

A MINIMAL-INCISION TECHNIQUE IN TOTAL HIP ARTHROPLASTY DOES NOT IMPROVE EARLY POSTOPERATIVE OUTCOMES

A PROSPECTIVE, RANDOMIZED, CONTROLLED TRIAL

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Background: Minimally invasive total hip arthroplasty has stirred substantial controversy with regard to whether it provides superior outcomes compared with total hip arthroplasty performed through longer incisions. The orthopaedic literature is deficient in well-designed scientific studies to support the clinical superiority of this approach. The objective of this study was to compare the results of a single mini-incision approach with those of a standard-incision total hip arthroplasty in the early postoperative period.

Methods: Two hundred and nineteen patients (219 hips) admitted for unilateral total hip arthroplasty between December 2003 and June 2004 were randomized to undergo surgery through a short incision of ≤ 10 cm or a standard incision of 16 cm. All patients were blinded to the size of the incision for the duration of the hospital stay. The anesthetic, analgesic, and postoperative physiotherapy protocols were standardized, with the staff also blinded to the technique used. A single surgeon, who had performed more than 300 short-incision hip replacements prior to the start of this study and who performs an average of 415 primary total hip replacements a year, performed all procedures through a single-incision posterior approach using a cementless cup and cemented stem.

Results: The two groups were matched for age, grade according to the system of the American Society of Anesthesiologists, and body mass index. No significant difference was detected with respect to postoperative hematocrit, blood transfusion requirements, pain scores, or analgesic use. We found no difference in early walking ability or length of hospital stay and no difference in component placement, cement-mantle quality, or functional outcome scores at six weeks. The patient variables significantly associated with a probability of early discharge independent of incision length were patient age and preoperative hemoglobin levels ($p < 0.05$). The surgical scars contracted significantly over six weeks ($p < 0.05$) but by a similar proportion of 11% to 12% in both groups.

Conclusions: Minimally invasive total hip arthroplasty performed through a single-incision posterior approach by a high-volume hip surgeon with extensive experience in less invasive approaches to the hip is safe and reproducible. However, it offers no significant benefit in the early postoperative period compared with a standard incision of 16 cm. As it is not known whether lower-volume and less-experienced surgeons can achieve similar results, the mini-incision technique merits further study before wide dissemination and implementation of this family of surgical approaches can be recommended.

Level of Evidence: Therapeutic Level I. See Instructions to Authors for a complete description of levels of evidence.

Minimally invasive total hip arthroplasty has stirred substantial controversy in the orthopaedic community and has received extensive coverage in the

popular press. While less invasive approaches, as seen in laparoscopic cholecystectomy, have resulted in less pain and faster recovery for patients^{1,2}, it remains to be proven whether these same benefits can be derived from a shorter incision in total hip arthroplasty. The potential benefits cited by enthusiasts of minimally invasive total hip arthroplasty, but as yet unproven in well-designed trials, include reduced soft-tissue



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TABLE I Demographic Data on the Patients

	Mini-Incision Group	Standard Incision Group	P Value
No. of hips	109	110	
Age* (yr)	67.42 ± 9.84	65.85 ± 10.33	0.25
Gender (M/F)	49/60	58/52	
Body mass index*	28.22 ± 4.33	28.94 ± 4.33	0.21
Preoperative diagnosis (no. of patients)			
Osteoarthritis	107	107	
Osteonecrosis	0	2	
Rheumatoid arthritis	2	1	

*The values are given as the mean and the standard deviation.

trauma, reduced operative blood loss and blood transfusion requirements, less postoperative pain, and faster rehabilitation reducing the length of hospital stay³.

The potential disadvantages of these approaches include reduced visualization, a possible increased risk of neurovascular injury, and component malpositioning, thereby compromising the long-term results of an already successful procedure. Some authors have questioned the justification for these not insignificant risks for the sake of unproven short-term benefits⁴. The orthopaedic literature is deficient in well-designed studies to support the clinical superiority of minimally invasive total hip arthroplasty in the early postoperative period. Most of the available evidence is derived from retrospective cohort studies or personal case series from the pioneers of the minimally invasive approaches. Hartzband⁵ described a series of 100 consecutive total hip arthroplasties performed through a posterolateral minimal incision without a control group for comparison. He concluded that the patients had a more rapid rehabilitation and a more prompt return to activities of daily living. Sculco et al.⁶ found no difference in blood loss or length of stay for forty-two patients undergoing minimally invasive total hip arthroplasty compared with a cohort of forty-two patients undergoing total hip arthroplasty through a traditional incision, but the Harris hip score was slightly higher in the mini-incision group at five years. Wenz et al.⁷ reported that patients managed with a minimal-incision technique were able to walk sooner and with less assistance than were those managed with a standard technique, but no difference was found in the length of hospital stay. Woolson et al.⁸, in a retrospective cohort study, reported the results of 135 hip replacements by three different surgeons. The mini-incision group was found to include thinner and healthier patients than the standard-incision group. No difference was detected with respect to operative time, blood loss, transfusion rate, or length of stay. The mini-incision group had a significantly higher risk of wound complications, acetabular component malposition, and poor fit and fill of the cementless femoral components.

Orthopaedic surgeons have an obligation to ensure that an innovation in surgical technique is put through rigorous scientific evaluation to determine its efficacy before it is widely

promoted as beneficial. We hypothesized that minimally invasive total hip arthroplasty performed through a single-incision posterior approach would result in lower intraoperative blood loss and less postoperative pain and would allow earlier mobilization and discharge from the hospital with no increase in the rate of intraoperative or early postoperative complications.

Materials and Methods

Two hundred and nineteen patients (219 hips) admitted for unilateral total hip arthroplasty were enrolled in this randomized, blinded study between December 2003 and June 2004. The patients were randomly allocated to have surgery through either a minimally invasive incision of ≤10 cm or a standard incision of 16 cm. The regional research ethics committee approved the study protocol. Informed consent was obtained from all patients. Prior to providing informed consent, all patients were made aware that they would be blinded to the length of their incisions for the duration of their hospital stays. The exclusion criteria were a history of previous surgery on the affected hip and inflammatory polyarthritis if the severity of the disease was likely to compromise postoperative mobility. Of the five patients with rheumatoid arthritis who were admitted for total hip arthroplasty during the study period, only two were not enrolled for this reason.

Preoperatively, demographic data, body mass index, preoperative diagnosis, and the grade according to the system of the American Society of Anesthesiologists⁹ were recorded. Hip function, quality of life, and general health were assessed with use of the Harris hip score¹⁰, the Oxford hip score¹¹, the Western Ontario and McMaster University Osteoarthritis Index (WOMAC)¹², and a Short Form-12 (SF-12) general health questionnaire^{13,14} (Tables I and II).

Baseline preoperative hemoglobin and hematocrit levels were recorded. Postoperatively, the hematocrit was measured at eight hours and hemoglobin levels were measured on the first, second, and third postoperative days. Any blood replacement during the period of hospitalization and the hematocrit at discharge were also recorded.

Serum levels of C-reactive protein have been shown to increase as part of the inflammatory response to surgical trauma following total hip arthroplasty, with peak levels being

reached on the second to third postoperative day¹⁵⁻¹⁷. Baseline C-reactive protein levels were measured preoperatively and were remeasured on the second postoperative day to determine whether there was any difference in the magnitude of the inflammatory response between the two patient groups.

A single surgeon (D.B.) who performs an average of 415 primary total hip replacements a year performed all procedures through a single-incision posterior approach with a posterior capsular repair. He had already performed more than 300 short-incision hip replacements before starting this study. On the evening before surgery, a sealed envelope was used to determine the patient randomization group. The operating surgeon, who was not involved in patient randomization, was then informed of the incision to be used at the time of templating of preoperative radiographs.

All patients underwent a hybrid total hip arthroplasty with use of a cementless cup (Pinnacle; DePuy, Warsaw, Indiana) and a cemented stem (Xpress Rapid Custom or C-Stem; DePuy, Leeds, United Kingdom). Preoperative measurements of the circumference of the thigh were made at the level of the trochanteric ridge and at the mid-thigh. The mid-thigh circumference was remeasured at forty-eight hours to assess postoperative swelling. All patients had a spinal anesthetic of intrathecal 0.5% bupivacaine with intravenous midazolam or propofol for intraoperative sedation. The length of the incision to be made was measured and marked with use of a sterile ruler and marker pen after draping. The surgical approach was the same in both groups. In the standard-incision group the subcutaneous tissues and fascia lata were divided in line with the skin incision, but in the minimal-incision group only the proximal 1 cm of the fascia lata was incised. The distal fibers of the gluteus maximus were split by blunt dissection, and the short external rotators were detached close to their insertion into the greater trochanter. After reduction of the newly inserted prosthetic hip, the posterior capsule and short rotators were separately repaired with use of nonabsorbable sutures passed through drill-holes in the greater trochanter. Therefore, the only difference in surgical technique between the two groups was the length of the skin incision and the shorter incision of the fascia lata in the mini-incision group.

Surgical time and wound length at the start and end of surgery as well as any intraoperative complications or techni-

cal difficulties encountered were recorded. No specialized minimal access surgical instruments were used. Intraoperative blood loss was estimated by measuring the volume of blood in the suction bottles and weighing the swabs used.

Following surgery, all patients had a standard-length wound dressing, ensuring that the patients and all staff, except those directly tending to wound care, were blinded to the technique used. When a change of dressing was required, the standard-length dressing was reapplied and was used for the duration of the hospital stay.

A standardized analgesic protocol was used for the management of postoperative pain. This consisted of use of a patient-controlled analgesia system that administered morphine at a concentration of 1 mg/mL for the first twelve hours. Patients were then managed with oral analgesia with 100 mg of tramadol (Zydol; Searle, High Wycombe, United Kingdom) alternating every three hours with two tablets each containing a combination of 30 mg of codeine and 500 mg of paracetamol (Solpadol; Sanofi-Synthelabo, Guildford, United Kingdom). The first dose of oral analgesia was given thirty minutes before the patient-controlled analgesia was discontinued. Intravenous administration of granisetron (Kytril; Roche, Basel, Switzerland) was used to control nausea.

Pain levels were recorded every two hours for the first twenty-four hours with use of a 100-mm visual analogue scale. The total volume of morphine used was recorded. An additional pain score was recorded at thirty-six hours. The standardized oral analgesic protocol was continued on discharge with the patients instructed to keep a score sheet of the worst pain levels for each of the first seven days following discharge. They reduced their analgesic intake as required thereafter.

Postoperative mobilization followed a set protocol supervised by a core team of experienced orthopaedic physiotherapists who were blinded to the type of incision used for the duration of the study. Unless they were not well medically, all patients were mobilized with full weight-bearing on the first postoperative day, as they had been instructed in the use of an appropriate walking aid preoperatively. On the second day, the patients were tested on a set of functionally related activities. This assessment was based on the Iowa level-of-assistance scale¹⁸, a validated physical therapy assessment tool, which has been shown to have good interobserver and good-

TABLE II Preoperative Functional Scores, SF-12 General Health Scores, and ASA Grade*

	Mini-Incision Group†	Standard-Incision Group†	P Value
Harris hip score	29.04 ± 11.65	27.41 ± 13.23	0.34
WOMAC osteoarthritis index	26.92 ± 11.82	26.23 ± 14.29	0.70
Oxford hip score	49.37 ± 5.04	50.14 ± 5.64	0.29
SF-12 physical component score	26.18 ± 5.39	26.14 ± 5.40	0.95
SF-12 mental component score	43.31 ± 12.78	41.96 ± 11.85	0.41
ASA grade	2.06 ± 0.64	2.02 ± 0.68	0.68

*WOMAC = Western Ontario and McMaster University Osteoarthritis Index, SF-12 = Short Form-12, and ASA = American Society of Anesthesiologists. †The values are given as the mean and the standard deviation.

to-excellent intraobserver reliability during the acute phase of rehabilitation following total hip and knee replacement. The tests performed comprised (1) the level of assistance required for a transfer from the supine to the sitting position and from the sitting to the standing position and for mobilization with a walking aid, (2) a timed 10-m walk to assess walking velocity, and (3) a timed stair-climbing test.

A cohort of 100 patients, who were chosen at random, underwent stride analysis to assess early walking ability. This was done by measuring temporal-spatial parameters during the timed 10-m walk. Felt markers that were 5 mm thick were attached to the soles of the patient's footwear at a distance of 5-cm from the tip. The markers were infused with nonpermanent ink, which marked the floor clearly with each step, and different colors of ink were used to define the right and left limbs. Measurements were made of step length (left-foot to right-foot markings), stride length (left-foot to left-foot markings), cadence (steps per minute), and walking velocity.

Patients were discharged when they were safely able to transfer and mobilize with the use of a walking aid.

Radiographic Analysis

An independent investigator, also blinded to the length of the incisions, analyzed the postoperative radiographs. The parameters recorded were cup abduction angle, stem alignment, and quality of the cement mantle. Stem alignment was measured as the angle between the long axis of the femoral stem and the anatomical axis of the femur on the anteroposterior radiograph. On the lateral radiograph, stem alignment was classified as neutral, posterior, or anterior. The cement mantle around the femoral component was graded according to the criteria of Mulroy et al.¹⁹.

Postoperative Follow-up

The patients were evaluated six weeks after surgery. They were assessed with use of the Harris and Oxford hip scores, the WOMAC osteoarthritis index, and an SF-12 general health

questionnaire. The lengths of the surgical scars were measured, and the patients performed a timed 10-m walking test to assess walking velocity. The use of a walking aid at this stage was also recorded.

Statistical Analysis

Sample-size estimation showed that 100 patients in each group would be required to show a difference in postoperative hemoglobin of 0.5 g/dL and a difference in length of stay of 0.5 day, with an alpha level of 0.05 and a beta level of 0.10, that is, a power of 90%.

Statistical analysis was done with use of the SPSS software package (SPSS, Chicago, Illinois) with the independent samples t test for continuous variables and chi-square tests for dichotomous values. A p value of <0.05 was considered to be significant. Principal component analysis with varimax rotation was used to identify the optimal way to handle repeated measures for the data collected with the visual-analogue pain scale every two hours in the first twenty-four hours. This suggested that the scores at two and four hours, scores from six to ten hours, scores from twelve to eighteen hours, and scores from twenty to twenty-four hours could be combined to yield four summary pain scores. This enabled us to perform t tests for four independent samples instead of the twelve that would otherwise have been required, thus reducing the impact of multiple testing. A Bonferroni approach was then to drop the p value required for statistical significance to 0.0125; that is, alpha/4.

Logistic regression analysis was used to determine patient variables that were significantly associated with the probability of discharge within three days after surgery.

Results

Operative Results

No significant difference between the two groups was found with respect to the preoperative values for the mid-thigh circumference, the circumference of the thigh at the trochanteric ridge, or the depth of the subcutaneous fat layer (Table III).

TABLE III Operative Data and Postoperative Hematological Data

	Mini-Incision Group	Standard-Incision Group	P Value
Mid-thigh circumference* (cm)	49.3 ± 5.3	50 ± 5.7	0.33
Thigh circumference at trochanteric ridge* (cm)	60.73 ± 5.7	61.53 ± 4.6	0.25
Depth of subcutaneous fat layer* (cm)	2.72 ± 1.59	2.83 ± 1.27	0.59
Incision length at start* (cm)	9.21 ± 0.44	16.00 ± 0.00	
Incision length at end* (cm)	9.50 ± 0.95	15.81 ± 0.93	
Mean change in wound length (cm)	+0.29	-0.19	0.00
Estimated intraoperative blood loss* (mL)	314 ± 162	366 ± 190	0.03
Hematocrit at 8 hr*	0.317 ± 0.058	0.325 ± 0.058	0.34
Mean total blood transfusion* (U)	0.42 ± 0.95	0.30 ± 0.66	0.27
Hematocrit at discharge*	0.275 ± 0.04	0.276 ± 0.04	0.75

*The values are given as the mean and the standard deviation.

The mean incision length (and standard deviation) measured 9.2 ± 0.44 cm at the start of surgery and 9.5 ± 0.95 cm at the end in the mini-incision group. The increase in length, we believed, was due to the stretching of the skin by the greater retraction required with use of this approach. For the standard-incision group, the mean incision length was 16.0 ± 0.00 cm at the start and 15.81 ± 0.93 cm at the end. The mean operative time was 5.6 minutes longer for the standard-incision group (65.9 ± 13.2 minutes) than that for the mini-incision group (60.3 ± 9.2 minutes). When the time was divided into three separate phases (incision to insertion of the acetabular liner, insertion of the liner to reduction of the hip, and reduction to closure of the skin), we found significant differences in the first and last phases of surgery ($p = 0.001$ and $p < 0.001$, respectively). The longer time for the first phase in the standard-incision group may have been due to the fact that the arthroplasty fellow performed the initial exposure in sixteen (15%) of the 110 patients in this group and in none of those in the mini-incision group. These were all performed under the direct supervision of the senior surgeon. The longer time for the last phase was due to our method of skin closure, as we used an absorbable continuous mattress suture rather than staples.

The mean estimated intraoperative blood loss was significantly greater in the standard-incision group (365.8 mL; range, 100 to 1100 mL) than in the mini-incision group (314.2 mL; range, 90 to 1310 mL) ($p = 0.03$). However, no difference was detected in the postoperative blood transfusion rate, the hematocrit at eight hours following surgery, or the hematocrit at discharge (Table III). Within the standard-incision group, the estimated blood loss for the patients in whom the initial approach was performed by the arthroplasty fellow (mean, 366.2 mL; range, 150 to 690 mL) was not found to be different from that for the patients in whom the entire operation had been performed by the senior surgeon (mean, 362.7 mL; range, 100 to 1100 mL) ($p = 0.67$).

Intraoperative Complications and Technical Difficulties

Two patients, both from the standard-incision group, had an intraoperative fracture; one had a fracture of the greater tro-

chanter and the other sustained a fracture of the medial acetabular wall during insertion of the press-fit acetabular component. Both fractures were treated nonoperatively, and the patients were allowed to walk with full weight-bearing postoperatively. Neither patient had any further problems related to the fracture. None of the mini-incisions had to be extended during the study; however, two hips that had been randomized to the standard-incision group—one with a non-union of a previous acetabular fracture and the other with a socket destroyed from rapidly progressive osteoarthritis—would have been difficult to manage through a mini-incision without extending the wound. Acetabular exposure through a mini-incision was subjectively thought to be more difficult in muscular male patients and grossly obese patients (a body mass index of >35). Subgroup analysis was done for all patients with a body mass index of >35 (five in the mini-incision group and ten in the standard-incision group) and male patients with a mid-thigh circumference of >55 cm (sixteen in the mini-incision group and twenty-six in the standard-incision group). The mean total operative time (and standard deviation) was significantly increased for patients in both groups with a body mass index of >35 (69.5 ± 11.2 minutes) compared with patients with a body mass index of <30 (62.0 ± 11.3 minutes) ($p < 0.001$). This increase was independent of the incision length ($p = 0.48$). With the numbers available, no significant difference between the mini-incision and standard-incision groups was seen for male patients with a mid-thigh circumference of >55 cm, with respect to mean operative time (61.4 ± 11.0 minutes and 66.9 ± 13.2 minutes, respectively; $p = 0.17$) or mean cup abduction angle ($48.3^\circ \pm 5.1^\circ$ and $48.8^\circ \pm 7.6^\circ$, respectively) ($p = 0.85$).

Postoperative Swelling and Inflammatory Response

The mean increase (and standard deviation) in the mid-thigh circumference at forty-eight hours, as a measure of postoperative swelling, was not significantly different between the mini-incision group (4.3 ± 4.2 cm) and the standard-incision group (3.7 ± 3.9 cm) ($p = 0.30$).

The mean serum level of C-reactive protein at forty-eight hours was 135.68 ± 51.18 mg/L for the mini-incision

TABLE IV Postoperative Pain Scores and Morphine Use*

	Mini-Incision Group	Standard-Incision Group	P Value
Pain score (mm)			
0 to 4 hr	15.7 ± 19.1	16.2 ± 17.5	0.85
6 to 10 hr	17.1 ± 16.3	14.5 ± 14.0	0.22
12 to 18 hr	8.9 ± 12.5	11.0 ± 12.8	0.23
20 to 24 hr	15.1 ± 16.3	17.8 ± 15.9	0.22
36 hr	16.8 ± 20.3	19.8 ± 21.2	0.29
Morphine used (mg)	42.9 ± 97.4	45.0 ± 96.8	0.89

*Pain scores were determined with a 100-mm visual analogue scale, and morphine was administered with a patient-controlled analgesia system. The values are given as the mean and the standard deviation.

TABLE V Postoperative Results for the Timed 10-Meter Walk and Timed Stair-Climbing Test*

	Mini-Incision Group	Standard-Incision Group	P Value
Walking time			
6-m segment (sec)	32.2 ± 19.0	32.8 ± 20.6	0.83
Total 10-m walk (sec)	54.4 ± 29.8	54.5 ± 32.7	0.97
Stair-climbing			
Ascending time (sec)	19.31 ± 8.78	19.58 ± 9.38	0.83
Descending time (sec)	19.42 ± 8.94	21.20 ± 11.27	0.22

*The values are given as the mean and the standard deviation.

group and 125.62 ± 59.39 mg/L for the standard-incision group. The difference was not significant ($p = 0.20$).

Postoperative Pain Scores and Morphine Use

No significant difference was detected between the mini-incision and standard-incision groups with respect to the postoperative pain scores or the volume of morphine used with the patient-controlled analgesia system (Table IV). After correcting for the variations in length of stay, we found no significant difference in the mean pain scores (and standard deviation) for the two groups in the first seven days following discharge from the hospital (33.0 ± 18.0 mm for the mini-incision group and 33.6 ± 19.6 mm for the standard-incision group; $p = 0.82$).

Physiotherapy and Postoperative Mobilization

Of the 219 patients in the study, 209 (104 in the mini-incision group and 105 in the standard-incision group) were well enough on the second postoperative day to be mobilized according to the set physiotherapy protocol. Ten patients were not able to mobilize because of hypotension (five patients), hypoxia (two), severe nausea (two), or acute renal insufficiency that resolved without the need for dialysis (one). No difference was detected between the mini-incision and standard-incision group with respect to the ability to transfer from the supine to the sitting position ($p = 0.27$) or from the sitting to the standing posi-

tion ($p = 0.28$) or with regard to the ability to walk with a walking aid ($p = 0.49$). In the timed 10-m walking test, the split time for the middle 6-m segment was measured, allowing for acceleration and deceleration in the first and last 2-m segments. The 6-m and total 10-m walking times for the groups were not found to be significantly different. In the timed stair-climbing test, the times needed to ascend and descend four steps were measured separately. Again, no significant difference in the stair ascending or descending times was detected (Table V). Stride analysis revealed no difference between the minimal-incision and standard-incision groups with respect to the mean stride length (70.7 ± 20.3 cm and 71.4 ± 19.2 cm, respectively; $p = 0.86$), mean step length (41.75 ± 8.73 cm and 43.27 ± 8.98 cm; $p = 0.41$), mean cadence (43.4 ± 15.6 steps per minute and 46.3 ± 16.1 steps per minute; $p = 0.41$), or mean walking speed (0.21 m/s [range, 0.70 to 0.90 m/s] and 0.26 m/s [range, 0.07 to 0.85 m/s]; $p = 0.40$).

Length of Hospital Stay and Discharge Disposition

All of our patients were admitted the day before surgery, which is the present practice at our institution. The length of hospital stay following surgery was similar for both groups, with a mean of 3.65 days (range, two to thirteen days) for the mini-incision group and 3.68 days (range, two to twenty-two days) for the standard-incision group ($p = 0.94$). A total of 192 patients (87.7%) were discharged to their homes; ninety-four were in

TABLE VI Femoral Stem Alignment on the Lateral and Anteroposterior Radiographs

	Mini-Incision Group (no. of hips)	Standard-Incision Group (no. of hips)
Mean alignment on lateral radiograph		
Neutral	76	74
Posterior	25	34
Anterior	4	1
Total	105	109
Mean alignment on anteroposterior radiograph		
Neutral	102	101
Varus	3	8
Valgus	0	0
Total	105	109

TABLE VII Grade of Cement Mantle Around the Femoral Component*

Grade According to System of Mulroy et al. ¹⁹	Mini-Incision Group (no. [%] of hips)	Standard-Incision Group (no. [%] of hips)	Total
A	32 (30.5)	29 (26.6)	61
B	45 (42.9)	54 (49.5)	99
C1	23 (21.9)	22 (20.2)	45
C2	5 (4.8)	4 (3.7)	9
D	0	0	0
Total	105	109	214

*Radiographs were not available for four patients in the mini-incision group and for one patient in the standard-incision group.

the mini-incision group and ninety-eight were in the standard-incision group. Of the remaining twenty-seven patients, two patients (1%) had died in the early postoperative period, eleven (5.0%) were transferred to a nursing home, seven (3.2%) were transferred to a rehabilitation unit, and seven (3.2%) went to the home of a relative. Thirty-five (32%) of the 110 patients in the standard-incision group were able to go home on day two compared with twenty-nine (27%) of the 109 patients in the mini-incision group. The patient variables significantly associated with the probability of discharge within three days were patient age (Wald chi-square value = 33.36; $p < 0.001$) and preoperative hemoglobin level (Wald chi-square value = 10.53; $p = 0.001$). The main determinant of discharge to home was the availability of adequate family support.

Radiographic Results

Complete sets of radiographs were available for 214 patients (105 in the mini-incision group and 109 in the standard-incision group). Two patients were transferred to acute care units before postoperative radiographs were made, and three patients who had only anteroposterior radiographs were excluded from the analysis. The mean cup abduction angle (and standard deviation) was $45.85^\circ \pm 5.0^\circ$ in the mini-incision group and $46.65^\circ \pm 5.6^\circ$ in the standard-incision group ($p = 0.28$). With use of a mean angle of $<30^\circ$ or $>50^\circ$ to define outliers, we found no difference between the two groups with respect to outliers; there were sixteen outliers in the mini-incision group and nineteen in the standard-incision group. Femoral stem alignment in both

the anteroposterior and lateral radiographs was similar for both groups (Table VI). The mean stem angle on the anteroposterior radiograph was $0.81^\circ \pm 1.25^\circ$ of varus for the mini-incision group and $1.02^\circ \pm 1.49^\circ$ of varus for the standard-incision group ($p = 0.27$). With use of the chi-square tests for analysis, the difference between the two groups with respect to the stem alignment on the lateral radiograph was not found to be significant ($p = 0.20$). The results for cement-mantle quality are shown in Table VII. Statistical analysis showed no difference between the two approaches in the grade of the cement mantle ($p = 0.93$). None of the patients in this study had a grade-D cement mantle, and the mini-incision approach was not associated with a higher prevalence of grade-C2 mantles.

Results of Six-Week Review

A total of 215 patients were evaluated at six weeks following surgery. One patient was seen at eight weeks, and another was seen at three months. The remaining two patients had died in the early postoperative period. Both were excluded from the analysis. Both groups showed substantial overall improvement in mobility and function relative to the baseline preoperative status, but no difference was detected between the groups with respect to the use of a walking aid ($p = 0.78$), Harris hip score, Oxford hip score, WOMAC osteoarthritis index, or SF-12 general health scores (Table VIII).

In the timed 10-m walk, no difference was found between the minimal-incision and standard-incision groups with respect to the mean time (and standard deviation) re-

TABLE VIII Functional Hip Scores and SF-12 General Health Scores at Six Weeks*

	Mini-Incision Group†	Standard-Incision Group†	P Value
Harris hip score	84.15 ± 10.56	83.36 ± 8.33	0.54
WOMAC osteoarthritis index	74.40 ± 13.88	73.95 ± 12.90	0.81
Oxford hip score	24.97 ± 7.33	25.88 ± 6.29	0.33
SF-12 physical component score	38.48 ± 10.20	37.73 ± 9.48	0.58
SF-12 mental component score	50.61 ± 11.05	51.11 ± 10.54	0.73

*WOMAC = Western Ontario and McMaster University Osteoarthritis Index, and SF-12 = Short Form-12. †The values are given as the mean and the standard deviation.

corded for the middle 6-m segment (7.86 ± 4.33 sec compared with 7.16 ± 2.80 sec; $p = 0.16$) or for the overall 10-m distance (13.52 ± 7.10 sec compared with 12.36 ± 4.69 sec; $p = 0.16$).

The scar measured a mean (and standard deviation) of 13.95 ± 1.26 cm in the standard-incision group and 8.44 ± 1.02 cm in the mini-incision group. This represents a significant mean contraction of 1.86 cm for the scar in the standard-incision group and 1.06 cm for the scar in the mini-incision group ($p = 0.01$) at six weeks. As a percentage of total wound length at the end of surgery, the wound from the standard incision had contracted by a mean of 12% (1.86/15.81 cm) and the mini-incision wound by 11% (1.06/9.5 cm). However, the difference between the two groups with respect to the proportional change in scar length at six weeks was not significant ($p = 0.70$).

Serious Complications

Two patients, both in the standard-incision group, died in the early postoperative period. One of them, a sixty-eight-year-old man with ischemic heart disease who had a previous angioplasty, suffered an acute myocardial infarct; the other, an eighty-three-year-old man, had extensive bowel infarction from mesenteric vessel thrombosis.

Complications in the mini-incision group included a deep infection, superficial wound infection, and early dislocation in one patient each, and complications in the standard-incision group included an early dislocation and proximal deep venous thrombosis in one patient each. The patient with a deep infection was treated with irrigation and débridement with retention of the components and six weeks of intravenous antibiotics. The C-reactive protein levels remained normal at eight months after reoperation. This patient was the only one who had had additional surgery at the time of writing.

Discussion

During the past forty years, total hip arthroplasty has become one of the most successful procedures for improving the quality of life for patients suffering from end-stage degenerative joint disease. As the emphasis in health-care provision shifts toward greater cost-effectiveness and patient choice, there is a danger of a widespread introduction of new procedures without initial rigorous scientific evaluation. As a result of pressure from both peers and patients, the orthopaedic community has widely embraced minimally invasive total hip arthroplasty without objective evidence of its efficacy in the early postoperative period, during which time its potential benefits are claimed to be substantial. There has also been a rush by implant companies to manufacture and aggressively market specialized surgical instruments for these procedures. This prospective, randomized blinded study is the first, to the best of our knowledge, to test whether minimally invasive total hip arthroplasty performed through a single-incision posterior approach has any benefits over the standard-incision total hip arthroplasty in the early postoperative period. To reduce confounding variables, a single surgeon using the same method of component fixation performed all operations. An arthroplasty fellow performed the initial approach in a small

number of patients (sixteen; 15%) in the standard-incision group, always under the direct supervision of the senior surgeon. While this may have had an impact on operative time, it did not affect estimated blood loss or component positioning. The standardization of anesthetic, pain management, and rehabilitation protocols combined with the blinding of patients and nursing and physical therapy staff ensured that patients recovered at their own pace. The study design also eliminated any possible improvement in functional performance resulting from the positive psychological impact that may be conferred by a new surgical technique, the so-called Hawthorne effect²⁰.

In our study, even though the reported intraoperative blood loss was significantly greater in the standard-incision group, no difference was found in the hematocrit at eight hours or at discharge or in the postoperative blood transfusion rates. This highlights the inherent weakness of the use of measurements of blood in suction bottles and weighed swabs to estimate blood loss. Sehat et al.²¹ reported that 26% of the blood loss following total hip arthroplasty is hidden and is not recognized by the usual methods of assessing intraoperative loss and postoperative drainage. The significantly higher estimated blood loss for the standard-incision group may also indicate some suggestibility on the part of operating-room staff, who, since they were not blinded, may have anticipated greater blood loss.

We did not use any specialized instrumentation for the minimally invasive approach. This did not affect the accuracy of component placement or contribute to an increase in the prevalence of wound problems.

Although reduced pain is one of the benefits that have been cited for the minimally invasive approach, none of the reported studies have included an objective assessment of this parameter. Sculco et al.⁶ reported that, with the mini-incision technique, postoperative rehabilitation can be accelerated, but the rationale for this was not stated. Dorr²², who described a series of ninety patients, reported that the daily pain score during hospitalization averaged 3 on a scale of 10. There was, however, no control group. We found no difference in postoperative pain scores or morphine use between the groups.

Reduced soft-tissue trauma is another of the potential benefits cited for minimally invasive total hip arthroplasty. Cytokines that include C-reactive protein are the main mediators of inflammation and response to trauma. Studies in general surgery have shown a reduced acute phase cytokine response in laparoscopic compared with open cholecystectomy or hernia repair^{23,24}. This has been attributed to the reduced amount of soft-tissue trauma. Following total hip arthroplasty, C-reactive protein is known to increase from baseline, peaking on the second postoperative day¹⁵⁻¹⁷. We compared the acute phase increase in C-reactive protein levels between our two groups and found no difference. This may imply that the mini-incision is no less traumatic than a 16-cm standard incision.

Safe and independent mobility is the key objective in physical therapy after minimally invasive total hip arthroplasty.

DiGioia et al.²⁵ reported that their patients had a significant improvement with respect to the limp and the ability to climb stairs at three months ($p = 0.04$ and $p = 0.009$, respectively); an improvement with respect to the limp, distance walked, and the ability to climb stairs at six months; and no difference at one year. Their study group, however, was selected from a larger cohort of 121 patients, and there was no indication of how these parameters were tested. Dorr²² considered the results of gait analysis in a subgroup of ten patients from a group of 105 patients. Higher levels of function were reported for the mini-incision group, but the postoperative protocols had differed. Our study, which used validated measures of function, did not show any significant benefit from the minimally invasive approach in the immediate postoperative period or at six weeks. The Harris hip score, Oxford hip score, and WOMAC osteoarthritis index are widely used and validated disease-specific measures for assessing outcome following total hip arthroplasty. The SF-12 health survey is a generic measure of health status developed to provide a shorter alternative to the Short Form-36 (SF-36) in monitoring large study samples. It is easier to administer and has proven reliability and validity. Our study is the first, as far as we know, to use this spectrum of outcome measures. Again, we found no significant benefit of the mini-incision over the standard incision, when assessed with use of these patient-derived outcome measures.

The impact of reduced visualization on the accuracy of component placement is seen as a potential disadvantage of the minimally invasive approach. Woolson et al.⁸ reported that a significantly higher percentage of the cementless stems in their mini-incision group were graded as having poor fit and fill ($p = 0.02$). In contrast, component placement on radiographic analysis was similar for both of our study groups. The rate of aseptic loosening has previously been shown to be significantly higher for grade-C2 cement mantles compared with grade-A, B, and C1 mantles¹⁹ ($p < 0.05$). In this study, the use of the minimal incision does not appear to have compromised the quality of the cement mantle. Even in the patient subgroups in which surgery was subjectively thought to be more difficult, objective measures such as operative time, component position, and cement-mantle quality were similar for both groups. These results, however, may be a reflection of surgeon experience.

Several authors have reported a reduced length of stay following minimally-invasive total hip arthroplasty^{3,25,26}. No mention was made, however, of the impact that changes in anesthetic, pain management, and physical therapy protocols had on overall patient recovery. Having standardized these, we found that the patient variables most strongly associated with the probability of early discharge were age and preoperative hemoglobin and not the surgical technique. Previous studies have established patient age as an independent predictor of the length of hospital stay following primary hip arthroplasty^{27,28}. The preoperative hemoglobin level has been shown to predict the likelihood of receiving a postoperative blood transfusion²⁹, which in turn is associated with an increased length of stay^{30,31}. In our study, a low preoperative hemoglobin level was associated with the likelihood of a hospital stay of

greater than three days, independent of the transfusion status. This finding suggests that the preoperative hemoglobin level may be useful as an independent predictor of the likelihood of early discharge following total hip arthroplasty. Additional studies are required to confirm this. Katz et al.³² found that postoperative morbidity and mortality following total hip arthroplasty was substantially lower in patients treated by surgeons with a high annual volume of caseloads working in high-volume hospitals. Similar results have been seen in other surgical specialties³³. This study, therefore, possibly represents a best-case scenario of an experienced, high-caseload surgeon working in a high-volume arthroplasty unit.

Although we did not specifically investigate patient attitudes to the cosmetic appearance, we found that the surgical scar contracted by an average of 11% to 12% over a period of six weeks.

Our follow-up period was short but covered the critical time when the benefits of the minimally invasive approach to total hip arthroplasty are proposed to be maximal. Longer-term studies are required to investigate the impact of the use of the minimally invasive approach on the durability of hip replacements.

In conclusion, minimally invasive total hip arthroplasty performed through a single-incision posterior approach by a high-volume hip surgeon with extensive experience is a safe and reproducible procedure, but it offers no significant benefit in the early postoperative period compared with a standard incision of 16 cm. Whether lower-volume or less experienced surgeons can achieve similar results is not known and merits further study before wide dissemination and implementation of this family of surgical approaches can be recommended. ■

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References

1. Mack MJ. Minimally invasive and robotic surgery. *JAMA*. 2001;285:568-72.
2. Rothschild JG. What alternatives has minimally invasive surgery provided the surgeon? *Arch Surg*. 1998;133:1156-9.
3. Howell JR, Garbus DS, Duncan CP. Minimally invasive hip replacement: rationale, applied anatomy, and instrumentation. *Orthop Clin North Am*. 2004;35:107-18.
4. Callaghan JJ. Skeptical perspectives on minimally invasive total hip arthroplasty. *J Bone Joint Surg Am*. 2003;85:2242-3.
5. Hartzband MA. Posterolateral minimal incision for total hip replacement: technique and early results. *Orthop Clin North Am*. 2004;35:119-29.
6. Sculco TP, Jordan LC, Walter WL. Minimally invasive total hip arthroplasty: the Hospital for Special Surgery experience. *Orthop Clin North Am*. 2004;35:137-42.
7. Wenz JF, Gurkan I, Jibodh SR. Mini-incision total hip arthroplasty: a comparative assessment of perioperative outcomes. *Orthopedics*. 2002;25:1031-43.
8. Woolson ST, Mow CS, Syquia JF, Lannin JV, Schurman DJ. Comparison of primary total hip replacements performed with a standard incision or a mini-incision. *J Bone Joint Surg Am*. 2004;86:1353-8.
9. American Society of Anesthesiologists. New classification of physical status. *Anesthesiology*. 1963;24:111-4.
10. Harris WH. Traumatic arthritis of the hip after dislocation and acetabular fractures: treatment by mold arthroplasty. An end-result study using a new method of result evaluation. *J Bone Joint Surg Am*. 1969;51:737-55.
11. Dawson J, Fitzpatrick R, Carr A, Murray D. Questionnaire on the perceptions of patients about total hip replacement. *J Bone Joint Surg Br*. 1996;78:185-90.
12. Bellamy N, Buchanan WW, Goldsmith CH, Campbell J, Stitt LW. Validation study of WOMAC: a health status instrument for measuring clinically important patient relevant outcomes to antirheumatic drug therapy in patients with osteoarthritis of the hip or knee. *J Rheumatol*. 1988;15:1833-40.
13. Ware JE, Kosinski M, Keller SD. SF-12: how to score the SF-12 Physical and Mental Health Summary scales. 2nd ed. Boston: The Health Institute, New England Medical Center; 1995.
14. Ware J Jr, Kosinski M, Keller SD. A 12-Item Short-Form Health Survey: construction of scales and preliminary tests of reliability and validity. *Med Care*. 1996;34:220-33.
15. White J, Kelly M, Dunsmuir R. C-reactive protein level after total hip and total knee replacement. *J Bone Joint Surg Br*. 1998;85:909-11.
16. Wirtz DC, Heller KD, Miltner O, Zilkens KW, Wolff JM. Interleukin-6: a potential inflammatory marker after total joint replacement. *Int Orthop*. 2000;24:194-6.
17. Bilgen O, Atici T, Durak K, Karaeminogullari O, Bilgen MS. C-reactive protein and erythrocyte sedimentation rates after total hip and total knee arthroplasty. *J Int Med Res*. 2001;29:7-12.
18. Shields RK, Enloe LJ, Evans RE, Smith KB, Steckel SD. Reliability, validity, and responsiveness of functional tests in patients with total joint replacement. *Phys Ther*. 1995;75:169-79.
19. Mulroy WF, Estok DM, Harris WH. Total hip arthroplasty with use of so-called second-generation cementing techniques. A fifteen-year-average follow-up study. *J Bone Joint Surg Am*. 1995;77:1845-52.
20. Draper SW. The Hawthorne effect and other expectancy effects: a note. www.psy.gla.ac.uk/~steve/hawth.html.
21. Sehat KR, Evans RL, Newman JH. Hidden blood loss following hip and knee arthroplasty. Correct management of blood loss should take hidden loss into account. *J Bone Joint Surg Br*. 2004;86:561-5.
22. Dorr LD. Single-incision minimally invasive total hip arthroplasty. *J Bone Joint Surg Am*. 2003;85:2236-8.
23. Suter M, Martinet O, Spertini F. Reduced acute phase response after laparoscopic total extraperitoneal bilateral hernia repair compared with open repair with the Stoppa procedure. *Surg Endosc*. 2002;16:1214-9.
24. Grande M, Tucci GF, Adorisio O, Barini A, Rulli F, Neri A, Franchi F, Farinon AM. Systemic acute-phase response after laparoscopic and open cholecystectomy. *Surg Endosc*. 2002;16:313-6.
25. DiGioia AM 3rd, Plakseychuk AY, Levison TJ, Jaramaz B. Mini-incision technique for total hip arthroplasty with navigation. *J Arthroplasty*. 2003;18:123-8.
26. Duwelius PJ, Berger RA, Hartzband MA, Mears DC. Two-incision minimally invasive total hip arthroplasty: operative technique and early results from four centers. *J Bone Joint Surg Am*. 2003;85:2240-2.
27. Forrest G, Fuchs M, Gutierrez A, Girardy J. Factors affecting length of stay and need for rehabilitation after hip and knee arthroplasty. *J Arthroplasty*. 1998;13:186-90.
28. Munin MC, Kwok CK, Glynn N, Crosssett L, Rubash HE. Predicting discharge outcome after elective hip and knee arthroplasty. *Am J Phys Med Rehabil*. 1995;74:294-301. Erratum in: *Am J Phys Med Rehabil*. 1995;74.
29. Salido JA, Marin LA, Gomez LA, Zorrilla P, Martinez C. Preoperative hemoglobin levels and the need for transfusion after prosthetic hip and knee surgery: analysis of predictive factors. *J Bone Joint Surg Am*. 2002;84:216-20. Erratum in: *J Bone Joint Surg Am*. 2002;84:799.
30. Bierbaum BE, Callaghan JJ, Galante JO, Rubash HE, Tooms RE, Welch RB. An analysis of blood management in patients having a total hip or knee arthroplasty. *J Bone Joint Surg Am*. 1999;81:2-10.
31. Kim DM, Brecher ME, Estes TJ, Morrey BF. The relationship of hemoglobin level and duration of hospitalization after total hip arthroplasty: implications for the transfusion target. *Mayo Clin Proc*. 1993;68:37-41.
32. Katz JN, Losina E, Barrett J, Phillips CB, Mahomed NN, Lew RA, Guadagnoli E, Harris WH, Poss R, Baron JA. Association between hospital and surgeon procedure volume and outcomes of total hip replacement in the United States Medicare population. *J Bone Joint Surg Am*. 2001;83:1622-9.
33. Hannan EL, O'Donnell JF, Kilburn H Jr, Bernard HR, Yazici A. Investigation of the relationship between volume and mortality for surgical procedures performed in New York State hospitals. *JAMA*. 1989;262:503-10.