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Patient Specific Instrumentation with Laser Guide Navigated THA: Clinical and CT Evaluation of the First 100 Cases

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Abstract: Obtaining a proper position for THA's components is a crucial aspect for the implant performance and consequently patient outcomes. Patient specific kinematic seems to be a key factor to reach the optimal implant positioning. The aim of this study was to assess the accuracy and safety of a computed dynamic analysis system which through patient specific guides tries to improve implant positioning and functional orientation according to patient's spinopelvic mobility and anatomy.A total of 100 consecutive patients were prospectively enrolled. All patients received an OPS dynamic hip preoperative planning. A TC scan protocol follow up analysis has done at 6 month after surgery.The mean deviation from the planned acetabular inclination and anteversion was 4.3° e 3.8° respectively. The 98% of cases was within +/- 10° of Lewinnek safe zone both for inclination and anterversion. The height of osteotomy deviated on the average of 1.6mm. The 100% cases were included within 4mm of osteotomy. Patient specific and laser guided instrumentation is safe and accurately reproduce the dynamic planning in terms of components orientation, osteotomy level, leg length and offset.

Keywords: hip-spine; planning; THA; patient-specific

1. Introduction

The functional success of a total hip arthroplasty (THA) is strictly related to surgical, implant, and patient factors. Proper positioning of components THA represents a crucial aspect for assuring adequate stability, equalising limb length discrepancies, and recreating the appropriate offset. Accurate positioning is key to optimize functional outcomes and to reduce rates of dislocation, impingement, aseptic loosening, and other wear-related complications. [1, 2]

The acetabular cup orientation is probably the most important factor surgeon's control dependent; malposition of the acetabular cup could lead to instability, edge loading, osteolysis, and squeezing, having a significant effect on the implant performance and consequently patient outcomes. [1,4]

Lewinnek has set the proper orientation for the prosthetic cup defining the *safe zone* (inclination 40°±10° and anteversion 15°±10°) [5] but some authors sustained that up to 60% of implant dislocation occur in well-positioned implant (within the safe zone) [6-9], suggesting that ideal generic safe zone can be deceptive. Moreover, the standard pre-operative plannings are based on plane radiographs taken in static supine position. [10] The acetabular orientation is not a static parameter, but the functional version and inclination change during daily activities according to pelvic movement in sagittal plane [10]. The pelvis usually rotates backward moving from supine to standing and sitting positions. [12-13]. Pelvic sagittal activity, lumbar disease (ankylosing spondylitis, lumbar arthritis, lumbar fusion, spine-pelvic fusion), and other factors related to the tilt are THA risk factors for postoperative dislocation. [11] The sagittal postural balance varies for each patient and is affected by many factors including the lumbar and spino-pelvic diseases [15]. It has been demonstrated that

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patients affected by spine stiffness have an increased risk of instability and dislocation after THA due to impaired spinopelvic kinematics. [16,17]

Thereby an implant placed within the canonical safe zone intraoperatively, could not be safe and appropriate during daily activity and in fact, edge loading, impingement, and dislocation occur more commonly during activities rather than in a static position. [10,14]

Several authors recommended to perform standing and sitting lateral radiographs to evaluate for spinopelvic balance. [13-15, 18]

About the femoral side of THA, the femoral neck osteotomy and stem placement influence the leg length, stem anteversion and femoral offset, especially in cementless implants [19- 21]

Patient-specific kinematic planning seems to be a key factor to reach the optimal implant positioning, however, it is essential to accurately deliver it intraoperatively. Literature report a mismatch between preoperative planning and final components positioning ranging from 20% to 40% of the cases. [22-24].

Optimise Positioning System (OPS™, Corin Ltd, Cirencester UK) is a recent system that provides a preoperative planning with patient-specific component alignment as a result of computed dynamic analysis. The functional analysis is based on imaging studies, which includes low dose CT scans and lateral X-rays in three functional positions: standing, step-up and flexed-seated. The computer-based preoperative planning aims to optimise the implant positioning and the functional orientation of components according to the patient's spinopelvic mobility and anatomy, with the goal to avoid potential impingement and instability during daily life activities. The patient-specific instrumentation (PSI) is laser guided intraoperatively and includes 3D printed patient-specific reaming guides for both the acetabular and femoral side.

The main purpose of this study was to verify the reliability and accuracy of a PSI and laser-guided technique to replicate the preoperative dynamic planning by evaluating the first 100 cases of THA.

2. Materials and Methods

From January 2019 to December 2022 all patients with a diagnosis of hip osteoarthritis requiring THA were eligible for inclusion in the present study. Exclusion criteria applied were: previous hip surgery, hip ankylosis, contralateral hip prosthesis and the disability to sit and stand during the radiographic study, age <18.

All patients who agreed to follow the preoperative and postoperative imaging protocol were enrolled in this prospective study. All patients received an OPS™ (Corin Ltd, Cirencester UK) dynamic hip preoperative planning. The preoperative planning included: an anteroposterior radiograph of the pelvis, three functional lateral spinopelvic X-rays (standing, flexed-seated and stepping-up) and a low dose CT scan (mean dose 2.8 to 4.1 mSv per scan) of the lower limbs. The images were sent to the manufacturer for analysis. On functional X-rays images, pelvic tilt with pelvic rotation from different positions, pelvic incidence, lumbar lordotic angle and lumbar flexion were measured. The kinematic inputs drove the dynamic planning. The surgeon could choose the optimal cup orientation for the patient evaluating contact patch paths that are presented in polar plots for nine different cup orientations. The pre-plan included a proposed cup type, size and orientation; the stated cup alignment was referenced to the coronal plane when the subject is supine. Planning included also level of the osteotomy, stem type, position and size and estimated change in leg length and offset compared to the pre-operative state. All these parameters were recorded to make a comparison with the corresponding postoperative measurements. The preoperative plan with the virtual implant templating was approved before surgery by the surgeon. After planning approval, acetabular and femoral 3D printed PSI guides were delivered.

Surgical technique

The procedures were performed using, in lateral decubitus position, the direct lateral surgical approach. The femoral and acetabular PSI guide were placed according OPS™ (Corin Ltd, Cirencester UK) technique; then using a laser attached to the guides, the planned osteotomy femoral

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cut and the acetabular reaming were performed. Femoral broaching was then performed according to the preoperative plan. The final implant of the stem was performed using the manual conventional instrumentation. Range of motion, impingement and stability were then tested in the standard way.

All patients received an uncemented acetabular cup (Trinity™ cup, Corin Ltd, Cirencester UK) and a taper wedged blade stem (TriFit TS™, Corin Ltd).

Postoperative CT evaluation

Six months after surgery, a second imaging protocol analysis were performed and compared to pre-operative scans.

Furthermore, height of the femoral neck, hip offset and postoperative leg length were recordered and compared to the preoperative planning data.

Surgical time and complications rate were also recorded for each procedure.

Clinical outcomes measures

Two different questionnaires, the Forgotten Joint Score (FJS) [42] and The Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) [41], were applied to the patients to evaluate clinical outcomes at 6 months after surgery.

Statistical analysis

The statistical analysis was conducted with STATA software 14.1. The variables were expressed as means (standard deviation). The normality of the data was verified by the Shapiro–Francia test. For the variables whose distribution was normal, a Student's t-test for paired samples was performed while for the variables whose distribution was not normal, a Wilcoxon's signed rank test was used. $p < 0.05$ was considered to be significant.

3. Results

Results

All patients were available at follow-up; One hundred consecutive patients were prospectively enrolled in the study (53 men and 47 women) with a mean age of 74 years (range of 59 - 81 years), the mean BMI was 24.3 (range 23-30).

The results shown no statistically significant difference comparing the planned and the achieved values (Table 2).

Table 2. Mean planned and postoperative values.

	Mean Planned Value (range)	Mean Postoperative Value (range)	*p*-Value
Cup Inclination	39.4° (32° - 45°)	37.2° (30° - 45°)	0.345
Cup Anteversion	20.8° (12° - 28°)	18.8° (12° - 30°)	0.093
Osteotomy Hight	10.26 mm (5 - 24 mm)	10 mm (4 - 28 mm)	0.234
Offsett Change	1 mm (0 - 5 mm)	3 mm (1 - 8 mm)	0.134
Length Change	2.5 mm (1 - 3mm)	3.1 mm (2 - 5 mm)	0.098

The mean planned and postoperative cup anteversion was respectively 20.8° (range 12° to 28°) and 18.8° (range 12 to 30°) and the mean cup inclination was 39.4° (range 32° to 45°) in the planned measures and 37.2° (range 30° to 45°) postoperatively; the mean absolute deviation from the planned inclination and anteversion was 4.3° and 3,8° respectively.

Postoperative inclination and anteversion were, respectively for inclination and anteversion, within +/− 5° from the planned values in 78% and 81% of cases, while a deviation within +/− 10° was detected in 98% and 97% of cases (Table 3) .

Table 3. Deviation from the planned cup values.

	Absolute Deviation, Mean	% Within +/− 5° (n)	% Within +/− 10° (n)
Cup Inclination	4.3°	78	98
Cup Anteversion	3.8°	81	97

The mean level of the femoral osteotomy was 10.26 mm (range 5 to 24 mm) in preoperative planning and 10 mm (range 4 to 28 mm) at the postoperative control; The mean absolute deviation from the planned height of the resection was 1.6 mm (range 0 to 4 mm). In 75% of cases, the level of the osteotomy was found to be within 2 mm of the planned height of the resection. All osteotomies were within 4 mm of the planned level.

The mean postoperative offset variation was 3 mm (range 1 to 8 mm) and did not statistically differ from the mean planned offset change that was 1 mm (range 0 to 5 mm), the mean deviation from planning was 2.3 mm (range 1 to 4 mm).

The effective mean hip length change compared with the preoperative status was 3.1 mm (range 2 to 5 mm) and did not significantly differ from the mean planned lengthening of 2.5 mm (range 1 to 7 mm); the mean deviation from planning was 1.9 mm (range 1 to 6 mm).

The results are summarized in Table 4.

Table 4. Deviation from the planned cup values.

	Absolute Deviation, Mean (Range)	% Within +/− 2mm (n)	% Within +/− 4mm (n)
Osteotomy Height	1.6 mm (0 - 4 mm)	75	100
Offset Change	2.3 mm (1 - 4 mm).	78	100
Length Change	1.9 mm (1 - 6 mm).	68	80

The acetabular cup size matched that in the preoperative planning in all of cases.

The femoral stem size matched what was preoperatively planned in all but 2 cases.

The mean Clinical Outcome score rated with WOMAC and FJF score was 92 (80 to 98) and 90 (76 to 96) respectively.

At the last follow-up (mean 11.7, range 6-24) two complications occurred; one patient had a THA dislocation 2 months after surgery and one suffered an acute periprosthetic infection.

4. Discussion

The study highlights that the OPS™ PSI guides and the related laser-guided technique gave to surgeons a dynamic functional preoperative planning providing information about size and orientation of implant components, the femoral osteotomy height and variation in offset and limb length. In authors experience the planning has proved to be reproducible an accurate in surgery room, with an acceptable percentage of discrepancies from planning.

About the patient who suffered THA dislocation, the radiological findings shown that it was due to inaccurate positioning of the acetabular guide intraoperatively (anteverted 38°) probably due to a surgeon related PSI malposition; The patient was treated with revision THA surgery and then excluded from the study.

The second complication was an acute periprosthetic joint infection that was successfully treated with a DAPRI technique (Debridement, Antibiotic Pearls, and Retention of the Implant) 3 weeks after surgery.

The component positioning in THA in dynamic function setting have been widely investigated as it plays a significant role in implant stability and survival. [12,21,25,26]

Literature sustains that the individual lumbopelvic sagittal kinematics affects the cup alignment functionality in daily life activities. [16,27,28] The pelvic tilt may vary according to the patient position (supine, standing or sitting), this led to functional effect on acetabular anteversion and inclination. [12,26,30]

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When the pelvis rotates posteriorly, the acetabular functional anteversion increases in order to prevent posterior dislocation and the edge loading during hip flexion, even if in extension it can lead to posterior impingement and anterior instability [26], while during the anterior pelvis rotation, the functional anteversion decreases, thus preventing the anterior dislocation and edge loading in hip extension (but not in flexion) [10,15,29].

However, there is wide interindividual variability, as the pelvic range of motion varies from 70° to 5° in stiffer patients. [10,30] If lumbopelvic stiffness occurs, it affects the sagittal kinematics; therefore the stiff spine can lead to insufficient pelvic retroversion while sitting and excessive pelvic anteversion in standing position. Moreover, this condition promotes the occurrence of some complications: impingement, edge loading and prosthetic implant instability. The presented conditions suggest that Lewinneck's safe zone may not fit for all patients and the prosthetic implant may not be in the safest position during more functionally-relevant postures. [3,11,15]

As a result, more and more surgeons are shifting away from conventional implantation techniques for THA to adopt kinematic techniques that consider the dynamic spinopelvic relationships. [3,31] The literature regarding acetabular cup placement is quite extensive while there are limited data on the femoral stem position [21,15,18]. Recent literature agrees about the relevance of femoral osteotomy planning for a successful THA; The femoral cut mainly affects the leg length, the hip offset, and the tracking of the implant [20,33]. Errors in this field can severely affect the THA function and survival as well as the patient quality of life.

The dynamic planning also needs to be properly reproduced in surgery room. The main errors and malposition of components mainly derive from wrong patient positioning, intraoperative pelvic motion and surgeon manual mistakes during the surgery [34]. To better achieve the planned target, several techniques were proposed, including computer navigation, robotic surgery and patients specific instrumentation (PSI). While navigation and robotics, have a limited use because of their high costs, increased surgical time and other logistical issues [35,36], the PSI is gaining more and more prominence. Henckel et al. demonstrated that using PSI for acetabular components reduces the number of outliers comparing with the use of standard instrumentation (0% versus 23.7% respectively) [37].

The Optimized Positioning SystemTM (Corin, Cirencester, UK) is a technological version of the kinematic alignment technique, which aims to reduce the risk of a poor functional component implantation. Its purpose is to achieve the best cup position so that to restore most of the hip anatomy through 3D planning and PSI. [18,38,39]

Spencer et al [18] evaluated the same PSI navigation system as the authors studied for THA on 100 patients showing a good accurancy, they reported a mean absolute deviation from the planned patient-specific inclination and anteversion was 3.9° and 3.6° respectively. Their results did not differ so much from those presented in this study (see table 3).

The 98% of all cases, the anteversion and inclination value were within the traditional Safe zone described by Lewinnek [43]. In two cases the final acetabular anteversion was out of the conventional safe zone (26° and 28°) as suggested by the preoperative planning. These Patients had no major complication and they get good clinical result at 6 months follow up.

Although Navigation systems seem to guarantee a better accuracy positioning of prostetic components a 2% dislocation rate still believe. A percentage of dislocation between 54-58% involve prostetic components within Lewinnek safe zone. [43-46]

The literature point out that mismatch between the preoperative and the final position of the femoral prosthetis occurs in 40% of cases. [47] A leg length discrepancy more than 2cm can lead to some complications such as back pain, increased risk of joint dislocation, sciatic nelve palsy [48] involving about 25% of patient undergoing THA surgery. [49] In the present series the mean leg lengthening after surgery was 2.5 mm (range 1 to 7 mm) with a mismatch from planning of 1.6mm; no one patient reported any symptoms attributable to dysmetria perception.

Among the limits in the use of OPS technique, the authors wants to emphasize that it is necessary for the patient to be able to perform a proper preoperative study, as some conditions may preclude it; they believe that a severe bilateral hip arthritis and stiffness may affect the reliability of the preoperative planning, because it is difficult to obtain valid preoperative images (expecially for the flexed-seated position); Moreover the OPS technique is more expensive economically than the standard although the benefits may be greater in the long term by reducing the rate of complications related to THA malposition. Furthermore, the acetabular reaming depth is still determined by surgeon and it depends a lot on the experience of the surgeon such as fore femoral stem version that in not guided by PSI instrumentation.

Limits: there is no comparison of the accuracy of component positioning in the group undergoing THA with standard technique; there was not a control group; the follow-up was not always adequate.

5. Conclusions

Patient-specific and laser-guided instrumentation is safe and accurately reproduce the dynamic planning in terms of components orientation, osteotomy level, leg length and offset.

6. Patents

This section is not mandatory but may be added if there are patents resulting from the work reported in this manuscript.

Conflicts of Interest: The authors declare no conflict of interest

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