

Transitioning to the direct anterior approach in total hip arthroplasty. Is it a true muscle sparing approach when performed by a low volume hip replacement surgeon?

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Abstract

Purpose We conducted this study to establish if the transition from a lateral approach (LA) to the direct anterior approach (DAA) for a low volume hip arthroplasty surgeon during the steep learning curve can be performed maintaining the muscle sparing approach of the DAA without increasing the complication rates.

Methods In this controlled, prospective, randomized clinical study we investigated 70 patients (35 DAA, 35 LA) with similar demographics that underwent a total hip arthroplasty. Assessment of the two approaches consisted of determining the invasiveness through serum markers for muscle damage (i.e. myoglobin, creatine kinase and lactate dehydrogenase), the operative parameters such as post-operative pain and rescue medication consumption, the component positioning and complication rates.

Results Post-operative myoglobin levels were higher ($p < 0.001$) in the LA group (326.42 ± 84.91 ng/mL) as compared to the DAA group (242.80 ± 71.03 ng/mL), but with no

differences regarding other biomarkers for muscle damage. Pain levels were overall lower in the DAA group, with a statistical and clinical difference during surgery day ($p < 0.001$) associated with lower ($p < 0.001$) rescue medication consumption (median 1 (1; 3) mg morphine vs. 3 (2; 4) mg morphine). Most patients in the LA group reported chronic post-operative pain throughout all three evaluated months, while the majority of patients in the DAA group reported no pain after week six. Component positioning did not differ significantly between groups and neither did complication rates.

Conclusion The DAA can be transitioned from the LA safely, without higher complication rates while maintaining its muscle sparing advantages when performed by a low volume hip arthroplasty surgeon.

Keywords Direct anterior approach · Low-volume surgeon · Total hip arthroplasty · Learning curve · Lateral approach

Introduction

The direct anterior approach (DAA) is becoming the standard minimally invasive surgical approach for total hip arthroplasty (THA). The DAA was developed to take advantage of nervous and muscular neutral planes that could enhance patient satisfaction and functional outcome [1].

Although the benefits of the muscle sparing approach entices patients [2] and surgeons alike [3], the technique can be quite challenging to embrace, with many young surgeons using the approach they have trained in and are more comfortable with. This might be the reason why many of the existing studies are performed by high volume, experienced hip arthroplasty surgeons [4–6].

Despite the risk of gluteal insufficiency [7] that comes with using the lateral approach (LA), which can often lead to high

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chronic pain and a longer rehabilitation period [8–10], the DAA was just recently introduced in our hospital with the onset of this study, together with the expectations of lower pain levels and complication rates [1, 10–12], as well as quicker short-term recovery and cessation of walking aids [1, 13]. All of the above are differences between the two approaches that are more likely to be seen in the three post-operative months during which muscle healing processes take place [14]. This is backed by findings from previous studies [6, 7, 15].

Even though there are some drawbacks that can be associated with this approach, especially during the learning curve, (i.e. lateral femoral cutaneous nerve injury, longer operative and setup times and wound complications) [11, 16–18], the possibility of faster rehabilitation and greater patient satisfaction are more than enough to attempt the transition, even as a low volume hip replacement surgeon.

The aim of this study was to determine if the transition to the DAA from the lateral transgluteal approach done by a low volume hip surgeon within the steep learning curve is feasible without jeopardizing patient safety while keeping the muscle sparing advantages that the approach is known for.

Materials and methods

This study is a prospective, randomized, controlled clinical trial, approved by the Institutional review board (IRB-approval number 517/2015). All patients provided written informed consent after receiving appropriate study information.

Patient selection

Between February 2015 and November 2016, 35 patients were enrolled in the DAA group and an equal number in the LA group. Randomization to the anterior or lateral group was computer generated. Seventy-six patients met the inclusion criteria and were approached. Four patients declined participating in the study and one patient from the lateral group voluntarily withdrew from the study after surgery. One patient from the lateral group developed a pulmonary embolism in the second postoperative week and was excluded from the study. We had no loss to follow-up.

The inclusion criteria were: patient age between 35 and 85 that were diagnosed with end-stage primary degenerative hip arthritis verified on plain radiographs, and elected to undergo a primary total cementless hip arthroplasty. Exclusion criteria were: diagnosis of secondary arthritis, femur fractures, previous hip operations, presence of a contralateral joint implant, any muscle diseases, recent heart attacks or rhabdomyolysis and any type of mental or physical disability.

Surgical procedure

The DAA group underwent the THA through a modified Smith-Peterson direct anterior approach as described by Lovell [19], in a supine position, on a standard operating table that could be flexed so that hip hyperextension could be achieved. Both legs were completely draped separately to facilitate proximal femoral exposure (e.g. extension, adduction and external rotation with the operative leg underneath the nonoperative leg). An 8 cm skin incision was made over the body of the tensor fascia lata muscle (TFL) and then lengthened as needed for a proper exposure. The fascia of the TFL was incised lengthwise and the TFL muscle dissected and retracted laterally. After coagulation of the anterior femoral circumflex vessels, the anterior capsulectomy was performed and joint exposure was accomplished. Osteotomy of the neck was made with excision of a napkin ring, followed by hip dislocation. Acetabular reaming, femur preparation to receive the stem and final component placing were facilitated by offset handles of the instruments.

For the LA group, a direct lateral approach was used to perform the THA as described by Hardinge [20]. With the patient on a standard operating table, in a supine position, skin incision was initiated 3 cm proximal to the tip of the greater trochanter and was continued 5 cm distally. The 8 cm incision that resulted was then lengthened if needed for a better exposure. Fascia lata was then split and the gluteus medius and vastus lateralis were divided. Antero-lateral capsulectomy was performed and the hip was dislocated. After the neck osteotomy was performed the head was extracted. The acetabular reaming and preparation of the femur, as well as final component pressfitting were done in a traditional way, with usage of standard instruments.

Fluoroscopy guidance was not used in any of the two groups during THA. Moreover, a surgical drainage system was used in every case. All participants received only spinal anesthesia, with an intravenous analgesia during the intervention at the anesthesiologist's discretion. Antibiotic prophylaxis was administered for 48 hours, consisting of cefuroxime, starting 30 minutes prior to skin incision. Thromboembolic prophylaxis measures included low molecular weight heparin for 35 days, adjusted for patient weight, according to national standard protocols.

All patients received the same implant, a Metabloc™ uncemented femoral stem system, cobalt-chrome Versys® 32 mm diameter femoral head, polyethylene liner form Trilogy® acetabular system, and Trilogy® uncemented acetabular system shell, with acetabular self-tapping bone screws if needed (Zimmer Warsaw, IN 46580 U.S.A.).

There were no hip replacements performed using the DAA during this period on any other patients. All THAs were performed by the same surgeon, with an average of

three patients per month, ranging from one to six, thus the maintaining the attribute of a low-volume surgeon regarding this procedure.

Evaluation

Prior to the THA we recorded demographics data including sex, age, body-mass index (BMI) and affected hip. Baseline values for all biomarkers were collected prior to surgery. The evaluated biomarkers were myoglobin, creatine kinase (CK) and lactate dehydrogenase (LDH). Myoglobin was evaluated 24 hours after surgery and all other markers were assessed daily for the first five post-operative days. Intra-operative blood loss was calculated by subtracting post-operative hemoglobin (HGB) from pre-operative HGB. Post-operative blood loss was evaluated with the aid of the surgical drainage system.

Pain levels were assessed using the visual analog scale (VAS) ranging from 0 = no pain, to 10 = worst pain imaginable. Pain levels were evaluated after surgery, on a daily basis for eight consecutive days, during bed rest as well as after ambulation. To evaluate chronic pain, patients were asked to keep a written diary on which they noted pain levels on a weekly basis for three months.

Postoperative pain medication consisted of paracetamol 1 g and ketorol 15 mg i.v. every eight hours with rescue analgesia consisting of morphine 2 mg i.v. for the first 24 hours, while the patient was cared for in the Post Surgery Care Unit (PSCU). After day of surgery until discharge day, pain relief medication protocol was identical between groups.

All complications that occurred during or after surgery were recorded. To assess possible trauma to the lateral femoral cutaneous nerve in the anterior group, patients were evaluated and questioned at one week and also three months post-operative.

Peri-operative variables collected were setup time (time between spinal anesthesia and skin incision), operative time, incision length, intra-operative blood loss, need for blood transfusion and post-operative blood loss.

The patient, the physician who assessed the patient and the physiotherapist were blinded in regards of applied surgical method. Physiotherapy started on the first post-operative day with patients walking using a walker with weight bearing as tolerated.

Cup abduction was evaluated on plain radiographs with the help of a stencil on which the safety zone between 35° and 55° was marked. The horizontal line referenced on AP radiographs was the inter teardrop line. All malrotated and oblique views were excluded. Due to technical difficulties in obtaining standardized axial views, cup anteversion was not evaluated. The femoral component placement was assessed using a similar stencil showing 3° of varus and 3° of valgus relative to the femoral shaft axis.

Statistics

An a priori power analysis was made to calculate the required number of patients for the study. Regarding biomarker changes, given the quiddity of the DAA of being a muscle sparing approach as opposed to the LA, a defined effect size of 1.0 was established [21]. Together with a significant level of 0.05, and a required 80% power, the sample size calculated for each group was 17. For our goal of comparing post-operative pain levels we used estimates from Mjaaland et al. [11], who reported for the direct anterior group a mean value for the post-operative VAS of 2.6 ± 2.0 and 4.0 ± 2.3 for the lateral group. Assuming the same variations to be observed in the current study, the sample size calculated for each group was 31, for a power of 80%.

Continuously and normally distributed variables were compared using Student's t-test, and reported as mean and standard deviation, while non-normally distributed variables were compared with the Mann-Whitney test and reported as median and Q1 and Q3 quartiles (values provided in round brackets). The Shapiro-Wilk test was used to determine the normality of the distribution. Categorical variables are reported as frequency and percentage and the Chi-square test and Fisher's exact test were used to compare differences. Statistical significance was established at $p < 0.05$. Statistical analysis was carried out with R version 3.1.1 (R Core Team, Vienna, Austria) and power analysis with G*Power 3.1.9.2 [22].

Results

There were no differences in the demographic characteristics between the two groups in terms of age, BMI and affected hip. However, there was a significantly higher percentage of female patients in the DAA group (Table 1).

Regarding markers for muscle damage, myoglobin levels (Table 2A) were significantly lower in the DAA group

Table 1 Patients demographics

	DAA (<i>n</i> = 35)	LA (<i>n</i> = 35)	<i>P</i> -value
BMI (kg/m ²) ^a	27.45 ± 3.76	28.63 ± 3.12	0.157
Age (years) ^b	67 (53.5; 72.5)	64 (54.5; 67.5)	0.435
Gender, female ^c	26 (74.3)	16 (45.7)	0.014*
Laterality, right ^c	16 (45.7)	17 (48.6)	0.810

BMI = body mass index; DAA = direct anterior approach; LA = lateral approach

^a mean ± standard deviation; Student t-test for independent sample;

^b median (Q1; Q3), where Q = quartile; Mann-Whitney test;

^c no, (%); Chi-square test or Fisher exact test

Table 2 Myoglobin levels (A) and peri-operative data (B)

	DAA group (n = 35)	LA group (n = 35)	P-value
A. Myoglobin levels (ng/mL)			
Myoglobin preoperative ^a	31.1 (26.75; 32.15)	28.3 (24.75; 38.35)	0.823
Myoglobin postoperative ^a	219 (203; 309)	311 (285; 376)	<0.001*
Myoglobin difference ^a	199.80 (170.85; 274.95)	288.20 (259.20; 318.10)	<0.001*
B. Perioperative data			
Setup time (minutes) ^a	22 (20; 25)	20 (19; 23)	0.092
Incision length (cm) ^b	12.18 ± 1.91	14.79 ± 2.25	<0.001*
Procedure time (minutes) ^a	70 (70; 75)	70 (60; 75)	0.029*
First 10 procedure time (minutes) ^b	80 ± 7.4	67 ± 14.3	0.024*
Last 10 procedure time (minutes) ^b	69.1 ± 3.2	68.4 ± 7.6	0.794
Pre-operative HGB (g/dL) ^a	14.1 (13.15; 14.5)	14.25 (13.75; 10.7)	0.090
Post-operative HGB(g/dL) ^a	11.2 (10.5; 12.25)	11.6 (10.7; 12.4)	0.545
HGB difference(g/dL) ^a	2.7 (1.9; 3.9)	2.8 (2.25; 4.2)	0.526
Transfusions, yes ^c	29 (82.85)	27 (77.14)	0.550
Post-operative blood loss (mL) ^a	500 (350; 625)	550 (300; 625)	0.981
Morphine consumption (mg) ^a	1 (1; 3)	3 (2; 4)	<0.001*

DAA = direct anterior approach; LA = lateral approach;

^a median (Q1; Q3), where Q = quartile; Mann-Whitney test;

^b mean ± standard deviation; Student t-test for independent sample;

^c no, (%); Chi-square test or Fisher exact test

($p < 0.001$) but there was no significant difference in terms of CK or LDH levels (Table 3).

Post-operative pain levels on VAS during bed rest are shown in Fig. 1 and weekly pain assessment on VAS in Fig. 2. Pain levels after mobilization in the first post-operative day was significantly lower ($p = 0.004$) in the DAA group with a median of 2 (2; 3) on the VAS, while patients in the LA group had a median of 4 (2.5; 6). Although in the second post-operative day the DAA still had a lower physiotherapy pain level median of 2 (2; 4), compared to the LA median of 4 (2; 5.5), it did not reach a statistically significant difference ($p = 0.140$).

We found no difference in complication rates between the two groups ($p = 0.690$). There were four complications (11.35%) recorded in the DAA group (one case of

superficial haematoma, two cases of lateral femoral cutaneous nerve injury and one case of greater trochanter tip fracture that did not require any additional surgical treatment) and three complications (8.57%) in the LA group (two cases of superficial haematoma and one case of suture granuloma that was surgically excised at ten post-operative weeks). None of the patients that developed a superficial haematoma needed to undergo a secondary surgery of incision and drainage. There were no cases of infection, dislocation or any other indications for revision.

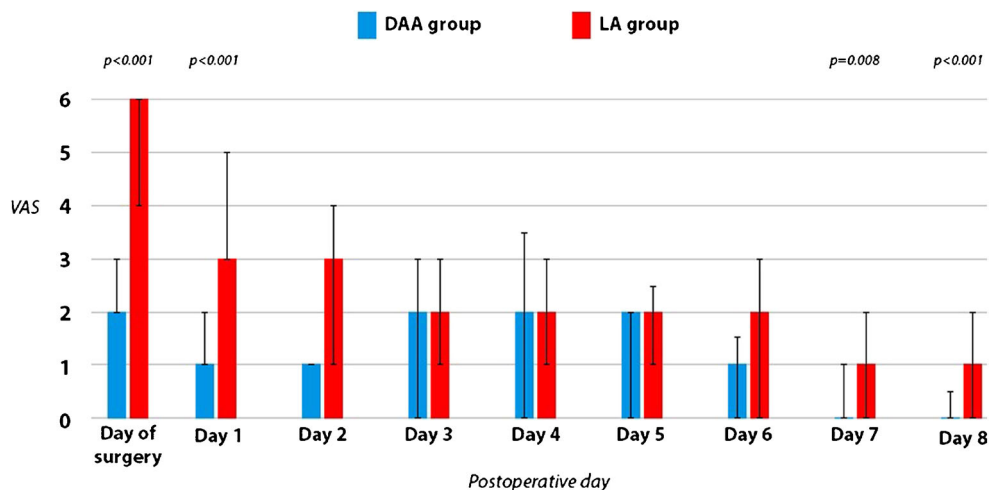
The incision length was on average 2.6 cm longer in the LA group (95% CI, 3.60–1.60, $p < 0.001$), ranging from 9.2 to 16.2 in the DAA group and 10.7 to 19.1 in the lateral approach group. Procedure time was statistically significantly longer in the DAA group, where the first

Table 3 Pre-operative and post-operative levels of creatine kinase (CK) and lactate dehydrogenase (LDH)

	CK (U/L)			LDH (U/L)		
	DAA group	LA group	p value	DAA group	LA group	p value
Pre-operative	59 (52; 80)	59 (49; 74)	0.755	160 (139.5; 177)	158 (131.5; 162.5)	0.082
Day 1 post-op.	333 (260; 499)	364 (246; 447)	0.883	159 (146; 187)	166 (135; 181.5)	0.856
Day 2 post-op.	469 (257; 589)	357 (285; 510)	0.711	159 (131.5; 176)	163 (140; 194)	0.332
Day 3 post-op.	352 (206;411)	275 (197;429.5)	0.257	169 (147; 195)	149 (136.5; 169.5)	0.321
Day 4 post-op.	253 (167.5;362)	210 (149.5;397.5)	0.638	168 (154,183)	160 (138;179)	0.371
Day 5 post-op.	201 (129;278.5)	167 (126; 287)	0.642	178 (149;202.5)	156 (148; 196.5)	0.634

DAA = direct anterior approach; LA = lateral approach

Fig. 1 Median and interquartile range pain levels at rest up to post-operative day 8 by Visual Analog Scale



ten patients operated upon by this approach had a longer procedure time with an average of 10.9 minutes than the last ten patients (95% CI, 5.80–15.99, $p < 0.001$). The LA group had no such variance in the time span of this study (Table 2B).

All components were positioned within the safety zone accepted for both groups. For the DAA group, the mean cup abduction was $36.97^\circ \pm 1.85^\circ$, and for the LA group the mean cup abduction was $39.63^\circ \pm 2.88^\circ$, $p < 0.001$. All stems were positioned either neutral or in a varus up to 3° . For the DAA group the mean stem varus was $1.40^\circ \pm 0.99^\circ$ and for the LA group the mean stem varus was $1.29^\circ \pm 1.13^\circ$, $p = 0.65$.

Discussion

In this single surgeon prospective randomized study we demonstrated that the transition to the DAA from the LA can be carried out safely when done by a low volume hip replacement surgeon during the steep learning curve. One of the assets of this study is the inclusion of all patients that underwent the THA performed through the muscle sparing approach, starting with the surgeon’s very first patient.

While patient demographics were similar with the exception of gender distribution due to randomization, we consider this not to have influenced the outcome of the study. Regarding the inclusion and exclusion criteria, we tried to

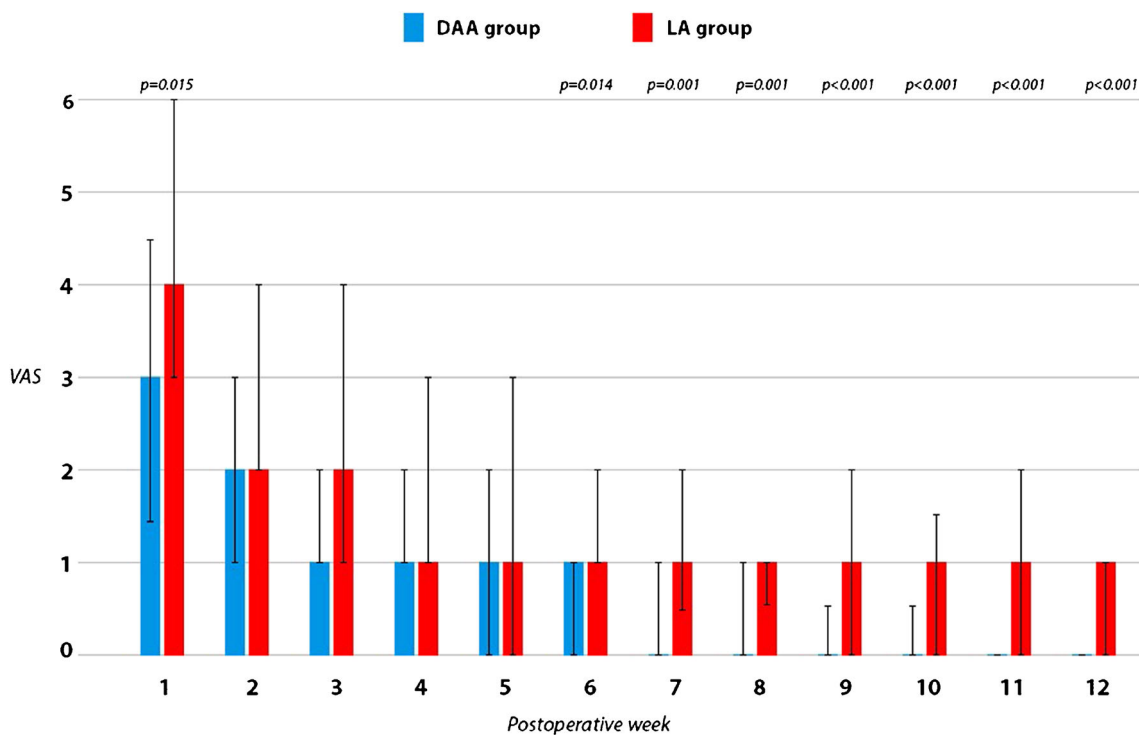


Fig. 2 Median and interquartile range pain level during the first 12 post-operative weeks (3 months) by visual analog scale

eliminate all possible bias related to the enrolled patients, without favouring one of the two approaches. There are previous studies [1, 11] that set an exclusion criteria for patients with high BMI, but a recent prospective randomized trial done by Dienstknecht et al. [5] which proved that obese patients gain similar benefits with a minimally invasive approach as the non-obese patients, led us not to set such an exclusion criteria in our study.

The invasiveness difference between the surgical approaches was sought to be objectified with the help of the more specific and commonly [7, 11] used markers for muscle damage, i.e. myoglobin, CK and LDH. Post-operative myoglobin levels had a statistically ($p < 0.001$) higher median difference in the LA group, reaching 288.20 ng/mL (259.20; 318.10) ng/mL than the DAA approach with a median of 199.80 ng/mL (170.85; 274.95) ng/mL. CK levels reached a peak level in both groups during the second post-operative day, but with no significant difference between them. Regarding LDH levels, there was no difference recorded during any of the five post-operative days. These results are similar with findings from experienced, high-volume surgeons. De Anta-Díaz et al. [7] conducted a similar study in which they evaluated muscle damage between the approaches by means of serum markers and MRI. According to their findings, the LA resulted in greater muscle damage than the DAA, but they concluded that muscle damage due to the surgical approach does not influence functional outcome after threemonths. Mjaaland et al. [11] compared the same approaches performed by five experienced surgeons that had higher CK levels in the minimally invasive approach group but with no difference regarding other inflammatory biomarkers suspecting muscle trauma caused by the retractors, and concluded that the lower pain levels and better functional outcome are more important than post-operative CK levels.

With regards to pain levels, we found significantly lower post-operative pain levels on VAS in the DAA group during surgery day, associated with a lower ($p < 0.001$) consumption of rescue medication (see Table 2B). Throughout the daily pain evaluation we found overall lower pain levels on VAS for the DAA group, reaching a statistically significant difference during post-operative day one, seven and eight (Fig. 1). Pain levels recorded during physiotherapy over the first two post-operative days were higher in the LA group, with a statistical difference during the first day. These results are similar to those reported by several previous studies [1, 11, 17].

During the three month period in which we evaluated pain levels weekly on the VAS (Fig. 2), patients reported, in median, higher pain levels in the LA group, lasting until the end of the third month, while the DAA group reported, in median, no pain after week seven. This is consistent with the literature stating fairly unanimous lower pain levels associated with better time frames to recovery when using the DAA [1, 6, 7, 15].

Although statistically significant differences are very important when comparing pain levels, we consider that for the patient and the influence on his physical recovery, the clinically significant differences [23] are more important. We found such a difference on the day of surgery when the DAA group reported less pain on VAS, and also between the sixth and 12th post-operative weeks, when the LA group reported on median chronic pain, while the DAA group reported no pain what so ever.

With regard to complication rates, the results were similar between groups, however some complications in the DAA group seem more approach-related (lateral femoral cutaneous nerve palsy and trochanteric tip fracture). Symptoms related to femoral cutaneous nerve injury were seen in two patients, with one of them completely subsiding at three months. The transitory nerve palsy as well as the femoral trochanteric tip fracture were seen early in the transition, within the first 15 patients operated through the anterior approach. Yi et al. [24] reported similar results showing that most complications occurred within the first 32 cases. Although nerve palsy is a common complication of the DAA [6, 25], a recent study [16] showed it does not affect hip functionality.

A high percentage of patients received a blood transfusion due to improper criteria for administration set by the anesthesiologist (i.e. postoperative blood loss more than 350 ml or clinical signs of anemia), as all but 14 patients received a blood transfusion, significantly more than reported by others [4, 17]. We cannot determine the influence that this had on our results, although there is no difference in transfusion rate between the two groups.

The operative time was overall statistically higher in the DAA group, with a significant difference between the first ten total hip replacements done through the DAA compared to the first 10 in the LA group with the mean difference between groups of 13 minutes. Our findings extrapolate on a study by Schwartz et al. [4], who performed a retrospective cohort study on 412 patients comparing the DAA to the posterior approach, finding a large decrease in operative time within the first 20 cases, with a gradual improvement from that point on, but with the DAA continuing to have an overall longer operative time. These findings are consistent with previous reports [1, 17]. The longer operative time might be caused by the learning curve period of the DAA, or perhaps by the general increased complexity of the approach, as found in other studies evaluating the approaches outside the learning curve [5, 7, 11].

Even though the DAA is technically more challenging especially during the learning curve [6, 26], possibly due to limited exposure and access to the proximal femur, we found this not to be an issue when it comes to component positioning, similar to what is described in previous high volume THA surgeon studies [10, 18]. With regards to

cup positioning, both groups had cup abduction within the safety zone and no stem was in more than 3° of varus.

During the learning curve we found that proximal femur elevation and preparation was the most difficult part of the operation, thus adequate training, especially regarding capsular releases around the proximal femur could be the key for a safe transition.

We consider that our study has several limitations. One of the limitations is related to the complications that might occur later in time, although a recent Bayesian meta-analysis study [25] that analysed 38 studies (6485 patients) reported that most complications relative to the approach occur in the early post-operative settings. Moreover, a prospective cohort study of 1104 hip arthroplasties carried out by Ilchmann et al. [27] comparing the short and long term risks of infection between the two approaches also reported no increased risk for the DAA. Therefore, we consider our follow-up period to be sufficient to detect approach-related complications. However, we are aware that the incidence of some rare but serious complications, like infections and intra-operative fractures cannot be accurately detected given the relatively small number of patients in this study. Therefore, our study could have a false no difference results in regard to serious complications and this is one of its main limitation.

Pre-operative and post-operative as well as physical therapy had identical protocols for both groups during hospitalization. Even though the take home recommendations and the physical therapy protocol that were given to the patient when discharged were the same, we could not assess the patient adhesion to them nor the influence that it could have on pain levels and complication rates.

Given that the DAA has a learning curve defined more by a gradual transition than an exact case number [4, 10, 18, 24, 25], embracing the approach is highly dependent on the surgeon's training and ability to cope with a more challenging technique. Therefore, our results might not extrapolate to other low volume hip arthroplasty surgeons, and this is another main limitation of our study. Moreover, the surgeon cannot be blinded to the procedure; therefore, he could unwillingly influence the results by favouring one of the approaches.

By the current study we had no intention to compare either the short term or long term clinical outcomes by means of hip and quality of life scores, as this has been widely dissected by previous studies, with a virtually unanimous conclusion of no long term difference, regardless of objectified muscle sparing findings [6, 7, 15, 27].

In view of our results as well as findings of experienced surgeons [6, 7, 11, 15] we found no clear differences linking the surgeon's experience or the attribute of being a low volume hip arthroplasty surgeon to a potentially harmful transition to the DAA.

Conclusions

The direct anterior approach can be transitioned from the lateral approach safely, without higher complication rates while maintaining its muscle sparing advantages when performed by a low volume hip arthroplasty surgeon. Our desire was to provide a scientific-based inquiry for low volume hip surgeons, who are willing to transition to the muscle sparing approach, but are concerned about patient safety and possible complications that might appear during the learning curve.

Compliance with ethical standards

Conflict of interest The authors have no conflict of interest to declare.

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Ethical approval Institutional Review Board approval was obtained prior to starting this research. All procedures performed in this study were in accordance with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Informed consent Informed consent was obtained from all individual participants included in the study.

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