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Original research

A randomized controlled trial to compare component placement in navigated total knee arthroplasty using original and streamlined registration processes

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ABSTRACT

Background: This randomized controlled trial validated a redesigned version of navigated total knee arthroplasty software with a streamlined registration (Smart) against the previous version (Classic). The objectives were to determine if Smart software had the same accuracy of component positioning and whether registration and operative time were reduced.
Methods: A total of 220 patients were recruited and had a navigated total knee arthroplasty performed. With the exception of the software, all patients had the same perioperative care. At 6-week follow-up with an independent arthroplasty service, all patients had a computerized tomography scan. This was assessed by an independent radiologist to measure the mechanical alignment of the components.
Results: The mean postoperative mechanical femorotibial angles were equivalent between groups (mean difference −0.2°, 95% confidence interval −0.7° to 0.3°, $P = .407$). Component positions were similar in both groups. Mean registration time was significantly shorter for the Smart group (2 minutes 30 seconds ± 54 seconds) than the Classic group (3 minutes 23 seconds ± 39 seconds), $P < .001$. The mean operative time was 72 ± 12 minutes in both groups ($P = .855$). At 6-week follow-up, both groups had similar clinical outcomes with 96.5% of patients being satisfied or very satisfied.
Conclusions: The study verified that a reduced registration time did not alter the accuracy of component placement. However, despite a shorter registration time, the overall surgical time was not reduced.

Introduction

Although it has been shown that image-free computer-navigated total knee arthroplasty (TKA) improves component positioning and overall lower limb alignment [1-4], it has not been widely adopted. This is due to a number of criticisms including that it increases operation times and the risks of problems with the tracker bone screw insertion sites [1,5-11].

Many studies have shown that the use of navigation increases operative time when compared to conventional instrumentation [1,5-12]. The increase in operation time is both due to the setup of the navigation system (including positioning the camera and bone pin fixation to mount trackers) and then undertaking the registration of the lower limb which involves collecting palpated anatomical landmarks and kinematic centers to allow the computer software to compute the patient's frame of reference and calculate lower limb position. These steps are additional and disruptive. The increase in operating time can also lead to a higher risk of infection and additional further morbidity [13,14] and increased cost [15]. The placement of bone pins also has other risks with fracture and superficial infection at the tracker pin site being reported [12,16,17].

This work was carried out at the Golden Jubilee National Hospital.

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To minimize the disadvantages of the navigation setup "pinless," tracker mountings have been developed to reduce both complications and time [8,17]. There has also been a focus on reducing registration times. Other authors have assessed updates of navigation systems (hardware and software) and have found that operative time was reduced but that there was no difference in radiological or 1-year outcomes [17,18].

To try and address the increase in time in navigated TKA, BBraun Aesculap (Tuttlingen, Germany) revised their Orthopilot Knee Suite TKA software. The workflow for the previous version ("Classic" encompassing TKA 4.3 and 4.4) was assessed and each step analyzed. A new workflow order was designed to improve the ergonomics. This grouped registration tasks, such as collecting all palpated points consecutively, to reduce the changing and moving of instruments. The ankle center registration was also modified to keep only the most reliable method of anatomical palpation instead of using both anatomical palpation and the kinematic center. This change did not alter the underlying algorithms but reordered the existing software routines and removed 2 steps that were now deemed unnecessary (Fig. 1).

Our institution routinely undertakes navigated TKA using Orthopilot software (BBraun Aesculap). We were provided with the updated version of the Knee Suite TKA software (Smart) that embodied the streamlined version of the registration process described above. However, the change in the registration introduced the possibility that the performance of the Orthopilot system would be altered. Therefore, the aim of this study was to validate a version of software with a streamlined registration (Smart) against the previous version (Classic). The study objectives were to determine if the Smart software had the same accuracy of component positioning and whether there was a decrease in registration and operative time.

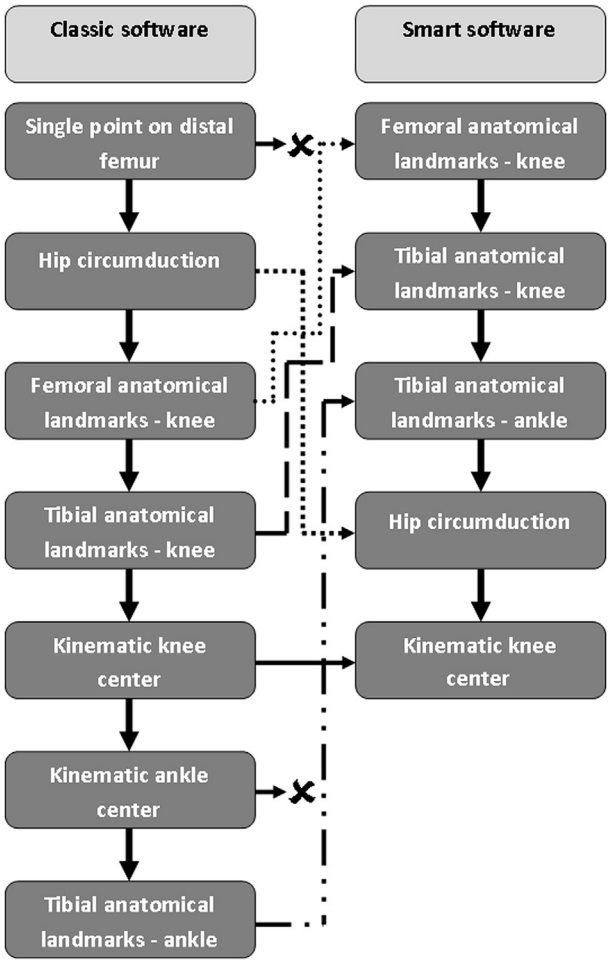

Figure 1. The reordering of the registration steps between the Classic and Smart version of the Orthopilot Knee Suite software.

Material and methods

Ethical approval was gained from the West of Scotland Research Ethics Committee 5 for a prospective randomized controlled trial which was registered on www.controlled-trials.com (ISRCTN7 1883082). The trial started in February 2012, and patients were recruited through to October 2013. Patients, who were suitable to undergo a primary navigated TKA using the Columbus CR knee implants and the Orthopilot navigation system, were under the care of one of the 3 consultants involved in the study and those who fulfilled the selection criteria were approached for inclusion in the study at the preassessment clinic. The inclusion criteria for the study were: able to give informed consent and able to return for follow-up. The exclusion criteria were as follows: patients with a body mass index (BMI) > 40, patients where the surgeon preoperatively decided that they wished to use the additional gap management software module which was only available in the Classic software, patients who were known preoperatively to require patellar resurfacing, patients unable to give informed consent, and patients who were unable to attend for follow-up. Figure 2 shows the CONSORT patient recruitment flow diagram.

Written consent was obtained on admission for surgery from those willing to take part. Patients were randomized to one of two Conformité Européenne (CE) marked and Food and Drug Administration (FDA) approved versions from the Orthopilot TKA KneeSuite software using sequentially-numbered, opaque-sealed envelopes [19]. The software used in the study was Classic (4.3 and 4.4; the changes between these 2 versions made no difference to the user interface, registration process, or computational modules) or Smart. The research coordinator (or nominated person), who was independent of the approach and consent of the patients to the study and of the surgery, carried out the randomization and informed the study team. The patients were blinded to allocation, that is, they were not told which software was used. All TKAs were carried out by one of the 3 consultants involved in the study. The consultant completed all steps of the operative procedure themselves, using their standard operative practice. All the consultant surgeons were well past their learning curve with >1000 (Frederic Picard), >500 (Joe Baines), and >300 (David Allen) navigated cases using the study platform. They had used both the versions of the software, with the newer software being available for 3 months before the study started so meaning they were past any learning curve. All patients received the same cruciate-retaining Columbus CR knee prosthesis (BBraun). The femoral component was implanted with an aim of neutral (90° to the mechanical axis) in the coronal and sagittal planes. The tibial component aim was 90° to the mechanical axis in the coronal plane and 2° posterior slope in the sagittal. The rotation of the femoral component was adjusted to the surgical transepicondylar axis (nominally 3° external rotation to the posterior condylar axis) or at 90° to Whiteside's line as per the surgeon's choice. The rotation of the tibial component was adjusted in relation to the tibial tuberosity. However, there is no agreed rotational value within the literature, and therefore, there was no specific aim in terms of tibial rotation. The registration time was recorded by taking a screenshot at the start and end of the registration process (enabled by the foot pedal). These screenshots were automatically named with the time and date of creation so allowing the calculation of the

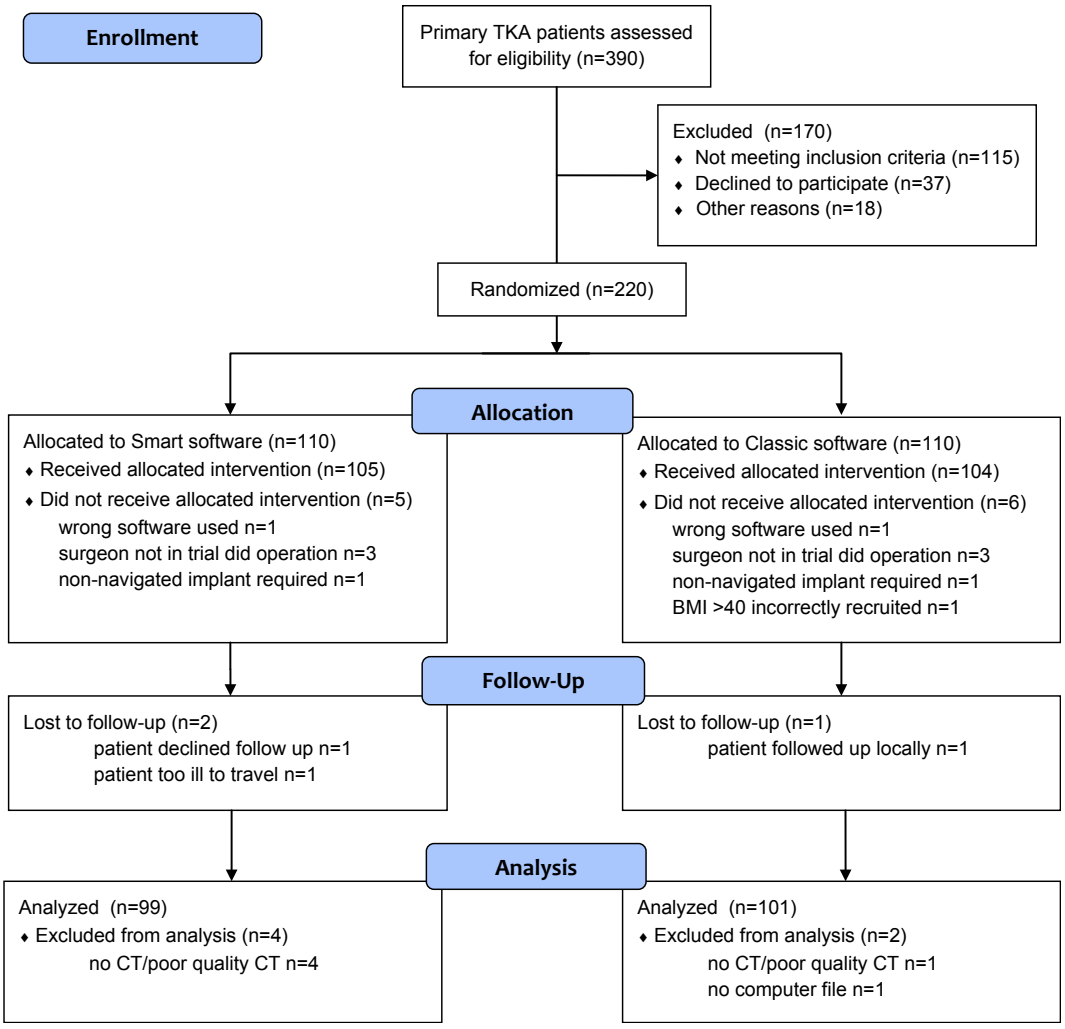

Figure 2. Consolidated Standards of Reporting Trials (CONSORT) flow diagram for study cohort.

registration time. The total operation time was defined as the "skin-to-skin" time (first incision to completion of closure) and was recorded by an independent theater nurse. Due to the surgeon knowing which software was being used, the registration and operation times were not blinded outcome measurements.

For the surgery, patients were all in a supine position with lateral support. A spinal/epidural anesthetic and tourniquet were routinely used. The routine approach was a medial parapatellar one; however, one patient with a large uncorrectable valgus deformity underwent a lateral parapatellar approach. All components were cemented, and no patellae were resurfaced. Standard 3-layer closure completed the surgical procedure. All patients followed standard perioperative care as defined by our institution's enhanced recovery program including local infiltration of analgesia [20].

At 6-week follow-up, all patients were seen by an independent arthroplasty service. The arthroplasty practitioners recorded patient satisfaction, active extension and flexion using a handheld goniometer, Oxford Knee Score, and the Knee Society Score. The practitioners were blinded to group allocation. Patients had a computerized tomography (CT) scan. The "low dose" imperial knee protocol [21] was used to scan hip, knee, and ankle to enable accurate measurements of the mechanical alignment of the components. Using a CT scan gives a more accurate measurement of the 3D lower limb alignment than a hip-knee-ankle radiograph [21]. All CT measurements were taken by an independent radiologist who was not involved in the patients' care and was blinded to the allocation of the patients to treatment groups. The mechanical femorotibial (MFT) angle was recorded as the angle between the axes from the center of the femoral head to the center of the knee joint at the midcondylar point and from the midcondylar point to the center of the tibial plafond. Coronal femoral angle was measured from the center of the femoral head to the midcondylar point as referenced to the inferior condylar line of the prosthesis (medial angle). The coronal tibial angle was measured from the tibial plafond to the center of the tibial tray, as referenced to the superior surface of the tibial tray (medial angle). Sagittal femoral angle was measured from the center of the femoral head to the base of the femoral component peg, as referenced to the angle of the peg. Sagittal tibial angle was measured from the center of the tibial plafond to the superior tibial tray (midpoint of the stem), as referenced to the posterior tibial component slant. Femoral rotational alignment was measured as the Cobb angle between the surgical transepicondylar axis and the prosthesis posterior condyles [22] (Fig. 3). Tibial rotational alignment was measured as per Berger's protocol [23]. The measured angles were defined as follows: coronal femoral component position >90° indicated valgus

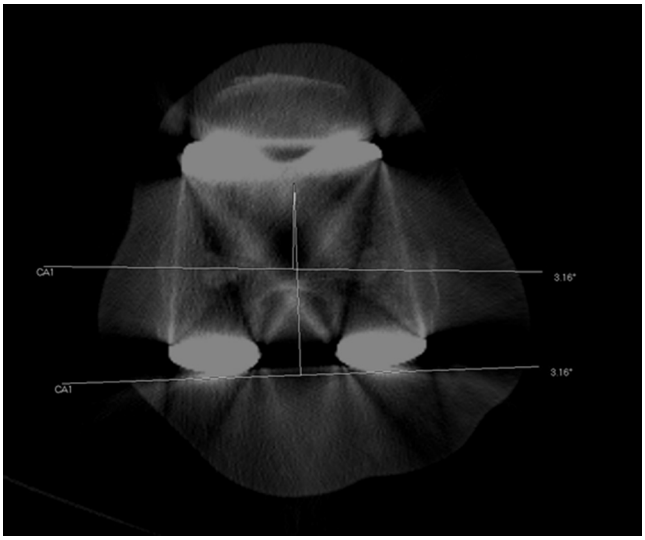

Figure 3. Example of measurements on CT. Measurement of the surgical trans-epicondylar axis.

alignment, sagittal femoral >90° indicated extension, coronal tibial component position >90° indicated valgus alignment, sagittal tibial component position <90° indicated a posterior slope, and rotation of the femoral and tibial components +ve indicated external rotation.

Demographic data (gender, age at operation, American Society of Anesthesiologists (ASA), BMI, etiology, and preoperative Oxford Knee Score) and preoperative type of knee (varus/valgus knee, range of movement, degree of fixed flexion if present, Kellgren Lawrence score, and Ahlback classification) were collected from the patient casenotes, electronic records, and radiographs.

Statistical analysis

The power calculation for the study was carried out using Sample Power 3 (IBM Corp., Somers, NY). The primary outcome was the MFT angle. The study was sized to show equivalence of MFT angle between the 2 groups with 98 patients in each arm (mean MFT angle = 0°, standard deviation (SD) = 2.8°, difference = 1°, power = 80%, and alpha = 0.05). At 80% power, this could also show a reduction in operation time of 6 and a half minutes. Two hundred twenty patients (110 in each group) were recruited to account for loss to follow-up.

Statistical analysis was performed using SPSS version 19 (IBM Corp., Somers, NY). As the aim of the study was to show equivalence data were analyzed on a per protocol basis. The number of outliers beyond ±2° and ±3° of the aim for each measured angle (excluding tibial rotation) were calculated for each group [24]. The number of the 5 alignment angles (excluding rotations) within these limits, as per Jenny's recommendation, was calculated [25]. Continuous variables were compared between groups using independent *t* tests. Categorical variables were compared using chi-squared test. Continuous variables are presented as mean ± SD, 95% confidence intervals (CIs) of the mean.

Results

Of the 110 patients recruited to each group, 9 in the Classic and 11 in the Smart were excluded (Fig. 1). These were: 2 where the randomization was not followed, 1 where the patient's BMI was >40, 2 did not return for 6-week review, 1 patient who was scheduled for telehealth review at 6 weeks, 5 where no CT scan was taken or the CT scan was of poor quality, 1 where a different (TS) prosthesis had to be used, 1 where a highly constrained prosthesis had to be used, 1 patient who had a patellar femoral joint replacement, 6 who were operated on by a different surgeon not in the study, and 1 where the computer navigation file was lost. Therefore, study data were analyzed for 200 patients (101 in Classic and 99 in Smart group). Demographics of the 2 groups are given in Tables 1 and 2.

The mean postoperative MFT angles were equivalent between groups (mean difference −0.2°, 95% CI −0.7° to 0.3°, $P = .407$). There were 7 patients (7%) out with ±3° in the Classic group and 6 (6%) in the Smart group (Fig. 4, Table 3). Component positions were similar (Table 4) with relatively small numbers of outliers (Table 3). There was a statistically but not clinically significant higher mean sagittal femoral angle in the Classic group. In the Classic group, 42 (42%) patients had 5 component angles within 2° of neutral/ideal aimed orientation. In the Smart group this was 36 (36%) patients ($P = .449$).

Registration time was recorded for 96 patients in the Classic group and 98 in the Smart group. The mean registration time was significantly shorter for the Smart software group (2 minutes 30 seconds ± 54 seconds, 95% CI 2 minutes 22 seconds to 2 minutes 38 seconds) than the Classic software group (3 minutes 23 seconds ±39 seconds, 95% CI 3 minutes 12 seconds to 3 minutes 34 seconds), $P < .001$. The mean operative time was 72 minutes (Classic ±12 minutes, 95% CI 70 minutes to 74 minutes; Smart ±12 minutes, 95% CI 69 minutes to 74 minutes) in both groups ($P = .855$).

At 6-week follow-up, both groups had similar clinical outcomes (Table 5). Overall for the 200 patients, 193 (96.5%) were satisfied or very satisfied, 4 were unsure of their satisfaction, 2 were dissatisfied, and 1 patient did not have their satisfaction recorded.

Discussion

This double-blinded randomized controlled trial showed that the simplified registration did not alter accuracy of component placement in TKA. However, shorter registration times achieved did not reduce overall surgical time. It confirms that registration in CT-free navigation represents very small amount of overall operative time.

The study has a number of limitations. The center where it was carried out routinely uses navigation so all staff are used to it; therefore, timings may not extrapolate to other centers. Although the registration time was recorded, the setup of the navigation system was not quantified. This should have been the same for either software, but it is not possible to see how much time was added to the surgery due to this. However, the overall operative

Table 1
Patient demographics.

	Classic	Smart
n	101	99
Male:female	53:48	50:49
Age (y)	67.9 [45-84]	69.1 [40-91]
BMI	30.8 [21.5-39.2]	31.1 [22.7-39.9]
Preoperative alignment—radiographic (°)[a]	−5 [−23 to 17]	−5 [−19 to 18]
Preoperative alignment—navigation system (°)[a]	−4 [−17 to 15]	−4 [−11 to 9]
Preoperative OKS[b]	17 [2-37]	17 [5-36]

OKS, Oxford Knee Score.
Mean [range].
[a] Varus negative, valgus positive, neutral 0°.
[b] Scale 0-48, 48 being best.

Table 2
Categorical demographics.

	Classic	Smart
n	101	99
ASA		
1	5	7
2	83	75
3	13	17
Kellgren Lawrence		
2	16	19
3	54	48
4	31	32
Ahlback		
1	26	24
2	40	36
3	23	30
4	10	8
5	2	1
Etiology		
Osteoarthritis	96	98
Rheumatoid arthritis	4	0
Other	0	1

time does include the tracker placement. The fact that the surgeons were all experienced with navigation could mean that the results for alignment would not extrapolate to surgeons who are not used to navigation. However, it has been shown that the learning curve with navigation affects the operative time but not component placement [16]. The study does not have longer term clinical outcomes, data were only collected at the first postoperative follow-up at 6 weeks as it was not the purpose of the study to investigate clinical outcomes. In addition, the CT scan was not weight bearing. This should mean that it is closer to the alignment measured by the navigation system intraoperatively, but it does not necessarily represent the functional alignment of the knees. Further to this, only one observer measured the CT scans. This was largely due the practicalities of finding independent radiologists outside of the direct care and research teams prepared to be involved in the study. The musculoskeletal radiologist who was involved in the study has a strong background in orthopaedics having undertaken orthopaedic training rotations over 3 years. He is, therefore, highly skilled at understanding images of TKAs and taking accurate measurements. Possibly, the major limitation is that the main outcome is only of interest to navigators [17]. However, this study has shown that navigated knee surgery is not necessarily slow when compared to other published data on operative times and has confirmed the accuracy and precision of component placement.

Computer-assisted knee arthroplasty is still not mainstream. Several reasons have been suggested to explain this, such as risk of infections and fractures related to tracker fixation and increasing time of surgery [17,18]. It is clear that tracker setup and registration are both additional tasks that are not required when using manual instrumentation, and it has been shown that knee navigation increases the overall time of surgery in comparison to conventional TKA by up to 30 minutes [1,5-11,26,27]. The Smart software was developed to reduce registration and consequently overall operative time. The main difference of the Smart software with respect to previous Classic software was the order of registration tasks (anatomical landmarks followed by kinematics rather than mixing both) to make the process faster and more ergonomic. This study found a statistically significant shorter registration with the Smart software, but this was not clinically significant as the study did not demonstrate any decrease in overall surgical time. Other authors have found that software and hardware updates do shorten operative time, but our study operative times were much shorter than theirs, possibly leaving less room for improvement [17,18]. In addition, the definition of operative time and recorded operation time appears to be highly variable between institutions and surgeons [7]. Our times were recorded from first-skin incision to completion of closure of the wound (skin-to-skin) to give a measure of the actual time the operation takes. The mean “skin-to-skin” time of 72 minutes seen in this study is virtually identical to recent studies comparing conventional and patient specific jigs, which are claimed to have shorter operating times [7] and much shorter than times quoted for other recent navigation series [3,7,17]. In our

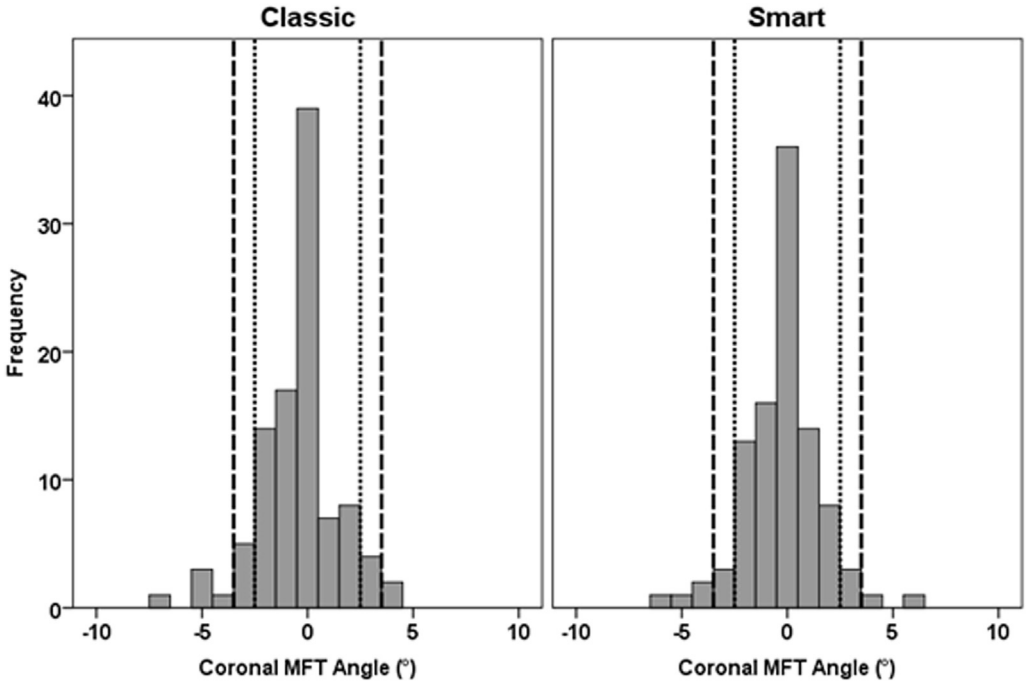

Figure 4. Distribution of MFT angle in both groups (−ve indicates varus alignment and +ve valgus).

Table 3
Percentage of outliers from ±2° and ±3° of desired component placement angle.

	±2°		±3°	
	Classic (%)	Smart (%)	Classic (%)	Smart (%)
MFT angle	16	12	7	6
Coronal femoral angle	30	41	16	16
Sagittal femoral angle	18	24	8	9
Coronal tibial angle	12	14	4	4
Sagittal tibial angle	11	6	2	1
Femoral rotation angle	44	44	27	21

Table 5
Outcomes at 6 weeks.

	Classic	Smart
Very satisfied/satisfied (n)	97 (97%)	96 (96%)
Maximum active extension (°)	2 (3) [0-15]	2 (4) [0-30]
Maximum active flexion (°)	100 (10) [70-120]	98 (12) [60-130]
OKS	33 (7) [12-47]	34 (7) [9-46]
KSS Knee score	74 (16) [36-99]	77 (14) [38-98]
KSS Function score	66 (17) [30-100]	67 (19) [10-100]

OKS, Oxford Knee Score; KSS, Knee Society Score.
Continuous variables presented as mean (SD) [range].

institution, with the use of navigation routinely, operation times appear to still be within the range that would be expected for non-navigated surgery. In addition, it should be noted that our standard operative procedure included the use of local infiltration of analgesia which also adds time to the surgery [20]. We, therefore, agree with Burnett and Barrack [12] that once experience is gained that operative time becomes comparable to conventional techniques.

As the Smart software is an arrangement of the Classic registration steps with the same calculation modules used, it was not surprising to find no difference in alignment. It has been noted in the literature that many studies only report radiographic assessments which have inaccuracies; therefore, this study used CT scans [28-30]. It has also been highlighted that "two groups could have had substantially different distributions of alignment values centering on similar mean values. Consequently, … the percentage of outliers (defined as alignment ±2° or 3° from the desired position) are a better method for evaluating the alignment of implants" [4]. This study showed not only that the means of the 2 groups were the same but also the numbers of outliers in each group were similar. The overall lower limb coronal alignment within ±3° was obtained in 93% of cases with, respectively, 6% of outliers with the Smart and 7% with Classic software and 86% within ±2° which is similar or better than other recent navigation series and meta-analysis [3,4,7,18]. It has also been emphasized that many authors have only looked at overall coronal alignment rather than individual component position which means that "Complementarily mal-aligned tibial and femoral prostheses (ie, one in varus and the other in valgus) may give rise to deceivingly normal axis" so these errors are not identified [7]. To overcome this, this study measured the component placement.

For the femoral component in this study, the sagittal positioning (γ [3,31]) was more consistent than the coronal (α [3,31]). When compared to recent studies, our study had more outliers at ±2° and ±3° limits [7,18]. However, it should be noted that both these studies used radiographs. When compared to a CT-based study, we had similar numbers of outliers for femoral coronal alignment to our study but had substantially less for sagittal positioning when using a ±3° limit [3]. When compared to a more recent meta-analysis for femoral component positioning for both ±2° and ±3°, our study had more outliers in the coronal plane; however, for sagittal alignment, our results were very similar. The variation seen in the coronal plane could be due to the cementation process [32]. Also if the soft-tissue management in extension is imperfect, allowing the cement to set with the lower limb in extension will introduce a slight obliquity to the femoral implant. The majority of the knees had a varus preoperative alignment which would, if the soft-tissue management were responsible for the change in angle of the femoral component, tend to leave the component in slight varus. It is not clear from our results whether or not this is the case.

For the tibial component in this study, both the coronal (β [3,31]) and sagittal (δ [3,31]) positioning were accurate with less than 5% of outliers for each at ±3°. This is better than results reported by other authors [3,7]. When compared to a meta-analysis, our tibial coronal alignment had more outliers at ±2° but was similar at ±3° and for sagittal position we had fewer outliers [4]. This meta-analysis of navigation to conventional techniques also showed that navigation improved all component alignments apart from the sagittal tibial alignment [4]. In our study, the sagittal alignment was the most accurate cut and was within ±3° for 98.5% of components. This alignment is less dependent on the soft-tissue balancing.

The femoral component rotation (λ [3]) showed the widest variation with the highest numbers of outliers. The literature contains few small studies (<35 knees) some of which have shown <10% of outliers [33,34], one showing a similar mean, SD, and range to our study [35] and one showed only 60% within ±3° which is worse than our results [36]. This shows the wide range of femoral rotation seen, and it has been suggested that ±6° is a better limit for rotational accuracy than ±3° [25]. If this was used for our cohort then 100% would have acceptable rotation. For the tibial rotation, we did not show the mean 18° rotation from the tibial tuberosity often quoted [37]. The range of tibial rotation was the widest, which might be expected as there is no agreed aim for this parameter.

Table 4
Component positions on CT scans.

	Classic	Smart	*P* value
MFT angle (°)	−0.4 (1.9) [−7 to 4]	−0.2 (1.8) [−6 to 6]	.407
Coronal femoral angle (°)	91.4 (2.2) [82-97]	91.8 (1.6) [88-95]	.187
Sagittal femoral angle (°)	91.1 (1.6) [−87 to 97]	90.5 (2.0) [85-95]	.019
Coronal tibial angle (°)	89.0 (1.3) [85-92]	89.0 (1.5) [80-91]	.614
Sagittal tibial angle (°)	88.0 (1.6) [85-92]	88.3 (1.4) [85-92]	.289
Femoral rotation angle (°)	−1.1 (2.8) [−6 to 5]	−0.9 (2.7) [−6 to 5]	.588
Tibial rotation angle (°)	−8.7 (5.4) [−20 to 5]	−10.8 (5.6) [−29 to 1]	.008

Mean (SD) [range].

Conclusions

This study confirmed that the registration in CT-free navigation represents a very small amount of the overall operative time which was 4.7% with Classic software and 3.5% with the Smart software. The study verified that a reduced registration time did not alter the accuracy of component placement, with the whole series having low numbers of outliers for all the component angles measured. Despite a shorter registration time, the overall surgical time was not reduced. However, the actual operative times indicate that, for

those experienced with the system, navigation is maybe not as time consuming or cumbersome as it is commonly described.

Acknowledgments

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