

## Clinical outcomes of modified direct lateral approach of Hardinge for total hip arthroplasty

B. OBADA<sup>1,2</sup>, D.-M. ILIESCU<sup>3</sup>, I.-A. POPESCU<sup>4</sup>, L.C. PETCU<sup>2</sup>, M.G. ILIESCU<sup>2,5</sup>, V.-A. GEORGEANU<sup>6,7</sup>

<sup>1</sup>Orthopaedic Traumatology Department, Emergency Clinical County Hospital, Constanta, Romania; <sup>2</sup>Faculty of Medicine, "Ovidius" University of Constanta, Romania; <sup>3</sup>Department of Anatomy, Faculty of Medicine, "Ovidius" University of Constanta, Constanta, Romania; <sup>4</sup>Romanian Shoulder Institute, Ortopedicum – Orthopaedic Surgery & Sports Clinic, Bucharest, Romania; <sup>5</sup>Balneal and Rehabilitation Sanatorium Techirghiol, Romania; <sup>6</sup>Clinic of Orthopaedics and Trauma Surgery, "St. Pantelimon" Hospital, Bucharest, Romania; <sup>7</sup>University of Medicine and Pharmacy "Carol Davila", Bucharest, Romania.

Correspondence at: Bogdan Obada MD, Orthopaedic Traumatology Department, Emergency Clinical County Hospital, Tomis 145, Constanta, Romania, Phone 0040723209201, Email: bogdanobada@yahoo.com

**The aim of the study was to evaluate a modified direct lateral approach for total hip arthroplasty in terms of clinical and functional outcomes, rate of complications and hospitalization.**

We retrospectively reviewed the data of 526 patients with THA operated in our department between January 2017 and December 2021. Clinical examination, functional outcome and radiographic evaluation were performed during follow-up. Patients were evaluated at the following time points: preoperatively and postoperatively at 3 days, 6 weeks, 12 weeks and 1 year and we registered surgery related data, complications, Visual Analogue Scale pain score, Harris Hip Score, the Western Ontario McMaster Osteoarthritis Index. Low intraoperative blood loss, short operation time, short hospitalization, early mobilization of the patient and good range of motion imposed the modified direct lateral approach as a valuable procedure for the patients with THA. VAS score evaluated at 3 days and 6 weeks indicated a very good overall postoperative experience. The HHS and Womac scores were evaluated at 6 weeks, 12 weeks and 1 year and showed excellent results. Trendelenburg gait and abductor weakness, traditionally related with direct lateral approach, were not significant statistically and complete reversible. We registered a very low complication rates with good functional outcome. The modified direct lateral approach can lead to superior outcomes, improved quality of life, with reduced intra and postoperative complications rate.

**Keywords:** hip arthritis, total hip arthroplasty, direct lateral approach, outcomes.

### INTRODUCTION

Total hip arthroplasty (THA) is most often performed to relieve pain, restore function and improve quality of life for the patients who have advanced primary or secondary hip arthritis, avascular necrosis of the femoral head or femoral neck fractures. Coxarthrosis alone accounts 70% of elected THA cases<sup>1</sup>.

The surgical approach can directly influence the outcome of THA. There is currently no consensus on an optimal approach for total hip arthroplasty, each of them having advantages and disadvantages. Traditional surgical approaches in THA include anterior, anterolateral, direct lateral, transtrochanteric and posterior paths. A variety of minimally invasive approaches were lately developed including anterior, anterolateral and posterolateral. As data began to accumulate, it became apparent that length of incision was less important to surgical outcome than disruption

of muscles, impairment of soft tissue vascularization and preservation of bone<sup>2</sup>.

The aim of the study was to evaluate a modified direct lateral approach for total hip arthroplasty with regard to intraoperative blood loss, operative time, duration of hospital stay, quality of mobilization, clinical and functional outcomes and the rate of complications. We were particularly interest in the effect of approach on gait mechanics and abductor function.

### MATERIALS AND METHODS

This study was approved by the ethical committee of Emergency Clinical County Hospital "St Apostle Andrei" of Constanta, Romania and written informed consent was obtained from all the patients. We retrospectively reviewed the records of 526 patients with THA performed by 6 senior orthopedic surgeons between January 2017 and December 2021

in Orthopedics and Traumatology Clinic. Inclusion criteria were primary/secondary hip arthritis and direct lateral approach used in these cases. Exclusion criteria were femoral neck fractures, arthritis after acetabular fractures, bilateral hip arthroplasty, hip revision arthroplasty, prior hip surgery, dementia or other cognitive disorders. We did not exclude any patient based on body mass index.

The data collected for analysis were age, gender, associated pathology, diagnosis, prosthesis type, duration of hospitalization and postoperative complications (local hematoma, early and delayed periprosthetic joint infection, dislocations). We also recorded characteristics related to the surgery: incision length, surgery time, blood loss, postoperative transfusion needs and intraoperative complications (fractures, neurological and vascular lesions).

Cemented or uncemented (depending on age and bone condition) prosthesis were used. As cemented implant we used Zimmer Biomet ZCA App-Poly acetabular cup with 32mm CoCr head, Taperloc hip femoral stem and as uncemented implant we used Zimmer Trilogy acetabular system, 32mm liner Longevity crosslinked polyethylene with 32mm CoCr head, Taperloc porous coated stem.

Perioperatively, most of the patients received the same standard intravenous antibiotic prophylaxis. All the patients received prophylaxis of thromboembolism (enoxaparin sodium) for 6 weeks. Drainage was used for all the cases for 24 h. for all the operations. Blood management included administration of blood products or allogenic transfusion. For cemented prosthesis, antibiotic loaded cement was used.

Clinical examination, functional outcome and radiographic evaluation were performed during follow-up. Patients were evaluated at the following time points: preoperatively, postoperatively at 3 days, 6 weeks, 12 weeks and 1 year and we registered Visual Analogue Scale (VAS) pain score, Harris Hip Score (HHS), the Western Ontario McMaster Osteoarthritis Index (WOMAC), internal and external rotation of the hip and operated limb length compared with the opposite. Conventional antero-posterior pelvis and cross table lateral radiographic projections were obtained pre-operative, postoperative, at 6 weeks and at 12 months.

The hip range of motion was determined in the standard manner using an universal goniometer. Special attention was paid to internal/external rotation that were measured with the patient in the seated position, with the hip and knee flexed 90°. These hip motions, especially in the extremes are traditionally related to

hip dislocation in the early postoperative period, so is very important to gain them without additional risks.

The patient was placed in supine position on the radiotransparent operating table under spinal anesthesia. A lateral incision gently curved posteriorly was made centering on trochanter. Fascia lata was incised in line with the skin incision; anterior and posterior borders of the gluteus medius and the vastus lateralis were evidenced. Blunt dissection was used to split the anterior third of the gluteus medius in the direction of the muscle fibre at 45° to the skin incision. We used a Kocher clamp as a marker between anterior fibers of gluteus medius and joint capsule to be sure that we limit dissection of the muscle anteriorly to minimum necessary. (Fig.1) The split was not extended more than 3 cm proximal to the trochanter to avoid inferior branch of the superior gluteal nerve. Blunt dissection continued distally through the anterior part of the vastus lateralis for about 3 cm. In that way, a large posterior 2/3 of gluteus medius remains undisturbed at its point of insertion on the greater trochanter. After elevating this anterior flap, the patient's leg was externally rotated to visualize the entire capsule, capsulotomy was performed, and the hip was dislocated. Acetabular and femoral preparation was conducted in a conventional manner. Careful closure of the muscular layers is very important. The gluteus medius and vastus lateralis are repaired to the tendinous cuff on the anterior aspect of the greater trochanter. Acetabular and femoral component positioning was made under fluoroscopy. The most important aspect of this approach is that the gluteus medius was left almost intact according to Pai et al.<sup>3</sup>

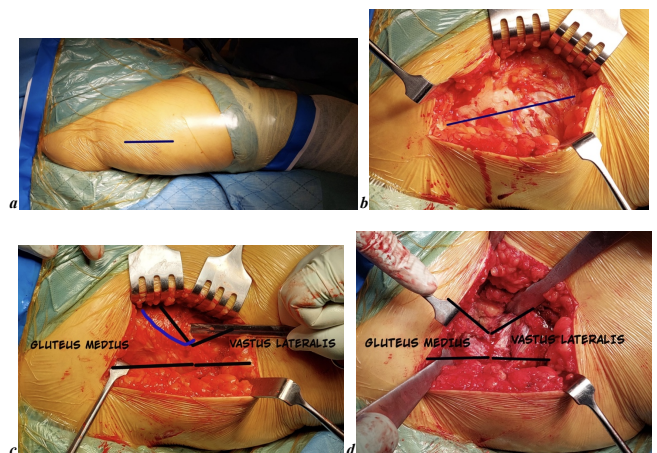


Fig. 1. — Surgical technique: incision of the skin (a) and fascia lata (b), limited dissection (blue line) of the anterior part of the gluteus medius using a Kocher clamp as a mark between it and capsule (c), then placement of the retractors for capsulotomy (d).

**Table I.** — Demographic data

Age	Min	Max	Mean	Std. deviation
	30	86	63.84	9.765
<b>Gender</b>	<b>N=526</b>		<b>Percent (%)</b>	
Male	275		52.3	
Female	251		47.7	
<b>Associated pathology</b>				
Diabetes	67		12.7	
High blood pressure	336		63.9	
Obesity	92		17.5	
Heart diseases	197		37.5	
<b>Diagnosis</b>				
Femoral head necrosis	42		8	
Hip arthritis	484		92	
<b>Prosthesis type</b>				
Cemented	226		43	
Noncemented	300		57	
<b>Complications</b>				
Iatrogenic femur fracture	2		0.4	
Deep hematoma	9		1.7	
Thrombophlebitis	2		0.4	
Pulmonary thromboembolism	3		0.6	
Dislocation of prosthesis	2		0.4	
Late periprosthetic fracture	3		0.6	
Heterotopic ossification	6		1.1	
Prosthesis loosening	3		0.6	
Deep infection	3		0.6	
Limb lengthening	9		1.7	
Trendelenburg gait preoperative	18		3.4	
Trendelenburg gait at 3 days	43		8.2	
Trendelenburg gait at 6 weeks	11		2.1	

The statistical analysis was performed using IBM SPSS statistics software version 25. Data are presented as mean  $\pm$  standard deviation (SD) for continuous variables, or as percentages for categorical variables. An ANOVA Test with repeated measures was used to see changes to the intervention. The normality of the test variables was estimated with Kolmogorov-Smirnov Tests of Normality. Sphericity was tested with Mauchly's test. If sphericity is violated ( $p < 0.05$ ), the Greenhouse-Geisser, Huynh-Feldt and lower bound methods are used to correct the within-subjects tests. Post hoc analysis with a Bonferroni adjustment for multiple comparisons was used to discover which specific mean values differed. The McNemar test was used to determine if there are differences on a dichotomous dependent variable between two related groups. The significance level  $\alpha$  was set at 0.05.

## RESULTS

Our study included 526 patients with the age ranged between 30 and 86 years and a mean age of 63.84 years ( $\pm 9.765$  standard deviation). From these group 275 patients were male (52.3%) and 251 were female (47.7%). The most frequent diagnosis was idiopathic hip arthritis (92%), followed by femoral head necrosis (8%). As associated disease we recorded high blood pressure (63.9%), heart diseases (37.5%), obesity (17.5%) and diabetes (12.7%). (Table I).

Decision regarding cemented or uncemented THA was taken based on the age of the patient, the quality of bone and geometry of the proximal femur. Incision length was between 10 and 20 cm with a mean of  $13.44 \pm 2.08$  cm; longer incisions was noted in obese patients. Mean operative time was  $119.44 \pm 17.88$

**Table II.** — Characteristics related to surgery and hospitalisation

	N	Mean	SD	Min	Max	Percentiles		
						25	50	75
Incision length (cm)	526	13.44	2.08	10.00	20.00	12.00	13.00	14.25
Duration of surgery (minutes)	526	119.44	17.88	90.00	170.00	110.00	120.00	130.00
Surgical blood loss (ml)	526	309.43	102.52	120.00	770.00	210.00	300.00	400.00
Postoperative transfusion (units)	526	0.87	1.16	0.00	13.00	0.00	1.00	1.00
Postoperative drainage (days)	526	2.31	0.78	1.00	8.00	2.00	2.00	3.00
Active mobilisation - walking (days)	526	3.10	1.14	1.00	12.00	2.00	3.00	4.00
Duration of hospitalization (days)	526	11.07	3.67	4.00	33.00	9.00	10.00	13.00
Antibiotherapy (days)	526	3.50	1.86	2.00	30.00	3.00	3.00	4.00

**Table III.** — Evaluation by scores - Statistics

	N	Mean	SD	Min	Max	Percentiles		
						25	50	75
Harris score (preop)	526	57.33	6.33	40.00	80.00	54.00	56.00	60.00
Harris score (6 w)	526	80.95	3.18	70.00	91.00	79.75	81.00	83.00
Harris score (12 w)	526	90.56	2.63	80.00	97.00	89.00	90.00	92.00
Harris score (1 y)	526	96.57	1.86	90.00	100.00	95.00	97.00	98.00
Womac score (preop)	526	9.51	1.08	6.00	12.00	9.00	10.00	10.00
Womac score (6 w)	526	7.26	1.23	4.00	10.00	7.00	7.00	8.00
Womac score (12 w)	526	4.63	1.06	1.00	8.00	4.00	5.00	5.00
Womac score (1 y)	526	2.14	0.92	1.00	6.00	2.00	2.00	3.00
VAS (preop)	526	6.29	1.44	2.00	10.00	5.00	6.00	7.00
VAS (3 d)	526	4.07	1.11	1.00	7.00	3.00	4.00	5.00
VAS (6 w)	526	1.95	0.81	1.00	6.00	1.00	2.00	2.00
ROM IR* (preop)	526	17.24	2.00	10.00	25.00	16.00	17.00	19.00
ROM IR* (6 w)	526	22.67	2.86	14.00	34.00	21.00	22.00	25.00
ROM IR* (12 w)	526	37.36	2.01	30.00	49.00	36.00	37.00	39.00
ROM ER* (preop)	526	18.71	2.13	12.00	25.00	17.00	19.00	20.00
ROM ER* (6 w)	526	25.17	2.78	19.00	35.00	24.00	25.00	27.00
ROM ER* (12 w)	526	40.12	2.36	33.00	45.00	39.00	40.00	41.00

\*ROM – Range of motion, IR – internal rotation, ER – external rotation.

minutes with an interval between 90 and 170 minutes. Duration of surgery was longer in case of cemented THA, obese patient or intraoperative incidents (iatrogenic femur fracture 2 cases). Blood loss was between 120 and 770 ml with a mean of 309±102.52ml. Blood loss was higher in case of uncemented THA. The mean amount of blood units used postoperatively per patient was 0.87±1.16 with an interval between 0 and 13 units. Duration of hospitalization was between 4 and 33 days, with a mean of 11.07±3.67 days. Most of the cases discharged from the hospital after 6 days, but longer hospitalization needed the patients with some complications as iatrogenic intraoperatively femur fracture (0.4%), deep hematoma which needed

surgical approach (1.7%), and patients who developed pulmonary thromboembolism (0.6%) and needed intensive care. (Table II)

A repeated measures ANOVA with a Greenhouse-Geisser correction determined that mean Harris score differed statistically significantly between time points ( $F(1.380, 724.502) = 14514.127, P < 0.001$ ). Post hoc analysis with a Bonferroni adjustment revealed that Harris score was statistically significantly increased from pre-operative to 6 weeks (-23.624 (95% CI, -24.330 to -22.917),  $p < 0.001$ ), from 6 weeks to 12 weeks (-9.605 (95% CI, -9.847 to -9.362),  $p < 0.001$ ), and from 12 weeks to 1 year (-6.010 (95% CI, -6.253 to -5.766),  $p < 0.001$ ). (Table III, Fig. 2a)



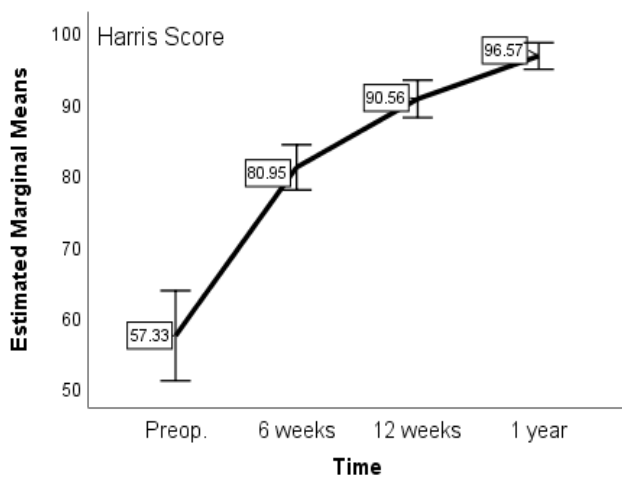


Fig. 2a. — Line chart: Harris mean Score function of time.

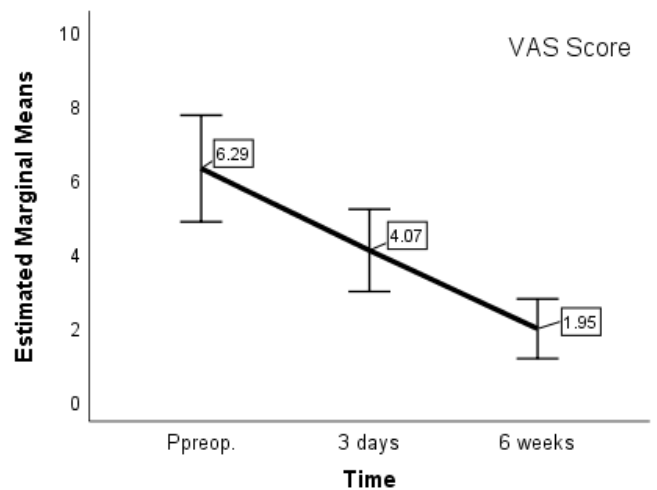


Fig. 2c. — Line chart: VAS mean Score as a function of time.

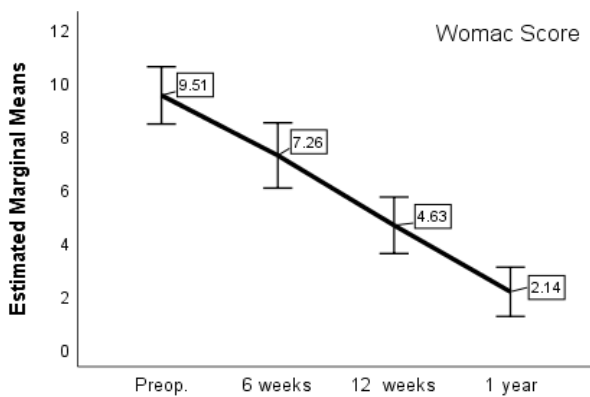


Fig. 2b. — Line chart: Womac mean Score function of time.

Limb lengthening comparative with contralateral limb was recorded in 9 cases, but it was not disturbing for the patient. Preoperative mean Hip score was  $57.33 \pm 6.33$  and at 1 year we recorded a mean Hip score of  $96.57 \pm 1.86$ .

A repeated measures ANOVA with a Huynh-Feldt correction determined that mean Womac score differed statistically significantly between time points ( $F(2.485, 1304.711) = 10745.512, P < 0.001$ ). Post hoc analysis with a Bonferroni adjustment revealed that Womac score was statistically significantly decreased from pre-operative to 6 weeks (2.255 (95% CI, 2.165 to 2.345),  $p < 0.001$ ), from 6 weeks to 12 weeks (2.622 (95% CI, 2.519 to 2.724),  $p < 0.001$ ), and from 12 weeks to 1 year (2.492 (95% CI, 2.375 to 2.610),  $p < 0.001$ ). We recorded a preoperative WOMAC mean score of  $9.51 \pm 1.08$  and at 1 year was  $2.14 \pm 0.92$ . (Table III, Fig. 2b)

Preoperative mean VAS was  $6.29 \pm 1.44$  and postoperative at 6 weeks was  $1.95 \pm 0.81$ . A repeated measures ANOVA with a Huynh-Feldt correction determined that mean VAS score differed statistically

significantly between time points ( $F(1.666, 874.567) = 4020.937, P < 0.001$ ). Post hoc analysis with a Bonferroni adjustment revealed that VAS score was statistically significantly decreased from pre-operative to 3 days (2.217 (95% CI, 2.111 to 2.322),  $p < 0.001$ ), and from 3 days to 6 weeks (2.122 (95% CI, 2.023 to 2.221),  $p < 0.001$ ). (Table III, Fig. 2c)

Preoperative recorded mean internal rotation was  $17.24^\circ \pm 2^\circ$  and postoperative at 12 weeks was  $37.36^\circ \pm 2.01^\circ$ . Post hoc analysis with a Bonferroni adjustment revealed that ROM Internal Rotation score was statistically significantly increased from pre-operative to 6 weeks (-5.428 (95% CI, -5.699 to -5.156),  $p < 0.001$ ), and from 6 weeks to 12 weeks (-14.698 (95% CI, -14.985 to -14.410),  $p < 0.001$ ). (Table III, Fig. 3a)

Preoperative recorded mean external rotation was  $18.71^\circ \pm 2.13^\circ$  and postoperative at 12 weeks was  $40.12^\circ \pm 2.36^\circ$ . Post hoc analysis with a Bonferroni

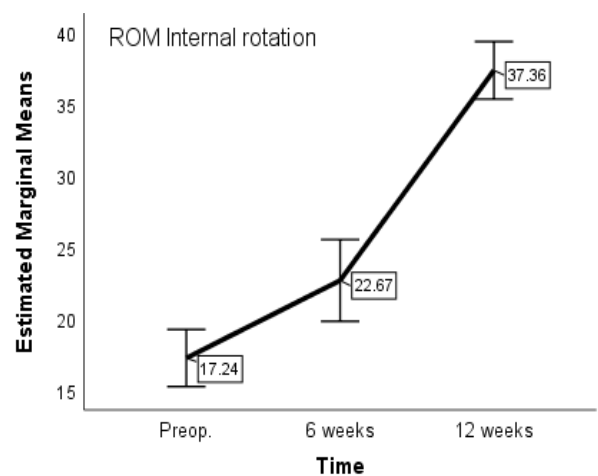


Fig. 3a. — Line chart: ROM Internal Rotation mean Score as a function of time.

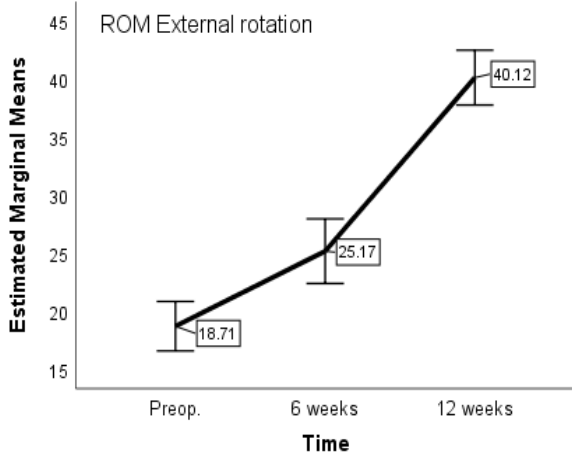


Fig. 3b. — Line chart: ROM External Rotation mean Score as a function of time.

adjustment revealed that ROM Internal Rotation score was statistically significantly increased from pre-operative to 6 weeks (-6.464 (95% CI, -6.776 to -6.152),  $p < 0.001$ ), and from 6 weeks to 12 weeks (-14.947 (95% CI, -15.299 to -14.595),  $p < 0.001$ ). (Table III, Fig. 3b)

McNemar's test determined that there was a statistically significant difference in the proportion of Trendelenburg gait at 3 days (8.2%) and the proportion

of Trendelenburg gait at 6 weeks (2.1%),  $p < 0.001$ . At 6 months none of the patients had Trendelenburg gait and the walk was normal.

## DISCUSION

Although several versions of direct lateral have been used since McFarland and Osborne described theirs in 1954, the today used direct lateral approach was popularized by Hardinge in 1982 and is also called transgluteal approach<sup>4</sup>.

Restrepo et al reported subtle improved HHS and WOMAC at 6 weeks, 6 months and 1 year with direct anterior over direct lateral approach, but these significant differences in clinical outcomes were not found any more at 2 years postoperatively. The authors found no significant differences in postoperative analgesic requirement, duration of surgery, blood loss, need for blood transfusions or length to stay in hospital between the 2 groups. No patient reported having any lateral nerve lesion or any iatrogenic intraoperative fracture. A limitation of the study is that the authors excluded the patients with body mass index over 30kg/m<sup>2</sup> because is a contraindication for the anterior approach. In our study we included all the patients because the direct lateral approach has the advantage that it is not limited by this aspect.



Fig. 4. — Radiographs showing different aspects of cemented or uncemented THA.

Regarding HHS and WOMAC scores, at 6 weeks, Restrepo et al registered the value of 93.64 and 4.4 for direct anterior and 88.8 and 9.70 for direct lateral approach and at 2 years was 97.34 and 2.24 for direct anterior and 97.55 and 1.90 for direct lateral. In our study, HHS at 6 weeks was  $80.95 \pm 3.18$  which is discrete lower, HHS at 12 weeks was significant better ( $90.56 \pm 2.63$ ) and at 1 year ( $96.57 \pm 1.86$ ) was similar with Restrepo's study at 2 years. WOMAC score at 6 weeks in our study was  $7.26 \pm 1.23$ , significantly better than both approaches evaluated in the study mentioned above and at 1 year was similar with WOMAC at 2 years from the same study<sup>5</sup>.

Trudelle-Jackson et al evaluates range of motion and postural stability at 1-year post surgery for the patients with THA operated by an antero-lateral approach and they recorded internal rotation  $24.1 \pm 7.8$  and external rotation  $21.2 \pm 5.1$ . In our study, 1-year evaluation recorded superior values for internal rotation  $37.36 \pm 2.01$  and external rotation  $40.12 \pm 2.36$ .

We think that the length of the hospitalization depends much more on factors as patient comorbidities, pain management and postoperative rehabilitation. The surgical approach is not so important on this aspect.

Jolles and Bogoch made one of the most completed syntheses from literature, using Medline, Embase, Cinhal and Cochrane database, and compared posterior versus lateral approach for THA. They indicated no significant difference between approaches regarding dislocation, 1.3% versus 4.2%. The measure of the Trendelenburg gait seems to favor slightly the posterior approach (16.7%) versus lateral approach (8%). Pain recorded was similar. Internal rotation data recorded was favorable to posterior approach ( $35^\circ \pm 13^\circ$ ) to the detriment of lateral approach ( $19^\circ \pm 13^\circ$ ). HHS postoperative was similar<sup>6</sup>. We recorded Trendelenburg gait at 3 days 8.2%, at 6 weeks 2.1% and at 12 weeks complete remitted. It is very important to evaluate Trendelenburg sign before surgery to know exactly how much the approach could influence abductor weakness, because most of the studies didn't do it. We recorded 3.4% of the patients with Trendelenburg gait preoperatively. We must take in count that some patients with advanced coxarthrosis and important symptomatology have preoperatively Trendelenburg gait.

Wayne et al made a comparison between the lateral Hardinge approach and an anterior mini-invasive approach and reported that the mini-invasive approach had a significantly longer operating time, more bleeding, higher rate of nerve damage, a higher percentage of acetabular component malpositioning and led to clinically unacceptable results<sup>7</sup>.

Infection is an important complication of THA which is reported in literature with an incidence between 0.2% and 1.2%. Christensen et al reported a greater number of wound infections associated with direct anterior approach compared with other approaches<sup>8</sup>. In our study we had an incidence of 0.6% of deep infection and it was early diagnosed, and it was successfully treated by surgical debridement associated in particular cases with negative pressure therapy.

A series of studies reported dislocation rates of 0.6%-1% for direct anterior approach, 0.3-0.6% for direct lateral approach and 1.7-5.3% for posterior approach. Posterior approaches are more likely to be predisposed to dislocation of the prosthesis<sup>9-11</sup>.

Our rate of dislocation was low (0.4%) and was simple solved by changing the size of the prosthesis neck with a higher one, and all the patients with this complication have had preoperative neurological problems considered by many authors as favorizing factor for hip dislocation. The low dislocation rate of the Hardinge approach has been attributed to verifying both acetabular and femoral component positioning via fluoroscopy and preserving static stabilizers structures, such as the posterior joint capsule. We have used fluoroscopy for every case, so the component malposition, the factor most often involved in THR dislocation was excluded, so we made these principles as routine.

Intraoperative fracture of the greater trochanter or trochanteric fractures is a common complication for direct anterior approach can happen during THA especially with anterior approach because due to the forced elevation of the proximal femur<sup>12,13</sup>. We registered 0.4% femur fractures which happened during femoral canal preparation with the femoral shaft rasp or when uncemented femoral stem was inserted.

2.2%-42.5% of patients were reported to have at least some symptoms of superior gluteal nerve lesion after direct lateral approach which results in temporary abductor weakness and in rare cases this problem can be persistent. In our series there is no iatrogenic nerve injury registered<sup>14,15</sup>.

Hunt et al and Jameson et al in their analyses of the linked national database of England and Wales reported a lower 90-day mortality and a slightly higher functional outcome with posterior approach<sup>16,17</sup>. On the other hand, Hailer et al, Lindgren et al studied the Swedish hip arthroplasty registry and found that posterior approach gave a higher risk of revision due to dislocation and a lower risk of revision due aseptic loosening<sup>18,19</sup>.



The minimally invasive techniques have not significantly improved the outcomes of THA compared to the standard approaches. Technical difficulties associated with these approaches like malpositioning of the prosthetic components can lead to an increased risk of perioperative complications<sup>20</sup>.

Witzleb et al compared clinical outcomes after THA through a posterior and lateral approach and both showed similar improvements across the HHS, WOMAC and SF-36 questionnaires, and the rate of dislocation and fracture did not differ significantly between the groups<sup>21</sup>.

Realyvasquez et al evaluated direct anterior approach by reviewing the literature and concluded that the published literature remains inconclusive about the superiority of these approach. Besides the complications associated with the approach and mentioned above, there is contraindication in using it for the patients with higher body mass index<sup>22</sup>. Hardinge approach has no contraindication regarding the obese patients due to versatility and extensibility and we didn't recorded risk of complications (longer operative time, increased operative bleeding, intraoperative fracture or nerve injury) related to the surgery time for these patients. It allows good exposure of acetabulum, facilitating cup positioning which decrease rates of hip dislocation. It also diminishes the risk of injury to the sciatic nerve which is not close to the operative field.

Müller et al evaluated a minimally invasive antero-lateral approach and a modified direct lateral approach (similar with our approach) and found no differences on gait pattern and or pain after surgery. The minimally invasive anterolateral approach did not appear to provide functional benefits in outcome over the modified direct lateral approach. Consequently, both surgical approaches seem to be equally applicable approaches with good to very good functional results<sup>23</sup>.

Petis et al reviewed anterior, lateral and posterior approaches by performing a comprehensive literature search using Pubmed and Medline and demonstrated that each approach have unique advantages and disadvantages and they recommend that surgeons choose the approach which they have the most experience and ease<sup>24</sup>.

## CONCLUSION

Direct lateral approach provides adequate exposure of both the proximal femur and acetabulum with the benefit of providing an extensive exposure to the femur as required. We registered a very low complication rates and good functional outcomes. The recovery is

fast enough and after 1 year they are no differences compared with other approaches, including MIS The ROM improvement is very effective and internal and external rotation are both improved without THR dislocation additional risk.

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