Impingement-free range of movement, acetabular component cover and early clinical results comparing ‘femur-first’ navigation and ‘conventional’ minimally invasive total hip arthroplasty

A RANDOMISED CONTROLLED TRIAL

We report the kinematic and early clinical results of a patient- and observer-blinded randomised controlled trial in which CT scans were used to compare potential impingement-free range of movement (ROM) and acetabular component cover between patients treated with either the navigated ‘femur-first’ total hip arthroplasty (THA) method (n = 66; male/female 29/37, mean age 62.5 years; 50 to 74) or conventional THA (n = 69; male/female 35/34, mean age 62.9 years; 50 to 75). The Hip Osteoarthritis Outcome Score, the Harris hip score, the Euro-Qol-5D and the Mancuso THA patient expectations score were assessed at six weeks, six months and one year after surgery. A total of 48 of the patients (84%) in the navigated ‘femur-first’ group and 43 (65%) in the conventional group reached all the desirable potential ROM boundaries without prosthetic impingement for activities of daily living (ADL) in flexion, extension, abduction, adduction and rotation (p = 0.016). Acetabular component cover and surface contact with the host bone were > 87% in both groups. There was a significant difference between the navigated and the conventional groups’ Harris hip scores six weeks after surgery (p = 0.010). There were no significant differences with respect to any clinical outcome at six months and one year of follow-up.

The navigated ‘femur-first’ technique improves the potential ROM for ADL without prosthetic impingement, although there was no observed clinical difference between the two treatment groups.

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Primary total hip arthroplasty (THA) is one of the most commonly performed and high-cost procedures in orthopaedic surgery.\(^1\)\(^2\) Instability is the most common early complication, as well as the most common cause of early revision surgery following THA. Impingement between the prosthetic components, or between the prosthesis and the host bone and soft-tissues, is associated with early dislocation.\(^3\)\(^6\) Additionally, impingement in THA may be associated with increased component wear/loosening, reduced hip function with limited range of movement (ROM) and increased pain.\(^7\)\(^8\) Several authors have proposed preparation of the femur before the acetabulum and then adjusting the orientation of the acetabular component relative to the proposed femoral component position (‘femur first’, ‘combined anteversion’) in order to minimise the risk of impingement and dislocation.\(^9\)\(^12\)

The use of imageless navigation systems, without the need for exposure to radiation during surgery, has been shown to increase the accuracy of acetabular component placement.\(^13\)\(^14\) More recently, it has been shown that impingement can be detected with the help of navigation technology.\(^15\)

Following the concept of ‘femur first’, we have developed a method for optimum acetabular component orientation using navigation in primary THA. We undertook a randomised controlled trial (RCT) to assess whether the use of the ‘minimally invasive’ femur-first navigation method would lead to a potential increased ROM, sufficient acetabular component coverage and improved clinical outcomes compared with results obtained with conventional ‘minimally invasive’ THA.

Patients and Methods

The study design, procedures and consent were approved by our local medical ethics committee (10-121-0263). As the patients were blinded to the treatment allocation, ethics approval
included the use of stab incisions for reference pins on the anterior iliac crest and the anterolateral third of the distal femur in the conventional (non-navigated) THA group. Pelvic and femoral CT scans six weeks post-operatively were approved by the ethics committee and the German Federal Office for Radiation Protection. This single-centre patient- and observer-blinded RCT was registered at the German Clinical Trials Register under the Main ID (DRKS00000739). The study design was published before the start of the study.16

**Sample size.** A sample size calculation was made based on the observation that peri-prosthetic impingement occurs in up to 50% of cases in conventional THA.7 We hypothesised that computer-navigated ‘femur-first’ THA would reduce this rate to at least 25% (absolute risk reduction). Therefore, the chi-squared test was used for statistical assessment of the primary study hypothesis. In order to detect differences of at least 25% in the primary outcome criteria between the study groups at a two-sided significance level of 5% with 80% power, a group sample size of 60 patients was required. A ‘learning sample’ of five patients was incorporated to allow the surgeons to familiarise themselves with the prototype software.

**Randomisation.** Patients were randomly allocated to receive either computer-navigated minimally invasive ‘femur-first’ THA or conventional minimally invasive THA without the use of a navigation system. The random allocation sequence was generated by computer in a permuted block randomisation, designed by the associate statistician (KU) using certificated randomisation software (Rancode 3.6 Professional, IDV, Gauting, Germany). Permutest blocks of four, six and eight participants were used to ensure a balanced allocation sequence. This sequence was then placed into sealed, consecutively numbered opaque envelopes. The random allocation sequence was not revealed to the clinical examiners conducting the baseline or the follow-up assessments.

**Recruitment of participants, inclusion and exclusion criteria.** Eligible participants between the ages of 50 and 75 years with an American Society of Anesthesiologists (ASA) score17 ≤ 3 were recruited from patients admitted for primary uncemented THA for the treatment of primary or secondary osteoarthritis at our institution between December 2011 and February 2013. No patients had significant disease in the contralateral hip. Exclusion criteria were age < 50 (as a post-operative CT scan was required) and > 75 years (to ensure post-operative follow up was achieved), ASA score > 3, arthritis of the secondary to hip dysplasia, post-traumatic hip deformities, and previous hip surgery. Informed consent was acquired by one of four clinical investigators (MW, MW, H-RS, TR). In all patients and both groups THA was performed in the lateral decubitus position using the same minimally invasive single-incision anterolateral approach using an intermuscular and interneural tissue plane between the tensor muscle and the gluteus medius muscle.18 A total of 160 THAs were performed by four orthopaedic surgeons (JG, ES, MW, TR) from Regensburg University Medical Centre. Each surgeon had experience with > 200 fluoroscopy and navigation-controlled THAs. Press-fit acetabular components, un cemented hydroxyapatite-coated femoral components (Pinnacle acetabular component, Corail femoral component (both DePuy, Warsaw, Indiana), neutral polyethylene liners and 32 mm diameter metal heads were used in all patients. **Navigated minimally invasive ‘femur-first’ THA.** In the navigated group, an imageless navigation system (Hip 6.0 prototype, Brainlab, Feldkirchen, Germany) with newly developed ‘femur-first’ prototype software was used. The registration process for navigated THA in a lateral decubitus position and the measurement of stem anteversion has been described previously.14,16,19 The four points defining the anterior pelvic plane (anterior superior iliac spines and pubic tubercles) were registered using a reference pointer positioned on the skin’s surface. On the femoral side, the medial and lateral aspects of the epicondyles and ankle points were registered.18 The position of the final broach alignment was saved and the broach was removed. The acetabular anatomy was then registered and reamed. Based on the information gathered during the preparation of the femur and acetabulum, the navigation system calculated an impingement-free coverage-optimised acetabular component position, which was presented to the surgeon on a screen (Fig. 1). Guided by the three-dimensional (3D) projections on the navigation screen, the acetabular component was inserted, followed by insertion of the uncemented femoral component.

**Conventional minimally invasive THA.** Acetabular components were placed freehand without the use of any alignment guides. The target position for the acetabular component for all patients was within the ‘safe zone’ as defined by Lewinnek et al 20 (40° inclination; standard deviation (SD) 10° and 15° anteversion; SD 10°), as estimated visually by the surgeon. The femoral components were similarly inserted using observational assessment of the ideal femoral component position by the treating surgeon.

**CT-based evaluation of potential impingement-free ROM, acetabular component coverage and positioning.** At a mean of six weeks (five to seven) post-operatively, pelvic and fem oral CT scans were performed (Somatom Sensation 16; Sie mens, Erlangen, Germany). Independent segmentation was performed on the pelvic bone, the femur and the metal acetabular and femoral components by an independent external institute (MeVis Medical Solutions, Bremen, Germany), blinded to individual patient data, including the type of surgical approach. Based on the segmented bone models, the theoretical or potential post-operative ROM was calculated by a previously described algorithm, which automatically determines bone–prosthesis impingement and calculates the bony cover as a ratio between acetabular component and bony acetabulum.13 We compared the proportion of patients reaching the potential hip joint ROM benchmarks without osseous or prosthetic impingement that have been defined as...
necessary for activities of daily living (ADL). Specifically, these measurements are > 110° of flexion, 30° of extension, 45° of external rotation at 0° of hip flexion, 30° of internal rotation at 90° of hip flexion, 50° of abduction and 30° of adduction.

Moreover, the acetabular component inclination, anteversion and femoral component anteversion were evaluated on the segmented CT reconstructions of the pelvis and the femur using image-processing software (based on MeVisLab, MeVis Medical Solutions). The intra- and post-operative definitions of the pelvic planes for acetabular component inclination/anteversion used the same radiographic planes and co-ordinate systems for both groups, as defined by Murray.

Clinical measurement tools. For the pre- and post-operative clinical examination, the validated Hip Osteoarthritis Outcome Score (HOOS) and the Harris hip score (HHS) were used as disease-specific outcome measures. The EuroQol 5D (EQ-5D) was used to measure health-related quality of life. Patients’ expectation (PE) and satisfaction with the results of the surgical procedure were measured with the THA Patient Expectations Score, as described by Mancuso et al. Clinical ROM testing (cROM) was performed by a blinded examiner (TW) in flexion, abduction, adduction and internal/external rotation during 90° of hip flexion. Participants attended clinic visits at the time of randomisation (baseline HOOS, HHS, EQ-5D, PE, cROM), at six weeks post-operatively (HOOS except for the sport/recreation subscale), HHS, EQ-5D, cROM) and one year (HOOS, HHS, EQ-5D, PE, cROM) post-operatively. Patients were also assessed by postal survey (HOOS, EQ-5D, PE) at six months post-operatively. Patients and examiners were blinded to the treatment group allocation at all times of clinical assessment.

Statistical analysis. Calculation of the study results and statistical evaluation were performed at the Institute of Medical Statistics and Epidemiology, Technische Universität München, Germany. Data were presented as mean and SD, or as a median together with the interquartile range (IQR) for continuous variables or as numbers and percentages for qualitative variables. Our primary endpoint was the proportion of patients showing post-operative optimal ROM configurations without bony and/or prosthetic impingement. Secondary endpoints were early clinical outcomes in terms of hip function, patient satisfaction and health-related quality of life. The analysis of the primary endpoint and all secondary endpoints is based on the intention-to-treat population. The data between the two treatment groups were compared with the Mann–Whitney U test (continuous variables) or the two-sided chi-squared test for qualitative data. The secondary endpoints were clinical outcome and function. For all secondary endpoints with data, peri-operative regression data were presented as mean and SD or as a median together with the IQR for continuous variables, or as numbers and percentages for qualitative variables. Analyses were performed using the treatment and the baseline data as independent variables.

Statistical analyses were performed using SPSS v22.0.0 (IBM, Armonk, New York). Statistical significance was defined as a p-value < 0.05.

Results
Patients were recruited between December 2011 and March 2013. The numbers of patients who were assessed for eligibility, exclusions, and those who were randomised and underwent clinical follow-up are shown in Figure 2. Patient characteristics according to allocation (‘femur-first’ navigated vs conventional THA) are presented in Table I.

Of the 135 patients, five (3.7%) did not receive the allocated intervention. Of these five, three (2.2%) (two in the navigated group and one in the conventional group) needed an offset liner (4 mm) for sufficient reconstruction of the acetabular offset. One patient (0.75%) received a cemented stem because of severe femoral osteoporosis. According to
our study protocol, these four cases were excluded from the analysis. In one patient (0.75%) the navigation system shut down during the procedure and registration was lost. This patient remained in the intention-to-treat analysis. A total of four (2.9%) of the 135 patients withdrew their informed consent and refused further participation in the study. According to our informed consent and after consultation of our statistician, these four data sets were regarded as lost. In three patients (2.2%) the anatomical pelvic landmarks needed for ROM calculations were missing on the CT scan, and one patient (0.75%) missed the CT examination. These eight patients (5.9%) were excluded from the analysis.

At the six-week follow-up 16 patients (13.0%) were not available for examination. Six patients (6.5%) and eight patients (4.9%), respectively, were not willing to participate in the six-month/one-year examinations after surgery and were therefore lost to follow-up. For the patients who had been lost to follow-up, reviews of hospital records and, when available, local physician records suggested that no dislocations or any revision surgery had occurred.

Impingement-free potential ROM, acetabular component coverage and component position as demonstrated by CT data. Data for the calculated potential impingement-free hip joint ROM are presented in Figure 3. Potential ROM without bone to prosthesis impingement was significantly
higher in flexion in the navigated THA group (p = 0.039, Mann–Whitney U test). Potential ROM without prosthesis to prosthesis impingement was significantly higher in flexion in the navigated THA group (p = 0.050, Mann–Whitney U test), and potential ROM before impingement was higher in external rotation at 0° hip flexion (p = 0.048, Mann–Whitney U test) in the conventional THA group. Data for potential joint ROM configurations without bony or prosthetic impingement required for ADL are presented in Table II. Overall, the measurements of potential ROM showed that 49 patients (86%) in the navigated THA group and 44 (66%) in the conventional THA group reached the ROM boundaries for ADL (> 110° of flexion, > 30° of extension, > 45° of external

<table>
<thead>
<tr>
<th>Male gender (%; 95 CI)</th>
<th>Navigated femur-first THA (n = 66)</th>
<th>Conventional THA (n = 69)</th>
<th>Total (n = 135)</th>
</tr>
</thead>
<tbody>
<tr>
<td>29 (43.9; 31.6 to 56.2)</td>
<td>35 (50.7; 38.6 to 62.8)</td>
<td>64 (47.4; 38.9 to 55.9)</td>
<td></td>
</tr>
</tbody>
</table>

BMI, body mass index; ASA: American Society of Anesthesiologists; CI, confidence interval

Fig. 3a and 3b

Box and whisker plots comparing potential hip joint range of movement a) without bone with prosthetic impingement and b) without prosthesis with prosthesis impingement in the navigated femur-first and conventional total hip arthroplasty (THA) groups. The box height contains the interquartile ranges, with the horizontal line indicating the median value. The minimum and maximum values are represented by the vertical lines with outliers plotted separately. Data between the two treatment groups were compared with the Mann–Whitney U test.
rotation at $0^\circ$ of hip flexion, > $30^\circ$ of internal rotation at $90^\circ$ of hip flexion, > $50^\circ$ of abduction, > $30^\circ$ of adduction) ($p = 0.016$, chi-squared test).

There was no significant difference between the navigated femur-first THA group and the conventional THA group with regard to sufficient acetabular component cover (Table III).

**Clinical results.** In the pre-operative situation, we found comparable score results between the navigated and conventional group. In summary, there was a significant difference in the HHS at six weeks post-operatively in the navigated group ($p = 0.010$, Mann–Whitney U test). Clinical ROM, as documented by a blinded examiner, was greater in the navigated THA group for mean flexion six weeks post-operatively, however, this only constituted 6.3° ($95\% \text{ CI 2.5 to 10.1}$) ($p = 0.002$, Mann–Whitney U test). Analysis of the patient-reported outcomes at six months and the clinical observations at one year post-operatively did not reveal any significant differences between the two treatment groups in any of the outcome measures as demonstrated by the overlapping 95% CIs.

**Intra-operative/post-operative complications.** There were four significant complications, three in the navigated THA group and one in the conventional THA group. One patient in the navigated THA group had a hip dislocation two weeks after surgery. A CT analysis was undertaken which showed an acetabular component position in the Lewinnek ‘safe zone’ and a stem anteversion of $7^\circ$. Closed reduction and revision surgery on the following day were performed, following the hospital’s standard treatment protocol for early non-traumatic dislocations. Intra-operatively, impingement between the unusually prominent inferior iliac spine and the greater trochanter in $90^\circ$ of flexion and $20^\circ$ of internal rotation was detected. Offset was improved by changing the standard acetabular component liner to an offset liner (4 mm) and by changing the head–neck length. One patient in the navigated THA group returned three weeks after surgery with signs of infection and elevated serum inflammatory markers. Revision surgery was performed with debridement, antiseptic lavage and a change of the liner/head. According to the hospital’s standard for early post-operative prosthetic associated infections, we

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**Table II.** Comparison of hips meeting the essential hip joint range of movement (ROM) boundaries for activities of daily living (ADL) without potential bony/prosthetic impingement and without potential prosthetic impingement in the navigated femur-first and conventional total hip arthroplasty (THA) groups. Data presented are the absolute number and (in parentheses) the percentage and 95% confidence intervals, unless otherwise stated.

<table>
<thead>
<tr>
<th>ROM for ADL without bony and prosthetic impingement (%)</th>
<th>Navigated femur-first THA (n = 57)</th>
<th>Conventional THA (n = 66)</th>
<th>p-value*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Flexion &gt; 110</td>
<td>49 (86.0; 76.7 to 95.3)</td>
<td>44 (66.7; 55.0 to 78.3)</td>
<td>0.013</td>
</tr>
<tr>
<td>Extension &gt; 30</td>
<td>53 (93.0; 86.1 to 99.8)</td>
<td>61 (92.4; 85.9 to 99.0)</td>
<td>0.830</td>
</tr>
<tr>
<td>External rotation at $0^\circ$ hip flexion &gt; 45</td>
<td>41 (71.9; 59.9 to 84.0)</td>
<td>45 (68.2; 56.6 to 79.7)</td>
<td>0.625</td>
</tr>
<tr>
<td>Internal rotation at $90^\circ$ hip flexion &gt; 30</td>
<td>44 (77.2; 66.0 to 88.4)</td>
<td>41 (62.1; 50.1 to 74.1)</td>
<td>0.071</td>
</tr>
<tr>
<td>Abduction &gt; 50</td>
<td>53 (93.0; 96.1 to 99.8)</td>
<td>64 (97.0; 92.7 to 1.0)</td>
<td>0.306</td>
</tr>
<tr>
<td>Adduction &gt; 30</td>
<td>45 (78.9; 68.0 to 89.9)</td>
<td>46 (69.7; 58.3 to 81.1)</td>
<td>0.132</td>
</tr>
</tbody>
</table>

**Table III.** Comparison of operating time, component size/position and component coverage at the time of primary total hip arthroplasty (THA) according to allocation to the navigated femur-first or conventional THA groups. Data presented in parentheses are standard deviation and range, unless otherwise stated.

<table>
<thead>
<tr>
<th>ROM for ADL without prosthetic impingement (%)</th>
<th>Navigated femur-first THA (n = 57)</th>
<th>Conventional THA (n = 66)</th>
<th>p-value*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Flexion &gt; 110</td>
<td>51 (89.5; 81.3 to 97.7)</td>
<td>49 (74.2; 63.4 to 85.1)</td>
<td>0.031</td>
</tr>
<tr>
<td>Extension &gt; 30</td>
<td>57 (100.0)</td>
<td>65 (98.5; 95.5 to 1.0)</td>
<td>0.351</td>
</tr>
<tr>
<td>External rotation at $0^\circ$ hip flexion &gt; 45</td>
<td>57 (100.0)</td>
<td>63 (95.5; 90.3 to 1.0)</td>
<td>0.103</td>
</tr>
<tr>
<td>Internal rotation at $90^\circ$ hip flexion &gt; 30</td>
<td>49 (86.0; 76.7 to 95.3)</td>
<td>47 (71.2; 60.0 to 82.4)</td>
<td>0.049</td>
</tr>
<tr>
<td>Abduction &gt; 50</td>
<td>56 (98.2; 94.7 to 1.0)</td>
<td>65 (98.5; 95.5 to 1.0)</td>
<td>0.917</td>
</tr>
<tr>
<td>Adduction</td>
<td>57 (100.0)</td>
<td>66 (100.0)</td>
<td>/</td>
</tr>
</tbody>
</table>

| Combination for all essential ROM boundaries     | 48 (84.2; 74.4 to 94.0)           | 43 (65.2; 53.3 to 77.0)  | 0.016    |

* Chi-squared test

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**Table IV.** Comparison of operating time, component size/position and component coverage at the time of primary total hip arthroplasty (THA) according to allocation to the navigated femur-first or conventional THA groups. Data presented are the absolute number and (in parentheses) the percentage and 95% confidence intervals, unless otherwise stated.

<table>
<thead>
<tr>
<th>ROM for ADL without prosthetic impingement (%)</th>
<th>Navigated femur-first THA (n = 56)</th>
<th>Conventional THA (n = 69)</th>
<th>p-value*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean operating time (mins)</td>
<td>71.8 (13.6; 51 to 126)</td>
<td>64.1 (13.9; 43 to 115)</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Mean acetabular component size</td>
<td>53.9 (3.2; 48 to 62)</td>
<td>54.1 (3.0; 48 to 60)</td>
<td>0.525</td>
</tr>
<tr>
<td>Mean femoral component size</td>
<td>12.2 (1.7; 6 to 16)</td>
<td>11.9 (1.5; 9 to 15)</td>
<td>0.388</td>
</tr>
<tr>
<td>Mean acetabular component inclination (%)</td>
<td>42.5 (5.1; 30.8 to 59.1)</td>
<td>42.4 (6.4; 25.1 to 54.8)</td>
<td>0.899</td>
</tr>
<tr>
<td>Mean acetabular component anteversion (%)</td>
<td>18.3 (6.9; -2.9 to 31.8)</td>
<td>17.5 (8.9; -4.1 to 40.8)</td>
<td>0.353</td>
</tr>
<tr>
<td>Mean stem anteversion (%)</td>
<td>9.1 (10.3; -12.6 to 37.7)</td>
<td>6.9 (8.7; -18.9 to 25.4)</td>
<td>0.344</td>
</tr>
<tr>
<td>Mean acetabular component coverage (%)</td>
<td>875 (8.9; 65.8 to 99.8)</td>
<td>879 (9.6; 51.8 to 98.8)</td>
<td>0.749</td>
</tr>
</tbody>
</table>

* Mann–Whitney U test
included an antibiogram-adjusted six-week course of double antibiotics for control of infection. In one patient in the navigated THA group, a small fracture near the calcar was detected during stem insertion and a cerclage wire was placed beneath the lesser trochanter. One patient in the conventional THA group suffered a partial sciatic nerve palsy, which partially recovered within the following 12 months.

Discussion
The purpose of this patient- and observer-blinded RCT was to determine whether the use of the minimally invasive, femur-first computer navigation method would lead to increased ROM, sufficient coverage and improved clinical outcome within the first year after THA compared with ‘conventional’ minimally invasive THA. The results of this trial indicate that the potential joint ROM, as determined by CT assessment without bony or prosthetic impingement, was higher in flexion/internal rotation at $90^\circ$ of hip flexion for patients who received a navigated femur-first THA and higher in external rotation at $0^\circ$ hip flexion in the conventional THA group. In this context, we observed that men had a higher likelihood of impingement than women. From the CT assessments we found a 19% increase in patients reaching all ideal hip joint ROM patterns, without potential component-to-component impingement, for ADL in the navigated ‘femur-first’ group. In the navigated group there was a statistically significant but clinically insignificant improvement in the HHS and also for ‘clinical’ ROM testing in flexion six weeks post-operatively. We were unable to identify any differences in the clinical outcomes between the two groups six months and/or one year after surgery.

Bony or prosthetic impingement has been identified as a significant factor in post-operative THA instability, accelerated polyethylene wear and component loosening. Prosthetic impingement, followed by levering out of the femoral head, is by far the most common mode of dislocation in THA.6,8,10,32

Two studies33,34 have reported that ‘femur-first/combined anteversion navigation’ provides accurate real-time determination of the acetabular component and femoral stem position during THA. A third study35 reported that this concept could not be achieved with navigation systems that solely provide the option of measuring the acetabular component position but not stem anteversion during surgery. However, the results of these studies are not comparable and, therefore, we believe that our randomised trial design makes a significant contribution to the understanding of this concept.

We developed new navigation software for the navigated ‘femur-first’ surgical technique that combines the concepts of combined anteversion, femoral tilt and acetabular component coverage with impingement-free ROM.15,36 To the best of our knowledge, this is the first study with a patient- and observer-blinded prospective randomised controlled design, investigating navigation in THA. We used computer navigation as an intra-operative aid for four reasons. First, various studies have shown that surgeons regularly fail to achieve the planned angular positions of the prosthetic femoral and acetabular components intra-operatively.37-39 Second, there is a linear correlation between combined anteversion of the acetabular and femoral components, and similarly between acetabular component abduction and the neck–shaft angle of straight, non-modular femoral components. In such a situation, neck–shaft angle and anteversion of the femoral component both determine how the acetabular component should be positioned.10 Third, the difficulty of obtaining and maintaining a stable pelvic position during THA, especially in the lateral decubitus position, has been reported by numerous authors.37,39 This may lead to errors in the estimation of pelvic orientation relative to mechanical guides and surgical instruments used in conventional THA surgery. Finally, the position of the acetabular component can alter during insertion of the final component into the pelvis, secondary to pelvic movement and the impaction of the acetabular component into the host bone. With the help of navigation, it is possible to control for all four aforementioned factors.

Our study has some limitations. First, our acetabular component optimisation algorithm predicts a scenario of patient-specific impingement-free ROM. More obese patients may not reach these boundaries owing to soft-tissue restrictions or impingement. Second, we did not include the influence of pelvic tilt in our acetabular component optimisation algorithm, as we believe that the issue of dynamic pelvic tilt is yet to be resolved.6,40,41 Theoretically, navigation offers the chance to measure the pelvic tilt on the operating table and to adjust the recommended position of the acetabular component with pelvic tilt nomograms.42 The use of navigation has four general limitations. First, especially in obese patients, pelvic landmarks can become obscured by overlying soft-tissue, which can make direct referencing for computer-assisted surgery difficult.14,43 Second, computers are susceptible to electronic failure, which happened once during our study. Therefore, surgeons using navigation always need to be aware of potential malfunctions in the system and should be able to continue operating without the assistance of a computer at any time. Third, navigation systems and their service are expensive. Last, both the registration and intra-operative measurement process of navigated THA significantly extend the operating time. In our study this was by approximately ten minutes per operation. A strength of the study is the fact that we used a single manufacturer’s THA design, with a single-head diameter across all patients, thereby minimising confounding factors. Any difference with regard to individual hip joint ROM outcome in our analysis is due purely to the operative technique, rather than the prosthetic design of the component. Additional features that are more specific to individual designs, such as the depth of the acetabular component (whether greater than or less than a hemisphere) and the cross-sectional geometry of the neck (trapezoidal vs circular), can also influence impingement-free...
ROM. Theoretically, femoral stems with a modular neck could allow control of femoral version and varus/valgus angulation of the neck. However, such modularity has been the source of serious concern due to the potential release of metal ions.

We experienced one post-operative dislocation in our navigated group, owing to impingement between an unusually prominent inferior iliac spine and the greater trochanter in 90° of flexion and 20° internal rotation, despite the acetabular component's position within Lewinnek's 'safe zone' and the acetabular and femoral component 'combined anteversion' (between 40° and 60° according to Jolles et al., between 25° to 50° according to Dorr et al.). This case illustrates that neither previously published 'safe zones' nor current navigation technology is able to prevent dislocation in all circumstances.

The observed statistically significant differences between the 'navigated' and the 'conventional' groups in the HHS and in clinical flexion ROM at six weeks post-operatively are clinically irrelevant. There were no measurable differences in clinical outcomes at six months and one year after THA. Patient satisfaction, the clinical outcomes and manual ROM testing one year after surgery showed no difference in either group. THA is a very successful surgical procedure. In this study, four highly experienced surgeons used the same tissue-sparing surgical approach in the setting of a high-volume centre for total joint arthroplasty. Future studies could use a multicentre approach with different levels of experience and different surgical approaches. This might better discriminate any influence on clinical outcome of computer-assisted navigation in THA.

In conclusion, the navigated 'femur-first' technique improves the theoretical or potential ROM before potential prosthetic impingement. However, acetabular component cover and early clinical outcomes at one-year follow-up show no difference between computer-navigated and 'conventional' minimally invasive THA.

Supplementary material

A table showing a comparison of the mean clinical results in the navigated femur-first and conventional total hip arthroplasty groups is available alongside the online version of this article at www.bjj.boneand-joint.org.uk

Author contributions:
T. Renkawitz: Performed surgeries, Acquisition of third-party funds, Data analysis, Writing the paper.
M. Weber: Data collection, Data analysis, Proofreading.
H.-R. Springorum: Data collection, Patient management.
E. Sendtner: Performed surgeries, Data collection.
M. Woerner: Performed surgeries, Data collection, Acquisition of third-party funds.
K. Ulm: Data management, Randomisation, Data analysis, Writing the paper.
T. Weber: Data management, Patient database, Data collection.
J. Griftka: Performed surgeries, Acquisition of third-party funds, Proofreading.

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