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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 total hip arthroplasty components is a crucial aspect of implant performance and consequently of patient outcomes. Restoring the original hip center and maintaining the limb length are key factors in reaching the optimal implant positioning. The aim of this study was to assess the accuracy and safety of a computed dynamic analysis system that, through patient-specific guides, tries to improve implant positioning and functional orientation according to patients' spinopelvic mobility and anatomy. A total of 100 consecutive patients were prospectively enrolled. All patients received an Optimized Positioning System dynamic hip preoperative planning schedule. A CT scan protocol follow-up analysis was performed 6 months after surgery. The mean deviations from the planned acetabular inclination and anteversion were 4.3° and 3.8°, respectively. In total, 98% of cases were within ± 10° of the Lewinnek safe zone, both for inclination and anteversion. The height of osteotomy deviated, on average, 1.6 mm. In total, 100% of cases were included within 4 mm of osteotomy. Patient-specific and laser-guided instrumentation was found to be safe and accurately reproduced dynamic planning in terms of the component orientation, osteotomy level, leg length and offset.

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

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1. Introduction

The functional success of a total hip arthroplasty (THA) is strictly related to surgical, implant, and patient factors. The proper positioning of components during THA represents a crucial aspect of ensuring adequate stability, equalising limb length discrepancies, and recreating the appropriate offset [1]. Accurate positioning is key to optimizing functional outcomes and to reducing the rates of dislocation, impingement, aseptic loosening, and other wear-related complications [2,3].

Both the acetabular cup orientation and the relative stem positioning are important factors that are dependent upon the surgeon's control; the malposition of the acetabular cup can lead to instability, edge loading, osteolysis, and squeezing, having a significant effect on the implant performance and consequently on patient outcomes [2,4]. The shape, size and positioning of the components depends on the design and implant parameters of the acetabular cup and stem [5].

Lewinnek set the proper orientation of the prosthetic cup and defined this as the safe zone (inclination 40° ± 10° and anteversion 15° ± 10°) [6]; however, some authors have suggested that up to 60% of implant dislocation can occur in well-positioned implants (within the safe zone) [7–10], suggesting that the ideal generic safe zone can be deceptive. Moreover, standard pre-operative planning is based on plane radiographs taken in the static supine position [11]. The acetabular orientation is not a static parameter, but the functional version and inclination change during daily activities according to pelvic movement in the sagittal plane [11].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 tilt are THA risk factors for postoperative dislocation [14]. The sagittal postural balance varies for each patient and is affected by many factors, including lumbar and spinopelvic diseases [15]. It has been demonstrated that 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 intraoperatively placed within the Lewinnek safe zone may not be safe or appropriate during daily activity; in fact, edge loading, impingement, and dislocation occur more commonly during activity than when in a static position [11,18].

Several authors have recommended that standing and sitting lateral radiographs be performed to evaluate spinopelvic balance [13,15,18,19].

Regarding 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 [20–22].

Patient-specific planning seems to be a key factor in reaching the optimal implant positioning; however, it is essential that it is accurately delivered intraoperatively. The literature reports a mismatch between preoperative planning and the positioning of final components, ranging from 20% to 40% of cases [23–25].

The Optimized Positioning System (OPS™, Corin Ltd., Cirencester, UK) is a recent system that provides preoperative planning with patient-specific component alignment using computed dynamic analysis. The functional analysis is based on imaging studies, and 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 optimize the implant positioning and the functional orientation of components according to the patient's spinopelvic mobility and anatomy, with the goal being 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 when replicating 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. The exclusion criteria applied were as follows: previous hip surgery, hip ankylosis, contralateral hip prosthesis and the inability to sit or stand during the radiographic study, and 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 schedule. The preoperative planning included the following: 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. Using the functional X-ray images, the 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 by evaluating the contact patch paths that were 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 referred to as the coronal plane when the subject was supine. Planning also included the level of the osteotomy, the stem type, position and size, and the estimated change in the leg length and offset compared to the pre-operative state (Figure 1). 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, the acetabular and femoral 3D-printed PSI guides were delivered.

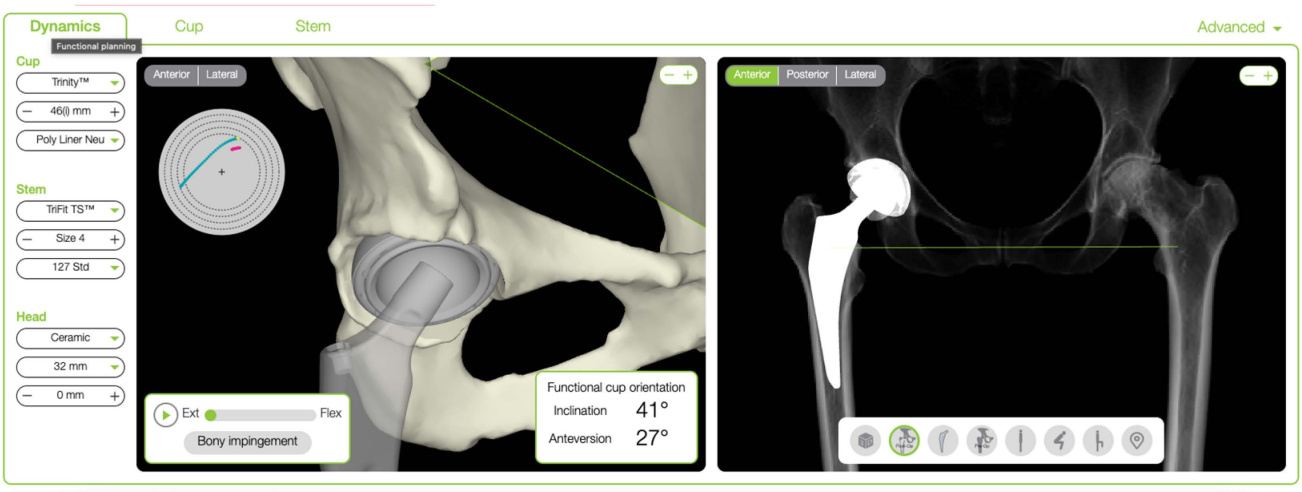

Figure 1. Web interface for pre-operative planning approval.

All participants gave informed consent to their inclusion in the study, which was approved by the University's Ethics Committee.

2.1. *Surgical Technique*

The procedures were performed using, in the lateral decubitus position, the direct lateral surgical approach. The femoral and acetabular PSI guides were placed according to the OPS™ (Corin Ltd., Cirencester, UK) technique. The femoral and acetabular exposure was performed according to standard practice: The femoral PSI guide was fit on the femur, and the osteotomy cut was then performed as planned (Figure 2). Once the acetabulum was exposed, the acetabular PSI guide was fitted inside (Figure 3). A laser was attached to the guide using a proper handle. A reference pin with an articulated laser pointer on the top was placed on the superior edge of the acetabulum. Both lasers were converged on the wall of the surgery room (Figure 4). The acetabular PSI and the corresponding laser were then removed. A new laser was adapted to the back side of the acetabular reamer. Reaming was guided by manually ensuring the coincidence of the projected lights (reference laser and acetabular reamer laser) in all phases of the procedure. Using the same method, a laser was also adapted to the top of the impaction handle. After positioning the cup, the reference pin was removed.

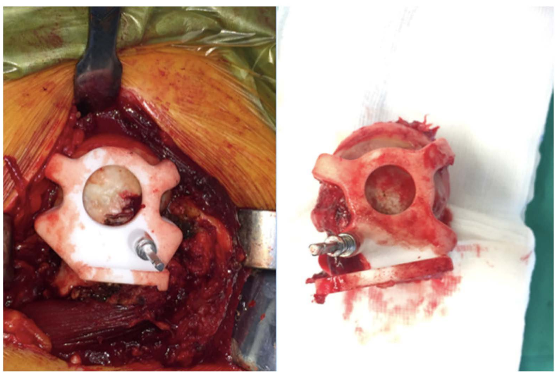

Figure 2. Femoral PSI guide positioning and femoral neck osteotomy.

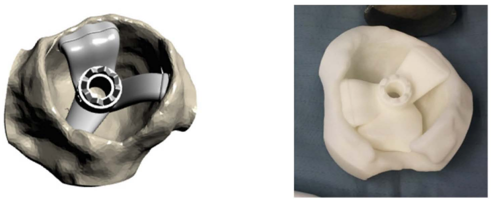

Figure 3. Acetabula PSI guide.

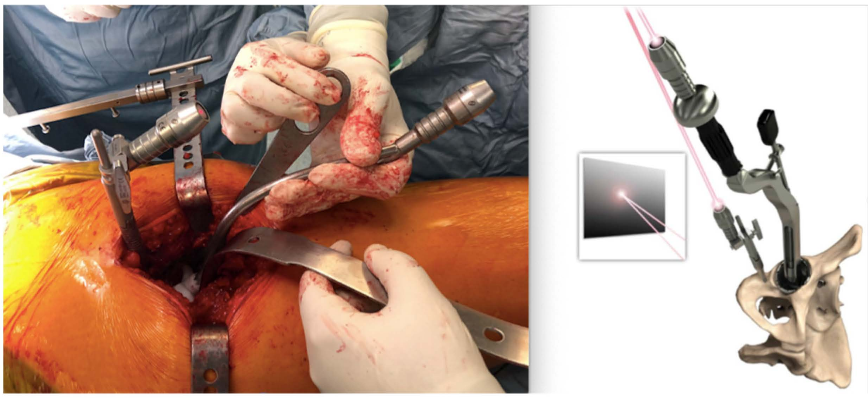

Figure 4. Laser on the supra-acetabular pin was made to converge with the acetabular PSI guide laser.

Femoral broaching was then performed according to the preoperative plan. The final implant of the stem was performed using the manual conventional instrumentation. The 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.).

2.2. Postoperative CT Evaluation

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

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

The surgical time and complications rate were also recorded for each procedure.

2.3. Clinical Outcomes Measures

Two different questionnaires, the Forgotten Joint Score (FJS) [26] and The Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) [27], were applied to the patients to evaluate the clinical outcomes 6 months after surgery.

2.4. 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 using the Shapiro–Francia test. For the variables whose distribution was normal, 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

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 showed no statistically significant difference when the planned and achieved values were compared (Table 1).

Table 1. 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 (1–3 mm)	3.1 mm (2–5 mm)	0.098

The mean planned and postoperative cup anteversion values were, 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 deviations from the planned inclination and anteversion were 4.3° and 3.8°, respectively.

The postoperative inclination and anteversion were, respectively, within ±5° from the planned values in 78% and 81% of cases; meanwhile, a deviation within ±10° was detected in 98% and 97% of cases (Table 2).

Table 2. Cup orientation results, 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, which 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 mean surgical time was 68.6 min in the PSI group and 61.5 min in the conventional THA group.

The results are summarized in Table 3.

Table 3. Femoral anc hip results, deviation from the planned cup values.

	Absolute Deviation, Mean (Range)	% Within ±2 mm (n)	% Within ±4 mm (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 the cases.

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

The mean Clinical Outcome scores, rated with the WOMAC and FJF score, were 92 (80 to 98) and 90 (76 to 96), respectively, at the last follow-up.

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.

Regarding the patient who suffered THA dislocation, the radiological findings showed that this was due to the 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.

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.

4. Discussion

This study demonstrates that the OPS™ PSI guides and the related laser-guided technique offer surgeons preoperative planning by considering spinopelvic relationships, providing information about the size and orientation of implant components, the femoral osteotomy height and the variation in offset and limb length. The authors found that the planning was reproducible and accurate in the surgery room, with an acceptable percentage of discrepancies from planning.

The component positioning in THA when using the dynamic function setting has been widely investigated, as it plays a significant role in implant stability and survival [12,22,28,29].

The literature sustains that the individual lumbopelvic sagittal kinematics affect the cup alignment functionality in daily life activities [16,30,31]. The pelvic tilt may vary according to the patient position (supine, standing or sitting), and this leads to functional effects on acetabular anteversion and inclination [12,29,32].

When the pelvis rotates posteriorly, the acetabular functional anteversion increases in order to prevent posterior dislocation and edge loading during hip flexion, even if it can lead to posterior impingement and anterior instability during extension [29]; meanwhile, during anterior pelvis rotation, the functional anteversion decreases, thus preventing anterior dislocation and edge loading during hip extension (but not in flexion) [11,15,33].

However, there is wide interindividual variability, as the pelvic range of motion varies from 70° to 5° in stiffer patients [11,32]. If lumbopelvic stiffness occurs, it affects the sagittal kinematics; therefore, a stiff spine can lead to insufficient pelvic retroversion while sitting and excessive pelvic anteversion in the standing position. Moreover, this condition promotes the occurrence of some complications: impingement, edge loading and prosthetic implant instability. The presented conditions suggest that Lewinnek's safe zone may not be suitable for all patients and that the prosthetic implant may not be in the safest position during more functionally relevant postures [14,15,34].

As a result, more and more surgeons are shifting away from using conventional implantation techniques for THA and are starting to adopt kinematic techniques that consider the dynamic spinopelvic relationships [34,35]. The literature regarding acetabular cup placement is quite extensive, while there are limited data on the femoral stem position [15,19,22]. The recent literature agrees regarding 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 [21,36].

The planning also needs to be properly reproduced in the surgery room. The main errors and malposition of components mainly derive from incorrect patient positioning, intraoperative pelvic motion, and the manual mistakes of the surgeon during surgery [37]. To better achieve the planned target, several techniques have been proposed, including computer navigation, robotic surgery, and patient-specific instrumentation (PSI). While navigation and robotics have limited use because of their high costs, increased surgical time and other logistical issues [38,39], PSI is gaining more and more prominence.

The Optimized Positioning System™ (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 in order to restore most of the hip anatomy through 3D planning and PSI [19,40,41].

Spencer et al. [19] evaluated the same PSI navigation system as the authors of this study, and analyzed the use of THA on 100 patients, showing a good level of accuracy;

they reported mean absolute deviations from the planned patient-specific inclination and anteversion of 3.9° and 3.6°, respectively. Their results did not differ significantly from those presented in this study (see Table 3).

For 98% of all cases, the anteversion and inclination values were within the traditional safe zone described by Lewinnek [7]. 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 experienced no major complications and they presented good clinical results at the 6-month follow-up.

Although navigation systems seem to guarantee the more accurate positioning of prosthetic components, a 2% dislocation rate still exists. A percentage of dislocation between 54–58% exists for prosthetic components within the Lewinnek safe zone [7,9,42,43].

The literature points out that a mismatch between the preoperative and final position of the femoral prosthesis occurs in 40% of cases [23]. A leg length discrepancy of more than 2 cm can lead to complications such as back pain, an increased risk of joint dislocation, and sciatic nerve palsy [44], which affect approximately 25% of patients undergoing THA surgery [45]. In the present series, the mean increase in leg length after surgery was 2.5 mm (range of 1 to 7 mm), with a divergence from planning of 1.6 mm; no patients reported dysmetria.

Among the limitations of the use of the OPS technique, the authors want 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 severe bilateral hip arthritis and stiffness may affect the reliability of the preoperative planning, because it is difficult to obtain valid preoperative images (especially for the flexed seated position). Moreover, the OPS technique is more expensive economically than the standard; however, its benefits may be greater in the long term because the rate of complications related to THA malposition can be reduced. Furthermore, the acetabular reaming depth is still determined by the surgeon and depends significantly on the experience of the surgeon; this includes the fore femoral stem version, which is not guided by PSI instrumentation.

The limitations of this study are as follows: there is no comparison between the accuracy of the component positioning in the group undergoing THA and that of the standard technique; there was not a control group; and the follow-up was not always adequate.

5. Conclusions

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

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Informed Consent Statement: Written informed consent has been obtained from the patients to publish this paper.

Data Availability Statement: All data are collected and available in the Orthopaedic Unit of Sant'Andrea Hospital of Rome.

Conflicts of Interest: The authors declare no conflict of interest.

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