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# Sliding hip screw versus IM nail in reverse oblique trochanteric and subtrochanteric fractures. A study of 2716 patients in the Norwegian Hip Fracture Register

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#### ABSTRACT

Background: Intramedullary nailing is commonly recommended as the treatment of choice for transverse/reverse oblique trochanteric (AO/OTA type A3 = intertrochanteric) and subtrochanteric fractures. However, only to a limited extent is this approach supported by superior results in well designed clinical trials, and the sliding hip screw (SHS) is still a frequently used implant for these fractures. The aim of the present study was to compare IM nails and SHS in the treatment of transverse/reverse oblique trochanteric and subtrochanteric fractures using data from the Norwegian Hip Fracture Register (NHFR).

Methods: Data on 2716 operations for acute transverse/reverse oblique trochanteric or subtrochanteric fractures were collected from the NHFR from 2005 to 2010. Surgeons reported patient characteristics and details from initial surgery and reoperations, and patients answered questionnaires about pain, satisfaction, and quality of life (EQ-5D) 4, 12, and 36 months postoperatively. Reoperation rates were calculated using Kaplan–Meier analyses. Primary outcome measures were pain (Visual Analogue Scale (VAS)), satisfaction (VAS), quality of life (EQ-5D), and reoperation rates at one year.

Results: The treatment groups were similar regarding age, gender, ASA-class, cognitive impairment, and preoperative EQ-5Dindex score. At one year reoperation rates were 6.4% and 3.8% for SHS and IM nails, respectively (p = 0.011). Patients treated with SHS also had slightly more pain (VAS 30 vs. 27, p = 0.037) and were less satisfied (VAS 31 vs. 36, p = 0.003) compared to patients treated with IM nail. There was no statistically significant difference in the EQ-5Dindex score, but the mobility was significantly better for the IM nail group.

Conclusion: 12 months postoperatively patients with transverse/reverse oblique trochanteric and subtrochanteric fractures operated with a SHS had a higher reoperation rate compared to those operated with an IM nail. Small differences regarding pain, satisfaction, quality of life, and mobility were also in favour of IM nailing. Consequently, a change in our treatment strategy for these fractures could be considered.

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### Introduction

The management of transverse/reverse oblique trochanteric (AO/OTA type A3 = intertrochanteric) and subtrochanteric fractures is still a subject to debate, and different intra- or extramedullary implants may be used. In Scandinavia, these

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fractures are usually treated with either an IM nail or a SHS, whereas an IM nail might be considered the only option in other countries. The scientific evidence supporting either treatment is scarce and to some extent conflicting. Therefore, a final consensus has not been reached. Better biomechanical properties and lower failure rates are highlighted by several authors to recommend IM nailing as the treatment of choice for these fractures. <sup>1–4</sup> Still, results are not unambiguous, and good results with more favourable reoperation rates for the SHS have been reported in other series. <sup>5–7</sup> Blade plates and the dynamic condylar screw (DCS) may be used, and good results have been reported in selected

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groups of fractures and patients.<sup>8,9</sup> However, in more recent studies these implants have been associated with poor outcome and high failure rates in this particular group of hip fractures.<sup>1,10,11</sup>

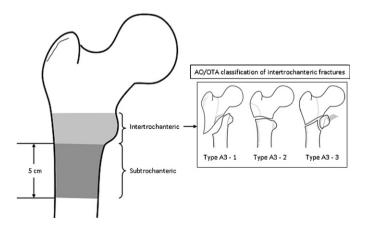
To enhance fracture stability and prevent medialization of the femoral shaft, an additional trochanteric stabilizing plate (TSP) may be added to the SHS. Several clinical studies have reported favourable results using this construct. 12-14 The ability of the TSP to resist dislocating forces causing excessive lag screw sliding and medialization of the femoral shaft has also been confirmed in biomechanical studies. 15,16 Nevertheless, despite the ability to retain acceptable fracture reduction, produce satisfactory functional results, and low complication rates, the use of the TSP has not gained any widespread popularity. In our country, however, the SHS including a TSP has remained the implant of choice for the majority of transverse/reverse oblique trochanteric and subtrochanteric fractures. 17

In the present study, the aim was to assess any implant dependent difference in pain, patient satisfaction, quality of life, or reoperation rates in these fracture types.

## Materials and methods

The NHFR has been described in detail by Gjertsen et al. 17 17,148 primary operations for trochanteric and subtrochanteric fractures were registered in the NHFR from January 1, 2005 until December 31, 2010. Patient characteristics, fracture classification, and details from the primary operations were reported by the surgeons. Trochanteric fractures were classified as transverse/ reverse oblique trochanteric (intertrochanteric) according to the AO/OTA classification, 18 whereas fractures between the lower border of the lesser trochanter, and 5 cm distal to this, were defined as subtrochanteric (Fig. 1). For the present study we selected patients of all ages with these unstable transverse/ reverse oblique trochanteric or subtrochanteric fractures (n = 2841). Fractures operated with other implants than a SHS or a nail (n = 24) and pathological fractures (n = 101) were excluded. This left 2716 fractures treated with a SHS (n = 1792) or an IM nail (n = 924) for final analysis. The Norwegian Data Inspectorate has approved the recording of data in the NHFR, and the patients sign an informed consent form which is kept in their medical records.

Any type of secondary surgery during follow-up was considered a reoperation and these were reported to the register by the surgeons who performed the reoperations. Reoperations were categorised according to reason for reoperation and type of reoperation performed. In some patients more than one reason for reoperation or more than one type of reoperation were



**Fig. 1.** Classification of intertrochanteric (transverse/reverse oblique trochanteric or AO/OTA type A3) and subtrochanteric fractures.

recorded. The patients, or their relatives/care-givers, answered questionnaires containing questions about pain from the operated hip (VAS with 0 indicating no pain and 100 indicating unbearable pain), satisfaction with the result of the operation (VAS with 0 indicating very satisfied and 100 indicating very dissatisfied), and quality of life (EQ-5D) 4, 12, and 36 months postoperatively. The EQ-5D questionnaire assesses mobility, degree of self care, ability to perform usual activities, pain/ discomfort, and anxiety/depression. 3 levels are registered for each of these dimensions (no problems, some problems, severe problems). The EQ-5Dindex score is calculated from these answers and gives a value with a maximum score of 1.0, indicating a very good quality of life, and 0 being equivalent to death.<sup>19</sup> Preoperative information was given in retrospect at 4 months follow-up. A detailed flow chart for inclusion, patientreported outcome, and follow-up is presented in Fig. 2.

The SHS was the most common implant and comprised 1792 out of 2716 operations (66%). Overall, an additional TSP was used in 1120 out of the1792 fractures treated with a SHS (63%). The TSP was most frequently used in transverse/reverse oblique trochanteric fractures (240 out of 294 fractures (82%)), whereas 880 out of 1498 subtrochanteric fractures (59%) were operated with a TSP. Patients treated with a nail (n = 924) received a long nail in 688 out of 924 cases (74%), and 98% (902 out of 924) of all nails were locked distally.

# Statistical analyses

For the categorical outcome variables; reason for reoperation, type of reoperation, and walking ability, we used the Pearson chisquare test. Student's *t*-test was used for analyzing continuous variables like pain, patient satisfaction and EQ-5Dindex score.

In the survival analyses, the endpoint was any reoperation. For implants without reoperation survival times were censored at their dates of death or emigration, or at the end of study inclusion (December 31, 2010). Information on deaths or emigrations was retrieved from the National Population Register. All patients were included in the Kaplan-Meier analyses applied to determine the proportion of reoperations after 1 and 3 years follow-up. The log rank test was used for testing the statistical significance of overall differences in survival. A multiple Cox regression model was used to assess the relative reoperation risk for the two treatment groups and for the potential confounding factors: age, gender, ASA-class, cognitive impairment, and fracture type. Only patients with complete information regarding these factors were included in this analysis (n = 2611). To adjust for potential differences in baseline characteristics between the two groups, additional analyses using the propensity score method<sup>20</sup> were performed. p values less than 0.05 were considered statistically significant (two-sided tests).

### Source of funding

No external funding has been received for this specific study, but the NHFR is funded by the regional Health Board of Western Norway. The first author has also received a grant for hip fracture research from the same regional health board.

# Results

At inclusion, baseline characteristics regarding age, gender, ASA-classification, cognitive impairment, and preoperative quality of life (EQ-5Dindex score) were similar for the two groups (Table 1). However, a larger proportion of fractures were transverse/reverse oblique in the SHS group. An overview of type implants is presented in Table 2. The surgical time was similar for

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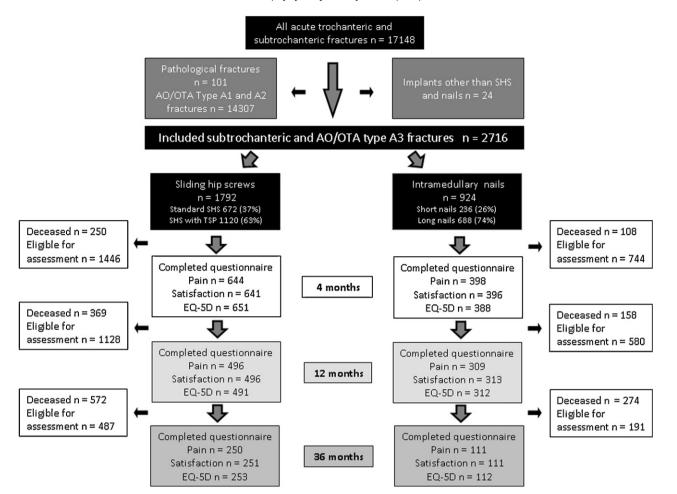


Fig. 2. Flow chart of patients and follow-up assessments. Kaplan–Meier analyses were used to assess mortality rates and number of patients under observation at follow-up (eligible for assessment).

**Table 1**Baseline characteristics

Patients and fractures	Sliding hip screws	IM nails	p value	
Total number ( <i>n</i> = 2716)	1792	924		
Mean age, years $(n = 2716)$ (SEM <sup>a</sup> )	79.1 (0.309)	79.6 (0.419)	0.35 <sup>b</sup>	
Gender (n = 2716)			0.35 <sup>c</sup>	
Female (%)	1358 (75.8)	685 (74.1)		
$ASA-class^{d} (n=2677)$	1769	908	0.15 <sup>c</sup>	
ASA 1 (%)	176 (9.9)	73 (8.0)		
ASA 2 (%)	590 (33.4)	328 (36.1)		
ASA 3 (%)	889 (50.3)	452 (49.8)		
ASA 4 (%)	108 (6.1)	55 (6.1)		
ASA 5 (%)	6 (0.3)	0		
Cognitive impairment (n = 2650)	1754	896	0.42 <sup>c</sup>	
Yes (%)	367 (20.9)	168 (18.8)		
No (%)	1211 (69.0)	637 (71.1)		
Uncertain (%)	176 (10.0)	91 (10.2)		
Injured right side (%) $(n = 1375)$	465 (50.3)	910 (50.8)	0.37 <sup>c</sup>	
Mean preoperative EQ-5Dindex score	0.71 (0.014)	0.71 (0.011)	0.76 <sup>b</sup>	
$(n = 1048) (SEM^a)$	, ,	, ,		
Fracture type				
Intertrochanteric <sup>e</sup>	294	96	< 0.001	
Subtrochanteric	1498	828		
Total (% TSP/long nails)	1792 (63%)	924 (74%)		

<sup>&</sup>lt;sup>a</sup> Standard error of the mean.

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b Student's t-test.

<sup>&</sup>lt;sup>c</sup> Pearson chi-square test.

 $<sup>^{\</sup>rm d}\,$  American Society of Anesthesiologists classification of comorbidities.

e Intertrochanteric (AO/OTA type 31-A3) fractures were not classified as such before 2008.

**Table 2**Used implants.

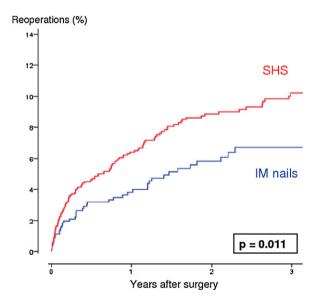
Implants	Numbers (%)
Sliding hip screws	
Richards CHS (Smith & Nephew) <sup>a</sup>	1127 (62.9)
Omega Plus (Stryker) <sup>b</sup>	7 (0.4)
Dynamic Hip Screw (DHS) (Synthes) <sup>c</sup>	521 (29.1)
Locking Compression Plate DHS (Synthes)	137 (7.6)
Total	1792 (100)
Intramedullary nails	
Gamma 3 (Stryker)	431 (46.6)
T-Gamma (Stryker)	122 (13.2)
T2 recon (Stryker)	16 (1.7)
TriGen (Smith & Nephew)	96 (10.4)
Trigen Intertan (Smith & Nephew)	129 (14.0)
Intramedullary Hip Screw (IMHS, Smith & Nephew)	7 (0.8)
Proximal Femoral Nail (PFN, Synthes)	8 (0.9)
Proximal Femoral Nail Antirotation (PFNA, Synthes)	54 (5.8)
Lateral Femoral Nail (LFN, Synthes)	16 (1.7)
ACE (DePuy) <sup>d</sup>	36 (3.9)
Other nails/data missing	9 (1.0)
Total	924 (100)

- <sup>a</sup> Smith & Nephew, Memphis, Tennessee (US).
- <sup>b</sup> Stryker, Selzach, Switzerland.
- <sup>c</sup> Synthes, Basel, Switzerland,
- <sup>d</sup> DePuy, Leeds, UK.

the two groups, 91 and 92 min for IM nail and SHS, respectively (p = 0.33), and we found no difference in preoperative waiting time for the groups (p = 0.386).

#### Reoperations

A higher proportion of reoperations were found in the SHS group as compared to the IM nail group (log rank test, p = 0.011) (Fig. 3). The percentage of reoperations at one year was 6.4% (n = 96) for the SHS group and 3.8% (n = 30) for patients treated with IM nails. At three years the percentage of reoperations was 10.2% (n = 128) and 6.7% (n = 43), respectively. In an unadjusted Cox regression analyses there was a 56% increased risk of reoperation in the SHS group compared to the IM nail group (RR 1.56, 95% CI 1.1–2.2, p = 0.012). Adjusted for age, gender, ASA-class, cognitive impairment, and fracture type there was a 43% increased risk of having a reoperation after operation with a SHS (RR 1.43, 95% CI 1.01–2.03, p = 0.044). As presented in Table 3, the



 $\textbf{Fig. 3.} \ \, \textbf{Cumulative reoperation rates the first 3 years after surgery (Kaplan-Meier analysis).}$ 

**Table 3**Cox regression analysis of factors with possible influence on the risk of reoperation.

Variable	RR	95% CI	p value
Type of implant			
IM nails	1		
SHS	1.43	1.01-2.03	0.044
Gender			
Men	1		
Women	1.02	0.70-1.49	0.91
Age	0.985	0.973-0.997	0.017
ASA-class	0.505	0.575 0.557	0.017
ASA 1	1		
ASA 2	1.87	1.06-3.33	0.032
ASA 3	1.37	0.76-2.49	0.30
ASA 4	1.41	0.53-3.73	0.49
Cognitive impairment			
No	1		
Uncertain	0.89	0.49-1.59	0.68
Yes	0.73	0.44-1.21	0.22
Fracture type			
Subtrochanteric	1		
Transverse/revere oblique	1.41	0.92-2.18	0.12

Patients were followed until reoperation, end of study inclusion, or the time of emigration or death.  $\$ 

reoperation risk was not statistically significantly affected by gender, cognitively impairment, or fracture type. The probability of being reoperated was, however, influenced by age and ASA-classification. In subgroup analyses for the two fracture types (Kaplan–Meier analyses) we found three years reoperation rates of 6.7% and 9.8% for IM nail and SHS in subtrochanteric fractures (p = 0.041), and 5.6% and 10.3% in transverse/reverse oblique fractures (p = 0.18), respectively. Within the two treatment groups there was no significant difference in reoperation rates between a SHS with or without a TSP (p = 0.55), or between short and long nails (p = 0.67) using unadjusted Cox regression analyses.

A detailed description of reasons for reoperation and type of reoperations performed is presented in Table 4. For the overall category "failure of osteosynthesis", significantly more reoperations were encountered in the SHS group (3.3% vs. 1.1%, p = 0.001). There was, however, no statistical significant difference in percentage of reoperations between the two implant groups for any single reason such as non-union, local pain from the implant, infections, cutout, or peri-implant fractures.

# Functional outcome data

Patient-reported outcome data are presented in Table 5. At 4 and 12 months there were small, but statistically significant, differences in terms of pain and patient satisfaction in favour of patients treated with IM nails. At 36 months, no statistically significant differences were found. The quality of life assessments (EQ-5Dindex score) were also slightly in favour of IM nailing, but statistically significant only at 4 months (0.51 vs. 0.47, p = 0.012). However, separately assessing the different dimensions of the EQ-5D-questionnaire, the mobility (walking ability) was clearly in favour of the IM nail group the first postoperative year (Table 6). Patients operated with a SHS reported more frequently "I have some problems in walking about", and at 1 year the difference was close to 10% in disfavour of the SHS (77.9% vs. 68.0% for the SHS and IM nail group, respectively, p = 0.003).

The observed differences between implants were independent of fracture type, and whether operations were performed with long or short nails did not influence pain, patient satisfaction, or quality of life significantly. Patients with a standard SHS, however, reported slightly better quality of life at 4 and 12 months, compared to those treated with an additional

**Table 4**Different *reasons* for reoperation and *types of* reoperations vs. type of implant in 172 reoperated hips.

Sliding hip screws, $n$ (%)		IM nails, n (%)	p value <sup>a</sup>	
Reoperated hips				
Overall 172/2716 (6.3%)	129/1792 (7.2%)	43/924 (4.7%)	0.010	
Reported reasons <sup>b</sup>				
Failure of osteosynthesis	59 (3.3)	10 (1.1)	0.001	
Nonunion	17 (0.9)	8 (0.9)	0.83	
Local pain from implant	16 (0.9)	5 (0.5)	0.32	
Infection (deep and superficial)	14 (0.8)	4 (0.4)	0.29	
Cutout	6 (0.3)	3 (0.3)	0.97	
Fracture around implant	5 (0.3)	2 (0.2)	0.76	
Other reasons	14 (0.8)	7 (0.8)	0.95	
All reported reasons	131 (7.3)	39 (4.2)	0.002	
Reported reoperations <sup>c</sup>				
Implant removal	19 (1.1)	7 (0.8)	0.44	
New osteosynthesis	52 (2.9)	14 (1.5)	0.026	
Bipolar hemi arthroplasties	23 (1.3)	3 (0.3)	0.015	
Total hip arthroplasties <sup>d</sup>			0.98	
Drainage	11 (0.6)	4 (0.4)	0.55	
Other	12 (0.7)	7 (0.8)	0.80	
All reported reoperations	142 (7.9)	48 (5.2)	0.008	

<sup>&</sup>lt;sup>a</sup> Pearsons chi-square test.

**Table 5** Pain, satisfaction, and quality of life.

Patient reported outcome	ome Sliding hip screws IM nails Mean difference (95% CI)		p value	
Pain (mean VAS) <sup>a</sup>				
4 months	33 (n = 644)	29 (n = 398)	3.9 (1.3-6.6)	0.004
1 year	30 (n = 496)	27 (n = 309)	3.2 (0.2-6.3)	0.037
3 years	25(n=250)	22(n=111)	2.8 (-1.8 to 7.4)	0.23
Satisfaction (mean VAS)b				
4 months	35 (n = 641)	30 (n = 396)	4.7 (2.0-7.5)	0.001
1 year	36 (n = 496)	31 (n=313)	5.0 (1.7-8.3)	0.003
3 years	31 (n = 251)	28 (n = 111)	2.7 (-2.4 to 7.8)	0.29
EQ-5Dindex score <sup>c</sup> (mean)	, ,	•	·	
Preoperative	0.71 (n = 661)	0.71 (n = 387)	0.01 (-0.03 to 0.04)	0.76
4 months	0.47 (n=651)	0.51 (n = 388)	-0.04 (-0.07  to  -0.01)	0.012
1 year	0.55 (n=491)	0.57 (n=312)	-0.02 (-0.06 to 0.01)	0.23
3 years	0.60 (n=253)	0.60 (n = 112)	-0.01 (-0.07 to 0.06)	0.79

<sup>&</sup>lt;sup>a</sup> VAS (Visual Analogue Scale) for pain. 0 indicating no pain, 100 indicating unbearable pain.

TSP (EQ-5Dindex score 0.52 vs. 45, p = 0.002 and 0.60 vs. 0.53, p = 0.007, respectively). Otherwise, no significant difference in patient outcome was evident for the subgroups of implants up to 3 years postoperatively.

Performing analyses for our main outcome measures using the propensity score method gave practically the same estimated average treatment effects and test results as those reported.

# Discussion

In the present study, comparing SHS and IM nail for transverse/reverse oblique trochanteric and subtrochanteric fractures, we found significantly more reoperations for patients operated with a SHS. In addition, results regarding pain, patient satisfaction, quality of life, and mobility were all slightly in favour of IM nailing.

**Table 6**Patient reported walking ability (EQ-5D questionnaire = "mobility").

Time	Implant	No problems (%)	Some problems (%)	Bedridden (%)	Total (%)	p value <sup>a</sup>
Pre-operative	IM nail (n=403)	57.1	40.9	2.0	100	0.81
	SHS $(n = 678)$	57.1	41.4	1.5	100	
4 months	IM nail $(n = 407)$	15.5	80.3	4.2	100	< 0.001
	SHS $(n = 674)$	6.5	87.1	6.4	100	
1 year	IM nail $(n = 325)$	28.0	68.0	4.0	100	0.003
	SHS $(n = 524)$	17.9	77.9	4.2	100	
3 years	IM nail $(n = 117)$	36.8	58.1	5.1	100	0.39
-	SHS $(n = 266)$	29.7	64.3	6.0	100	

<sup>&</sup>lt;sup>a</sup> Pearson chi-square test.

b More than one reason per reoperation possible. 170 reasons for reoperations were reported in 134 hips.

<sup>&</sup>lt;sup>c</sup> More than one type of reoperation possible for each patient. 190 types of reoperations were reported in 172 hips.

d 38 hips were reported to the Norwegian Arthroplasty Register as they were reoperated with a total hip replacement. For these patients no specific reason for reoperation was recorded.

b VAS for satisfaction. 0 the best score, indicating very satisfied, 100 the worst score, indicating very dissatisfied.

<sup>&</sup>lt;sup>c</sup> EQ-5Dindex score. 0 indicating the worst possible quality of life, 1 indicating the best possible quality of life.

Treating transverse/reverse oblique trochanteric and subtrochanteric fractures with a SHS is by some authors considered inappropriate, in particular due to biomechanical considerations.<sup>2,4,21</sup> However, the evidence in the literature is sparse and conflicting, and the debate whether to use a SHS or a nail in these fractures has not come to a final or indisputable conclusion. To the best of our knowledge, no randomised clinical trial comparing the SHS with a nail in these unstable fracture types has been published. In the present study 2/3 of the patients were operated with a SHS, however, a TSP working as a buttress to the greater trochanter was frequently added. The aim of the TSP is to reduce medialization and shortening of the femoral shaft, while at the same time to provide sufficient stability to allow full postoperative weight bearing. Favourable outcome using a TSP has been published in several clinical series, 12-14 and the ability of a TSP to resist dislocating forces causing excessive lag screw sliding and medialization of the femoral shaft in unstable fracture patterns has been confirmed in biomechanical studies. 15,16 However, as we had no radiographs available for initial fracture classification or later follow-up, assessing the exact significance of a TSP in this register study was not possible. In addition, clinical data in our register-based study are limited, and a randomised controlled study design would be the best way to assess any usefulness of the TSP.

Our reoperation rates of 3.8% and 6.4% at one year for IM nails and SHS, respectively, are in the lower range compared to most other studies on transverse/reverse oblique trochanteric and subtrochanteric fractures. 5,22-28 and significantly higher failure rates, for the SHS in particular, have been reported for reverse oblique- and subtrochanteric fractures in some studies. 1,11,29 In a retrospective review of 55 patients with reverse oblique fractures operated with different types of implants over a 10 year period, Haidukewych et al.<sup>1</sup> reported a failure for 9 out of 16 patients operated with a SHS (56%). However, what we consider mandatory for the reverse oblique fractures, no TSP was used in their operations. Other implants were also associated with high failure rates in the same study, but due to a retrospective study design and a small number of patients, conclusions on failure rates and implant selection based on that study alone should be drawn with caution. Brammar and colleagues found a considerably lower overall fracture healing complication rate of 9% in a review of 101 reverse oblique and transverse trochanteric fractures, and no statistically significant difference in reoperation rates between SHS and IM nails was found in that study.<sup>6</sup> More favourable complication rates for the SHS have also been reported in other studies. 5,13,25 A few randomised clinical trials assessing extramedullary implants other than the SHS in subtrochanteric fractures (frequently including AO/OTA type A3 trochanteric fractures) exist. Two studies comparing the Medoff sliding plate (MSP) with a nail had inconsistent findings regarding reoperations and failure rates.<sup>28,30</sup> Ekstrøm et al. reported a significantly higher reoperation rate in the nailing group (9% vs. 1% reoperations, p < 0.02), whereas Miedel et al. found a non-significant trend towards a higher reoperation rate in the MSP group, 3 out of 12 (25%) compared to 0 out of 16 in the nailing group (p = 0.067).<sup>28</sup> However, in studies by Sadowski and Rahme, comparing a nail to a DCS or a blade plate, reoperation rates were clearly in favour of IM nailing. 10,11 Lunsjö et al. compared the MSP to 3 other extramedullary screwplate devices, a SHS with or without a TSP included, and they found fewer fixation failures with the MSP (1 vs. 8, p = 0.01).<sup>31</sup>

The additional use of a TSP, for the reverse oblique fracture type in particular, may to some extent account for the lower rate of reoperations in our study. Recent improvements in implant design and surgeons becoming more aware of surgical pitfalls in treating these fractures may also have had a positive impact on failure rates. Incomplete reporting is another possible explanation for our rather low reoperation rates. In addition, as some elderly, demented, or frail

patients may have been considered unsuitable candidates for further surgery, we might suspect the actual failure rates to be higher than our reoperation rates indicate. Therefore, the difference in reoperation rate between the two implants is probably more important than the absolute numbers. We may have underestimated the reoperation rates, but any under-reporting of reoperations is most likely similar for the two groups. The number of primary operations reported to the register was validated in 2006. and at that time 79% of the operations were reported. <sup>17</sup> However. reoperations have not been validated in a similar way.

Historically, a high rate of peri-implant fractures has been a major concern after IM nailing for trochanteric fractures. In the present series of 924 patients treated with IM nails only two patients were reported with a second femoral fracture around the implant during a follow-up of 12 months. This is also in line with the findings by Bhandari et al., where the rate of subsequent femoral fractures after Gamma nailing was low and comparable to sliding hip screws in more recently published studies.<sup>32</sup> Still, such a low rate of peri-implant fractures might represent an underreporting of these injuries to the register, but, as suggested by Bhandari and co-workers, improvements in operative technique and implant design could be other reasonable explanations. Finally, the frequent use of long IM nails (74%) in the present study may also have prevented some peri-implant fractures.

Data on pain and functional outcome in comparative trials for inter- and subtrochanteric fractures are to a variable extent reported in the existing literature, and no standardised criteria for assessments have been used. To the best of our knowledge, no consistent or major difference in such outcome parameters has been published. 33,34 and this is also in accordance with our findings. However. due to a large number of patients in the present study, also small differences in pain, patient satisfaction, and EQ-5Dindex score reached statistical significance. The clinical relevance of these minor differences, though, is debatable. In addition, at 3 years no statistically significant difference in clinical outcome was evident. A difference of 10 points in VAS-pain has been considered a clinically significant difference for an individual patient,<sup>35</sup> but at no time during follow up we were close to such a difference between the two implant groups. Nevertheless, at a group level, a difference in VAS pain score of 3-4 points should not be neglected. Similar, statistically significant differences regarding patient satisfaction within the first year cannot be ignored. A minimally clinical relevant difference in the EQ-5Dindex score has been suggested to be in the range of 0.06-0.08.<sup>36,37</sup> Accordingly, the importance of a statistically nonsignificant difference of 0.02 at one year should not be overemphasised in our study. However, with a similar level of mobility at baseline, the patients' self-assessment of significantly better mobility in the IM nail group at 4 and 12 months postoperatively is an important finding and very relevant for this group of patients.

Less pain in the IM nail group may be a result of mini invasive surgery and/or better stability of the implant in the initial postoperative phase, whereas long term differences could be due to more local pain from protruding hardware or more secondary fracture displacement and malunions in the SHS group. Detailed information on such issues is, however, not retrievable from our register data. Pain is most probably influential on patient satisfaction and quality of life measures, and may to some extent explain the slightly superior results in favour of the IM nail for these outcomes. Even though the differences were small, we found that patients one year postoperatively had less pain and were more satisfied after operation with an IM nail compared to a SHS.

# Strengths and limitations

The major strength of this study is the large number of patients with these rather uncommon fractures. To achieve results with

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sufficient statistical power comparing treatment groups with small differences in outcome is a challenge. In such instances register data assessing patient reported outcome and complication rates may provide valuable information.

Still, there are several limitations to our study. Since this is a register study and no RCT, we cannot exclude possible selection bias. For instance, in our register the clinically relevant information regarding each patient is limited, and we have no information regarding the surgeons' level of experience. In addition, differences in implant preferences/surgical indications, and rehab programmes might represent important bias in the interpretation of our results. However, as patient characteristics regarding age, gender, ASA-class, and cognitive function at baseline were similar for the two groups, a selection bias is less likely. A selection bias is also less probable as treatment policy and implant selection in our country usually is a matter of administrative decisions in each hospital, and less based on the surgeons' individual preference.

Patients with hip fractures in this age group have a high one year mortality rate, and in the present study also a large number of patients were cognitively impaired. These facts not only influence the response rate, but also the quality of the patient reported outcome. Further, we rely on the fracture classification done by the operating surgeons, and even though there are pictures and guidelines for classification on the report form, the accuracy of the fracture classification might also be an uncertainty. Finally, we have compared two main surgical principles and groups of implants in our study, and no single implants. Consequently, our findings should be interpreted with caution.

In our health care system, implant costs are usually not considered an argument to select one implant to another for the individual patient. However, when hospitals establish routines regarding implant selection for certain fracture types, in particular if results are otherwise considered equivalent, costs may play an important role and should be considered.

Performing a large randomised controlled trial (RCT) would have been the best solution to provide a more definitive answer regarding any possible implant superiority. However, performing RCTs in these rather uncommon fractures is a major challenge. To prove small differences between implants large numbers of patients need to be included, and to the best of our knowledge no such study exists in the current literature.

#### **Conclusions**

Patients with transverse/reverse oblique trochanteric or subtrochanteric fractures operated with a SHS had a significantly higher reoperation rate compared to those treated with an IM nail. 4 and 12 months postoperatively we also found a small difference in pain, patient satisfaction, walking ability, and quality of life in favour of the nail. The clinical significance of these differences, however, is uncertain. Further, at 3 years no statistically significant difference in functional outcome was evident.

Based on the present study, and as opposed to our current practice, a change in our treatment algorithm for these unstable fracture types could be considered. For colleagues already treating these patients with an IM nail, the current study provides scientific evidence to support such an approach.

## **Conflict of interest**

Leif Ivar Havelin, Jan-Erik Gjertsen, Tarjei Vinje, Birgitte Espehaug, and Jonas M. Fevang have no personal or financial conflict of interest to disclose related to the current study.

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