The iAssist Navigation System Demonstrated Superior Radiological Outcomes in Restoring Mechanical Alignment and Component Sagittal Positioning in Total Knee Arthroplasty

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Research Article

Keywords: Total knee arthroplasty, Accelerometer-based navigation, iAssist, Mechanical axis, Component sagittal positioning

Posted Date: December 9th, 2020

DOI: https://doi.org/10.21203/rs.3.rs-117247/v1

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Version of Record: A version of this preprint was published at BMC Musculoskeletal Disorders on April 13th, 2021. See the published version at https://doi.org/10.1186/s12891-021-04213-9.
Abstract

**Background:** This study aimed to determine whether the iAssist navigation system (NAV) could improve the accuracy of restoring mechanical axis (MA), component positioning, and clinical outcomes compared to conventional (CON) total knee arthroplasty (TKA).

**Methods:** A total of 301 consecutive patients (NAV: 27, CON: 274) were included. A 1:4 propensity score matching (PSM) was performed between the two groups according to preoperative demographic and clinical parameters. The postoperative MA, femoral coronal angle (FCA), femoral sagittal angle (FSA), tibial coronal angle (TCA) and tibial sagittal angle (TSA) were compared. Absolute deviations of aforementioned angles were calculated as the absolute value of difference between the exact and ideal value and defined as appropriate if within 3°, otherwise regarded as outliers. Additional clinical parameters, including the Knee Society knee and function scores (KSKS and KSFS) and range of motion (ROM), were assessed at the final follow-up (mean follow-up time was 21.88 and 21.56 months respectively for NAV and CON group).

**Results:** A total of 98 patients/102 knees were analyzed after the PSM (NAV: 21 patients/24 knees, CON: 77 patients/78 knees). In the NAV group, the mean MA, FCA and TSA were significantly improved ($p = 0.019, 0.006, <0.001$, respectively). Proportions of TKAs within a ±3°deviation were significantly improved in all the postoperative radiological variables except for TCA ($p = 0.003, 0.021, 0.017, 0.013$, respectively for MA, FCA, FSA, and TSA). The absolute deviations of FSA and TSA were also significantly lower in the NAV group ($p = 0.016, 0.048$, respectively). In particular, no significant differences were found in either mean value, absolute deviation or outlier ratio of TCA between two groups. For the clinical outcomes, there were no significant differences between two groups, although KSKS, KSFS and ROM ($p<0.01$, respectively) dramatically improved compared to baseline.

**Conclusions:** We suggested that the iAssist system could improve the accuracy and precision of mechanical alignment and component positioning without significant improvement of clinical outcomes. Further long-term high-quality studies are necessary to validate the results.

Background

Contemporary TKA has evolved over the past 50 years since it was initially introduced in 1968. As a successful procedure for end-stage osteoarthritis, TKA played an important role in patient's pain relief and functional restoration. Several key elements, such as optimal mechanical alignment and component positioning as well as proper soft tissue balance, would influence the outcomes [1]. The optimal range of alignment stayed controversial [2], nonetheless, it has been found that malalignment of greater than ±3° would lead to apparent polyethylene wear [1], premature failure, and implant loosening [3], with a rising revision rate as high as 24% [4].

The accuracy of conventional technique on bone resection might be restricted in cases with severe varus/valgus, extra-articular deformities (EAD), excessive anterior femoral bowing and etc [5]. Moreover,
errors in MA of greater than ±3°, within these above mentioned challenging clinical scenarios, may be as high as 22% to 35% [6]. Considering the growing demand for technical accuracy and precision, computer-assisted system (CAS) has rapidly developed and been well applied. A number of comparative research has demonstrated that CAS was able to minimize cases of outliers in MA and component position in comparison with conventional instrumentations [7–9]. Nevertheless, utilizing CAS would take longer surgery time and is related to higher cost [4].

The iAssist navigation system (Zimmer, Warsaw, IN) is one novel handheld accelerometer-based navigation system, with short learning curve on account of similar surgical workflow to traditional TKAs [10]. However, several meta-analysis found debatable results on whether the accelerometer-based navigation system could improve mechanical alignment and component positioning [11, 12]. The objectives of this retrospective, propensity score-matched comparative study were to compare the postoperative radiological and clinical outcomes between patients undertaking TKA with iAssist system and conventional techniques, and figure out if this system could better restore MA and improve the accuracy and precision of component positioning, as well as the clinical outcomes.

Methods

Patient selection:

A retrospective review of institutional medical record database was conducted, which was approved by the local Ethics Committee of Peking University People's Hospital (2020PHB171-01). Consecutive cases of patients who received a primary posterior-stabilized TKA by using either iAssist (Zimmer, Warsaw, IN) navigation system (NAV group) or conventional techniques (CON group) from May 2017 to September 2019 were included. Exclusion criteria included: (1) hip and/or ankle pathology with a severe limited range of motion (2) or causing severe functional limitation, (3) patients lost to follow-up. The surgery was performed by one experienced arthroplasty surgeon (LJH).

Data collection:

Preoperative demographic data was collected. Preoperative Knee Society knee scores and function scores (KSKS and KSFS) and range of motion (ROM) were also recorded.

Surgical technique:

The primary difference on surgical techniques exclusively existed in bone cutting, except for which, all other surgical procedures, i.e. approach (medial parapatellar approach), soft tissue balancing (gap balancing technique) and cementing techniques remained the same between both groups. In the NAV group, the surgeon completed femoral and tibial registration by moving the extremity in space, enabling the stereotaxic pods and its in-built accelerometer to carry out a three-dimensional triangulation in between the device and hip/knee/ankle joint centers, therefore identifying the optimal MA along with component position. The pods could exhibit the alignment information after which guided coronal and
sagittal resection. A validation procedure was performed following every cuts and make additional adjustments when necessary.

As for the CON group, standard intra-medullary alignment technique on femoral side and extra-medullary alignment technique on tibial side were used. Preoperative radiographs, including weight-bearing anteroposterior (AP) view, lateral view and long-leg standing X-ray, were referred to determine the appropriate distal femoral valgus angle and tibial posterior slope for bone cuts.

**Radiological evaluation:**

Radiological assessment was carried out by utilizing standardized postoperative radiographs, including long-leg standing AP film, along with AP and lateral knee films [13]. All electronic radiographs were analyzed and measured by 2 independent observers (GJX and HYF) who had not participated in the surgery and been blinded to the allocation of groups, as well as patient's demographic data. The intra- and inter-observer reliability was evaluated and rated based on the method described by Konigsberg et al [14].

Three radiographic measurements were carried out on the AP hip-to-ankle radiographs (Fig. 1a): (1) lower extremity MA which was formed by the angle bisecting the center of the femoral head, the center of the knee joint, and the center of the talus[15]; (2) femoral coronal angle (FCA), the lateral angle between femoral MA and intercondylar line; (3) tibial coronal angle (TCA), the medial angle between the tibial MA and the line parallel to the tibial tray. Two measurements were performed on the lateral films (Fig. 1b): (1) femoral sagittal angle (FSA), the posterior angle between the anterior cortical axis (the line linking two points of the anterior cortex at 5 and 15 cm proximal to the joint line [16]) of femur and the slope of distal femoral cut; (2) tibial sagittal angle (TSA), the posterior angle between the proximal anatomical axis (the line linking midpoints of outer cortical diameter at 5 and 15 cm distal to the knee joint[17]) of tibia and the slope of the proximal tibial cut. Absolute deviations of above mentioned angles were calculated as the absolute value of difference between the exact and ideal value (MA, 0°; FCA, 90°; TCA, 90°; FSA, 90°; TSA, 83°[18]) In line with the consensus of most research, absolute deviations of these angles were defined as appropriate if within 3°, otherwise they were regarded as outliers [2, 19, 20].

**Clinical evaluation:**

Clinical outcomes were assessed using the Knee Society knee scores (KSKS) and function scores (KSFS) [21], as well as range of motion (ROM), which was measured by a goniometer on the basis of the active maximum range of motion of the knee. All the clinical outcomes were collected by two co-authors (LZC and LRJ) who were blinded to the patient group.

**Propensity-matched analysis (PSM):**

PSM analysis is a statistical technique aiming to minimize the effects confounding factors attributable to measured covariates in observational studies [22]. A propensity score was defined to be a patient's conditional likelihood of being assigned a treatment based upon patient's pre-treatment characteristics by
logistic regression using the R (V.3.6.1) package "MatchIt" (V. 3.0.2) and "tableone" (V.0.10.0). In this particular study, propensity score match was conducted between the NAV group and the CON group with a 1:4 ratio and a caliper of 0.02, based on age, gender, side of surgery, body mass index (BMI), ROM, KSKS and KSFS scores along with preoperative MA at baseline.

**Statistical comparisons:**

Radiological and clinical date were compared between two groups. Continuous data (age, BMI, KSKS, KSFS, MA, FCA, TCA, FSA, and TSA), were presented as means ± standard deviations (SD) and compared by utilizing either Student's t test (for normally distributed data with equal variances), Welch's t test (for normally distributed data with unequal variances), or the Mann-Whitney U test (for non-normally distributed data). While the categorical data (gender, side of surgery, prosthesis type, and outlier ratio) were presented as counts and percentages, for which Fisher's exact test (when expected count was less than 5) or Chi-Square-test (when expected count was no less than 5) was used to compare between groups. Specifically, gender, prosthesis type and outlier ratio of TCA were compared using Fisher’s exact test, while the rest of categorical variables were analyzed by Chi-Square-test. Pre- and post-operative comparisons were also conducted for clinical parameters using paired t-test. Statistical comparisons were conducted using SPSS (version 20.0; IBM SPSS Statistics, Chicago, IL, USA), with statistical significance set at p < 0.05.

**Results**

**Patient characteristics**

A total of 301 patients/332 knees were included in this study (NAV group: 27 patients/33 knees, CON group: 274 patients/299 knees). After PSM analysis, 98 patients/102 knees were finally included for analysis (NAV group: 21 patients/24 knees; CON group: 77 patients/78 knees). Demographic data before and after PSM were summarized in Table 1, revealing no significant differences in all demographic and clinical data after matching.
Table 1
Demographic characteristic of included patients

<table>
<thead>
<tr>
<th></th>
<th>Unmatched group</th>
<th>P value</th>
<th>Propensity-matched group</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>NAV group</td>
<td>CON group</td>
<td>NAV group</td>
<td>CON group</td>
</tr>
<tr>
<td>Number of cases/knees</td>
<td>27/33</td>
<td>274/299</td>
<td>21/24</td>
<td>77/78</td>
</tr>
<tr>
<td>Age (years)</td>
<td>70.52 ± 6.50</td>
<td>69.36 ± 7.00</td>
<td>0.368</td>
<td>71.04 ± 6.75</td>
</tr>
<tr>
<td>Gender (female)</td>
<td>31 (93.9%)</td>
<td>234 (78.3%)</td>
<td>0.033*</td>
<td>22 (91.7%)</td>
</tr>
<tr>
<td>Knee (right)</td>
<td>16 (48.5%)</td>
<td>122 (40.8%)</td>
<td>0.507</td>
<td>10 (41.7%)</td>
</tr>
<tr>
<td>Prosthesis type</td>
<td></td>
<td></td>
<td>0.040*</td>
<td>0.137</td>
</tr>
<tr>
<td>LPS-Flex</td>
<td>29 (87.9%)</td>
<td>198 (66.2%)</td>
<td>21 (87.5%)</td>
<td>51 (65.4%)</td>
</tr>
<tr>
<td>Legion PS</td>
<td>2 (6.1%)</td>
<td>53 (17.7%)</td>
<td>1 (4.2%)</td>
<td>14 (17.9%)</td>
</tr>
<tr>
<td>Attune PS</td>
<td>2 (6.1%)</td>
<td>48 (16.1%)</td>
<td>2 (8.3%)</td>
<td>13 (16.7%)</td>
</tr>
<tr>
<td>BMI (kg/m2)</td>
<td>27.12 ± 2.87</td>
<td>26.88 ± 3.72</td>
<td>0.718</td>
<td>27.80 ± 2.85</td>
</tr>
<tr>
<td>ROM (°)</td>
<td>95.15 ± 18.94</td>
<td>95.20 ± 19.90</td>
<td>0.989</td>
<td>95.83 ± 18.51</td>
</tr>
<tr>
<td>KSKS</td>
<td>42.24 ± 14.75</td>
<td>40.41 ± 16.17</td>
<td>0.534</td>
<td>40.79 ± 15.21</td>
</tr>
<tr>
<td>KSFS</td>
<td>46.06 ± 22.94</td>
<td>52.93 ± 20.75</td>
<td>0.075</td>
<td>46.46 ± 19.31</td>
</tr>
<tr>
<td>MA (°)</td>
<td>4.38 ± 11.87</td>
<td>9.50 ± 11.87</td>
<td>0.021*</td>
<td>7.80 ± 8.76</td>
</tr>
<tr>
<td>Follow-up (month)</td>
<td>21.79 ± 1.65</td>
<td>21.99 ± 8.03</td>
<td>0.754</td>
<td>21.88 ± 1.42</td>
</tr>
</tbody>
</table>

Abbreviations: BMI, body mass index; ROM, range of motion; KSKS, Knee society knee score; KSFS, Knee society function score; MA, mechanical axis; (neutral MA = 0°, valgus = negative, varus = positive).

Continuous data were expressed as mean ± standard deviations. Dichotomous data were expressed as number (percentage). P value < 0.05 were strengthened by *.

Radiographic outcomes of NAV group vs CON group
The distribution of deviations in degrees from ideal angle was shown in Fig. 2a-e. Table 2 presented all the aforementioned radiological variables of interest. As indicated by the figure and the table, in the NAV group, proportions of TKAs within a ± 3° deviation were significantly higher in all postoperative radiological variables except for TCA (p = 0.003, 0.021, 0.017, 0.013, respectively for MA, FCA, FSA, and TSA). The absolute deviation of FSA and TSA were also significantly lower (p = 0.016, 0.048, respectively). The mean MA, FCA and TSA were significantly improved as well (p = 0.019, 0.006, < 0.001, respectively). In particular, no significant differences were found in all three statistical parameters of TCA between two groups.

<table>
<thead>
<tr>
<th></th>
<th>NAV group (n = 24)</th>
<th>CON group (n = 78)</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>MA value</td>
<td>0.32 ± 2.17</td>
<td>1.74 ± 3.38</td>
<td>0.019*</td>
</tr>
<tr>
<td>MA absolute deviation</td>
<td>1.85 ± 1.12</td>
<td>2.97 ± 2.36</td>
<td>0.058</td>
</tr>
<tr>
<td>MA within ± 3° (n, %)</td>
<td>23 (95.8%)</td>
<td>51 (65.4%)</td>
<td>0.003*</td>
</tr>
<tr>
<td>FCA value</td>
<td>89.75 ± 2.22</td>
<td>91.66 ± 3.09</td>
<td>0.006*</td>
</tr>
<tr>
<td>FCA absolute deviation</td>
<td>1.66 ± 1.45</td>
<td>2.56 ± 2.38</td>
<td>0.145</td>
</tr>
<tr>
<td>FCA within ± 3° (n, %)</td>
<td>22 (91.7%)</td>
<td>53 (67.9%)</td>
<td>0.021*</td>
</tr>
<tr>
<td>TCA value</td>
<td>89.53 ± 1.76</td>
<td>89.99 ± 1.82</td>
<td>0.287</td>
</tr>
<tr>
<td>TCA absolute deviation</td>
<td>1.38 ± 1.15</td>
<td>1.47 ± 1.07</td>
<td>0.507</td>
</tr>
<tr>
<td>TCA within ± 3° (n, %)</td>
<td>22 (91.7%)</td>
<td>74 (94.9%)</td>
<td>0.624</td>
</tr>
<tr>
<td>FSA value</td>
<td>88.79 ± 1.90</td>
<td>87.69 ± 4.18</td>
<td>0.311</td>
</tr>
<tr>
<td>FSA absolute deviation</td>
<td>1.88 ± 1.20</td>
<td>3.55 ± 3.18</td>
<td>0.016*</td>
</tr>
<tr>
<td>FSA within ± 3° (n, %)</td>
<td>20 (83.3%)</td>
<td>44 (56.4%)</td>
<td>0.017*</td>
</tr>
<tr>
<td>TSA value</td>
<td>83.22 ± 2.27</td>
<td>85.64 ± 3.50</td>
<td>&lt; 0.001*</td>
</tr>
<tr>
<td>TSA absolute deviation</td>
<td>1.89 ± 1.21</td>
<td>3.39 ± 2.77</td>
<td>0.048*</td>
</tr>
<tr>
<td>TSA within ± 3° (n, %)</td>
<td>21 (87.5%)</td>
<td>47 (60.3%)</td>
<td>0.013*</td>
</tr>
</tbody>
</table>

Abbreviations: MA, mechanical axis (optimal value = 0°, valgus = negative, varus = positive); FCA, femoral coronal angle (optimal value = 90°); TCA, tibial coronal angle (optimal value = 90°); FSA, femoral sagittal angle (optimal value = 90°); TSA, tibial sagittal angle (optimal value = 83°).

Continuous data were expressed as mean ± standard deviations. Dichotomous data were expressed as the number (percentage). P value < 0.05 were strengthened by *.
Short-term clinical outcomes of NAV group vs CON group

All the clinical parameters significantly improved postoperatively comparing to the baseline in two groups (p < 0.001, p < 0.001, p = 0.002, respectively for KSKS, KSFS, and ROM in the NAV group; And p < 0.001 for all 3 parameters in the CON group). Nevertheless, no significant differences were found in mean postoperative KSKS, KSFS and ROM (Table 3) between two groups. As for the changes of these clinical parameters from baseline, the differences were also not statistically different between two groups (Table 3).

Table 3
Short-term clinical outcomes between iAssist (NAV) group and conventional (CON) group

<table>
<thead>
<tr>
<th>Clinical outcomes at final follow-up</th>
<th>NAV</th>
<th>CON</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>KSKS</td>
<td>90.38 ± 10.45</td>
<td>88.09 ± 13.81</td>
<td>0.806</td>
</tr>
<tr>
<td>KSFS</td>
<td>84.58 ± 14.14</td>
<td>84.48 ± 14.96</td>
<td>0.968</td>
</tr>
<tr>
<td>ROM</td>
<td>109.38 ± 13.70</td>
<td>109.71 ± 16.78</td>
<td>0.933</td>
</tr>
</tbody>
</table>

Changes of clinical outcomes from preoperative baseline

<table>
<thead>
<tr>
<th>clinical outcomes at final follow-up</th>
<th>NAV</th>
<th>CON</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>KSKS</td>
<td>49.58 ± 15.34</td>
<td>48.30 ± 15.32</td>
<td>0.717</td>
</tr>
<tr>
<td>KSFS</td>
<td>38.13 ± 16.67</td>
<td>34.60 ± 16.48</td>
<td>0.720</td>
</tr>
<tr>
<td>ROM</td>
<td>11.79 ± 16.72</td>
<td>17.17 ± 16.94</td>
<td>0.060</td>
</tr>
</tbody>
</table>

Abbreviations: KSKS, Knee society knee scores; KSFS, Knee society function scores; ROM, range of motion.
Continuous data were expressed as mean ± standard deviations.

Discussion

Postoperative alignment and component positions are critical factors affecting patients’ functional outcomes and longevity of the implants. Although traditional CAS has been proven to lessen the risk of mal-alignment, several concerns still exist which may limit its widely usage, including the variation within surgical workflows, requirement for extra pins and radiological examinations as well as longer learning curve and operative time[15]. Generally, CAS can be identified in terms of three categories: image-based large-console navigation; imageless large-console navigation, and accelerometer-based handheld navigation systems, i.e. [23]. The iAssist navigation system, which is the third type, has acted as an accurate and reproducible method [24]. Our results demonstrated that with comparable clinical improvement in the NAV and the CON group, the iAssist system could not only restore MA accurately and
precisely, but also significantly improve prosthesis positioning, especially for the sagittal alignment of both femoral and tibial components.

With the exception of one study suggesting no significant difference in the ratio of outliers for lower limb alignment and component placement [24], the results of the present study were consistent with most published investigations comparing accelerometer-based navigation system with conventional techniques (Table 4) [15, 25–27]. A prospective randomized controlled study found significant improvements in postoperative mean MA, FCA, and TCA, along with lower combined outlier ratios of femoral and tibial component (4.0% in the iAssist group, in comparison with 32% in the conventional group) [15], though the authors did not analyze the radiological variables in the sagittal plane. Nam et al. retrospectively compared the tibial component positioning between KneeAlign system, whose working rationale was similar to that of iAssist, with conventional instrumentations, and observed less outliers for TCA and TSA as well [27]. In addition, another retrospective comparative study has also yielded similar results for restoring lower limb MA and achieving proper component positioning [26].

<table>
<thead>
<tr>
<th>Study design</th>
<th>Parameters</th>
<th>Radiological outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gao 2019[25]</td>
<td>iAssist system (both sides) vs CON</td>
<td>MA, FCA, TCA, FSA, TSA</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Improved absolute deviation of MA, FCA, TCA, FSA, TSA</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Improved optimal(within ± 3°) ratio of MA(95.1%), FCA(100%), TSA(95.1%)</td>
</tr>
<tr>
<td>Kinney 2018[15]</td>
<td>iAssist system (both sides) vs CON</td>
<td>MA, FCA, TCA</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Improved mean MA, FCA, TCA</td>
</tr>
<tr>
<td>Liow 2016[26]</td>
<td>iAssist system (both sides) vs CON</td>
<td>MA, FCA, TCA</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Improved mean MA, FCA, TCA</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Improved optimal(within ± 3°) ratio of MA(91.3%)</td>
</tr>
<tr>
<td>Moo 2018[24]</td>
<td>iAssist system (both sides) vs CON</td>
<td>MA, FCA, TCA, FSA, TSA</td>
</tr>
<tr>
<td></td>
<td></td>
<td>No difference in optimal(within ± 3°) ratio of MA, FCA, FSA, TSA</td>
</tr>
<tr>
<td>Nam 2014[27]</td>
<td>KneeAlign system (only at tibial side) vs CON</td>
<td>TCA, TSA</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Improved optimal(within ± 2°) ratio of TCA(95.7%), TSA(95%)</td>
</tr>
</tbody>
</table>

As for the clinical outcomes, we found no significant differences in KSS and ROM between two groups, which was consistent with the existing literatures. Liow et al. found no differences in both KSS and Oxford Knee Score (OKS) between the iAssist group and the conventional group at 6 months postoperatively [26]. Another prospective cohort study also demonstrated no differences in ROM, KSS and OKS following TKA between the two groups at both 6 months and 2 year follow-up [28]. These negative results may raise a concern that the improvement of mechanical alignment and component positioning might not result in incremental improvements in clinical outcomes in the short term, when compared to conventional
techniques. Therefore, more high quality mid- to long-term studies are required to further explore the association between better radiological outcomes and the clinical function with the use of accelerometer-based navigation.

In the present study we found no significant difference in the parameters of TCA, regardless of the mean value, the absolute deviation or the outlier ratio. Different from the anatomical structure of the femur, the tibial mechanical and anatomical axis nearly coincide with each other. The utilization of iAssist system may rarely provide critical assistance to acquire the accurate tibial MA in the coronal plane, attributable to the point that all the landmarks of tibia may be found or pictured by experienced surgeons, making it possible to envision the center of malleoli and tibia plateau.

One crucial finding was the superior efficacy of iAssist system for aligning the components in the sagittal plane, especially for the femoral side, which has been rarely discussed by previous studies in a systematic approach. Sagittal plane positioning and alignment of component would affect patients’ functional outcomes. The femoral sagittal alignment, in particular, appeared to have a major impact on patellar kinematics [29]. In addition, Keshmiri et al. exhibited a linear model indicating that at 90° of flexion, a change in flexion of femoral component of 1° would make a difference in mediolateral patellar shift by approximately 0.5 mm [29]. An over-flexed femoral component, especially in patients of short stature, was also associated with increased occurrence of persistent flexion contracture [30], while extraordinary femoral component extension might cause anterior knee pain in the long term [31]. Kim et.al highlighted the effect of femoral component's sagittal positioning on prosthesis survivorship: a surgeon should intend to place the femoral component within 0–3° flexion in the sagittal plane, if not outliers would impact the component survival at a mean follow-up of 15.8 years.[32]

Studies have also demonstrated that the tibial slope related linearly to the postoperative ROM [33, 34], when posterior tibial slope was within 10°, a 1° increase would lead to a 2.6° increase in the knee flexion angle for cruciate-retaining (CR) TKA [34]. While excessively increased tibial slope might cause a greater contact stress on the tibial post, leading to increased polyethylene wear [35]. Additionally, a prior study noted anterior impingement between the tibial post and the femoral component, which was observed at near-full extension in patients with an excessive tibial slope of 10° or more [36]. Therefore it is required to restore sagittal alignment of both femoral and tibial components accurately and precisely, which was not easy to be accomplished via conventional techniques. The flexion of femoral component was highly varied in conventionally aligned TKA [37], and a recommended femoral sagittal alignment of within 3° flexion could be acquired in only 25% of the studied cases [38]. In addition, Iorio et.al found that traditional instrumentations failed to achieve ideal tibial component positioning, with a tendency towards decreased tibial slope [39].

There were several benefits for accelerometer-based navigation system in comparison to the other CAS systems. The iAssist technique avoids utilizing pin site reference arrays on both femur and tibia, thus avoiding the pin-tract complications such as pain, infections and periprosthetic fractures [40]. Moreover, surgeons can operate the device completely inside the operative field which facilitates the workflow and
reduces the learning curve [41]. We furthermore proposed several suitable indications on the basis of our clinical experiences and previous research. For patients with a femoral or tibial EAD, being accurate could be technically demanding due to the distorted bony landmarks [33], in which cases surgeons could not obtain a "standard" pre-op X rays and might fail to figure out the proper valgus cut angle of distal femur (Fig. 3a). In such cases, the iAssist system appeared to be valuable [42]. Individuals with lower limb fracture malunion may develop EAD and also have deformations of bony canal or the presence of hardware (Fig. 3b). It was also a potential advantage of the iAssist system to obtain the desired component positions without irritating the medullary. In the similar rationale, the surgery was performed for one patient with benign bone tumor in distal femur uneventfully with the use of iAssist, without offending the tumor (Fig. 3c). Moreover, for individuals with extraordinary anterior femoral bowing, similar to those with an EAD, femoral component flexion would have a significant increase [43]. The implementation of iAssist system could also make sense under this particular circumstance.

In the current study and similar investigations, there were outliers as well in the NAV group. It was speculated that during femoral registration, large movements of the thigh, especially adduction, might induce not only the medial and distal motion, but also anterior lift of the femoral head [44], which could introduce technical errors. Thus, small movements during registration is recommended. Fujimoto et.al have discovered that in patients with tibia vara deformity, the tibial component was likely to be in valgus alignment (approximately 1°) even if a neutral angle (0°) had been selected in the procedure [44]. The deformity could cause medial positioning of the tibial eminence center against the tibial shaft, which would consequently produce a shift of the tibial MA identified by the system [45]. Moreover, in these patients with varus knees, the sclerotic bones of medial plateau are oftentimes harder compared to that of lateral plateau, which may lead to less medial bone removed than the lateral side when a neutral (0°) angle was selected. And this might contribute to the error as well. Cut validation is valuable and highly recommended following every cuts. Last but not least, uneven cementation and impaction of implants can also introduce errors on alignment despite accurate resection planes [46]. Thus, a meticulous cementation and implantation technique is needed.

There were several limitations of this study. On the one hand, it was a retrospective study in nature, and selection bias existed. Moreover, the arthroplasty surgeon selected optimal patients for the NAV group, primarily based on his experience, i.e. iAssist was more prone to be used in patients with EAD or severe varus/valgus deformities in the current study. We mitigate the negative effects by utilizing the PSM analysis, to minimize the inherent bias produced from covariates, and further lower the influence of confounding factors. On the other hand, all procedures were performed by a single experienced surgeon who had a good command of the navigation system, but the learning curve still existed. We started to include patients for analysis one year after his initial experience with the system. In order to explore the effect of iAssist system in a more comprehensive fashion, future prospective studies focusing on radiological, functional and survival outcomes as well as learning curve effects are warranted. Finally, only two male patients undertook primary TKA with the iAssist system during May 2017 to September 2019, which seemed to be a coincidence accounting for this great gender disparity.
Conclusions

The results of the current study demonstrated that the use of iAssist system aided in achieving better radiological results accurately and precisely, including postoperative MA and component positioning, especially for sagittal component alignment (FSA and TSA), which could potentially have profound influences on patients outcome and prosthesis survivorship.

List Of Abbreviations

The iAssist navigation system: NAV; Mechanical axis (MA); Conventional: CON; Total knee arthroplasty: TKA; Propensity score matching: PSM; Femoral coronal angle: FCA; Femoral sagittal angle: FSA; Tibial coronal angle: TCA; Tibial sagittal angle: TSA; Knee Society knee scores: KSKS; Knee Society function scores: KSFS; Range of motion: ROM; Extra-articular deformities: EAD; Computer-assisted system: CAS; Anteroposterior: AP; Oxford Knee Score: OKS.

Declarations

Ethics approval and consent to participate:

All procedures performed in this study were in accordance with the ethical standards of the institutional and national research committee and with 1964 Helsinki declarations and its later amendments. The study commenced after receiving its ethical approval from the institutional review board of Peking University People's Hospital (2020PHB171-01). Written informed consent was obtained from all of the patients before the surgery.

Consent for publication:

Written informed consent for publication was obtained from all participants.

Availability of data and material:

All of the data will be available for secondary analysis in necessary cases from the corresponding author through email address.

Competing interests:

The authors declare that they have no conflict of interests.

Funding:
None.

**Author contributions**


**Acknowledgement:**

The authors thank Liyi Zhang for statistical input when collecting the data.

**References**


Figures
Figure 1

(a) Long-leg standing anteroposterior film for radiographic measurements in the coronal plane, including MA, FCA, and TCA. (b) Lateral radiograph for measuring component alignment in the sagittal plane, including FSA and TSA. Abbreviations, MA, mechanical axis; FCA, femoral coronal angle; TCA, tibial coronal angle; FSA, femoral sagittal angle; TSA, tibial sagittal angle.
Figure 1

(a) Long-leg standing anteroposterior film for radiographic measurements in the coronal plane, including MA, FCA, and TCA. (b) Lateral radiograph for measuring component alignment in the sagittal plane, including FSA and TSA. Abbreviations, MA, mechanical axis; FCA, femoral coronal angle; TCA, tibial coronal angle; FSA, femoral sagittal angle; TSA, tibial sagittal angle.
Figure 2

(a) Deviation from neutral mechanical axis of lower limb in the coronal plane. (b) Deviation from 90° FCA in the coronal plane. (c) Deviation from 90° TCA in the coronal plane. (d) Deviation from 90° FSA in the sagittal plane. (e) Deviation from 83° TSA in the sagittal plane.
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Figure 3

(a) Pre- and postoperative radiographs of patient with femoral EAD. (b) Pre- and postoperative radiographs of patient with lower limb fracture malunion and hardware retaining. (c) Pre- and postoperative radiographs of patient with benign bone tumor in distal femur.
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