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A new technology-assisted orthopaedic surgery to reduce the risk of dislocation in Total Hip Arthroplasty

Settore Scientifico Disciplinare *MED/33*

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Summary

Appropriate component alignment is critical for improving stability after Total Hip Arthroplasty. Due to the large variation in patient kinematics during functional activities, current technologies lack definition of what constitutes correct target alignment. Apparently, well-orientated components on standard radiographs can still fail due to "functional" component malalignment. Evidently, previously defined "safe zones" are not appropriate for all patients, as they do not consider the dynamic behaviour of the hip joint. Aim of this project is to valuate and develop a new technology-assisted orthopaedic surgery device to preform preoperative planning based on a patient-specific dynamic analysis, and patient-specific instrumentation for delivery of the target component alignment of the cup to reduce the risk of dislocation in patients with spinopelvic imbalance who undergo a Total Hip Arthroplasty.

Introduction

Dislocation after total hip arthroplasty (THA) is a relatively infrequent, yet frustrating, complication. After aseptic loosening, it is the second most common major complication of THA, and after Periprosthetic Joint Infection and aseptic loosening is the third major cause of revision THA[1].

The reported incidence of postoperative dislocation[2] varies widely from less than 1 % to nearly 10%, with most studies[2-3] of primary THA reporting an incidence of 0.2% to 7%.

Postoperative dislocation in THA may occur in a posterior, anterior, or superior direction. Although the majority of dislocations occur posteriorly, the type of

surgical approach directly influences the direction of dislocation. In a review of 10500 THA, Woo and Morrey[4] observed that after a posterior surgical approach, 77% of dislocations occurred posteriorly; 20%, superiorly; and 3%, anteriorly. When an anterior approach was used, 46% of dislocations occurred anteriorly; 46%, posteriorly; and 8%, superiorly.

The majority of initial dislocations occur early, with approximately 60% to 70% reported within the first 8 to 12 weeks following the operative procedure[5-7]. Patients suffering an initial dislocation after this early period are at greater risk of experiencing recurrent dislocation. The risk of recurrent dislocation is highly variable, with two large series[8-9] showing an incidence of approximately 33%.

Component malposition has long been recognized as a critical risk factor in the dislocation of THA[10-12]. In 1978, Lewinnek et al.[13] determined the "safe zone" of acetabular component position in 40°±10° of abduction and 15°±10° of anteversion. They reported a statistically lower incidence of dislocation (1.5%) when the acetabular component was positioned within the safe zone, compared with a 6% dislocation rate when the acetabular component was oriented outside this range ($p < 0.05$). Over the last 4 decades, this concept has been referred to as the "Lewinnek safe zone" for cup placement in total hip arthroplasty. The article has been cited in close to 2000 publications in the English language. However, despite the cup was positioned in this "safe zone", THAs yet dislocate.

Recent searches have identified that the acetabulum changes from a closed position over the femoral head while standing to an open position as the pelvis tilts posteriorly with sitting. This functional acetabular reality reduces the reliance on a static operative coronal position (Lewinnek zone). Several studies have recently studied the effect of pelvic motion on cup positioning showing an increased occurrence of dislocation of THA related to the resultant limited change

in the orientation of pelvic tilt because of stiff arthritic spines or spinal pelvic fusion[14-15]. The concept of spinopelvic imbalance (SPI) has begun to take hold. Hip arthroplasty surgeons have come to recognize that the cup position obtained at surgery, even if it were within the Lewinnek safe zone, might not be satisfactory for functional spatial cup positioning during postural change to prevent impingement or dislocation[15-16].

In high-volume hospitals, among patients with spinopelvic imbalance, the prevalence of concurrent THA is 4.6%, and among primary THA patients, the prevalence of concurrent spinopelvic imbalance[15] is 0.1%. Bedard et al.[15] reported an alarmingly high THA dislocation rate among THA patients with concurrent spinopelvic fusion at their institution (20%) and within a large national database (8.3%)[17-18].

Aims of the study

First goal of this study was to evaluate the incidence of SPI in patients who undergo THA in high-volume hospital and if an anterior approach, the Anterior-based Muscle Sparing Approach (ABMS), could be related to a low risk of dislocation in these patients.

Secondly, we wanted to evaluate if a new technology-assisted orthopaedic device to perform ABMS approach THAs in patients with SPI could reduce the incidence of dislocation to zero.

Materials and Methods

We retrospectively evaluated primary THAs performed from January 2015 to January 2019 at our Orthopaedic Clinic.

All THAs included in the study were performed with the ABMS approach in supine position. The ABMS approach is a minimally invasive anterior hip approach, which utilized the intermuscular plane between the tensor fasciae latae (TFL) and the gluteus medius (GM) muscles, without incising or detaching muscles and tendons. We perform this approach in supine position with both legs draped sterile into the operative field.

With a preliminary telephone history collection, we detected patients with spinopelvic imbalance. Therefore, during the history collection, patients have been asked for a normal, hypermobile, stiff, stuck standing, stuck sitting and fused spine. Patients with arthrodesis, thoracic iper-kyphosis, lumbar fusion, spondylolisthesis or spondylolysis, multiple slipped discs, have been enrolled in the study. These patients underwent a radiographic study to confirm spinopelvic imbalance measuring the spinopelvic parameters.

As part of the usual follow-up, these patients received a free orthopaedic visit on the day of the radiographic study. In agreement with the Radiology Service of our Department, two radiographic sessions per week are performed, including 6-8 patients.

The radiographic study consisted of a Pelvis antero-posterior (AP) projection in standing position to evaluate the cup inclination and an operated hip cross-table lateral projection to evaluate the cup version (Figures 1 and 2). A Lumbar lateral standing and upright-seated functional projections were then performed to evaluate the spinopelvic parameters: Sacral slope (SS), pelvic rotation, ante-inclination (AI), pelvic femoral angle (PFA) and the Combined Sagittal Index (CSI). Pelvic Rotation is defined as the pelvic tilt change from standing to sitting position and is measured as the difference in SS. Sacral Slope is the angle between the line along the S1 end plate and the reference horizontal line. Ante-Inclination is the angle between a line

from anterior and posterior cup edges and a horizontal reference line. Pelvic Femoral Angle is the angle centered at femoral head, between mid-sacral base and down femoral shaft. Combined Sagittal Index is the sum of the cup AI and the PFA, measured in both the standing and the sitting position. It represents the functional angle of the hip (the anterior hinge) and may predict impingement and dislocation. (Figure 3).

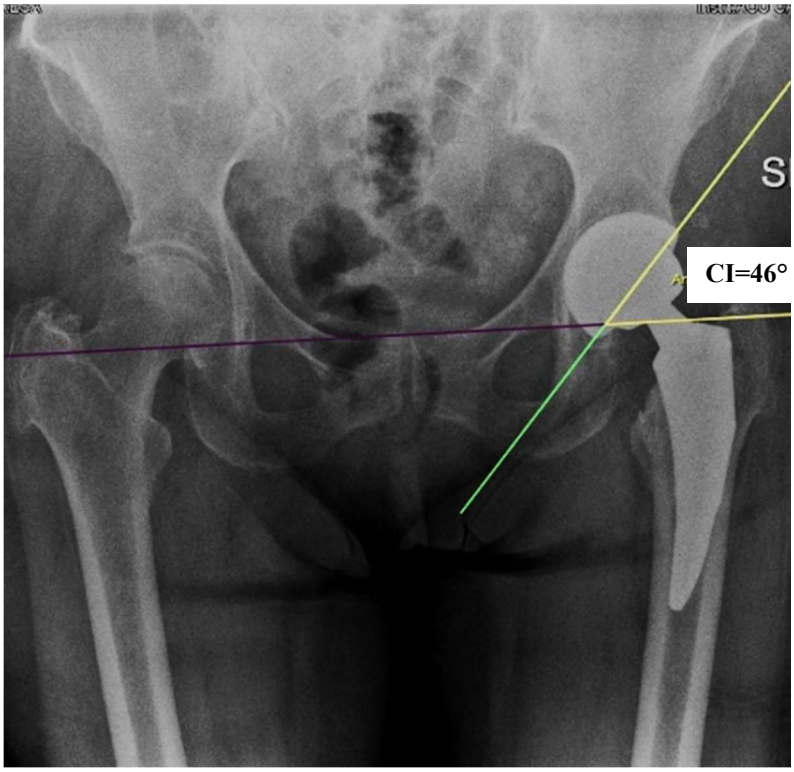


Figure 1 *Cup Inclination (CI): on pelvis AP projection, the angle between the interteardrop line and the edges of the cup*

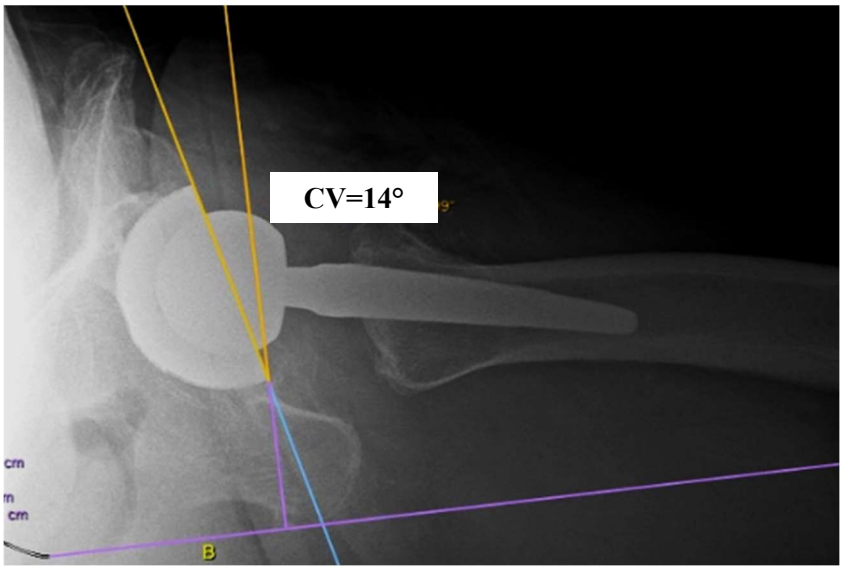


Figure 2 *Cup Version (CV): on cross-table lateral projection, the angle between the line touching the opening surface of the acetabular component and a line perpendicularly drawn to sciatic tuberosity tangent*

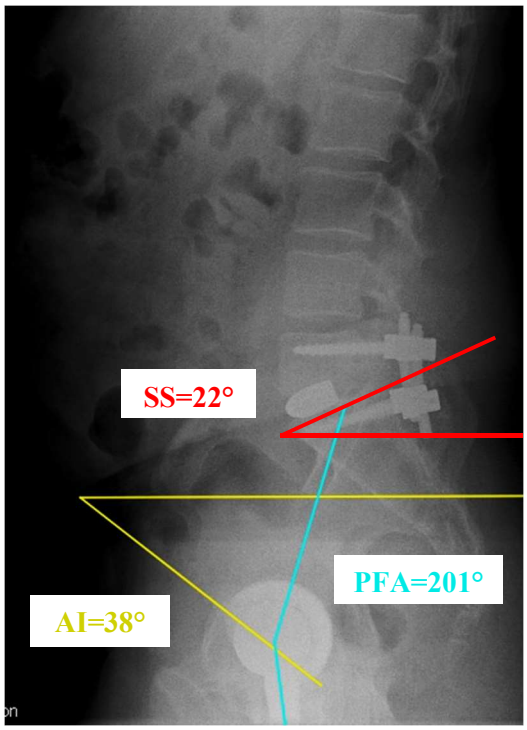


Figure 3 *Ante Inclination (AI), Pelvic Femural Angle (PFA), Sacral Slope (SS).*

According to the normal range of spine-pelvis-hip unit measurements as defined in table 1, spinopelvic imbalance and the risk for posterior impingement and anterior dislocation was defined as a Standing SS < 29°, standing PFA > 196° or CSI > 234°; the risk for anterior impingement and posterior dislocation was defined as Pelvic rotation (SS Δ) < 10°, Sitting PFA < 110° or Sitting CSI < 161°.

When spinopelvic imbalance has been confirmed with these parameters and patients divided into the "Anterior dislocation risk" group and "Posterior dislocation risk" group, the event "dislocation" has been investigated and the dislocation rate in these 2 groups reported.

	Range (°)		
	Standing	Sitting	Standing to Sitting Position (Δ)
SS	30-50	11-29	11-29
PFA	165-195	110-140	51-69
AI	25-45	41-63	
CSI	203-233	162-198	

Table 1 *Range of normal spino-pelvic measurements*

To evaluate the new technology device, 20 patients were recruited from December 2020 to January 2022.

Patients features to be eligible: unilateral primary or secondary hip osteoarthritis and spinopelvic imbalance.

Patients were recruited during the institutional outpatient clinic activities of the Orthopaedic Operative Unit and placed on the waiting operating lists. The standard prehospitalization protocol of the Hospital was applied.

For each patient the Optimized Positioning System (OPS™) Technology imaging protocol was organized according with the Radiology service.

OPS™ (Corin Group, The Corinium Centre, Cirencester Gloucestershire, GL7 1YJ) is a state-of-the-art technology platform that identifies a target orientation of the acetabulum unique to each individual. These target orientations are calculated from a dynamic pre-operative functional simulation, which accounts for the patient's physiological profile of pelvic motion throughout a range of daily activities.

Once the target orientation for a specific patient has been decided, a unique acetabular guide is produced for the individual. The planned orientation is built into the axis of the guide that is used intraoperatively with a simple laser system to allow the surgeon to deliver on the planned cup orientation.

The femoral neck resection can be accurately controlled by utilising the OPS™ femoral osteotomy guide. Once the target osteotomy plane has been identified using pre-operative three-dimensional templating software, a unique, patient specific 3D printed guide is created. The OPS™ femoral osteotomy guide incorporates an open capture system that controls the resection, allowing the surgeon to precisely recreate the pre-operative femoral plan.

OPS™ uses patient specific CT scans and functional X-Rays as critical inputs to deliver dynamic and functional hip analysis solutions for THA patients.

This hip CT scanning and X-Ray protocol consists of several requirements for obtaining specific static and functional images of patients. The CT scan is required to develop accurate models of the patient's bone geometry for analysis

and design of patient specific instrumentation (Table 2). Functional X-Rays are used to determine the patient's centre of gravity and the position of the pelvis and femur when the patient is in different positions. Compared to the x-ray protocol in the first part of the study, this protocol included two additional projections, flexed-seated and step-up, to complete the dynamic functional hip analysis.

Patient position	**Image acquisition**	**Slice increment/thickness**	**Field of view**	**Other parameters**
Instruct the patient to hold completely still during the scan	Single pass, bilateral CT scan through the entire pelvis, both knees and both ankles	Pelvis required at a slice increment and thickness of 2.0mm (1.25-2.0mm acceptable)	Use the smallest Field of View (FOV) possible to capture the required bone regions	Pixel Matrix: 512x512
Patient supine, with both legs fully extended and parallel to the horizontal plane	All image data must be in the same global coordinate system	Knees and Ankles required at a slice increment and thickness of 2.0mm (2.0-2.5mm acceptable)	Capturing all of the soft tissue is not necessary Use the same FOV for all slices	Recommended current and voltage: 100-400mA 120-140kV
Feet positioned shoulder-width apart, in a comfortable, natural and unforced position	Any smoothing or metal artefact reducing algorithms must be applied to improve bone delineation	Contiguous slices required, no overlap or gaps		Dose: 2.8-4.0 mSv per scan (low dose)
Do not put anything between the patient's legs or tie them together	Any scout images obtained (AP and/or lateral) should be provided to Corin			
Do not place a sponge or pillow beneath the knees or ankles				
Do not raise/lower the CT table between scans				
Do not alter X and Y centring between scans				

Table 2. *CT protocol*

Every patient signed an informed consent for the surgery and for the imaging protocol.

The CT scans and the x-rays has been sent, via a dedicated web portal, to a team of engineers who work in a CORIN center in the Unit Kingdom or Australia.

After 1-2 weeks the engineers in the same web portal sent back a report (Figure 4).

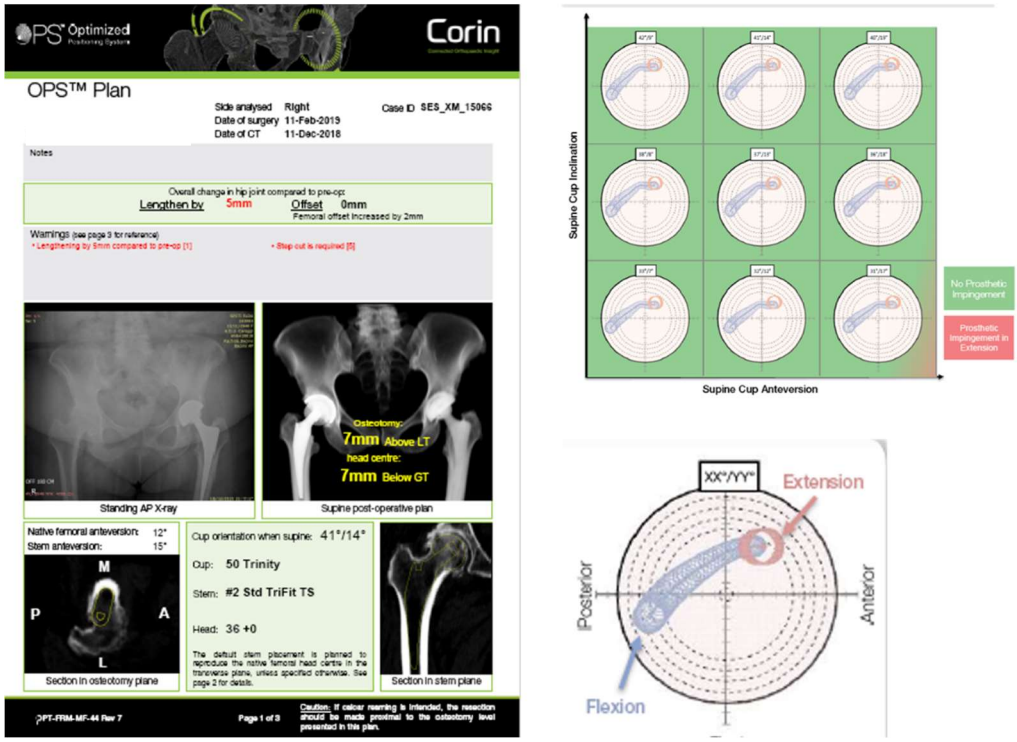


Figure 4. *The OPS™ report contains the planned size of the implant which best fit with the CT reconstructed anatomy of the patient, the leg length discrepancy correction and the level of femur neck osteotomy, a graphic with a series of combination of inclination/version of the cup and the relative risk of impingement and edge loading planned in the functional x-rays.*

The surgeon checked the report and confirmed the planning.

When the 3D printed guides were created, usually in about 2-3 weeks, patients were scheduled for the surgery.

All procedures has been performed or supervised by two adult reconstruction trained orthopaedic surgeons using a cementless acetabular component (Trinity®,

CORIN), with a cementless stem (TriFit®, CORIN). A ceramic on Vitamin E-stabilized UHMWPE coupling was used.

In all cases an ABMS approach in supine position was performed.

Surgical technique

Once the proximal femur is exposed, without dislocating the hip, the femoral guide is applied to perform the in-situ osteotomy.

A pelvic screw is assembled onto a T-handle inserter and placed either around the acetabulum within the incision or percutaneously in the iliac crest.

The guide is placed into the acetabular model after a meticulous removal of the fat pad and remnants of the ligamentum teres from the acetabular fossa, ensuring the thin layer of cartilage is removed from the fossa lip. A laser canister is attached to the end of the curved guide handle and the guide is firmly held in place, the curved guide handle is slide into the guide.

A laser canister is attached onto the adjustable clamp and the pelvic laser is aligned to converge with the acetabular guide laser as projected on the ceiling or wall and secured with dial.

When acetabulum is reamed, a laser canister is connected to a magnetic adaptor attached to the end of the cup introducer. The cup is placed in the acetabulum and the orientation is adjusted until the laser converges with the pelvic laser on the ceiling or wall. After removal of the magnetic adaptor from the end of the introducer and the cup is impacted. The correct orientation is confirmed during and at the end of impaction.

The rest of surgery proceeds conventionally.

The primary outcome was to have a short-term (8 weeks) dislocation rate inferior to that recorded in the first part of the study, when OPS™ technology had not been used. Patients were clinically followed-up at 1, 2, 3 and 6 months after surgery and underwent a Pelvis AP radiograph the first and sixth month post-operative.

The second outcome was to restore the planned orientation of the cup using the OPS™ technology and verify the accuracy of the system. Therefore, the first day post-operative a CT scan was performed to confirm the correct position of the implant.

Results

Six hundred forty-three (643) ABMS-primary THAs were performed from January 2015 to January 2019 at our Institution.

After the preliminary telephone history collection, only ninety-one (91) were eligible for the radiographic study.

Spinopelvic imbalance was radiographically confirmed in seventy-five (75) patients (33 men, 42 women). Forty-six (46) patients (61.3%) were in the "Posterior dislocation risk" group and 29 patients (38.7%) were in the "Anterior dislocation risk" group.

In the "Posterior" group and in the "Anterior" group, we found respectively, none and two (2) dislocations (6.9%). In Table 3, spinopelvic measurements relative to the 2 cases of anterior dislocation are reported.

The incidence of spinopelvic imbalance in patients who underwent a THA was 11.6 % at our Institution and the overall dislocation rate in these patients was 2.7% with a mean dislocation time from surgery of 9.2 weeks.

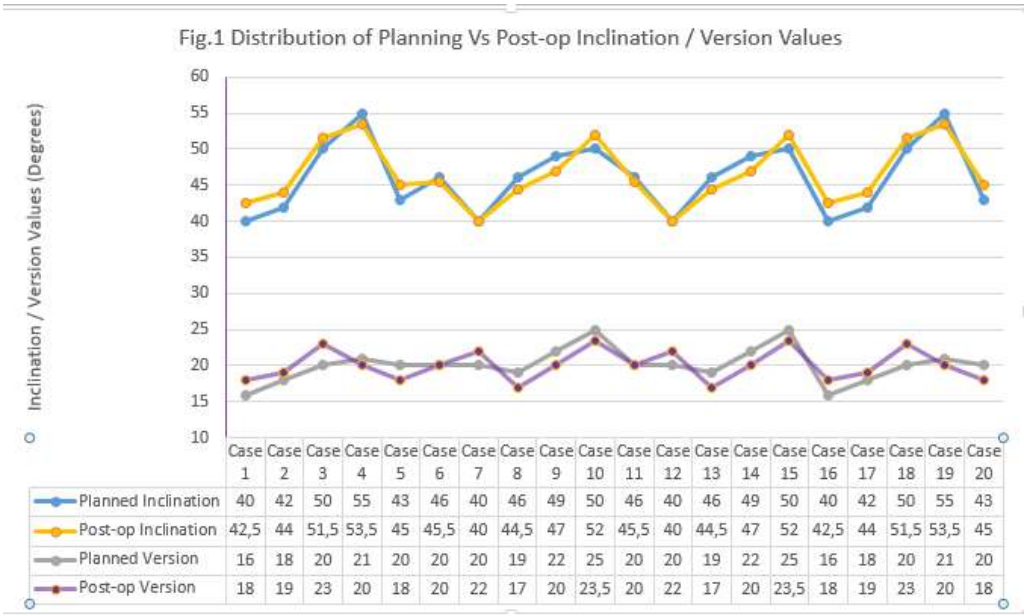
Twenty (20) ABMS-primary THAs with OPS™ technology were performed from December 2020 to January 2022 at our Institution.

We reported no dislocation and a mean ± 2.1° standard deviation (SD) cup inclination/version from the planned position (Fig. 5).

PFA			**AI**		**CSI**		**SS**		
Stand	Sit	Δ	Stand	Sit	Stand	Sit	Stand	Sit	Δ
201†	109†	92†	36	40†	237†	149†	**19†**	17	**2†**

PFA			**AI**		**CSI**		**SS**		
Stand	Sit	Δ	Stand	Sit	Stand	Sit	Stand	Sit	Δ
211†	125	86†	47†	45	**258†**	170	**28†**	25	**3†**

Table 3 *Case 1 and 2: Anterior dislocation. Standing SS were fixed in a posterior direction and there is a pathological decreased motion from Standing to sitting position. Standing PFA and Standing CSI were over range, identifying a hyper-extended femur compensating for spino-pelvic motion decrease. This has led to a posterior impingement and anterior dislocation. "†" means for abnormal values.*



	Case 1	Case 2	Case 3	Case 4	Case 5	Case 6	Case 7	Case 8	Case 9	Case 10	Case 11	Case 12	Case 13	Case 14	Case 15	Case 16	Case 17	Case 18	Case 19	Case 20
Planned Inclination	40	42	50	55	43	46	40	46	49	50	46	40	46	49	50	40	42	50	55	43
Post-op Inclination	42,5	44	51,5	53,5	45	45,5	40	44,5	47	52	45,5	40	44,5	47	52	42,5	44	51,5	53,5	45
Planned Version	16	18	20	21	20	20	20	19	22	25	20	20	19	22	25	16	18	20	21	20
Post-op Version	18	19	23	20	18	20	22	17	20	23,5	20	22	17	20	23,5	18	19	23	20	18

Figure 5. *Distribution of Planning Vs Post-op Inclination / Version Values*

Discussion

Component malposition has long been recognized as a critical risk factor in the dislocation of THA[10-12]. However, whereas some investigators have found no differences in the incidence of dislocation among the various surgical approaches[8], these influence the risk of dislocation too, most studies suggesting a higher risk of dislocation with use of the posterolateral approach[12, 19]. The percentage of dislocation increased even more when a concurrent spinopelvic imbalance exist[20-23]. We reported an 11.6 % incidence of spinopelvic imbalance in patients who underwent a THA at our Institution with a 2.7% overall dislocation rate with a mean dislocation time from surgery of 9.2 weeks. This low risk of dislocation is related to the use of the ABMS Approach to perform the THAs. This approach is a protective factor for posterior dislocation; the two reported anterior dislocations in the study were linked to “relative” cup malposition due to patients with spinopelvic imbalance. Excluding a priori a bias related to the

surgical technique in the first phase of the study, we subsequently used the OPS™ device to perform with the same approach THAs in patients with SPI and evaluate if the eventual reduction of dislocation depends exclusively on OPS™. We reported a 0% rate of dislocation.

The limited precision, with which a defined target alignment can be achieved intraoperatively, without assistive technologies, has been widely published[24-26]. Whether aiming for a generic or patient-specific target, the challenge remains for surgeons to introduce the component in the desired position intra-operatively. Historically, values > 10° outside of the planned orientation for inclination and anteversion have been considered outliers. Traditional free hand techniques are inaccurate, with reported rates of successfully achieving target ranges for both inclination and anteversion as low as 20%, and at, or near, 50%, in two separate large studies[24-25, 27-28]. There is evidence of improved accuracy and fewer outliers when conventional computer navigation or robotic assisted surgery are used, but with the introduction of added time and cost[29-31]. The limited acceptance of these assistive technologies is likely due to the poor definition of what constitutes the correct target alignment for an individual. As reported above, hip kinematics are specific to each individual and change the functional alignment of the components[32]. Consequently, component alignment should be planned individually, using dynamic information, if we want to optimise to reduce failure. A medical device for patient-specific preoperative planning, intraoperative delivery and postoperative analysis in THA, should allow achieving this target. Furthermore, the development of 3D printing technology and image based patient-specific guides in total joint arthroplasty offers the surgeon improved accuracy without the burden of time associated with conventional computer-assisted navigation or robotic surgery.

OPS™ technology allowed reaching all these targets. We reported no dislocation and a mean ± 2.1° standard deviation (SD) cup inclination/version from the planned position.

Some limitations has to be considered. The number of treated cases is small; however, the incidence of SPI in patients who undergo THA is low too.

Another limitation could be the absence of a control group with other approaches in this kind of patients; nevertheless, literature has largely demonstrated the most safety of anterior approaches compared to posterior or direct lateral.

Conclusion

ABMS approach is a protective approach for posterior dislocation in patients with spinopelvic imbalance who undergo THA. To reduce the risk of anterior dislocation, the OPS™ technology is a safe, accurate and smart device to be used.

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