



A prospective randomized trial of 100 patients using trochanteric support plates; worth their mettle? ☆



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ABSTRACT

Background and purpose: To compare the radiological and clinical results of sliding hip screw (SHS) fixation with or without a Trochanteric Support Plate (TSP) on unstable three-or-more-part trochanteric fractures.

Methods: A randomized prospective non blinded study of one hundred patients with trochanteric fractures; Evans-Jensen type 3, 4 and 5, reduced and fixed with SHS. Patients were randomized into two study groups; with or without TSP supplementation ("TSP" and "NoTSP" groups). Radiologic measurements of the hip in the frontal plane (primary outcome), including fracture movement, nonunion and loss of fixation were measured, as well as pain, ambulation, mobility, institution residence, complications and death, twelve months post operatively (secondary outcomes).

Results: At one-year follow-up four patients in the TSP and ten patients in the NoTSP group had either died or been lost in follow-up. Within this period, forty-three fractures healed and three had a loss of fixation in the TSP group; thirty-nine fractures healed and one had a loss of fixation in the NoTSP group. Frontal X-rays showed fracture subsidence on average 1 mm less in the TSP group compared to the NoTSP group.

This difference was negligible, as was the difference in all subgroups, in fixation failure/cutout, modified Merle d'Aubigne Postel scores (measuring function and pain), institution residence, complications and death between the groups.

Interpretation: This study cannot confirm that TSP has any beneficial effects on unstable three-or-more-part trochanteric fractures. If any effect at all, the difference is most likely slight and clinically irrelevant.

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Level 2 Evidence.

Introduction

Nowhere else in the body other than the proximal femur, are fractures routinely treated with controlled dynamic compression (such as SHS), as opposed to a static construct. In unstable trochanteric fractures, this treatment is not always successful. To attain controlled subsidence and compression laterally, the principle demands an intact and strong lateral wall; which is often lacking. Lack of lateral wall integrity may cause a failure of the fixation leading to gross deformity of the original anatomic position and patient disability [1]. While simple two-part trochanteric fractures seldom

are problematic when treated by this method, studies have shown that unstable fractures (defined here as three-parts or more) end up with an alarming rate of deformity [2], probably causing discomfort, pain, patient disability and sometimes construct failure.

Typically, unstable trochanteric fractures show medialization and shortening of the shaft in relation to the caput. The lateral wall is often unable to hold the construct of the sliding hip screw in place. Even when the lateral wall seems to be intact preoperatively, the lateral wall can fracture and lose lateral integrity both intra-operatively, and postoperatively after the start of weight bearing. In a retrospective study of 216 patients treated at our hospital, we found an insufficiency of the lateral wall in 25% of unstable trochanteric fractures where the lateral wall was originally deemed intact on preoperative radiographs [3]. Palm showed that three quarters of fractures of the lateral wall occur during the operation itself and that postoperative fracture of the lateral wall was the main predictor for reoperation [4].

Parker et al. showed that a loss of structural lateral support resulting in medialization of the distal fragment increased the risk of cutout by a magnitude of 7 [1]. Hsu et al. showed that lateral wall

☆ A trial including one hundred patients treated with sliding hip screws for multi-fragmental trochanteric fractures randomized with or without Trochanteric Support Plates, showing negligible effect on radiological and clinical parameters.

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thickness was the main risk factor for postoperative lateral wall failure [5]. Postoperative lateral wall integrity in unstable trochanteric fractures is therefore generally considered an important factor for a stable fixation.

Trochanteric support plates (TSP) were introduced several decades ago to try to solve this problem of a broken or weak lateral wall. The purpose of the plate was to provide a strong lateral wall against which the collar could compress against. While there is worldwide use of this device, there are only a few studies pertaining to them [5–8] and studies are mainly retrospective and including only a few hundred patients in total.

While nailing of trochanteric fractures has gained popularity in many parts of the world [9,10] the gold standard of treatment of these fractures, according to the latest Cochrane meta-analysis is still a sliding screw and hip plate construct [11]. While some studies of nails show results on par with plates [12], very few studies have been able to show better results using other implants [13]. In accordance with these results, the use of sliding hip and screw plates (with a TSP when deemed needed), is still one of the main ways of treating these unstable fractures in much of Northern Europe. Over eight thousand Trochanteric Support Plates have been used in Norway alone since 2005, and therefore further investigation of their use seems warranted (Norwegian National Hip Fracture Report [14]).

The aim of this trial was to study whether the addition of a TSP is an advantage on unstable trochanteric fractures treated with sliding hip screws. We wanted to include all unstable fractures, where there was a present, or potential, loss of lateral wall integrity based on our observations described above. Our main objective was to study the biomechanics of the constructs by radiological analysis of the movement of the femoral head in relation to the femoral shaft (in this paper called subsidence), and secondly correlate these results to patients' clinical outcomes, including pain, ambulation, mobility and need for care at an institution. Our hypothesis was that the TSP would reduce the secondary subsidence of the fracture giving better function; an advantage for patients.

Patients, materials and methods

Power calculation

Our main objective was to observe radiologic changes of anatomy. Our aforementioned retrospective study showed a mean sliding of screw against plate without TSP of 15 mm, comparable with Madsen's study showing 12 mm [7]. With TSP we expected a restraint on this sliding of at least 4 mm. Standard deviation was expected from our retrospective study to be 7 mm giving us a power of over 0.80 with 50 patients treated with TSP.

Inclusion

During the span of the trial, from 2008 to 2013, 648 patients with trochanteric fractures were operated at our hospital. We suspect approximately half of this number, over 300, were unstable fractures [3]. We included 100 of these patients with low energy, unstable, trochanteric fractures (Evans Jensen type 3–5) (Type 3 – three-part fracture with separate greater trochanter fragment, Type 4 – three-part fracture with lesser trochanter fragment and Type 5 – four-part fracture with separate greater and lesser trochanter fragments) [15]. This classification was chosen as it was one of the better systems for describing lateral wall integrity when the study was being planned. Reverse oblique fractures were excluded as we deemed it unethical not to use a TSP with the sliding screw or nail the fracture [16] and they are relatively rare. Subtrochanteric fractures were not included. Until 2011, only

patients with no cognitive impairment were included, however due to slow recruitment, we opened the trial, with new ethical committee approval, to also include patients with cognitive impairment if next of kin consented, on the grounds that the results from this study would help provide care for this kind of patient population.

Patients were included by the registrar on call. The patient, or next of kin, was invited to the study and signed the consent form. Patients were not always included consecutively often due to workload problems of the registrars, patients declining the invitation, and in the case of cognitive weakness, not having next of kin available. Nevertheless, once included in the trial, all patients were randomized and protocol was followed in all cases. Randomization for treatment was done before the start of the study using a computer randomization program and instructions to either implant or not implant a TSP were stored in sealed envelopes. Envelopes were opened at the start of the operation. The patients were operated by the orthopedic registrars at our hospital, under the supervision of a consultant.

Surgery

The first patients were operated with Synthes Dynamic Hip Screw and 135 degree Plate with a Synthes ULTSP, when randomized to the TSP group. In 2009 our hospital changed supplier and Smith and Nephews 135 degree CHS with their corresponding TSP was used from then on. Both TSP types use 3 screws for fixation through both the sliding hip plate and femur and extend 4¹/₂ cm proximal from the lateral side of the SHS plate.

Radiograph measurements

Front and lateral standard radiographs were obtained pre- and immediately postoperatively and new radiographs were obtained at the 12 month follow-up. Movement of the center of the femoral head was calculated in relationship to the femoral shaft. (In this text we have defined this movement as subsidence). Radiographic distances were calibrated using known lengths of the sliding hip screw. Firstly we checked that the plate did not move in relationship to the femur. Secondly the proximal end of the lag screw was measured in relationship to the femoral head, and changes in position of the screw inside the head as compared to the immediate postoperative radiographs were recorded, as were changes in varus/valgus angulation. Thirdly, the lagscrew movement inside the plate chamber was measured. From these parameters, using Euclidian geometry and trigonometrical analysis, we could obtain a reasonable description of femoral shaft movement in relation to the caput in the frontal plane. We could not measure quantitative differences in anteversion/retroversion angulation or movements in AP direction because of large differences in the angle that the standard lateral radiographs were obtained. Neither could we measure rotation of the caput in the sagittal plane.

In most cases the lagscrew stayed fixed in the caput, so movement was only along the axis of the plate barrel. We also recorded radiographic evidence of healing and failures such as screw cutout.

Clinical outcomes

On admittance, pre-trauma information was obtained on patients' type of residence and walking mobility. At one year follow-up information was registered using a standard protocol pertaining to type of residence, modified Merle d'Aubigne–Postel score (a score rating pain, ambulation and ROM of the hip) [17] and complications.

Table 1
Patient characteristics by allocated group.

Pasient Demographics	TSP	NoTSP
No.	50	50
Age (average)	81.9	82.4
Sex		
Male	10	12
Female	40	38
Ambulation (score 1-6) before admission (part score from Mod.Merle D'Aubigne scoring system)	3.5	3.5
Type of Residence		
Own house	37	35
Temporary rehabilitation center	5	6
Permanent institution	8	9
Fracture type		
Evans Jensen 3	6	6
Evans Jensen 4	23	33
Evans Jensen 5	21	11

Statistics

IBM SPSS statistics Data Editor was used. Independent samples Student's *t*-test was used for numeric data and Chi Squared test for categorical data. The *p*-value (defined as the probability of obtaining a result equal to or "more extreme" than what was actually observed, when the null hypothesis is true) was set at 0.05.

Ethics

The study was approved by the regional medical ethics committee and is registered on <https://www.clinicaltrials.gov/ct2/show/NCT00626470>.

Funding

This study was funded solely by our employer, St.Olavs University Hospital.

Results

100 patients were included. Patient characteristics were similar (Table 1).

We were not able to obtain complete follow-up information from all patients due to deaths, cognitive and mobility problems, and one 'no show' (Table 2).

Thirteen patients died before the twelve-month follow-up. Lagscrew movement in the femoral head (movement of caput relative to the collum screw) was evident in 10 cases but only went on to cutout in 4 patients and stabilized and healed in 6 patients. By three months 8 fractures had not healed; 4 went later on to heal and 4 had fixation failure within 12 months resulting in a hip arthroplasty (Table 3). Complications included two deep infections, one DVT, one stroke, one pulmonary embolism and one ileus all within 6 weeks, and one amputation at four months.

Table 4
Subsidence of fractures measured on X-ray in frontal plane (combined medialization and shortening of femur in relation to the caput) within one year.

	Total number (No. with radiographs obtained at one year in parenthesis. Excluding also fixation failures)	TSP group (mm with SD)	NoTSP group (mm with SD)	Average difference (mm)	<i>p</i>	95% confidence interval (mm)
Evans Jensen type 3	12 (10)	9.9 (±8.7)	14.1 (±9.9)	4.2	0.49	−9.4 to +17.9
Evans Jensen type 4	56 (46)	14.9 (±9.2)	14.3 (±9.2)	−0.6	0.82	−6.1 to +4.9
Evans Jensen type 5	32 (26)	15.5 (±6.9)	18.4 (±11.8)	2.9	0.43	−4.6 to +10.4
Pooled Evans Jensen type 3&5 (all fractures with broken lateral wall)	44 (36)	14.0 (±7.6)	17.1 (±11.0)	3.1	0.33	−3.3 to +9.3
All fractures	100 (82)	14.5 (±9.7)	15.2 (±9.8)	0.7	0.70	−3.2 to +4.8

Table 2
Outcome data obtained from patients at 12 month follow-up. (Reasons for missing data include death, cognitive impairment and organizational difficulties).

Outcome data	Number of patients from whom information could be obtained. (87 patients alive)
Housing	84
Mod.Merle d'Aubigne-Postel score	70
Post-operative radiographs	86

Table 3
Patient clinical and fracture outcomes at one year of all 100 patients.

Clinical outcome	TSP	NoTSP	<i>p</i>
Fracture outcomes (no of patients)			
Healed	43	39	0.38
Fixation failure (all resulting in reoperation; arthroplasty)	3	1	
Dead	3	10	0.08
Unknown	1	0	
Mod.Merle d'Aubigne-Postel score. (average and SD)	9.9 (±2.6)	10.6 (±2.3)	0.21
Pain (part-score from Merle) (average and SD) (6;no pain-1;severe pain)	4.9 (±1.2)	5.3 (±0.8)	0.08
Place of residence (no. of patients)			
Home	24	23	0.38
Temporary rehabilitation	9	4	
Institution	11	13	

Analysis of clinical parameters between the groups operated with and without TSP, (both with and without subdivision into 3 groups according to Evans–Jensen classification) and clinical parameters were analyzed (Table 3). Only small and nonsignificant statistical differences could be identified with regards to death, Modified Merle-d'Aubigne–Postel scores, institution residency, reoperation due to loss of fixation or other complications at 12 months.

Radiographic distances were measured for movement of the caput relative to the femoral shaft relative to the caput (subsidence) within 12 months, excluding fixation failures (Table 4). Our data showed 1 mm less subsidence in the TSP group for all unstable fractures, 3 mm less subsidence in The TSP group for all fractures where the lateral wall was broken (Evans–Jensen type 3 and 5), and 4 mm less subsidence in the TSP group for subgroup Evans–Jensen type 3. None of the differences were statistically significant.

Madsen et al. [7]. divided their patients into two groups pertaining to lagscrew sliding over 20 mm. Table 5 demonstrates our results using a similar method of subdivision for the measured subsidence, and includes the fixation failures.

Discussion

Our study was not able to support our hypothesis that TSP used on unstable trochanteric fractures has any clinically relevant effect

Table 5

Subsidence of caput relative to femur of all 86 patients with radiographs. (no. of patients).

Subsidence	TSP	NoTSP	Total	<i>p</i>
Under 20 mm	36	30	66	0.5
Over 20 mm	7	9	16	
Fixation failure	3	1	4	

on secondary impaction or subsidence of the fracture on radiographs, patient's survival, fixation failure, modified Merle d'Aubigne Postel scores or institutional residency.

The study does, however, have certain weaknesses. Patients were not consecutively included in our study. An attempt to keep a record of the reasons eligible patients were excluded was unsuccessful and it is a potential flaw in the randomization process.

Inclusion of patients with cognitive impairment, as described earlier, had a negative effect on the results pertaining to the clinical questionnaire (especially regarding pain), where many of the answers had to be recorded as 'uncertain' and left blank. Seven patients had 12 month follow-up at another clinic; modified Merle d'Aubigne-Postel scores were not recorded but we were able to retrieve radiographs and housing information. Our clinical data is

therefore weaker than our radiological data. A summary of the amount of outcome data that could be collected is illustrated in [Table 2](#).

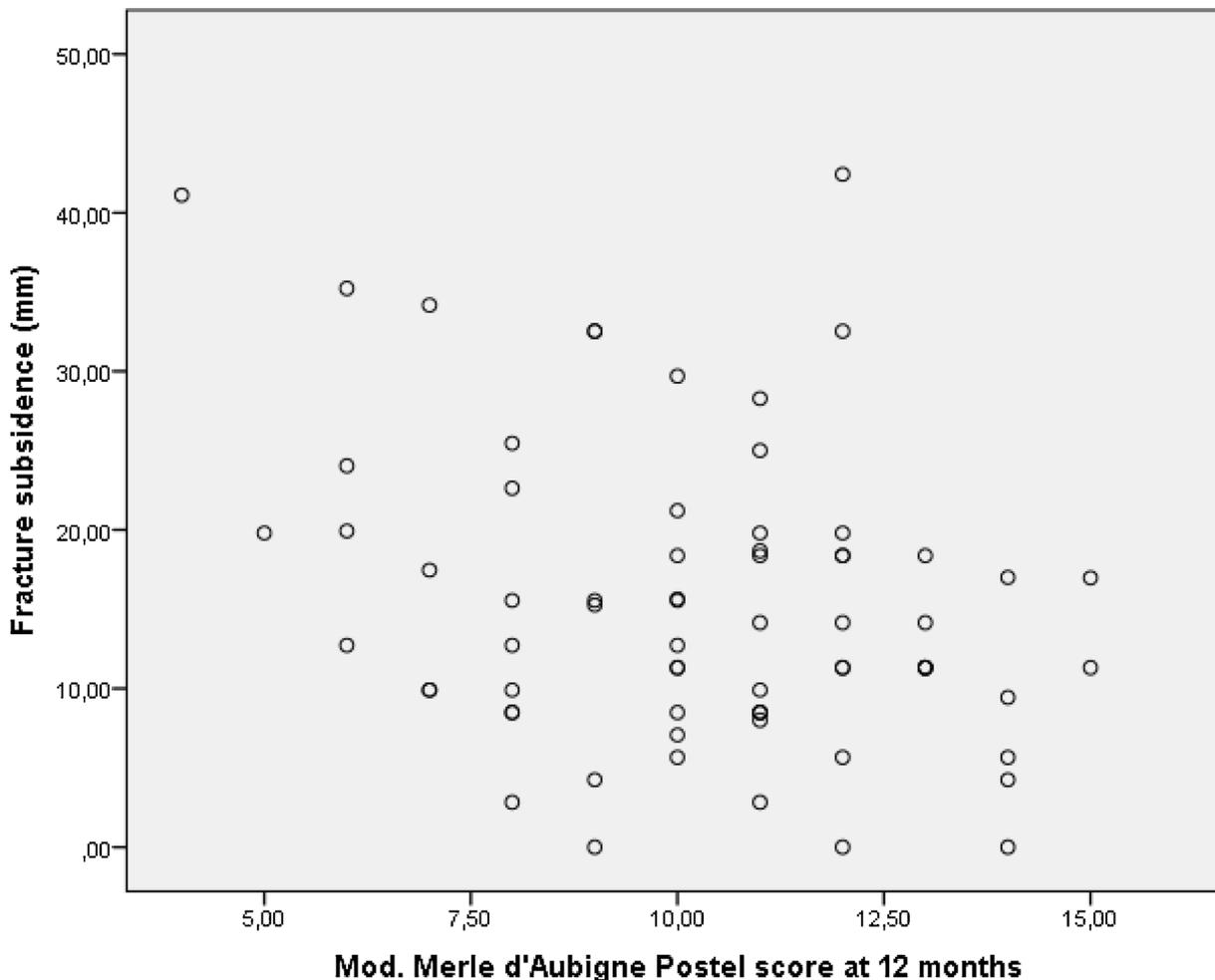
We were nevertheless able to obtain radiographs at postoperative follow-up for 86% of our patients; all but one patient alive at 12 months; giving us acceptable data for radiological analysis of the fractures ([Tables 2 and 4](#)).

Another weakness with this study is our power calculation. We had expected a difference in lag screw sliding of at least 4 mm with a standard deviation of 7 mm, based on our own retrospective study [3] as well Madsens study [7]; what we considered to be the best study available at that time. In our study we found a difference of less than 1 mm with an even larger standard deviation. These results make the power analysis underpowered; calculations show that one would need well over 1000 patients. (This number would have been well beyond the scale of our resources and could perhaps only be done in a multicenter study.) Even if we had demonstrated a significant difference between the groups the amount of difference as inferred by the 95% confidence interval is of questionable clinical relevance.

Madsen [7] found a significant difference in the number with lagscrew sliding over 20 mm (20% in NoTSP group vs 3.5% in TSP group, $p = 0.007$). We found no such difference; 9 (18%) vs 7 (14%), $p = 0.5$ ([Table 5](#)). They also demonstrated a significant difference

Table 6

The relationship between the amount of fracture subsidence versus modified Merle d'Aubigne Postel score in all patients; both groups (with and without TSP). (Subsidence defined as medialization and shortening of the femoral shaft measured from the femoral head).



between their two groups with NoTSP lag screw sliding an average of 11.7 mm and TSP group lag screw sliding 5.7 mm; a difference of 6 mm. We could not show a significant difference in subsidence; our groups showed a subsidence of 15.2 mm in the NoTSP group vs 14.5 mm in the TSP group, a difference of under 1 mm ($p=0.7$), again a non-significant difference (Table 4). It must be pointed out however, that Madsen's study had somewhat different inclusion criteria from ours; including not just trochanteric fractures but also some subtrochanteric fractures, as opposed to our study. Our study cannot really be correlated to these fractures.

The authors are not aware of any literature defining how much subsidence in trochanteric fractures is clinically relevant. Madsen et al. divided their data into groups of hip screw sliding more than, and less than, 20 mm. While this decision was possibly somewhat arbitrary, it may still be of interest to note that none of our 95% confidence intervals are of this magnitude.

Lag screw movement in relation to the caput is often considered to be strongly correlated to cutout. Nevertheless, this study showed only four cases of lagscrew cutout of ten cases where lagscrew movement in relation to the caput was present. This means that, though a serious risk factor for cutout, some of these fractures can still heal, and this movement of the screw within the head is not synonymous with failure.

Earlier studies have shown that shortening of the femoral neck in intracapsular fractures negatively affects function and gait [18,19]. The authors have not been able to identify such studies pertaining to extracapsular fractures. Nevertheless it would seem logical that increased subsidence would be in direct relationship with increased loss of function. Subsidence versus modified Merle d'Aubigne-Postel scores for all our data (both with and without TSP) is illustrated in Table 6. Parametric tests show a huge variation and there is no basis to conclude such a direct relationship. Keeping in mind this, it is not surprising that no difference in Merle d'Aubigne-Postel scores can be further identified between our sub groups, with or without TSP.

Summary and conclusion

This study demonstrates that the effect of a TSP on unstable three-or-more-part trochanteric fractures is at best probably quite minimal. The reduction of subsidence of the internal fixation was only on average 1 mm with TSP, and even when the lateral wall was broken, reduction of subsidence was only 3 mm. The differences are not statistically significant and all values within the 95% confidence interval seem clinically irrelevant. Due to weaknesses in our study, including our exclusion of reverse oblique fractures, it is nevertheless difficult to rule out that there may be a place for these plates in certain cases where there is lateral wall instability.

We conclude that the routine use of Trochanteric Support Plates on most unstable multi-fragment trochanteric fractures is questionable, and we find no evidence to recommend the routine use of these plates. We must conclude that Trochanteric Support Plates have yet to prove their mettle.

Contribution of authors

*1 (Performed study including patient follow-up and writing), *2 (Study idea, design and discussion), *3 (Statistics help and discussion)

Conflict of Interest

There are no conflicts of interest present for any of the authors.

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