrasound have been used to detect pulmonary [17, 39, 41, 43, 93] and cranial emboli [26] with methods of calibration to eliminate noise from flow and cavitation in one study [86] described as arbitrary. Maximum embolic load [17, 39, 43, 93] has been reported to occur immediately after tourniquet release and continues for 15 to 120 seconds and no showers of emboli seen during IM canal instrumentation. In contrast, Kalairajah et al. [56] and Church et al. [31] showed emboli occurred at the time of IM instrumentation, favoring the navigated TKA technique over conventional TKA. However, this has not translated to decreased rates of postoperative confusion or respiratory thromboembolic events comparing navigated TKA with conventional TKA [40], and in a recent meta-analysis [10], no difference in venous thromboembolism events was found. O'Connor et al. [90] used TE echo in navigated TKA compared with conventional TKA and measured emboli after tourniquet deflation for five consecutive 1-minute intervals and found no major difference, and Kim et al. [62] studied arterial samples of fat and marrow and found no difference between navigated TKA versus conventional TKA samples. Cognition after navigated TKA compared with conventional TKA has been studied [43], revealing no difference in mental status examination, oxygen requirements postoperatively, and at 6 months after surgery.

A decrease in blood transfusion requirements [40] or blood loss [24, 56, 81, 104] secondary to no IM canal instrumentation has been proposed as an advantage by surgeons who favor navigated TKA. However, contradictory evidence exists and many studies do not support that conclusion [29, 36, 57] and have not demonstrated any difference in hemoglobin drop, transfusion rates, or blood loss. One study [56] used three suction drains for blood salvage and claimed substantial savings in terms of cross-matching of blood with navigated TKA only requiring a type and screen.

Fractures [8, 10, 24, 31, 44, 54, 63, 68, 94] have been reported to occur around pin sites used in navigated TKA and are unique to this procedure, occurring approximately 1% [12] of the time (Fig. 1A–G). More commonly these fractures occur in the distal femoral diaphysis [8, 23, 63] or supracondylar [31] region. These fractures have been reported as having a complicated course, requiring retrograde nailing or locking plate fixation, and are considerable [8] but with functional knee scores equivalent to before the fracture [6] reported. Fractures typically may occur with minimal trauma (rising from a chair) and preceding symptoms of thigh pain without trauma are common. Fractures may occur intraoperatively or up to 12 months postoperatively [6, 24] and pin site holes from navigation pins are not routinely visualized on standard radiographs postoperatively, often requiring a longer radiograph to see these pin site bone changes. The etiology has been attributed to multiple risk factors [49]: female sex, osteoporosis [27, 30, 67], larger pin diameters (5 mm), bicortical pin placement [24, 27], multiple pin passes, increased stress riser, thermal necrosis of bone [24, 31, 68], a pin design with a lower risk fluted tip, and 1-mm (increased) pitch with self-tapping and self-drilling pin designs preferred. Fractures have also been reported in the tibia [22, 34, 52, 76, 107] treated successfully with nonoperative treatment. In one cadaver study [77], pins directed from the anterolateral to the posteromedial distal femur were in close proximity (within 5 mm) to the popliteal vessels. Other nonfracture pin site minor complications [44] have been described including multiple pin insertion attempts, aborting navigated TKA as a result of pin loosening, inability to

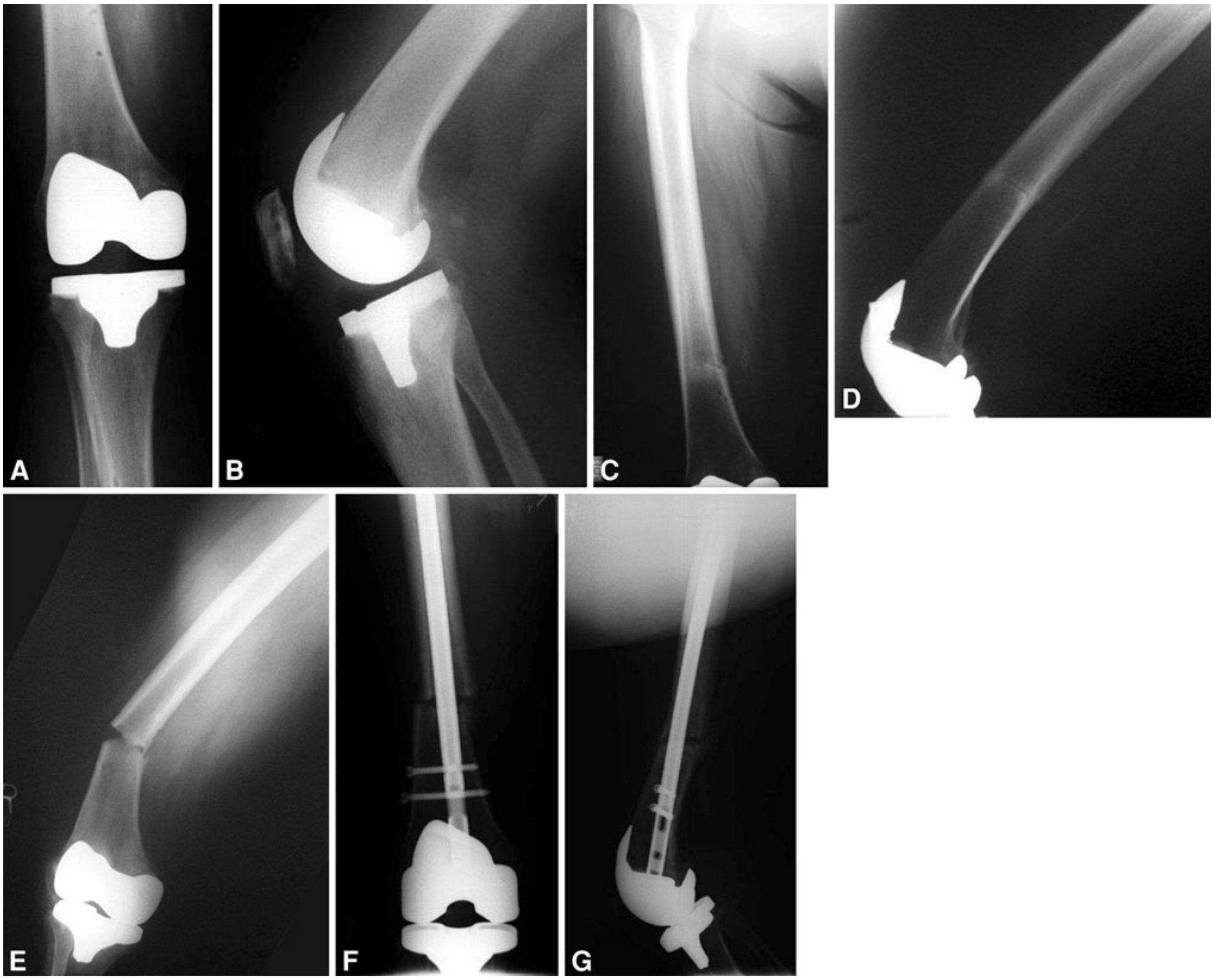

Fig. 1A–G A 65-year-old woman presents at 6 months postoperatively with distal thigh pain; routine AP (**A**) and lateral (**B**) radiographs were performed. Longer leg femur films (**C**–**D**) demonstrate the distal pin sites with periosteal bone reaction. Two weeks later the patient presented with a transverse distal femur fracture (**E**) requiring retrograde nailing (**F**–**G**).

insert iliac crest pins, hematoma, infection [110], and nerve injury [8, 54]. There is a potential for a hyperextended position of the femoral component with navigated TKA, leading to a risk of anterior femoral cortex notching [16, 25, 37, 82]. There is a conflict between the perpendicular cut to the sagittal mechanical axis and notching in 40% to 85% in males and 65% to 100% of females. Navigated TKA must account for this conflict and the surgeon must recognize this potential intraoperatively.

Discussion

Improved alignment in navigated TKA in the coronal plane and a reduction in radiographic outliers have been demonstrated in the reports we have reviewed for this study. That question has been answered previously by numerous studies confirming the same or similar results. Despite this fact, previous meta-analyses, RCTs, and nonrandomized studies of short-, medium-, and long-term followup have not demonstrated any improvement in clinical function scores, revision rates, or improved survival for TKA performed with navigation compared with conventional TKA. The presumption that if improvement in coronal plane alignment with a reduction in outliers is achieved and that this might then translate to improved function, survival of TKA implants, and lower revision rates is not supported by any research to date. We focused our review on clinical trials performed within the last 10 years to include older studies with longer followup, but also to include the more modern versions of navigated TKA with contemporary technology and surgical technique. We hypothesized that although navigated TKA does indeed demonstrate improvements in coronal plane alignment and may reduce outliers, the clinical outcomes will not yet be improved. However, the question of whether this translates into improved functional and clinical outcomes has been the focus of this review. Our research questions are (1) does navigated TKA produce improved clinical outcomes and lower revision rates; and (2) are other parameters including sagittal alignment, axial rotation, cost of technology, patient satisfaction, AP and mediolateral stability, and complications improved with navigated TKA, at least in the medium term and/or long term?

We identified deficiencies in the literature and not several related to our review. First, there is no evidence for medium- to longer-term studies supporting functional improvements or reduced revision rates for navigated TKA. Although there is one recently published medium-term study, the results and analysis are confusing and contradictory and do not support the numerous other publications that demonstrate no functional improvements. Thus, to argue that navigated TKA may produce improved results and/or that we are just unable to currently realize these improved results with our current measurement tools is not practical and may mislead surgeons who perform TKA. Until we have definitive evidence from different centers with prospectively collected data at longer-term followup, this statement and concept are not supported. Second, even published meta-analyses using the same or similar studies cannot agree on the consensus of whether there is evidence to support any functional improvements in navigated TKA. Different methods of statistical analyses, incomplete power calculations, and cohort studies combined together lead to confusing and contradictory results. Third, many of the studies have been performed at high-volume academic centers by surgeons with an interest or even conflict of interest with industry and the development of navigation technology and who perform many TKA procedures already. Thus, we note a paradox: navigation is likely most affordable (ie, the costs can be distributed) in high-volume centers where surgeons are least likely to need navigation to achieve proper alignment in most patients and surgeons who could likely most benefit from the ability of navigation to reduce the number of outliers (presuming that is important) are in low-volume centers where navigation would likely be impractical from the point of view of costs and learning curves. Finally, there are unfortunately many studies that we reviewed that have no functional followup, or only radiographic results, or less than 2 years of clinical results. Clearly these studies, although providing useful feedback to surgeons about radiographic and alignment results, do not add to the body of evidence in favor of navigated TKA in terms of the question of long-term functional gains and lower revision rates.

Demonstration of alignment, rotational, and functional improvements in navigated TKA continues to remain controversial. Studies differ in which measurements are improved, and short- to medium-term functional benefit has not been demonstrated despite multiple studies comparing navigated TKA with conventional TKA. There is evidence to support improvements in coronal plane alignment. However, sagittal plane and axial/rotational alignment have been less well studied. Although there is no improvement in knee stability or restoration of joint line, the additional costs, longer operative times, and increased complications associated with navigated TKA continue to raise concerns about this procedure. We agree that surgeons with experience in navigation have reduced operating room time (compared with surgeons less experienced in navigated TKA), improved mechanical axis alignment, and possibly less cutting errors compared with experienced TKA surgeons without navigation training and surgeons with limited knee arthroplasty experience [75]. However, navigation is not a substitute for meticulous intraoperative surgical technique and training in TKA without clinical, functional, or survival benefits in the medium term. Surgeons who perform relatively few TKAs should be cautious about adopting navigated TKA. Surgeons may rely on the navigation, perform minimal or not enough bone resections, and prolong operating room times even further in combination with a TKA that is performed less frequently.

Improvements in coronal alignment (with fewer outliers) unfortunately have not produced improved clinical knee scores, implant survival, better TKA function, or durability, and this may be attributed to three potential causes: (1) the better alignment in two planes is mitigated by the remaining errors in the axial (rotational) plane either because of an incorrect definition of the Cartesian coordinate system through which the navigation system is referencing or by the shear malalignment of the components in the axial plane; (2) alignment goals of a neutral mechanical axis are not the correct goal, and individual adjustments need to be made based on each patient's anatomic variability; and (3) the groups studied are too small (insufficient power) and/or the clinical scoring systems measuring functional status are not refined enough and suffer early ceiling effects, not allowing to prove superiority. These three causes are not sufficient to conclude that surgical navigation has to be abandoned; on the contrary, the better accuracy in the coronal and sagittal planes is needed if we want to refine alignment goals.

Although navigated TKA in its current form is arguably the best objective tool to measure our accuracy of component alignment in the operating room, orthopaedic surgeons lack the individual or collective surgical/anatomical targets to improve on the short-term functional scores at the present time. The majority of the studies reported in this review support this view. One of the main questions for knee arthroplasty surgeons that remains to be answered is how to create, modify, and identify knee (or other) functional assessment tools, imaging techniques, and reliable component alignment parameters to determine the benefits of navigated TKA. We are confident that the technology may improve component positioning and reduce imaging outliers; this is encouraging. Currently, however, it may be the case that we just do not have the appropriate tools (yet) to realize the true advantages of navigated TKA. Furthermore, we are encouraged by the few recent midterm reports of functional improvements with navigated TKA, yet remain discouraged by the study design flaws in this research.

Factors other than limb alignment may affect the long-term durability of TKA [45, 53, 60, 118]. The dynamic loading of the knee [109] is multifactorial and thus the traditional 0° to 3° for mechanical axis alignment may not predict long-term TKA implant survival. The goal of achieving neutral mechanical axis in all patients has recently been brought into question. A recent study by Bellemans et al. [13] reported that over 30% of normal males had “constitutional varus” of the knee and returning such individuals to neutral alignment would change their native alignment, ligament balance, and potentially compromise the clinical result.

The use of navigation in TKA requires extra training and results in additional operating room time and costs, which are a factor in implementing this technology. Combining navigated TKA [20, 21] with the already questionable and poor results [4] of minimally invasive TKA with an experienced surgeon may be considered; however, added time, increased costs, more complications, and no proven clinical advantages have been reported, and we disfavor this combination of technology and surgical techniques.

If routine use of navigated TKA led to consistently improved patient care, it would be expected that the studies should show improvements in the same parameters. A reduction in outliers of mechanical axis malalignment may be achieved with navigated TKA; however, the costs, additional operating time, increased training, potential for new and increased complications, and the lack of reproducible evidence in favor of navigated TKA question its role in routine TKA. The established roles for navigated TKA include use in patients with extraarticular deformity or retained implants and hardware that does not allow for traditional extra- or intramedullary alignment guides. In addition, use in resident teaching to provide immediate feedback regarding the accuracy of cutting guide placement may be helpful. To effectively evaluate the medium- and longer-term results of navigated TKA, future clinical trials should be designed to follow patients at short and medium term to document improved clinical function and longer term to establish whether lower revision rates are achieved.

References

1. Alan RK, Shin MS, Tria AJ Jr. Initial experience with electromagnetic navigation in total knee arthroplasty: a radiographic comparative study. *J Knee Surg.* 2007;20:152–157.
2. Australian Orthopaedic Association National Joint Replacement Registry. *Computer Assisted Surgery in Primary Total Knee Replacement Between 2006 and 2008.* Adelaide, Australia: AOA NJRR; 2010.
3. Babazadeh S, Dowsey MM, Swan JD, Stoney JD, Choong PF. Joint line position correlates with function after primary total knee replacement: a randomised controlled trial comparing conventional and computer-assisted surgery. *J Bone Joint Surg Br.* 2011;93:1223–1231.
4. Barrack RL, Barnes CL, Burnett RS, Miller D, Clohisy JC, Maloney WJ. Minimal incision surgery as a risk factor for early failure of total knee arthroplasty. *J Arthroplasty.* 2009;24:489–498.
5. Barrack RL, Schrader T, Bertot AJ, Wolfe MW, Myers L. Component rotation and anterior knee pain after total knee arthroplasty. *Clin Orthop Relat Res.* 2001;392:46–55.
6. Barrett WP, Mason JB, Moskal JT, Dalury DF, Oliashirazi A, Fisher DA. Comparison of radiographic alignment of imageless computer-assisted surgery vs conventional instrumentation in primary total knee arthroplasty. *J Arthroplasty.* 2011;26:1273–1284.e1271.
7. Bathis H, Perlick L, Tingart M, Luring C, Grifka J. CT-free computer-assisted total knee arthroplasty versus the conventional technique: radiographic results of 100 cases. *Orthopedics.* 2004;27:476–480.
8. Bathis H, Perlick L, Tingart M, Luring C, Perlick C, Grifka J. Radiological results of image-based and non-image-based computer-assisted total knee arthroplasty. *Int Orthop.* 2004;28:87–90.
9. Bathis H, Perlick L, Tingart M, Luring C, Zurakowski D, Grifka J. Alignment in total knee arthroplasty. A comparison of computer-assisted surgery with the conventional technique. *J Bone Joint Surg Br.* 2004;86:682–687.
10. Bauwens K, Matthes G, Wich M, Gebhard F, Hanson B, Ekkernkamp A, Stengel D. Navigated total knee replacement. A meta-analysis. *J Bone Joint Surg Am.* 2007;89:261–269.
11. Bejek Z, Solyom L, Szendroi M. Experiences with computer navigated total knee arthroplasty. *Int Orthop.* 2007;31:617–622.
12. Beldame J, Boisrenoult P, Beaufils P. Pin track induced fractures around computer-assisted TKA. *Orthop Traumatol Surg Res.* 2010;96:249–255.
13. Bellemans J, Colyn W, Vandenneucker H, Victor J. The Chitranjan Ranawat award: is neutral mechanical alignment normal for all patients? The concept of constitutional varus. *Clin Orthop Relat Res.* 2012;470:45–53.
14. Berend ME, Ritter MA, Meding JB, Faris PM, Keating EM, Redelman R, Faris GW, Davis KE. Tibial component failure mechanisms in total knee arthroplasty. *Clin Orthop Relat Res.* 2004;428:26–34.
15. Berger RA, Crossett LS, Jacobs JJ, Rubash HE. Malrotation causing patellofemoral complications after total knee arthroplasty. *Clin Orthop Relat Res.* 1998;356:144–153.
16. Blakeney WG, Khan RJ, Wall SJ. Computer-assisted techniques versus conventional guides for component alignment in total knee arthroplasty: a randomized controlled trial. *J Bone Joint Surg Am.* 2011;93:1377–1384.
17. Bohling U, Schamberger H, Grittner U, Scholz J. Computerised and technical navigation in total knee arthroplasty. *J Orthop Traumatol.* 2005;6:69–75.
18. Bolognesi M, Hofmann A. Computer navigation versus standard instrumentation for TKA: a single-surgeon experience. *Clin Orthop Relat Res.* 2005;440:162–169.

19. Bonutti P, Dethmers D, Stiehl JB. Case report: femoral shaft fracture resulting from femoral tracker placement in navigated TKA. *Clin Orthop Relat Res.* 2008;466:1499–1502.
20. Bonutti PM, Dethmers D, Ulrich SD, Seyler TM, Mont MA. Computer navigation-assisted versus minimally invasive TKA: benefits and drawbacks. *Clin Orthop Relat Res.* 2008;466:2756–2762.
21. Bonutti PM, Dethmers DA, McGrath MS, Ulrich SD, Mont MA. Navigation did not improve the precision of minimally invasive knee arthroplasty. *Clin Orthop Relat Res.* 2008;466:2730–2735.
22. Bottros J, Klika AK, Lee HH, Polousky J, Barsoum WK. The use of navigation in total knee arthroplasty for patients with extra-articular deformity. *J Arthroplasty.* 2008;23:74–78.
23. Brin YS, Nikolaou VS, Joseph L, Zukor DJ, Antoniou J. Imageless computer assisted versus conventional total knee replacement. A Bayesian meta-analysis of 23 comparative studies. *Int Orthop.* 2011;35:331–339.
24. Chauhan SK, Scott RG, Breidahl W, Beaver RJ. Computer-assisted knee arthroplasty versus a conventional jig-based technique. A randomised, prospective trial. *J Bone Joint Surg Br.* 2004;86:372–377.
25. Cheng T, Zhang G, Zhang X. Clinical and radiographic outcomes of image-based computer-assisted total knee arthroplasty: an evidence-based evaluation. *Surg Innov.* 2011;18:15–20.
26. Cheung KW, Chiu KH. Imageless computer navigation in total knee arthroplasty. *Hong Kong Med J.* 2009;15:353–358.
27. Chin PL, Yang KY, Yeo SJ, Lo NN. Randomized control trial comparing radiographic total knee arthroplasty implant placement using computer navigation versus conventional technique. *J Arthroplasty.* 2005;20:618–626.
28. Choi WC, Lee S, An JH, Kim D, Seong SC, Lee MC. Plain radiograph fails to reflect the alignment and advantages of navigation in total knee arthroplasty. *J Arthroplasty.* 2011;26: 756–764.
29. Choong PF, Dowsey MM, Stoney JD. Does accurate anatomical alignment result in better function and quality of life? Comparing conventional and computer-assisted total knee arthroplasty. *J Arthroplasty.* 2009;24:560–569.
30. Chung BJ, Kang YG, Chang CB, Kim SJ, Kim TK. Differences between sagittal femoral mechanical and distal reference axes should be considered in navigated TKA. *Clin Orthop Relat Res.* 2009;467:2403–2413.
31. Church JS, Scadden JE, Gupta RR, Cokis C, Williams KA, Janes GC. Embolic phenomena during computer-assisted and conventional total knee replacement. *J Bone Joint Surg Br.* 2007;89:481–485.
32. Czurda T, Fennema P, Baumgartner M, Ritschl P. The association between component malalignment and post-operative pain following navigation-assisted total knee arthroplasty: results of a cohort/nested case-control study. *Knee Surg Sports Traumatol Arthrosc.* 2010;18:863–869.
33. Decking R, Markmann Y, Fuchs J, Puhl W, Scharf HP. Leg axis after computer-navigated total knee arthroplasty: a prospective randomized trial comparing computer-navigated and manual implantation. *J Arthroplasty.* 2005;20:282–288.
34. Delp SL, Stulberg SD, Davies B, Picard F, Leitner F. Computer assisted knee replacement. *Clin Orthop Relat Res.* 1998;354:49–56.
35. Dong H, Buxton M. Early assessment of the likely cost-effectiveness of a new technology: a Markov model with probabilistic sensitivity analysis of computer-assisted total knee replacement. *Int J Technol Assess Health Care.* 2006;22:191–202.
36. Ensini A, Catani F, Leardini A, Romagnoli M, Giannini S. Alignments and clinical results in conventional and navigated total knee arthroplasty. *Clin Orthop Relat Res.* 2007;457: 156–162.
37. Figgie HE 3rd, Goldberg VM, Heiple KG, Moller HS 3rd, Gordon NH. The influence of tibial-patellofemoral location on function of the knee in patients with the posterior stabilized condylar knee prosthesis. *J Bone Joint Surg Am.* 1986;68:1035–1040.
38. Gothesen O. Norwegian register shows inferior 2-year results for computer-navigated TKR. *Orthopedics Today.* 2011;May:24–25.
39. Gothesen O, Espehaug B, Havelin L, Petursson G, Furnes O. Short-term outcome of 1,465 computer-navigated primary total knee replacements 2005–2008. *Acta Orthop.* 2011;82:293–300.
40. Graham DJ, Harvie P, Sloan K, Beaver RJ. Morbidity of navigated vs conventional total knee arthroplasty: a retrospective review of 327 cases. *J Arthroplasty.* 2011;26:1224–1227.
41. Haaker RG, Stockheim M, Kamp M, Proff G, Breitenfelder J, Ottersbach A. Computer-assisted navigation increases precision of component placement in total knee arthroplasty. *Clin Orthop Relat Res.* 2005;433:152–159.
42. Harvie P, Sloan K, Beaver RJ. Computer navigation vs conventional total knee arthroplasty five-year functional results of a prospective randomized trial. *J Arthroplasty.* 2011 Sep 27 [Epub ahead of print].
43. Haytmanek CT, Pour AE, Restrepo C, Nikhil J, Parvizi J, Hozack WJ. Cognition following computer-assisted total knee arthroplasty: a prospective cohort study. *J Bone Joint Surg Am.* 2010;92:92–97.
44. Hernandez-Vaquero D, Suarez-Vazquez A. Complications of fixed infrared emitters in computer-assisted total knee arthroplasties. *BMC Musculoskelet Disord.* 2007;8:71.
45. Hernandez-Vaquero D, Suarez-Vazquez A, Iglesias-Fernandez S. Can computer assistance improve the clinical and functional scores in total knee arthroplasty? *Clin Orthop Relat Res.* 2011; 469:3436–3442.
46. Hernandez-Vaquero D, Suarez-Vazquez A, Sandoval-Garcia MA, Noriega-Fernandez A. Computer assistance increases precision of component placement in total knee arthroplasty with articular deformity. *Clin Orthop Relat Res.* 2010;468:1237–1241.
47. Hiscox CM, Bohm ER, Turgeon TR, Hedden DR, Burnell CD. Randomized trial of computer-assisted knee arthroplasty: impact on clinical and radiographic outcomes. *J Arthroplasty.* 2011;26: 1259–1264.
48. Hoffart HE, Langenstein E, Vasak N. A prospective study comparing the patient functional knee scores of computer-assisted and conventional total knee replacement. *J Bone Joint Surg Br.* 2010;94:194–194.
49. Hoke D, Jafari SM, Orozco F, Ong A. Tibial shaft stress fractures resulting from placement of navigation tracker pins. *J Arthroplasty.* 2011;26:504.e505–508.
50. Ishida K, Matsumoto T, Tsumura N, Kubo S, Kitagawa A, Chin T, Iguchi T, Kurosaka M, Kuroda R. Mid-term outcomes of computer-assisted total knee arthroplasty. *Knee Surg Sports Traumatol Arthrosc.* 2011;19:1107–1112.
51. Jeffery RS, Morris RW, Denham RA. Coronal alignment after total knee replacement. *J Bone Joint Surg Br.* 1991;73:709–714.
52. Jenny JY, Boeri C. Computer-assisted implantation of total knee prostheses: a case-control comparative study with classical instrumentation. *Comput Aided Surg.* 2001;6:217–220.
53. Jung HJ, Jung YB, Song KS, Park SJ, Lee JS. Fractures associated with computer-navigated total knee arthroplasty. A report of two cases. *J Bone Joint Surg Am.* 2007;89:2280–2284.
54. Jung KA, Lee SC, Ahn NK, Song MB, Nam CH, Shon OJ. Delayed femoral fracture through a tracker pin site after navigated total knee arthroplasty. *J Arthroplasty.* 2011;26:505.e509–505.e511.
55. Jung YB, Lee HJ, Jung HJ, Song KS, Lee JS, Yang JJ. Comparison of the radiological results between fluoroscopy-assisted

and navigation-guided total knee arthroplasty. *Knee Surg Sports Traumatol Arthrosc.* 2009;17:286–292.

56. Kalairajah Y, Cossey AJ, Verrall GM, Ludbrook G, Spriggins AJ. Are systemic emboli reduced in computer-assisted knee surgery? A prospective, randomised, clinical trial. *J Bone Joint Surg Br.* 2006;88:198–202.
57. Kamat YD, Aurakzai KM, Adhikari AR, Matthews D, Kalairajah Y, Field RE. Does computer navigation in total knee arthroplasty improve patient outcome at midterm follow-up? *Int Orthop.* 2009;33:1567–1570.
58. Katz JN, Barrett J, Mahomed NN, Baron JA, Wright RJ, Losina E. Association between hospital and surgeon procedure volume and the outcomes of total knee replacement. *J Bone Joint Surg Am.* 2004;86:1909–1916.
59. Kim K, Kim YH, Park WM, Rhyu KH. Stress concentration near pin holes associated with fracture risk after computer navigated total knee arthroplasty. *Comput Aided Surg.* 2010;15:98–103.
60. Kim SJ, MacDonald M, Hernandez J, Wixson RL. Computer assisted navigation in total knee arthroplasty: improved coronal alignment. *J Arthroplasty.* 2005;20(Suppl 3):123–131.
61. Kim YH, Kim JS, Choi Y, Kwon OR. Computer-assisted surgical navigation does not improve the alignment and orientation of the components in total knee arthroplasty. *J Bone Joint Surg Am.* 2009;91:14–19.
62. Kim YH, Kim JS, Hong KS, Kim YJ, Kim JH. Prevalence of fat embolism after total knee arthroplasty performed with or without computer navigation. *J Bone Joint Surg Am.* 2008;90:123–128.
63. Kim YH, Kim JS, Yoon SH. Alignment and orientation of the components in total knee replacement with and without navigation support: a prospective, randomised study. *J Bone Joint Surg Br.* 2007;89:471–476.
64. Klein GR, Austin MS, Smith EB, Hozack WJ. Total knee arthroplasty using computer-assisted navigation in patients with deformities of the femur and tibia. *J Arthroplasty.* 2006;21: 284–288.
65. Kumar PJ, Dorr LD. Severe malalignment and soft-tissue imbalance in total knee arthroplasty. *Am J Knee Surg.* 1997;10:36–41.
66. Laskin RS, Beksac B. Computer-assisted navigation in TKA: where we are and where we are going. *Clin Orthop Relat Res.* 2006;452:127–131.
67. Lee DH, Padhy D, Lee SH, Nha KW, Park JH, Han SB. Osteoporosis affects component positioning in computer navigation-assisted total knee arthroplasty. *Knee.* 2011 Apr 27 [Epub ahead of print].
68. Li CH, Chen TH, Su YP, Shao PC, Lee KS, Chen WM. Periprosthetic femoral supracondylar fracture after total knee arthroplasty with navigation system. *J Arthroplasty.* 2008;23:304–307.
69. Longstaff LM, Sloan K, Stamp N, Scaddan M, Beaver R. Good alignment after total knee arthroplasty leads to faster rehabilitation and better function. *J Arthroplasty.* 2009;24:570–578.
70. Lutzner J, Gunther KP, Kirschner S. Functional outcome after computer-assisted versus conventional total knee arthroplasty: a randomized controlled study. *Knee Surg Sports Traumatol Arthrosc.* 2010;18:1339–1344.
71. Lutzner J, Krummenauer F, Wolf C, Gunther KP, Kirschner S. Computer-assisted and conventional total knee replacement: a comparative, prospective, randomised study with radiological and CT evaluation. *J Bone Joint Surg Br.* 2008;90:1039–1044.
72. Macule-Beneyto F, Hernandez-Vaquero D, Segur-Vilalta JM, Colomina-Rodriguez R, Hinarejos-Gomez P, Garcia-Forcada I, Seral Garcia B. Navigation in total knee arthroplasty. A multicenter study. *Int Orthop.* 2006;30:536–540.
73. Mahaluxmivala J, Bankes MJ, Nicolai P, Aldam CH, Allen PW. The effect of surgeon experience on component positioning in 673 Press Fit Condylar posterior cruciate-sacrificing total knee arthroplasties. *J Arthroplasty.* 2001;16:635–640.
74. Manley M, Ong K, Lau E, Kurtz SM. Total knee arthroplasty survivorship in the United States Medicare population: effect of hospital and surgeon procedure volume. *J Arthroplasty.* 2009; 24:1061–1067.
75. Manzotti A, Cerveri P, De Momi E, Pullen C, Confalonieri N. Relationship between cutting errors and learning curve in computer-assisted total knee replacement. *Int Orthop.* 2010;34: 655–662.
76. 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;16:493–496.
77. Marchant DC, Rimmington DP, Nusem I, Crawford RW. Safe femoral pin placement in knee navigation surgery: a cadaver study. *Comput Aided Surg.* 2004;9:257–260.
78. Mason JB, Fehring TK, Estok R, Banel D, Fahrbach K. Meta-analysis of alignment outcomes in computer-assisted total knee arthroplasty surgery. *J Arthroplasty.* 2007;22:1097–1106.
79. Matsumoto T, Tsumura N, Kurosaka M, Muratsu H, Yoshiya S, Kuroda R. Clinical values in computer-assisted total knee arthroplasty. *Orthopedics.* 2006;29:1115–1120.
80. Matziolis G, Krocker D, Weiss U, Tohtz S, Perka C. A prospective, randomized study of computer-assisted and conventional total knee arthroplasty. Three-dimensional evaluation of implant alignment and rotation. *J Bone Joint Surg Am.* 2007;89:236–243.
81. Millar NL, Deakin AH, Millar LL, Kinnimonth AW, Picard F. Blood loss following total knee replacement in the morbidly obese: effects of computer navigation. *Knee.* 2011;18:108–112.
82. Minoda Y, Kobayashi A, Iwaki H, Mitsuhiko I, Kadoya Y, Ohashi H, Takaoka K, Nakamura H. The risk of notching the anterior femoral cortex with the use of navigation systems in total knee arthroplasty. *Knee Surg Sports Traumatol Arthrosc.* 2010;18:718–722.
83. Mizu-uchi H, Matsuda S, Miura H, Okazaki K, Akasaki Y, Iwamoto Y. The evaluation of post-operative alignment in total knee replacement using a CT-based navigation system. *J Bone Joint Surg Br.* 2008;90:1025–1031.
84. Molfetta L, Caldo D. Computer navigation versus conventional implantation for varus knee total arthroplasty: a case-control study at 5 years follow-up. *Knee.* 2008;15:75–79.
85. Mombert M, Van Den Daelen L, Gunst P, Missinne L. Navigated total knee arthroplasty: a radiological analysis of 42 randomised cases. *Acta Orthop Belg.* 2007;73:49–54.
86. Morawa LG, Manley MT, Edidin AA, Reilly DT. Transesophageal echocardiographic monitored events during total knee arthroplasty. *Clin Orthop Relat Res.* 1996;331:192–198.
87. *National Joint Registry for England and Wales 6th Annual Report*. Hemel, Hempstead, UK: NJR Centre; 2009:72.
88. Novak EJ, Silverstein MD, Bozic KJ. The cost-effectiveness of computer-assisted navigation in total knee arthroplasty. *J Bone Joint Surg Am.* 2007;89:2389–2397.
89. Novicoff WM, Saleh KJ, Mihalko WM, Wang XQ, Knaebel HP. Primary total knee arthroplasty: a comparison of computer-assisted and manual techniques. *Instr Course Lect.* 2010;59: 109–17.
90. O'Connor MI, Brodersen MP, Feinglass NG, Leone BJ, Crook JE, Switzer BE. Fat emboli in total knee arthroplasty: a prospective randomized study of computer-assisted navigation vs standard surgical technique. *J Arthroplasty.* 2010;25:1034–1040.
91. Oberst M, Bertsch C, Wurstlin S, Holz U. [CT analysis of leg alignment after conventional vs. navigated knee prosthesis implantation. Initial results of a controlled, prospective and randomized study] [in German]. *Unfallchirurg.* 2003;106: 941–948.
92. Ohmann C, Verde PE, Blum K, Fischer B, de Cruppé W, Geraedts M. Two short-term outcomes after instituting a national

regulation regarding minimum procedural volumes for total knee replacement. *J Bone Joint Surg Am.* 2010;92:629–638.

93. Ooi LH, Lo NN, Yeo SJ, Ong BC, Ding ZP, Lefi A. Does computer-assisted surgical navigation total knee arthroplasty reduce venous thromboembolism compared with conventional total knee arthroplasty? *Singapore Med J.* 2008;49:610–614.
94. Ossendorf C, Fuchs B, Koch P. Femoral stress fracture after computer navigated total knee arthroplasty. *Knee.* 2006;13: 397–399.
95. Parratte S, Pagnano MW, Trousdale RT, Berry DJ. Effect of postoperative mechanical axis alignment on the fifteen-year survival of modern, cemented total knee replacements. *J Bone Joint Surg Am.* 2010;92:2143–2149.
96. Partington PF, Sawhney J, Rorabeck CH, Barrack RL, Moore J. Joint line restoration after revision total knee arthroplasty. *Clin Orthop Relat Res.* 1999;367:165–171.
97. Perlick L, Bathis H, Tingart M, Perlick C, Grifka J. Navigation in total-knee arthroplasty: CT-based implantation compared with the conventional technique. *Acta Orthop Scand.* 2004;75: 464–470.
98. Rand JA, Coventry MB. Ten-year evaluation of geometric total knee arthroplasty. *Clin Orthop Relat Res.* 1988;232:168–173.
99. Rauh MA, Boyle J, Mihalko WM, Phillips MJ, Bayers-Thering M, Krackow KA. Reliability of measuring long-standing lower extremity radiographs. *Orthopedics.* 2007;30:299–303.
100. Restrepo C, Hozack WJ, Orozco F, Parvizi J. Accuracy of femoral rotational alignment in total knee arthroplasty using computer assisted navigation. *Comput Aided Surg.* 2008;13:167–172.
101. Ritter MA, Faris PM, Keating EM, Meding JB. Postoperative alignment of total knee replacement. Its effect on survival. *Clin Orthop Relat Res.* 1994;299:153–156.
102. Robertsson O, Dunbar M, Pehrsson T, Knutson K, Lidgren L. Patient satisfaction after knee arthroplasty: a report on 27,372 knees operated on between 1981 and 1995 in Sweden. *Acta Orthop Scand.* 2000;71:262–267.
103. Schmitt J, Hauk C, Kienapfel H, Pfeiffer M, Efe T, Fuchs-Winkelmann S, Heyse TJ. Navigation of total knee arthroplasty: rotation of components and clinical results in a prospectively randomized study. *BMC Musculoskelet Disord.* 2011;12:16.
104. Schnurr C, Csecsei G, Eysel P, Konig DP. The effect of computer navigation on blood loss and transfusion rate in TKA. *Orthopedics.* 2010;33:474.
105. Seon JK, Song EK. Navigation-assisted less invasive total knee arthroplasty compared with conventional total knee arthroplasty: a randomized prospective trial. *J Arthroplasty.* 2006;21:777–782.
106. Seon JK, Song EK, Yoon TR, Park SJ, Bae BH, Cho SG. Comparison of functional results with navigation-assisted minimally invasive and conventional techniques in bilateral total knee arthroplasty. *Comput Aided Surg.* 2007;12:189–193.
107. Seon JK, Song EK, Yoon TR, Seo HY, Cho SG. Tibial plateau stress fracture after unicondylar knee arthroplasty using a navigation system: two case reports. *Knee Surg Sports Traumatol Arthrosc.* 2007;15:67–70.
108. Sharkey PF, Hozack WJ, Rothman RH, Shastri S, Jacoby SM. Insall Award paper. Why are total knee arthroplasties failing today? *Clin Orthop Relat Res.* 2002;404:7–13.
109. Sikorski JM. Alignment in total knee replacement. *J Bone Joint Surg Br.* 2008;90:1121–1127.
110. Sikorski JM, Blythe MC. Learning the vagaries of computer-assisted total knee replacement. *J Bone Joint Surg Br.* 2005;87: 903–910.
111. Song EK, Seon JK, Yoon TR, Park SJ, Cho SG, Yim JH. Comparative study of stability after total knee arthroplasties between navigation system and conventional techniques. *J Arthroplasty.* 2007;22:1107–1111.
112. Sparmann M, Wolke B, Czupalla H, Banzer D, Zink A. Positioning of total knee arthroplasty with and without navigation support. A prospective, randomised study. *J Bone Joint Surg Br.* 2003;85:830–835.
113. Spencer JM, Chauhan SK, Sloan K, Taylor A, Beaver RJ. Computer navigation versus conventional total knee replacement: no difference in functional results at two years. *J Bone Joint Surg Br.* 2007;89:477–480.
114. Stiehl JB, Jackson S, Szabo A. Multi-factorial analysis of time efficiency in total knee arthroplasty. *Comput Aided Surg.* 2009; 14:58–62.
115. Stockl B, Nogler M, Rosiek R, Fischer M, Krismer M, Kessler O. Navigation improves accuracy of rotational alignment in total knee arthroplasty. *Clin Orthop Relat Res.* 2004;426:180–186.
116. Stulberg SD, Loan P, Sarin V. Computer-assisted navigation in total knee replacement: results of an initial experience in thirty-five patients. *J Bone Joint Surg Am.* 2002;84(Suppl 2):90–98.
117. Stulberg SD, Yaffe MA, Koo SS. Computer-assisted surgery versus manual total knee arthroplasty: a case-controlled study. *J Bone Joint Surg Am.* 2006;88(Suppl 4):47–54.
118. Tew M, Waugh W. Estimating the survival time of knee replacement. *J Bone Joint Surg Br.* 1982;64:579–582.
119. van der Linden-van der Zwaag HM, Bos J, van der Heide HJ, Nelissen RG. A computed tomography based study on rotational alignment accuracy of the femoral component in total knee arthroplasty using computer-assisted orthopaedic surgery. *Int Orthop.* 2011;35:845–850.
120. Victor J, Hoste D. Image-based computer-assisted total knee arthroplasty leads to lower variability in coronal alignment. *Clin Orthop Relat Res.* 2004;428:131–139.
121. Wasielewski RC, Galante JO, Leighty RM, Natarajan RN, Rosenberg AG. Wear patterns on retrieved polyethylene tibial inserts and their relationship to technical considerations during total knee arthroplasty. *Clin Orthop Relat Res.* 1994;299:31–43.
122. Watters TS, Mather RC 3rd, Browne JA, Berend KR, Lombardi AV Jr, Bolognesi MP. Analysis of procedure-related costs and proposed benefits of using patient-specific approach in total knee arthroplasty. *J Surg Orthop Adv.* 2011;20:112–116.
123. Weng YJ, Hsu RW, Hsu WH. Comparison of computer-assisted navigation and conventional instrumentation for bilateral total knee arthroplasty. *J Arthroplasty.* 2009;24:668–673.
124. Wysocki RW, Sheinkop MB, Virkus WW, Della Valle CJ. Femoral fracture through a previous pin site after computer-assisted total knee arthroplasty. *J Arthroplasty.* 2008;23:462–465.
125. Yaffe MA, Koo SS, Stulberg SD. Radiographic and navigation measurements of TKA limb alignment do not correlate. *Clin Orthop Relat Res.* 2008;466:2736–2744.
126. Yang JH, Seo JG, Moon YW, Kim MH. Joint line changes after navigation-assisted mobile-bearing TKA. *Orthopedics.* 2009;32 (Suppl):35–39.
127. Zhang G, Chen J, Chai W, Liu M, Wang Y. Comparison between computer-assisted-navigation and conventional total knee arthroplasties in patients undergoing simultaneous bilateral procedures. A randomized clinical trial. *J Bone Joint Surg Am.* 2011;93:1190–1196.
128. Zorman D, Etuin P, Jennart H, Scipioni D, Devos S. Computer-assisted total knee arthroplasty: comparative results in a preliminary series of 72 cases. *Acta Orthop Belg.* 2005;71:696–702.
129. Zumstein MA, Frauchiger L, Wyss D, Hess R, Ballmer PM. Is restricted femoral navigation sufficient for accuracy of total knee arthroplasty? *Clin Orthop Relat Res.* 2006;451:80–86.