# TRIGEN INTERTAN Intramedullary Nail Versus Sliding Hip Screw

## A Prospective, Randomized Multicenter Study on Pain, Function, and Complications in 684 Patients with an Intertrochanteric or Subtrochanteric Fracture and One Year of Follow-up

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**Background:** Both intramedullary nails and sliding hip screws are used with good results in the treatment of intertrochanteric and subtrochanteric fractures. The aim of our study was to assess whether use of the TRIGEN INTERTAN nail, as compared with a sliding hip screw, resulted in less postoperative pain, improved functional mobility, and reduced surgical complication rates for patients with an intertrochanteric or subtrochanteric fracture.

**Methods:** In a prospective, randomized multicenter study, 684 elderly patients were treated with the INTERTAN nail or with a sliding hip screw with or without a trochanteric stabilizing plate. The patients were assessed during their hospital stay and at three and twelve months postoperatively. A visual analogue scale (VAS) pain score was recorded at all time points, and functional mobility was assessed with use of the timed Up & Go test. The Harris hip score (HHS) was used to assess hip function more specifically. Quality of life was measured with the EuroQol-5D (EQ-5D). Radiographic findings as well as intraoperative and postoperative complications were recorded and analyzed.

**Results:** Patients treated with an INTERTAN nail had slightly less pain at the time of early postoperative mobilization (VAS score, 48 versus 52; $p = 0.042$), although this did not influence the length of the hospital stay and there was no difference at three or twelve months. Regardless of the fracture and implant type, functional mobility, hip function, patient satisfaction, and quality-of-life assessments were comparable between the groups at three and twelve months. The numbers of patients with surgical complications were similar for the two groups (twenty-nine in the sliding-hip-screw group and thirty-two in the INTERTAN group, $p = 0.67$).

**Conclusions:** INTERTAN nails and sliding hip screws are similar in terms of pain, function, and reoperation rates twelve months after treatment of intertrochanteric and subtrochanteric fractures.

**Level of Evidence:** Therapeutic Level I. See Instruction for Authors for a complete description of levels of evidence.

Both intramedullary and extramedullary implants are currently used in the treatment of intertrochanteric and subtrochanteric fractures. The sliding hip screw remains the best documented implant, and in several randomized trials it has been associated with lower complication and reoperation rates compared with intramedullary nails[1-3]. In addition, the

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**A commentary by Hans J. Kreder, MD, FRCSC,** is linked to the online version of this article at jbjs.org.

sliding hip screw is a less expensive implant. Nevertheless, there has been a recent trend toward more widespread use of intramedullary nails for these fractures[4,5], even though documentation to support this change is lacking[4-6].

The TRIGEN INTERTAN nail (Smith & Nephew, Memphis, Tennessee) was recently introduced, and according to the manufacturer the shape of the nail should enhance stability and offer greater resistance to implant cutout[7]. Ruecker et al.[8] reported good clinical results in a study on their first 100 patients treated with an INTERTAN nail. However, we are not aware of any study comparing the INTERTAN nail with a sliding hip screw. The aim of the present randomized controlled trial was to compare the INTERTAN nail with the sliding hip screw, with or without a trochanteric stabilizing plate, to determine if use of the nail decreased postoperative pain, improved function, and lowered the surgical complication rate in elderly patients with a trochanteric or subtrochanteric fracture.

## Materials and Methods

### *Patients and Fractures*

Patients over sixty years of age in whom a trochanteric or subtrochanteric fracture had been treated surgically at one of five hospitals from February 2008 to February 2009 were included in the study. Prior to the study, the sliding hip screw was the favored implant for both intertrochanteric and subtrochanteric fractures in the participating hospitals; therefore, patients with a subtrochanteric fracture were included. We also included cognitively impaired patients, even if they were unable to give informed consent, a decision that was supported by our ethical committee. Cognitive impairment was categorized by the surgeons as "no," "yes," or "uncertain." If there was any doubt, the clock-drawing test[9] was used to determine the cognitive status of the patient. Patients with a pathologic fracture were excluded. Fractures were classified by an independent radiologist according to the AO/OTA classification[10]. Fractures distal to, but with the main fracture line within 5 cm from, the lesser trochanter were classified as subtrochanteric.

The inclusion of 684 patients (341 treated with an INTERTAN nail and 343, with a sliding hip screw) is described in the CONSORT flow diagram[11] (Fig. 1). Two patients received the incorrect implant after allocation in error, in four patients the stabilization choice was changed during surgery, and six patients were not operated on according to the randomization code for unknown reasons. According to the intention-to-treat principle, these twelve patients remained in the group to which they had been originally allocated.

### *Implants*

A short or long version of the INTERTAN nail with distal locking was used with two integrated screws inserted into the femoral head-neck fragment (see Appendix). The nail design was described in detail by Ruecker et al.[8]. Two different sliding hip screw implants were used (see Appendix): the Compression Hip Screw (Smith & Nephew), and the Dynamic Hip Screw (Synthes, Basel, Switzerland). A trochanteric stabilizing plate, either as an integrated part of the sliding hip screw or added as a separate device onto the sliding hip screw, was used when indicated (see Appendix). A trochanteric stabilizing plate is indicated for all transverse or reverse oblique (A3) fractures to prevent excessive medialization of the femoral shaft. A trochanteric stabilizing plate can be considered for A1 or A2 fractures in osteoporotic bone, where it supports a weak lateral trochanteric wall susceptible to breakage after weight-bearing. A pilot study was performed in each hospital before patients were enrolled in the study, and the surgeons participated in at least five operations involving use of the INTERTAN nail before they could participate in the study.

### *Follow-up*

All general and fracture-related intraoperative and postoperative complications were recorded, as were the surgeons' level of experience, the duration of the surgery, the patient's hemoglobin level, the number of blood transfusions, and the length of the hospital stay. Whenever possible, the patients were examined on the fifth postoperative day. However, some patients left the hospital before day 5, and performing day-5 examinations during weekends was not always possible. The time distribution of the postoperative examinations is presented in the Appendix. Clinical examination, radiographs, and completion of a EuroQol-5D (EQ-5D) questionnaire[12] were scheduled at three and twelve months. If patients were too frail or sick to return for follow-up, the EQ-5D questionnaire was sent to them. A returned questionnaire, radiographs, or attendance at the outpatient clinics was each considered acceptable follow-up. Depending on local preferences, the clinical examination of the patients was carried out through collaboration among a physician, a physiotherapist, and a study nurse.

Postoperative pain was our primary outcome measure. The results of the timed Up & Go test[13], the length of the hospital stay, the complication and reoperation rates, and all other variables were defined as secondary outcomes. On day 5 and later follow-up intervals, the patients indicated the pain from the treated hip on a visual analogue scale (VAS) ranging from 0 to 100, with 0 meaning no pain and 100 meaning unbearable pain. Pain at rest and at mobilization was recorded in the hospital, whereas the average pain from the operatively treated hip during the previous month was recorded at three and twelve months. In the timed Up & Go test, the patient rises from a chair with armrests, walks 3 m, turns around, walks back, and sits down again. Walking aids are allowed while the patient performs the test, but active assistance is not. The time needed for this exercise (the score for the timed Up & Go test) is the outcome. VAS pain scores and timed Up & Go test results were measured at all follow-up visits.

Additional secondary outcomes were the patients' residence, walking ability, Harris hip score (HHS), quality of life (EQ-5D score), and mortality. Failure of the osteosynthesis, including poor initial reduction and implant positioning, deep infection or postoperative hematoma requiring surgical intervention, cutout, femoral fracture, and removal or planned removal of whole implants were considered "major" complications and reoperations. Locking screws missing the nail or removal of a single locking or lag screw were classified as "minor" complications and reoperations in the INTERTAN group. In the sliding-hip-screw group, surgical removal of a drain was considered a minor reoperation and all other reoperations were considered major.

As described by Baumgaertner et al., all postoperative radiographs were assessed for the quality of the fracture reduction (good, acceptable, or poor)[14] and the implant position in the femoral head (tip-apex distance [TAD])[15]. In addition, shortening and medialization of the femoral shaft, changes in the femoral neck-shaft angle, and fracture-healing were recorded.

### *Sample Size*

A difference in VAS scores of ≥10 points was considered a clinically relevant difference[16]. Sixty-three patients were required in each group to have an 80% chance of detecting such a difference in VAS scores with a 5% significance level with an assumed standard deviation (SD) of 20. To detect a reduction in the length of stay of one day (SD, 3), 142 patients would be needed in each group. A difference in reoperation rates of 5% versus 7% would require 2313 patients in each group to detect a significant difference (with 80% power and $p < 0.05$). Accordingly, although reoperation rates are of major interest in hip fracture surgery, it was not realistic to design this trial with this as a primary outcome. A high mortality rate, a high number of cognitively impaired patients, and an expected high dropout rate were considered when the sample size for the study was determined. Thus, assuming a one-year attrition rate of up to 40%, we aimed to recruit at least 500 patients.

### *Randomization Procedure*

Sealed, opaque, and consecutively numbered envelopes were used to randomly allocate the patients to receive one of the two implants. Block randomization

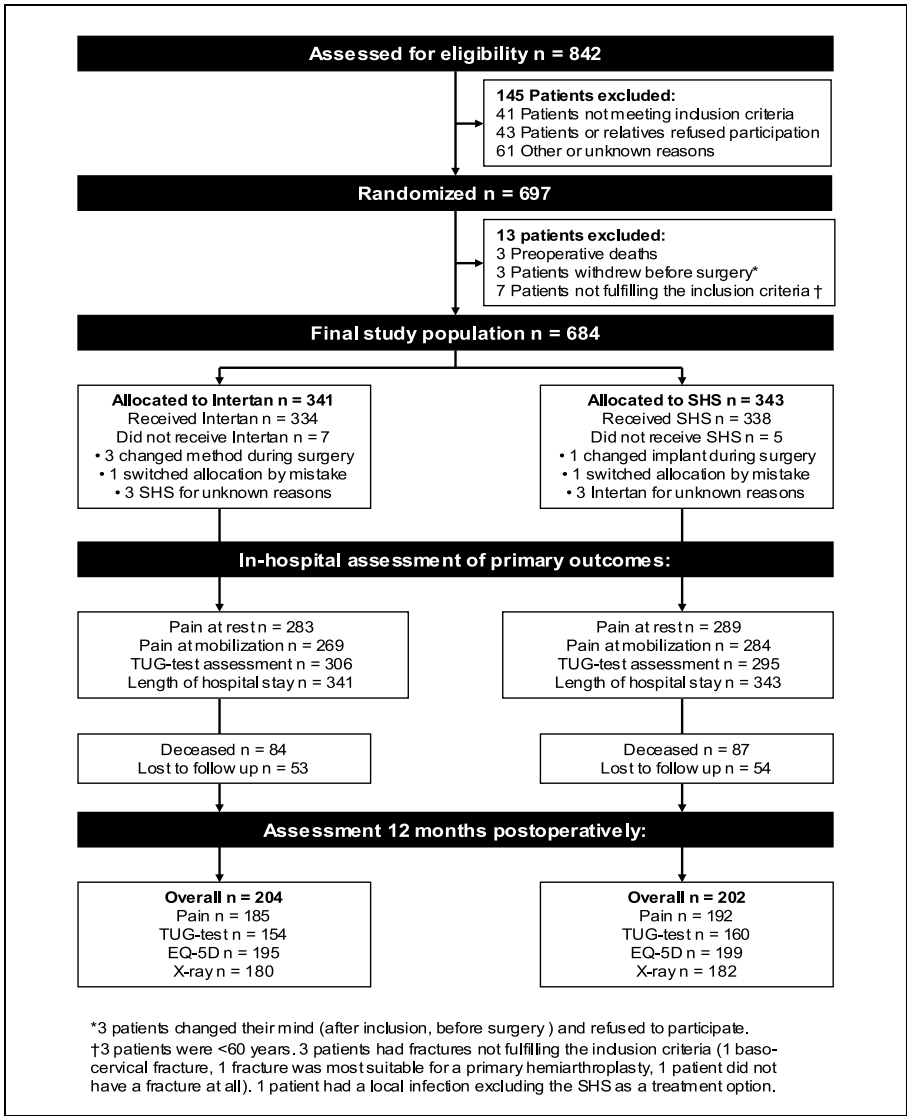


Fig. 1

CONSORT flow diagram of patients and outcome analyses[11]. SHS = sliding hip screw. TUG = timed Up & Go.

with varying block sizes unknown to the surgeon was used to ensure nearly equal treatment numbers within each hospital.

### *Statistical Analysis*

To test for group differences, the chi-square test was used for categorical variables and the independent t test, for continuous variables. P values of $<0.05$ were considered significant (two-sided tests). The results were analyzed according to the intention-to-treat principle. Linear regression analyses of pain and timed Up & Go test results were performed with adjustment for the rate of cognitive impairment and the surgeons' experience, and we also analyzed these outcomes after excluding the cognitively impaired patients. The in-hospital pain and timed Up & Go test results were also analyzed with adjustment for differences in the time of examination.

The Regional Committee of Ethics in Western Norway (203.07) approved the study, and the ClinicalTrials.gov registration number is NCT00621088.

### *Source of Funding*

Smith & Nephew supported the study, but otherwise the company had no influence on the study protocol, performance of the study, data analysis, or

**TABLE I Baseline Characteristics**

| | INTERTAN* | Sliding Hip Screw* | P Value† |
|---|---|---|---|
| No. of patients | | | |
| Total (n = 684) | 341 | 343 | |
| Diakonhjemmet Hospital (n = 182) | 92 | 90 | |
| Levanger Hospital (n = 36) | 18 | 18 | |
| Akershus University Hospital (n = 171) | 83 | 88 | |
| Vestfold Hospital (n = 133) | 68 | 65 | |
| Haukeland University Hospital (n = 162) | 80 | 82 | |
| Mean age *(yr)* (n = 684) | 84.1 | 84.1 | 0.98† |
| Female (n = 684) | 258 (75.7%) | 255 (74.3%) | 0.69§ |
| ASA class# (n = 670) | | | 0.56§ |
| 1 | 22 (6.6%) | 15 (4.5%) | |
| 2 | 138 (41.2%) | 143 (42.7%) | |
| 3 | 164 (49.0%) | 162 (48.4%) | |
| 4 | 11 (3.3%) | 15 (4.5%) | |
| Cognitive impairment (n = 665) | | | **0.002**§ |
| Yes | 105 (31.3%) | 68 (20.6%) | |
| No | 192 (57.3%) | 231 (70.0%) | |
| Uncertain | 38 (11.3%) | 31 (9.4%) | |
| Preoperative residential status (n = 669) | | | **0.02**§ |
| Home | 208 (62.1%) | 230 (68.9%) | |
| Nursing home | 94 (28.1%) | 62 (18.6%) | |
| Other | 33 (9.9%) | 42 (12.6%) | |
| Mean preop. HHS** (n = 646) | 68 | 69 | 0.44† |
| Fracture AO/OTA type (n = 684) | | | 0.93§ |
| A1 | 150 | 140 | |
| A2 | 113 | 122 | |
| A3 | 71 | 68 | |
| Subtrochanteric | 7 | 13 | 0.22§ |
| Fracture on right side (n = 684) | 186 (54.5%) | 174 (50.7%) | 0.32§ |
| Preop. mobility (n = 650) | | | 0.41§ |
| Walking outdoors alone | 186 (58.1%) | 198 (60.0%) | |
| Walking outdoors with living support | 24 (7.5%) | 31 (9.4%) | |
| Walking indoors alone, not outdoors | 79 (24.7%) | 77 (23.3%) | |
| Walking indoors with living support | 26 (8.1%) | 23 (7.0%) | |
| No walking ability | 5 (1.6%) | 1 (0.3%) | |

*The values are given as the number of patients with the percentage in parentheses unless otherwise indicated. †Significant p values are in bold. ‡Independent samples t test. §Pearson chi-square test. #American Society of Anesthesiologists classification of comorbidities. **Harris hip score (modified, with no value for range of movement [maximum, 5 points]).

presentation of the results. The first author (K.M.) received a research grant from the Regional Health Board of Western Norway.

## Results

The baseline characteristics of the two treatment groups are presented in Table I. More patients in the INTERTAN group were rated as cognitively impaired (31% versus 21%, p = 0.002) and accordingly more lived in nursing homes (p = 0.02). There was also a tendency toward more experienced surgeons implanting INTERTAN nails (p = 0.02).

The pain scores and timed Up & Go test results are presented in Table II. During the initial hospitalization, there was a minor but significant difference in pain at the time of postoperative mobilization in favor of the INTERTAN group (VAS score, 48 versus 52, p = 0.042). However, this difference was no longer evident at later follow-up times: at three and twelve months, both groups had pain scores of 25 and 17,

**TABLE II Primary Outcomes**

| | INTERTAN | Sliding Hip Screw | Mean Difference (95% Confidence Interval) | P Value* |
|---|---|---|---|---|
| Mean VAS score for pain | | | | |
| Postop. | | | | |
| At rest | 22 (n = 283) | 21 (n = 289) | 1.1 (−2.3-4.5) | 0.54† |
| At mobilization | 48 (n = 269) | 52 (n = 284) | −3.7 (−7.4-0.04) | **0.042**† |
| 3 mo | 25 (n = 226) | 25 (n = 206) | −0.5 (−4.6-3.6) | 0.82 |
| 12 mo | 17 (n = 185) | 17 (n = 192) | 0.05 (−4.0-4.1) | 0.98 |
| Timed Up & Go test | | | | |
| Postop. *(no. [%] of patients)* | | | | |
| Total no. assessed | 306/341 | 295/343 | | 0.14 |
| Unable to perform test | 167 (55%) | 163 (55%) | | 0.87 |
| Test performed, not passed‡ | 7 (2%) | 6 (2%) | | 0.83 |
| Test performed and passed‡ | 132 (43%) | 126 (43%) | | 0.92 |
| Mean score *(sec)* | | | | |
| Postop. | 74 (n = 132) | 69 (n = 126) | 5.1 (−3.5-14.3) | 0.20† |
| 3 mo | 29 (n = 177) | 29 (n = 164) | 0.04 (−4.3-4.4) | 0.99 |
| 12 mo | 27 (n = 154) | 25 (n = 160) | 1.3 (−3.6-6.2) | 0.60 |

*Significant p value is in bold. †Adjusted p values; adjustments were made because of differences in the time distribution of patient examinations. The unadjusted p value for pain at mobilization was 0.053. ‡A timed Up & Go test of more than three minutes and thirty seconds was considered to be a test not passed.

respectively. We found no significant difference in the timed Up & Go test score between the groups postoperatively or at three or twelve months, and the rate of patients who were able to perform the test was the same in the two groups. The lengths of the hospital stays were also similar (see Appendix). In the linear regression analyses, with adjustment for cognitive impairment and surgeons' experience, the results regarding pain, the timed Up & Go test, and the length of stay remained unchanged. These results also persisted in the analyses based on the actual implants that the patients received as well as after exclusion of the twelve patients who, according to the allocation at baseline, received the "incorrect" treatment. No significant differences in pain or the timed Up & Go test results between the two treatment groups were found in separate analyses of the A3 and subtrochanteric fractures.

Operative details and early postoperative results are summarized in the Appendix. There was no significant difference in the operating time between the groups. The mean estimated blood loss was greater in the sliding-hip-screw group (263 mL versus 183 mL, $p < 0.001$), and more patients treated with a sliding hip screw had a blood transfusion (171 [52%] versus 143 [43%], $p = 0.02$). However, the lowest measured hemoglobin value during the hospital stay was almost identical in the two groups.

At three and twelve months, we found no significant difference in the HHS or quality of life (EQ-5D score). These results were also reflected by similar rates of patients regaining their prefracture mobility and residential status.

Surgical complications and reoperations are presented in Table III. More intraoperative technical or implant-related problems were reported in the INTERTAN group compared with the sliding-hip-screw group (sixty-two [19%] of 328 versus twenty-one [7%] of 315, $p < 0.001$). However, the majority were minor problems without consequence for the patients. We found no difference regarding in-hospital general medical complications. At twelve months, twenty-eight and twenty-seven patients had had a reoperation in the INTERTAN and sliding-hip-screw groups, respectively. Five postoperative femoral fractures occurred in the INTERTAN group, all during the first three months; one fracture was at the distal tip of a long nail, and the other fractures appeared around the tips of short nails. One fracture occurred through the distal screw hole in a four-hole sliding hip screw-plate (see Appendix). The difference between the groups was not significant ($p = 0.10$). Cutouts of implants were observed in twenty-four patients (3.5%), eleven in the sliding-hip-screw group and thirteen in the INTERTAN group ($p = 0.67$) (see Appendix). However, not all cutouts led to revision surgery, which was performed for nine of the eleven sliding-hip-screw cutouts and six of the thirteen INTERTAN-nail cutouts. Subgroup analyses of A3 and subtrochanteric fractures showed no significant difference in complication and reoperation rates between the groups.

Details of the radiographic assessments are described in the Appendix**.** The quality of the reduction was similar for the two groups, but the postoperative femoral neck-shaft angle demonstrated more varus in the INTERTAN group (131° versus 138°, $p < 0.001$). Accordingly, lag screws for INTERTAN nails were more frequently positioned in the superior part of the femoral head. Furthermore, the intramedullary nails were

**TABLE III Intraoperative, Early, and Late Postoperative Complications and Reoperations in the Two Treatment Groups**

| | INTERTAN* (N = 341) | Sliding Hip Screw* (N = 343) | P Value† |
|---|---|---|---|
| Intraop. complications | | | |
| Technical or implant-related (n = 643)‡ | 62/328 (18.9%) | 21/315 (6.7%) | **<0.001** |
| Requiring surgical intervention§ | 4 | 2 | 0.41 |
| Other in-hospital complications | | | |
| General medical | 104 | 110 | 0.79 |
| Early postop. death | 8 | 14 | 0.20 |
| Postop. surgical complications (including those with nonop. treatment)# | 32 (9.4%) | 29 (8.5%) | 0.67 |
| Major | 26 (7.6%) | 27 (7.9%) | 0.90 |
| Minor | 7 (2.1%) | 2 (0.6%) | 0.09 |
| Reoperation in 1st 12 mo | 28 (8.2%) | 27 (7.9%) | 0.87 |
| Indications for reoperations | | | |
| Major reoperations** | 23 (6.7%) | 28 (8.2%) | 0.48 |
| Cutout | 6 (1.8%) | 9 (2.6%) | |
| Infection | 2 (0.6%) | 3 (0.9%) | |
| Fracture around implant | 5 (1.5%) | 1 (0.3%) | |
| Mechanical failure/nonunion | 3 (0.9%) | 10 (2.9%) | |
| Poor reduction/implant position | 4 (1.2%) | 3 (0.9%) | |
| Other | 3 (0.9%) | 2 (0.6%) | |
| Minor reoperations | 5 (1.5%) | 1 (0.3%) | 0.10 |
| Removal of drain | | 1 | |
| Adding distal locking screw | 3 | | |
| Removal of distal locking screw | 1 | | |
| Removal of separate lag screw | 1 | | |
| 1-yr mortality†† | 24.6% | 25.4% | 0.83 |

*The values are given as the number of patients with the percentage in parentheses unless otherwise indicated. †Pearson chi-square test. The significant p value is in bold. ‡Technical or implant-related problems were mainly minor problems without any crucial influence on the surgical procedure or the outcome of the operation. Exceptions are listed in the row below. §One femoral fracture after nailing was treated with a long INTERTAN nail as planned. One long nail was converted to a short nail because of distal anterior cortex penetration. Two planned long nails were converted to a short nail because of a short femur in one case and a narrow femur in the other. One intraoperative fissure with a sliding hip screw was treated with a longer plate. Another intraoperative fracture/fissure with a sliding hip screw was not detected initially and was treated with a reoperation eleven days later. #More than one complication per patient is possible. Seven patients in the INTERTAN group and two patients in the sliding-hip-screw group with a cutout left surgically untreated are included. **More than one reason per patient possible. ††Kaplan-Meier survival analyses.

associated with more initial shortening than the sliding hip screws, and this difference persisted at one year. Femoral shaft medialization of >5 mm at one year was more frequent in the sliding-hip-screw group. The number of patients with medialization of >5 mm at twelve months also depended on the fracture type (5.2% for A1, 11.4% for A2, and 22.3% for A3), and patients with >5 mm of medialization had more postoperative pain compared with those with <5 mm of medialization (VAS score, 23 and 16, respectively). The timed Up & Go test results, however, were independent of medialization. Within the sliding-hip-screw group, twelve of the fourteen fractures with >10 mm of medialization had been treated with a trochanteric stabilizing plate. The average TAD was shorter and more favorable in the INTERTAN group (18 mm versus 21 mm, $p < 0.001$). The average TAD for all patients who had an implant cutout was 26 mm, whereas the average for those without a cutout was 20 mm ($p < 0.001$). Similarly, a poor reduction and a lower femoral neck-shaft angle were associated with more surgical complications. Poorly reduced fractures were associated with an 18% complication rate, whereas those with a good reduction were associated with a 7% complication rate ($p = 0.007$). Patients with complications also had a lower postoperative femoral neck-shaft angle compared with those without surgical complications (132° and 135°, respectively; $p = 0.038$).

### *Mortality*

The one-year mortality rate was approximately 25% for the INTERTAN and sliding-hip-screw groups (24.6% and 25.4%, respectively; $p = 0.83$).

## Discussion

Overall, we found comparable results between patients treated with the INTERTAN intramedullary nail and those

treated with the sliding hip screw. The INTERTAN group had less pain at the time of early postoperative mobilization, but this difference was not reflected in better functional mobility or a shorter hospital stay and may not be clinically important. No differences in pain, function, quality of life, or complication rates were evident at three or twelve months postoperatively. This finding is in agreement with those of most recent studies and meta-analyses[1,6,17-19].

For an individual patient, a VAS pain-score difference of 10 points is considered clinically relevant[16]. Although this may be interpreted differently at a group level, a difference of 4 points in the early postoperative phase, as was found in the present study, is probably of minor clinical relevance. The mean estimated blood loss was 80 mL higher in the sliding-hip-screw group, but assessing "internal" blood loss after nailing is difficult. More patients in the sliding-hip-screw group received a blood transfusion, but we had no protocol for when to perform transfusions, and the hemoglobin level at the time of transfusion was not known. The differences in blood loss and in the number of blood transfusions did not seem to influence the length of hospital stay or in-hospital complication rates. Therefore, the clinical relevance of these differences is unclear.

The timed Up & Go test[13] and the HHS[20] are outcome measures commonly used to assess function after hip fractures[21]. Regardless of the functional outcome measure used in the present study, we did not detect any significant difference between the two implant groups during follow-up, which is in agreement with the findings of recent meta-analyses[1,2,22].

Since the introduction of nailing for intertrochanteric fractures, peri-implant femoral fractures have been well-known complications[23-26]. According to Bhandari et al.[19], this should no longer be an issue with modern nail designs and more experience; however, the authors of a Cochrane review[1] came to a different conclusion. In our study, two intraoperative and five postoperative femoral fractures occurred in the INTERTAN group, all within the first three months. In another recent study using INTERTAN nails, a 6% rate of postoperative femoral fractures was reported[27]. This implies that the problem with fractures around the tips of intramedullary nails has not been completely solved.

To date, no consistent difference in implant-cutout rates has been found between intramedullary nails and sliding hip screws in randomized trials[1]. In a prospective study on patients treated with the INTERTAN nail, Ruecker et al.[8] reported two implant cutouts in forty-eight patients with one year of follow-up. In the present study, implant cutout was the most common cause of failure of the osteosynthesis, but we found no significant difference between the treatment groups.

Treating unstable reverse oblique and subtrochanteric fractures with a sliding hip screw is controversial, and is not recommended by many authors[6,28-30]. However, in our view, the scientific evidence from well-designed clinical studies supporting the exclusive use of intramedullary nails in this subgroup of fractures is lacking. Recent meta-analyses also demonstrated that more high-quality studies are required before definitive conclusions regarding implant selection for these fractures can be drawn[1,29,31]. We have continued to favor the use of the sliding hip screw for these fractures, but we are using an additional trochanteric stabilizing plate to prevent excessive medialization of the femoral shaft.

It is well known that poor reduction and implant position result in a poor prognosis in hip fracture treatment[16,32-35]. In the present study, implant cutout and other surgical complications were associated with a higher TAD, poor reduction, or reduction more into varus but were independent of the type of implant. Therefore, an increased focus on surgical perfection, rather than implant selection, is probably the best way to address this problem. Fewer patients in the INTERTAN group had medialization exceeding 5 mm, probably because of the intramedullary position of the nail providing solid resistance to excessive sliding along the axis of the lag screw. The increased medialization in the sliding-hip-screw group could not be prevented by the trochanteric stabilizing plate, and our data do not allow us to quantify the extent to which a trochanteric stabilizing plate may have helped. Despite radiographic differences in femoral neck-shaft angle, shortening, TAD, and medialization, no difference in pain, function, or surgical complication rate between the two groups was evident. Similarly, no significant differences in these outcomes were found in subgroup analyses of A3 and subtrochanteric fractures. We are not aware of any randomized controlled trial comparing the use of a sliding hip screw (including a trochanteric stabilizing plate) with intramedullary nailing in this specific group of patients. Two randomized controlled trials[36,37] comparing an intramedullary nail with other extramedullary implants in the treatment of A3 fractures were, however, reported in the Cochrane Database Review[1]. One study demonstrated a higher reoperation rate for patients treated with a Dynamic Condylar Screw (DCS) compared with the Proximal Femoral Nail (PFN)[36], whereas one study comparing a blade plate with a gamma nail revealed no difference in reoperation rates[37]. These studies, however, included only small numbers of patients (thirty-nine and twenty-six, respectively). Contradictory findings were also reported for patients with subtrochanteric fractures when either a 95° blade plate[38] or the Medoff sliding plate[39,40] was compared with an intramedullary nail. In our trial, the sliding hip screw (including a trochanteric stabilizing plate) appeared to be a valid option for treatment of these fractures.

A major strength of the present study is the number of patients included. To our knowledge, this is the largest published series of its kind. In addition, due to its multicenter design, many different surgeons and several hospitals participated in the study, closely resembling a real-life setting.

There are some limitations to our study. Preoperatively, some potential risk factors for a poor outcome could have been assessed with more detail. Still, American Society of Anesthesiologists (ASA) class, preoperative mobility, quality of life (EQ-5D score), preoperative health status, and HHS were recorded as baseline characteristics. In addition, the randomization and large number of patients included should reduce the risk of any selection bias and the risk of baseline differences between the two groups.

Cognitively impaired patients were included in our study. It might be difficult to obtain accurate information regarding pain from such patients, who may also find it difficult to perform functional tests. Nevertheless, many patients with a hip fracture are cognitively impaired, and we found it important to include this group of patients. Despite the randomization, rates of dementia differed slightly between the groups. We sought to minimize this problem by adjusting for differences between the groups. Analyses performed with the cognitively impaired patients excluded provided similar results.

We were not able to examine all patients on the same postoperative day, and this could potentially have biased our results. However, for this reason, a linear regression analysis with adjustment for differences in the time distribution of postoperative examinations was performed, and the timing of the postoperative evaluations did not influence our results significantly.

The higher number of experienced surgeons performing the operations with the INTERTAN nails was a concern, but the overall percentage of consultants operating on patients in our study was low (11%). In addition, regression analyses adjusting for the surgeons' formal qualifications did not influence our results. Finally, the lack of blinding of patients and examiners may have potentially influenced our findings. However, in this multicenter study involving large numbers of patients, physicians, and other research personnel in five hospitals with a duration of follow-up of one year, we considered blinding the patients (and examiners) with respect to the treatment to be too ambitious, if possible at all.

Our long-term follow-up rate was 79% of those still alive at one year, which is less than desirable. Still, with the large number of patients included and with no difference in follow-up rates between the groups, we believe that our main findings are valid.

In conclusion, we found similar results regarding pain, function, complications, and reoperation rates at one year in this randomized controlled trial comparing the INTERTAN nail and the sliding hip screw for the treatment of intertrochanteric and subtrochanteric fractures. Patients treated with the INTERTAN nail had slightly less pain at the time of initial postoperative mobilization and received fewer blood transfusions. However, this did not influence the length of the hospital stay, function, or complication rate.

Improving outcomes and reducing complication rates after treatment of these fractures remain a challenge, but to achieve a good outcome, optimizing hip fracture reduction and implant position is probably more important than the choice of implant.

## Appendix

eA Tables showing operative and postoperative data and radiographic findings as well as figures demonstrating INTERTAN nails, sliding hip screws, the trochanteric stabilizing plate, the time distribution of the evaluations for early postoperative pain and performance of the timed Up & Go test, postoperative femoral fractures, and cutout are available with the online version of this article as a data supplement at jbjs.org. ■

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# Appendix



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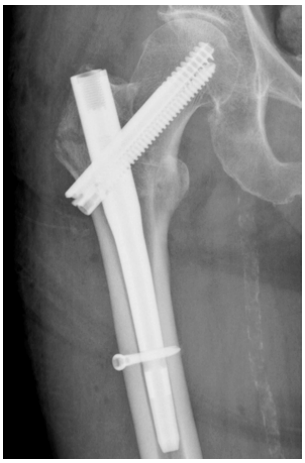

Fig. E1-A
The INTERTAN nail was short or long.

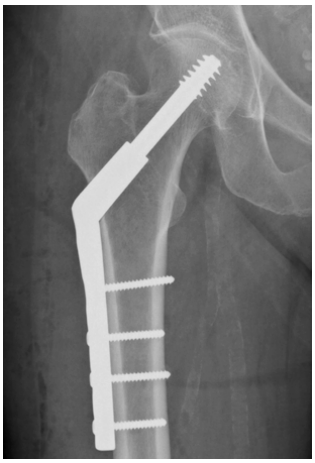

Fig. E1-B
The sliding hip screw comes in different lengths, and is used with or without a trochanteric stabilizing plate.

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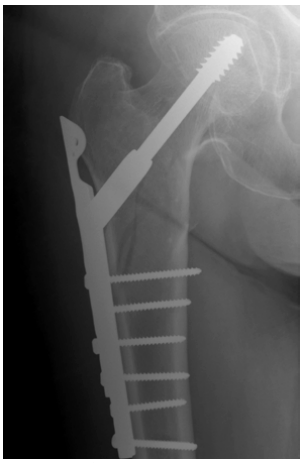

Fig. E1-C
The trochanteric stabilizing plate was either an integrated part of the sliding hip screw or a separate plate added onto the sliding hip screw.

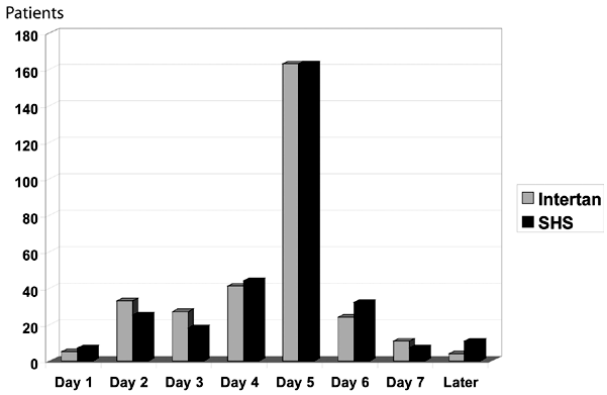


Fig. E2
Time distribution of the evaluations for early postoperative pain and performance of the timed Up & Go test. Sixty-nine patients were not evaluated either with the timed Up and Go test or with the VAS pain scores. SHS = sliding-hip-screw group.

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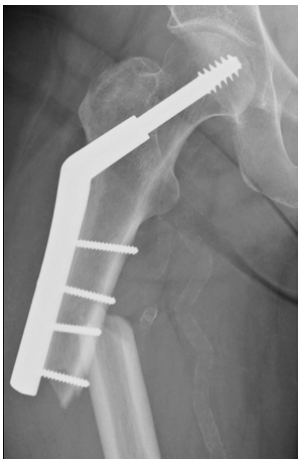
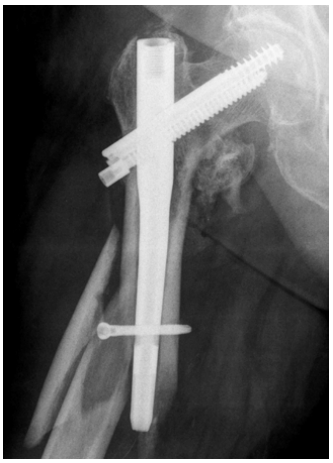

Fig. E3-A Fig. E3-B

**Figs. E3-A and E3-B** Postoperative femoral fractures included one femoral fracture in the sliding-hip-screw group and five fractures in the INTERTAN group (four associated with short nails and one associated with a long nail). **Fig. E3-A** A sliding hip screw with a periprosthetic fracture at the level of the distal screw. **Fig. E3-B** A short INTERTAN nail with a periprosthetic fracture at the tip of the nail.

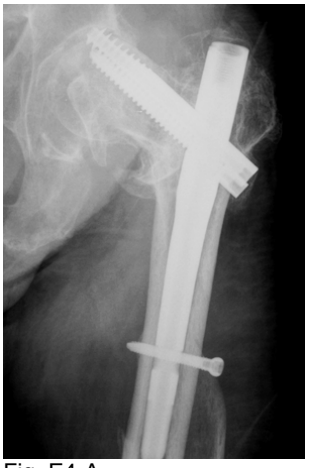
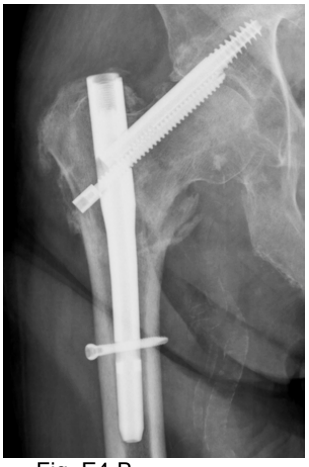
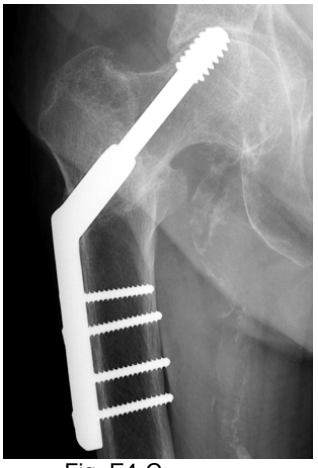

Fig. E4-A Fig. E4-B Fig. E4-C

**Figs. E4-A, E4-B, and E4-C** There were thirteen cases of cutout/cut-through in the INTERTAN group and eleven cases of cutout in the sliding-hip-screw group. **Fig. E4-A** A short INTERTAN nail with cutout in the femoral head. **Fig. E4-B** A short INTERTAN nail with cutout in the femoral head and migration of the proximal lag screw into the acetabulum. **Fig. E4-C** A sliding hip screw with a cutout in the femoral head.

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TABLE E-1 Operative and Postoperative Data in the Two Treatment Groups*

| | INTERTAN* (N = 341) | Sliding Hip Screw* (N = 343) | P Value† |
|---|---|---|---|
| Op. data | | | |
| Preop. delay (n = 666) | | | 0.65‡ |
| <24 hr | 181 (54.0%) | 167 (50.5%) | |
| 24-48 hr | 109 (32.5%) | 116 (35.0%) | |
| >48 hr | 45 (13.4%) | 48 (14.5%) | |
| Anesthesia (n = 667) | | | 0.82‡ |
| Spinal | 304 (90.7%) | 303 (91.3%) | |
| General | 31 (9.3%) | 29 (8.7%) | |
| Surgeon's experience (n = 664) | | | **0.02**‡ |
| Resident <2 yr | 70 (21.4%) | 101 (30.0%) | |
| Resident >2 yr | 183 (56.0%) | 184 (54.6%) | |
| Resident assisted by consultant | 34 (10.4%) | 20 (5.9%) | |
| Consultant | 40 (12.2%) | 32 (9.5%) | |
| Duration of surgery (n = 661) *(min)* | | | |
| All fractures | 54.7 (n = 331) | 55.6 (n = 330) | 0.69§ |
| AO/OTA type A1 | 46.1 (n = 145) | 44.0 (n = 133) | 0.39§ |
| AO/OTA type A2 | 57.1 (n = 112) | 54.4 (n = 118) | 0.44§ |
| AO/OTA type A3 and subtrochanteric | 67.8 (n = 74) | 76.5 (n = 79) | 0.10§ |
| Long nail or sliding hip screw w/trochanteric stabilizing plate# | | | |
| AO/OTA type A1 | 8/149 (5%) | 9/141 (6%) | |
| AO/OTA type A2 | 38/113 (34%) | 39/122 (32%) | |
| AO/OTA type A3 | 44/70 (63%) | 51/69 (74%) | |
| Subtrochanteric | 7/7 (100%) | 6/13 (46%) | |
| Total** | 97/339 (29%) | 105/345 (30%) | |
| Postop. data | | | |
| Transfusion (n = 663) | 143 (43.1%) | 171 (51.7%) | **0.02**‡ |
| Mean est. external blood loss (n = 650) *(mL)* | 183 | 263 | **<0.001§** |
| Mean hemoglobin value (g/dL) | | | |
| Preop. (n = 660) | 12.1 | 12.0 | 0.81§ |
| Lowest postop. (n = 650) | 9.2 | 9.1 | 0.26§ |
| Mean length of postop. hospital stay (n = 684) *(days)* | 8.5 | 8.4 | 0.85§ |
| Residence after discharge (n = 650) | | | 0.81‡ |
| Home | 39 (11.9%) | 47 (14.6%) | |
| Nursing home | 190 (57.9%) | 168 (52.2%) | |
| Rehab. | 47 (14.3%) | 47 (14.6%) | |
| Other | 52 (15.9%) | 60 (18.6%) | |

*The values are given as the number of patients with the percentage in parentheses unless otherwise indicated. †Significant p values are in bold. ‡Pearson chi-square test. §Independent samples t test. #The use of different implants was based on the fracture classification and degree of osteoporosis. All hospitals received a guide describing when to use long nails or an additional trochanteric stabilizing plate, but this decision was finally left to the surgeon. **The actual implants used were not identical with the randomization code for twelve of the 684 patients (Fig. 1). Therefore, the numbers are slightly different compared with other (intention-to-treat) analyses.

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TABLE E-2 Radiographic Findings

| | INTERTAN* | Sliding Hip Screw* | P Value† |
|---|---|---|---|
| Postop. fracture reduction‡ | | | 0.25§ |
| Good | 147 (44%) | 164 (48%) | |
| Acceptable | 141 (43%) | 143 (42%) | |
| Poor | 44 (13%) | 32 (9%) | |
| Total | 332 (100%) | 339 (100%) | |
| Shortening at 12 mo | | | **0.007§** |
| None | 88 (49%) | 111 (61%) | |
| <10 mm | 71 (39%) | 47 (26%) | |
| 10-20 mm | 11 (6%) | 19 (11%) | |
| >20 mm | 10 (6%) | 4 (2%) | |
| Total | 180 (100%) | 181 (100%) | |
| Medialization at 12 mo | | | **0.002§** |
| <5 mm | 153 (85%) | 127 (71%) | |
| 5-10 mm | 18 (10%) | 23 (13%) | |
| 10 mm | 9 (5%) | 28 (16%) | |
| Total | 180 (100%) | 178 (100%) | |
| Radiographic fracture-healing at 12 mo | | | 0.80§ |
| Yes | 154 (86%) | 158 (87%) | |
| No | 13 (7%) | 14 (8%) | |
| Uncertain | 13 (7%) | 10 (6%) | |
| Mean postop. tip-apex distance (TAD)# (n = 655) *(mm)* | 18 | 21 | **<0.001**** |
| Mean femoral neck-shaft angle *(deg)* | | | |
| Postop. (n = 678) | 131 | 138 | **<0.001**** |
| 12 mo (n = 361) | 126 | 132 | **<0.001**** |

*The values are given as the number of patients with the percentage in parentheses unless otherwise indicated. †Significant p values are in bold. ‡The postoperative reduction was considered "good" with no more than 4 mm of displacement of any fracture fragment and normal or slight valgus alignment on the anteroposterior radiograph, and <20° of angulation on the lateral radiograph. Fractures that had either good alignment or no more than 4 mm of displacement, but not both, were rated as "acceptable." Fractures that fulfilled neither criterion were categorized as "poor." §Pearson chi-square test. #TAD = the sum of the distance from the (superior) lag screw to the apex of the femoral head on the frontal and lateral view, adjusted for magnification. **Independent samples t test.