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Greater accuracy in positioning of the acetabular cup by using an image-free navigation system

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Abstract In a prospective and randomised clinical study, acetabular cups were implanted free-hand (control group n=22) or with computer assistance using an image-free navigation system (study group n=23). The cup position was determined postoperatively on pelvic CT. An average inclination of 42.3° (range: 30°–53°; SD±7.0°) and an average anteversion of 24.0° (range: −3° to 51°; SD±15.0°) were found in the control group, and an average inclination of 45.0° (ranage: 40°–50°; SD±2.8°) and an average anteversion of 14.4° (range: 5°–25°; SS±5.0°) in the computer-assisted study group. The deviations from the desired cup position (45° inclination, 15° anteversion) were significantly lower in the computer-assisted study group (p<0.001 each). While only 11/22 of the cups in the control group were within the Lewinnek safe zone, 21/23 of the cups in the study group were placed in this target region (p=0.003).

Résumé Dans un étude clinique prospective et randomisé, les cupules acétabulaires ont été implantées de façon habituelle (n=22; groupe témoin) ou avec assistance d'un ordinateur qui utilise un système de navigation image—libre (n=23; groupe d'étude). La place de la cupule a été déterminée après l'opération sur un scanner pelvien. Une inclinaison moyenne de 42,3° (30° à 53°; ±7.0°) et une antéversion moyenne de 24,0° (−3° à 51°; ±15.0°) ont été trouvées dans le groupe témoin et une inclinaison moyenne de 45,0° (40° à 50°; ±2.8°) et une antéversion moyenne de 14,4° (5° à 25°; ±5.0°) dans le groupe de l'étude assistée par ordinateur. Les déviations par rapport à la position désirée de la cupule (45° d'inclinaison, 15° d'antéversion) étaient notablement inférieures dans le groupe de l'étude assistée par ordinateur (p<0.001 chacun). Alors que seulement 11 des 22 cupules du groupe témoin étaient dans la zone sûre de Lewinnek, 21 des 23 cupules du groupe d'étude ont été placées dans cette région cible (p=0.003).

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Introduction

Dislocation of a total hip replacement joint is most often caused by incorrect position of the acetabular cup. This may limit the range of movement and may lead to increased wear and even aseptic loosening of the prosthesis [1–3, 8, 10, 11, 17]. Lewinnek et al. [13] correlated the complication rates of total hip arthroplasty (THA) with cup alignment and defined a "safe" zone with an inclination of 40°±10° and an anteversion of 15°±10° of the acetabular cup. Numerous studies have, however, shown that alignment of the acetabular cup within this "safe" zone is not reached by the conventional surgical technique—not even for experienced surgeons [5, 18]. It is believed that the surgeon's lack of information on the actual and variable position of the patient's pelvis during surgery may be the cause. Intra-operative orientation is difficult, and the actual pelvic inclination is generally not taken into account during surgery [6, 14].

Computer-assisted navigation reduces intra-operative inaccuracy, and significant benefits have already been shown in several studies [4, 12]. CT-based navigation systems require a pre-operative CT scan of the pelvis, however, to allow for operative planning and are considered time consuming and more costly. They have, therefore, gained only limited popularity.

Image-free navigation systems do not require additional pre-operative imaging, and only a few additional intra-operative working steps are necessary, so their use in routine clinical work appears feasible.

Materials and methods

Patients

Fifty patients scheduled for THA were enrolled prospectively in this single-centre study between August and December 2004. All patients had primary osteoarthritis of the hip. The study was approved by the local ethics committee and the Federal Radiological Protection Authority (Z5-22462/2-2003-027), and patients gave written consent. The patients were randomised by lot to a control group with conventional total hip replacement or to a study group where the total hip replacement was performed using an image-free navigation system. Five patients were excluded from the study. In three patients the primary stability of the trial cup was considered inadequate, in one patient the pelvic reference base of the navigation system became loose and in one patient the navigation system gave an error message. Thus, 22 patients remained in the control group and 23 patients in the study group (Table 1).

Table 1 Age, gender and body-mass-index (BMI) of the patients in the control and study groups, peri-operative drop in haemoglobin (Hb) within the first 24 h and volume of shed blood within the first 48 h [mean values, ranges and standard deviations (SD)]

	Control group (free-hand) n=22	Study group (computer-assisted) n=23	p value
Age	62.4 years	63.5 years	p=0.964
Range	50–77	50–79	
SD	±8.6	±7.5	
Gender			
Male:female	9:13	8:15	p=0.763
Mean body mass index	28.7 kg/m^2	28.0 kg/m^2	p=0.528
Range	20–36	21–34	
SD	±4.4	±3.7	
Mean op. time (skin–skin)	77.0 min	85.3 min	p=0.137
Range	40–120	62–102	
SD	±21.8	±13.9	
Mean decrease in Hb/24 h	3.3 mg/dl	3.1 mg/dl	p=0.583
Range	1.5–5.7	0.4–5.5	
SD	±0.8	±1.3	
Mean wound secretion/48 h	409 ml	358 ml	p=0.677
Range	50–1090	100–730	
SD	±250	±176	

Surgical procedure

The operations were performed by two senior consultants through an antero-lateral approach with the patient supine, implanting press-fit cups (Duraloc, DePuy, Warsaw, IN, USA) and cement-free hydroxyapatite-coated stems (Corail, DePuy). The surgeons had experience in using the navigation system and brought the same proportion of patients to the two groups. The surgeons were asked to strive for an inclination of 45° and an anteversion of 15° of the acetabular cup. In the control group the acetabular cup was positioned without mechanical aids for alignment. In the study group the image-free navigation system VectorVision ct-free hip 3.1 (BrainLAB AG, Heimstetten, Germany) was used. The reference bases were fixed by means of two 3.5-mm wires to the ipsilateral iliac crest and ipsilateral distal femur. The centre of rotation of the hip was determined kinematically, and the anterior superior iliac spine and pubic tubercle were used to determine the reference plane corresponding to the “anterior pelvic plane concept” of Jaramaz et al. [6]. The duration of the surgical procedure was recorded, and the decrease in haemoglobin within the first 24 h and the volume of shed blood measured within the first 48 h were documented and compared.

CT-based determination of acetabular cup position

Post-operatively, all patients had a pelvic CT scan. The position of the acetabular cups was determined using the planning software VectorVision hip 3.1 (BrainLAB) as previously described [18]. The inclination and anteversion of the implanted acetabular cups were documented according to the definition of Murray [15]. In the study group the intra-operative recorded inclination and anteversion were also documented to evaluate the accuracy of the navigation method. We used the algorithm described by Murray to convert the operative value [15] in order to represent the cup positions graphically with reference to Lewinnek’s safe zone [13].

Statistical analysis

Statistical analysis was performed by using Student’s t test, Mann–Whitney rank sum test, Fisher exact test and the Pearson product moment correlation (SPSS 11.5, LEAD Technologies Inc, Haddonfield, NJ, USA). A p value of <0.05 was considered statistically significant.

Results

The average increase in the duration of the surgical procedure in the study group was 8 min (Table 1). There were no significant differences between the control and study groups with regard to age, gender, BMI distribution and peri-operative blood loss. There were no complications. In the study group the average inclination of the acetabular cup was 45.0° (range: 40°–50°, SD±2.8°), and the average anteversion 14.4° (range: 5°–25°, SD±5.0°). In the control group the average inclination was 42.3° (range: 30°–53°, SD±7.0°), and the average anteversion 24.0° (range: −3° to 51°, SD±15.0°). The lower variability in cup position when the image-free navigation system was used is expressed mainly by the lower scatter and the lower standard deviations (Fig. 1a,b).

The average deviation from the aimed inclination of 45° was 5.6° (range: 0°–15°, SD±3.9°) in the control group, and the average deviation from the aimed anteversion of 15° was 13.7° (range: 1°–37°, SD±10.4°). In the study group the average deviation from the aimed inclination was 2.3° (range: 0°–5°, SD±1.6°), and the average deviation from the aimed anteversion was 4.0° (range: 0°–10°, SD±2.9°). The deviations were significantly lower in the study group than in the control group (p<0,001 each) (Table 2).

When the intra-operative recorded values for inclination and anteversion in the study group were compared with the corresponding values of the postoperative CT-based evaluation, there was an average deviation of 2.4° (range: 0°–5°, SD±1.7°) for inclination and an average deviation of 4.6° (range: 1°–11°, SD±3.6°) for anteversion. There was no correlation between BMI and the degree of these deviations. If the Lewinnek safe zone is taken as standard, 11 of 22 of the acetabular cups in the control group were outside this target. In the study group, two cups showed slightly too great a radiological inclination, and one cup had a borderline low anteversion (p=0.003) (Fig. 2).

Table 2 Operative cup inclination (Incl) and operative anteversion (AV) in the control and study groups, and deviations from the desired cup position of 45° inclination and 15° anteversion [mean values, ranges and standard deviations (SD)]

	Control group (free-hand) n=22	Study group (computer-assisted) n=23	p value
Mean Incl	42.3°	45.0°	p=0.204
Range	30–53°	40–50°	
SD	7.0°	2.8°	
Mean deviation from 45° Incl	6.2°	2.3°	p<0.001
Range	0°–15°	0°–5°	
SD	±4.06°	±1.60°	
Mean AV	24.0°	14.4°	p=0.008
Range	−3–51°	5–25°	
SD	15.0°	5.0°	
Mean deviation from 15° AV	14.2°	4.0°	p<0.001
Range	1–36°	0–10°	
SD	10.0°	2.9°	

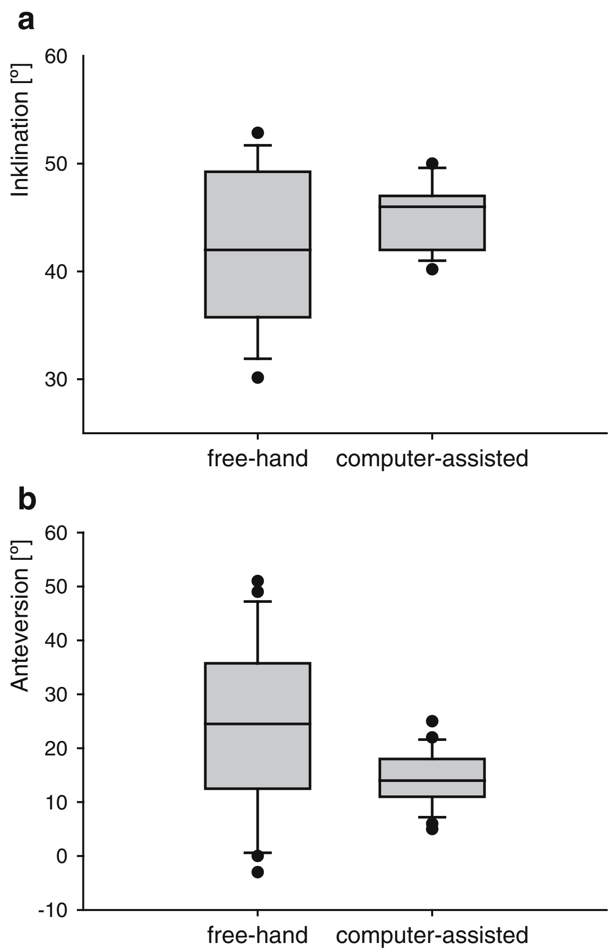

Fig. 1 Results for operative inclination (**a**) and operative anteversion (**b**) after free-hand (control group) and computer-assisted (study group) cup placement. The *boundaries* of the boxes indicate the 25th and the 75th percentiles, the *lines* within the boxes mark the mean values. *Whiskers* above and below the box indicate the 90th and the 10th percentiles.

Discussion

The high proportion of acetabular cups placed outside the safe zone after free-hand cup placement accords with other

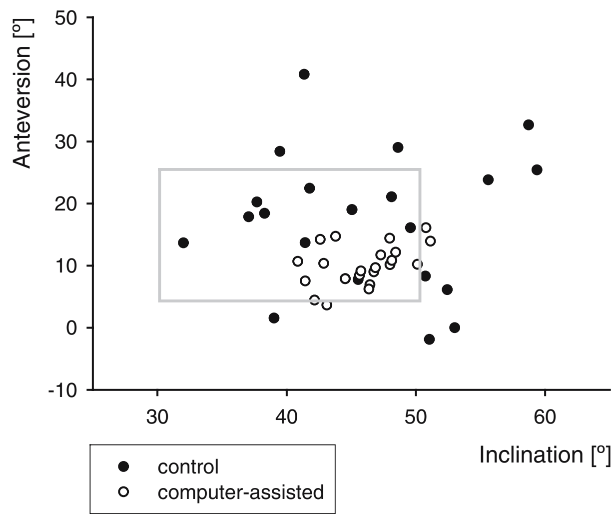

Fig. 2 Cup positions (radiological inclination and radiological anteversion) relative to Lewinnek safe zone (*grey frame*).

studies. In a multi-center investigation, Saxler et al. [18] showed that high variability and considerable imprecision of the cup position can be expected using free-hand cup placement even when performed by experienced surgeons. In the study only 27/105 of cups placed free-hand were inside the safe zone, and the inclination and anteversion of the cup positions measured by computed tomography showed great variability and considerable deviation from the desired cup position at 45.8°±10.1° (range: 23.0°–71.5°) and 27.3°±15.0° (range: −23.5° to 59.0°), respectively.

Mechanical alignment aids have not significantly reduced these inaccuracies either in vitro investigations or in clinical use [7]. In a study by Hassan et al., 42% of cups placed with the aid of mechanical alignment were outside the desired target [5]. In the present study, the accuracy of cup placement was significantly improved by using the image-free navigation system in patients with primary osteoarthritis of the hip, and angulations outside the safe zone were largely avoided. The clinical results of image-free navigation for cup inclination and anteversion ranges and standard deviations were comparable to anatomical studies of image-free navigation and also with clinical studies of CT-based and fluoroscopy-assisted navigation methods [9, 12, 16, 19, 20]. In contrast to the image-assisted CT-based or fluoroscopy-based navigation methods, however, image-free navigation requires neither pre- operative nor intra-operative imaging. The image-free navigation method thus does not cause any additional radiation burden for the patient or the operation team, and the additional time is acceptably low.

Furthermore, with a computer-assisted operation, it is not always possible maintain the exact angle of the desired inclination and anteversion. Deviations of cup position arise during impaction of press-fit cups depending on the strength of the bony acetabulum, the extent of under-reaming or over-sizing and the changing position of the pelvis during cup placement [4]. However, while the deviations and position changes are usually not perceived or their extent is inadequately estimated with the conventional operation technique, navigation support enables constant monitoring of the current cup position in relation to the pelvis and the surgeon can assess intra-operatively whether the deviation from the desired inclination and anteversion targets is acceptable or whether the cup position will have to be corrected.

The deviations listed in the present study between the intra-operative angles given by the image-free navigation system and the post-operative CT-based controls can be explained primarily by inaccuracies when referring to the bony landmarks to determine the virtual co-ordinate system. Although no correlation was shown between the extent of the deviations and BMI in this study, it becomes apparent, with the clinical use of the navigation system, that correct location of the anterior superior iliac spines and the pubic tubercles can be more difficult in obese patients. A blunt reference pointer was used for the navigation method in this study, and the bony landmarks for determining the anterior pelvic plane were measured without perforation of the covering soft tissue. Supplementary studies will investigate whether using a reference pointer with perforation directly onto the bony landmarks can diminish these inaccuracies.

In this study, the accuracy of cup placement was significantly improved by the use of image-free navigation in patients with primary osteoarthritis of the hip compared to the conventional operation technique. Image-free navigation requires only a few additional surgical steps and needs no pre-operative or intra-operative imaging. Its acceptance for clinical use is therefore likely to be much higher than the more complex CT-based or fluoroscopy-assisted navigation methods especially as it is compatible with minimally invasive hip arthroplasty. Image-free navigation is a promising and easy-to-use technical aid that can help reduce mechanical complications due to incorrect cup placement.

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