Accuracy of acetabular cup placement in computer-assisted, minimally-invasive THR in a lateral decubitus position

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Abstract In a prospective and randomised clinical study, we implanted acetabular cups either by means of an image-free computer-navigation system (navigated group, $n=32$) or by free-hand technique (freehand group $n=32$, two drop-outs). Total hip replacement was conducted in the lateral position and through a minimally invasive anterior approach (MicroHip). The position of the component was determined postoperatively on CT scans of the pelvis using CT-planning software. We found an average inclination of 42.3° (range $32.7\text{--}50.6^\circ$; $SD\pm 3.8^\circ$) and an average anteversion of 24.5° (range $12.0\text{--}33.3^\circ$; $SD\pm 6.0^\circ$) in the computer-assisted study group and an average inclination of 37.9° (range $25.6\text{--}50.2^\circ$; $SD\pm 6.3^\circ$) and an average anteversion of 23.8° (range $5.6\text{--}46.9^\circ$; $SD\pm 10.1^\circ$) in the freehand group. The higher precision of computer navigation was indicated by the lower standard deviations. For both measurements we found a significant heterogeneity of variances ($p<0.05$, Levene's test). The mean difference between the cup inclination/anteversion values displayed by computer navigation and the true cup position (CT control) was 0.37° ($SD\ 3.26$) and -5.61° ($SD\ 6.48$), respectively. We found a bias (underestimation) with regard to anteversion determined by the imageless computer navigation system. A bias for inclination was not found. Registration of the landmarks of the anterior pelvic plane in lateral

position with undraped percutaneous methods leads to an error in cup anteversion, but not to an error in cup inclination. The bias we found is consistent with a correct registration of the anterosuperior iliac spine (ASIS) and with a registration of the symphysis 1 cm above the bone, corresponding to the less compressible overlying soft tissue in this region. There was no significant correlation between the bias and the thickness of soft tissue above the pubic tubercles. We suggest use of a percutaneous registration of ASIS and an invasive registration above the pubic tubercles when computer-assisted navigation is performed in minimally invasive THR in a lateral position.

Introduction

Nowadays, total hip replacement (THR) is increasingly performed on active patients using less invasive, tissue-preserving techniques. Accordingly, the use of computer navigation in total joint arthroplasty has become more prevalent and the method has proved to be reliable for acetabular component positioning. Studies showed higher accuracy in plastic pelvis models [1], in human cadaver models [2] and in clinical use [3]. While there are some randomised controlled trials comparing the use of computer navigation with freehand component placement in a supine position [4], there is, so far, only one randomised study referring cup position to postop 3D computed tomography (CT) measurements in a lateral decubitus position using imageless navigation and a minimally-invasive approach [5]. Accuracy of acetabular cup placement in THR may be different when using a minimally-invasive approach and with the patient in a lateral decubitus position. A higher incidence of dislocations has been reported with the lateral decubitus position [6] and minimally invasive total hip

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replacement is accompanied by concerns about the loss of direct visualisation of the bony landmarks, which may result in a higher percentage of malpositions of acetabular components [7].

We conducted this prospective randomised trial to find out whether the accuracy of acetabular component placement using computer-assisted imageless navigation is significantly better than that obtained by the freehand technique in minimally invasive total hip replacement with the patient in lateral decubitus position. Second, we researched the accuracy of imageless navigation measurements by comparing the intraoperative values for cup inclination and anteversion to postoperative CT reconstructions.

Materials and methods

This study was conducted after authorisation by the Institutional Ethical Board (No. 06/100) and the Federal Office for Radiation Protection (Z5-22462/2-2007-008). Between September 2007 and October 2008, patients requiring total hip arthroplasty for primary osteoarthritis were prospectively enrolled in this single-centre study. Exclusion criteria were arthritis secondary to hip dysplasia, post-traumatic deformities of the pelvis, and—because a postoperative pelvic CT scan was required—age below 50 years at the time of surgery. After giving written consent to participate in the clinical and radiological studies, patients were randomly allocated into one of two groups: (1) minimally invasive, navigated THR or (2) minimally invasive THR.

Surgical procedure

Surgery was performed by two senior consultants (ES, TK), who operated on the same number of patients in each of the two groups. Both had familiarised themselves with

minimally-invasive computer-assisted surgery by means of more than 50 navigated total hip arthroplasties. All operations were done with the patient in the lateral position through a minimally invasive, modified Smith-Petersen approach (MicroHip®) [8]. The anterior pelvic plane was registered in lateral decubitus position without surgical draping. For the registration process of the anterior pelvic plane within the minimally invasive navigated THR group, the dorsal support is slightly released so that the patient is tilted backwards a little which makes the contralateral anterior superior iliac spine (ASIS) accessible. The surgeon then registers both ASIS points and pubic tubercle points with a sterile pointer which is set aside afterwards. The patient is stabilised and re-positioned in a straight lateral position. The rest of the leg is cleaned with a disinfectant and the operation field is covered with sterile drapes in a usual manner. A second sterile pointer is needed for the registration of bony landmarks during the further navigation process. We used press-fit components (Pinnacle, DePuy, Warsaw, Indiana) and cement-free hydroxyapatite-coated stems (Corail; DePuy). For the minimally invasive, navigated THR group, an imageless navigation system was used (Hip unlimited 5.0; BrainLAB AG, Feldkirchen, Germany). In the freehand group, acetabular components were placed free-hand without the aid of mechanical or computerised alignment guides. Our target acetabular component position for all patients was 40–45° inclination and 15–20° anteversion according to Lewinnek et al. [9]. No patient showed any unsatisfactory fixation of the acetabular component, thus no cemented polyethylene acetabular components were used. Each patient underwent a postoperative CT examination.

Outcome measurement

The duration of each operation was recorded. To provide an indication of the level of perioperative blood loss, we

Table 1 Baseline characteristics, duration of THR and decrease in Hb/24 h by group

Characteristic	Navigation	Freehand	Total
No. of patients, <i>n</i> (%)	32 (51.6)	30 (48.4)	62 (100.0)
Gender, <i>n</i> (%)			
Male	13 (40.6)	11 (36.7)	24 (38.7)
Female	19 (59.4)	19 (63.3)	38 (61.3)
Age (years)			
Median (IQR)	68 (60–72)	70 (66–75)	69 (65–73)
BMI (kg/m ²)			
Median (IQR)	28 (25–30)	26 (24–29)	27 (25–30)
Duration of THR (min)			
Median (IQR)	85 (76–96)	62 (57–75)	75 (61–86)
Decrease in Hb/24 h (xx)			
Median (IQR)	2.30 (1.10–3.00)	2.17 (1.43–2.68)	2.10 (1.25–2.90)

THR total hip replacement, IQR interquartile range, BMI body mass index

Table 2 Inclination and anteversion values

Parameter measured		Navigation (<i>n</i> =32)	Freehand (<i>n</i> =30)	<i>p</i> -value
Inclination	Mean	42.3°	37.9°	0.002
	Range	32.7–50.6°	25.6–50.2°	
	SD	3.8°	6.3°	
Anteversion	Mean	24.5°	23.8°	0.739
	Range	12.0–33.3°	5.6°–46.9°	
	SD	6.0°	10.1°	

Target acetabular component position for all patients was 40–45° inclination and 15–20° anteversion (operative definition)

assessed the reduction in the haemoglobin level during the first 24 hours. All patients included in the study had a pelvic CT scan three to five weeks after surgery. The position of the acetabular component was evaluated by an independent external institute (MeVisLab, MeVis, Bremen, Germany) blinded to the allocations. The position of the acetabular component was measured twice by two independent examiners on a 3D reconstruction of the pelvis with image-processing software (based on MeVisLab, MeVis, Bremen, Germany).

Operative inclination and anteversion as defined by Murray [10] were determined. Intraoperative inclination and anteversion was documented by screenshot software for the navigation system.

Differences between the cup positions desired and the cup positions achieved were analysed for both groups. Accuracy of the image-free navigation values were determined by comparing the intraoperative values for cup inclination and anteversion with the postoperative computed tomography reconstructions.

Statistical analysis

Since both bias and precision of navigation methods are important criteria for the evaluation of overall performance, assessment of competitive procedures has to consider both

bias and variability simultaneously. Whereas any evident bias may be repaired by application of a suitable correction formula, a method's precision can not. For this reason and due to an expected negligible systematical deviation between the methods to be compared, sample size rationale was based on comparison of variability.

According to the results of previously published data [3], standard deviation of inclination and anteversion measurements are expected to be about 4° and 6° for navigation and about 7° and 14° for non-navigated methods, respectively. This translates to a least expected ratio of variances of $7^2/4^2=3$. Power calculations revealed that a group sample size of about 30 patients would be sufficient to detect such a clinically relevant difference in variability with 80% power using Levene's test for equality of variances at a two-sided 0.05 level of significance.

All analyses were performed on the intention-to-treat population. For continuous data, values were presented as *N*, mean, standard deviation (SD), median, interquartile range (IQR, i.e. 1st quartile–3rd quartile), minimum, and maximum. Categorical data were expressed as frequency counts and percentages. For continuous variables, unpaired *t*-test was used for comparisons between the two groups. Homogeneity of variances was assessed by means of the

Fig. 1 Inclination of the acetabular component following freehand and navigation. Levene's test for homogeneity of variances, $p=0.007$

Fig. 2 Anteversion of the acetabular component following freehand and navigation. Levene's test for homogeneity of variances, $p=0.024$

Fig. 3 Inclination: deviation of the navigation values to CT values compared to their mean. Dotted lines represent the 95% limits of agreement (Bland-Altman graph)

Levene test. The significance level was set to 0.05 (two-sided). No adjustment for multiple testing was performed. The 95% limits of agreement method was used to assess the agreement between navigation and CT [11]. First, the mean and SD of the differences between the two methods were calculated. Second, the 95% limits of agreement were calculated as mean difference ± 1.96 SD. Plots of differences against means were used to examine the assumptions of the limits of agreement. Statistical analyses were carried out with SPSS version 15.0 (SPSS Sciences, Chicago, IL).

Results

Sixty-four patients were randomised into two groups; two patients from the freehand group (32) were lost to follow-up since they withdrew consent to participate in the postoperative computer tomography examination. In total, 32 patients were assigned to the navigation group and 30 to the freehand group. Demographic and perioperative data are presented in Table 1. Operation time was increased by 23 minutes by the use of the imageless navigation system.

Fig. 4 Anteversion: deviation of the navigation values to CT values compared to their mean. Dotted lines represent the 95% limits of agreement (Bland-Altman graph)

Fig. 5 Soft tissue thickness overlying **a** the pubic tubercles (PT) and **b** the anterior superior iliac spine (ASIS) measured in axial CT images. Soft tissue overlying ASIS potentially contains abdominal wall and bowel structures

This included the two-stage fixation of the reference arrays, registration of anterior pelvic plane, skin disinfection and draping. No neurovascular complications, infections or dislocation in the first six weeks after surgery were observed within the groups.

Mean acetabular inclination and anteversion values within the two groups are summarised in Table 2. We found a clinically relevant difference in variability using Levene's test for equality of variances at a two-sided 0.05 level of significance for inclination and anteversion with significant higher variation of measurements in the free-hand group ($p=0.007$ and $p=0.024$, Levene's test).

The smaller variability when using the navigation technique is illustrated by box plot diagrams for inclination and anteversion (Figs. 1 and 2). The boxes indicate the 25th and 75th percentiles.

Accuracy of navigation measurements: The Bland-Altman approach

For evaluating the precision and bias of the navigation system, the differences in the intraoperative values (navigation tool) and postoperative values (CT measurement) were calculated. Regarding inclination, the differences between navigation and CT had mean 0.4° (SD 3.3). Hence, we can say that for 95% of patients in the navigation group, a measurement by navigation would be between 6° less and 7° greater than measurement by CT (Fig. 3).

Regarding anteversion the differences between navigation and CT measurement had mean -5.6° (SD 6.5). Hence, we can say that for 95% of patients, a measurement by navigation would be between 18° less and 7° greater than measurement by CT (Fig. 4).

We evaluated the effect of soft tissue thickness on the discrepancy of intra- and postoperative measurements. Soft tissue thickness overlying the pubic tubercles (PT) and the anterior superior iliac spine (ASIS) was measured in axial CT images (Fig. 5a, b) and averaged 48 mm (SD 14 mm, range 20–96 mm) and 21 mm (SD 17 mm, range 2–75 mm), respectively. We found no significant correlation (Spearman-Rho) between the bias and the thickness of soft tissue above the ASIS ($r=0.126$) nor above PT ($r=0.209$). While the soft tissue overlying ASIS can be shifted away, the soft tissue above pubic tubercles is less deformable. While measuring soft tissue thickness overlying the ASIS in axial CT images we noticed that soft tissue overlying ASIS potentially contains abdominal wall and bowel structures (Fig. 5b).

Discussion

In this study we investigated the variability and reliability of computer-assisted, minimally-invasive cup placement during THR in a lateral decubitus position, compared to minimally-invasive cup placement using the freehand technique. With the patient in the lateral decubitus position, it is difficult to be sure about the precise orientation of the pelvis [12], and this may compromise the registration of the contralateral anterior superior iliac spine for referencing the anterior pelvic plane. Our data confirms that a significantly lower variability for the minimally invasive acetabular cup position can be obtained by using navigation [3, 13, 14], even when using a minimally invasive technique [5, 15, 16]. Our data confirms that cup anteversion is generally less accurate than cup inclination with the imageless navigation technology [17].

The differences between navigation and CT values (intra- and postoperative measurements) shown in this study correspond with previously published comparisons between computer navigation values and computed tomography values for cup inclination and anteversion. Ybinger et al. [14] found that cup inclination and anteversion, as recorded by the navigation system intraoperatively and measured on postoperative CT scans, differed by a mean of 3.5° (SD 4.4°) and 6.5° (SD 7.3°), respectively. Compared to these results, we found less bias with respect to inclination in our study. Dorr et al. [5] reported higher precision and less bias especially for anteversion. Using a posterior hip approach the precision (95% limit on the difference between the two test results) for inclination was 4.4° with a bias of 0.03° and 4.1° with a bias of 0.73° for anteversion. This may be explained by a different method of registering the anterior pelvic plane. The authors “flipped” the patient to the lateral position after registration of the anterior pelvic plane with the patient in a supine position. Moreover, the anterior pelvic plane registration was performed by puncturing the skin to obtain bony contact to both the anterior superior iliac spine and the pubic bone near the pubic tubercles.

Intraoperative palpation of defined bony landmarks by the surgeon using a referenced pointer is a decisive step during the computer navigation data entry process. This procedure remains an important source of inaccuracy in imageless navigation systems. In a previous cadaver study different conditions of landmark acquisition were investigated [18]. Percutaneous registration methods with and without draping showed a significant error in cup anteversion but not in inclination. This error, caused by overlying soft tissue above the anterior pelvic plane, was quantified in a sawbone model by Lee et al. [19]. When palpating 10 mm above the pubic tubercles and 0 mm above the anterior superior iliac spine, an underestimation of anteversion of approximately 7° was found in this study. This scenario is very close to our data and translates to the clinical experience that soft tissue overlying ASIS (mean thickness 21 mm) can almost entirely be shifted away. Soft tissue above the pubic tubercles (mean thickness 48 mm) obviously is compressible to a mean thickness of 10 mm. In the situation shown in Fig. 5b, we presume, that invasive registration of ASIS might be dangerous and, as opposed to the pubic tubercles, not necessary. The results in this study suggest that the bias regarding anteversion could be avoided by applying a semi-invasive registration technique by puncturing the skin to obtain bony contact to the pubic bone near the pubic tubercles. Alternatively, ultrasound acquisition of the ASIS might be helpful [18].

There are several limitations to this study. First, three different definitions are used to determine cup orientation: the anatomical, radiographic and the operative definitions [10]. The data in this study are expressed by the operative

definition according to Murray. At present, there is no common measurement technique, so the results of different studies may not be comparable. Second, pelvic tilt was not taken into account [20]. Cup orientation values refer to the anterior pelvic plane, not to the frontal plane, where the difference is the pelvic tilt. Some authors therefore use tilt adjusted values, which may not be comparable. Critics of computer-assisted surgery in THR have legitimately always pointed out that the pelvis and the pelvic orientation is not a static unit. The pelvic tilt may change both after THR and during functional activities, which could lead to malpositioning of the acetabular component when solely trying to hit a fixed target. Third, we used an anterior hip approach with visualisation of cup position in the operative definition. Surgeons who operate with the patient in the supine position or through an posterior approach might view the orientation of the cup in a different (anatomical/radiographic) plane. Fourth, every navigation system is prone to errors. We found a systematic deviation of anteversion due to landmark acquisition. Errors produced by each navigation system are a combination of errors of registration, landmark identification, optical camera and tracking devices, and of the different algorithms used in the software. Therefore, the accuracy of this navigation system cannot be transposed to other navigation systems.

In summary, computer-assisted, minimally-invasive THR in a lateral decubitus position offers the potential for more accurate placement of hip components. The future generation of imageless navigation systems will switch from simple measurement tasks to real navigation tools. These software algorithms will consider cup and stem as components of a coupled biomechanical system, navigating the orthopaedic surgeon to find an optimised complementary component orientation rather than target values intraoperatively. In this context, further investigations are necessary to work out the role of pelvic tilt, femoral stem antetorsion, combined anteversion and hip kinematics [21, 22] in order to improve the clinical outcome of computer-assisted total hip replacement in the future.

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