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Simultaneous versus staged bilateral direct anterior Total Hip Arthroplasty: Are early patient-centered outcomes equivalent?

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While accumulating data on the direct anterior approach to total hip arthroplasty (THA) have demonstrated clinical benefit and durable results, there is little data that exists on patient-centered outcomes and satisfaction when comparing simultaneous bilateral procedures with staged arthroplasty.

The aim of this study was to determine whether simultaneous bilateral THA and staged arthroplasty result in equivalent early (1) patient-centered outcomes and patient satisfaction; while maintaining acceptable rates of (2) objective clinical outcome scores, (2) complication rates; and (3) radiographic results.

In retrospective review, 41 patients who underwent bilateral one-stage THA were compared to 44 patients who underwent staged bilateral THA during the same time period. The minimum clinical follow up was two years. Generic (EQ-VAS and EuroQoL-5D index) and condition-specific (Oxford Hip Score) instruments were used to assess patient-reported outcomes. Other variables included length of hospital stay (LOS), operative and anesthetic times, blood loss, intra- and post-operative (local and systemic) complications, and radiographic analysis.

No significant differences between the two groups were found for patient-reported outcomes, complications, or radiographic assessment. The simultaneous THA group had shorter LOS and operative and anesthetic times, as well as less blood loss.

One of the authors (ML) is a paid consultant for Smith and Nephew, Inc. and owns stock/stock options in Pivot Medical.

Each author certifies that his or her institution approved the human protocol for this investigation and that all investigations were conducted in conformity with ethical principles of research Simultaneous and staged bilateral THA using the direct anterior approach offer equivalent short-term patient-reported outcomes, with acceptable safety and efficacy profiles. Simultaneous arthroplasty may offer superior benefit with respect to length of stay, operative time, and blood loss. These results may inform the patient-surgeon discussion regarding simultaneous versus staged THA.

Keywords : Total hip arthroplasty

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INTRODUCTION

Standard primary total hip arthroplasty (THA) can reliably alleviate pain, improve function, and improve the quality of life in a wide range of patients with end-stage arthritis of the hip. A substantial proportion of patients undergoing unilateral THA require a contralateral treatment thereafter (1,11,33).

Some studies have reported a higher incidence of medical and surgical complications after the introduction of one-stage bilateral THA (4,17). The complications reported include increased incidence of heterotopic ossification, higher prevalence of deep vein thrombosis, and greater risk of pulmonary complications (4,15,27,28,37,43). Improvements in anesthetic and surgical techniques and postoperative care have resulted in improved outcomes in one-stage bilateral THA in patients with bilateral hip osteoarthritis, and potential benefits include a single episode of anesthesia, more efficient use of resources (32), reduced overall hospitalization and shorter rehabilitation periods (5,11,15,17,32,39). A number of articles report advantages of simultaneous operation, or at least similar results of one-stage versus two-stage procedures (3,5,22,28,32,37,40).

In more recent years, minimally invasive approaches to hip arthroplasty have been introduced, and each has its reported pros and cons (12,21,24,25,26). They have been devised with the goal of decreasing peri-operative pain, speeding early postoperative function, and improving patient satisfaction when compared with standard THA. These patient-centered goals are combined with the surgeon's desire of a safe, reproducible minimally invasive procedure that has durable, properly positioned components. The direct anterior approach to the hip for THA was developed to try to address some of the complications of THA, including dislocation, leg-length discrepancy, and abductor dysfunction, and it is regarded as allowing faster patient recovery to ambulation, normal abductor strength and decreased dislocation rate. It also takes advantage of supine positioning, which allows improved intraoperative monitoring and anesthesia care. However, femur canal preparation and correct component placement is considered difficult with this approach (2).

The aim of this study was to determine whether simultaneous bilateral THA results in equivalent early (1) patient-centered outcomes and patient satisfaction when compared with staged THA; while maintaining acceptable rates of (2) objective clinical outcome scores, (2) complication rates; and (3) radiographic results.

PATIENTS AND METHODS

In retrospective review, 41 consecutive patients who underwent bilateral one-stage THA were compared to 44 consecutive patients who underwent staged bilateral THA during the same time period. The mean age at time of surgery was 60.7 years (SD 11.5) for the one-stage group and 68.7 years (SD 8.2) for the staged group (p<0.001). In the one-stage group, there were 24 males (59%) and 17 females; in the staged group, there were 18 males (41%) and 26 females. The minimum clinical follow up for all patients was two years. No differences were found regarding key pre-operative baseline characteristics, including Body Mass Index (BMI), Tönnis grade, American Society of Anesthesiologists (ASA) classification, and sociodemographic data (Table I). Degenerative osteoarthritis was the primary diagnosis in both groups.

All THA were performed by a single senior surgeon, under general anesthesia, using the same minimally invasive direct anterior approach in the supine position without the use of a traction table. Patients were recommended to undergo one stage bilateral THA if both hips were severely symptomatic at the time of presentation. The first side to undergo the operation was the more symptomatic; if the operation on the first side was concluded uneventfully, the procedure was continued on the other side. No patients required postponement of the second side procedure, due to medical or surgical complications, in either group. Standard perioperative intravenous antibiotics were administered to all patients. Post-operative management included low molecular weight heparin and compression stockings for thromboprophylaxis. Patients were mobilized as tolerated, with full weight bearing allowed on the first post-operative day. All patients received daily physiotherapy while hospitalized.

		Single stage		St		
	Unit	Mean	SD	Mean	SD	P level
Body mass	kg	77.8	11.8	72.7	14.9	0.130
Height	cm	172.4	7.5	169.0	6.9	0.063
Tönnis Classification		2.5	0.5	2.6	0.5	0.352
ASA Classification		Percent		Percent		
Ι		18.0		12.0		
II		58.0		65.0		
III		24.0		23.0		
Education level						
Primary school		7		6		
University		19		14		
High school		7		11		
Graduate school		67		69		
Living area						
Rural		74		46		
City		26		54		
Marital status						
Divorced		10		17		
Married		84		57		
Single		0		3		
Widowed		6		23		
Work status						
Disabled		0		3		
Full time		29		15		
Homemaker		6		9		
Part time		19		12		
Retired		45		62		

Table I. - Pre-operative patient characteristics and demographic data

ASA = American Society of Anesthesiologists

During the study period, patients were seen at 6 weeks, 3 months, 6 months, 1 year and 2 years post-operatively.

Ata on the bilateral were as good as those who developed unilateral hip arthritis at two different time points.

Patient-reported outcomes

At the pre-operative visit, as well as at latest follow-up, all patients completed a cross-culturally adapted and validated country-specific version (9) of the Oxford Hip Score (OHS) (10,23), the Eurogol-Five Dimensions (EQ-5D) and the Euroqol-"visual analogue scale" (EQ-VAS). The EQ-5D and the EQ-VAS are standardized generic instruments for quantifying health outcome and have been developed for use in a wide range of health conditions (31,42). The EQ-5D comprises five single items measuring mobility, self-care, usual activities, pain/ discomfort and anxiety/ depression. Each item is rated using a three-point scale. Summary index scores (ranging from -0.59 to 1) for the EQ-5D were calculated using the method of Prieto and Sacristán (30). The EQ-VAS measures "overall health state" on a 0-100 VAS scale. The University of California at Los Angeles (UCLA) Activity score was also assigned at pre- and post-operative time points.

At follow-up, the patients were also asked to rate the Global Outcome of Treatment (GOT; "how much did the operation help your hip problem?") on a five-point Likert-scale (response options: operation helped a lot, helped, helped only little, didn't help, made things worse) (13,18). As in previous studies, the first two categories of the five-point scale for GOT (i.e. "operation helped/helped a lot") were taken to represent the cut-off for a "successful" outcome (13,18).

Peri-operative data and complications

Per-operative data recorded were operating time (incision to skin closure), anesthesia time, total blood loss, transfusion support, duration of intensive care unit (ICU) post-operative monitoring, and hospitalization length of stay. All patients were seen

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pre-operatively by a consultant physician to assess their fitness for anesthesia. All intra-operative complications, systemic and local post-operative complications (e.g. cutaneous neuropraxia), and mortality were registered.

Radiographic assessment

Radiographic assessment was performed by an independent reviewer comparing serial antero-posterior radiographs of the pelvis and cross-table views taken at each visit (pre-operatively, 6 weeks post-operatively, 6 months, and 1 and 2 years post-operatively). Cup abduction angle was measured and heterotopic ossification was classified according to Brooker et al (7). All radiographs were also examined for evidence of loosening. Any radiographic change in the position or alignment of the component was also noted.

Statistical analysis

Measures of centrality and dispersion include means and standard deviations (SD), unless otherwise stated. Sociodemographic descriptive data were reported as percentages. Betweengroup differences in patient-reported outcomes were examined using the analysis of covariance (ANOVA), entering the baseline values (i.e. preoperative) and age as covariates. The between-group differences have been reported as mean difference with the corresponding 95% confidence interval. All the other group differences (e.g. in intra-operative data and clinical measures) were examined using independent t-tests. All the analyses were carried out using SPSS (version 17, SPSS, Inc., Chicago, IL, USA). P values <0.05 were considered to be statistically significant.

RESULTS

Patient-reported outcomes

No differences between groups were observed for pre-operative patient-reported outcome scores (Table II). Both groups improved in clinical scoring

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		Single stage		Sta		
		Mean	SD	Mean	SD	P level
	Range (worst-best)			-		
EQ5D-index	-0.59 to 1.00	0.432	0.247	0.523	0.230	0.265
EQ-VAS	0 to 100	63.5	19.4	65.0	17.9	0.814
OHS	0 to 48	21.6	6.6	26.2	8.0	0.081
UCLA	0 to 10	5.1	2.0	5.1	1.8	0.883

Table II. - Pre-operative clinical and patient-reported outcome scores

EQ5D = Euroqol - Five Dimensions

EQ-VAS = Euroqol Visual Analog Scale

OHS = Oxford Hip Score

UCLA = University of California at Los Angeles Activity Score

Table III. - Post-operative clinical and patient-reported outcome scores, adjusted for baseline values and age

	One stage			Staged		Group-difference			
	Range (worst-best)	Mean	SD	Mean	SD	Mean	Lower (95% CI)	Upper (95% CI)	P level
EQ5D-index	-0.59 to 1.00	0.927	0.105	0.813	0.271	-0.113	-0.291	0.065	0.203
EQ-VAS	0 to 100	86.7	7.7	84.4	15.0	-2.4	-12.2	7.5	0.624
OHS	0 to 48	45.5	3.0	45.5	5.7	-0.8	-4.7	3.2	0.691
UCLA	0 to 10	6.4	1.0	6.8	1.3	0.4	-0.4	1.2	0.346

EQ5D = Euroqol - Five Dimensions

EQ-VAS = Euroqol Visual Analog Scale

OHS = Oxford Hip Score

UCLA = University of California at Los Angeles Activity Score

Table IV. — Peri-operative and in-hospital patient data	
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	Single	e stage	Sta			
	Unit	Mean	SD	Mean	SD	P level
Operative time	Minutes	134.8	29.1	151.5	28.8	0.010
Anesthesia duration	Minutes	241.3	35.9	341.1	32.7	< 0.001
Estimated intra-operative blood loss	mL	738.8	519.2	943.2	423.0	0.049
Hospital length of stay	Days	11.2	3.4	15.2	5.8	< 0.001
Post-operative ICU recovery monitoring	Minutes	450.1	397.5	705.6	524.1	0.014

ICU = Intensive care unit

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after surgery, with no differences between groups at final follow-up (Table III). All patients declared that the operation helped or helped a lot (i.e. a successful outcome) in the GOT question.

Peri-operative data and complications

As presented in Table IV, the one-stage procedure had a shorter mean operative time (p=0.01) and anesthesia duration (p<0.001). The intra-operative estimated blood loss was also lower for the one-stage group, although this difference was border-line significant (p=0.049) (Table IV). None of the patients required a blood transfusion. The mean length of hospital stay was shorter for the one-stage THA group (p<0.001), and the duration of post-operative ICU recovery monitoring was also less in the one-stage group (p=0.014) (Table IV).

Complications were identified in 7.3% of the one-stage patients and 6.8 % of the two-stage patients (p=0.28). These complications included three hematomae not requiring surgical intervention (all patients in the one-stage group) and two lateral cutaneous femoral nerve (LCFN) neuropraxia (all patients in the staged group). The paresthesias all resolved by six months after surgery. There was one intra-operative calcar fracture in the staged group managed with modification of intra-operative stem preparation; the post-operative clinical course was unremarkable. There was no in-hospital or post-operative mortality recorded in the study period. No cases of wound dehiscence or deep infection, and there were no dislocations.

Radiographic assessments

No statistically significant differences were observed across measured radiographic parameters (Table V), and post-operative leg-length discrepancies were similar between groups (Table V). Ten percent of patients in the staged THA group and 7.9 % of patients in the one-stage procedure developed asymptomatic heterotopic ossification (no difference between groups; Table V). No signs of loosening or change in the position and/or alignment of the components were noted.

DISCUSSION

While accumulating data on the direct anterior approach to total hip arthroplasty (THA) have demonstrated clinical benefit and durable results, there is little data that exists regarding patient-centered outcomes and satisfaction when comparing simultaneous and staged bilateral THA. Moreover, there is limited data comparing bilateral direct anterior hip arthroplasty in the one- versus two-stage settings (Table VI).

Ritter et al. reported that, in the contralateral osteoarthritic hip of a patient with one THA, the patient has a 78.5% chance of progression of osteoarthritis and a 54% chance of requiring a second THA within 10 years (34). This suggests the considerable importance of comparing one-stage bilateral THA versus two-stage bilateral THA, and it represents an important and frequent clinical decision between patient and surgeon. This study compared simultaneous bilateral THA with a timematched group of unilateral THA using the direct anterior approach to examine validated patientreported outcome measures and patient satisfaction at a minimum of two year follow-up. Peri-operative data, complications, and radiographic analysis were also performed.

The major limitations of this study are the retrospective study design and relatively small sample size. As our primary goal was to examine early postoperative patient reported outcomes, rather than focusing on more rare complication events such as venous thromboembolic events, we feel the study design is commensurate with this primary goal. The single-surgeon design with similar surgical technique and rehabilitation protocols also strengthens the study quality despite limited patient numbers. While the two groups were comparable, the difference in age at time of surgery may be associated with an inherent selection bias, and future randomized study should address this limitation. However, the authors feel that the selection of patients for either staged or simultaneous arthroplasty based on clinical hip symptoms closely mirrors the decision process when indicating patients for surgery. It is also important to note that the institution where this study was conducted provides extended in-patient

		One	One stage		Staged		
	Unit	Mean	SD	Mean	SD	P level	
Cup abduction, Right hip	degrees	42.5	3.0	41.1	4.3	0.095	
Cup abduction, Left hip	degrees	44.0	4.0	43.1	4.5	0.371	
Limb length discrepancy	mm	1.1	1.8	1.3	1.7	0.652	
				-			
Heterotopic ossification, Right hip		N		Ν			
Brooker 0		40		39			
Brooker 1		1		2			
Brooker 2		0		3			
Heterotopic ossification, Left hip							
Brooker 0		38		40			
Brooker 1		3		2			
Brooker 2		0		2			
Stem positioning, Right hip				-			
Neutral		40		44			
Valgus		1		0			
Stem positioning, Left hip						-	
Neutral		40		44			
Valgus		1		0			

Table V. - Post-operative radiographic data

rehabilitation, which explains the rather long hospital stay for some of the patients.

Patient-reported outcomes

Postoperative patient-reported clinical outcomes did not differ between groups, and both groups experienced improvements from baseline functional levels. This study demonstrates that short-term clinical outcome of one stage bilateral THA is comparable to that of two-stage THA. While it has been suggested in prior study that optimal functional recovery can be achieved more quickly with a one-stage than a two-stage approach (44), further analysis is required for the minimally invasive direct anterior approach.

The patient-surgeon discussion regarding the decision to pursue one- versus two-stage THA may

likely be aided by the patient satisfaction associated with less length of hospital stay, cost, and recovery periods.

Complications

The possibly increased likelihood for intra- and postoperative local and systemic complications is one most frequently cited argument against simultaneous bilateral THA. In our study there was no statistically significant difference between the one-stage and two-stage THA groups regarding peri-operative and post-operative complications. Similarly, Salvati *et al.* found no differences in postoperative and long-term complications between one-stage and two-stage bilateral THA through a different approach (*37*). Simultaneous THA has been shown to be advantageous compared with

	Authors	Year	Study period	Study arms	Number of patients	Inter- operative days	Follow-up (months)	Functional outcome	Complications	Pro/contra
1	Alfaro Adriàn	1999	1989 - 1995	1/2 stage	202 (95/107)	0/60-730 (300)	0	similar	>blood transfusions	pro: <hospital stay, costs</hospital
2	Berend KR	2007	1997 - 2005	1/2 stage	277 (167/110)	0/14-730 (240)	30 (6-108)	early: <function< td=""><td>>blood transfusions >revisions</td><td>contra: <reimburse- ment</reimburse- </td></function<>	>blood transfusions >revisions	contra: <reimburse- ment</reimburse-
3	Bhan	2006	1996 - 2001	1/2 stage	168 (83/85)	0/90-210	60 (48-96)	similar	>blood transfusions	pro: < hospital stay
4	Eggli	1996	1982 - 1992	1/2 stage	255 (64/63/128)	0/>42/ 42-180	>18	similar; >stiff hip	similar	pro: <hospital stay, costs</hospital
5	McBryde	2007	1994 - 2006	1/2 stage	92 (37/55)	0/1-365	15 (1-60)/34 (1-131)	early better	similar, >intubation time	pro: <hospital stay, costs</hospital
6	Parvizi	2006	1997 - 2004	1/2 stage	196 (98/98)	0/25-303 (138)	0	similar	 transfusions <complications< td=""><td>pro: <costs, >rehabilitation</costs, </td></complications<>	pro: <costs, >rehabilitation</costs,
7	Reuben	1998	1991 - 1994	1/2 stage/ unilat	154 (7/8/139)	0/7/unilat	0	-	-	pro: <costs< td=""></costs<>
8	Salvati	1978	1970 - 1976	1/2 stage	461 (122/134/205)	0/same hosp/2nd hosp	36 (12-96)	similar	similar	pro: <hospital stay, costs, OP time</hospital
9	Schiessel	2005	1996 - 2002	1/2 stage	30 (15/15)	0/120-665 (485)	66 (SD 19.5)	similar (subject- ively>)	similar	pro: <hospital stay, costs</hospital
10	Shih	1985	1979 - 1982	1/2 stage	35 (20/15)	0/14-365	12/17.7	similar but <rom< td=""><td>similar</td><td>pro: <hospital stay, OP time</hospital </td></rom<>	similar	pro: <hospital stay, OP time</hospital

Table VI. — Summary of lit	erature.
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staged THA with regard to reduced length of hospitalization, one anesthetic induction, and one hospitalization (34). In our study we found that one-stage THA has a shorter hospital stay as well as a shorter ICU stay; likewise, the total duration of the surgical procedure and anesthesia times were also diminished.

Other of the major controversies regarding the safety of one stage bilateral THA is the potentially higher prevalence of pulmonary embolism. The incidence of fatal pulmonary embolism has been reported as being between 1.04% and 1.5%, and that of non-fatal pulmonary embolism between 7.89% and 11.5% in patients undergoing elective unilateral THA (8,16). In early publications comparing bilateral with unilateral THA, a higher incidence of pulmonary embolism and somewhat increased morbidity for bilateral THA was reported (6,34,35). In this study, we did not observe any thromboembolic events. This could be due to the small number of patients in this study or, as concluded by Ritter and Stringer, the introduction of

hypotensive anesthesia, improvement of operative environment, anticoagulation therapies, and early postoperative ambulation of patients, leading to a decrease in complication rates after bilateral THA (35). Another factor taken into account is that, with this approach, the patient is positioned supine. According to a study by Camissa *et al.*, the lateral decubitus position could be an important etiological factor for complications such as pulmonary embolism, myocardial infarction, and fat embolism syndrome secondary to hypoxemia (8).

Although blood losses may not correspond to the simple sum of the two procedures, the estimated blood loss was higher in the two-stage versus the one-stage group. However, no blood transfusions were administered in either group. Blood loss may be related to anesthetic and operative times, which were shorter in the one-stage group. The supine position allows time saving, because no reposition or re-draping of the patient is needed, and one surgical team can close the first surgical wound while another team starts the contralateral hip.

It is thought that the lack of tissue release and anterior capsulotomy involved in the direct anterior approach favor a lower post-operative dislocation rate. Siguier et al reported a dislocation rate 10 of 1037 (0.96%), with the majority occurring early post operatively (41). In our series no dislocations were reported. We did report one proximal femur fracture (calcar) in a staged bilateral THA patient, which required no osteosynthesis but led the surgeon to change from a cementless to a cemented stem. No additional measures were taken postoperatively compared to the other patients, which is consistent with some other authors' management (21). We believe that the surgeon feel for the degree of tension being applied to the femur during exposure for broaching and component position is paramount in avoiding iatrogenic fracture. We reported 3 unilateral cases of subjective LCFN hypoesthesia in the simultaneous bilateral THA, all of which resolved spontaneously (all patients reported full recovery at 6 months follow-up). This is in line with other studies published (14,20,21) and we believe that LCFN problems are mainly related to a reversible neuropraxia due to tension by the retractors rather than an irreversible dissection injury. Jewett et al

reported 4.6% of wound complications (800 cases) using the anterior approach. 24 were deemed to be noninfectious dehiscence, with the remaining 13 diagnosed as wound infection all requiring irrigation and debridement (14). The authors postulated this high rate of wound complication may be due to the difference in skin thickness over the anterior proximal thigh and tension imparted at that site from the hip flexion crease which could negatively affect wound healing. We report no wound dehiscence in our series, which might be due to the use on a "bikini" incision (in the majority of cases) and a double layer of Ioban (3M, Inc., St. Paul, MN, USA) to protect the skin from retractor injury.

Radiographic assessment

The direct anterior approach for THA has been promoted as a safe procedure that reliably recreates leg length, offset, and component positioning. Inaccurate acetabular component placement has been shown to increase dislocation and wear (29). Masonis *et al.* were able to demonstrate accurate component position in a series of 300 direct anterior THA with an average cup abduction angle of 44° (range $32.0-52.0^{\circ}$) (19). Matta *et al.* reported accurate component positioning overall with 96% of acetabular components within the target abduction range (21). Our observations suggest that this approach is effective in providing an accurate and precise cup abduction angle in both staged and simultaneous bilateral THA.

All patients received meticulous surgical technique to minimize surgical trauma to the soft tissues and to minimize contamination of the soft tissues with particulate bone debris. No significant heterotopic ossification was reported in previous studies using this approach for unilateral THA (20,38). We found no difference in the rates of heterotopic ossification between the two groups and the values we report are in line with what has been published. (36).

CONCLUSION

Simultaneous and staged bilateral THA using the direct anterior approach offer equivalent short-

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term patient-reported outcomes, with acceptable safety and efficacy profiles. Simultaneous arthroplasty may offer superior benefit with respect to length of stay, operative time, and blood loss. These results may inform the patient-surgeon discussion regarding simultaneous versus staged THA. While the rate of complications does not increase when comparing single- and two-stage procedures, the potential economic and patient-related benefits may be better with a single stage approach in the appropriately selected patient.

Because post-operative clinical, functional, and radiographic outcomes did not differ between groups, future study should examine key patientreported outcomes and measures of satisfaction that might better inform the decision whether to stage the two procedures. Future study should more closely explore sociodemographic differences that might guide the choice of procedure. One of the major advantages of a single-stage procedure highlighted in the literature is saving of hospital resources. Besides patient-reported benefits in one hospitalization, the single-stage approach may have an important economic impact and should be studied in a formal cost analysis of simultaneous and staged direct anterior THA.

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