

Intramedullary nail versus sliding hip screw for stable and unstable trochanteric and subtrochanteric fractures in 17 341 patients from the Norwegian Hip Fracture Register

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## 1 **Abstract**

### 2 **Aims**

3 To investigate if there are differences in outcome between sliding hip screw (SHS) and  
4 intramedullary nail (IMN) with regard to fracture stability.

### 5 **Patients and Methods**

6 We assessed data from 17 341 patients with trochanteric or subtrochanteric fractures treated  
7 with SHS or IMN in the Norwegian Hip Fracture Register from 2013 to 2019. Primary  
8 outcome measures were reoperations for stable fractures (AO/OTA type A1) and unstable  
9 fractures (AO/OTA type A2, A3 and subtrochanteric fractures). Secondary outcome measures  
10 were reoperations for A2, A3 and subtrochanteric fractures individually, one-year mortality,  
11 quality of life (EQ-5D-3L), pain (Visual Analogue Scale (VAS)), and satisfaction (VAS) for  
12 stable and unstable fractures. Hazard rate ratios (HRRs) for reoperation were calculated using  
13 Cox regression analysis with adjustments for age, sex and ASA-score.

### 14 **Results**

15 Reoperation rate was lower after surgery with IMN for unstable fractures one year (HRR:  
16 0.82, 95% CI: 0.70 to 0.97,  $p=0.02$ ) and three years postoperatively (HRR: 0.86, 95% CI: 0.74  
17 to 0.99,  $p=0.036$ ), compared to SHS. For individual fracture types, no clinically significant  
18 differences were found. Lower 1-year mortality was found for IMN compared to SHS for  
19 stable (HRR: 0.87, 95% CI: 0.78 to 0.96,  $p=0.007$ ), and unstable fractures (HRR: 0.91, 95%  
20 CI: 0.84-0.98,  $p=0.014$ ).

### 21 **Conclusion**

22 This national register-based study indicates a lower reoperation rate for IMN than SHS for  
23 unstable trochanteric and subtrochanteric fractures, but not for stable fractures or individual  
24 fracture types. The choice of implant may not be decisive to the outcome of treatment for

25 stable trochanteric fractures in terms of reoperation rate. One-year mortality rate for unstable  
26 and stable fractures was lower in patients treated with IMN.

27 **Bullet points**

28 - Lower reoperation rate for unstable fractures treated with IMN compared to SHS

29 - Comparable outcomes in SHS and IMN in stable fractures and individual fracture types

30 - Lower 1-year mortality rates in patients treated with IMN

31 - In the treatment of unstable fractures, the use of SHS was more likely to lead to infection  
32 and complications that required THA

33 - In the treatment of stable fractures, IMN was associated with increased prevalence of peri-  
34 implant fracture as a cause for reoperation

35

36 **Introduction**

37 The choice of implant in the treatment of trochanteric fractures and subtrochanteric fractures  
38 has been debated for decades without reaching consensus.<sup>1,2</sup>

39 The most common implants are extramedullary sliding hip screws (SHS) and  
40 intramedullary nails (IMN),<sup>2</sup> skewing towards IMN over the past two decades.<sup>3</sup> The IMN has  
41 historically had a higher risk of peri-implant fractures.<sup>2</sup> However, modern nail designs may  
42 have reduced this difference.<sup>2,4</sup> Accordingly, results from earlier studies comparing the two  
43 treatment methods may no longer be valid in the context of revised treatment  
44 recommendations.<sup>4</sup> Results from the available literature are conflicting. Recent studies have  
45 been unable to demonstrate any significant differences in outcome<sup>5,6</sup>, whereas others report a  
46 beneficial effect of IMNs in the treatment of unstable trochanteric and subtrochanteric  
47 fractures.<sup>7,8</sup> A long IMN is now recommended as the implant of choice for AO/OTA A3  
48 trochanteric fractures and subtrochanteric fractures in several countries,<sup>9</sup> although the  
49 superiority of the IMN is still debatable. An association between increased 30-day mortality  
50 and intramedullary nails in the treatment of trochanteric fractures has been proposed,<sup>10</sup> and  
51 there are still reports on higher risk of peri-implant fracture with IMN than SHS.<sup>11</sup> In this  
52 study, based on data from the Norwegian Hip Fracture Register (NHFR) from 2013-2019, we  
53 compared reoperation rates between SHS and IMN in stable fractures (AO/OTA A1) and  
54 unstable fractures (AO/OTA A2, AO/OTA A3 and subtrochanteric combined) one and three  
55 years postoperatively. Secondary aims were to compare reoperation rates between SHS and  
56 IMN in A2, A3 and subtrochanteric fractures separately, and to compare mortality and  
57 patient-reported outcomes after SHS and IMN for stable and unstable fractures one year after  
58 surgery.

59

## 60 **Materials and Methods**

61 This prospective cohort study is based on data from a national registry, the NHFR. The  
62 reporting rate was 88% for primary osteosynthesis and 80% for reoperations in 2018.<sup>12</sup> The  
63 surgeon reports information on the patient, the fracture, and the operation in a one-page form.  
64 PROMs (patient-reported outcome measures) questionnaires are sent to all patients four,  
65 twelve and thirty-six months postoperatively, where the four-month questionnaire also  
66 includes questions on preoperative status. Preoperative status and data from the twelve-month  
67 questionnaire were included in the present study. Trochanteric fractures were classified  
68 according to the AO/OTA classification system as AO/OTA type A1 (simple two-part), A2  
69 (multifragmentary), and A3 (intertrochanteric/reverse oblique).<sup>13</sup> Subtrochanteric fractures  
70 were defined as diaphyseal fractures with the centre of the fracture less than five cm distal to  
71 the lesser trochanter.<sup>13</sup> Further, we defined all A1 fractures as stable and A2, A3 and  
72 subtrochanteric fractures as unstable.<sup>14</sup>

73 We included patients with trochanteric or subtrochanteric fractures treated with an SHS  
74 with or without a trochanteric support plate (TSP) or a short or long IMN, treated from  
75 January 2013 to December 2018. Patients aged < 60 years, patients treated with other  
76 implants than SHS or IMN, patients with pathological fractures (other than osteoporosis), and  
77 patients with missing data (ASA classification, fracture type, type of implant) were excluded.  
78 Finally, 17 341 patients were included in the reoperation analysis. Of these, 9 830 (56.7%)  
79 were treated with an SHS and 7 511 (43.3%) with an IMN (Figure 1). Reoperations were  
80 categorized according to indication and type. Cause of reoperation was not readily available  
81 in patients receiving THA as these operations are recorded in the Norwegian Arthroplasty  
82 Register (NAR), using a different form. Consequently, cause of reoperation recorded in the  
83 NAR was labelled “unspecified sequelae (THA)”. More than one cause may be given for each  
84 reoperation in the NHFR. The following hierarchy was chosen to identify the most severe

85 cause in each case: infection, peri-implant fracture, mechanical complications (non-union,  
86 implant failure, cut-out), unspecified sequelae (treated with THA), pain alone, other. Risk of  
87 reoperation at one and three years was calculated. One-year mortality was calculated and  
88 compared for patients treated with SHS and IMN. Patient reported outcome was compared  
89 one year postoperatively using the EQ-5D index score (EQ-5D-3L, EuroQol Group,  
90 Rotterdam, The Netherlands) a visual analogue scale (VAS) 0-100 for pain (0 = no pain, 100  
91 = unbearable pain), and a VAS 0-100 for satisfaction (0 = least satisfied, 100 = most  
92 satisfied). Of the 17 341 patients included, 12 810 (73.9%) patients were still alive after one  
93 year. A twelve-month questionnaire was sent to 12 694 patients (73.2%). Of these, 6 632  
94 (52.2%) responded and were included in the PROM analysis. Stable fractures (A1) and  
95 unstable fractures (A2, A3 and subtrochanteric) were analysed separately with regard to  
96 reoperation rates and PROM data. Further, subgroup analyses for each of the unstable fracture  
97 types were performed. SHS with and without a TSP were analysed as one group, as were  
98 short and long IMNs.

99 We chose to compare SHS and IMN in the treatment of stable fractures and unstable  
100 fractures, as A3 and subtrochanteric fractures are less common and classification errors  
101 between A2, A3 and subtrochanteric fractures are frequent.<sup>15, 16</sup> Erratic coding may obscure  
102 the true complication rates of implants used to treat different fracture subgroups.<sup>14</sup> To make  
103 the statistical analysis more robust and more clinically relevant, we considered A2, A3 and  
104 subtrochanteric as one group, acknowledging fracture instability as the common denominator.

#### 105 *Statistical analysis*

106 Baseline data were analysed using the Pearson chi-square test and ANOVA for categorical  
107 variables, and the independent sample t-test for continuous variables. Hazard rate ratios  
108 (HRRs) of reoperations and hierarchical cause of reoperation were calculated using Cox



109 regression analysis, adjusted for age, sex and ASA classification. Patients were followed from  
110 primary operation to reoperation, death, or 31 December 2019 (end of study), whichever  
111 occurred first. One-year mortality for SHS and IMN was calculated for stable and unstable  
112 fractures using Cox regression analysis adjusted for age, sex and ASA classification. The  
113 proportional hazards assumption was tested using log-minus-log plots and was fulfilled.  
114 Patient-reported quality of life (EQ-5D-3L), pain (VAS 0-100), and satisfaction (VAS 0-100)  
115 twelve months postoperatively were recorded, and we used the independent sample t-test to  
116 compare means between SHS and IMN. The significance level was set at 0.05. The statistical  
117 analysis was performed using IBM SPSS Statistics, version 26 (IBM Corp, Armonk, NY,  
118 USA) and the R statistical package (<http://CRAN.R-project.org>).

119 The STROBE (STrengthening the Reporting of OBservational studies in Epidemiology)  
120 guidelines were followed.<sup>17</sup>

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123 Authority. No other funding has been received by any of the authors.

## 124 **Results**

125 The study population included 9 830 patients operated with an SHS and 7 511 with an IMN.  
126 Overall, 71% of the patients with an SHS and 73% of those with an IMN were women, and  
127 the mean age was 83.2 and 82.9 years, respectively. Approximately 70% of the patients were  
128 classified as ASA 3 or 4 in both treatment groups (Table I). An SHS with TSP was chosen in  
129 7% of A1 fractures, 50% of A2 fractures, 82% of A3 fractures, and 68% of subtrochanteric  
130 fractures treated with an SHS. A long nail was chosen in 9% of A1 fractures, 29% of A2  
131 fractures, 65% of A3 fractures, and 88% of subtrochanteric fractures treated with an IMN.

## 132 *Reoperations*

133 Number and type of reoperation for each fracture type are listed in Table II. No difference in  
134 overall risk of reoperation was found between SHS and IMN for stable fractures one year  
135 postoperatively (HRR: 1.1, 95% CI: 0.79 to 1.51, p=0.60) or three years postoperatively  
136 (HRR 1.0, 95% CI: 0.75 to 1.32, p=0.98),-but peri-implant fracture was a more frequent cause  
137 of reoperation with the use of IMN (HRRs: 5.9 and 5.8 respectively) (Table III). For unstable  
138 fractures there was a lower overall risk of reoperation for IMN than for SHS one year  
139 postoperatively (HRR: 0.82, 95% CI: 0.70 to 0.97, p=0.022) and three years postoperatively  
140 (HRR: 0.86, 95% CI: 0.74 to 0.87, p=0.009). Further, the risk of reoperation due to infection  
141 one and three years postoperatively (HRRs: 0.6 and 0.6 respectively), and the risk of  
142 reoperation with THA one and three years postoperatively (HRRs: 0.6 and 0.7 respectively),  
143 were lower for IMN than for SHS (Table IV). Implant survival curves for SHS and IMN for  
144 stable fractures and unstable fractures are shown in Figure 2. When the unstable fracture types  
145 were investigated individually, SHS was found to have a higher risk of reoperation for any  
146 cause for A3 fractures at one year and for A2 fractures at three years, compared to IMN.  
147 Otherwise no major difference in reoperation risk could be found between the two treatment  
148 methods when the fracture types were analysed individually (Table V).

#### 149 Mortality

150 One-year mortality was lower for IMN compared to SHS for stable fractures (HRR: 0.87,  
151 95% CI: 0.78 to 0.96, p=0.007), and for unstable fractures (HRR: 0.91, 95% CI: 0.84-0.98,  
152 p=0.014).

#### 153 *PROM data*

154 Patients with unstable fractures treated with an SHS reported a lower EQ-5D-3L index score  
155 (0.55 vs 0.58, p=0.001), inferior walking ability based on the mobility dimension of the EQ-  
156 5D-3L (p<0.001), and were less satisfied with the result of the operation (mean VAS 33 vs.

157 30,  $p < 0.001$ ) than patients treated with an IMN (Table VI). The differences found in the EQ-  
158 5D-3L were persistent when calculating delta values. In patients with unstable fractures  
159 treated with SHS and IMN, respectively, 23% and 26% regained pre-fracture index score  
160 ( $p = 0.019$ ), while 53% and 60% regained pre-fracture walking ability ( $p < 0.001$ ).

## 161 **Discussion**

162 The results of this national register-based cohort study may indicate that IMN in the treatment  
163 of unstable fractures (A2, A3 and subtrochanteric fractures combined) is associated with  
164 lower reoperation rates than SHS. Infection and unspecified sequelae leading to THA were  
165 more prevalent causes of reoperation with the use of an SHS. We found similar reoperation  
166 rates for SHS and IMN in the treatment of A1 fractures, but peri-implant fracture was a more  
167 prevalent cause of reoperation in patients with A1 fracture treated with an IMN. Otherwise,  
168 there were no clinically relevant differences in individual fracture types between SHS and  
169 IMN in terms of reoperation rates or PROM data. There was however, a lower 1-year  
170 mortality rate in patients treated with IMN compared to SHS for stable and unstable fractures  
171 alike.

172 The most recent Cochrane review in 2010 recommended SHS for the majority of  
173 trochanteric fractures, mainly due to the higher incidence of peri-implant fractures associated  
174 with IMNs.<sup>2</sup> There were indications that IMNs may have advantages in the treatment of  
175 intertrochanteric fractures (A3) and subtrochanteric fractures, but further studies required. A  
176 recent propensity-matched comparative study of 8000 patients with A1, A2 and A3 fractures  
177 did not identify any major differences between SHS and IMN<sup>6</sup>. Similar results were reported  
178 in a multicentre randomized controlled trial (RCT) comparing SHS and IMN (InterTAN) in  
179 684 patients with A1, A2, A3 and subtrochanteric fractures.<sup>18</sup>

180 In the present study we aimed to identify potential differences in reoperation rate between  
181 SHS and IMN in stable fractures (A1) and in unstable fractures (A2, A3 and subtrochanteric  
182 fractures combined) as such differences might be more clinically relevant and provide a more  
183 robust statistical analysis. In previous studies from the NHFR, lower reoperation rates have  
184 been found for SHS than for IMN in type A1 fractures one and three years postoperatively,<sup>19</sup>  
185 and higher reoperation rates for SHS compared to IMN in type A3 and subtrochanteric  
186 fractures combined.<sup>8</sup> A2 fractures were not included in these studies. In the present study we  
187 were unable to reproduce the differences in reoperation rate regarding individual fracture  
188 patterns, but we found a statistically significant lower risk of reoperation with the use of IMN  
189 in the treatment of the unstable fractures pooled together. Our results support the conclusion  
190 in a previous study from the NHFR that recommended the use of IMN in the treatment of A3  
191 and subtrochanteric fractures.<sup>8</sup> In our study we included A2 fractures in the analysis of  
192 unstable fractures, thus also extending the recommendation to this group of fractures.  
193 Previous studies have highlighted only moderate to fair inter- and intraobserver reliability in  
194 the AO classification system regarding proximal femur fractures, particularly with regards to  
195 stability assessment of A2 fractures. This implies caution with use in day-to-day decision  
196 making or in register data interpretation.<sup>15, 16</sup>

197 Infection was a more prevalent cause of reoperation in patients with unstable fractures  
198 treated with SHS compared to those treated with IMN in our study. This also applied to the  
199 separate analysis of A2 and A3 fractures. Peri-implant fracture was a more prevalent cause of  
200 reoperation with the use of IMN in A1 fractures, but not in A2, A3 and subtrochanteric  
201 fractures individually or pooled together. Some authors claim that long nails reduce the risk of  
202 peri-implant fracture, but the literature is inconclusive regarding the protective effect of long  
203 versus short IMNs.<sup>20</sup> A3 and subtrochanteric fractures were almost exclusively treated with  
204 long nails/SHS with TSP and A1 fractures almost exclusively treated with short nails/regular

205 SHS. Therefore, we were not able to compare outcomes of long vs short nails in this study,  
206 nor variations between SHS vs SHS with TSP.

207 The high overall mortality in this population may pose a challenge in the statistical  
208 analyses. In the present article we focus on time to reoperation and we argue that the results  
209 from Cox regression are straight forward to interpret for these analyses. The statistical  
210 interpretation from Kaplan-Meier and Cox analysis for analysis of reoperation have been  
211 advocated.<sup>21</sup> Furthermore, using Fine and Gray models to condition on mortality may  
212 introduce collider bias and misinterpretation of the results.<sup>22</sup>

213 We found a lower mortality rate in patients treated with IMN compared to patients treated  
214 with SHS, applicable to stable and unstable fractures. This is contradictory to Whitehouse et  
215 al,<sup>10</sup> reporting a 12,5% increase in 30-day mortality risk after IMN. These results are not  
216 readily comparable. Our population was collected during a later period of time, the percentage  
217 of females was higher, we included both trochanteric and subtrochanteric fractures and we  
218 excluded pathological fractures.

219 The choice of implant is an important issue that affects patient outcomes, at least for  
220 certain groups of patients and fractures, but other factors might be even more important. More  
221 emphasis should probably be placed on fracture reduction, correct implant positioning and  
222 pre- and postoperative care to reduce reoperation rates and improve patient satisfaction<sup>23</sup>.  
223 Furthermore, economic considerations inevitably play a role in choice of implants in all  
224 fracture treatment.<sup>24</sup>

225 The EQ-5D-3L has been extensively studied and is regarded as a useful and relevant  
226 outcome measure for this patient population.<sup>25, 26</sup> We found a lower EQ-5D-3L index score at  
227 one year for patients with unstable fractures treated with an SHS compared to an IMN, and a  
228 lower VAS satisfaction score. Although the differences in mean EQ-5D-3L index score and

229 mean VAS satisfaction score between the two groups were small, a sizable number of patients  
230 in one of the groups may still have reported a clinically significant better outcome.  
231 Accordingly, we performed additional analyses to identify the number of patients returning to  
232 their pre-fracture EQ-5D-3L score, VAS satisfaction score and walking ability, confirming  
233 the differences.

#### 234 *Strengths and limitations*

235 Complications after a trochanteric or subtrochanteric fracture are rare, and large study  
236 populations are required to reveal statistically significant differences in implant performance  
237 or population characteristics. Some primary fracture patterns are uncommon, such as the A3  
238 and the subtrochanteric fracture, and a sufficiently powered RCT is difficult to implement  
239 within a reasonable time frame. A large register-based study such as this one addresses some  
240 of these issues. In our study, patient characteristics at baseline were similar for the two  
241 groups, and selection bias unlikely. In the Norwegian health care system, the individual  
242 hospital chooses the implant, rather than the orthopaedic surgeon. This also reduces the risk of  
243 selection bias. Finally, register data from a national database describe the results of the  
244 average surgeon and hospital, and may reveal differences lost to RCTs performed in  
245 individual centres and by a limited number of surgeons.

246 This study has several limitations. Register-based studies such as the present can only  
247 describe associations, and do not aspire to prove causality. The completeness of registration  
248 of reoperations in the NHFR is lower than for primary operations,<sup>12</sup> at 80% versus 88%.  
249 Underreporting of complications is a possible bias, but we have no reason to suspect a  
250 difference in reporting between implants. IMNs and SHSs were assessed as two implant  
251 groups. Accordingly, our results might not apply equally to all implant dimensions and  
252 brands. Further, NHFR data do not provide radiological evidence of the primary fracture, and

253 there might be classification errors obscuring the true complication rates of implants used to  
254 treat different fracture subgroups.<sup>14-16</sup> We have included all A2 fractures in the group of  
255 unstable fractures, as subclassification was not possible based on the NHFR data. A2-1  
256 fractures are often considered stable, whereas the majority of A2 fractures are unstable and  
257 may pose as great a challenge to the orthopaedic surgeon as an A3 or subtrochanteric fracture.  
258 Additionally, combinations of fracture patterns are common but not mentioned in the NHFR  
259 data. Finally, analyses of PROM data must be used with caution. After one year, 24% of the  
260 study population had died, and only 52% of the remaining patients answered the  
261 questionnaire. With such a large amount of missing data we cannot draw any inferences based  
262 on PROM analyses, but we chose to still include these results as we have no reason to believe  
263 there are more non-responders in either group.

264 In conclusion, this national register-based study indicates a lower reoperation rate for IMN  
265 than SHS for unstable trochanteric and subtrochanteric fractures, but not for stable fractures  
266 or individual fracture types. The choice of implant may not be decisive to the outcome of  
267 treatment for stable trochanteric fractures in terms of reoperation rate. One-year mortality rate  
268 for unstable and stable fractures was lower in patients treated with IMN.

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348

**Table I.** Baseline characteristics of patients

|                               | AO/OTA A1 fractures |             |         | AO/OTA A2 fractures |             |         | AO/OTA A3 fractures |             |         | Subtroch. fractures |             |         |
|-------------------------------|---------------------|-------------|---------|---------------------|-------------|---------|---------------------|-------------|---------|---------------------|-------------|---------|
|                               | SHS                 | IMN         | P-value | SHS                 | IMN         | p-value | SHS                 | IMN         | p-value | SHS                 | IMN         | p-value |
| Total number                  | 4811                | 2030        |         | 4139                | 2975        |         | 407                 | 645         |         | 473                 | 1861        |         |
| Women, n (%)                  | 3280 (68)           | 1399 (69)   | 0.55    | 3042 (74)           | 2187 (74)   | 0.99    | 307 (75)            | 494 (77)    | 0.67    | 355 (75)            | 1392 (75)   | 0.91    |
| Mean age, yrs (SD)            | 83.0 (9.0)          | 83.0 (8.7)  | 0.99    | 83.5 (8.6)          | 83.3 (8.7)  | 0.48    | 83.6 (8.5)          | 82.9 (8.8)  | 0.18    | 82.4 (9.7)          | 82.2 (9.3)  | 0.71    |
| Age groups, n (%)             |                     |             | 0.022   |                     |             | 0.91    |                     |             | 0.46    |                     |             | 0.068   |
| 60-74                         | 924 (19)            | 347 (17)    |         | 692 (17)            | 515 (17)    |         | 67 (17)             | 123 (19)    |         | 114 (24)            | 406 (22)    |         |
| 75-79                         | 542 (11)            | 272 (13)    |         | 490 (12)            | 349 (12)    |         | 46 (11)             | 90 (14)     |         | 38 (8)              | 224 (12)    |         |
| 80-84                         | 922 (19)            | 389 (19)    |         | 779 (19)            | 548 (18)    |         | 68 (17)             | 103 (16)    |         | 76 (16)             | 341 (18)    |         |
| 85-89                         | 1153 (24)           | 517 (26)    |         | 1081 (26)           | 793 (27)    |         | 117 (29)            | 178 (28)    |         | 122 (26)            | 456 (25)    |         |
| > 90                          | 1270 (26)           | 505 (25)    |         | 1100 (27)           | 770 (26)    |         | 109 (27)            | 151 (23)    |         | 123 (26)            | 434 (23)    |         |
| ASA class, n (%)              |                     |             | 0.22    |                     |             | 0.39    |                     |             | 0.85    |                     |             | 0.33    |
| ASA 1                         | 85 (2)              | 30 (2)      |         | 51 (1)              | 44 (2)      |         | 6 (2)               | 8 (1)       |         | 14 (3)              | 40 (2)      |         |
| ASA 2                         | 1555 (32)           | 617 (30)    |         | 1261 (31)           | 911 (31)    |         | 118 (29)            | 199 (31)    |         | 146 (31)            | 571 (31)    |         |
| ASA 3                         | 2794 (58)           | 1233 (61)   |         | 2483 (60)           | 1802 (61)   |         | 249 (61)            | 379 (59)    |         | 268 (57)            | 1109 (60)   |         |
| ASA 4                         | 377 (8)             | 150 (7)     |         | 344 (8)             | 218 (7)     |         | 34 (8)              | 59 (9)      |         | 45 (10)             | 141 (8)     |         |
| Cognitive impairment (%)      |                     |             | 0.007   |                     |             | 0.029   |                     |             | 0.88    |                     |             | 0.70    |
| Yes                           | 1280 (27)           | 550 (27)    |         | 1137 (28)           | 748 (25)    |         | 104 (26)            | 161 (25)    |         | 117 (25)            | 420 (23)    |         |
| No                            | 3010 (63)           | 1230 (61)   |         | 2537 (61)           | 1927 (65)   |         | 267 (66)            | 417 (65)    |         | 311 (66)            | 1255 (67)   |         |
| Uncertain                     | 384 (8)             | 207 (10)    |         | 370 (9)             | 238 (8)     |         | 27 (7)              | 51 (8)      |         | 38 (8)              | 149 (8)     |         |
| Missing                       | 137 (3)             | 43 (2)      |         | 95 (2)              | 62 (2)      |         | 9 (2)               | 16 (3)      |         | 7 (2)               | 37 (2)      |         |
| PROM preoperative, n          | 1981                | 875         |         | 1740                | 1280        |         | 182                 | 301         |         | 216                 | 810         |         |
| EQ-5D index score (SD)        | 0.71 (0.28)         | 0.70 (0.27) | 0.45    | 0.72 (0.27)         | 0.71 (0.28) | 0.18    | 0.69 (0.28)         | 0.74 (0.25) | 0.034   | 0.71 (0.29)         | 0.74 (0.27) | 0.17    |
| Preoperative mobility (EQ-5D) |                     |             | 0.035   |                     |             | 0.28    |                     |             | 0.098   |                     |             | 0.55    |
| No problems                   | 1142 (56)           | 463 (51)    |         | 1001 (56)           | 732 (56)    |         | 90 (48)             | 183 (58)    |         | 127 (58)            | 489 (58)    |         |
| Some problems                 | 868 (43)            | 419 (47)    |         | 771 (43)            | 565 (43)    |         | 96 (51)             | 131 (41)    |         | 86 (39)             | 338 (40)    |         |
| Confined to bed               | 30 (2)              | 20 (2)      |         | 13 (1)              | 17 (1)      |         | 2 (1)               | 4 (1)       |         | 6 (3)               | 14 (2)      |         |

350 **Table II.** Number and type of reoperations

|                                 | <b>Total</b> | <b><u>AO/OTA A1 fractures</u></b> |            | <b><u>AO/OTA A2 fractures</u></b> |            | <b><u>AO/OTA A3 fractures</u></b> |            | <b><u>Subtroch. fractures</u></b> |            |
|---------------------------------|--------------|-----------------------------------|------------|-----------------------------------|------------|-----------------------------------|------------|-----------------------------------|------------|
|                                 |              | <b>SHS</b>                        | <b>IMN</b> | <b>SHS</b>                        | <b>IMN</b> | <b>SHS</b>                        | <b>IMN</b> | <b>SHS</b>                        | <b>IMN</b> |
| N                               | 17 341       | 4811                              | 2030       | 4139                              | 2975       | 407                               | 645        | 473                               | 1861       |
| Reoperations 3 years, n (%)     | 982 (5.7)    | 159 (3.3)                         | 67 (3.3)   | 303 (7.3)                         | 182 (6.1)  | 46 (11.3)                         | 63 (9.8)   | 36 (7.6)                          | 126 (6.8)  |
| Total joint replacement, n (%)  | 319 (1.8)    | 58 (1.2)                          | 18 (0.9)   | 110 (2.7)                         | 59 (2.0)   | 13 (3.2)                          | 19 (2.9)   | 11 (2.3)                          | 31 (1.7)   |
| Bipolar hemiarthroplasty, n (%) | 184 (1.2)    | 34 (0.7)                          | 16 (0.8)   | 62 (1.5)                          | 37 (1.2)   | 5 (1.2)                           | 10 (1.6)   | 6 (1.3)                           | 14 (0.8)   |
| Re-osteosynthesis, n (%)        | 257 (1.5)    | 29 (0.6)                          | 23 (1.1)   | 66 (1.6)                          | 45 (1.5)   | 18 (4.4)                          | 17 (2.6)   | 14 (3.0)                          | 45 (2.4)   |
| Soft tissue debridement, n (%)  | 106 (0.6)    | 26 (0.5)                          | 3 (0.1)    | 40 (1.0)                          | 13 (0.4)   | 7 (1.7)                           | 5 (0.8)    | 0                                 | 12 (0.6)   |
| Removal of implant, n (%)       | 86 (0.5)     | 12 (0.2)                          | 2 (0.1)    | 26 (0.6)                          | 19 (0.6)   | 3 (0.7)                           | 7 (1.1)    | 1 (0.2)                           | 16 (0.9)   |
| Other, n (%)                    | 121 (0.7)    | 19 (0.4)                          | 6 (0.3)    | 38 (0.9)                          | 22 (0.7)   | 6 (1.5)                           | 11 (1.7)   | 6 (1.3)                           | 13 (0.7)   |

351 >1 reoperation type may be performed per fracture

352

353

354 **Table III.** Cause of reoperation after stable fractures (AO/OTA A1) one and three years postoperatively, hierarchically arranged

|                                | <b>SHS, n (%)</b> | <b>IMN, n (%)</b> | <b>HRR*</b> | <b>95% CI</b> | <b>p</b> |
|--------------------------------|-------------------|-------------------|-------------|---------------|----------|
| <b>1 year postoperatively</b>  |                   |                   |             |               |          |
| All reoperations               | 116 (2.4)         | 54 (2.7)          | 1.1         | 0.79 to 1.51  | 0.60     |
| Infection                      | 25 (0.5)          | 5 (0.2)           | 0.5         | 0.18 to 1.21  | 0.12     |
| Peri-implant fracture          | 6 (0.1)           | 15 (0.7)          | 5.9         | 2.30 to 15.3  | <0.001   |
| Mechanical complications†      | 48 (1.0)          | 17 (0.8)          | 0.8         | 0.47 to 1.43  | 0.48     |
| Unspecified sequelae (THA) ‡   | 33 (0.7)          | 11 (0.5)          | 0.8         | 0.40 to 1.56  | 0.49     |
| Other reason§                  | 4 (0.1)           | 4 (0.2)           | 2.4         | 0.61 to 9.78  | 0.21     |
| Pain alone                     | 0 (0)             | 2 (0.1)           | -           |               |          |
| <b>3 years postoperatively</b> |                   |                   |             |               |          |
| All reoperations               | 159 (3.3)         | 67 (3.3)          | 1.0         | 0.75 to 1.32  | 0.98     |
| Infection                      | 27 (0.6)          | 5 (0.2)           | 0.43        | 0.16 to 1.13  | 0.85     |
| Peri-implant fracture          | 7 (0.1)           | 17 (0.8)          | 5.80        | 2.40 to 13.99 | <0.001   |
| Mechanical complications†      | 56 (1.2)          | 18 (0.9)          | 0.74        | 0.43 to 1.26  | 0.27     |
| Unspecified sequelae (THA) ‡   | 56 (1.2)          | 18 (0.9)          | 0.78        | 0.46 to 1.32  | 0.35     |
| Other reason§                  | 7 (0.1)           | 6 (0.3)           | 2.07        | 0.70 to 6.16  | 0.19     |
| Pain alone                     | 6 (0.1)           | 3 (0.1)           | 1.22        | 0.31 to 4.88  | 0.78     |

355 \*SHS is reference in Cox regression model adjusted for age, sex and ASA

356 † including hardware failure, cut-out, non-union

357 ‡ Operation with THA recorded in the Norwegian Arthroplasty Register

358 § All other reasons for reoperations except pain alone

359

360 **Table IV.** Cause of reoperation after unstable fractures (AO/OTA A2, AO/OTA A3 and subtrochanteric) one and three years postoperatively, hierarchically arranged

|                                | SHS, n (%) | IMN, n (%) | HRR* | 95% CI       | p     |
|--------------------------------|------------|------------|------|--------------|-------|
| <b>1 year postoperatively</b>  |            |            |      |              |       |
| All reoperations               | 290 (5.8)  | 270 (4.9)  | 0.82 | 0.70 to 0.97 | 0.022 |
| Infection                      | 53 (1.1)   | 34 (0.6)   | 0.6  | 0.38 to 0.90 | 0.016 |
| Peri-implant fracture          | 16 (0.3)   | 23 (0.4)   | 1.3  | 0.69 to 2.46 | 0.43  |
| Mechanical complications†      | 132 (2.6)  | 127 (2.3)  | 0.9  | 0.85 to 1.09 | 0.19  |
| Unspecified sequelae (THA) ‡   | 81 (1.6)   | 57 (1.0)   | 0.6  | 0.43 to 0.85 | 0.003 |
| Other reason§                  | 8 (0.2)    | 17 (0.3)   | 1.9  | 0.83 to 4.46 | 0.13  |
| Pain alone                     | 0 (0)      | 12 (0.2)   | -    |              |       |
| <b>3 years postoperatively</b> |            |            |      |              |       |
| All reoperations               | 385 (7.7)  | 371 (6.8)  | 0.86 | 0.74 to 0.99 | 0.036 |
| Infection                      | 55 (1.1)   | 34 (0.6)   | 0.57 | 0.37 to 0.87 | 0.009 |
| Peri-implant fracture          | 20 (0.4)   | 36 (0.7)   | 1.66 | 0.96 to 2.87 | 0.07  |
| Mechanical complications†      | 150 (3.0)  | 153 (2.8)  | 0.91 | 0.72 to 1.14 | 0.39  |
| Unspecified sequelae (THA) ‡   | 130 (2.6)  | 100 (1.8)  | 0.67 | 0.52 to 0.88 | 0.003 |
| Other reason§                  | 12 (0.2)   | 22 (0.4)   | 1.66 | 0.82 to 3.36 | 0.16  |
| Pain alone                     | 18 (0.4)   | 26 (0.5)   | 1.27 | 0.69 to 2.31 | 0.44  |

361 \*SHS is reference in Cox regression model adjusted for age, sex and ASA

362 † including hardware failure, cut-out, non-union

363 ‡ Operation with THA recorded in the Norwegian Arthroplasty Register

364 § All other reasons for reoperations except pain alone

365

366 **Table V.** Risk of reoperation for SHS and IMN for AO/OTA A1, A2, A3 and subtrochanteric fractures individually

367

|  | <b><u>SHS</u></b> | <b><u>IMN</u></b>     |          |                       |             |               |                |
|--|-------------------|-----------------------|----------|-----------------------|-------------|---------------|----------------|
|  | <b>n</b>          | <b>Reoperation, n</b> | <b>n</b> | <b>Reoperation, n</b> | <b>HRR*</b> | <b>95% CI</b> | <b>p-value</b> |
| <b><u>Reoperations one year</u></b>    |                   |                       |          |                       |             |               |                |
| AO/OTA A1                              | 4811              | 116                   | 2030     | 54                    | 1.1         | 0.79 to 1.51  | 0.6            |
| AO/OTA A2                              | 4139              | 221                   | 2975     | 135                   | 0.83        | 0.67 to 1.03  | 0.093          |
| AO/OTA A3                              | 407               | 41                    | 645      | 45                    | 0.65        | 0.43 to 1.00  | 0.050          |
| Subtrochanteric fractures              | 473               | 28                    | 1861     | 90                    | 0.79        | 0.52 to 1.21  | 0.28           |
| <b><u>Reoperations three years</u></b> |                   |                       |          |                       |             |               |                |
| AO/OTA A1                              | 4811              | 159                   | 2030     | 67                    | 1.0         | 0.75 to 1.32  | 0.98           |
| AO/OTA A2                              | 4139              | 303                   | 2975     | 182                   | 0.83        | 0.69 to 1.00  | 0.050          |
| AO/OTA A3                              | 407               | 46                    | 645      | 63                    | 0.83        | 0.57 to 1.21  | 0.33           |
| Subtrochanteric fractures              | 473               | 36                    | 1861     | 126                   | 0.89        | 0.61 to 1.29  | 0.54           |

368 \* Hazard rate ratio calculated using Cox regression with SHS as reference. Adjusted for age, sex and ASA

369

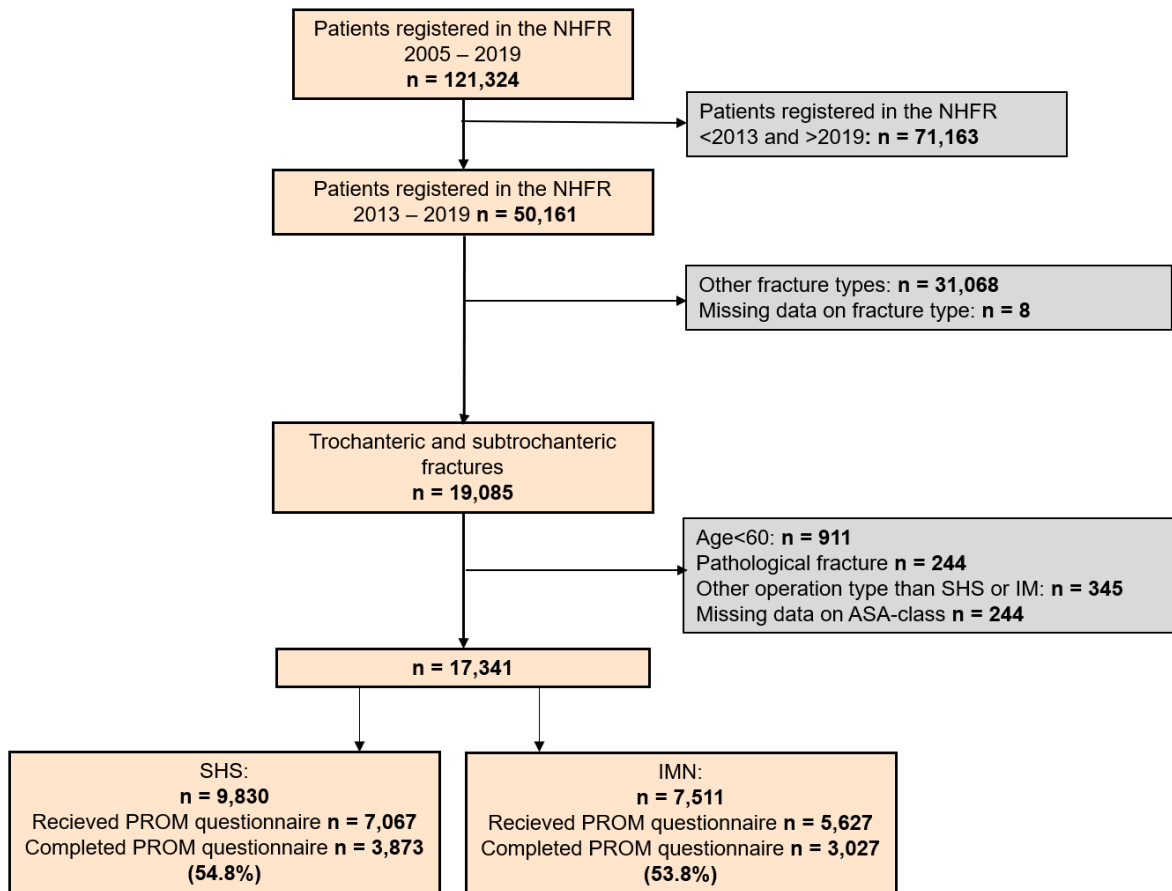
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371

372 **Table VI.** Pain, satisfaction and quality of life 12 months after primary operation

|  | <b>SHS</b>     | <b>IMN</b>     | <b>Mean difference (95% CI)</b> | <b>p-value</b>   |
|--|----------------|----------------|---------------------------------|------------------|
| <b>Mean EQ-5D-3L index score</b>                 |                |                |                                 |                  |
| Stable fractures                                 | 0.59 (n=1746)  | 0.58 (n=692)   | 0.01 (-0.02 to 0.02)            | 0.96             |
| Unstable fractures                               | 0.55 (n=1776)  | 0.58 (n=2052)  | -0.04 (-0.05 to -0.02)          | <b>&lt;0.001</b> |
| <b>EQ-5D-3L: mobility for stable fractures</b>   |                |                |                                 | 0.505            |
| No problems                                      | 26.9% (n=485)  | 29.1% (n=211)  |                                 |                  |
| Some problems                                    | 68.9% (n=1243) | 66.6% (n=482)  |                                 |                  |
| Confined to bed                                  | 4.3% (n=77)    | 4.3% (n=31)    |                                 |                  |
| <b>EQ-5D-3L: mobility for unstable fractures</b> |                |                |                                 | <b>&lt;0.001</b> |
| No problems                                      | 20.4% (n=377)  | 26.6% (n=571)  |                                 |                  |
| Some problems                                    | 74.3% (n=1372) | 69.4% (n=1488) |                                 |                  |
| Confined to bed                                  | 5.3% (n=97)    | 3.9% (n=84)    |                                 |                  |
| <b>Mean VAS score for pain</b>                   |                |                |                                 |                  |
| Stable fractures                                 | 24.2 (n=1777)  | 24.3 (n=704)   | -0.1 (-1.9 to 1.7)              | 0.91             |
| Unstable fractures                               | 27.3 (n=1820)  | 25.8 (n=2104)  | 1.5 (0.2 to 2.8)                | 0.029            |
| <b>Mean VAS score for satisfaction</b>           |                |                |                                 |                  |
| Stable fractures                                 | 27.9 (n=1773)  | 27.5 (n=710)   | 0.5 (-1.4 to 2.3)               | 0.63             |
| Unstable fractures                               | 32.5 (n=1821)  | 30.0 (n=2110)  | 2.5 (1.1 to 4.0)                | <b>&lt;0.001</b> |

**Fig 1. Flowchart of the study population**





**Fig 2. Implant survival curves for SHS and IMN in stable (AO/OTA A1) fractures versus unstable (A2, A3 and subtrochanteric) fractures**

