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Alternative techniques in trochanteric hip fracture surgery

Clinical and biomechanical studies on the Medoff sliding plate and the Twin hook

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THESIS

ACTA ORTHOPAEDICA SCANDINAVICA SUPPLEMENTUM NO. 295, VOL. 71, 2000

Abstract

In allowing compression along the femoral shaft (uniaxial dynamization) and optional compression along the femoral neck (biaxial dynamization), the Medoff sliding plate (MSP) represents a new principle in the fixation of trochanteric hip fractures. The Twin hook with 2 apical hooks was designed as an alternative to the lag screw. In 3 prospective consecutive case series and 1 prospective randomized study together comprising 342 trochanteric fractures, these alternative techniques were investigated.

3 postoperative fixation failures occurred in the unstable intertrochanteric fractures treated with biaxial dynamization with the MSP (n=194), and 5 in those treated with the sliding hip screw (n=62) (p=0.04). A mean femoral shortening of 15 mm with the MSP and 11 mm with the sliding hip screw was found (p=0.03). More medialization of the femoral shaft occurred with the sliding hip screw (26%) than with the MSP (12%) in patients with marked femoral shortening (p=0.03). 3 postoperative fixation failures occurred in subtrochanteric fractures treated with uniaxial dynamization (n=29) and 2 in those treated with biaxial dynamization (n=19). Medialization of the femoral shaft occurred in 9 of the 19 biaxially dynamized fractures.

The Twin hook was used in 50 patients and appeared to provide similar fixation stability as the lag screw.

Biomechanical tests confirmed improved stress transmission over the fracture area with the MSP compared to the sliding hip screw in intertrochanteric fractures, and similar fixation stability with the MSP and the Intramedullary Hip Screw in subtrochanteric fractures. In axial and torsional loading, the Twin hook demonstrated gradually increasing resistance to migration. With the lag screw, the peak load was higher, but after migration with failure of the support by the threads, the loads were similar.

Biaxial dynamization with the MSP appears to control fracture impaction effectively and minimizes the rate of postoperative fixation failure in intertrochanteric fractures. In subtrochanteric fractures, uniaxial dynamization prevents medialization of the femoral shaft and is therefore preferred to biaxial dynamization. The Twin hook appears to provide adequate fixation stability, and with potential for simplified intraoperative handling and reduced dissection, the Twin hook may pose advantages compared to the lag screw.

List of papers

This thesis is based on the following papers:

I. Olsson O, Ceder L, Lunsjö K, Hauggaard A. Biaxial dynamization in unstable intertrochanteric fractures. Good experience with a simplified Medoff sliding plate in 94 patients. Acta Orthop Scand 1997; 68: 327-31.

II. Ceder L, Lunsjö K, Olsson O, Stigsson L, Hauggaard A. Different ways to treat subtrochanteric fractures with the Medoff sliding plate. Clin Orthop 1998; 348: 101-6.

III. Olsson O, Ceder L, Lunsjö K, Hauggaard A. Twin hook or lag screw in extracapsular hip fractures – a prospective study of 102 consecutive patients. International Orthopaedics. Accepted.

IV. Olsson O, Ceder L, Hauggaard A. Femoral shortening in intertrochanteric fractures. A prospective study of 114 patients randomised to fixation with the Medoff sliding plate or the Compression hip screw. In manuscript.

V. Olsson O, Kummer F J, Ceder L, Koval K J, Larsson S, Zuckerman J D. The Medoff sliding plate and a standard sliding hip screw for unstable intertrochanteric fractures. A mechanical comparison in cadaver femurs. Acta Orthop Scand 1998; 69(3): 266-72.

VI. Kummer F J, Olsson O, Pearlman C A, Ceder L, Larsson S, Koval K J. Intramedullary versus extramedullary fixation of subtrochanteric fractures. A biomechanical study. Acta Orthop Scand 1998; 69(6): 580-4.

VII. Olsson O, Tanner K E, Ceder L, Ryd L. Twin hook or lag screw for extracapsular hip fractures – a biomechanical study on fixation stability in artificial cancellous bone. Submitted for publication 2000.

The papers are referred to by Roman numerals in the text.

Introduction

The greater and lesser trochanter (from the Greek word for a runner) are terms that refer to the lateral and medial prominences of the proximal femur. As a rule, the trochanteric region is defined as the area bordered proximally by the line of attachment of the hip joint capsule and distally by the inferior aspect of the lesser trochanter. The words intertrochanteric or pertrochanteric are usually used synonymously to depict fractures within this region. Subtrochanteric fractures engage the femoral shaft in the region within 5 cm of the distal margin of the lesser trochanter, but often with extensions to the level of the lesser or sometimes also the greater trochanter. Due to a number of unpropitious factors, trochanteric fractures pose a challenge to the orthopedic surgeon – typically, an elderly patient who tolerates recumbency poorly, suffers an unstable fracture in osteoporotic bone, engaging the area of the skeleton with the highest loads.

In this thesis, the technical aspects of achieving fracture fixation, allowing immediate mobilisation with as safe fracture consolidation as possible are discussed. However, it must be emphasised, that the overall impact of a hip fracture on an elderly person is severe. With primary effects on ambulatory function, and secondary ones on general health and the capacity to take care of oneself, a hip fracture is a major threat to the independence or even the life of the aging person. The task of the orthopedic surgeon is to optimize the conditions for early mobilisation and uneventful fracture-healing, thereby creating the best possible means for rehabilitation of the patient to previous function.

Internal fixation of trochanteric fractures was introduced in the 1930s and 1940s (Thornton 1937, Jewett 1941, McLaughlin 1947), but skeletal traction remained the commonest treatment for several years. With increasing evidence of the superiority of surgical treatment permitting early mobilisation (Boyd and Griffin 1949, Evans 1949, 1951, Cleveland et al. 1947, 1959, Holt 1963), general acceptance was gained. With the rigid devices used, fixation failures in terms of nail or screw cut-out of the femoral head or neck, penetration of the femoral head, bending or breakage of the plate or non-union, occurred in 20–50% in unstable multifragmentary fractures (Clawson 1964, Jensen and Michaelsen 1975, Jacobs et al. 1976, Jensen et al. 1980, Heyse-Moore et al. 1983, Esser et al. 1986, Chinoy and Parker 1999).

As early as 1917, Koch stated that the medial aspect of the proximal femur around the lesser trochanter is subjected to the largest compressive stresses in the body during weight-bearing, and it was later recognised that failure of fixation was related to lack of posteromedial support (Evans 1949, Clawson 1964). In fractures involving the lesser trochanter, poor load transfer over the fracture surfaces occurred with rigid implants, which remained subjected to high loads. Various types of osteotomies were proposed to achieve a primary stable fracture configuration (Dimon and Hughston 1967, Sarmiento and Williams 1970), and these procedures appeared to be beneficial in selected unstable fractures. However, complications were reported related to the extended procedure, such as an increase in the rate of infection and impaired functional outcome (Laros and Moore 1974, Hunter and Krajbich 1978, Clark and Ribbans 1990).

Dynamic fixation devices, allowing secondary fracture impaction by a telescoping mechanism between the barrel of the plate and the screw or nail inserted into the femoral neck and head, were presented already in the 1950s (Schumpelick and Jantzen 1953, 1955, Pugh 1955). Results superior to those achieved with rigid devices were reported (Clawson 1964, Mulholland and Gunn 1972, Sahlstrand 1974, Jacobs et al. 1976), but it took more than 20 years from the invention for the sliding hip screw to become the main method used for these fractures (Treharne 1982). By allowing fracture compression along the axis of the femoral neck, the sliding hip screw facilitates interfrag-

Table 1. Postoperative fixation failures in the last 10 years published prospective consecutive series, which include more than 40 unstable intertrochanteric fractures operated with a sliding hip screw and with a minimum follow-up of 3 months

Author	Patients (n)[a]	Postop. fixation failures (n)[b]	Failure rate
Davis et al. 1990	85	19	0.22
Clark and Ribbans 1990	55	7	0.13
Nungu et al. 1991	59	9	0.16
Leung et al. 1992	73	3	0.04
Barrios et al. 1993	42	11	0.26
Desjardins et al. 1993	57	3	0.05
Radford et al. 1993	43	3	0.07
Stappaerts et al. 1995	47	2	0.04
Watson et al. 1998	62	9	0.15
Buciuto et al. 1998	111	12	0.11
Lunsjö et al. 2000[c]	238	8	0.03

[a] Including only unstable intertrochanteric fractures
[b] Lag screw penetration or superior cut-out, breakage or loosening of the implant or nonunion
[c] Submitted for publication

mentary stress transfer (Larsson et al. 1988a, 1988b), thereby unloading the implant and transferring some of the load to the bone. However, the dynamic function of the device is aligned parallel to the femoral neck and depending on the geometry of the fracture, the device may not allow sufficient fracture impaction to achieve posteromedial bony contact. If this area is not supported, the device remains subjected to high loads, with subsequent substantial risk of fixation failure (Table 1).

Already in their first report on the dynamic sliding screw plate, Schumpelick and Jantzen (1953) pointed out that the oblong holes for the cortical screws holding the plate to the femoral shaft could provide an additional dynamic function, aligned parallel to the femoral shaft, in subtrochanteric fractures. Clawson (1964) suggested the same modification of the plate. Kelly was the first to point out that the entry hole of the plate barrel in the lateral cortex must be enlarged distally, otherwise the plate barrel would impinge on the intact lateral cortical bone and prevent axial compression in intertrochanteric fractures (Jarrett et al. 1984).

In 1991, Robert Medoff presented a novel device with a biaxial sliding capacity. Its design is similar to that of the sliding hip screw, but the side-plate constrains a sliding element, holding the barrel for the lag screw. Medoff considered the axial sliding capacity along the femoral shaft to be the important feature of the fixation, and used a locking set screw to prevent the lag screw from sliding. This pilot study comprised 25 patients with unstable inter- and subtrochanteric fractures, and no fixation failures were observed (Medoff and Maes 1991).

Evaluation of the Medoff sliding plate in consecutive case series was begun in Helsingborg, Sweden, in 1992. The first study (Lunsjö et al. 1995) comprised 104 patients with intertrochanteric fractures and the plate was used with sliding only along the axis of the femoral shaft, according to the inventor (uniaxial dynamization). 7 postoperative lag screw penetrations occurred. In a second series (Lunsjö et al. 1996) of 108 patients with intertrochanteric fractures, the plate was used with sliding along both the femoral neck and the femoral shaft (biaxial dynamization). Only 1 lag screw penetration was noted.

The original Medoff sliding plate is fixed to the femoral shaft with 6 cortical bone screws. Since fixation to the femoral shaft with 4 screws in general is considered adequate, a simplified plate was designed. The new 4-hole Medoff sliding plate was used in a third consecutive case series (I) with intertrochanteric fractures in 1993. The resulting femoral shortening after intertrochanteric fractures treated with the Medoff sliding plate or with a sliding hip screw was compared in a randomized trial (IV) during 1998 and 1999. Subtrochanteric fractures were also operated on with the Medoff sliding plate and included in a consecutive case series (II) during 1992–1994. During different parts of the study period, uniaxial or biaxial dynamization was used, and the potential advantages and disadvantages of the respective methods were analyzed.

The early rigid fixation devices consisted of a plate and a nail. With the introduction of the dynamic devices, the nail in most devices was replaced by a screw, and today the lag screw is by far the commonest type of implant used for the femoral neck and head fixation. In contrast, many types of screws, nails or pins are in practice for femoral neck fractures. In the 1980s, the Hansson hook pin was introduced in Lund, Sweden. As always with displaced femoral neck fractures, the failure rate was high. However, penetration of the femoral head is extremely uncommon with the Hansson hook pin (Strömqvist et al. 1987, 1992). Due to this experience, a new nail, the Twin hook, was designed. With potential for increased resistance to rotation, migration and penetration, and with obvious advantages in terms of possibilities for simplified intraoperative handling, the Twin hook was compared to a lag screw in a controlled case series (III).

For the development of new techniques of fracture fixation, biomechanical testing is of fundamental importance. The postulated theoretical advantages of new designs must be confirmed by tests using simulated fracture models, and in order to gain improved understanding of the course of events that governs the progress of fracture consolidation or the occurrence of fixation failures, these data must be related to clinical results. Biomechanical tests of the Medoff sliding plate has been undertaken in intertrochanteric (V) and subtrochanteric (VI) fracture models using cadaver bone, and the femoral head purchase of the Twin hook has been evaluated and compared to the lag screw in an artificial cancellous bone model (VII).

Aims of the studies

The Medoff sliding plate in intertrochanteric fractures

To determine whether the low rate of postoperative fixation failure obtained with biaxial dynamization in intertrochanteric fractures could be reproduced.

To determine whether the 4-hole Medoff sliding plate could be used for intertrochanteric fractures without adverse effects from the simplification of the device.

To determine whether fixation with the Medoff sliding plate or with the sliding hip screw involved different amount of femoral shortening in stable and unstable intertrochanteric fractures.

To evaluate the postulated improved load-sharing ability of the Medoff sliding plate in an intertrochanteric fracture model.

To determine if the Medoff sliding plate provided fixation stability comparable to a conventional sliding hip screw device in an intertrochanteric fracture model.

The Medoff sliding plate in subtrochanteric fractures

To investigate what outcome of treatment that was achieved with axial compression in subtrochanteric fractures.

To evaluate the advantages and disadvantages of uni- or biaxial dynamization in subtrochanteric fractures.

To evaluate the postulated improved load-sharing ability of the Medoff sliding plate in a subtrochanteric fracture model.

To evaluate the effect of uni- and biaxial dynamization on medialization of the femoral shaft in a subtrochanteric fracture model.

To determine whether the Medoff sliding plate provided fixation stability comparable to that with the Intramedullary Hip Screw in a subtrochanteric fracture model.

The Twin hook in trochanteric fractures

To evaluate if the Twin hook provided adequate fixation stability for use in trochanteric fractures.

To evaluate the theoretical advantages of simplified intraoperative handling that were postulated with the Twin hook.

To compare the fixation stability of the Twin hook and of a lag screw in axial and torsional loading in a femoral head test model.

To evaluate the applicability of cellular rigid polyurethane foam as a substitute for cancellous bone in biomechanical tests.

The original Medoff sliding plate, the 4-hole Medoff sliding plate and the Twin hook

The original Medoff sliding plate and the 4-hole Medoff sliding plate

The Medoff sliding plate is similar to a sliding hip screw with a proximal barrel enclosing the lag screw, providing a slide function along the axis of the femoral neck. The side-plate consists of a coupled pair of sliding elements providing a slide function along the axis of the femoral shaft. The bone screws, which hold the plate on the femoral shaft, are aligned in 30° converging directions. The original plate has 6 bone screws, and the distal closed part of the plate sleeve holds a compression screw, allowing intraoperative axial static compression to be applied. A locking set screw can be used to prevent sliding of the lag screw.

Since 2 bone screw holes were omitted and the plate sleeve is open distally, the 4-hole Medoff sliding plate is 26 mm shorter than the original 6-hole plate (Figure 1). The distal compression screw was considered superfluous, since the intraoperative static compression should be eliminated immediately during postoperative weight-bearing. The option to use a proximal locking set screw was also omitted, since the 4-hole plate was only intended for biaxial dynamization in intertrochanteric fractures. The axial sliding features of both plates are identical with a slide span of 25 mm.

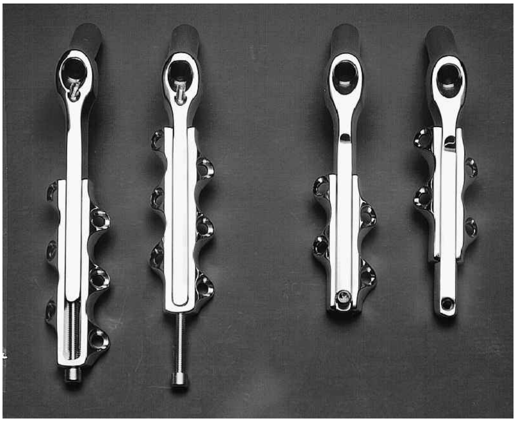

Figure 1. The original 6-hole Medoff sliding plate (left) and the simplified 4-hole Medoff sliding plate (right). Both devices have equal sliding capacity along the axis of the femoral neck and shaft.

If the entry hole of the barrel of the plate through the lateral cortex is in the intact distal fragment, a distal enlargement of up to 25 mm must be made. Otherwise the barrel will impinge on the lateral cortex and plate sliding will be prevented. If the fracture line runs less than 25 mm below the entry hole, an enlargement must also be made to ensure that the barrel does not impinge during the 25 mm slide span.

The Twin hook

The Twin hook resembles the Hansson pin with a cannulated nail, but it has 2 apical apertures for the hooks on opposite sides of the nail (Figure 2). The nail body and the hooks are bolder than on the Hansson pin. The shaft dimensions (6.8 mm x 7.9 mm) are similar to those of a conventional lag screw.

The Twin hook is pushed into a reamed channel and, by rotating the handle of the insertion assembly, the hooks are forced out through the apertures into the subchondral bone of the femoral head in anterior and posterior directions. The shape of the nail apertures bend the hooks in arches with their convexity facing the periphery of the femoral head. Similar to a conventional lag screw, the flat long sides of the Twin hook are keyed by the plate barrel preventing rotation between the 2 device parts. In contrast to the standard operation with a lag screw, the plate may be placed in its correct position on the femoral shaft before the Twin hook is inserted into its reamed channel through the plate barrel.

Figure 2. The Twin hook with 2 apical apertures for the hooks on opposite sides of the nail.

Material and methods

Clinical studies

Patients

During 1992 to 1999, 340 patients with trochanteric fractures were included in 4 prospective consecutive series (I–IV) (Table 2). 2 patients with basicervical fractures were also included (III). Pre injury residential status and ambulatory function, in terms of what walking aids that were used, were registered.

Fracture classification and distribution

Intertrochanteric fractures were classified according to the Jensen and Michaelsen modification (1975) of Evans classification (Figure 3). Fractures types III, IV and V, which lack medial and/or lateral support, were considered unstable. Subtrochanteric fractures were classified according to Seinsheimer (1978) (Figure 4) and all subtrochanteric fractures were regarded as inherently unstable.

Table 2. Patient characteristics of the 342 patients with trochanteric fractures included in the 4 series

	Intertrochanteric fractures [a]	Subtrochanteric fractures
Patients (n)	294	48
Female:male	205:89	32:16
Median age (years)	84 (39–102)	81 (29–96)
Living in own home before injury (n)	203	42
Unsupported walking before injury (n)	138	31

[a] Including 2 basicervical fractures

Inclusion criteria

In all series, prospective consecutive patient inclusion according to the respective study protocol was made. Patients with pathological fractures or previous surgery on the ipsilateral proximal femur were excluded.

During 1993 (I), patients with intertrochanteric fractures Jensen and Michaelsen type II, III, IV or V were included and treated with a 4-hole Medoff sliding plate. During 1992–1994 (II), subtrochanteric fractures were operated on with the original 6-hole Medoff sliding plate. In 1992 and in 1994, uniaxial dynamization was used and in 1993, biaxial dynamization. During 1996 (III), all basicervical, intertrochanteric and subtrochanteric fractures were included. During the first half of the study period, the Twin hook was used, and during the second half of the study period, a lag screw (Osteo AG, Selzack, Switzerland). The Twin hook or the lag screw was combined with the plate of a sliding hip screw device (Osteo AG, Selzack, Switzerland) in basicervical and in stable intertrochanteric fractures (Jensen and Michaelsen types I and II). In unstable intertrochanteric fractures, the Medoff 4-hole plate was used and in subtrochanteric fractures, the original 6-hole plate with uniaxial dynamization. In the following, the data on the 2 basicervical fractures (III) are incorporated with the data on the intertrochanteric fractures. During 1998 and 1999 (IV), all intertrochanteric fractures were included and randomized to fixation with the Medoff sliding plate or the Compression hip screw (Smith and Nephew, Memphis, TN, USA).

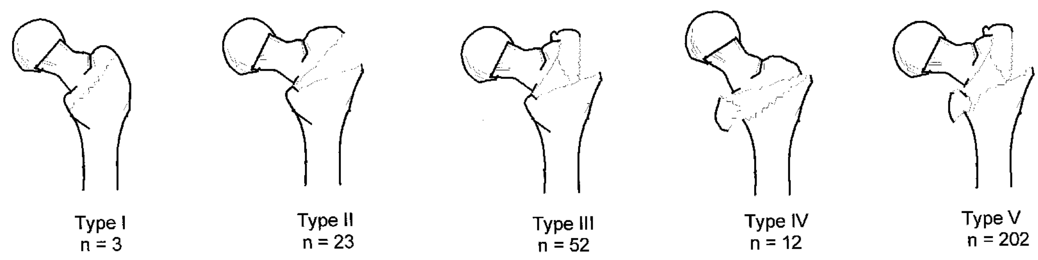

Figure 3. Distribution of the intertrochanteric fractures according to the classification by Jensen and Michaelsen (1975).

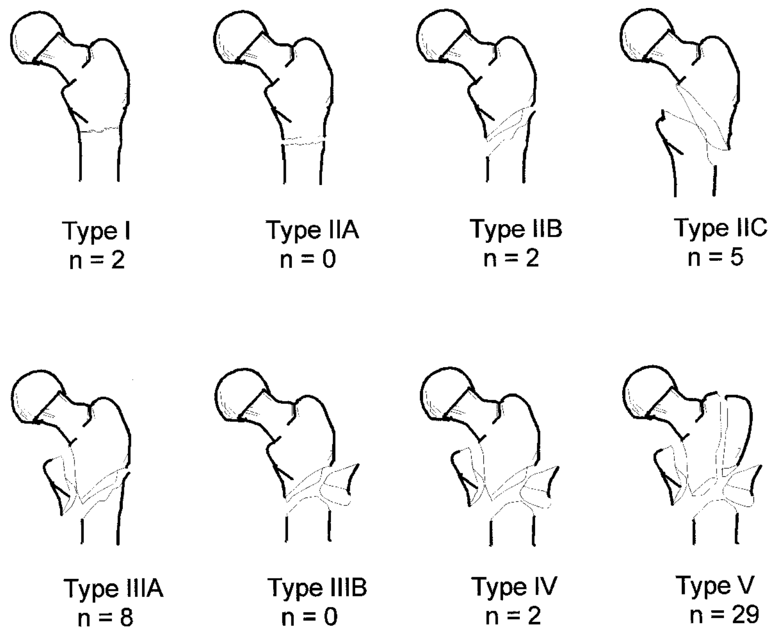

Figure 4. Distribution of the subtrochanteric fractures according to the classification by Seinsheimer (1978).

Pre-, intra- and postoperative measures

During 1992 to 1994, tibial pin traction was used on all patients unless surgery was scheduled within a few hours of admission. In 1996, pin traction was abandoned and used only if a prolonged delay in surgery was expected. Surgery was performed on a fracture table under biplane fluoroscopic control. During 1992–1994, the patients were given 0.5 L Dextran 70 intravenously before surgery, and from 1996–1999 40 mg Enoxaparin subcutaneously, as prophylactic anticoagulant therapy. Enoxaparin was given daily until the patient was mobilised in all the series. During 1992–1994, intravenous prophylactic antibiotic therapy (750 mg Cefuroxime) was started during surgery with 3 subsequent doses at 8-hour intervals. From 1996–1999, 1500 mg Cefuroxime was given intraoperatively and at 24 h.

The intraoperative bleeding as estimated by the anesthetist nurse, the operating time and any intraoperative deviations from the standard procedure were registered. The length of the skin incision was measured. In study IV, preoperative and postoperative hemoglobin levels and the number of packed red cell units given within 3 days of the operation, were registered. During the hospital stay, deep venous thrombosis (verified by phlebography), pulmonary embolus (verified by pulmonary scintigraphy) and wound infection were recorded. The length of the hospital stay was also noted.

Follow-up

Radiographs were obtained postoperatively on day 1, at 1 week, 4 months and 1 year, except in study IV, in which the length of follow-up was 4 months. In study IV, radiographs of both femurs parallel in extension and parallel to the film cassette were obtained at the 4-month control. At the 4-month and 12-month controls the patients, or relatives if the patient suffered from dementia, were questioned for residential status and walking ability. Pain on weight-bearing (none, slight or severe) was recorded for lucid patients. For patients who could not attend the scheduled postoperative controls, telephone information was obtained whenever possible.

Radiographic analysis

The final classification of the fracture type was made after the last follow-up, when the whole set of radiographs was available. Radiographic signs of intraoperative errors by the surgeon in terms of primary malpositioning of the device or inadequate reduction were noted. In study IV, the femoral shortening was determined by measuring the distance from the top of the femoral head to the center of a line drawn between the most distal part of the medial and lateral femoral condyles. The uninjured contralateral femur served as control. The degree of medialization of the femoral shaft was measured on the anteroposterior radiograph as a fraction of the femoral diameter at the fracture level. Migration of the lag screw or of the Twin hook was estimated by dividing the femoral head into 4 sectors by 2 perpendicular lines on both the anteroposterior and lateral views. Similarity of femoral rotation was estimated by measuring the angle between the plate and the plate-barrel. The position of the tip of the device was then compared between the first postoperative and the final radiographs. An estimated movement of 3 mm or more was considered to represent migration. Varus angulation was estimated by measuring the angle between a line drawn through the center of the femoral head and the center of the femoral neck, and a line drawn parallel to the femoral shaft. The intact contralateral hip on the initial pelvic radiograph, or previous radiographs of any of the hips, served as reference. An estimated reduction in the angle exceeding 5° was considered to represent varus angulation. If the femoral rotations on the 2 sides were not considered similar, varus angulation could not be determined. Sliding of the lag screw or the Twin hook was estimated by measuring the difference in length of the proximal part of the Twin hook or of the lag screw protruding from the plate-barrel on the first postoperative and the final anteroposterior radiographs. If rotation appeared to be different on the 2 radiographs, correction was made by measuring the relative length of the plate-barrel. Sliding of the Medoff sliding plate was estimated by measuring the length of the distal protruding part of the sliding element on the anteroposterior radiograph. The radiographs were scrutinised for presence of postoperative fixation failure, defined as lag screw or Twin hook penetration of the femoral head or superior cut-out, breakage or loosening of the implant or non-union. If fracture healing had occurred, varus angulation or medialization of the femoral shaft was not considered as fixation failure. All measurements on radiographs were corrected for an estimated magnification of 15%.

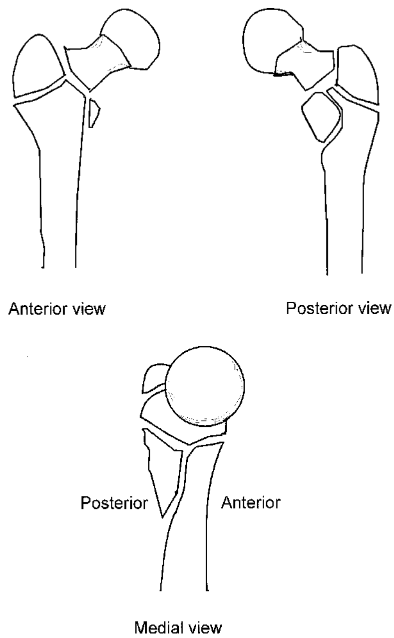

Figure 5. The fracture model used to simulate an unstable intertrochanteric fracture in various views.

Biomechanical studies

Test models for intertrochanteric and subtrochanteric fractures

The biomechanical studies on intertrochanteric (V) and subtrochanteric (VI) fracture models were performed at the Department of Bioengineering, Hospital for Joint Diseases Orthopaedic Institute, New York, NY, USA. The intertrochanteric test model was developed by Chang et al. (1987) in the same laboratory and was designed to simulate an unstable intertrochanteric fracture in line with the views on stability expressed by the Jensen and Michaelsen classification (Figure 5). The subtrochanteric test model was designed to simulate a reverse oblique 2-part fracture (Seinsheimer type IIC) and a 3-part fracture with a lateral defect (Seinsheimer type IIIB) (Figure 6).

Fresh-frozen femurs from North American Caucasian donors older than 65 years were used. In the subtrochanteric study, it was possible to obtain matched pairs of femurs, but the samples used in the intertrochanteric study were unmatched. All samples were radiographed to exclude morphologic abnormalities. Bone mineral density in Ward's triangle was 0.3–0.7 g/cm^2, determined by dual energy X-ray absorptiometry.

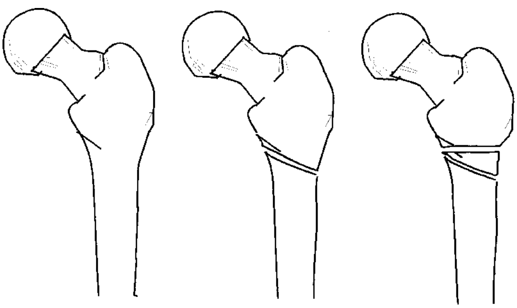

Figure 6. The fracture model used to simulate a 2-part and a 3-part subtrochanteric fracture.

To simulate the direction of the hip joint force during single leg stance (Chang et al. 1987), the femurs were mounted in a vise in 25° adduction on the table of a hydraulic materials testing machine. Cortical strains were determined by fitting the specimens with unidirectional strain gauges on the medial cortex of the femur above the intertrochanteric line. In the intertrochanteric model, a lateral strain gauge was placed on the lateral surface of the plate. Digital linear displacement gauges were used to determine lateral and inferior displacements of the proximal fracture fragment (Figure 7).

A total of 24 femurs were used, with 6 samples in each test group for each fixation method. The femurs were randomly allocated to the type of fixation. In the intertrochanteric model, the 4-hole Medoff sliding plate was compared to a conventional sliding hip screw and in the subtrochanteric model, the original 6-hole Medoff sliding plate with uni- or biaxial dynamization was compared to the Intramedullary Hip Screw (Smith and Nephew, Memphis, TN, USA) with or without interlocking screws. The intact femurs were tested before instrumentation. By using the initial strain values obtained as reference values for each specimen, all sequential values could be expressed as fractions of the base values. The femurs were tested after insertion of the fixation devices and during sequential destabilization, by creating the osteotomies described.

Vertical compressive loads were applied to a sliding holder on the femoral head. In the subtrochanteric model, a horizontal bar was placed on the femoral head and one end of the bar was attached to the greater trochanter by cerclage wires. By this lever arrangement, concurrent abductor

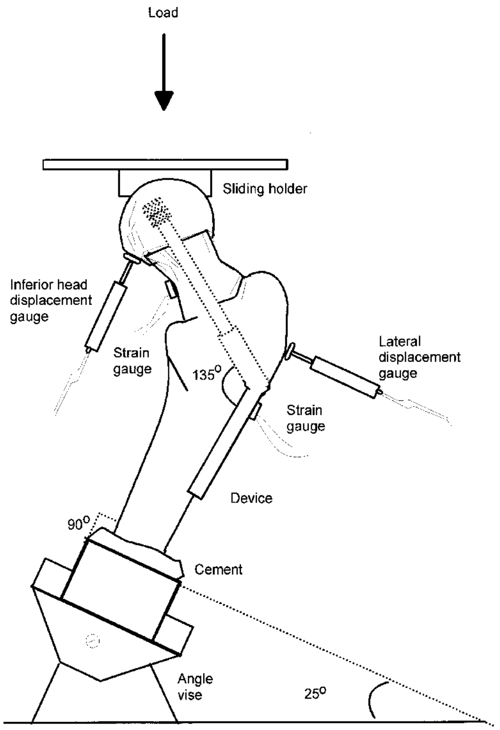

Figure 7. The test set-up for the intertrochanteric fracture model.

forces of 0%, 50% and 86% of the femoral head load could be applied by adjusting the point on the bar where the vertical compressive load was applied (Figure 8).

Static loading was made in load-control mode on 7 loading levels from 400 N to 1600 N in 200 N increments in the intertrochanteric model. In the subtrochanteric model, femoral head loads of 500 N, 750 N and 1000 N were applied. The most unstable fracture configurations were also subjected to cyclic loading at a rate of 1 Hz, the intertrochanteric model for 10^3 cycles and the subtrochanteric model for 10^4 cycles. Finally, the intertrochanteric model was loaded at a rate of 40 N/s to failure, defined as a marked discontinuity in the slope of the load/deformation graph. After testing, the intertrochanteric test samples were radiographed to analyze the mode of failure.

Test model for device purchase in the femoral head

The biomechanical study, using a test model for device purchase in the femoral head (VII), was performed at the Biomechanics Laboratory, Department of Orthopedics, Lund University Hospi-

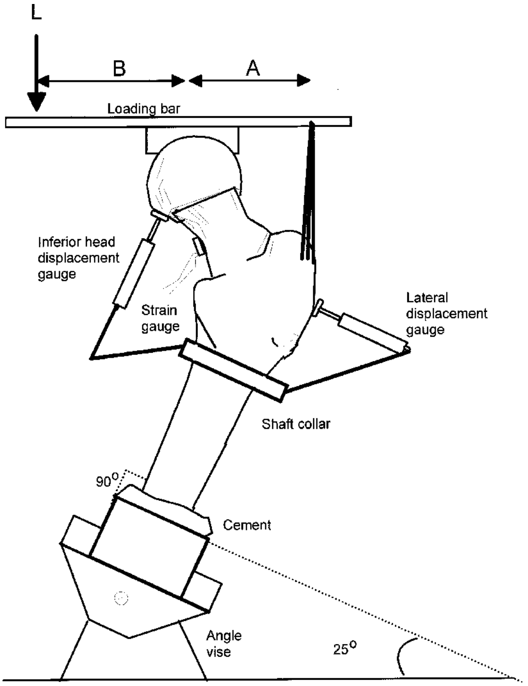

Figure 8. The test set-up for the subtrochanteric fracture model. Different distances (B) to the point of application of load (L) on the bar was used, and this lever arrangement of the bar permitted various relations between the head load and the abductor load.

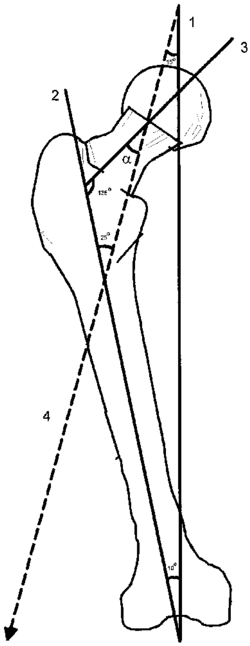

Figure 9. From the vertical body axis (1), the orientation of the femoral shaft and plate (2), and the orientation of the Twin hook or the lag screw (3), the proper inclination of the foam block (a) (20°) relative to the direction of the hip joint reaction force (4) (15°) could be calculated.

tal, Sweden. 3 different densities (160 kg/m^3, 240 kg/m^3 and 320 kg/m^3) of cellular rigid polyurethane foam (Sawbones Europe AB, Malmö, Sweden) were used to model the interior cancellous bone of the femoral head with varying degrees of osteoporosis. The Twin hook was compared to a standard lag screw and the devices were inserted to a depth of 35 mm into reamed channels in 50x50 mm foam blocks. 6 samples for each device were tested with each load and foam quality combination. The tests were performed using the hydraulic materials testing machine. The foam blocks, mounted in a vise on the test table, were subjected to axial or torsional loading in deformation-control mode. Axial loading was applied at a deformation rate of 0.5 mm/s until 10 mm deformation, and torsion loading at a rate of 4°/s to 40° clockwise rotation, followed by a return to the starting position, and then 40° counterclockwise rotation. Tests were also performed with the foam blocks held at a 70° angle to the load direction, to simulate a direction of the hip joint reaction force of 15° from the vertical body axis (Figure 9). 5 femoral heads from patients with primary degenerative arthritis of the hip joint or malunion of a femoral neck fracture operated on with total hip replacement were obtained and tested to confirm the relevance of the deformation behavior and properties of the foam. The mean bone mineral density of the femoral heads was 260 (190–360) kg m^{-3}, assessed by CT scans according to Nilsson et al. (1988).

Deformation, load and torque were recorded during testing. After the tests, radiographs in frontal and lateral views were obtained of the foam blocks and femoral heads.

Statistical methods

Proportions were compared with the Fisher exact test or odds ratio with 95% confidence interval. The Mann-Whitney U-test was used for comparisons between groups and the Wilcoxon signed-rank test for groups with matched pairs. Due to the presence of extreme values, comparisons of cortical strains were also made using the median test. The relations between bone mineral density and bone strains and between bone mineral density and load to failure were assessed, using linear regression analyzis. On the load-deformation and torque-deformation graphs, linear regression analyzis was also done to determine the stiffness of the Twin hook and lag screw foam constructs. Normal distribution was assessed by the Kolmogorov-Smirnov goodness-of-fit procedure. Mean or median values with ranges or 95% confidence intervals are used. A p-value of <0.05 was considered significant.

Results

Clinical studies

Follow-up

Of the 228 patients included in the 3 series with a 1-year follow-up (I–III), 52 died within 1 year of the injury. 153 of the remaining 176 patients had a complete 1-year radiographic and clinical follow-up. 22 of the 23 patients, not available for the 1-year follow-up, were radiographed 4 months after the injury and, except for 2 patients, information was obtained by telephone at 1 year. In study IV, 16 of the 114 patients died before the 4-month control. 90 patients attended the 4-month control, and information was obtained by telephone about the remaining 8 patients. No signs of threatening healing disturbances were detected in the radiographs available for the patients, who had had an incomplete follow-up.

Intra- and postoperative parameters

The patients with subtrochanteric fractures had larger intraoperative bleeding, longer operating time and longer hospital stay than those with intertrochanteric fractures, but they were younger and had a lower 1-year mortality (Table 3). According to the study protocols, the Medoff 4-hole plate or a conventional 4-hole sliding hip screw was used in intertrochanteric fractures, and the original 6-hole Medoff sliding plate was used in subtrochanteric fractures. Only in a few patients where preoperative and final fracture classification differed, a 4-hole plate had been used in a subtrochanteric fracture, or when 4 screws were considered insufficient for fixation to the femoral shaft, a 6-hole plate had been used in an intertrochanteric fracture. Therefore, the differences between the intertrochanteric and subtrochanteric fracture groups were almost identical, when the patients were instead divided into 4-hole or 6-hole plate treatment groups. There were no differences between the patients treated with a Twin hook or with a lag screw in these aspects. The 54 patients in study IV, who were operated on with the Medoff sliding plate, had a 3-minute longer median operating time (p=0.23) and 25 ml larger median intraoperative bleeding (p=0.07) than the 60 patients who were operated on with the Compression hip screw.

Radiographic analysis

Intraoperative erratic positioning of the device with protrusion through the subchondral bone of the femoral head was noted in 7 of the 50 patients treated with a Twin hook, and in 2 of the 292 treated with a lag screw (p<0.0001). However, adverse symptoms warranting reoperation were observed in only 1 of these patients. Apart from these surgical errors, no problems related to the use of the Twin hook were observed, and there were no differences in device migration in the femoral head between the Twin hook and the lag screw groups.

In study IV, the mean femoral shortening in unstable intertrochanteric fractures was 15 (0–28) mm with the Medoff sliding plate and 11 (0–40) mm with the Compression hip screw (p=0.03). In the one third of patients with the largest femoral

Table 3. Intra- and postoperative parameters of the 342 patients with trochanteric fractures included in the 4 series

	Intertroch. fractures	Subtroch. fractures	P-value
Patients (n)	294	48	
Intraoperative bleeding (ml)	200	600	<0.0001[c]
Operating time (min)	58	85	<0.0001[c]
Hospital stay (days)	12	17	0.004[c]
Wound infection (n)	4	1	
Thromboembolism (n)	3	0	
Mortality at one year (n)	48[a]	4	0.008[c]
Living in own home at 1 year / before injury (n)[b]	49/76[a]	35/40	0.01[d]
Independent walking at 1 year / before injury (n)[b]	39/72[a]	17/34	0.9[d]

Median values are given for continuous variables
[a] 180 patients in studies with a 1-year follow-up included
[b] Only patients alive after 1 year included
[c] Mann-Whitney U-test
[d] Fisher exact test

shortening in each group, the mean femoral shortening was 26 (19–28) mm with the Medoff sliding plate and 24 (15–40) mm with the Compression hip screw (p=0.27). However, in these patients with large femoral shortening, the mean medialization of the femoral shaft was 12% with the Medoff sliding plate and 26% with the Compression hip screw (p=0.03). Medialization exceeding 30% occurred in 9 patients with the Compression hip screw, but in no patients with the Medoff sliding plate (p=0.003). A tendency towards more pronounced lag screw migration and varus angulation was noted in the third of patients with the largest femoral shortening in the Compression hip screw group compared to those in the Medoff sliding plate group.

Uniaxial dynamization was used in 29 subtrochanteric fractures. 5 of these were secondary dynamized due to threatening or manifest penetration of the femoral head or superior cut-out, and 4 of these fractures went on to heal uneventfully. Biaxial dynamization was used in 19 patients. A mean medialization of the femoral shaft of 42 (10-90) % was noted in 9 of these, all Seinsheimer type 5 fractures. Only 2 reverse oblique fractures (Seinsheimer type 2C) were treated with biaxial dynamization.

The sliding of the lag screw was larger with the Compression hip screw (14 mm) than with the Medoff sliding plate (7 mm) in unstable intertrochanteric fractures in study IV (p=0.0004). In subtrochanteric fractures with biaxial dynamization, the mean sliding of the lag screw was 11 mm. The plate slide of the 4-hole Medoff sliding plate was 6 (0–16) mm in stable and 9 (0–25) mm in unstable intertrochanteric fractures (p=0.09). In subtrochanteric fractures, the sliding of the original 6-hole Medoff sliding plate was 16 (0–25) mm in uniaxial dynamization and 17 (8–25) mm in biaxial dynamization (p=0.73). With 1 exception, a Seinsheimer type 5 fracture with biaxial dynamization and 50% medialization of the femoral shaft (III), sliding of the plate was not found after the 4-month control.

Estimation of completed fracture consolidation was made in only the 3 studies with a 1-year follow-up. Radiographic consolidation was documented in 147 of the 153 patients with a complete 1-year follow-up. However, another 112 patients were radiographed after at least 4 months and 109 of these had signs of progressing fracture consolidation and no signs of impending fixation failure.

Postoperative fixation failures

14 postoperative fixation failures occurred (Table 4). Fixation failures occurred exclusively in intertrochanteric fractures Jensen and Michaelsen type V or in subtrochanteric fractures Seinsheimer types IV or V. 3 postoperative fixation failures occurred in the 194 unstable intertrochanteric fractures treated with biaxial dynamization with the Medoff sliding plate and 5 fixation failures in the 62 unstable intertrochanteric fractures treated with the sliding hip screw (p=0.04). In the randomized comparison in study IV, more fixation failures occurred with the Compression hip screw than with the Medoff sliding plate (p=0.03). In the 10 patients with fixation failure treated with the Compression hip screw or with the Medoff sliding plate biaxially dynamized, a mean medialization of the femoral shaft of 41% was noted. In the fixation failures that occurred with the Medoff sliding plate in intertrochanteric fractures (n=4) or in subtrochanteric fractures (n=5), incorrect application of the device was documented in 7 patients (Table 4). In the remaining 2 cases, no plate sliding capacity remained after 4 months with insufficient fracture impaction and non-union ensued. No divergence from the intended intraoperative procedure was documented in the 5 patients with postoperative fixation failure treated with the Compression hip screw.

Biomechanical studies

In the 2 fracture model studies with fresh-frozen cadaver femurs a large spread in the data within test groups was observed (V and VI). Standard deviations, in general were 30–100% of the means. Therefore, in several of the comparisons between groups, sufficient statistical power could not be reached with a reasonable number of specimens, despite substantial differences in mean and median values. In the femoral head purchase study, using artificial cancellous bone (VII), results were in general consistent within test groups, with standard deviations between 5% and 30% of the

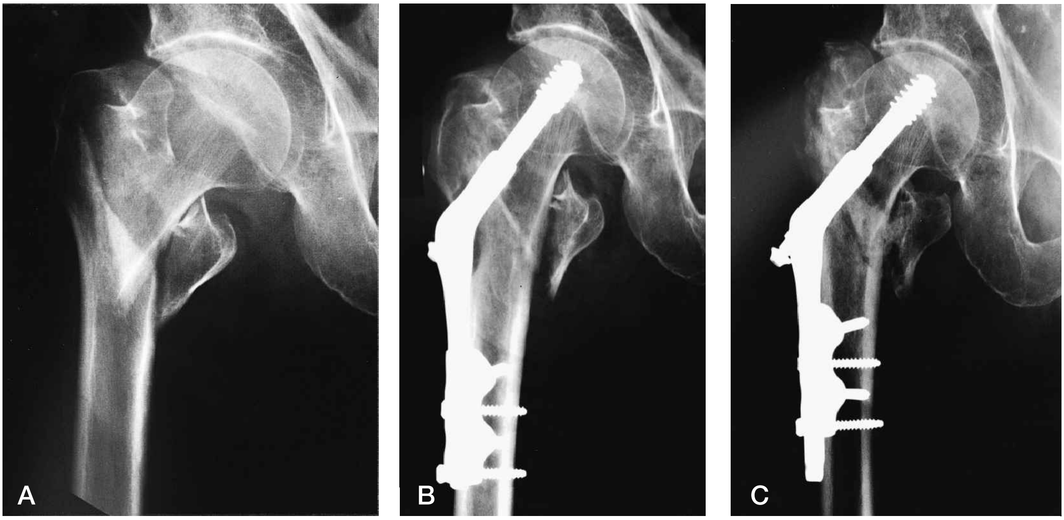

Figure 10. Preoperative (A) and postoperative (B) radiographs of an unstable intertrochanteric fracture (Jensen and Michaelsen type 5) treated with a 4-hole Medoff sliding plate. Axial shortening of 22 mm, but no varus angulation or migration, occurred and the fracture was healed at the 4-month control (C).

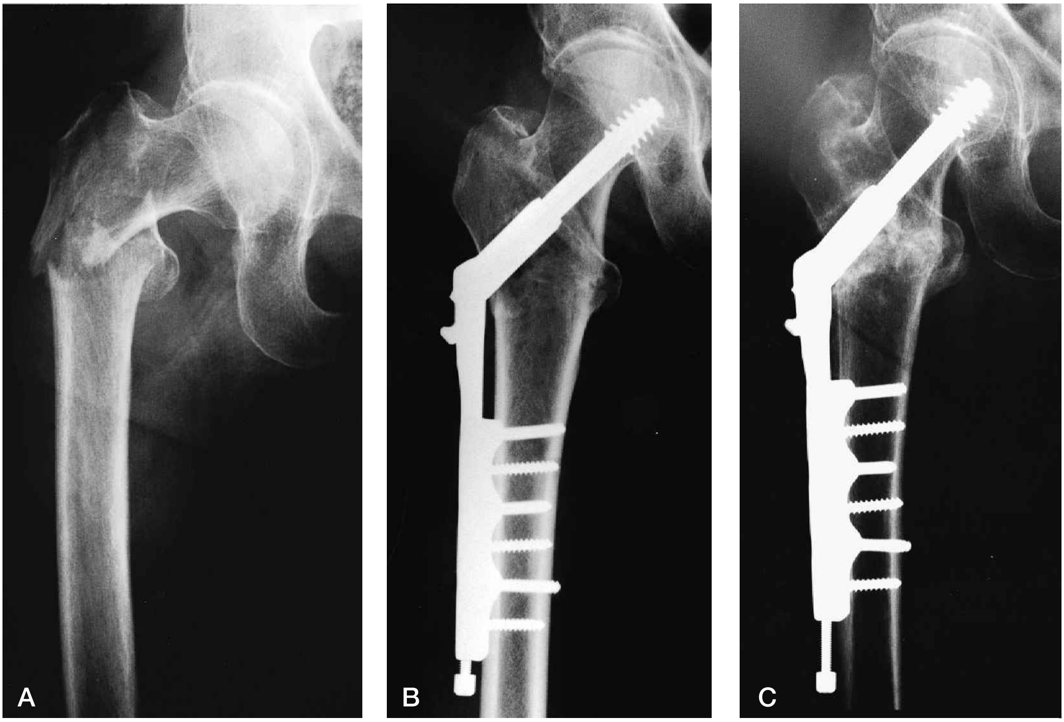

Figure 11. Preoperative (A) and postoperative (B) radiographs of a subtrochanteric fracture (Seinsheimer type 5) treated with a locked original 6-hole Medoff sliding plate. Axial shortening of 18 mm, but no medialization of the femoral shaft, varus angulation or migration, occurred and the fracture was healed at the 4-month control (C).

means and significant differences between groups could be shown whenever divergent means were evident.

Test model for intertrochanteric fracture

A slight decrease in compressive medial cortex strain was noted already by the device insertion itself for both the Medoff sliding plate and the slid-

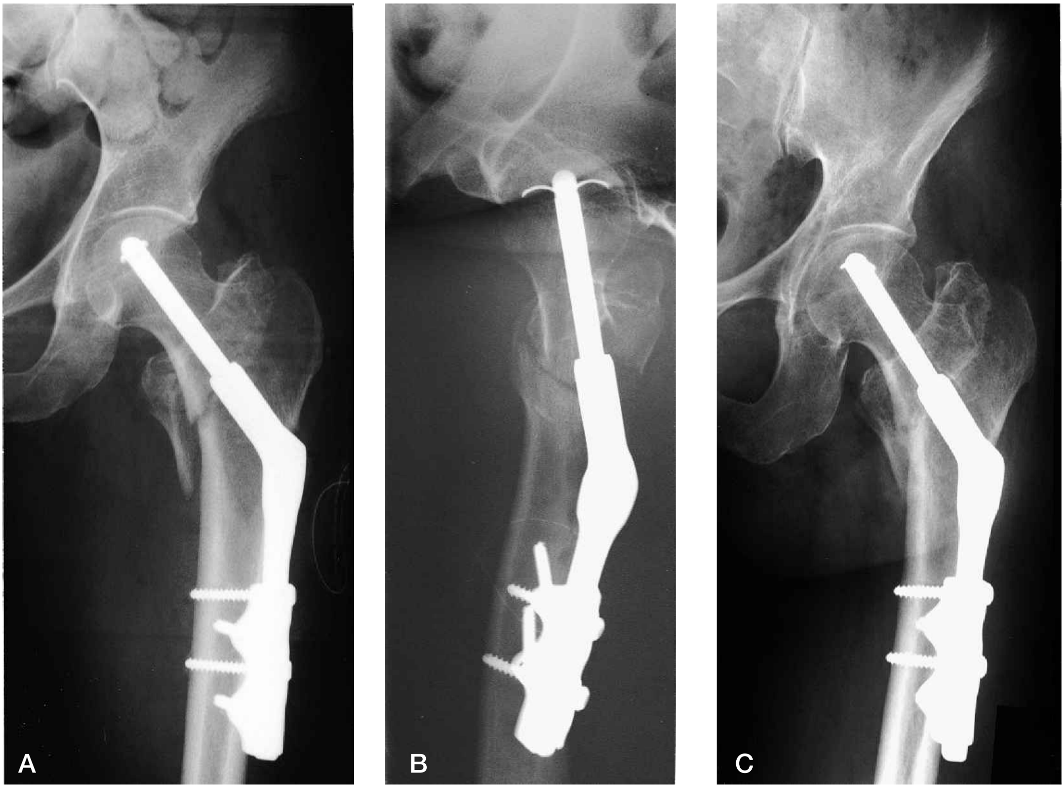

Figure 12. Radiographs postoperatively in the anterior (A) and lateral (B) views of an unstable intertrochanteric fracture (Jensen and Michaelsen type 5) treated with a 4-hole Medoff sliding plate and a Twin hook. No migration of the Twin hook occurred. The fracture was healed at the 4-month control (C).

ing hip screw. During sequential destabilization of the fracture model, the medial cortex strain decreased more with the sliding hip screw than with the Medoff sliding plate, indicating better stress transfer through bone with the latter device. For the unstable 4-part fracture, residual medial cortex strain was 73% with the Medoff sliding plate and 39% with the sliding hip screw, compared to the intact bone (p=0.04). The mean residual medial cortex strain was higher with the Medoff sliding plate than with the sliding hip screw in all fracture types at all loading levels (Figure 13). During cycling, the mean medial cortex strain increased by 20% with the Medoff sliding plate and decreased by 10% with the sliding hip screw, but the difference was not significant.

The tensile plate strain values showed a wide range and no differences between the 2 devices could be documented. During cycling, the mean plate strain increased by 10% with the Medoff sliding plate and by 50% with the sliding hip screw. Plate sliding during static loading was less than 1 mm, but during cyclic loading, a mean plate sliding of 4 mm was noted.

The fixation stability offered by the 2 devices appeared to be similar with a median inferior head displacement and lateral shaft displacement of 1 mm or less in the unstable 4-part fracture for both devices. The mean maximum load to failure was 3050 N for the Medoff sliding plate and 3450 N for the sliding hip screw (p=0.3). It was noted that 2 of the Medoff sliding plate samples failed by fracture through the distal surface of the 4-part osteotomy, engaging the slot in the lateral cortex created for the plate sliding. Most of the remaining samples in both groups failed by bending of the lag screw.

Test model for subtrochanteric fracture

The compressive medial cortex strain decreased to a similar extent with both devices throughout the test sequence. In the 2-part fracture, strains de-

Table 4. Postoperative fixation failures

Fracture type Fixation	Failure	Secondary procedure	Divergence from intended line of treatment
Jensen and Michaelsen, type 5			
4-hole Medoff sliding plate Lag screw	Cut-out	No reoperation due to poor general condition	Insufficient distal enlargening of the entry hole of the lag screw
4-hole Medoff sliding plate Lag screw	75% medialization and non-union	Late Girdlestone procedure	No indication of intraoperative error Plate slide completed on the 4-month radiographs
4-hole Medoff sliding plate Twin hook	90% medialization and cut-out	No reoperation due to poor general condition	No release of overdistraction Plate slide completed on the first postoperative radiographs
Uniaxial 6-hole Medoff sliding plate, Twin hook	Penetration	Early reoperation with withdrawal of nail and staged dynamization[a]	No distal enlargening of the entry hole of the Twin hook. Erratic locking of the Twin hook
Compression hip screw	Cut-out and non-union	No reoperation due to poor general condition	No indication of intraoperative error
Compression hip screw	Cut-out	No measures since patient asymptomatic[a]	No indication of intraoperative error
Compression hip screw	Cut-out	No reoperation due to poor general condition[a]	No indication of intraoperative error
Compression hip screw	Cut-out	Early reoperation with hemiarthroplasty Late Girdlestone procedure due to deep infection	No indication of intraoperative error
Compression hip screw	Cut-out	Early reoperation with open rereduction and fixation with the MSP Late Girdlestone procedure due to deep infection	No indication of intraoperative error
Seinsheimer, type 4			
Uniaxial 6-hole Medoff sliding plate. Lag screw	Penetration	No measures since patient asymptomatic[a]	No release of overdistraction Plate slide almost completed on the first postoperative radiographs
Seinsheimer, type 5			
Uniaxial 6-hole Medoff sliding plate. Lag screw	Cut-out and non-union	Early staged dynamization Late hip arthroplasty	The most proximal of the cortical plate screws traversed the fracture line
Biaxial 6-hole Medoff sliding plate	Non-union	Revision surgery at 1 year with distal placement of the side plate of the Medoff sliding plate[b]	No release of overdistraction Plate slide almost completed on the first postoperative radiographs
Biaxial 6-hole Medoff sliding plate. Twin hook	90% medialization	Early reoperation with open rereduction and locking of the Twin hook[c]	No locking of the Twin hook
Uniaxial 6-hole Medoff sliding plate, Twin hook	Non-union	No measures since patient asymptomatic	No indication of intraoperative error Plate slide completed on the 4-month radiographs

[a] Fractures healed within 1 year of the injury
[b] The fracture was healed at 8 months after revision surgery
[c] The patient died 4 months after the injury

creased to approximately 70% of those for intact bone and in the 3-part fracture, to approximately 50%. Application of a concurrent abductor force of 86% of the head load caused a significant reduction in the medial cortex strains to 10-15% of the intact bone. A slight increase in medial cortex

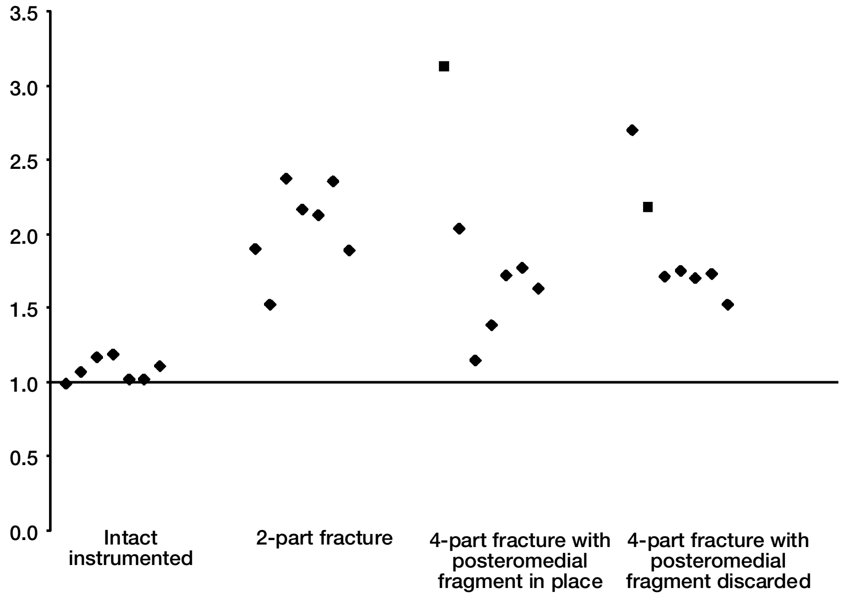

Figure 13. The medial cortex strain at all loading levels in each fracture type was calculated as fraction of medial cortex strain in the intact femur and the mean value for the Medoff samples was divided by the mean value for the sliding hip screw samples. The values are given from left to right for the 7 loading levels from 400 to 1600 N for each fracture type. All values are above 1.0, since the mean strain values are higher for the Medoff samples than for the sliding hip screw samples in all fracture types at all loading levels. Square symbol denotes statistically significant difference between the 2 groups ($p<0.05$).

strain occurred during cycling.

With a 750 N head load and 86% concurrent abductor force, the mean inferior head displacement was 1.6 mm for the Medoff sliding plate and 2.1 mm for the Intramedullary Hip Screw in the 3-part fracture ($p<0.05$). After cycling, the inferior head displacement increased by approximately 50% with both devices. During cycling, after release of the sliding of the lag screw of the Medoff sliding plate, and after distal unlocking of the Intramedullary Hip Screw, a further slight increase in inferior head displacement occurred. With the devices locked, no lateral displacement of the proximal fragment was observed. However, during cycling after release of the sliding of the lag screw of the Medoff sliding plate, a significant lateral displacement of the proximal fragment of 2 (1.5–2.9) mm was noted.

Test model for device purchase in the femoral head

During axial loading, a distinct yield point was observed for the lag screw, but for the Twin hook the load gradually increased during the 8 mm test (Figure 14). The peak loads were higher for the lag screw ($p<0.01$), but after an 8 mm deformation, the loads were similar with both devices. When the load angle was adjusted by 20°, to re-

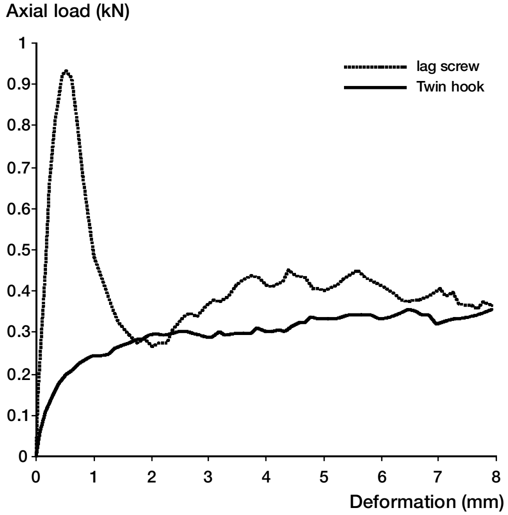

Figure 14. Load-deformation graph in axial loading of a lag screw and a Twin hook in 160 kg m^{-3} foam during 8 mm deformation.

semble more closely the loading conditions during single leg stance, the peak and mean loads increased by 70% for the Twin hook and by 25% for the lag screw ($p<0.01$). The correlation between foam density and loads was fairly linear.

As in axial loading, in clockwise torsional loading a yield point in torque was easily defined for the lag screw, and for the Twin hook, the torque gradually increased throughout the test. The peak torques were significantly higher for the lag screw in the 160 kg/m^3 and in the 240 kg/m^3 bone. Since the increase in torque with increasing foam density was linear for the lag screw and relatively much higher for the Twin hook, no difference in peak torques remained in the 320 kg/m^3 foam. With 20^o correction of the foam block inclination, peak torque and yield torque increased significantly with both devices.

In counterclockwise rotation, similar peak torques were produced by the lag screw and the Twin hook. However, whereas the torque deformation graph was similar with gradually increasing torque in clockwise and counterclockwise rotation for the Twin hook, the lag screw produced a constant torque during counterclockwise rotation, much lower than in clockwise rotation.

The femoral head tests produced load-deformation and torque-deformation graphs with similar shapes as in the foam tests. In axial loading, the peak load and the mean load during 7 to 8 mm deformation for the lag screw and for the Twin hook, relative to the bone mineral density, were in good agreement with the corresponding values for the 3 different densities foam tests. In torsional loading, a similar relation was observed for the lag screw. For the Twin hook, the peak torque, related to the bone mineral density, was twice that expected from the foam tests. The radiographs taken after torsional loading showed a slight twisting of some of the Twin hook wings in the 2 denser foams and in the femoral heads.

Discussion

The epithet “the unsolved fracture” applies to the displaced femoral neck fracture (Speed 1935). With far less frequent fixation failures and healing complications, trochanteric fractures are considered by many orthopedic surgeons a less demanding injury. However, the impact of the primary injury on the patients´ health is profound and a fixation failure implies a considerable increase in the risk of persisting disability, loss of capacity for independent living, and of death (Keating et al. 1993). With an estimated residual average life time risk of a hip fracture at the age of 60 years of 14% for women and 6% for men (Lauritzen 1997), and with an expected continued increase of the elderly in the population (Cooper et al. 1992), the numbers of trochanteric fractures will continue to rise world-wide (Gullberg et al. 1997, Kannus et al. 1999). Unstable intertrochanteric and subtrochanteric fractures at risk of fixation failure will therefore increase in number with time, constituting a continuous challenge to the orthopedic community to minimize fixation failure by further improvements in the treatment methods (Ceder 1998).

Divergent opinions still exist concerning which basic principles are best applied to the fixation of unstable trochanteric fractures in the elderly patient. Should the aim be as rigid an osteosynthesis as possible with the objective of maintaining as close to pre-fracture anatomy as possible? Or should the fixation be dynamic providing impaction of the main proximal and distal fracture fragments as quickly as possible, at the expense of an altered anatomy and shortening of the leg?

The early experiences with rigid nail plate devices confirmed that anatomical reduction was not appropriate with use of a rigid fixation device in an unstable fracture. In an elderly patient who must be allowed to mobilise and who is unable to protect the injured leg from weight-bearing, a bone defect in the fracture can not be protected by the osteosynthesis in fragile osteoporotic bone during the consolidation process. If fracture impaction occurs without parallel movement of the device, varus angulation, cut-out or penetration ensues. If the fixation should be able to maintain the fracture gap, the implant will remain subjected to high loads with an increased risk of implant breakage or loosening. It has been shown that load transmission across the fracture site is an important determinant of the efficacy of the healing process (Goodship and Kenwright 1985) and persisting fracture defects that are unloaded by a rigid fixation increase the risk of non-union. Therefore, it appears that the implant of choice should control, but not prevent, fracture impaction to a position where optimal load transmission over the fracture is allowed, while maintaining angular orientation of the proximal fragment and alignment of the femoral shaft.

The improvement in treatment results with the sliding hip screw ultimately led to general acceptance of the concept of dynamic fixation and the sliding hip screw has been the gold standard for fixation of intertrochanteric fractures since the 1970s. All novel methods must be compared primarily to this device (Ceder 2000). With its introduction, the incidence of fixation failure in unstable fractures was reduced by at least two thirds, but fixation failures were not eliminated. Insufficient fracture impaction is still allowed with some fracture types and the failure rate is still substantial (Table 1). Despite the sliding capacity of the lag screw, biomechanical studies of unstable intertrochanteric fractures have shown significant unloading of the medial cortex (Chang et al. 1987, Meislin et al. 1990, Rosenblum et al. 1992, Mahomed et al. 1994, Choueka et al. 1995). Kyle et al. (1980) also found that the resistance to sliding increased substantially with a lower plate-barrel angle and that a short barrel combined with a long lag screw compromised the slide function, with jamming of the lag screw in the barrel.

During the last decade, intramedullary hip screws have gained increased interest. The intramedullary rods are strong, and with the intramedullary position, the shortened lever arm reduces the bending moment on the nail. Several complications with intraoperative fractures engaging the greater trochanter or intraoperative femoral shaft fractures were reported, as well as a number of postoperative femoral shaft fractures near the tip of the device (Bridle et al. 1991, Boriani et al. 1991, Radford et al. 1993, Aune et al. 1994, Friedl et al. 1994, Valverde et al. 1998). With design adjustments and modified instructions for insertion involving over-reaming and less traumatic insertion technique, these problems seem to have been reduced, but not eliminated (Leung et al. 1992, 1996, Park et al. 1998, Rantanen and Aro 1998). Still, meta-analyzis of randomized studies comparing the sliding hip screw with the Gamma nail (Parker and Handoll 1999) reveals no advantages with the intramedullary device. In biomechanical tests, the intramedullary nail has also been shown to unload the medial cortex to a degree similar to the sliding hip screw (Mahomed et al. 1994, Bostrom et al. 1995). Loch et al. (1998) found in laboratory tests that higher loads were required to initiate sliding of the lag screw of intramedullary nails than of the lag screw of a sliding hip screw.

The theoretical and laboratory disadvantages and the occurrence of clinical short-comings with the sliding hip screw and subsequently, also with intramedullary hip screws, were important inducements to develop an implant allowing biaxial dynamization. Biomechanical studies are then essential to evaluate the efficacy of the intended improved load-sharing properties of a new implant, as well as to confirm the achievement of adequate fixation stability. Our experimental study of the Medoff sliding plate in an unstable intertrochanteric fracture model confirmed that improved load-sharing is obtained with biaxial dynamization, a finding that has later been reproduced in a similar study (Mahomed et al. 2000). It was also concluded that the fixation stability was comparable to that with a sliding hip screw. In previous testing of subtrochanteric fractures, 3 to 4 times higher plate strain was recorded with the sliding hip screw than with the Medoff sliding plate (Medoff and Maes 1990). With the fracture type simulated in our subtrochanteric study, comparable loads were transmitted to the medial cortex with the Medoff sliding plate and the Intramedullary Hip Screw. However, the bone defect that was created was lateral and included no medial cortical gap. The most important findings of this study were the demonstration of similar fixation stability with the 2 devices, and the occurrence of medialization of the femoral shaft when the Medoff sliding plate was biaxially dynamized.

The clinical experiences with biaxial dynamization with the Medoff sliding plate in unstable intertrochanteric fractures support the above theories, with better results than what is reported with the sliding hip screw in the present studies, as well as in a previous consecutive case series (Lunsjö et al. 1996) and a randomized trial (Watson et al. 1998). Subtrochanteric fractures comprise only about 10% of trochanteric fractures and, due to the relative rarity of this fracture type of fracture, clinical reports in general are on small case series (Whitelaw et al. 1990, Mullaji et al. 1993, Blatter and Janssen 1994, Vanderschot et al. 1995). Comparisons of methods are therefore more uncertain. However, in a randomized study of 107 patients (Lunsjö et al. 1999), significantly fewer fixation failures occurred with the Medoff sliding plate than with other extramedullary methods.

It has been argued that the axial impaction along the femoral shaft permitted by the Medoff sliding plate should cause more pronounced shortening of the femur. In unstable intertrochanteric fractures, this view was confirmed by the present studies, but the difference in femoral shortening was marginal. Since impaction will only occur until stable contact is attained between the proximal and distal main fragments, a different choice of implant allowing less impaction will, by definition, maintain a fracture defect with impaired load transmission, thereby putting the healing process at hazard, with enhanced risk of the failure modes stressed above. Since leg-length discrepancy is easily compensated for, an increased risk of fixation failure and of prolonged healing time, is a high price for the elderly patient to pay. It should be pointed out that particularly subtrochanteric fractures more often are non-fragility fractures sustained by younger patients who have better bone quality and are able to load-protect their fracture. A different approach with preservation of anatomy with maintenance of bony defects during the healing process may be more applicable in these patients, an attitude that is advocated by several authors (Holt 1963, Friedl 1993, Buciuto et al. 1998, Baixauli et al. 1999). The fixation device should then be as strong as possible (Wheeler et al. 1998) to withstand the large loads it is subjected to while unloading the bone during fracture consolidation.

Medialization of the femoral shaft is a well known risk in dynamic fixation, particularly of subtrochanteric fractures with a reverse oblique fracture line, i.e. parallel to the sliding direction of a sliding hip screw or of the lag screw in a Medoff sliding plate. Parker (1996) and Lunsjö (1998) have also shown that lack of lateral support in intertrochanteric fractures implies an increased risk of medialization of the femoral shaft. Parker (1996) stated that when medialization of the femoral shaft of one third or more occurred, the risk of fixation failure was increased sevenfold. A similar relation between medialization of the femoral shaft and the occurrence of fixation failures was obvious in the present studies with the Compression hip screw as well as with the Medoff sliding plate, when biaxially dynamized. In the fractures having a considerable impact, less lag screw sliding and medialization of the femoral shaft occur with the Medoff sliding plate than with the Compression hip screw. From the device geometry, lag screw sliding implies medialization of the femoral shaft irrespective of type of device. The mechanism reducing medialization of the femoral shaft with the Medoff sliding plate is not apparent, but it seems reasonable to presume that the axial impaction allows an improved interdigitation of the main fracture fragments to occur, thereby increasing resistance to sideway movements. The substitution of lag screw sliding for plate sliding, synonymous with replacing medialization of the femoral shaft by axial impaction, may be an important key to the ability of biaxial dynamization to reduce the risk of fixation failure in unstable intertrochanteric fractures.

Medialization of the femoral shaft is prevented with the Medoff sliding plate if the lag screw is locked. Both uni- and biaxial dynamization have been used in subtrochanteric fractures. All the fixation failures that occurred in the present studies and in that by Lunsjö et al. (1999) with uniaxial dynamization have been attributable to insufficient or compromised axial dynamic capacity. Staged dynamization with secondary release of the lag screw has proved a simple and effective salvage procedure in some of these cases. With biaxial dynamization, medialization of the femoral shaft occurred in several cases, requiring major revision surgery in 1 patient with non-union and plate breakage, and 90% medialization in another. The risk of medialization after dynamization of the lag screw in some subtrochanteric fracture types has previously been demonstrated in biomechanical tests, using composite femurs (Kummer et al. 1997) and this was also documented in the present biomechanical subtrochanteric fracture model. On the basis of studies with both dynamization modes, we do not consider biaxial dynamization recommendable for uncritical use, but consider uniaxial dynamization with careful radiographic surveillance during the early postoperative period, with preparedness for secondary dynamization of the lag screw when needed, the best treatment for subtrochanteric fractures. With more experience, it may be possible in the future to identify unstable intertrochanteric fractures that would also benefit from uniaxial dynamization with the Medoff sliding plate.

Another method for dealing with the risk of excessive medialization is the sliding hip screw with a trochanteric stabilizing plate (David et al. 1996, Babst et al. 1998, Madsen et al. 1998). This method reduces medialization, but in doing so the fixation may in fact turn rigid, since the dynamic slide function along the femoral neck is compromised by the lateral support. Intramedullary hip screws will prevent medialization if the intertrochanteric region is intact, but not in case of comminution. Since lag screw sliding inevitably involves medialization of the femoral shaft, intramedullary hip screws with distal locking are also rigid, if medialization is prevented.

The demand for meticulous attentiveness to correct techniques in the use of the Medoff sliding plate is stressed by the documentation of inadequate appliance of the procedures associated with the application of uni- or biaxial dynamization in 7 of the 9 fixation failures that occurred in the present studies. Similarly, in a randomized multicenter trial on intertrochanteric fractures, Lunsjö et al. (2000) reported that the biaxial dynamic capacity of the Medoff sliding plate had been inactivated due to technical errors made by the surgeons in 14 of the 18 failures. It therefore appears that, in order to realise the potential outcome improvements in terms of avoidance of fixation failures, a satisfactory understanding of the criteria for judging fracture instability and of the prerequisites for effective uni- or biaxial dynamization are required.

Use of the simplified 4-hole Medoff sliding plate seems to have had no adverse effects. The 4 holes provided adequate fixation to the femoral shaft, as expected, since this is the accepted number of screws used for plates in intertrochanteric fractures (Koval and Zuckerman 1994). Loosening of the Medoff sliding plate has never been described, either in the present studies or in other published reports, covering a total of more than 900 patients (Medoff and Maes 1991, Lunsjö et al. 1995, 1996, 1999, 2000, Watson et al. 1998). Reduced operating time or intraoperative bleeding with the use of the shorter Medoff sliding plate compared to the original plate was not documented, but no sophisticated evaluation methods were employed, since the study did not focus on these aspects. The surgeons involved were also all novel users of the plate and, with continued use, appreciation of the possibilities for reduced dissection would increase. With surgeons equally familiar with the Medoff sliding plate and the Compression hip screw, the 3 minute longer operating time with the Medoff sliding plate is in good concordance with the time needed to achieve the distal enlargening of the entry hole of the plate barrel.

Different strategies have been employed to increase the device purchase in the femoral head. A threaded lag screw is the commonest method in use, but the cancellous bone of the osteopenic femoral head does not offer a firm grip for the threads. A larger lag screw head as well as cement augmentation increase the fixation stability, but is associated with increased unloading of the medial cortex (Choueka et al. 1996). An improved grip in the femoral head will counteract stress transfer over the fracture, unless a dynamic mechanism over the fracture area is effectuated. The device of choice therefore should be firmly fixed to the main proximal and distal fracture fragments and connected with a mechanism allowing controlled collapse between the 2 parts.

The fixation principle of the Twin hook differs from that of the lag screw. With similar sizes of the axial stress-supporting areas, the addition of the shear cylinder of the lag screw should theoretically provide stronger primary fixation stability with this device. However, any migration leads to failure of the thread purchase. With the Twin hook, displacement will, in theory, involve impaction of the supporting bone with gradually increased resistance to displacement. These assumptions were confirmed by biomechanical testing.

From the results of the clinical study, the Twin hook appeared to provide adequate femoral head purchase similar to that with the lag screw. Only when evidence of inadequate fracture impaction existed, did failures, in terms of cut-out or penetration, occur with both devices. If the Twin hook can be demonstrated to achieve as reliable fixation as the lag screw, it may be a preferable method, because of the advantages offered in the intraoperative handling. Since the Twin hook may be introduced after the barrel of the side plate is introduced into its reamed channel, the plate may be rotated in under the distal muscle belly and a reduced dissection is possible. If necessary, later withdrawal, change or removal of the Twin hook can also be done with the plate still in place. In the present study, reductions in operating time, intraoperative bleeding or length of skin incision were not documented, but all surgeons were novel users of the Twin hook not expected to make optimal use of the possibilities with the new device. Better information and increased experience should also reduce the occurrence of intraoperative errors.

The choice of test material in biomechanical studies must be poised by the demand for relevancy in terms of achievement of a model with adequate resemblance to the *in vivo* conditions it strives to emulate, and by the demand for control of confounding factors with reproducible data, allowing the comparisons intended between study groups with a reasonable number of test specimens. In the 2 studies using cadaver bones, a wide spread of data complicated the interpretation of the results. When an artificial bone substitute is chosen, several confounding factors are eliminated and reproducibility of the data is improved, but satisfactory documentation of similar material properties and test responses to those of real bone is mandatory. The similarity of the load responses of the foams and of the bones, as well as the relative loads and torques with various foam and bone densities in the femoral head device purchase study, implies material properties resembling those of cancellous bone with different degrees of osteoporosis. This type of bone substitute therefore appears to be a good alternative to cadaver bone for biomechanical testing of fixation in cancellous bone.

The 4 generic stages depicted by Fuson et al. (1997) in the clinical trials with a new surgical method were applied by Lunsjö (1998) to the evaluation process of biaxial dynamization with the Medoff sliding plate. In the first step, the applicability and the safety of the concept are assessed in a limited pilot study. In the second step, the methodology is perfected and clinical studies expanded to larger well-defined groups of patients who are carefully observed. The third step involves clinical validation by attempts to reproduce the initial results in multiple centers and by randomized comparisons with previously accepted methods. The fourth step, general acceptance, should still include post market surveillance of the product.

The patients treated in Helsingborg were elderly, with a median age of approximately 80 years, and a vast majority of the patients had unstable fractures. The results obtained with biaxial dynamization with the Medoff sliding plate in the previous consecutive case series (Lunsjö et al. 1996) and in the present series compare favorably with all previous methods used in similar patient groups. A significantly lower rate of fixation failure was reported in the first published randomized study comparing the Medoff sliding plate to the sliding hip screw in unstable intertrochanteric fractures (Watson et al. 1998). This finding was reproduced in the present randomized study and the evaluation process is thereby brought through the third step, the validation stage. The evaluation of a new implant must also include documentation of other effects related to the new method and possible differences compared to previous methods must be reviewed. The present studies provide further proof of the applicability of biaxial dynamization without adverse effects in the intraoperative or postoperative process.

With the case series in this study, the evaluation process of the Twin hook was brought through the second step according to Fuson et al. (1997). Documentation of the postulated advantages of the Twin hook by a randomized controlled trial should be the natural next step.

Conclusions

The Medoff sliding plate in intertrochanteric fractures

The previously reported minimized rate of postoperative fixation failure with biaxial dynamization in unstable intertrochanteric fractures could be reproduced.

The 4-hole Medoff sliding plate provides the same dynamic features as the original 6-hole Medoff sliding plate, without adverse effects from the device simplification.

The Medoff sliding plate causes a marginally larger femoral shortening than the sliding hip screw in unstable intertrochanteric fractures. Major shortening is equally common with both devices, but involves more medialization of the femoral shaft and fixation failures with the sliding hip screw.

Biomechanical tests confirmed improved load-sharing capacity and similar fixation stability with the Medoff sliding plate, compared to the sliding hip screw in an unstable intertrochanteric fracture model.

The Medoff sliding plate in subtrochanteric fractures

The use of uniaxial or biaxial dynamization in subtrochanteric fractures is associated with a low rate of postoperative fixation failure.

Uniaxial dynamization under careful radiographic surveillance appears to be preferable to biaxial dynamization in subtrochanteric fractures. The minor secondary procedure of staged biaxial dynamization, when needed, may be a better alternative than a major revision that may ensue by the increased risk of medialization of the femoral shaft and possibly of non-union, that is associated with the use of biaxial dynamization.

Uniaxial dynamization with the Medoff sliding plate provided similar fixation stability as the Intramedullary Hip Screw in biomechanical testing of a subtrochanteric fracture model. With biaxial dynamization, medialization of the femoral shaft was documented.

The Twin hook in trochanteric fractures

The Twin hook appeared to provide appropriate fixation stability when used in trochanteric fractures.

An increased risk of intraoperative malpositioning of the Twin hook, compared to the lag screw, may exist, requiring more attention to central positioning by the surgeon. With adoption of the different plate insertion technique permitted by the Twin hook, minimized skin incision and reduced surgical dissection should be possible. Postoperative adjustment or removal of the Twin hook, if needed, is a simple procedure.

In biomechanical testing, the lag screw provided a stronger primary fixation than the Twin hook but, after failure of the lag screw threads, the ultimate fixation strength was similar. A gradually increasing resistance to movement occurred throughout displacement of the Twin hook.

Cellular rigid polyurethane foam provided consistency and reproducibility not found in biological tissues. By giving responses similar to those of bone on loading, and with relative differences in load responses between various foam densities, the test material appeared to be a suitable substitute for cancellous bone in biomechanical tests.

Acknowledgements

I wish to express my sincere gratitude to:

Leif Ceder, my tutor and friend, whose persistent enthusiasm and support have been crucial incitements in my work throughout these studies.

Karl Lunsjö, my colleague and friend, who broke new ground in the accomplishment of clinical research leading to a doctoral dissertation in the setting of the Orthopedic Department of Helsingborg Hospital, and who has been consistently helpful and encouraging during these years.

Björn M Persson, former, and Harald Roos, present Heads of the Department of Orthopedics, Helsingborg Hospital, for creating and encouraging the environment making clinical research on this level possible, parallel with the daily duties of the clinical work.

Anders Hauggaard, for the patient scrutiny of all those radiographs and for the recurrent flow of inspiring comments.

Leif Ryd, for valuable support and advice.

Sune Larsson, for competent and generous assistance in designing and interpreting the fracture model studies.

Liz Tanner, for her dedicated help with the laboratory work and for instructive discussions on biomechanics.

F J Kummer, for sharing his biomechanical expertise and making his department laboratory available for my work.

Jan Åke Nilsson, for statistical guidance.

All the colleagues and staff in the Department of Orthopedics, Helsingborg Hospital, for their help during the carrying through of all the clinical but particularly the randomized studies.

Anna, my beloved wife, for all her love and support, and for actually retaining her starting point attitude of encouragement and certainty throughout the work with this thesis.

My children, Ida and Gustav, for brightening every single day.

Their grandparents, for patiently looking after them.

The clinical studies were performed at:

The Department of Orthopedics, Helsingborg Hospital, Helsingborg, Sweden.

The biomechanical studies were performed at:

The Department of Bioengineering, Hospital for Joint Diseases Orthopaedic Institute, New York, NY, USA.

The Biomechanics Laboratory, Department of Orthopedics, Lund University Hospital, Lund, Sweden.

This work was supported by grants from:

The Stig and Ragna Gorthon Foundation, Helsingborg.

The Thelma Zoéga Foundation, Helsingborg.

The Clinical Research Foundation of Malmöhus County Hospital, Lund.

Stiftelsen för Bistånd åt vanföra i Skåne.

Alfred Österlunds Stiftelse.

The Medical Faculty of Lund University.

The Swedish Medical Research Council project 09509.

The Swedish Foundation for Strategic Research.

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