Mid-term results of cementless total hip replacement using a ceramic-on-ceramic bearing with and without computer navigation

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We have developed a CT-based navigation system using infrared light-emitting diode markers and an optical camera. We used this system to perform cementless total hip replacement using a ceramic-on-ceramic bearing couple in 53 patients (60 hips) between 1998 and 2001. We reviewed 52 patients (59 hips) at a mean of six years (5 to 8) post-operatively. The mid-term results of total hip replacement using navigation were compared with those of 91 patients (111 hips) who underwent this procedure using the same implants, during the same period, without navigation. There were no significant differences in age, gender, diagnosis, height, weight, body mass index, or pre-operative clinical score between the two groups. The operation time was significantly longer where navigation was used, but there was no significant difference in blood loss or navigation-related complications. With navigation, the acetabular components were placed within the safe zone defined by Lewinnek, while without, 31 of the 111 components were placed outside this zone. There was no significant difference in the Merle d’Aubigne and Postel hip score at the final follow-up. However, hips treated without navigation had a higher rate of dislocation. Revision was performed in two cases undertaken without navigation, one for aseptic acetabular loosening and one for fracture of a ceramic liner, both of which showed evidence of neck impingement on the liner. A further five cases undertaken without navigation showed erosion of the posterior aspect of the neck of the femoral component on the lateral radiographs. These seven impingement-related mechanical problems correlated with malorientation of the acetabular component. There were no such mechanical problems in the navigated group.

We conclude that CT-based navigation increased the precision of orientation of the acetabular component and control of limb length in total hip replacement, without navigation-related complications. It also reduced the rate of dislocation and mechanical problems related to impingement.

Improvements in the materials, design and instrumentation of total hip replacement (THR) have reduced the incidence of complications, but surgical skill remains a significant factor affecting the outcome. Computer navigation has been used to aid placement of the acetabular component, with improved positioning. More precise placement of the acetabular component should lead to a lower complication rate and fewer bearing-related problems due to impingement. However, there have been few reports of mid- to long-term clinical outcomes of THR with computer navigation.

We have developed a CT-based navigation system which can guide placement of the acetabular and femoral component and also measure the change in the length of the leg. We began using this system clinically in 1998 with a ceramic-on-ceramic bearing couple, the durability of which is thought to be more sensitive to impingement and vertical orientation of the acetabular component than that of polyethylene components, because of the specific risks of fracture at the margin of the liner and neck impingement. The purpose of this study was to assess the mid-term clinical efficacy of this navigation system.

Patients and Methods
Between April 1998 and April 2001, 180 consecutive uncemented THRs were performed in 143 patients (123 women, 153 hips; 20 men, 27 hips) using a ceramic-on-ceramic articulation (AnCA total hip system, Cremascoli, Milan, Italy) by three senior hip surgeons (NS, TN and one who is not an author) and three fellows (HM and two who are not authors).
under their supervision. The acetabular component was a hemispherical titanium shell coated with porous beads with an alumina ceramic liner which articulated with a 28 mm modular alumina ceramic femoral head (BioLox Forte, CeramTech, Flochigen, Germany) mounted on a 12/14 taper cone, resulting in a maximum range of available movement of 128°. The neck of the femoral component was also modular, allowing changes in the neck-shaft angle, anteversion and offset. All operations were performed via a posterolateral approach under general anaesthesia. The pre-operative diagnosis was osteoarthritis (OA) in 153 hips, osteonecrosis of the femoral head in 21, and rheumatoid arthritis (RA) in six. Osteoarthritis in 150 hips was secondary to dysplasia. The mean age at operation was 53 years (27 to 74). The mean height of the patients was 155 cm (140 to 178), their mean weight was 55 kg (35 to 90) and their mean body mass index (BMI) was 23 kg/m² (16 to 36).

The navigation system was used in 60 of the 180 hips. Permission for its clinical use had been obtained from the hospital’s ethics committee and informed consent was obtained from each patient. The remaining 120 hips underwent THR without the navigation system, and were used as the control group. Selection of the patients for navigation was not randomised.

The navigation system consisted of an optical 3D localiser (OPTOTRAK 3020, Northern Digital, Waterloo, Canada), a custom-made dynamic reference frame with active light-emitting diodes, custom-made surgical tools designed to work with the dynamic reference frame, an OPTOTRAK pen probe, and a UNIX-based Sun Ultra-SPARK workstation (Sun Microsystems, Santa Clara, California). The navigation software was developed in our Medical Image Analysis Division, using an open source software system (Visualisation Toolkit, Kitware, Clifton Park, New York).

Pre-operatively, transverse CT images from the level of the superior anterior iliac spine to the level of the ischium of the femoral canal were obtained using a helical CT scanner. The slice thickness was 3 mm, and the pitch was 3 mm, with the exception of a region between 2 cm below the lesser trochanter and the ischium of the femoral canal, where the slice pitch was 10 mm. Several reference images femoral condyles were also taken to measure anteversion, with a slice pitch of 3 mm. Image data were stored on an optical disc and then transferred to the workstation.

We reconstructed 3D surface models of the acetabular and femoral bone from the CT data. In order to measure the position and angle of the implants, the anterior pelvic plane, which defined the anterior superior iliac spine and the pubic tubercle, was identified. Next, the inter-teardrop line was used to define the horizontal axis. In order to match measurements of acetabular component orientation between the navigation and supine post-operative radiographs, the anteroposterior axis was tilted according to the tilt of anterior pelvic plane in the supine position on the CT table. We defined the ideal orientation of the acetabular component as 40° of inclination and 20° of anteversion, by considering the range of movement during various daily activities which could occur without impingement, and avoiding a high inclination angle to prevent the ceramic liner being fractured at its margin when the mean femoral anteversion was 30°. The angles of 40° of inclination (abduction) and 20° of anteversion equated to 13.2° of radiological anteversion, or 17.0° of operative anteversion, which was close to the centre of the safe zone described by Lewinnek et al. On the femoral side, a table top plane was determined by the posterior prominence of the greater trochanter and the posterior femoral condyles, and the proximal medullary axis was used for the longitudinal axis.

In the operating theatre, the OPTOTRAK sensor camera was positioned within 2.5 m of the operation site. In a lateral decubitus position, the dynamic reference frame for the pelvis was fixed to the iliac crest using two percutaneous apex pins and an extraskeletal fixation system (Hoffmann system, Stryker, Kalmazoo, Michigan). The dynamic reference frame for the femur was attached to the greater trochanter in the surgical wound using a plate. Surface registration of the patient’s anatomy to the previously constructed bone models of the pelvis and femur was performed in the operating theatre by touching 30 surface points of each bone with the pen probe after paired point matching using four pre-operatively determined landmarks. A root mean square analysis of registration of the points produced an error not exceeding 1 mm. The registration was verified by touching bony landmarks, including the sciatic notch, acetabular rim and fovea for the pelvis, and the femoral neck, greater trochanter and lesser trochanter for the femur. If the tip of the probe was within 1 mm of the landmarks, the registration was accepted for use in navigation. A reference point was then marked on the bone for later probing after measurements of the implant position and angle, to check for errors that might have arisen due to loosening of the dynamic reference frame. If an error was observed in locating the reference point the frame was resecured and registration repeated. The navigation system guided and recorded the level of the osteotomy of the femoral neck, the position of the centre of the acetabular component and its orientation, femoral anteversion and limb length discrepancy.

Clinical assessment was performed using the Merle d’Aubigne and Postel hip score, with a maximum score of six points for pain, range of movement and gait function, respectively. Thus, 18 points indicated full function. Each patient was assessed pre-operatively and at the last follow-up, by one of the senior authors, independent of the operating surgeon.

Radiological evaluation was performed immediately after surgery, at three and six months post-operatively, and then annually for a mean of six years (5 to 8), using standardised anteroposterior and lateral radiographs of the pelvis and femur. In order to measure the orientation of the acetabular component, an ellipse was fitted to its rim as projected on the early post-operative anteroposterior radio-
graphs which were obtained without obstructing the view by applying a lead shield. The measurements were made by a research assistant (WY) who was blinded to the surgical technique, using computer software (Computer Assisted Measurements of THA, JMM, Osaka, Japan). To reduce intra-observer variability, the measurements were repeated three times and the average value was used. The inter-observer variability was assessed in the first 20 hips with independent measurements by two of the authors (NS, HM). The mean inter-observer variation in abduction and anteversion of the acetabular component between the two observers was 3.0˚ and 1.2˚, respectively. In order to eliminate measurement error due to axial rotation of the pelvis on anteroposterior radiographs, measurements were only carried out on films where the pubic symphysis and the spinous processes of the sacrum produced a vertical line which was perpendicular to the teardrop line. The difference between anteversion and retroversion of the component was determined using the axial radiographs of the pelvis. In ten hips where the version was less than 10˚, post-operative CT images were taken to determine the direction of the version.

The vertical distance between the inter-teardrop line and the medial prominence of the lesser trochanter was measured on the post-operative anteroposterior radiographs. Leg-length discrepancy was evaluated by comparing these distances between the left and right sides, except for cases where the contralateral hip was abnormal due to subluxation. When the difference in lengths between the two sides exceeded 10 mm, the leg lengths were considered discrepant.

Radiologically, the mode of fixation of the femoral component at two years post-operatively was classified as bone-ingrowth fixation, stable fibrous fixation or unstable fixation, according to Engh’s criteria.15 Migration of the femoral components was assessed using the following measurements: the vertical distance from the shoulder of the stem to the medial prominence of the lesser trochanter, and the varus angle of the stem formed by the stem axis (defined as a line through the mediolateral midpoints of the stem at 1 cm below the lesser trochanter and at 1 cm above the stem tip) and the proximal femoral axis. Femoral subsidence exceeding 4 mm16 or a change in the varus angle exceeding 2˚ was considered to indicate stem migration and loosening. Loosening of the acetabular component was defined as migration (the vertical distance between the teardrop line and the medio-inferior edge of the component) in excess of 2 mm or a change in the abduction angle of more than 5˚.16 Osteolysis was also evaluated by comparing the latest follow-up radiographs and films obtained not more than three months post-operatively.

Statistical analysis of the outcome was performed using the non-parametric Mann-Whitney U-test, the chi-squared test, and Fisher’s exact probability test. Differences in variance between the groups were analysed using the F test.17 A p-value of < 0.05 was considered to indicate statistical significance.

Results
There were no significant differences between the two groups in respect of age, gender, diagnosis, height, weight or BMI (Table I).
In the navigated group one patient (one hip) died from gastric cancer two years post-operatively. In the non-navigated group two patients (two hips) were lost to follow-up at two years post-operatively. One patient (one hip) died from a subarachnoid haemorrhage four years post-operatively and a further five patients (six hips) in this group were lost to follow-up at five years post-operatively. These ten hips were excluded from the analysis. The mean period of follow-up of the remaining 59 hips in the navigated group and the 111 in the non-navigated group was 6.1 years (5 to 8) and 6 years (5 to 8), respectively.

None of the 143 patients used for analysis developed an infection or a pulmonary embolism. There were no intra-operative fractures. In the navigated group there were no complications arising at the pin sites. The mean operation time was 169 minutes (105 to 260) in the navigated group and 111 minutes (60 to 225) in the non-navigated group; the difference was statistically significant (Mann-Whitney U test, \( p < 0.0001 \)). There was no significant difference in mean blood loss of 827 ml (150 to 1800) in the navigated and 751 ml (80 to 1400) in the non-navigated group. During the follow-up period, no dislocation was seen in the navigated group but posterior dislocation occurred in seven hips in the non-navigated group, none of which required revision surgery. This was statistically significant (chi-squared test, \( p = 0.049 \)).

Measurements of orientation of the acetabular component are shown in Table II. There was no significant difference in the mean inclination, but the variance was significantly greater in the non-navigated group (F test, \( p < 0.0001 \)). The mean anteversion was significantly greater in the non-navigated group than in patients where navigation had been used (Mann-Whitney U test, \( p < 0.0005 \)). None of the cases in the navigated group was outside the safe zone defined by Lewinnek et al., \(^{11}\) whereas 31 were in the non-navigated group (Fig. 1). This difference was statistically significant (chi-squared test, \( p < 0.0001 \)). Two hips outside the safe zone dislocated, and as did five inside the zone. There was no statistical difference (chi-squared test, \( p = 0.47 \)) in the incidence of posterior dislocation between the acetabular components inside the safe zone and those outside.

The mean Merle d’Aubigne hip score before surgery was 9.5 (5 to 13) in the navigated group (pain, 2.1; mobility, 4.2; function, 3.2) and 9.5 (5 to 14) in the non-navigated
group (pain, 2.2; mobility, 4.1; function, 3.2). At the final examination, the mean hip score improved to 17.5 (15 to 18) in the navigated group (pain, 5.9; mobility, 5.9; function, 5.7) and 17.5 (13 to 18) in the non-navigated group (pain, 5.9; mobility, 5.9; function, 5.7). There was no significant difference in the mean hip scores between the two groups pre-operatively or at the final follow-up (Mann-Whitney U test, p = 0.94 and p = 0.74, respectively).

Leg-length discrepancy was evaluated using 44 hips in the navigated group and 83 in the non-navigated group. No leg-length discrepancy occurred in the navigated patients but was present in 11 hips in the non-navigated group. This difference was statistically significant (chi-squared test, p = 0.01).

No patient who underwent THR with navigational assistance required revision during the period of follow-up. Radiologically, all 59 hips used for analysis were classified as having stable bone ingrowth in the absence of osteolysis or expanding radiolucent lines at the bone-implant interface. In the non-navigated group one acetabular revision was performed for aseptic loosening three years after the primary THR. The retrieved specimen showed a black stain at the rim of the liner and a corresponding mark on the neck of the femoral component (Fig. 2). Another patient in this group, who was graded as having stable bone ingrowth two years post-operatively, developed a fracture of the liner and recurrent dislocation four years post-operatively. At revision after five years the acetabular component was well fixed and had to be released from the bone with osteotomes. The ceramic liner had multiple chips at the rim with a black-stained area (Fig. 3). The modular neck showed a V-shaped scar at the site of its impingement (Fig. 4). The remaining 109 hips were graded as having stable bone ingrowth and no osteolysis. These patients reported that they sometimes heard a click from their hip, without any pain.

The impingement-related problems comprised one acetabular component loosening, one liner fracture, and five femoral components with erosion at the neck, all in the non-navigated group. The incidence of impingement-related problems was significantly higher in the non-navigated patients than in the navigated group (chi-squared test, p < 0.05).

**Discussion**

The first surgical computer navigation systems used for guidance in THR were CT based. They provide greater accuracy and reproducibility than conventional instruments when they are used correctly. Prolonged operation time was a concern that affected the decision as to whether or not to use navigation systems. In this study, the mean operation time was 58 minutes longer with navigation than without it. The computer navigation in this study was developed in the 1990s with a Unix-based machine which was not as fast as the computers that are available nowadays. The relatively slow computation time and the learning curve of our navigation system appear to have increased the operating time. However, it is anticipated that this will be reduced by the subsequent developments in this technology.

In the present study, all cases treated with navigation achieved acetabular orientation within the safe zone with reduced variance, which is consistent with previous studies. Conventional freehand surgery produced a much larger scatter in positioning.

The clinical benefit of precise placement of the acetabular component using navigation remains unclear. We found no differences in the Merle d'Aubigne hip score between the groups at between five and eight years after surgery. However, we did not use a quality of life score, which is supposed to be a more sensitive tool than the Merle d'Aubigne score to identify differences between the two groups.
rate of dislocation was higher for hips without navigation, although placement of the acetabular component outside the safe zone of Lewinnek et al. did not correlate with dislocation. The cause of dislocation is multifactorial. Dislocation is related not only to the orientation of the acetabular component but also to the design of the rim, the diameter of the head of the femoral component, the angle of the femoral neck and its width, soft-tissue tension and the surgical approach. However, identical components were used in both groups in our study.

Further analysis of the remaining parameters, including the femoral neck angle and soft-tissue tension due to leg-length equalisation, may clarify the effect of navigation on the rate of dislocation in addition to the effect of the precision of orientation of the acetabular component. Nevertheless, the latter correlated with impingement-related problems found only in non-navigated patients.

Navigation on the femoral side was advantageous in determining the level of the osteotomy of the femoral neck to restore leg length, aligning the stem with the medullary axis and modifying anteversion of the femoral component, particularly in cases of dysplasia where femoral anteversion is known to be highly variable. However, we did not evaluate femoral anteversion after operation since CT assessment was not performed after surgery in all cases.

The lack of randomisation of the patients limits the usefulness of our results but there were no significant differences between the groups in respect to age, gender, diagnosis, height, weight, BMI, or pre-operative clinical score. Accordingly, we believe this study does offer valuable information about the effect of navigation on the mid- to long-term result of THR.

In conclusion, the CT-based navigation system increased the precision of orientation of the acetabular component and control of leg-length in THR, without complications. It also reduced the rate of dislocation and mechanical problems related to impingement in cementless THR using a ceramic-on-ceramic bearing during a minimum five-year follow-up period.

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References