Inconsistencies between navigation data and radiographs in total knee arthroplasty are system-dependent and affect coronal alignment

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Accepted for publication
Mar. 5, 2014

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DOI: 10.1503/cjs.031313

Background: Few studies have compared the effect of different computer navigation systems on postoperative alignment in patients who have had total knee arthroplasty (TKA). We examined 2 computed tomography (CT)–free computer navigation systems by comparing the accuracy of intraoperative measurements to postoperative alignment.

Methods: Patients underwent unilateral TKA performed by a single surgeon using 1 of 2 CT-free navigation systems. We compared final intraoperative tibial and femoral coronal angles and mechanical axis with the same angles measured on standing postoperative radiographs.

Results: Groups of 31 and 50 patients underwent TKA with the 2 systems, respectively. We noted a significant difference in the coronal tibial implant angle (1.29º ± 1.35º) and in the mechanical axis (1.59º ± 2.36º) for one navigation system (both $p < 0.001$), while only the coronal tibial implant angle showed a significant difference (1.17º ± 1.65º, $p < 0.001$) for the second system. The number of radiographic outliers also significantly differed. A significantly higher proportion (32%; $p < 0.01$) of patients in the second cohort exhibited unacceptable malalignment compared with the first cohort (24%).

Conclusion: Navigation systems for TKA continue to increase in sophistication and popularity. Owing to the significant difference in the proportion of alignment outliers in the 2 navigation systems tested in this study, orthopedic surgeons should not consider all TKA navigation systems equivalent. Additional investigations are needed to compare the accuracy of a variety of CT-free and CT-based navigation systems and to confirm our finding that accuracy is system-dependent.

Contexte : Il existe peu d'études ayant comparé divers systèmes informatiques de navigation de guidage servant à vérifier l'alignement postopératoire de l'articulation chez des patients ayant subi une arthroplastie totale du genou (ATG). On a évalué 2 systèmes de navigation de guidage sans base tomodensitométrique en comparant l'exactitude des mesures d'alignement intra-opératoires et celles des mesures postopératoires.

Méthodes : Des patients ont subi une ATG unilatérale, qui a été pratiquée par un seul chirurgien à l'aide de l'un des 2 systèmes de navigation de guidage sans base tomodensitométrique. On a comparé les mesures intra-opératoires finales de l'angle frontal de l'articulation tibiofémorale et de l'axe mécanique du genou aux angles mesurés sur les radiographies postopératoires en station debout.

Résultats : Un groupe de 31 patients et un groupe de 50 ont subi une ATG réalisée à l'aide des 2 systèmes respectivement. On a observé un écart significatif des mesures de l'angle frontal de l'embase tibiale de la prothèse (1,29 º ± 1,35º) et des mesures de l'axe mécanique du genou (1,59 º± 2,36 º) avec l'un des systèmes de navigation (avec les deux, $p < 0{,}001$), tandis qu'avec l'autre, on a observé seulement une différence appréciable des mesures de l'angle frontal de l'embase tibiale (1,17 º± 1,65 º, $p < 0{,}001$). On a aussi observé une grande variation du nombre d'aberrations radiographiques. Dans la deuxième cohorte, on a observé une proportion significativement plus importante (32 %; $p < 0{,}01$) de patients présentant un défaut d'alignement inacceptable que dans la première (24 %).

Conclusion : Les systèmes de navigation de guidage servant à réaliser les ATG ne cessent de se perfectionner et d'être de plus en plus prisés. Cependant, en raison de l'écart significatif de la proportion des défauts d'alignement dépistés entre les 2 systèmes de navigation testés au cours de cette étude, le chirurgien orthopédiste ne devrait pas croire que tous les systèmes sont équivalents. Il faudrait mener d'autres études pour comparer la précision de divers systèmes de navigation de guidage sans base tomodensitométrique à celle de systèmes à base tomodensitométrique pour corroborer notre constatation, c'est-à-dire que la précision dépend du système utilisé.

Computer-assisted orthopedic surgery (CAOS) for total knee arthroplasty (TKA) is generally considered to lead to component positioning that is more accurate and reproducible than conventional techniques.[1,2] Additional advantages for the use of COAS in TKA include decreased perioperative blood loss owing to the avoidance of intramedullary instrumentation,[1,3–5] fewer postoperative thromboembolic events[6] and fewer systemic emboli.[7–9] Hoffart and colleagues[10] also demonstrated that CAOS provides better clinical outcomes at 5 years than conventional TKA. Furthermore, recent meta-analyses by Cheng and colleagues[11] and Bauwens and colleagues[12] demonstrated that using COAS for TKA significantly reduced the relative risk of excessive implant misalignment by 25% compared with conventional TKA. Another recent meta-analysis by Hetaimish and colleagues[13] showed that CAOS produced better implant alignment in the coronal plane for both the tibial and femoral components as well as femoral and tibial slope than the conventional technique.

Although these investigations have demonstrated the improvement of component alignment with CAOS, they did not take into account a critical component of the operative procedure: the type of computer navigation system used. The only comparisons of alignment among different computer navigation systems have come from 2 studies that each compared a computed tomography (CT)–based system to a CT-free system.[14,15] Given that studies used in the meta-analysis by Cheng and colleagues[11] used a total of 6 different CT-free navigation systems and 2 CT-based systems while those used in the analysis by Bauwens and colleagues[12] included 5 CT-free systems and 3 CT-based systems, further investigations are required to confirm that computer navigation systems are equivalently accurate in measuring TKA alignment. Such investigations are especially needed in CT-free CAOS systems, whose differences in hardware and software design have been previously identified as a potential source of inaccuracy.[16]

The current gold standard for assessing the mechanical alignment of the lower extremity following TKA is the standing full lower extremity radiograph. Therefore, the ideal CAOS navigation system, when properly used, should provide intraoperative measurements for femoral and tibial cuts that match the final implant position and limb alignment as measured on postoperative radiographs. Using this logic, it is possible to compare CAOS navigation systems with one another by assessing the difference between intraoperative alignment measurements by the CAOS system to actual postoperative radiographic alignment values. Thus, it can be said that the smaller the difference between intraoperative and postoperative measurements, the more accurate the CAOS navigation system. The more accurate a CAOS navigation system is, the more confident the surgeon can be that measurements taken intraoperatively reflect the actual postoperative alignment. We have shown in previous work that angular measurements attained by a single CT-free CAOS navigation system intraoperatively can differ significantly from postoperative measurements taken from full length lower extremity radiographs.[17] The present study compares this initial system to a second CT-free CAOS navigation system in order to determine if one is more accurate overall and produces fewer alignment outliers (≥ 3° of varus/valgus alignment).

We hypothesized that the variation between final intraoperative CAOS bony cut measurements and postoperative implant and extremity alignment would be different between the 2 CT-free navigation systems. We also hypothesized that the number of postoperative mechanical outliers (≥ 3º of varus/valgus) would be decreased for the navigation system that had more similar intraoperative and postoperative measures.

Methods

Patient selection

We retrospectively reviewed the medical records and radiographs for all consecutive patients who underwent CAOS-TKA at a single orthopedic institution in 2 time periods (November 2007–February 2008 and March 2009–December 2010). For the first cohort, all operations were performed with the assistance of the ORTHOsoft Knee 2.1 Universal system. For the second cohort, all operations were performed with the assistance of the Brainlab AG Ci Knee essential 2.1.1 system. All procedures were performed by a single arthroplasty surgeon (D.J.Z.) who received formal training for each navigation system. The specific time periods were selected for study evaluation as they represented the time by which the surgeon had surpassed the accepted threshold for the learning curve (30–50 cases)[18,19] of each CAOS-TKA system. Consecutive patient inclusion was performed to minimize selection bias.

Operative procedure and perioperative data collection

All procedures were performed under spinal anesthesia, and the surgeon used a medial parapatellar approach. On exposure of the knee joint, articular landmarks and important bone areas were recorded using a pointer-like device, and external optical tracking devices were placed on the tibia and femur to template bony cuts. The 2 imaging systems used similar static landmarks, including the femoral condylar surfaces, centre of the talus, femoral intercondylar notch, borders of the tibial plateau and tibial spine, as well as dynamic motions to determine the centre of the femoral head. The main difference in landmark identification was the need to trace out (or “paint”) the entirety of the distal femoral and proximal tibial articular surfaces with the Brainlab system compared with several single point landmarks on the ORTHOsoft system. Apart from these differences and slight instrument sizing differences, the 2 navigation systems similarly use optical trackers that provide data regarding knee position to an infrared receiver, which then displays real-time positional information on a digital display. Following navigation-assisted femoral and tibial cuts, trial components and a fitting spacer were placed, and knee range of motion was assessed. Following cement application and component placement, a final alignment assessment could be performed in both the Brainlab and ORTHOsoft systems to allow any further alignment correction due to the cement mantle. Knee range of motion and mechanical axis were then clinically assessed, and the subcutaneous tissue and skin was closed with a Jones bandage.

Data were collected intraoperatively through each CT-free navigation system. For both systems, the following parameters were recorded after insertion of final components: the coronal angle of the tibial cut, the coronal angle of the femoral cut and the final mechanical axis of the lower extremity.

Postoperative data collection

As per standard protocol at our institution, all patients underwent a full weight-bearing long axis radiograph of the lower extremities 6 weeks after surgery. Standing radiographs were obtained using a long film cassette with a radiography tube distance of 305 cm to capture the hips, knees and ankles. Although use of a long cassette is not universal[20] and is subject to errors due to knee flexion and lower extremity rotation,[21–23] its use has been cited as an acceptable reference standard for alignment of the lower limb.[24–27] Radiographs were then viewed in their native DICOM format using Horizon Rad Station viewing software version 11.0.8.2172 (McKesson). Measured values were obtained by 2 individuals (A.C. and B.M), who did not participate in any of the surgical procedures, were blinded to the CAOS system allocation and who were both experienced in taking radiographic measurements for research purposes. Using the same methodology as described in our previous work,[17] the following measurements were obtained from postoperative radiographs: the coronal angle of the tibial component, the coronal angle of the femoral component and the final mechanical axis. Interrater reliability was calculated, and the average of each measurement made by the 2 researchers was then used for comparison. Furthermore, Knee Society scores were recorded for each patient at the 6-week visit.

Statistical analysis

We assessed interrater reliability for radiographic measurements by calculating the intraclass correlation coefficient using SPSS statistical software version 19, using a 2-way random-effects model assuming a single measurement and absolute agreement. An intraclass correlational coefficient of 1 represents perfect reliability, and any value greater than 0.8 indicates excellent reliability.[28] We compared intraoperative navigation and postoperative radiographs using paired *t* tests, with the level of significance set at $p < 0.05$. The proportions of postoperative complications and radiographic outliers were recorded for each system and compared using a χ^2 test. A radiographic outlier was defined as a postoperative measurement of 3º of varus/valgus or greater.

Results

Our study included 81 patients: 31 in the ORTHOsoft group and 50 in the Brainlab group. All patients successfully underwent unilateral TKA with no significant intraoperative complications. Patient demographics were similar in both groups. The mean patient age was 70.12 ± 10.66 years in the ORTHOsoft group and 74.27 ± 7.60 years in the Brainlab group. All patients began weight bearing by the second postoperative day and yielded similar rates of postoperative transfusions ($\chi^2 = 1.547$, $p = 0.21$) and deep vein thrombosis ($\chi^2 = 2.46$, $p = 0.11$). No major complications, including deep wound infection, myocardial infarction and pulmonary embolus, were noted in either group during the first 6 weeks. The mean Knee Society score at 6 weeks was comparable between the groups (mean 67.77 ± 14.15 in the ORTHOsoft group v. 67.09 ± 12.32 in the Brainlab group). Overall, interrater reliability for postoperative radiograph measurements was excellent, with intraclass correlation coefficients of 0.834 for the coronal angle of the tibial component ($p < 0.001$), 0.842 for the coronal angle of the femoral component ($p < 0.001$) and 0.962 for the mechanical axis ($p < 0.001$).

We noted significant differences between intraoperative navigation measurements and postoperative radiograph measurements in each navigation group (Table 1). However, such differences were not observed in the same measurements. In the ORTHOsoft group, we noted a significant difference in the coronal tibial implant angle (1.29º ± 1.35º, $p < 0.001$) and in the mechanical axis (1.59º ± 2.36º, $p < 0.001$). In the Brainlab group, only the coronal tibial implant angle showed a significant difference (1.17º ± 1.65º, $p < 0.001$); no difference was observed in the mechanical axis (0.75º ± 2.67º, $p = 0.05$). In both groups, the coronal angle of the femur showed no significant change from intraoperative data to postoperative radiographs (0.30 ± 1.74, $p = 0.33$ in the ORTHOsoft group v. 0.22 ± 1.94, $p = 0.49$ in the Brainlab group).

The number of radiographic outliers also differed in each navigation system. The overall percentage of patients with at least 1 radiographic parameter more than 3° was 32% (10 of 31) in the ORTHOsoft group and 24% (12 of 50) in the Brainlab group ($\chi^2 = 19.121$, $p < 0.01$). The percentage of outliers was higher in the ORTHOsoft group for both the mechanical axis (29% v. 22%; Fig. 1) and the coronal angle of the femoral component (6.4% v. 6%; Fig. 2). The Brainlab group had a higher percentage of coronal tibial angle outliers (12% v. 9.6%; Fig. 3).

DISCUSSION

Interest in comparing computer navigation systems in orthopedics is steadily emerging. Although not relevant to TKA, a study by Honl and colleagues[29] compared acetabular orientation in 5 computer-assisted navigation systems for total hip arthroplasty and found variations among the systems. Specific to TKA, Harvie and colleagues[30] prospectively followed

Table 1. Comparison of intraoperative navigation measures and manual radiolographic measurements made 6 weeks after surgery for the Brainlab and ORTHOsoft navigation systems*

	Group; mean ± SD				
Measure	Navigation system values	Radiograph values	Mean difference	95% CI	*p* value
Brainlab, *n* = 50					
Coronal plane of femoral implant	0.14 ± 0.95	0.35 ± 1.70	0.21 ± 0.75	–0.33 to 0.77	0.49
Coronal plane of tibial implant	0.59 ± 0.76	–0.58 ± 1.65	1.17 ± 0.89	–1.64 to –0.70	< 0.001
HKA angle	0.02 ± 0.70	–0.73 ± 2.69	0.75 ± 1.99	–1.51 to 0.01	0.05
ORTHOsoft, *n* = 31					
Coronal plane of femoral implant	0.17 ± 0.63	0.48 ± 1.65	0.30 ± 1.74	–0.33 to 0.94	0.33
Coronal plane of tibial implant	–0.66 ± 1.10	0.62 ± 1.78	1.29 ± 1.35	0.79 to 1.78	< 0.001
HKA angle	0.45 ± 1.20	2.04 ± 2.13	1.59 ± 2.36	0.73 to 2.46	< 0.001

CI = confidence interval; HKA = hip–knee–ankle; SD = standard deviation.
*Positive measurements represent valgus orientation; negative measurements represent varus orientation. Comparison was made using a paired *t* test, with significance set at $p < 0.05$.

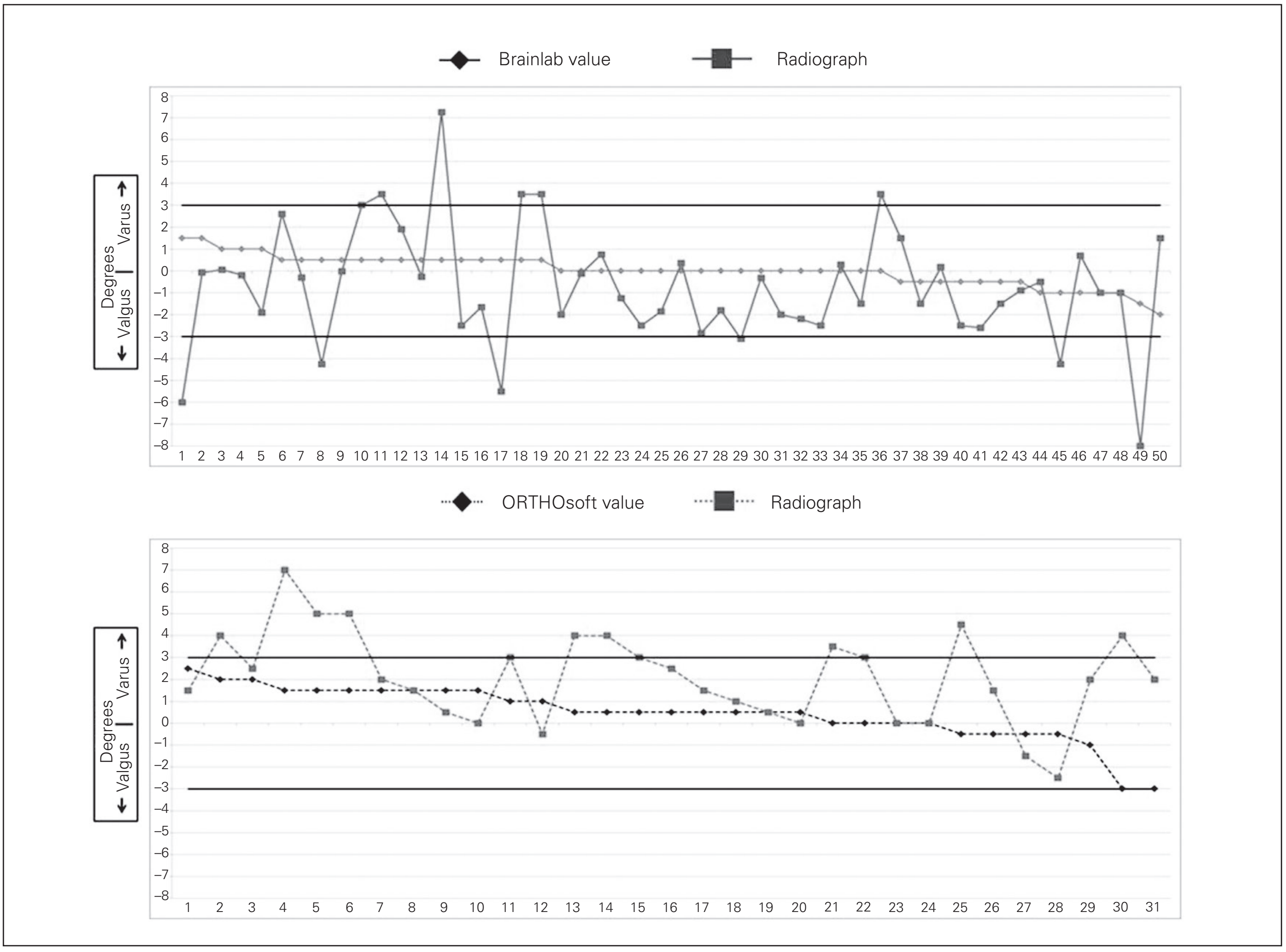

Fig. 1. Comparison of intraoperative measurements of the mechanical axis measured by Brainlab and ORTHOsoft navigation systems and postoperative measurements on standing radiographs. Intraoperative navigation measurements are organized from the most valgus to most varus.

40 patients who underwent the procedure using either an imageless full navigation system or an articular surface-mounted navigation system. They found no significant difference between the 2 systems with regard to the postoperative implant position verified. A comparison among imageless navigation systems has not been reported despite the general preference for CT-free over CT-dependent systems.

To our knowledge, the present study is the first to compare deviations between intraoperative navigation data and postoperative radiograph measurements of 2 CT-free navigation systems. It is also, to our knowledge, the first to propose that this form of intraoperative and postoperative comparison be used as a manner to measure accuracy for CAOS systems. Our results confirm our initial hypothesis that the greater the difference between intraoperative navigation system measurements and postoperative radiograph measurements, the greater the incidence of coronal misalignment in patients who have undergone TKA. It should be specifically emphasized that the differences between the 2 systems, although significant, were small and within 2° of each other. However, such small differences were enough to significantly change the overall proportion of radiographic outliers between systems, which is a pertinent finding given that one of the driving purposes of computer navigation in TKA was to eliminate knee malalignment. Since the difference between intraoperative and postoperative measurements was not the same for the 2 navigation systems studied, our results indicate that different CT-free navigation systems are not necessarily equivalent in predicting postoperative alignment during TKA.

Computed tomography–free navigation systems have been previously shown to decrease the prevalence of radiographic outliers to 10%.[31–34] In our study, neither navigation system met this threshold. The navigation system that provided intraoperative measurements that better matched postoperative alignment (Brainlab) had fewer mechanical outliers (24%) than its less accurate counterpart (ORTHOsoft). This latter system produced

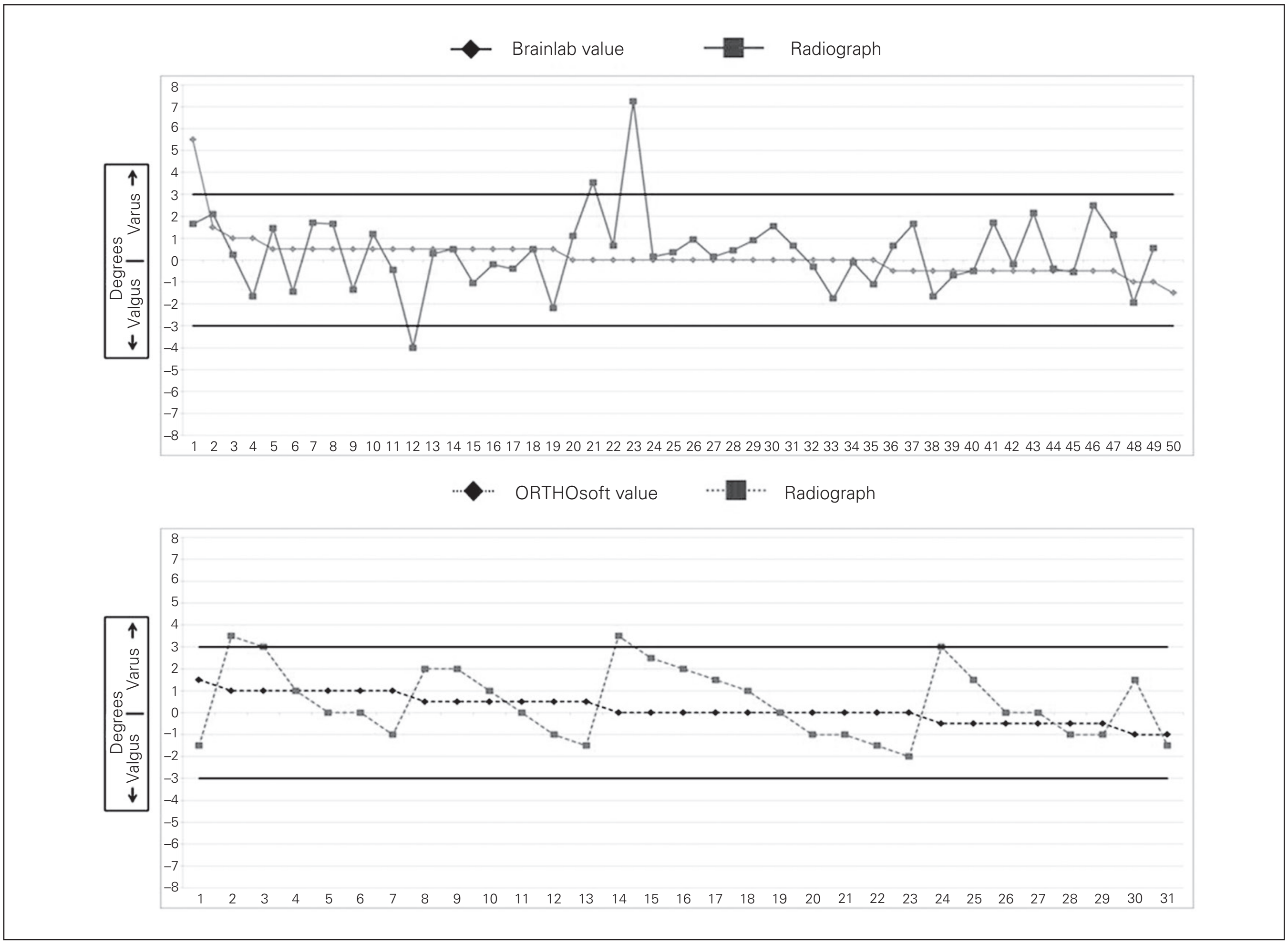

Fig. 2. Comparison of intraoperative measurements of the coronal orientation of the femoral implant measured by Brainlab and ORTHOsoft navigation systems and postoperative measurements on standing radiographs. Intraoperative navigation measurements are organized from the most valgus to most varus.

an incidence of mechanical outliers that surpassed the 30% rate seen with conventional instrumentation.[35,36]

Controversy exists in the literature regarding the clinical relevance of the improved coronal alignment attained through CAOS-TKA. Khan and colleagues[37] found that patients who underwent computer-assisted TKA with a mechanical axis alignment of 3° or more from neutral had lower Western Ontario and McMaster Universities Arthritis Index scores, indicating increased difficulty with daily activities. Furthermore, Lützner and colleagues[38] randomly assigned 80 patients to receive either conventional or navigated TKA and found that patients who underwent navigated TKA were less likely to have mechanical axis malalignment postoperatively and had significantly improved Knee Society scores. However, a follow-up study involving the same cohort revealed no difference between the groups 5 years after surgery.[39] A similar result was found at a 2-year follow-up of 71 patients who were also randomized to conventional or navigated TKA.[40]

In addition to findings of equivalent outcome scores despite improved alignment, concerns for higher revision rates after navigated TKA have been raised. Gotheson and colleagues[41] presented data from the Norwegian registry regarding 10 000 TKAs and found significantly higher revisions rates for navigation versus conventional (3.6% v. 2.1%) procedures. However, this finding is offset by findings of equivalent revision rates in a comparison study of 100 navigated and conventional TKAs[42] as well as a retrospective evaluation of 1121 TKAs that yielded a significantly lower revision rate for navigated TKAs.[43] Although these conflicting findings in the literature raise valid concerns regarding the long-term benefits of navigated TKA, it remains generally accepted that establishing a normal mechanical axis is a fundamental technical objective in TKA and that CAOS-TKA more reliably accomplishes this objective than conventional methods.[44] However, findings from the present study indicate that some CAOS-TKA systems may not be as reliable in providing intraoperative

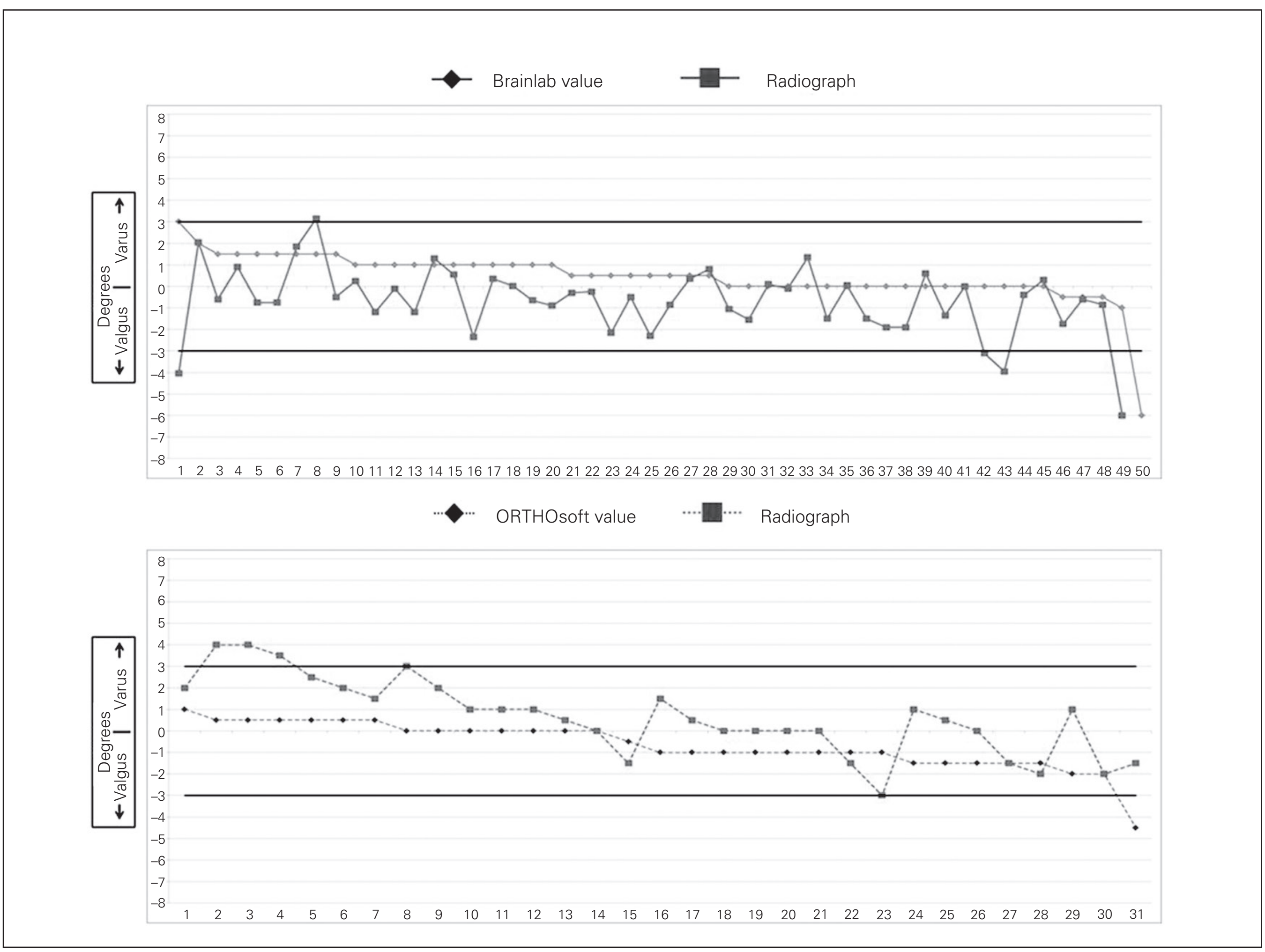

Fig. 3. Comparison of intraoperative measurements of the coronal orientation of the tibial implant measured by Brainlab and ORTHOsoft navigation systems and postoperative measurements on standing radiographs. Intraoperative navigation measurements are organized from the most valgus to most varus.

alignment information that adequately correlates with the postoperative mechanical axis. Ultimately, additional studies comparing multiple CAOS-TKA systems and how their respective divergences between intraoperative and postoperative alignment variables affect long-term clinical outcome must be performed to evaluate the relevance of the present findings.

Limitations

This study has limitations. Although the navigation data and postoperative radiograph measurements were taken prospectively, patients were not randomized to a specific navigation system. Preoperative alignment and range of motion data were not compared between the 2 groups, a notable limitation given that a previous study reported greater divergence between intraoperative and postoperative alignment indices in patients with more severe preoperative alignment deformities.[45] The study also does not provide short-term patient outcome information after the 6-week postoperative mark, making it difficult to determine the clinical importance of the observed discrepancies between intraoperative and postoperative alignment. Although patients in both groups were included only after the learning curve for each CAOS system had been surpassed, we acknowledge that the treating surgeon was more experienced in CAOS-TKA when performing surgeries on the Brainlab cohort and that this may have improved his intraoperative alignment technique for this group. Postoperative radiograph measurements, although recorded by the 2 blinded observers with excellent interrater reliability, are inherently susceptible to errors due to patient positioning as well as knee flexion and external rotation.[46–49] In addition, as remarked by Choi and colleagues,[50] intraoperative and postoperative measurements are performed under considerably different circumstances. Intraoperative measurements are taken before complete soft tissue closure in full extension and without weight bearing, whereas postoperative measurements are taken with full weight bearing and cannot control for soft tissue contractures elsewhere in the lower extremity.

Despite such differing circumstances, our inclusion of only a single surgeon performing the surgical procedures should minimize intersurgeon variation in how the intraoperative data were collected, making it less difficult to compare against postoperative radiographs. Furthermore, our choice to use long-cassette radiographs as the gold standard is justified, as this modality is considered an acceptable reference for alignment[27] and sufficient for routine postoperative assessment.[51] Another consideration is the cement mantle, which if applied unevenly can cause the final implant position to be different from the bony cut. Both systems used in the present study permit intraoperative alignment after cement and components are inserted, permitting the surgeon to apply coronal stresses or impact implants further before cement curing. This feature of final component alignment surveillance is not universal among CAOS-TKA systems and, along with various cementing techniques, could theoretically affect final component alignment. We are interested in evaluating the effect of cementing technique and CAOS final alignment capability, and we plan to perform a prospective evaluation at our centre. The slight difference in the way surface landmarks between the 2 systems were made is also of interest, but the effect this difference would have on alignment is unknown and should also be recorded in future system comparisons. Finally, long-term data were not included, making it difficult to conclude if such variability in discrepancy between navigation data and radiograph measurements impacted clinical outcome.

Conclusion

Computer-assisted orthopedic surgery for TKA continues to increase in sophistication and popularity, with new computerized systems attempting to incorporate aspects of both full navigation and conventional TKA.[30] Although a sizeable amount of literature exists advocating the advantages in alignment that accompanies the use of CAOS, results from the present study suggest that orthopedic surgeons should not consider all TKA navigation systems to be the same. Additional investigations are needed to compare the accuracy of a variety of CT-free and CT-based navigation systems and to confirm our finding that accuracy is system-dependent, with greater accuracy leading to fewer mechanical outliers. This finding should be taken into account when reviewing conflicting data obtained from pooled results involving different systems, and should also be considered when switching to different systems in clinical practice.

Competing interests: None declared

Contributors: A. Carli, A. Aoude, A. Reuven, J. Antoniou and D. Zukor designed the study and acquired the data. A. Carli, B. Matache, J. Antoniou and D. Zukor analyzed the data. A. Carli, A. Aoude, A. Reuven, J. Antoniou and D. Zukor wrote the article, which A. Carli, B. Matache, J. Antoniou and D. zukor reviewed. All authors approved the final version for publication.

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