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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.

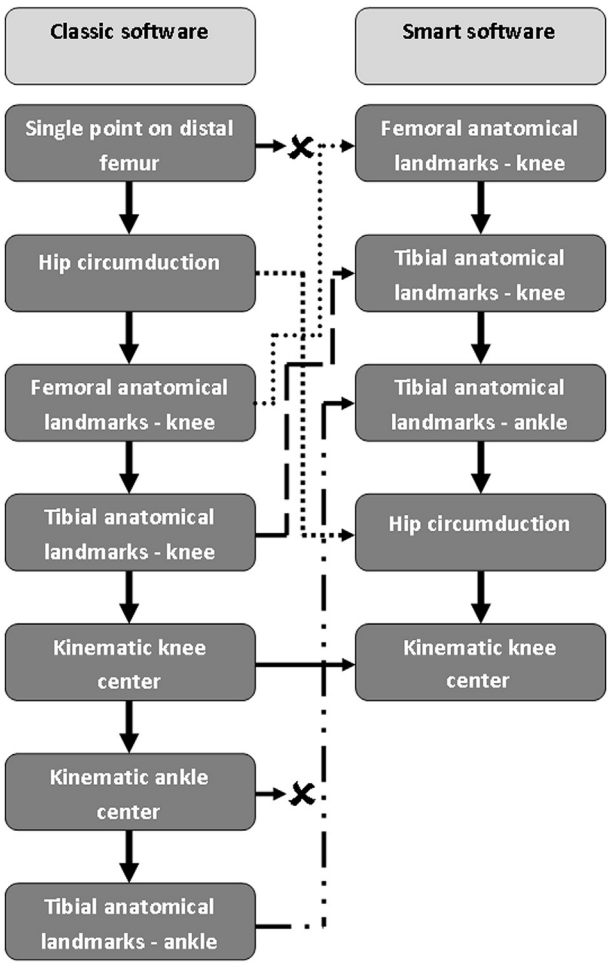

Figure 1. The reordering of the registration steps between the Classic and Smart version of the Orthopilot Knee Suite software.

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 (ISRCTN71883082). 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

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