

A double-blind, prospective, randomised, controlled clinical trial of minimally invasive dynamic hip screw fixation of intertrochanteric fractures

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ABSTRACT

Objective: To compare minimally invasive dynamic hip screw (MIDHS) fixation with conventional dynamic hip screw (CDHS) fixation for treatment of intertrochanteric femoral fracture.

Methods: Of the 66 participants in this double-blind study, 35 were randomised to MIDHS and 31 to CDHS fixation. Main outcome measurements were wound size, haemoglobin decrease, blood transfusion rate, pain score, analgesic consumption, Elderly Mobility Scale score, hip screw position, tip–apex distance, union rate, time to healing and complication rate.

Results: The groups had similar preoperative clinical data. Postoperatively the MIDHS group had significantly smaller wound size, less blood loss, lower blood transfusion rates, pain scores and rates of analgesic consumption, and higher early Elderly Mobility Scale scores. There were no significant differences in fracture alignment, hip screw position, tip–apex distance, union rate, time to healing or complication rate.

Conclusion: MIDHS fixation of intertrochanteric fractures is effective and safe and significantly reduces blood loss, pain and rehabilitation period, without sacrificing reduction alignment, screw position, fixation stability or bone healing.

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Introduction

As the number of elderly people and average life expectancy increase, orthopaedic surgeons will need to focus more on treating hip fractures, because the incidence of such fractures will double for each decade beyond the age of 50 years.^{20,28} It is estimated that the lifetime risk for hip fracture in industrialised countries is at present 6% for men and 18% for women.¹² Therefore, hip fracture represents one of the most common problems encountered by orthopaedic surgeons around the world.^{8,20,21,30,38,40} Intertrochanteric fracture of the femur is one of the most frequently occurring manifestations of this injury.^{25,31,37}

There are many options^{2,3,11,15,29,36} for achieving rigid fixation and early mobilisation of people with intertrochanteric femoral fracture; the use of the dynamic hip screw (DHS) and plates with varying numbers of holes is standard treatment in most centres.^{5,22,34,39,41} DHS was introduced in the 1950s³³ to replace the fixed nail plate and, in most fractures (usually stable and minimally displaced) DHS yields reproducibly reliable results.^{7,23}

Wide surgical exposure is traditionally important for the success of such a procedure. The potential drawbacks to DHS

are thus large skin incision and considerable soft-tissue dissection, blood loss and pain. Because of these drawbacks, the concept of minimally invasive surgery (MIS) has received enormous attention recently. MIS offers the theoretical advantages of decreased blood loss, better cosmetic results, less pain and faster rehabilitation. Orthopaedic surgeons have expressed an increased interest in MIS for various procedures, including spine surgery,¹⁹ shoulder surgery^{6,17} and total joint arthroplasty.^{9,13}

Recently several authors^{1,10,14,26} have reported on their application of MIS in DHS fixation for intertrochanteric femoral fracture, but apparently there have been no well-structured, randomised, controlled trials of this combination of techniques. Therefore we have conducted what is, to our knowledge, the first double-blind, randomised, controlled clinical trial to test the theoretical advantages of minimally invasive (MIDHS) fixation of intertrochanteric femoral fracture.

Methods

Between August 2006 and April 2007, cases of intertrochanteric fracture of the femur, classified according to Kyle,²³ were evaluated at the Pamela Youde Nethersole Eastern Hospital for inclusion in this trial. The study was conducted in accordance with the Helsinki declaration,¹⁸ and the protocol was approved by the hospital's institutional review board. People with dementia or psychiatric

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illness, those unable to walk before the injury, and those with non-united, pathological, subtrochanteric, reverse oblique or open fractures, concomitant fractures of other parts of the body and fractures sustained more than 2 weeks before presentation or requiring open reduction were excluded.

The inclusion criteria were met by 70 persons, 69 of whom agreed to participate by giving informed written consent; however, of these 3 died from other causes before completion of the trial. The final study population thus comprised 21 men and 45 women, with a mean age of 74 (51–97) years. Participants were randomly allocated to one of two treatment groups by blinded selection of a sealed envelope containing a slip of paper on which was noted either MIS or CONTROL. The allocation was concealed; neither participants nor researchers were informed of group assignment before surgery. The MIS group underwent closed reduction and MIDHS; all of these procedures were performed by the same surgeon (TCW). The CONTROL group underwent conventional dynamic hip screw (CDHS) fixation performed either by a surgeon with the same number of years of experience as the surgeon who performed MIDHS, or by a surgeon supervised by another with the same number of years of experience as TCW. Implants and instruments used were the same in both groups. The preoperative clinical details of each case were recorded. Blood transfusion was considered if the haemoglobin level was <8 g/dl and there were signs and symptoms of anaemia. All participants included in outcome analysis remained in their primary randomisation group regardless of secondary procedures, according to the intention-to-treat principle, and Consolidation Standards of Reporting Trials (CONSORT) guidelines were followed.

Minimally invasive surgical technique

All operations were performed under spinal anaesthesia. Participants were positioned on a radiolucent fracture table, and all fractures were successfully reduced by closed manipulation under fluoroscopic control to 10° of valgus on anteroposterior (AP) radiographs and $<5^\circ$ of posterior angulation on lateral radiographs, before surgery was begun.

A 135° guideplate was placed on the skin over the anterior part of the hip, to introduce a guidewire (Fig. 1). Under fluoroscopic guidance on the AP view, the plate was placed in line with the lateral border of the proximal femur. Within the lower half of the femoral neck and head region an AP line was traced along the guidewire with a skin marker, to terminate at the lateral cortex of

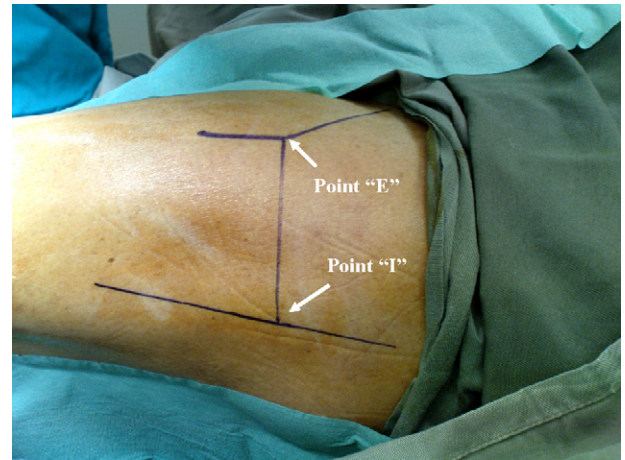


Fig. 2. Points E and I marked on the thigh.

the femur at point E where the guidewire entered the proximal femur (Fig. 2). A lateral radiograph was then obtained, a guidewire was placed along the centre of the femoral head and neck and a lateral line was traced. From point E a third line was traced perpendicular to the lateral line to make intersection point I (Fig. 2). An AP view was obtained to measure the distance (depth) here from skin to bone, using the guidewires. This measurement was then used to mark a point measuring the same distance along the lateral line distally (Fig. 3), an idea based on an isosceles triangle (Fig. 4). The guidewire was introduced through the skin at this point, and its advancement was adjusted on the basis of the AP line and lateral line, without fluoroscopic guidance. An incision 2.5 cm long was made from the guidewire distally along the lateral line. The fascia lata and vastus lateralis were incised by diathermy to minimise blood loss. After reaming, the lag screw was inserted. The guidewire was removed and a four-hole side plate was positioned under the soft tissue, turning the barrel from 180° to 90° (Fig. 5). The guidewire was reintroduced through the side plate barrel and the lag screw was inserted under fluoroscopic guidance (Fig. 6). The side plate screws were placed in the usual manner with the aid of a soft-tissue retractor. Stab incisions were sometimes necessary for the insertion of distal screws. Deep layers were closed with 1.0 Vicryl (Ethicon, Livingston, Edinburgh, UK) and the skin was closed with three stitches using 3.0 nylon. No drain was inserted.



Fig. 1. Guidewire placed through 135° guide plate on the anterior hip.

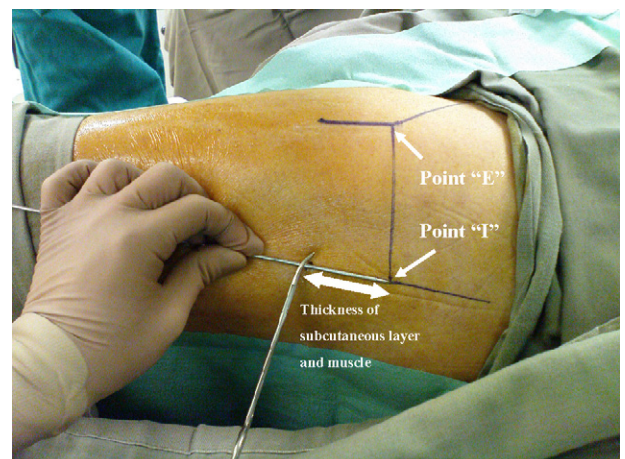


Fig. 3. Entry site of guidewire determined by marking a distance equal to the distance between skin to bone, along the lateral line from point I distally.

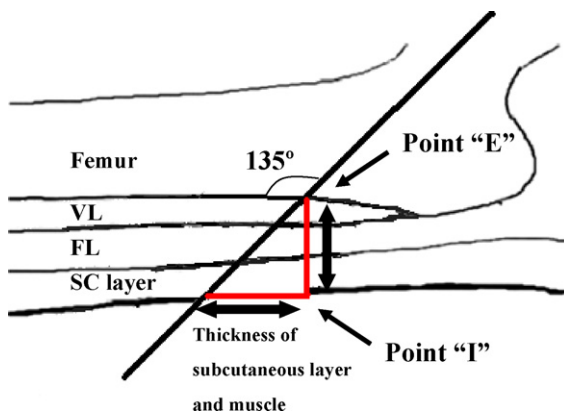


Fig. 4. Determination of guidewire entry site based on an isosceles triangle. VL, vascular layer; FL, fatty layer; SC, subcutaneous layer.

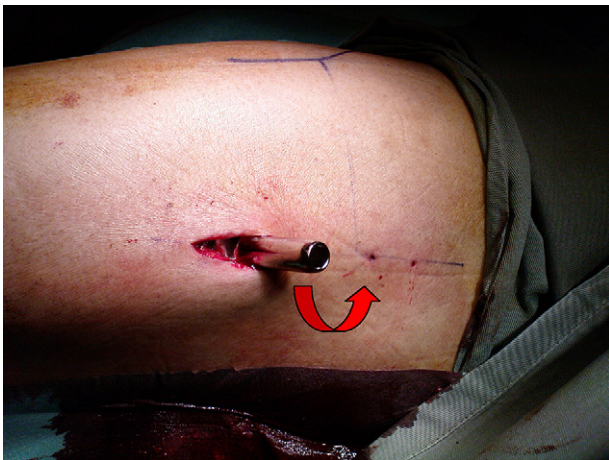


Fig. 5. Side plate placed with barrel at 180° of rotation, then turned to 90° of rotation.

Conventional surgical technique

After successful closed reduction, a longitudinal incision 10–15 cm in length was made over the lateral aspect of the thigh, beginning from the middle of the greater trochanter and extending down the lateral aspect of the femoral shaft. The fascia lata of the

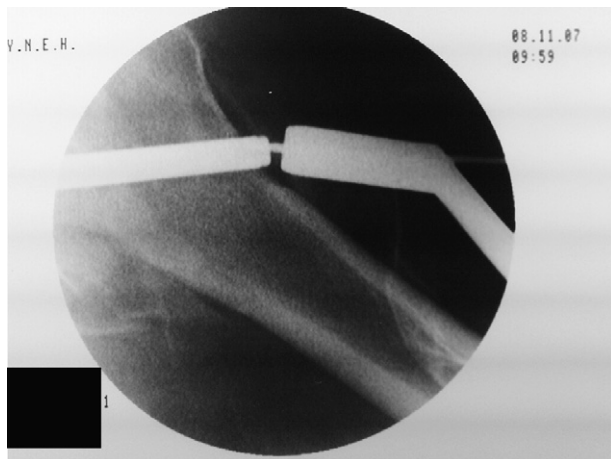


Fig. 6. Guidewire reinserted through the barrel to help in coupling the plate to the screw.

thigh was incised in line with the skin incision, and the takedown of the vastus lateralis was accomplished with a hockey-stick type of incision. The musculature of the lateral intermuscular septum was gently swept by a periosteum elevator and detached from its origin at the intertrochanteric line to allow the vastus lateralis to be retracted upward (anteriorly). The lateral aspects of the greater trochanter and proximal femur were thus exposed and the periosteum was preserved. Theoretically, this approach should incur less blood loss compared with a muscle-splitting approach. After fixation of the lag screw and plate, one vacuum drain was inserted and the incision was closed in layers.

Rehabilitation protocol and outcome assessment

After surgery, we followed the rehabilitation protocol standard at our institution. AP and lateral radiographs were obtained immediately postoperatively in all cases, for review of the adequacy of fracture reduction and screw position. Where a vacuum suction drain had been inserted, we preferred to check the radiographs again after removal of the drain. All participants were allowed full weight-bearing walking exercise and were instructed by an experienced orthopaedic physiotherapist. The postoperative analgesic protocol was standardised and consisted of oral acetaminophen/phenyltoloxamine tablets and intramuscular injection of pethidine only. For the initial 3 days, total analgesic use was recorded. Postoperative pain was assessed on day 3 using the visual analogue scale (score range, 1–100). The haemoglobin level was also checked on postoperative day 3, to avoid any haemoconcentration or haemodilution effects. All participants were assessed on postoperative day 3 and 3 months after surgery for physical function, using the Elderly Mobility Scale (EMS).³⁵ Assessment was by an experienced orthopaedic physiotherapist who was blinded as to which procedure the participant had undergone. The Harris Hip Score¹⁶ was also used to evaluate surgical results at 3 months after operation. All participants were considered ready for discharge to home when they could walk independently; all were re-examined at regular intervals, depending on individual clinical conditions. An orthopaedic specialist unaware of which procedure had been undergone assessed all radiographs for screw position as categorised by Kyle's system²³ and tip–apex distance.⁴ Fractures were regarded as healed only when definite bony trabeculae across the fracture were present in both AP and lateral radiographs and no hip tenderness could be elicited clinically on a provocation test. Complications were recorded for both groups.

Statistical analysis

Statistical analysis was performed with SPSS 13.0 for Windows (SPSS, Chicago, IL, USA). The statistical difference was calculated by Fisher's exact test for dichotomous variables with a frequency <5, and the chi-square test for variables with a frequency >5; Student's unpaired *t*-test analysed continuous variables of parametric data and the Mann–Whitney *U*-test was used for continuous variables of non-parametric data. All tests of significance were two-tailed. Statistical significance was defined as $p < 0.05$.

Results

Of the 69 people who qualified for our investigation, 66 were included; 3 died from other causes before completion of the trial. Of the 66, 35 were randomised to the MIDHS group and 31 to the CDHS group. Both groups had comparable preoperative demographics, body mass index, comorbidity factors, premorbid ambulatory status, injury mechanism, fracture pattern, time from

Table 1

Preoperative clinical details for both groups.

Detail	MIDHS, n = 35	CDHS, n = 31	p-Value
Men:women	10:25	11:20	0.57
Age in years, M ± S.D. (R)	80.6 ± 7.6 (56–97)	80.7 ± 9.9 (51–97)	0.98
Body mass index (kg/m ²), M ± S.D. (R)	20.2 ± 2.4 (16.9–25.8)	19.5 ± 1.2 (15.0–24.4)	0.24
Confounding medical conditions, n			
Hypertension	21	18	
Cerebrovascular accident	3	4	
Diabetes	11	7	
Cardiac disease	5	10	
Gastrointestinal disease	6	2	
Respiratory disease	3	4	
Renal disease	4	2	
Malignancy	6	2	
Thyroid disease	3	1	
Premorbid ambulatory status, n*			
Unaided	15	12	
Walking stick used	16	16	0.78
Quadripod walker used	1	0	
Walking frame used	3	3	
Injury mechanism, n			
Slipped and fell	33	29	
Motor vehicle accident	1	1	0.56
Fall from height	1	1	
Days from injury to surgery, M ± S.D. (R)	2.7 ± 1.8 (1–7)	3.0 ± 1.6 (1–7)	0.51
Right:left hip fracture, n	17:18	16:15	0.81
Kyle's classification, n			
I	6	3	
II	13	16	0.44
III	16	12	
Preoperative Hb (g/dl), M ± S.D. (R)	11.2 ± 1.7 (8.1–16.2)	11.8 ± 1.6 (8.7–15.3)	0.15
ASA classification, n			
I	4	2	
II	16	11	0.47
III	15	17	
IV	0	1	

MIDHS, minimally invasive dynamic hip screw (fixation) group; CDHS, conventional dynamic hip screw (fixation) group; M, mean; S.D., standard deviation; R, range; n, number of participants; Hb, haemoglobin; ASA, American Society of Anesthesiologists' classification of physical status.

* Statistically significant difference, $p < 0.05$.

injury to surgery and American Society of Anesthesiologists (ASA) classification (Table 1).

The MIDHS group showed significantly smaller decreases in haemoglobin levels and a lower blood transfusion rate, with

Table 2

Surgical data and clinical results.

Data	MIDHS	CDHS	p-Value
Duration of surgery (min), M ± S.D. (R)	35.7 ± 6.7 (25–50)	37.9 ± 9.2 (25–60)	0.27
Haemoglobin decrease (g/dl) M ± S.D. (R)	1.4 ± 1.0 (0–3.6)	2.6 ± 1.1 (0.8–4.9)	0.00 [†]
Blood transfusion (ml), M ± S.D. (R)	17.1 ± 101.4 (0–600)	135.5 ± 307.2 (0–1200)	0.04 [†]
Total analgesic consumption			
Tabs, M ± S.D. (R)	5.4 ± 2.0 (1–10)	8.6 ± 3.6 (2–14)	0.00 [†]
IM pethidine (mg), M ± S.D. (R)	8.6 ± 30.9 (0–150)	48.4 ± 55.5 (0–200)	0.00 [†]
Visual analogue scale score, M ± S.D. (R)	27 ± 21.3 (0–73)	65.3 ± 27.4 (0–100)	0.00 [†]
Days of hospital stay, M ± S.D. (R)	24.5 ± 10.7 (5–50)	30.0 ± 11.1 (6–55)	0.12
Number with complications	2 DVT	1 DVT, 1 fast AF, 1 UTI	0.90
Follow-up, months M ± S.D. (R)	12 ± 3.5 (8–17)	12 ± 3.4 (8–17)	0.90

MIDHS, minimally invasive dynamic hip screw (fixation) group; CDHS, conventional dynamic hip screw (fixation) group; M, mean; S.D., standard deviation; R, range; Tabs, tablets acetaminophen/phenyltoloxamine; IM, intramuscular; AF, atrial fibrillation; DVT, deep vein thrombosis; UTI, urinary tract infection.

[†] Statistically significant difference: $p < 0.05$.

Table 3

Radiological assessment in both groups.

Parameter	MIDHS	CDHS	p-Value
Fracture reduction, n			
Excellent	19	15	
Good	13	10	0.55
Average	3	5	
Fair	0	0	
Poor	0	1	
Kyle's screw position, n			
2/2	3	5	
2/3	9	7	
2/1	0	0	0.55
1/2	0	1	
1/3	0	0	
3/3	23	18	
Tip–apex distance, M in mm ± S.D. (R)	1.3 ± 0.4 (0.3–2.5)	1.4 ± 0.7 (0.4–2.8)	0.57
Weeks to union, M ± S.D. (R)	10.9 ± 2.3 (8–16)	12.0 ± 2.5 (8–16)	0.09

MIDHS, minimally invasive dynamic hip screw (fixation) group; CDHS, conventional dynamic hip screw (fixation) group; n, number of participants; M, mean; S.D., standard deviation; R, range.

significantly lower pain scores on postoperative day 3 and significantly lower total analgesic use during the initial 3 days. The average duration of hospital stay was shorter in the MIDHS group, but the difference between the two groups was not statistically significant; nor was difference in complication rates. We had one case of intraoperative conversion to the conventional approach because a longer side plate was used for subtrochanteric extension; the fracture subsequently healed without complication. The details of surgery are summarised in Table 2.

All fractures had healed by final follow-up. The screw position and tip–apex distance, and healing time were similar in both groups. Table 3 summarises the radiological findings among both groups.

At physical function assessment, the MIDHS group had significantly higher EMS scores on postoperative day 3 when compared with the CDHS group. There was no difference between groups in EMS scores or Harris Hip Scores at 3 months after surgery, and postoperative ambulatory status was similar in both groups (Table 4).

Discussion

The use of the dynamic hip screw and plate remains one of the most common methods for treating intertrochanteric fracture of the femur. The procedure provides rigid fixation and allows early

Table 4
Functional assessment in both groups.

Assessment	MIDHS	CDHS	p-Value
Elderly Mobility Scale score at day 3, $M \pm S.D.$ (R)	6 ± 4.4 (0–17)	2.6 ± 3.4 (0–14)	0.00*
Elderly Mobility Scale score at 3 months, $M \pm S.D.$ (R)	16.5 ± 3.1 (10–20)	15.7 ± 2.7 (10–20)	0.28
Harris Hip Score at 3 months, $M \pm S.D.$ (R)	87.5 ± 5.9 (76–97)	86.2 ± 5.3 (74–95)	0.32
Postoperative ambulatory status at 3 months, <i>n</i>			
Unaided	2	1	0.51
Walking stick used	15	9	
Quadripod walker used	7	6	
Walking frame used	11	15	

MIDHS, minimally invasive dynamic hip screw (fixation) group; CDHS, conventional dynamic hip screw (fixation) group; *M*, mean; *S.D.*, standard deviation; *R*, range; *n*, number of participants.

* Statistically significant difference: $p < 0.05$.

mobilisation because it enables optimal collapse and compression of the fracture site.²⁶ However, successful treatment depends on many additional factors, including the age of the patient, the time from fracture to surgery and the presence of concurrent medical disease.³² Therefore, any comparison of a minimally invasive technique with the conventional technique should control for all these factors.

Although reports of several studies^{1,10,14,26} of MIDHS fixation for the treatment of intertrochanteric femoral fracture have been published and claim good results, well-structured prospective, randomised, controlled trials are lacking.

Gotfried¹⁴ reported his experience with the percutaneous compression plating technique in treating intertrochanteric hip fracture using a minimally invasive technique. However, the Gotfried plating system is a newly designed implant that is not widely available. Besides, the 118 cases in his study were reviewed retrospectively, no comparison was made with any control group and details of surgical technique were not provided.

DiPaola et al.¹⁰ reported a series of 13 cases treated with minimal incision and a two-hole plate for fixation of stable intertrochanteric hip fractures. Again, there was no control group for comparison and the sample size was too small to justify extrapolation of the results. In reporting radiographic analysis, the authors did not mention screw position nor the adequacy of fracture reduction. Although the mean medial proximal femoral angle and neck-shaft angle were documented, this did not prove adequacy of fracture reduction and, as a two-hole plate was used, there could be no direct comparison with the results of a technique involving a four-hole plate.

Alobaid et al.¹ conducted a prospective, randomised trial comparing the MIDHS technique with the conventional technique for fixation of intertrochanteric hip fracture. However, their surgeon randomisation was not standard and was not clearly explained in their report. The side plate used in the study was not standard either; both two-hole and four-hole plates were used. The authors did not comment on radiological results, although these are of paramount importance because one of the prerequisites of a successful MIDHS procedure is that screw position and alignment should not be jeopardised.

Lee et al.²⁶ also reported good results with MIDHS, but the study was not a well-structured, prospective, randomised, controlled trial: The randomisation method was based on the shift worked by the surgeon, and the researchers did not specify the time from injury to treatment for either group, whether the allocation to groups was concealed nor whether participants and assessors remained unaware of group assignment. As they favoured a three-hole side plate for fixation, their results could not be directly compared with those of the four-hole side plate used in our study.

Although McLoughlin et al.²⁷ found no difference in biomechanical stability between two-hole and four-hole side plates, and

several authors^{5,10,24} have reported good results and no implant failures with two-hole side plate DHS fixation, there has been no randomised, controlled trial comparing the use of two-hole and four-hole side plates. We considered osteoporosis and unstable fracture pattern to be the major risk factors for implant failure; thus we inferred that a four-hole side plate would provide a greater pull-out strength, in particular before the fracture united, and would be beneficial for osteoporotic or unstable fractures which comprise a large proportion of hip fractures. In our study, the use of four-hole side plates did not affect wound size.

One problem with the minimally invasive approach was determining the entry site in the skin with the use of guidewires. In practice, site location varied between cases, particularly among obese individuals; yet no other author has addressed this important issue. We based our method on the concept of an isosceles triangle, in view of the logistics and because our past experience indicated that this method was very accurate. There is no unnecessary proximal extension if there is appropriate wire insertion initially. We did not find that a smaller incision for placing a DHS might lead to suboptimal exposure and hence increased operating time.

The limitations of our study were its relatively small sample size, low power, lack of long-term follow-up and lack of comparison of radiation requirements between the two techniques. In addition, there are a few confounding factors within the report; most importantly, one surgeon performed all the MIDHS operations, whereas several surgeons operated for the CDHS group. This reduced the external validity of the trial, i.e. the ease with which these results could be generalised. Similarly, diathermy was used in what appears to have been a lateral approach to the lateral aspect of the femur for the MIDHS group, whereas in the CDHS group the vastus lateralis was reflected from the linea aspera; in addition, drains were not used in MIDHS but were required for CDHS. Both these factors may have influenced the blood loss associated with the procedure.

Conclusions

It is clear from our prospective, randomised, controlled series that there was no significant difference between the MIDHS group and the CDHS group in duration of surgery. We found, however, that the shorter the incision and the less the amount of tissue disruption (particularly disruption of highly vascularised muscle), the smaller was the decrease in haemoglobin levels. Although the shorter duration of hospital stay for the MIDHS group was not statistically significant, it was coincident with significantly less pain and a significantly shorter rehabilitation period than was experienced by the CDHS group.

We emphasise that MIDHS is appropriate only when adequate closed reduction can first be achieved, which is not necessarily the case for all intertrochanteric fractures. In addition, basicervical

fractures treated with DHS and requiring antirotational proximal screw fixation may not be suitable for MIDHS. Nevertheless, for intertrochanteric femoral fractures MIDHS is superior to the conventional technique because it produces less blood loss, less pain and a shorter rehabilitation period, while still achieving good radiological outcome.

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