Extramedullary fixation of 107 subtrochanteric fractures

A randomized multicenter trial of the Medoff sliding plate versus 3 other screw-plate systems

Karl Lunsjö[1], Leif Ceder[1], Jan Tidermark[2], Per Hamberg[2], Bengt-Erik Larsson[3], Björn Ragnarsson[4], Richard W C Knebel[5], Ingemar Allvin[6], Krister Hjalmars[7], Sigge Norberg[8], Per Fornander[9], Anders Hauggaard[10] and Leif Stigsson[10]

We compared the efficacy of a load-sharing device, the Medoff sliding plate (MSP), with that of 3 other load-bearing screw-plate devices for the fixation of subtrochanteric fractures in a randomized multicenter trial of 107 elderly patients. 55 fractures were operated on with the MSP, and 52 with the dynamic hip screw (DHS) with or without a trochanteric stabilizing plate (TSP) or with the dynamic condylar screw (DCS). The patient material in the groups was similar regarding age, domestic situation, preinjury walking ability and fracture types. We followed the patients clinically and radiographically for a minimum of 1 year.

There was no significant difference in walking ability or return rate to the home at follow-up. Fixation failure occurred in 1/55 fractures operated on with the MSP, in 3/32 with the DHS, in 3/12 with the DCS and in 2/8 with the DHS/TSP. The difference in the rate of fixation failure was statistically significant, when the MSP group was compared to the 3 load-bearing devices in the other group (1 vs 8).

On the basis of this experience, we think that the load-sharing principle of the MSP, which seems to facilitate fracture impaction and stability, appears to be a good alternative in extramedullary fixation of subtrochanteric fractures.

Departments of [1]Orthopedics, Helsingborg Hospital, SE-251 87, Helsingborg, Sweden. Tel +46 42 102–410. Fax –450; [2]Orthopedics, South Hospital, SE-118 83, Stockholm, [3]Orthopedics, Falu Hospital, SE-791 82, Falun, [4]Orthopedics, Uppsala University Hospital, SE-751 85, Uppsala, [5]Orthopedics, Malmö University Hospital, SE-205 02, Malmö, [6]Orthopedics, Örebro Region Hospital, SE-701 85, Örebro, [7]Orthopedics, Östersund Hospital, SE-831 83, Östersund, [8]Orthopedics, Sundsvall Hospital, SE-851 86, Sundsvall, [9]Orthopedics, Lund University Hospital, SE-221 85 Lund, [10]Radiology, Helsingborg Hospital, SE-251 87, Helsingborg, Sweden
Submitted 98-11-24. Accepted 99-07-13

Most reports on subtrochanteric fractures are retrospective, comprise small numbers of patients, present devices with various biomechanical characteristics or mix up fractures sustained by low-energy trauma in elderly patients with fractures sustained by high-energy trauma in younger patients. Consequently, the reported rate of fixation failure for a particular implant varies (Waddell 1979, Sanders and Regazzoni 1989, Senter et al. 1990, Blatter and Janssen 1994). In addition, subtrochanteric fractures are relatively rare, which is why Whitelaw et al. (1990) recommended multicenter trials.

Standard extramedullary screw-plate devices act mainly as static implants in the pure subtrochanteric fracture, but they show some biomechanical differences in the combined inter/subtrochanteric fracture. In spite of its name, the dynamic condylar screw (DCS) acts as a rigid implant in this fracture, since the 95° angle is far from the direction of the load. The DHS provides compression along the femoral neck, and if the fracture finds a stable position, load-sharing between the bone and implant takes place. However, if the fracture does not stabilize, progressive medial displacement of the femoral shaft can occur, which may result in fixation failure and nonunion. The concept of the DHS with a trochanteric stabilizing plate is to prevent or to reduce medial displacement. However, if further compression of the fracture is impeded by the trochanteric stabilizing plate before the fracture has been stabilized, the fracture may angulate into varus with lag screw cut-out, loosening or breakage of the plate as a result.

The MSP differs from other extramedullary screw-plate systems because of its dynamization capacity along the femoral shaft (Medoff and Maes 1991). In addition, by placing a locking set screw to the lag screw, sliding along the femoral neck can be prevented. This procedure, which stops any medialization of the femoral shaft (Kummer et al. 1998), may be beneficial in fractures with an unstable lateral femoral cortex configuration or a reverse obliquity (Ceder et al. 1996, Parker 1996).

In a prospective randomized multicenter trial, we compared the efficacy of the biomechanical concept of the MSP to that of standard extramedullary screw-plate systems in the treatment of elderly patients who had sustained a subtrochanteric fracture from a low-energy trauma.

Table 1. Background parameters in the 107 patients operated on with different extramedullary devices

	DHS n 32	DCS n 12	DHS/TSP n 8	MSP n 55	P-value [a]
Female:male	27:5	10:2	7:1	42:13	0.3 [b]
Age, mean, years	81	77	82	79	0.6 [c]
range	61–93	21–94	73–95	49–99	
Walking ability prefracture					
No aids	20	6	6	36	0.8 [d]
Aids	12	4	2	15	
Non-walker	0	1	0	3	
Unknown	0	1	0	1	
Domestic situation prefracture					
Own home	25	10	7	45	0.6 [d]
Old people's home	5	1	0	8	
Institution	2	1	1	2	
Fracture type					
I	1	0	0	0	0.07 [d]
IIA	0	1	0	0	
IIB	4	0	0	1	
IIC	2	2	1	2	
IIIA	2	0	0	7	
IIIB	0	0	0	0	
IV	0	0	0	3	
V	23	9	7	42	

[a] Significance of differences between MSP and the other 3 screw-plate systems
[b] Chi-square test
[c] Wilcoxon two-sample test
[d] Fisher's exact test

Patients and methods

From March 1993 through June 1995, 107 patients who had sustained a subtrochanteric fracture (Seinsheimer 1978) were included in a randomized multicenter trial, which comprised 8 hospitals. The inclusion of the patients was done at each hospital during a 12-month period.

Approval was granted by the local ethics committees and informed consent was obtained from the patients or, when they were confused, from their relatives. The patients were randomized for treatment with the MSP, or one of the other extramedullary devices, according to the preference of the surgeon, by sealed envelopes opened just before starting an attempted closed fracture reduction. About half of the surgeons at the 8 hospitals agreed to participate in the study; the MSP had recently been introduced. The same protocol, covering the whole follow-up period, was used at the 8 hospitals.

Patients with pathological fractures or previous surgery of the proximal femur were excluded. Fractures extending more than 5 cm distal to the lesser trochanter were also excluded, since, if the MSP was to be used, the cortical bone screws could be placed in the proximal fragment and thus prevent sliding of the plate. The locking set screw of the MSP was intended to be used allowing dynamization only along the femoral shaft (uniaxial dynamization), to prevent any femoral medialization.

The mean age of the patients was 80 (21–99) years and the female:male ratio was 86/21. 87 patients were admitted to the hospital from their homes and 68 had been able to walk without aids before the fracture.

The patients, who had been operated on with one of the other 3 screw-plate systems (DHS, DCS, DHS/TSP) had similar background parameters, which also corresponded to the parameters for the patients operated on with the MSP (Table 1). The fractures had been sustained from low-energy trauma. All patients were elderly except a 21-year-old woman having paraplegia, who was included in the DCS group.

The patients were given low-molecular heparin as thromboembolic prophylaxis. Spinal anesthesia was the routine method at all hospitals. We recorded any deviation from the routine operation, the peroperative blood loss as estimated by the nurse anesthetist, postoperative blood loss from the drain, the operating time "skin-to-skin", and whether the patients were allowed immediate weight-bearing, as tolerated.

The length of the hospital stay was recorded, and during this, deep wound infection (defined as a positive bacterial culture from beneath the deep fascia), superficial wound infection (defined as a positive bacterial culture from above the fascia), pulmonary embolism (diagnosed by scintigraphy), and deep-venous thrombosis (diagnosed by phlebography).

Radiographs were taken on admission, and were scheduled to be taken on days 1 and 7, and again at 4 and 12 months postoperatively. The endpoint was a revision operation or a healed fracture at 12 months or later. The mean time of the final radiographic examination, not including patients with a revision operation before the 12-month follow-up, was 17 (10–40) months in the MSP group and 15 (11–41) months in the 3 screw-plate systems group. To obtain an independent and uniform interpretation of the classification of the fractures, the healing and technical failures, the patients' protocols and radiographs were sent to independent reviewers (Helsingborg Hospital) who had not participated in the surgical treatment of the patients. The radiographs were examined by the first author and 2 senior radiologists, all of whom had had long experience with these fractures and the fracture classification system used.

Fixation failures were defined as lag-screw penetration or cut-out of the femoral head, breakage or loosening of the plate, or nonunion of the fracture. Migration of the lag screw in the femoral head or varus angulation of the fracture without lag-screw penetration or cut-out was not regarded as a technical failure. Revision operations were recorded. A complete plate or lag-screw slide was recorded.

At 4 and 12 months after the operation, the domestic situation and walking ability were recorded. 4 patients in the 3 screw-plate systems group and 6 patients in the MSP group were lost to follow-up at 12 months. However, 1 of the 4 patients and 4 of the 6 patients in each group did attend the 4-month follow-up. At this time, the fractures of these 5 patients were healing well. An 88-year-old woman in the DCS group suffered a new trauma at 8 months after she had sustained the first fracture, which had healed. This time she had a femoral shaft fracture well below the device. The fracture was not regarded as a fixation failure. She was excluded from further follow-up, but not considered lost to follow-up at 12 months.

Statistics

The Kruskal-Wallis Anova test was used for comparisons between the 3 screw-plate systems involving quantitative variables. The Wilcoxon two-sample test was used for comparisons between the MSP and the other systems. Proportions of nominal variables were investigated with Fisher's exact test or the chi- square test. Values of $p < 0.05$ were considered significant.

Results

Operating time was longer and blood loss higher in the DCS and the DHS/TSP systems than in the DHS ($p = 0.01$, Kruskal-Wallis Anova test; Table 2). In addition, the patients operated on with the DCS were advised more often ($p = 0.03$, Fisher's exact test) to avoid immediate full weight-bearing (Table 3). Other intra- and postoperative parameters were similar with all 3 devices (Tables 2, 3 and 4).

No difference in operating time or in total blood loss was found between the MSP and the other 3 screw-plate systems (Table 2). A supplementary fracture fixation was used less often in the MSP group (Table 2), and more patients were allowed immediate full weight-bearing in this group (Table 3). No difference was found in walking ability or return rate to the home at the 12-month follow-up.

A complete lag-screw slide occurred in 3 of the 52 fractures in the other 3 screw-plate systems group. 28 of the 55 fractures in the MSP group had a complete plate-slide.

Table 2. Intraoperative parameters in the 107 patients operated on with different extramedullary devices

	DHS n 32	DCS n 12	DHS/TSP n 8	MSP n 55	P-value [a]
Median operating time in min	60	95	100	75	0.6 [c]
range	21–240	50–245	60–145	30–240	
Median intraoperative blood loss in L	0.48	1.1	0.92	0.45	0.1 [c]
range	0.12–3.5	0.35–3.3	0.30–1.9	0.10–4.0	
Median blood loss in drain in L	0.08	0.10	0.25	0.10	0.9 [c]
range	0–0.60	0–0.35	0–0.50	0–1.2	
Median total blood loss in L	0.62	1.17	1.1	0.65	0.2 [c]
range	0.12–3.5	0.45–3.3	0.42–2.3	0.17–4.0	
Deviation from routine operation					
No	21	9	6	34	0.4 [d]
Cerclage wire [b]	11	3	1	4	
Interfragmentary screw [b]	0	0	1	1 [e]	
No locking set screw				17 [e]	

[a] Significance of differences between MSP and the other 3 screw-plate systems
[b] The p-value for supplementary fixation is 0.005 derived from Fisher's exact test
[c] Wilcoxon two-sample test
[d] Fisher's exact test
[e] Same patient

Table 3. Postoperative parameters in the 107 patients operated on with different extramedullary devices

	DHS n 32	DCS n 12	DHS/TSP n 8	MSP n 55	P-value [a]
Immediate full weight-bearing	22	3	6	43	0.04 [b]
General complications					
Superficial wound infection	2	0	0	1	not tested
Deep wound infection	0	0	1	0	
Thromboembolism	1	0	0	3	
Median hospital stay in days	10	10	12	14	0.4 [c]
range	5–28	3–30	3–19	2–39	
Lost to follow-up at 12 months	3	0	1	6	0.7 [d]
Died at 12 months	4	2	1	9	0.7 [b]
Walks without aids at 12 months/prefracture [e]	5/15	2/5	1/3	14/30	0.4 [b]
Own home at 12 months/prefracture [e]	16/20	6/7	3/4	26/36	0.4 [b]

[a] Significance of differences between MSP and the other 3 screw-plate systems
[b] Chi-square test
[c] Wilcoxon two-sample test
[d] Fisher's exact test
[e] Only patients alive and not lost to follow-up at 12 months

Fixation failures

All fixation failures occurred in patients with a type V fracture (combined inter/subtrochanteric). A higher fixation failure rate was found in the other 3 screw-plate systems than in the MSP (Table 4). The type and rate of failures were equally distributed in the other 3 screw-plate systems.

In 1 fracture from the DCS group, the lag screw had been placed well short of the joint space and had a poor grip in the femoral head. Subsequently, a varus deformity of the fracture developed with lag-screw penetration. However, the fracture healed and the patient did not wish to undergo another operation. All other fixation failures in the 3

Table 4. Fixation failures and revisions in the 107 patients operated on with different extramedullary devices

	DHS n 32	DCS n 12	DHS/TSP n 8	MSP n 55	P-value [a]
Fixation failures					
Lag-screw penetration	2	1	1	0	0.01 [b]
Breakage or loosening of device	1	1	1	1 [c]	
Nonunion	0	1	0	0	
Revisions	2	2	2	1	0.06 [b]

[a] Significance of differences between MSP and the other 3 screw-plate systems
[b] Fisher's exact test
[c] The breakage of device was combined with nonunion

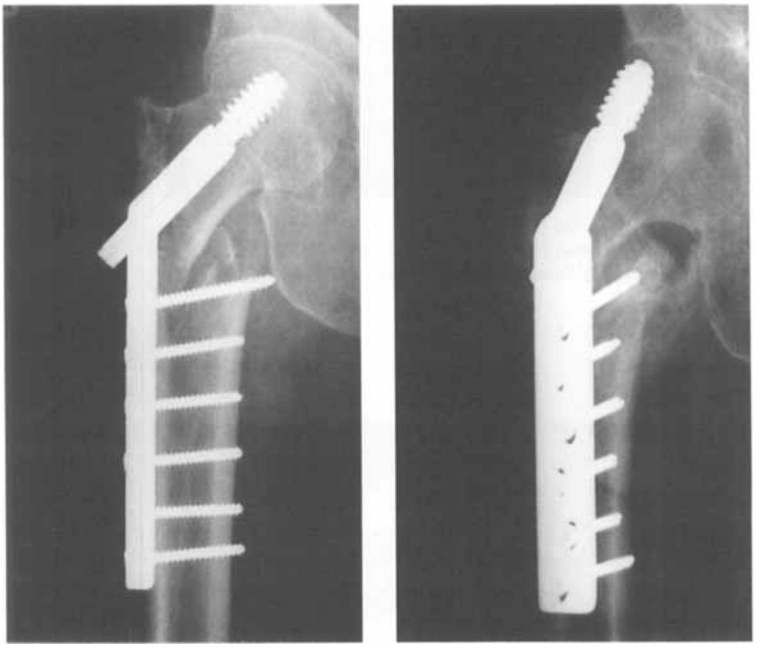

Figure 1. Type V fracture fixed with the DHS on day 1 (left) and at 4 months (right) postoperatively. An unstable lateral femoral cortex configuration was probably the cause of a major medial displacement of the femoral shaft, which resulted in varus angulation with cut-out of the lag screw.

screw-plate systems group were thought to have been caused by the biomechanical insufficiency of the device (Figures 1–3).

In the MSP group, the locking set screw was not used in the only patient with a fixation failure (Figure 4). A complete plate-slide with some sliding of the lag screw had occurred at the 4-month follow-up, followed by a complete slide of the lag screw with 50% medial displacement of the femoral shaft at the 12-month examination. The fracture showed delayed union and the patient, who used a walking-frame, had pain. A revision was not undertaken at this time. The fracture did not heal, and the plate broke 20 months later, when a revision was performed.

Discussion

The background parameters in the patients treated with one of the other 3 screw-plate systems were almost identical, which facilitated our primary in-

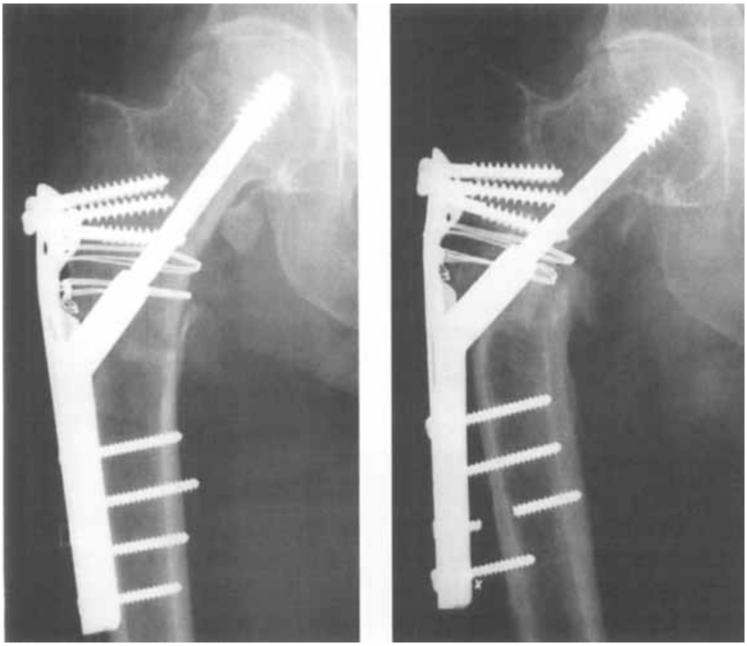

Figure 2. Type V fracture fixed with the DHS/TSP on day 1 (left) and at 6 months (right) postoperatively. In a well reduced fracture, lag-screw dynamization was probably impeded by the trochanteric stabilizing plate and loosening of the plate finally occurred.

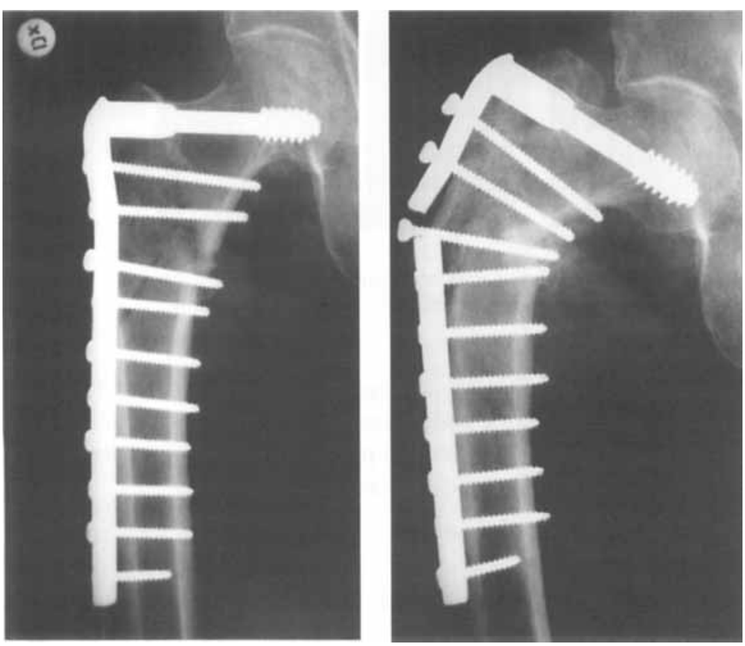

Figure 3. Type V fracture fixed with the DCS on day 1 (left) and at 3 months (right) postoperatively. In a well reduced fracture, the plate broke before the fracture had healed.

tention to assess them as one group in the comparison with the MSP. There was a longer operating time and a larger blood loss with the DCS and DHS/TSP than with the DHS, which was probably due to an extended proximal exposure.

As previously reported (Ruff and Lubbers 1986, Mullaji et al. 1993, Vanderschot et al. 1995, Ceder et al. 1998), the highly unstable type V fracture is the commonest subtrochanteric fracture. This was also true of our material. Lechner et al. (1990) and Kyle et al. (1994) found comminution of the trochanter region to be unfavorable for the use of intramedullary devices and recommended an extramedullary device for this type of fracture.

Standard extramedullary devices act as static implants in pure subtrochanteric fractures, and postoperative bone defects need to be bridged by callus before fracture stability is achieved. That is why many surgeons prefer postoperative toe-touch ambulation which is, however, difficult to manage for elderly patients (Parker and Pryor 1993). Ceder et al. (1998), who used the MSP in the treatment of subtrochanteric fractures, allowed immediate weight-bearing in 25 of their 32 patients and reported only 1 failure. In addition, in the present study, the surgeons used supplementary fixation signifi-

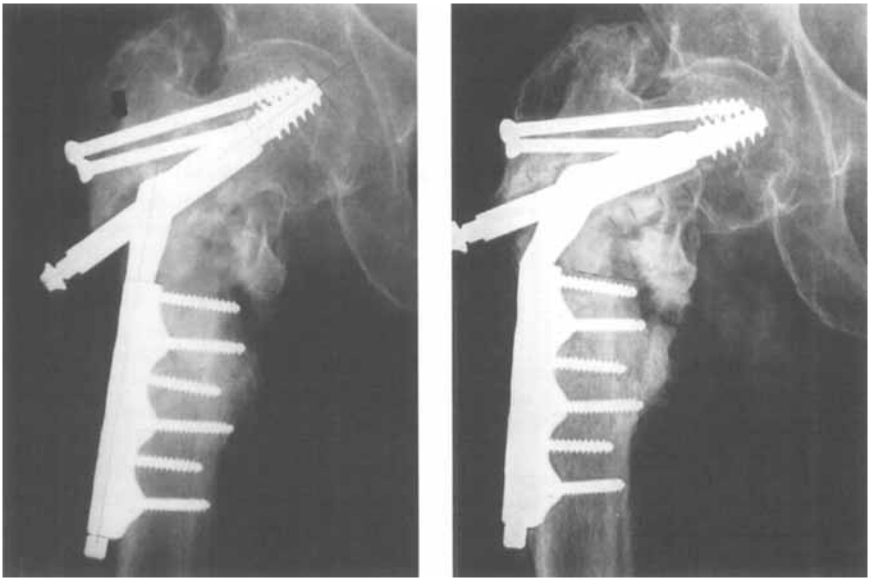

Figure 4. Type V fracture fixed with the MSP at 12 months (left) and at 32 months (right) postoperatively. The combination of an unstable lateral femoral cortex configuration and a dynamized lag-screw (it should have been locked) was the probable cause of a major medial displacement of the femoral shaft, later followed by nonunion and breakage of the plate.

cantly more often in the other 3 screw-plate systems in order to minimize the bone defects and to achieve fracture stability, which for the MSP was in part accomplished postoperatively by axial impaction at the fracture site. The greater load-sharing capacity of the MSP than of the DHS has been shown in biomechanical tests: in subtrochanteric fractures (Medoff and Maes 1990), 3–4 times higher plate strain was recorded for the DHS than for the MSP, and in unstable intertrochanteric fractures (Olsson et al. 1998), the MSP demonstrated more effective stress transfer to the fracture surface of the proximal medial cortex of the femur than the DHS. This biomechanical difference of stress transfer would probably be even more obvious in pure subtrochanteric fractures. An observation which may support this theory was that a complete plate-slide of the MSP occurred more often than a complete lag-screw slide of the other devices. We believe that the principle of load-sharing with the MSP in subtrochanteric fractures was the primary reason for the significant difference in the rate of fixation failure between the MSP and the 3 screw-plate systems.

Uniaxial dynamization with the MSP was meant to be achieved in all subtrochanteric fractures. The negligence in the use of the locking set screw in one third of the fractures was probably due to inexperience with the MSP. Ceder et al. (1998), however, found no difference in the rate of fixation failure in subtrochanteric fractures treated with uniaxial or biaxial dynamization.

We believe that the percentage of elderly patients lost to follow-up at 12 months in this study was acceptable and should not change our conclusions, especially since half of these patients attended the 4-month follow-up, by which time the fractures were healing. At the 8 hospitals, half of the surgeons declined to participate in the present study. Therefore all subtrochanteric fractures were not included. We have no reason to believe that this resulted in any selection bias, but we have no data on these patients. Since most of the surgeons in this trial had little experience with the MSP, the results achieved with the device were remarkably good.

In conclusion, we think that the sliding capacity along the femoral shaft with the MSP, which provides load-sharing and fracture impaction, is favorable in the treatment of high subtrochanteric fractures in the elderly.

We thank Jan Åke Nilsson, BS, Department of Statistics and Information Processing, Malmö General Hospital, Lund University, for the statistical analysis. This study was supported by grants from the Thelma Zoéga Foundation and the Stig and Ragna Gorthon Foundation, Helsingborg and the Clinical Research Foundation of Malmöhus County Hospital, Lund, Sweden. Other members of the Medoff study group include: Sune Larsson and Per-Olof Nilsson, Uppsala University Hospital, Lars-Erik Lindahl, Falu Hospital, Björn Skytting, South Hospital, Ingemar Sernbo, Malmö University Hospital and Karl-Göran Thorngren, Lund University Hospital.

Blatter G, Janssen M. Treatment of subtrochanteric fractures of the femur: reduction on the traction table and fixation with dynamic condylar screw. Arch Orthop Trauma Surg 1994; 113: 138- 41.

Ceder L, Lunsjö K, Olsson O, Stigsson L, Hauggaard A, Kummer F J. Can controlled biaxial dynamization lead to improved treatment of complex hip fractures? Orthop Trans 1996; 20: 162-3.

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.

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.

Kyle RF with contributors. Fractures of the proximal part of the femur. J Bone Joint Surg (Am) 1994; 76: 924-50.

Lechner J D, Rao J P, Stashak G, Adibe S O. Subtrochanteric fractures. A retrospective analysis. Clin Orthop 1990; 259: 140-5.

Medoff R J, Maes K. A new implant for the fixation of high subtrochanteric and unstable intertrochanteric fractures of the hip. Orthop Trans 1990; 14: 671.

Medoff R J, Maes K. A new device for the fixation of unstable pertrochanteric fractures of the hip. J Bone Joint Surg (Am) 1991; 73: 1192-9.

Mullaji A B, Orth D, Orth M S, Orth D N B, Thomas T L. Low-energy subtrochanteric fractures in elderly patients: results of fixation with the sliding screw-plate. J Trauma 1993; 34: 56-61.

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

Parker M J. Trochanteric hip fractures. Fixation failure commoner with femoral medialization, a comparison of 101 cases. Acta Orthop Scand 1996; 67 (4): 329-32.

Parker M J, Pryor G A. Hip fracture management. Blackwell Scientific Publications, Oxford 1993: 197-8.

Ruff M E, Lubbers L M. Treatment of subtrochanteric fractures with a sliding screw-plate device. J Trauma 1986; 26: 75-80.

Sanders R, Regazzoni P. Treatment of subtrochanteric femur fractures using the dynamic condylar screw. J Orthop Trauma 1989; 3: 206-13.

Seinsheimer F. Subtrochanteric fractures of the femur. J Bone Joint Surg (Am) 1978; 60: 300-6.

Senter B, Kendig R, Savoie F H. Operative stabilization of subtrochanteric fractures of the femur. J Orthop Trauma 1990; 4: 399-405.

Vanderschot P, Vanderspeeten K, Verheyen L, Broos P. A review on 161 subtrochanteric fractures - risk factors influencing outcome: age, fracture pattern and fracture level. Unfallchirurg 1995; 98: 265-71.

Waddell J P. Subtrochanteric fractures of the femur: a review of 130 patients. J Trauma 1979; 19: 582-91.

Whitelaw G P, Segal D, Sanzone C F, Ober N S, Hadley N. Unstable intertrochanteric/subtrochanteric fractures of the femur. Clin Orthop 1990; 252: 238-45.