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HIP ARTHROPLASTY

No difference in clinical outcome, bone density and polyethylene wear 5–7 years after standard navigated vs. conventional cementfree total hip arthroplasty

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Abstract
Introduction The purpose of this investigation was to compare clinical outcome, component loosening, polyethylene cup wear and periprosthetic bone mineral density between "cup first" navigated and conventional cementless total hip arthroplasty (THA) 5–7 years after surgery.
Materials and methods Fifty patients who received THA with ($n = 25$) or without ($n = 25$) the use of an image-free navigation system by a single surgeon were investigated after a mean follow-up of 6.4 (4.8–7.4) years. The Hip Osteoarthritis Outcome Score (HOOS) and the Harris Hip Score (HHS) were obtained; range-of-motion (ROM) was evaluated by a blinded examiner. Radiographic cup inclination, signs of radiographic loosening and polyethylene wear were analysed with the help of digital analysis software on anterio-posterior radiographs by a blinded examiner. Acetabular and femoral periprosthetic bone density was evaluated with the help of dual-energy X-ray absorptiometry.
Results We were unable to find any statistical significant or clinically relevant difference for the HOOS, HHS, ROM and polyethylene wear between the navigated and the conventional THA group 5–7 years after surgery. Cup inclination was more precise in the navigated THA group in relation to the target value of 45°.
Conclusions Standard "cup first" THA navigation does not improve mid-term functional outcome, bony ingrowth and/or polyethylene wear. New concepts in computer-assisted THA, considering cup and stem as coupled biomechanical partners are needed to justify the effort of navigation in routine operations.

Keywords Total hip arthroplasty · Computer navigation · Bone mineral density · Biomechanical reconstruction · Clinical outcome

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Introduction

Malpositioning of the acetabular cup in total hip arthroplasty (THA) is a known risk factor for postoperative impingement, reduced range of motion, hip dislocation and increased/premature wear [3, 19]. The problem of cup alignment is further increased by the use of less-invasive techniques and large volume arthroplasty surgeons are concerned in a similar manner as less experienced surgeons [5]. Imageless navigation technology without the need of additional pre- or intraoperative image acquisition improves surgical precision and reduces variability during the acetabular cup insertion [22, 30, 35]. Only few studies have focussed on the clinical outcome after navigated THA, and most of them evaluated only a short-term or mid-term postoperative period [2, 15, 37]. Therefore, the clinical benefit of navigated THA has not been proven yet. So far, the design, the size, the porous coating as well as patient-related factors such as the individual anatomy of the hip and quality of bone are mentioned as main factors affecting periprosthetic bone remodelling after cementless THA [1]. Dual-energy X-ray absorptiometry (DXA) has been used in orthopaedic surgery to evaluate periprosthetic bone mineral changes and bony ingrowth after THA for many years. Compared to conventional radiographs, DXA is stated to be more sensitive to detect small bone density changes [38]. We aimed to test the hypothesis that there are no differences either for the subjective Harris Hip Score (HHS), the Hip Disability and Osteoarthritis Outcome Score (HOOS), periprosthetic bone mineral density (BMD) or polyethylene cup wear between standard "cup first" navigated and conventional cementless total hip arthroplasty (THA) 5–7 years after surgery.

Materials and methods

This retrospective matched-pair analysis was conducted after authorisation by the Institutional Ethical Board of the Medical University of Regensburg (No. 12-101-0073) and written informed consent for participation in the study was obtained from all participants. Fifty patients who had received primary unilateral THA due to primary osteoarthritis with or without the use of an imageless navigation system (Hip unlimited 5.0; BrainLAB AG, Feldkirchen, Germany) were included in this study. There were 22 men and 28 women with a mean age at the time of surgery of 61 years (44–78). The matching criteria age, gender, body mass index (BMI), treated side, American Society of Anesthesiologists (ASA) Score, grade of osteoarthritis (Kellgren and Lawrence Score) and follow-up were similar in both groups (Table 1). All patients were recruited from a cohort of 400 patients. Exclusion criteria were imposed to avoid changes in BMD which were not related to the operation. These included rheumatoid arthritis, constant intake of oestrogen, calcium, vitamin D, calcitonin or any other medication for osteoporosis before, during or the time after surgery. THA in all patients was performed in the lateral decubitus position using a minimally invasive single-incision anterolateral approach. THAs were performed by a single orthopaedic surgeon in parallel from Regensburg University Medical Center with experience of more than 200 conventional and 100 navigation-controlled THAs. Indications for using the freehand or navigated technique were guided by random distribution of the operation theatres with or without an integrated navigation system.

Press-fit acetabular components, uncemented hydroxyapatite-coated stems (Pinnacle cup, Corail stem, DePuy, Warsaw, IN), polyethylene liners and metal heads with a diameter of 32 mm were used in all patients. In the navigated group, an imageless navigation system (Brainlab Hip, Germany) with a standard ("cup first") software was used. The registration process for navigated THA in a lateral decubitus position has been described previously [35]. 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 surface. The target acetabular component position for all patients was within the "safe zone" as defined by Lewinnek et al. [17] (40° ± 10° inclination and 15° ± 10°, anteversion). For the navigated group, the intraoperative definition of the acetabular plane for the insertion of the cup relied on the same (radiographic) plane and coordinate system as for the postoperative measurements of cup inclination on standard anteroposterior radiographs [23]. At a mean of 6.4 (4.8–7.4) years postoperatively, patients of both groups were invited for follow-up and underwent a radiographic evaluation.

Table 1 Demographic data in the conventional and navigated group (mean and SD)

	Conventional ($n = 25$)	Navigated ($n = 25$)
Gender	14 female, 11 male	14 female, 11 male
Age (years)	64.4 (9.3; 48.8–77.6)	61.7 (8.8; 43.9–77.6)
Weight (kg)	77.3 (12.9; 60–110)	78.0 (15.6; 60–115)
Height (m)	1.7 (0.1; 1.5–1.9)	1.7 (0.1; 1.5–1.9)
BMI (kg/m^2)	27.8 (4.8; 20.8–45.2)	27.1 (4.0; 20.3–39.8)
Degree of osteoarthritis (Kellgren and Lawrence Score)	3.8 (0.4; 3.0–4.0)	3.7 (0.5; 3.0–4.0)
Treatment side	12 left, 13 right	12 left, 13 right
ASA score	3×I, 20×II, 2×III	4×I, 19×II, 2×III
Follow-up (month)	76.3 (17.8; 48.0–102.0)	77.3 (18.5; 51.0–102.0)

Anthropometric differences between the conventional and the navigated total hip arthroplasty group

Sample size

We identified 66 patients (33 matched pairs) that met our inclusion criteria 5–7 years after cementless THA performed by a single surgeon. We excluded patients with a known history of osteoporosis and/or the use of bone remodelling drugs (calcitonin, vitamin D, oestrogens) pre- or postoperatively. All patients were contacted by phone and invited to participate in a clinical and radiographic examination. Four patients were excluded due to poor quality of radiographic images. Two patients had passed away and six patients were not able to return to the hospital for examination. All in all, eight pairs had to be excluded from analysis. In total, we were able to analyse 50 patients (25 pairs, Fig. 1).

Follow-up measurements

The validated Hip Osteoarthritis Outcome Score (HOOS) [24], the Harris Hip Score (HHS) [10, 20] and range-of-motion in flexion, extension, external and internal rotation, abduction and adduction were obtained from all patients as disease-specific outcome instruments [38, 40]. Assessment of all patients in both groups was performed by two orthopaedic surgeons; examiners were kept blinded to the used surgical technique of the patients at all times. Complications were monitored from the patient's records. In detail, we monitored the following: wound infection, deep infection, loosening and revision surgery.

Radiographic evaluation

All patients underwent DXA scanning (Lunar DPX; GE Healthcare General, Fairfield, USA) of the pelvis and proximal femur using the metal removing hip scanning mode. According to the manufacturer's instructions, patients were placed in the supine position, the leg in slight internal rotation. The leg was attached to a positioning device. Pelvic scan acquisition was set 3 cm above the proximal border of the acetabular cup and including the distal border of inferior pubic ramus. Acquisition of the femoral scan was commenced 2 cm distal to the tip of the femoral stem and ended 2 cm above the trochanter major. The acetabular scans were examined according to the zones of De Lee and Charnley [4] and the femoral scans were examined using the zones of Gruen, Mc Neice an Amstutz [5] (Fig. 2a). The zones according to De Lee were defined by bisecting the acetabular component with a horizontal and a vertical line [38, 40] (Fig. 2b). Additionally, postoperative cup inclination and component wear were evaluated. For all measurements, a digital planning software was used by a blinded and independent observer (MediCAD, Hectec, Germany). The used software showed excellent intraclass correlation coefficients (ICCs) from 0.896 to 0.995 in a recent investigation analysing deformities and the digital planning of osteotomies [33]. According to the software producer, no study has analysed the precision, accuracy and/or standard error of measuring cup inclination in correlation to CT scan measurements with this planning software so far. A recent study with a similar digital planning software (TraumaCAD, Brainlab, Germany) reported a standard error of 2.1° for measured cup inclination [41]. Magnification was corrected by the documented size of the femoral metal head on each X-ray. Radiographic cup inclination was defined as the angle between the line on which the long axis of the cup ellipse is located and the interteardrop line according to Lewinnek et al. [17]. For assessment of wear, the penetration of the femoral head into the polyethylene liner by comparison of postoperative AP pelvis radiographs with radiographs taken at follow-up was measured. The software calculated the head penetration by identifying the centres of the femoral head and the acetabular component. The average of individual patient wear rates was regarded as wear rate of each group [13, 21, 32]. Signs of radiographic loosening of the femoral component were analysed according to the criteria of of Engh et al. [7], signs of radiographic loosening of the acetabular component were evaluated according to the criteria of Hodgkinson et al. [12].

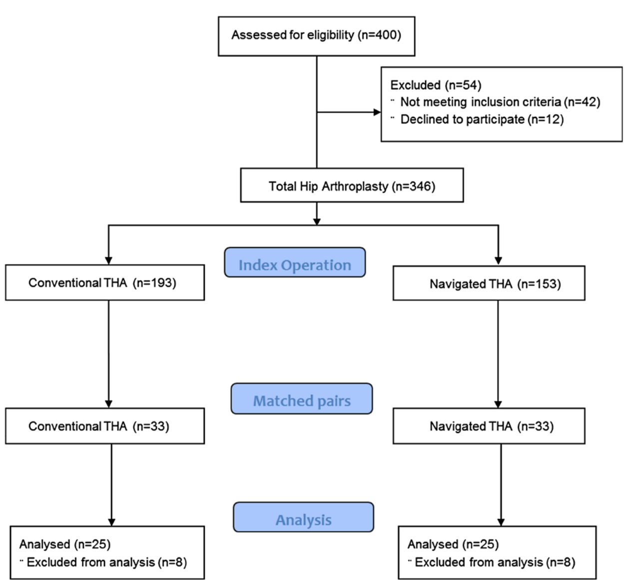

Fig. 1 Flow chart diagram illustrating patient selection for this study

Statistical analysis

Data were presented as mean ± standard deviation, as median together with the interquartile range for continuous variables or as numbers and percentages for qualitative variables. The data between the two treatment

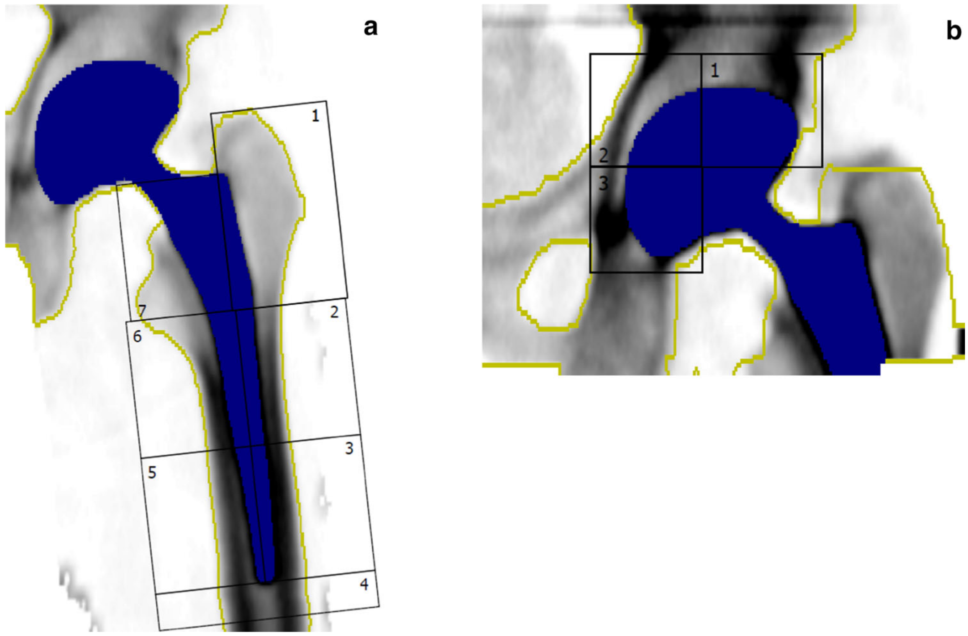

Fig. 2 Dual-energy X-ray absorptiometry analysis showing **a** the seven regions of interest (ROIs) around the femoral stem according to Gruen and **b** the three regions of interest (ROIs) around the acetabular cup Zones according to De Lee

groups were compared with the Mann–Whitney test (continuous variables). For comparing, the Harris Hip Score box plots were used. The box height is the interquartile range which represents half of all values; 25 % of values are higher and 25 % of values are lower than the box. The median is displayed as a horizontal line across each box. The minimum and maximum values are represented by the vertical lines. All analyses were performed using SigmaPlot 11.0 (Systat Software Inc., Chicago, IL, USA). Statistical comparisons were made at a 0.05 level of significance.

Results

HOOS

No significant difference between the navigated and conventional THA group was found for the HOOS. On average, patients in the navigated group reached 83.0 (SD 13.7; range 45.3–98.7) points and patients in the conventional group reached 82.3 (SD 15.6; range 47.7–100) points ($p = 0.87$). In detail, the mean values of the HOOS subscales in both group were: pain/navigated: 98.5 (SD 2.9) and pain/conventional: 98.4 (SD 2.6; $p = 0.90$); symptoms/navigated: 84.0 (SD 17.5) and symptoms/conventional: 86.0 (SD 16.9; $p = 0.68$); quality of life/navigated: 69.5 (SD 27.3) and quality of life/conventional: 64.2 (SD 32.0; $p = 0.53$); function, sports and recreational activities/navigated: 63.7 (SD 35.5) and function, sports and recreational activities/conventional: 63.6 (SD 38.5; $p = 0.99$); function, daily living/navigated: 99.2 (SD 1.4) and function, daily living/conventional: 99.5 (SD 0.9; $p = 0.50$) (Fig. 3).

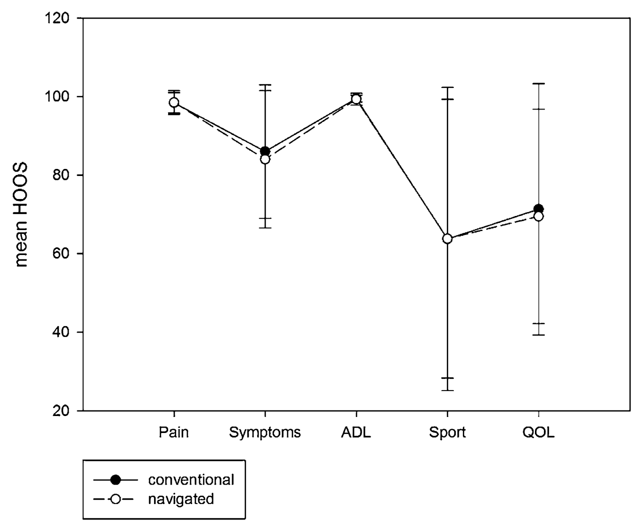

Fig. 3 HOOS subscores (pain, symptoms, ADL, sport, QOL) after conventional and navigated total hip arthroplasty presented by means and standard deviation

HHS

In total, the HHS demonstrated good results without any statistically significant differences. On average, patients in the navigated group reached 91.1 (SD 16.1; range 59–100) points and patients in the conventional group reached 91.8 (SD 7.7; range 61–100) points ($p = 0.11$) (Fig. 4). Range-of-motion testing in connection with the HHS showed no significant differences between both groups (Fig. 5).

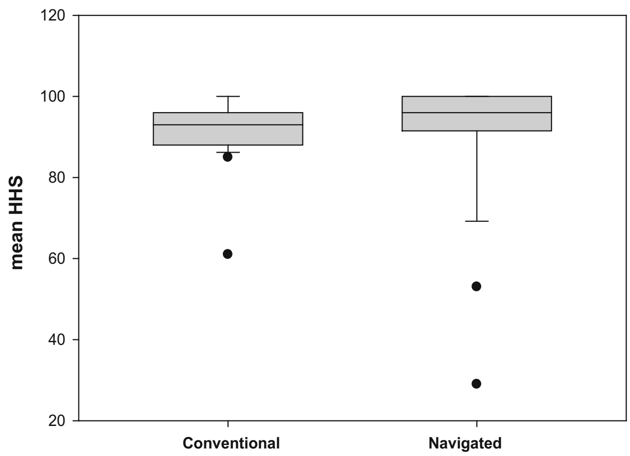

Fig. 4 *Box plot* representing the mean Harris Hip Score after conventional and navigated total hip arthroplasty

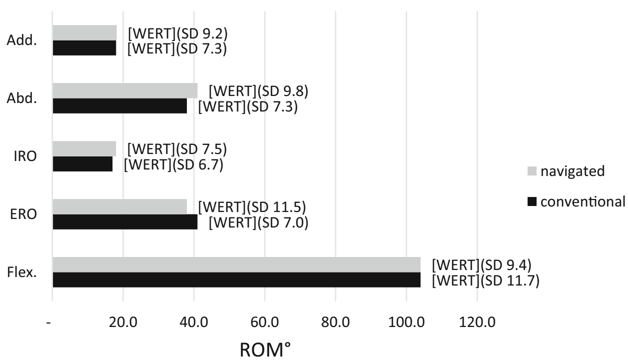

Fig. 5 Range of motion presented by means and standard deviation after conventional and navigated total hip arthroplasty

Radiographic evaluation

In summary, no statistically significant differences were found either for femoral ROIs 1–7 or acetabular ROIs 1–3 between the navigated and the conventional THA group ($p < 0.05$). However, higher femoral BMD values (except in ROI 5) in the conventional THA group and higher BMD values in all three acetabular ROIs within the navigated THA group were noticed (Fig. 6). Mean values and standard deviation of all ROIs are presented in Table 2. Cup inclination was more closely to the target value of 45° within the navigated THA group with a mean cup inclination of 45.3° (SD 4.2; range 40.0–58.0), while the conventional THA group showed a mean inclination of 48.0° (SD 4.2; range 41.4–59.4) ($p = 0.02$). Polyethylene wear was comparable between both groups. In the navigated group mean wear was 0.7 mm (SD 0.2; range 0.2–1.1), in the conventional group the mean wear was 0.7 mm (SD 0.7; range 0.2–2.5) ($p = 0.77$). No signs of radiographic loosening of the femoral or acetabular component according to the criteria of Engh and Hodgkinson could be detected in one of the groups.

Complications

We did not find any complications in terms of wound infection, deep infection, loosening, dislocation or re-operation in our study groups.

Discussion

This study was conducted to test the hypothesis that there are no differences in clinical outcome (HHS, HOOS), range-of-motion, periprosthetic BMD and polyethylene wear between navigated and conventional THA 5–7 years after surgery. So far, there are only a few studies available in literature evaluating the clinical short- and mid-term outcomes of navigated THA 6 years after surgery [2, 15, 18, 37]. In one study by Sugano et al. [37], a different navigation system (CT-based navigation) and also a different bearing system (ceramic-on-ceramic) were used. However, these authors reported no significant difference in clinical outcome (Merle d'Aubigne hip score) or cup inclination between the navigated and conventional groups. Also, Brown et al. [2] could not find any difference between navigated and conventional THA mid-term results in terms of component placement and clinical outcome. Another study by Lass et al. [15] analysed the short-term clinical outcome 1.5 years after surgery. They could not demonstrate a significant difference between both groups with regard to clinical outcome (Harris Hip Score, WOMAC Score) and cup inclination as well. No study so far investigated a possible difference in periprosthetic BMD or polyethylene wear between navigated and conventional THA. In the present investigation, we could not find any evidence that navigated THA has a significant influence on the postoperative clinical outcome or bony ingrowth of either the femoral or the acetabular component. However, cup inclination in the navigated THA group was more accurate to the target value of 45° when compared to the conventional THA. Since it has been shown that cup anteversion can only be measured precisely on computed tomography scans [36], we did not analyse this parameter. In the past, many studies using DXA in THA have focused on measuring postoperative bone mineral density in correlation to different prosthetic designs and component coatings [4, 31, 35]. Few studies have investigated the effects of surgical techniques on bony ingrowth [11, 26]. Interestingly, there was a tendency for higher bone mineral density values in all three periacetabular zones of De Lee in the navigated THA group. Previous studies have shown that the proximal areas of the

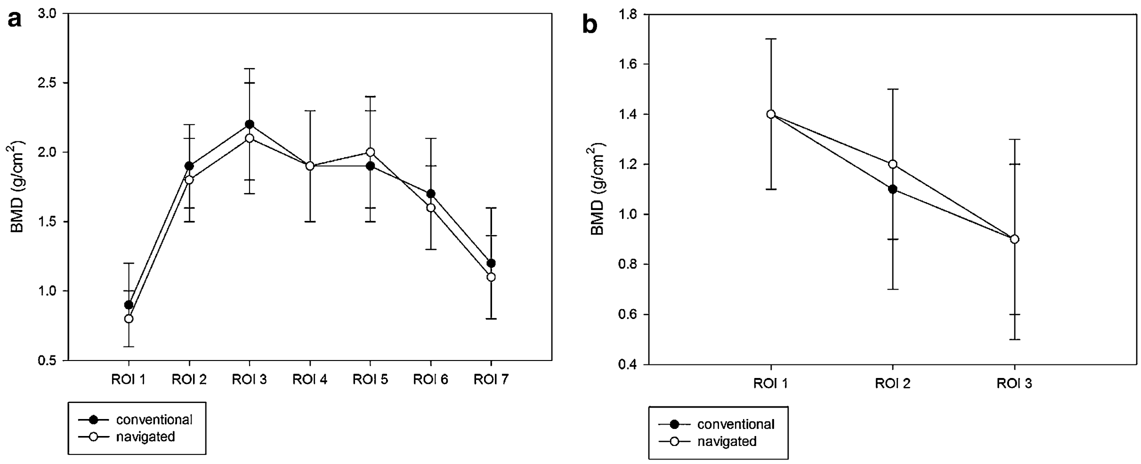

Fig. 6 Means and standard deviation of periprosthetic bone mineral density (BMD) after conventional and navigated total hip arthroplasty in **a** the seven Gruen regions (ROI 1–7) and **b** the three regions according to De Lee (ROI 1–3)

Table 2 Periprosthetic bone mineral density (g/cm^2) data in regions of interest of the femur (ROI 1–7) and the acetabulum (ROI 1–3)

	Conventional (n = 25)	Navigated (n = 25)
Femur		
ROI 1	0.9 (0.3)	0.8 (0.2)
ROI 2	1.9 (0.3)	1.8 (0.3)
ROI 3	2.2 (0.4)	2.1 (0.4)
ROI 4	1.9 (0.4)	1.9 (0.4)
ROI 5	1.9 (0.4)	2.0 (0.4)
ROI 6	1.7 (0.4)	1.6 (0.3)
ROI 7	1.2 (0.4)	1.1 (0.3)
Acetabulum		
ROI 1	1.4 (0.3)	1.4 (0.3)
ROI 2	1.1 (0.4)	1.2 (0.3)
ROI 3	0.9 (0.3)	0.9 (0.4)

Mean values and standard deviation of bone mineral density in the conventional and the navigated THA group

periprosthetic femur are more likely for bone loss with cementless implants [8, 14, 25, 27, 40]. Likewise, we found relatively lower BMD values in ROI 1 and 7 according to Gruen compared to other ROIs, but this was independent from navigated or conventional THA. We found lower BMD values in six femoral Gruen zones and higher BMD values in all three acetabular zones for the navigated THR group, but the differences to the conventional THA group were very small. Therefore, we also regard these changes as clinically irrelevant. As we used a very successful implant combination, there might be higher differences regarding bony ingrowth in less successful implants with lower survival rates [9]. Moreover, we did not find signs of loosening or early implant failure in any of the analysed cases. This study has some limitations: first, our trial has a retrospective and matched-pair character with a limited number of subjects. We identified 33 matched pairs according to the desired matching criteria. All patients were contacted by telephone and we were able to examine 25 matched partners of this cohort. None of the patients who were not willing to participate in the investigation reported pain, dissatisfaction or revision surgery during the telephone interview. When we performed a post hoc statistical calculation of sample size, it was found that more than 50 subjects per group would be needed for the clinical and more than 200 subjects per group would be needed for the radiographic parameters to detect a statistically significant difference between the two cohorts. However, the clinical question is whether it would be worthwhile and possible to enrol these additional subjects to attain statistical significance if the difference between the two groups is that small and probably of no clinical relevance. Without any doubt, a prospective randomised controlled trial remains the golden standard for comparing two different techniques. Nevertheless, our study represents one of the first mid-term reports comparing the clinical outcome in navigated vs. conventional THA and is therefore an important contribution to our understanding. Second, we were unable to obtain preoperative baseline values. Most of existing investigations compare BMD values over time to describe bony ingrowth during follow-up. However, in this study, we concentrated on the biomechanical effect on bone stock and resulting periprosthetic ingrowth after a settled time period, therefore, time scale was not our main objective. We tried to reduce this possible selection bias by excluding patients with a known history of osteoporosis and/or the use of bone remodelling drugs pre- or postoperatively. Third, radiographic measurements on anteroposterior radiographs of the pelvis and femur are susceptible to error since horizontal dimensional parameters are influenced by variations in positioning of the pelvis relative to the plane of the film, small changes of the body position by the patient and the divergence of the X-ray beams [39]. The reliability of these measurements is further reduced by the influence of pelvic tilt and rotation [16, 29]. We tried to reduce these effects using a standardised procedure with the help of an experienced radiological assistant using a patient positioner (patient stands straight, body weight equally distributed on both feet, lower limbs 15° internally rotated, the central ray perpendicular to the midline of the patient to place the femoral necks parallel to the plane, definite film-focus-distance). Furthermore, X-rays were conducted using a scaling ball. A strength of the study is the fact that we used a single manufacturer THA design with a single head diameter and a single surgeon series across groups preventing confounding. Any difference with regard to ROM, BMD and component wear in our analysis is mainly due to the operative technique rather than the design or the coating of the prosthetic component. Of course, in general many other influencing factors have to be taken into account to answer the question of premature polyethylene wear and loosening in THA. In summary, we could verify our tested hypothesis: There is no difference for the clinical outcome, periprosthetic BMD and polyethylene cup wear between standard navigated and conventional cementless THA 5–7 years after surgery.

Conclusion

The authors conclude that standard "cup first" THA navigation does not improve mid-term functional outcome, bony ingrowth and/or polyethylene wear. At that stage, the concept of impingement-free, combined component orientation following the concept of "femur first" seems to be one of the most promising developments in navigated THA [6, 28, 34]. Future studies could compare the clinical and radiologic outcome of this patient individual computer-assisted THA technique with the results from standard navigation presented in this study.

Conflict of interest Each author certifies that he has no commercial associations (e.g., consultancies, stock ownership, equity interest, patent/licensing arrangements, etc.) that might pose a conflict of interest in connection with the submitted article. The work was performed at the Department of Orthopaedic Surgery at the Medical University of Regensburg/Germany.

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