Extramedullary fixation of 569 unstable intertrochanteric fractures

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

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Submitted 00-02-28. Accepted 00-09-21

ABSTRACT – We compared the efficacy of the Medoff sliding plate (MSP) with 3 other screw-plate systems for fixation of unstable intertrochanteric fractures in a randomized multicenter trial of 569 elderly patients. The MSP has biaxial dynamic capacity along both the neck and the shaft of the femur unlike the other systems, which lack dynamic capacity along the shaft. 268 fractures were operated on with the MSP, and 301 with the dynamic hip screw (DHS), with or without a trochanteric stabilizing plate (DHS/TSP) or with the dynamic condylar screw (DCS). The MSP had recently been shown to the surgeons.The patients in the groups were similar as regards age, domestic situation, preinjury walking ability and type of fracture. We followed the patients clinically and radiographically for at least 1 year.

There was no significant difference in walking ability at follow-up or rate of return to home. Fixation failure occurred in 18/268 fractures operated on with the MSP, in 8/238 with the DHS, in 3/49 with the DHS/TSP and in 1/14 with the DCS. The difference in the rate of fixation failure was not statistically significant when the MSP group was compared to the 3 other groups. In 14 of the 18 fixation failures in the MSP group, the biaxial dynamic capacity of the MSP had not been used due to technical errors by surgeons, unfamiliar with the new method. No selection bias was found regarding fracture types in the 2 subgroups of patients with correct or inadequate biaxial dynamization.

Extramedullary fixation of unstable intertrochanteric fractures with these implants showed a low failure rate. When using the MSP, biaxial dynamization must be correctly performed.

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The DHS, DHS/TSP and DCS are extramedullary implants, which all have a rigid side-plate. However, there are differences in their dynamic capacity. The DHS permits fracture compression in the direction of the femoral neck. This means an increased risk of medialization of the femoral shaft if the main fracture pattern is oblique reverse or transverse, or if the lateral cortex around the entry hole of the lag screw is comminuted (Ceder et al. 1996). Parker (1996) found that femoral medialization was closely associated with fixation failure, and failures increased 7-fold, if medialization of more than 1/3 of the femoral diameter at the fracture site occurred. Although the DHS is the most widely used implant, the average fixation failure rate is about 10% in unstable intertrochanteric fractures (Bannister et al. 1990, Bridle et al. 1991, Leung et al. 1992, Desjardins et al. 1993, Buciuto et al. 1998, Watson et al. 1998). Addition of a trochanteric stabilizing plate to the DHS aims to prevent or reduce excessive femoral medializa-

tion (Madsen et al. 1998), but it may impede the function of the lag screw thus preventing bone-to-bone contact at fracture impaction. The DCS with its 95-degree angle of the barrel-plate has little effective dynamic capacity, since the hip joint reaction force is 159 degrees to the vertical plane on loading (Kyle et al. 1994).

The rigid side-plate has been replaced by 2 sliding elements in the MSP (Medoff and Maes 1991) to allow fracture compression in the direction of the femoral shaft. Kyle et al. (1994) stated that a sliding implant with a screw-plate angle closest to the hip joint reaction force permits optimal sliding and impaction. The MSP with its dual sliding provides dynamization along the femoral neck, 135 degrees to the vertical plane, and along the femoral shaft, 180 degrees to the vertical plane. The advantage of load-sharing supposedly should be impaction of the fracture with bone-to-bone contact, which improves fracture stability. This would improve healing and reduce the stress on the implant, thus minimizing the risk of fixation failure. Moreover, some of the sliding occurs in a direction parallel to the femoral shaft, which should reduce the degree of femoral medialization.

In a prospective, randomized multicenter trial, we compared the efficacy of the biaxial dynamic concept of the MSP to that of standard extramedullary screw-plate systems in the treatment of patients who had sustained an unstable intertrochanteric fracture.

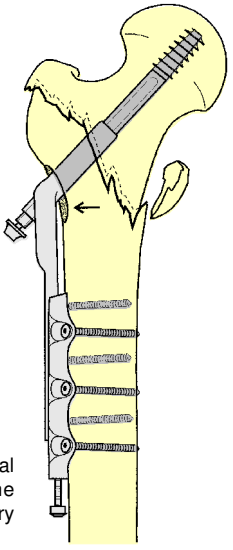

Figure 1. The MSP in a biaxial dynamization mode. Note the distal enlargement of the entry hole of the lag screw (arrow).

Patients and methods

From March 1993 through June 1995, 569 patients who had sustained an unstable intertrochanteric fracture 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. The inclusion period started at different times in the various hospitals.

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 screw-plates according to the preference of the surgeon. Sealed envelopes were opened just before the surgeon tried to perform closed reduction of the fracture. About half of the surgeons at the 8 hospitals took part in this study. The MSP had recently been shown to the surgeons, which is why many of them had little, if any, experience with this method. The same protocol for the whole follow-up period was used at the 8 hospitals.

Patients with pathological fractures or previous surgery of the proximal femur were excluded. 2-part fractures were also excluded, since they are considered stable after reduction and usually heal uneventfully regardless of the fixation method (Jensen et al. 1980). The principle of biaxial dynamization was intended to be followed, which meant that the lag screw of the MSP should be unlocked. To obtain sliding along the femoral shaft in intertrochanteric fractures, it is mandatory to enlarge distally the entry hole of the lag screw (Figure 1). Otherwise, the plate barrel would impinge on the lateral cortex of the femur, which then obstructs axial compression.

The mean age of the patients was 82 (42–99) years and the female:male ratio was 2.7/1. 382 (67%) of the patients were admitted to the hospital from their own homes and 264 (46%) had been able to walk without aids before the fracture.

The patients in the 4 osteosynthesis groups had similar background parameters (Table 1). The patients were given low-molecular heparin as thromboembolic prophylaxis. Spinal anesthesia was the routine method in all hospitals. We recorded any

Table 1. Background parameters in the 569 patients operated on with various extramedullary devices

	DHS n 238	DHS/TSP n 49	DCS n 14	MSP n 268
Women:men	167:71	37:12	12:2	201:67
Age, mean	81	83	81	81
range	50–97	50–97	47–95	42–99
Walking ability, prefracture				
No aids	117	15	7	12
Aids	103	24	6	115
Non-walker	10	5	0	14
Unknown	8	5	1	14
Domestic situation, prefracture				
Own home	157	31	11	183
Old people's home	59	13	1	60
Institution	22	5	2	25
Fracture type				
3	37	11	2	33
4	23	6	2	26
5	175	32	10	207
Preoperative radiographs missing	3	0	0	2

deviation from the routine operation, the peroperative blood loss as estimated by the nurse anesthetist, postoperative blood loss from the drain, the operative time "skin-to-skin", and whether the patients were allowed immediate weight-bearing, as tolerated.

The length of the hospital stay was noted, and during this period, deep wound infection (defined as a positive bacterial culture from below the deep fascia), superficial wound infection (defined as a positive bacterial culture from above the fascia), pulmonary embolism (diagnosed with scintigraphy), and deep-venous thrombosis (diagnosed with 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 when the final radiographic examination was done, not including patients with a revision operation before the 12-month follow-up, was 15 (8–45) months in the MSP group and 16 (8–48) months in the 3 screw-plate systems group. The fractures were classified by Jensen and Michaelsen method (1975), and the third or fourth fracture fragment had to be large. To obtain a uniform classification of the fractures, the healing and fixation failures, the patients' protocols and radiographs were sent to independent reviewers (Helsingborg Hospital), who had not participated in the clinical follow-up of the patients. The radiographs were examined by the first author and 2 senior radiologists, all of whom 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 fixation failure. Revision operations were recorded.

At 4 and 12 months after the operation, the domestic situation and walking ability were also recorded. At 12 months, 24 patients were lost to follow-up in the MSP group (9%) and the 3 other screw-plate systems group (8%). 9 of the 49 patients operated on with the DHS/TSP were lost to follow-up at 12 months.

Statistics

The Kruskal-Wallis Anova test was used for comparisons between the 3 other 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 studied with Fisher's

Table 2. Intraoperative parameters in the 569 patients operated on with various extramedullary devices

	DHS n 238	DHS/TSP n 49	DCS n 14	MSP n 268	P-value [a]
Median operating time in min	45	70	70	60	<0.01 [b]
range	13–231	30–150	37–120	25–160	
Median intraoperative blood loss in L	0.20	0.30	0.40	0.30	<0.01 [b]
range	0–1.30	0.10–2.30	0.10–0.80	0–2.50	
Median blood loss in drain in L	0.06	0.12	0.08	0.10	0.02 [b]
range	0–0.85	0–0.75	0–0.20	0–0.94	
Median total blood loss in L	0.30	0.42	0.50	0.40	<0.01 [b]
range	0.02–1.95	0.10–2.30	0.25–0.80	0.05–2.50	
Deviation from routine operation					
No	221	44	10	191	
Cerclage wire [c]	11	2	2	2	
Interfragmentary screw [c]	2	2	2	4	
Locking set screw used				29	
No enlargement of entry hole				40	
Postoperative radiographs missing	4	1	0	2	

[a] Significance of difference between MSP and the 3 other screw-plate systems
[b] Wilcoxon two-sample test
[c] The p-value for supplementary fixation is 0.049 derived from Fisher's exact test

exact test or the chi-square test. Values of $p<0.05$ were considered significant.

Results

When comparing the 3 standard screw-plate systems, the operating time was longer and blood loss higher in the DHS/TSP and the DCS systems than in the DHS system (Table 2). In addition, the patients operated on with the DCS were advised more often to avoid immediate full weight-bearing and their hospital stay was longer (Table 3). Other background, intra- and postoperative parameters were similar with all 3 devices including the ratio of 4-part fractures (Tables 1, 2, 3 and 4). Extraction of the plate in the DHS/TSP group had to be done in 4 healed fractures due to pain over the greater trochanter, which probably was caused by the plate.

The background parameters were similar in the MSP and the 3 other screw-plate systems (Table 1). Operating time was longer and blood loss higher in the MSP group than in the DHS group (Table 2). Supplementary fracture fixation was used more often in the 3 other screw-plate systems (Table 2). More patients were allowed immediate full weight-bearing in the MSP group (Table 3). No difference was found in walking ability or return-to-home rate at the 12-month follow-up.

Fixation failures

Almost all fixation failures occurred in patients with a type 5 fracture (4-part fracture). The exception was a patient with a type 3 fracture (3-part fracture, the third fragment was the greater trochanter) operated on with a DHS. The types and rate of fixation failures were equally distributed in the 3 screw-plate systems group. No difference was found between this group and the MSP group (Table 4).

In the Medoff group, fixation failure occurred in 9 of the 29 patients, in whom the locking set screw had been used (Figure 2), and in 5 of the 40 patients, in whom no distal enlargement of the entry hole had been made (Figure 3). Due to these deviations or mistakes from the intended surgical technique, the dynamic capacity of the device had been reduced or impeded. The remaining 4 fixation failures in the Medoff group occurred in the 199 patients with correctly used biaxial dynamization. There were no differences between the proportion of the most unstable intertrochanteric fracture (the 4-part fracture) in the correctly-operated patients (79%) and in the incorrectly-operated ones (74%).

Table 3. Postoperative parameters in the 569 patients operated on with various extramedullary devices

	DHS n 238	DHS/TSP n 49	DCS n 14	MSP n 268	P-value [a]
Immediate full weight-bearing	216	45	8	255	0.02 [b]
General complications					
Superficial wound infection	2	1	0	1	not tested
Deep wound infection	2	0	0	1	
Thromboembolism	1	0	0	0	
Median hospital stay in days	9	11	14	9	0.3 [b]
range	1–47	1–39	1–107	0–45	
Lost to follow-up at 12 months	14	9	1	24	0.7 [b]
Died at 12 months	59	11	2	60	0.7 [b]
Walking without aids at					
12 months/prefracture [c]	40/87	9/13	3/5	36/99	0.06 [b]
Own home at					
12 months/prefracture [c]	94/120	15/21	6/9	102/140	0.5 [b]

[a] Significance of difference between MSP and the 3 other screw-plate systems
[b] Chi-square test
[c] Only patients alive and not lost to follow-up at 12 months

Table 4. Fixation failures and revisions in the 569 patients operated on with various extramedullary devices

	DHS n 238	DHS/TSP n 49	DCS n 14	MSP n 268	P-value [a]
Fixation failures					
Lag screw penetration	6	2	0	15	0.15 [b]
Breakage or loosening of device	2	0	1	0	
Nonunion	0	1	0	3	
Revisions	3	3	1	9	0.46 [c]

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

Discussion

The background parameters in the patients treated with the 3 other screw-plate systems were similar, which simplified our main aim which was to compare them as a group with the MSP. To compare the standard screw-plate systems with one another or with one of the other screw-plate systems and the MSP was not the purpose of this study. However, we found important clinical differences which we wish to discuss.

The operating time was longer and the blood loss larger with the DHS/TSP and the DCS than with the DHS, which was probably due to an extended proximal exposure, findings that agree with our results on the same implants used in subtrochanteric fractures (Lunsjö et al. 1999). The trochanteric stabilizing plate had to be removed in some patients due to pain over the greater trochanter. The patients in the DCS group were told after surgery more often to avoid immediate full weight-bearing, and they also had a longer hospital stay. The fracture fixation was probably not considered stable enough with the DCS, which does not permit adequate fracture impaction postoperatively.

The operating time was longer and the blood loss larger in patients operated on with the MSP than in those operated on with the DHS, which is similar to the findings of Watson et al. (1998). Most of the DHS plates were fixed to the femur with 4 bone screws and the MSP with 6 screws.

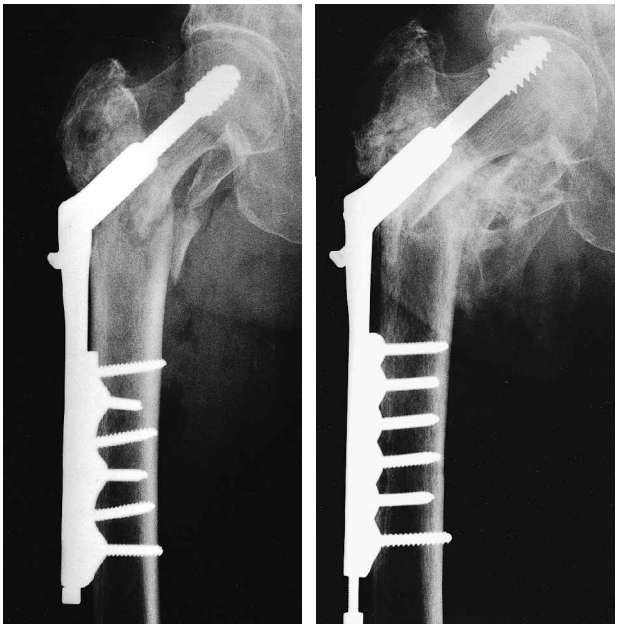

Figure 2. A type 5 fracture fixed with the MSP on day 1 (left) and at 4 months (right) postoperatively. The locking set screw prevented sliding of the lag screw, which was at variance with the biaxial dynamic principle. This caused varus angulation and cut-out of the lag screw.

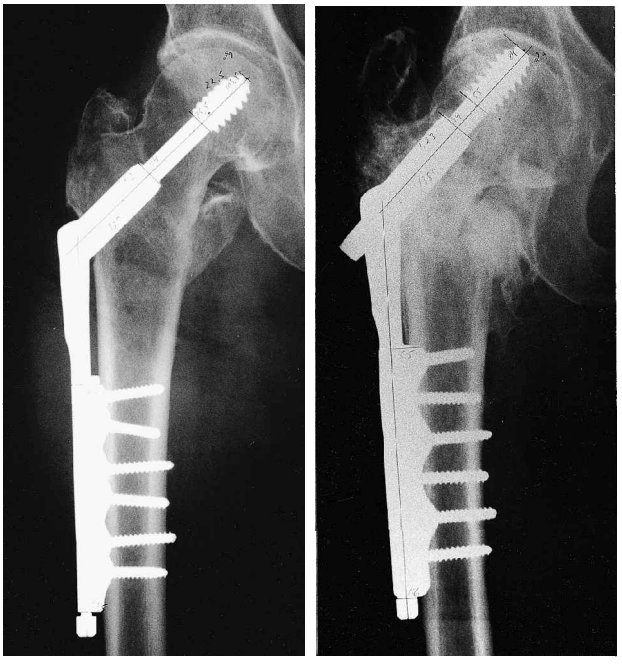

Figure 3. A type 5 fracture fixed with the MSP on day 1 (left) and at 4 months (right) postoperatively. The entry hole of the lag screw had not been distally enlarged. The plate barrel thus impinged on the lateral cortex of the femur and no sliding was possible along the shaft. This surgical error departed from the biaxial dynamization principle, and cut-out of the lag screw ensued.

The original 6-hole MSP is probably unnecessarily long for the treatment of intertrochanteric fractures. Although most cases were very unstable 4-part fractures, a high percentage of the patients were allowed immediate full weight-bearing postoperatively in the MSP group. This is important as mobilization with restricted weight-bearing is poorly tolerated by elderly patients.

Medoff and Maes (1991), who recommended dynamization only along the femoral shaft in both unstable intertrochanteric and subtrochanteric fractures, had no failures in a series of 25 patients. An independent evaluation of the MSP used with uniaxial dynamization in intertrochanteric fractures (Lunsjö et al. 1995) reported 7% fixation failures. A second prospective series with the MSP used with biaxial dynamization resulted in 1% fixation failure, which was a significant improvement (Lunsjö et al. 1996). The good results with biaxial dynamization have since been reproduced in another prospective series (Olsson et al. 1997) and in a randomized trial, comparing the MSP to the DHS, which showed significantly better results with the MSP (Watson et al. 1998). Mechanically, the MSP gave more effective stress transfer to the fracture surface of the proximal medial cortex than the DHS (Olsson et al. 1998), which should favor load sharing and stability. The MSP probably restores the medial cortical continuity better than the DHS, by reducing the medial fracture gap by its additional vertical impaction.

Most of the fixation failures in the MSP group occurred because the surgeons had not fully understood how to make use of the dual sliding capacity of the device. We found no selection bias due to fracture type between the correctly- and incorrectly-operated patients in the MSP group. A factor that might have confused the surgeons was that a similar study on subtrochanteric fractures was in

progress at the same time at the 8 hospitals where the surgeons were instructed to use the locking set screw (Lunsjö et al. 1999). In addition, distal enlargement of the entry hole is not needed in subtrochanteric fractures. The 2% rate of fixation failure in the correctly-operated patients in the present study agreed with other reports on the MSP used in the dual sliding mode in unstable intertrochanteric fractures, where the surgeons were familiar with the device and the biaxial dynamization principle (Lunsjö et al. 1996, Olsson et al. 1997, Watson et al. 1998). A shorter 4-hole MSP with obligatory dual sliding has since been designed for use in unstable intertrochanteric fractures to avoid errors as described above and to simplify the surgical procedure (Olsson et al. 1997).

We have not reported on the placement of the lag screw in the femoral head or on the adequacy of fracture reduction. In a large randomized trial, such variables are thought to be equally distributed among the groups. We believe that the percentage of patients lost to follow-up was acceptable and should not change our conclusions. At the 8 hospitals, half of the surgeons declined to participate in the present study. Therefore, all unstable intertrochanteric 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.

The 3% rate of fixation failure with the DHS was better than expected as regards previous reports on prospectively followed unstable intertrochanteric fractures (Bannister et al. 1990, Bridle et al. 1991, Leung et al. 1992, Desjardins et al. 1993, Buciuto et al. 1998, Watson et al. 1998). The sliding hip-screw is still the commonest implant in the treatment of extracapsular hip fractures and every new fixation method must be compared with this device (Parker 1999). With improvements in fixation methods, the assessment of any new implant becomes more difficult as more patients have to be studied, to obtain a statistically significant difference. More emphasis should be placed on the results of randomized studies. However, these are sensitive to performance bias, especially in a multicenter trial with many surgeons. With the MSP, it is important to use the right dynamization mode for the specific type of fracture, which requires a knowledge of fracture classification as well as understanding of the design and function of the device.

In conclusion, this study showed no superiority of the 6-hole MSP to the 3 other screw-plate systems. However, we think that the biaxial dynamization principle with the MSP, when correctly understood and used, is a suitable method for treatment of unstable intertrochanteric fractures and has a low failure rate.

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, the Clinical Research Foundation of Malmöhus County Council, Lund, and the Swedish Medical Research Council (project 08393), Sweden. Other members of the Medoff study group included: Per Hamberg, South Hospital, Bengt-Erik Larsson, Falu Hospital, Björn Ragnarsson, Lars-Erik Lindahl, Uppsala University Hospital, Ingemar Sernbo, Malmö University Hospital and Per Fornander, Lund University Hospital.

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