



Current concepts and future perspectives in computer-assisted navigated total knee replacement

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Abstract

Background Total knee replacements (TKR) aim to restore stability of the tibiofemoral and patella-femoral joints and provide relief of pain and improved quality of life for the patient. In recent years, computer-assisted navigation systems have been developed with the aim of reducing human error in joint alignment and improving patient outcomes.

Methods We examined the current body of evidence surrounding the use of navigation systems and discussed their current and future role in TKR.

Results The current body of evidence shows that the use of computer navigation systems for TKR significantly reduces outliers in the mechanical axis and coronal prosthetic position. Also, navigation systems offer an objective assessment of soft tissue balancing that had previously not been available. Although these benefits represent a technical superiority to conventional TKR techniques, there is limited evidence to show long-term clinical benefit with the use of navigation systems, with only a small number of studies showing improvement in outcome scores at short-term follow-up. Because of the increased costs and operative time associated with their use as well as the emergence of more affordable and patient-specific technologies, it is unlikely for navigation systems to become more widely used in the near future.

Conclusions Whilst this technology helps surgeons to achieve improved component positioning, it is important to consider the clinical and functional implications, as well as the added costs and potential learning curve associated with adopting new technology.

Keywords Total knee replacement (TKR) · Navigation · Computer-assisted surgery · Review

Introduction

Total knee replacement (TKR) is a highly successful procedure and the main aim in performing a TKR is to abolish pain and restore mobility with a high level of patient satisfaction [1–3]. This is in technical terms translates to a well-balanced and well-aligned tibiofemoral (TF) and patellofemoral (PF) articulation. Whilst success rates for this procedure are high, technical errors during surgery remain the major cause of implant failure [4, 5] and possibly patient dissatisfaction as well. This has driven the development of computer-assisted navigation systems that are aimed at optimising joint alignment by

ensuring accuracy in bone resection, component implantation and soft tissue balancing.

However, the utility of such systems remains highly controversial. Several large studies have shown an improvement in post-operative radiological alignment with their use; however, studies of patient satisfaction and other clinical outcomes have shown no significant improvements in the short- or mid-term follow-up [6–19]. Long-term outcomes such as revision rates remain unclear and require careful investigation in the near future [20].

This objective of this article therefore is to review the evidence and present the arguments surrounding the use of computer-assisted navigation systems in total knee replacement, and also to highlight the key areas for future investigation.

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Materials and methods

We conducted a literature search of journal articles using the PubMed (MEDLINE) and EMBASE databases in June 2017.

No date restrictions were placed. From the search results, articles with irrelevant titles were discounted, with remaining abstracts examined for relevance. Reference listings of the remaining articles were also searched and scrutinised for relevance.

Component orientation and restoration of the mechanical axis

Since the introduction of computer-assisted navigation systems for TKR, much focus has been placed on the post-operative radiological alignment achieved with their use, when compared with conventional arthroplasty techniques [6]. In most studies, a significant improvement in the navigated compared with conventional TKR is reported with fewer outliers in several alignment parameters including mechanical alignment and coronal and sagittal orientation of the component [4, 11, 13, 14, 19, 21–30]. However, some studies have reported no significant improvement in alignment with the use of a navigation system [5–9]. Several meta-analyses and systematic reviews have been conducted to investigate this controversy; these are summarised in Table 1.

A meta-analysis by Bauwens et al. in 2007 based on 33 studies including 11 randomised controlled trials (RCTs) found that a navigated TKR could not reach a significant benefit in terms of alignment over a conventional TKR [10]. However, in the same year, Mason et al. conducted a meta-analysis including 29 studies (9 RCTs) and concluded that a navigated TKR resulted in a significant improvement in component orientation and restoration of mechanical axis compared with the conventional technique [11]. They argued that an analytic error in Bauwens's review might be at fault for the differing conclusions of the two studies. Indeed, several more recent meta-analyses have reached the same conclusion of superiority in restoring the mechanical axis of the lower limb with more precise component orientation when navigation systems are used [12–15]. Based on current evidence, therefore, use of computer-assisted navigation systems results in superior alignment of the limb and component orientation compared with conventional techniques.

This superiority in the restoration of the mechanical axis does, however, have potential drawbacks. Navigation systems differ to conventional surgical techniques in that they utilise the mechanical axis, rather than the anterior femoral cortex for sizing and orientation of the components. Although this results in superior mechanical alignment, we have previously reported the potential for errors in alignment especially in the sagittal plane [13]. We compared 30 patients who underwent a TKR utilising the Vector Vision^R (Depuy–Brain LAB, Heimstetten, Germany) navigation system with 30 patients who underwent a conventional TKR using pre- and post-operative anterior-posterior (AP) and lateral radiographs. Although the AP radiographs revealed improved alignment in the navigation group, the lateral radiographs showed a

Table 1 Meta-analyses regarding alignment outcomes

Study	Journal	Number of studies	Cases	Results
Bauwens K (2007)	J Bone Joint Surg Am	3423 knees	33 studies (11RCTs)	Navigated > conventional TKR (HKA angle > ± 3°: risk ratio, 0.79, 95% CI, 0.71–0.87; HKA angle > ± 2°: risk ratio, 0.76; 95% CI, 0.71–0.82)
Mason JB (2007)	J Arthroplasty	3437 knees	29 studies (9 RCTs)	Navigated > conventional TKR (HKA angle > ± 3°: odds ratio, 0.35, 95% CI, 0.28–0.43) (femoral and tibial component alignment > ± 2° in coronal and sagittal plane)
Brin YS (2011)	Int Orthop	4163 knees	23 RCTs (10RCTs)	Navigated > conventional TKR (HKA angle > ± 3°: odds ratio, 0.29, 95% CI, 0.12–0.52; HKA angle > ± 2°: odds ratio, 0.31; 95% CI, 0.15–0.52) (femoral and tibial component alignment > ± 2° in coronal and sagittal plane)
Hetaimish BM (2012)	J Arthroplasty	2541 knees	23 RCTs	Navigated > conventional TKR (HKA angle > ± 3°: risk ratio, 0.37, 95% CI, 0.24–0.58; HKA angle > ± 2°: risk ratio, 0.54; 95% CI, 0.42–0.69) (femoral and tibial component alignment > ± 2° in coronal and sagittal plane)
Cheng T (2012)	Knee Surg Sports Traumatol Arthrosc	4286 knees	41 RCTs or qRCTs	Navigated > conventional TKR (HKA angle > ± 3°: risk ratio, 0.40, 95% CI, 0.31–0.51; HKA angle > ± 2°: risk ratio, 0.50; 95% CI, 0.40–0.62) (femoral and tibial component alignment > ± 2° in coronal plane, not sagittal plane)
Fu Y (2012)	Knee Surg Sports Traumatol Arthrosc	2414 knees	21 RCTs	Navigated > conventional TKR (HKA angle > ± 3°: odds ratio, 0.26, 95% CI, 0.17–0.38; HKA angle > ± 2°: odds ratio, 0.33; 95% CI, 0.26–0.42) (femoral and tibial component alignment > ± 2° in coronal and sagittal plane)

RCTs randomised controlled trials, qRCTs quasi-randomised controlled trials, TKR total knee replacement, HKA hip-knee-ankle, CI confidential interval

significant increase in the femoral AP dimension post-operatively in the navigation group. The consequences of this increase in the AP dimension were further examined by Minoda et al. in a simulation study which highlighted a higher risk of anterior femoral cortex notching when a navigation system is utilised [16]. Further studies of AP alignment following the use of navigation systems have highlighted the importance of the determined knee centre utilised by the navigation system. Furthermore, we have also shown that navigation systems utilising the posterior knee centre as a reference eliminated the increased AP dimension that resulted from the use of the anterior knee centre. A radiological study by Chung et al. revealed a 3° difference between the anterior and posterior knee centres, giving a likely explanation for the difference in component placement [17]. It is therefore recommended that the distal femoral cut is made in slight flexion in relation to the mechanical axis when using navigation systems that utilise the anterior knee centre as a reference point.

Appropriate axial rotational of the components in a TKR has been also recognised as an important issue for reducing patellar mal-tracking and anterior knee pain. Several studies have attempted to compare the accuracy with and without a navigation system, with no overall consensus on the effects on rotational alignment [5, 18–27]. However, it should be noted that the rotational alignment is subject to variations during the procedure itself because of movement of the pins, component insertion, bone loss and difficulty in locating and registering the epicondyles in a TKR performed with a navigation system [28].

Clinical outcomes

Although improved component alignment with navigation systems is encouraging, like any new medical device, a genuine clinical benefit must be demonstrated before its use can be fully justified. Consequently, there have been multiple studies comparing clinical outcomes in navigated versus non-navigated TKRs at various periods of follow-up. Encouragingly, some studies of early follow-up (less than 5 years) have shown improved functional outcome (as

evaluated by the Oxford Knee Score and Knee Society Score (KSS)) when computer-assisted navigation has been utilised [29, 30]. However, these results are contradicted equally by similar studies that show no clinical benefit with the use of navigation systems [24, 31]. Furthermore, two meta-analyses comparing short-term clinical outcomes in navigated and the conventional TKR have also produced differing results, leaving no current consensus on whether navigation systems offer a clinical benefit in the short term (see Table 2).

Several studies have investigated the mid-term clinical outcome of navigated TKR. Follow-up in these studies has ranged from five to ten years, and although many studies have demonstrated improved biomechanics, most of them have demonstrated that this does not result in improved patient-reported outcome scores [15, 20]. Quite recently, Baumbach et al. in a study of 217 TKRs reported that the ten year survival rates of the conventional TKR group and the navigated TKR group were 87 and 98%, respectively, and this difference was statistically significant ($P < 0.05$). Also, Saraglia et al. reported that after an average of 8.5 years follow-up, the mean KSS was 180 ± 22 points with 86.5 ± 16 points for the function score and 93.5 ± 8 points for the knee score, whilst knee flexion angle was $116^\circ \pm 10.5^\circ$ and average HKA angle was $179^\circ \pm 2^\circ$ using a mobile bearing CR prosthesis with computer navigation [32]. In addition, De Steiger et al. analysed data from the Australian Orthopaedic Association National Joint Replacement Registry to examine the effect of computer navigation on the rate of revision of primary TKR and reported that there was a significant difference in the rate of revision following non-navigated TKR compared with that following navigated TKR for patients younger than 65 years of age [33]. Moreover, navigation technologies have been reported to be useful in specific occasions such as in case of retained hardware or extra-articular deformity [34], or in minimally invasive TKR [35] as well.

There have been no meta-analyses or systematic reviews published for mid- or long-term follow-up in this group of patients. Continued follow-up in this cohort will shed light on any long-term clinical benefits gained from navigation systems.

Table 2 Meta-analyses regarding clinical outcomes

Study	Journal	Number of studies	Cases	Results
Cheng T (2012)	The Knee	2333 knees	21 RCTs or qRCTs	Navigated = conventional TKR (Knee Society Score at 3 and 6 months, complications: deep venous thrombosis, infection, delayed wound healing, knee stiffness, periprosthetic fracture, hematoma, pulmonary embolism, nerve injury)
Rebal BA (2014)	J Arthroplasty	1713 knees	21 RCTs	Navigated > conventional TKR (Knee Society Score: 68.5 in navigated TKR vs. 58.1 in conventional TKR at 3 months, 53.1 in navigated TKR vs. 45.8 in conventional TKR at 12–32 months)

RCTs randomised controlled trials, qRCTs quasi-randomised controlled trials, TKR total knee replacement

Soft tissue balancing

Current registry data attributes between 16.2 and 20.3% of prosthesis failure to inadequate soft tissue balancing, which has historically relied on subjective intra-operative assessment by the surgeon [36–38]. In order to address this inadequacy, several assessment tools such as the tensor/balancer were introduced to enable a more precise assessment of the soft tissues [39–42]. In addition, navigation systems have been developed with the ability to accurately assess knee kinematics and range of motion intra-operatively, with promising early results [30, 43, 44]. Matsumoto and Muratsu et al. investigated the use of navigation systems with an offset-type tensor and reported the importance of reduction of the patella-femoral joint and femoral component placement in soft tissue balancing [40, 45]. They reported the advantage of tibia first technique with a navigation system-assisted tensor in predicting final soft tissue balance before

the femoral bone cut [44]. Following femoral component placement, the range of motion tracking by the navigation system, including assessment of tibial rotation and anterior translation, can confirm the final soft tissue balance (Fig. 1). This intra-operative assessment plays an important role in restoring normal kinematics to the knee, which is key in ensuring patient satisfaction [46, 47].

Similar studies have also demonstrated the utility of navigation systems in ensuring soft tissue balancing regardless of procedure type. Matsumoto et al. assessed intra-operative soft tissue balancing using a navigation system in both cruciate-sparing and posterior-stabilised TKR and demonstrated a significant difference between the two [48]. The use of a navigation system allowed for fine intra-operative adjustments in balancing to be made, ensuring optimum post-operative kinematics.

Although these studies provide encouraging results, it is noteworthy that the use of navigation systems is limited to non-weight bearing conditions, and assessment of kinematics

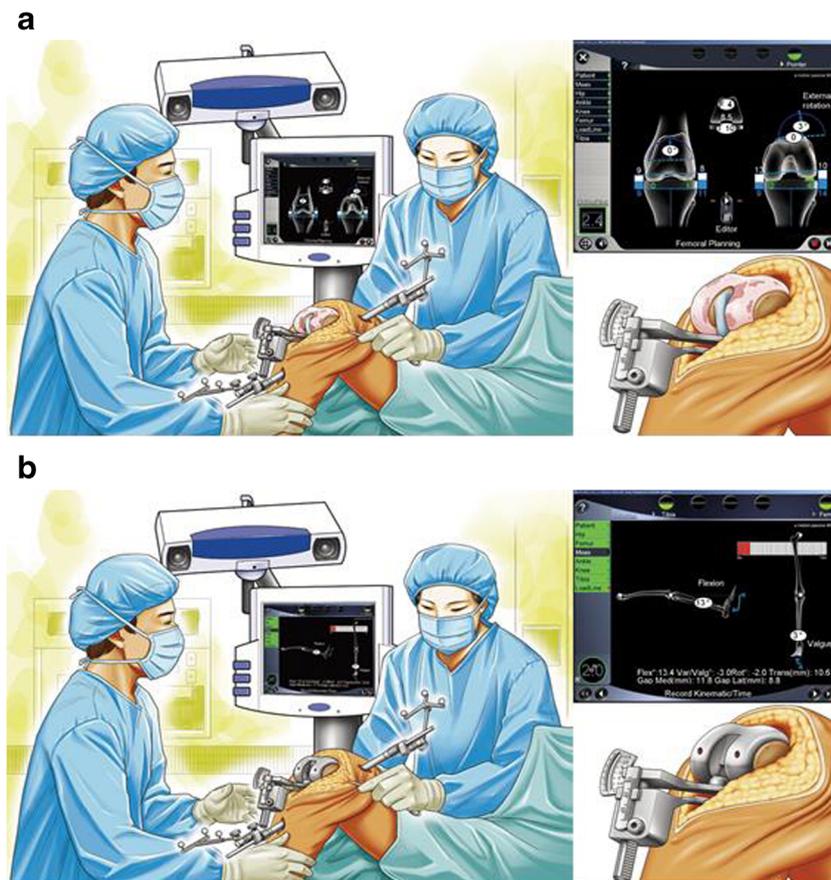


Fig. 1 Soft tissue balancing with tibia first technique. **a** After the tibial bone cut and step-by-step release of soft tissue, surgeons can assess intraoperative basic soft tissue balance including joint gap and varus/valgus balance with an offset-type tensor and navigation system. Then, based on the recorded soft tissue balance data, surgeons can plan the amount of bone cut, coronal alignment, prosthetic positioning, soft tissue balance and rotational alignment (right navigation panel). **b**

Following femoral cut based on the planning on the navigation screen, surgeons can finally assess intraoperative soft tissue balance with femoral component placement and confirm the equivalence to the basic soft tissue balance. In addition, surgeons can assess kinematic parameters including tibial rotation and anterior translation throughout the range of motion (right navigation panel)

under weight-bearing conditions presently requires the use of fluoroscopy or point cluster [47].

Future technologies

Although navigation systems offer improved component orientation and intra-operative soft tissue assessment, the lack of demonstrable clinical benefit combined with significant additional cost, increased operative time and extra instrumentation means their use amongst orthopaedic surgeons remains infrequent [49–51]. Furthermore, the development of newer technology in joint replacement, e.g. patient-matched instrumentation and robotics, may render navigation systems obsolete.

Patient-specific jigs are created using pre-operative imaging and can provide optimal prosthetic alignment with promising results, with aiming to shorten the conventional operative time based on pre-operative CT-Scan or MRI, whilst it is not on computer assistance. Several studies have investigated component orientation, operative time and cost in conventional, patient-specific and navigation-assisted TKR. MacDessi et al. recently reported that patient-specific TKR achieved similar accuracy when compared to navigated and conventional TKR in mechanical alignment (91.3, 90.7 and 80.4%, respectively within 3° of neutral alignment). Additionally, patient-specific procedures were significantly shorter (80.2 minutes in patient-specific TKR, 110.2 minutes in navigated TKR, 86 minutes in conventional TKR) [52]. A further study by Watters et al. reported that patient-specific TKR reduced operative time by 67 minutes and was associated with lower total procedure-related cost compared with navigated TKR [53]. In addition to this reduction in theatre time, the study attributed the reduction in cost to reductions in the hardware, software and maintenance costs associated with computer-assisted navigation.

Sensor technology is an emerging concept in joint replacement that allows intra-operative measurement and localisation of peak loads across the medial and lateral tibiofemoral interfaces following implantation of the prostheses, which in turn allows for fine surgical adjustments to be made in order to optimise balancing. Gustke et al. assessed intra-operative soft tissue tension with a sensor, which replaced the geometric tibial insert trials for patients undergoing TKRs [54]. This allowed outcomes to be compared in those patients who were found to have balanced ($n = 113$) and unbalanced joints ($n = 15$) intra-operatively. The study found that 96.7% of those with balanced joints reported being satisfied or very satisfied one year post-operatively, compared to 82.1% of those in the unbalanced group. Furthermore, they identified superior outcomes in the balanced group compared with the unbalanced group assessed by KSS, WOMAC and activity level scores [55, 56]. Although this sensor technology may represent a more readily accessible method of assessing soft tissue balancing, unlike navigation systems, its use is limited to conditions after prosthetic implantation. To this end, navigation

systems remain a reliable method for ensuring prosthetic alignment is optimal prior to implantation.

Other than patient-specific instruments and sensor technologies described above, new technologies such as based on iPod [57], accelerometer [58] and pin-less navigation [59] have emerged recently and several superior aspects of these new navigation technologies compared to existing navigation systems have been reported. These, however, have been described only in retrospective design, and the number of cases shown in each method was limited, which resulted in a limited quality to some extent.

Conclusions

The current body of evidence shows that the use of computer navigation systems for TKR significantly reduces outliers in the mechanical axis and coronal prosthetic position. In addition, navigation systems offer an objective assessment of soft tissue balancing that had previously not been available. Although these benefits represent a technical superiority to conventional arthroplasty techniques, there is limited evidence to show long-term clinical benefit with the use of navigation systems, with only a small number of studies showing improvement in outcome scores at short-term follow-up. The increased costs and operative time associated with their use as well as the emergence of more affordable and patient-specific technologies make it unlikely that navigation systems will become more widely used in the near future. Large, high-quality studies with long-term follow-up of patients receiving navigation-assisted TKR, along with the continued development of improved clinical outcome measures, will be essential if we are to fully evaluate the precise role of navigation systems in total knee replacement surgery.

Compliance with ethical standards

Conflict of interest The authors declare that they have no conflict of interest.

Ethical approval This article does not contain any studies with human participants or animals performed by any of the authors.

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