Displaced femoral neck fractures: towards better practice
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The Physiologic Status Score treatment protocol for displaced femoral neck fractures

A Dutch prospective multicenter study


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Abstract

Background: Meta-analysis results of internal fixation (IF, revision rate 35%) versus hemiarthroplasty (HA, revision rate 16%) for displaced femoral neck fractures have failed to generate agreement on the appropriate therapy in individual patients. Factors affecting outcome may depend on individual conditions. Mobility, accommodation, bone density, cognitive and medical condition were quantified into a Physiologic Status Score (PSS, maximum 26 points). Hypothesis: IF is appropriate in high PSS patients and HA in lower PSS patients. The aim was to validate application of a published PSS protocol for treatment selection, expecting a 10% reduction in revisions compared to meta-analysis data.

Methods: Patients aged 60-90 were included in 10 hospitals. Bone density was measured pre-operatively with Dual Energy X-ray Absorptiometry. If PSS ≥ 20 points, IF was performed and if PSS < 20, HA. Operative technique was specified and staff supervision was mandatory. Postoperatively, full weight-bearing was recommended. Follow-up (FU) was scheduled at 8 weeks, 1 and 2 years for Harris Hip Score (HHS) assessment and radiographs. End points were revision, mortality and function. IF technique was rated by an independent expert panel.

Results: 224 patients were included; FU rate was 98%. IF (PSS ≥ 20) was performed in 115 and HA (PSS < 20) in 109 patients. The realized 2 year revision rate after IF was 40% (expected outcome 25%, NS) and after HA 3% (expected outcome 6%, p < 0.05). Two-year mortality was 16% in IF and 50% in HA patients (p < 0.01). Revised and successful IF patients had a similar mortality rate (11% vs 16%, p = 0.53). Two-year mean HHS was significantly higher in both successful IF (79 ± 15) and revised IF (78 ± 16) patients compared with HA patients (71 ± 12, p = 0.007 and 0.001 respectively). Technical errors were found in 15 IF patients. Excluding technical failures, subanalysis showed that IF revision rate was 31% (24% in patients aged 60-79 and 41% aged ≥ 80 years).

Conclusions: Application of the PSS does not improve decision-making in a substantial way. This contradicts the original PSS results. The PSS protocol did lead to a low revision rate in patients selected for HA. Patients with a PSS ≥ 20, aged 60-79 years, can tolerate a 1 in 4 revision rate of appropriate IF while older patients nearly have a 1 in 2 risk of revision.

Level of Evidence: Level 2-1 therapeutic study; prospective multi-center design with concurrent controls.
Study background

In 1990 the estimated global incidence of hip fractures was 1.660,000. This figure is expected to rise to 6.260,000 in 2050. In 1999, 15,286 patients (11,649 women) over 55 years old were treated for a hip fracture in the Netherlands. The average admission length was 24 days, representing 3% of total national hospital days. Displaced femoral neck fractures represent approximately 40% all hip fractures in the Netherlands.

Discussion continues on the subject of optimal treatment for displaced femoral neck fractures. In 1976 Barnes showed that the percentage of union after internal fixation declines as age advances, to as much as 50% at 85 years of age. Three meta-analyses pooling the data of 17 prospective randomised studies, on internal fixation (IF) versus arthroplasty for displaced femoral neck fractures identified that IF led to significantly more operative revision. The first meta-analysis by Lu Yao calculated a median revision rate of 35% for IF and 16% for HA. Weighed means of revision rates after IF in two more recent meta-analyses were 28.6% and 18.5% for non-union and 8.3% and 9.7% for avascular necrosis. Compared with arthroplasty IF was shown to have less operation time, less perioperative blood loss, lower risk of deep wound infection and possibly a lower early mortality rate. Specific arthroplasty complications were: dislocation of the prosthetic head (4%), loosening of the stem (5%) and in the longer term the risk of acetabular protrusion (3%). In view of the two latter problems it has been suggested that patients with a longer life expectancy should not be treated with hemiarthroplasty. The pooled data of all three meta-analyses could not determine which therapy led to better pain relief and functional outcome in the short and long term. Larger randomised trials may solve the issues of early mortality and functional outcome, but there is still a need for studies to define which patient groups are better served by the different treatment methods.

Some crucial factors may be independent of the repair of the fracture and instead depend on individual conditions. In 1994 an interesting decision-score system to quantify the true physiologic status of individual patients between 65 and 85 years of age was published. Five individual qualities were quantified into a total Physiologic Status Score (PSS): mobility, accommodation, osteoporosis, cognition and medical condition. The developed PSS could be a useful guide for selection of the appropriate treatment. Patients with a high PSS aged between 65 and 85 years received IF and patients with a lower PSS an endoprosthesis. At 21 months follow-up the revision rates in both groups added up to 5%. This promising clinical outcome has not been independently verified. We considered the selection based on quantification of individual patient factors to be a
strategic refinement in decision-making between IF and arthroplasty and of possible benefit to the cost of hip fracture treatment for society.

Hypothetically, displaced femoral neck fracture patients aged between 60 and 90, assessed with the Physiologic Status Score and treated accordingly, should have less need for revisional procedures and better functional outcome at 2 year follow-up compared with meta-analysis data. The purpose of this study was to assess the validity of the Physiologic Status Score as a pre-operative selection method for the choice between IF and hemiarthroplasty for displaced femoral neck fractures in a multi-center setting.

**Materials and Methods**

**Design and inclusion** Patients from 4 university and 6 non-university teaching hospitals were prospectively included. An algorithm of the study design is shown in figure 1. Patients presenting with a displaced fracture of the femoral neck to the Emergency Department were eligible for inclusion in this study. In- and exclusion criteria are listed in table 1. Data analysis was performed per protocol. Uniform case report forms (CRF) were distributed to all participating centers. Inclusion of patients started on 1 June 2000 and closed on 30 November 2001. Inclusion of eligible patients was reported to the investigators by telephone. Inclusion and exclusion criteria were checked and any unclear issues resolved.

**Table 1. In- and exclusion criteria.**

<table>
<thead>
<tr>
<th>Inclusion criteria:</th>
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<tbody>
<tr>
<td>- Aged between 60 and 90 years old</td>
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<tr>
<td>- Displaced intracapsular femoral neck fracture, no trochanteric fractures</td>
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<table>
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<tr>
<th>Exclusion criteria:</th>
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<tbody>
<tr>
<td>- Undisplaced femoral neck fractures</td>
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<tr>
<td>- Displaced femoral neck fracture older than 48 hours</td>
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<tr>
<td>- Patients with advanced arthrosis of the ipsilateral hip joint who would normally be treated by total hip replacement. The diagnostic signs on plain X-ray of this condition were: subchondral sclerosis, narrowing of the articular deft, formation of osteofytes and subchondral cyst formation</td>
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<tr>
<td>- Patients with established rheumatoid arthritis or showing signs of this disease on plain X-ray</td>
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<tr>
<td>- Patients with a pathological fracture or who sustained a spontaneous fracture after a comparatively minor trauma with signs of osteolysis at the fracture sight on plain X-ray</td>
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<tr>
<td>- Preoperative immobility; patients who were already bed-ridden or bed-chair commuters</td>
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<tr>
<td>- Invalidity due to neurologic disease; M. Parkinson or CVA</td>
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</table>
The modified Physiologic Status Score (PSS) The scoring system of the modified PSS is shown in table 2. The cut-off point for IF was set at 20 points as proposed by Robinson. The original osteoporosis component of the PSS was determined using the Singh index, which has been proven to have an unacceptable interobserver variance. In the modified PSS bone density was therefore measured pre-operatively with the gold standard method: Dual-Energy X-ray Absorptiometry (DXA scan). The results of DXA were given as a Standard Deviation compared with the peak value of an adult aged 20-30 years (T-score) and a Standard Deviation compared with bone density of the same age group (Z-score). The contralateral uninjured femoral neck was measured for cortical bone density and representative lumbar vertebrae 1 to 4 (fractured or impressed vertebrae were excluded) were measured for cancellous bone density. Scanning duration was 10 minutes. The extra radiation of 2,0 microSievert (WHO classification group I) for the patient was considered minimal. If the uninjured hip contained a prosthesis, the mean T-score and Z score of the lumbar vertebrae 1 to 4 was used. The participating hospitals were required to have an easily accessible facility to perform the pre-operative DXA scans.

To assess the agreement on PSS scoring an interobserver study was performed among 3 staff surgeons and a fifth year surgical resident, who were asked to independently assess 15 hip fracture patients older than 60 years. Mobility, accommodation, cognition status, ASA class and therapy choice based on the total PSS score (table 2) were scored. The bone density component of the PSS was based on exact DXA measurement. The scorers were blinded to each other's findings.

Treatment

Pre-operatively: Antibiotic and thrombosis prophylaxis was administered according to hospital policy. A third or fourth generation Cefalosporin intravenously, 30 minutes before incision, was recommended. Low Molecular Weight Heparin 2850 IU subcutaneously once daily was recommended to prevent thrombosis. Traction of the ipsilateral leg was not necessary.

Intra-operatively: Operations of study patients were supervised by staff surgeons who performed > 20 procedures for displaced femoral neck fractures per year as operator or supervisor. In the Anterior-Posterior image intensified view reduction of the femoral head in 0-20 degrees of valgus was recommended. In the lateral view the line between head and long axis of the femoral shaft was recommended to be as close as possible to
Table 2. The modified Physiologic Status Score for patients aged 60-90 years old.

**Mobility assessment (maximum score, 5 points)**

- Full mobility without walking aids: 5
- Mobile with one walking aid: 4
- Mobile with two walking aids: 3
- Mobile with frame with or without wheels: 2
- Immobile/wheelchair bound: 1

**Accommodation assessment (maximum score, 5 points)**

- Fully independent in own home, able to do shopping/household chores: 5
- Living in own home but partially dependent on social services/relatives: 4
- Living in sheltered accommodation: 3
- Living in residential home without full time nursing care: 2
- Living in long time hospital care/nursing home requiring full nursing care: 1

**Osteoporosis assessment (maximum score, 6 points)**

- Normal bone density: 6
- Osteopenia (T score: 1.0-2.5 standard deviation), normal for age: 5
- Osteopenia (T score: 1.0-2.5 standard deviation), abnormal for age: 4
- Osteoporosis (T score: 2.5-3.5 standard deviation), normal for age: 3
- Osteoporosis (T score: 2.5-3.5 standard deviation), abnormal for age: 2
- Serious osteoporosis (T score: 3.5 standard deviation), normal or abnormal for age: 1

**Cognition assessment**

(most score of 5 points derived by dividing test result, for which 1 point is allocated for each correct answer, by 2)

- Age (to within one year): 1
- Time (to within one hour): 1
- Address to recall at end of test - eg 42 West street: 1
- Year: 1
- Name of hospital: 1
- Recognition of two persons (doctor, nurse etc): 1
- Date of birth: 1
- Year of First World War: 1
- Name of present monarch: 1
- Count backward from 20 to 1: 1

**Medical assessment**

- A normal healthy patient: 5
- A patient with mild systemic disease: 4
- A patient who has severe systemic disease that is not incapacitating: 3
- A patient who has incapacitating disease that is a constant threat to life: 2
- A moribund patient, not expected to survive for 24 hours with or without surgery: 1

**Total points < 20:** hemiarthroplasty
**Total points ≥ 20:** internal fixation
180 degrees. Retro- and anteversion of the femoral head up to 10 degrees was accepted.

Implants for internal fixation: In fracture angles up to 50 degrees (Pauwels type I and II), cannulated cancellous screws or sliding (compression) hip screws were recommended; in steeper, Pauwels 3 type fractures, a fixed-angle sliding hip screw was recommended. The three-point fixation method was advocated for internal fixation with cannulated screws. For sliding hip screw placement, a position of the screw over the inferior calcaneus and into the central to lower half (AP view) and central to dorsal (lateral view) part of the femoral head was advised.

All current uni- or bipolar endoprostheses could be used as implants for hemiarthroplasty. Surgical approach to the hip joint and capsulotomy or capsulectomy were not protocolled. Cementing of the stem was mandatory.

Post-operatively:
Depending on pain severity and with the aid of physiotherapy, full weight-bearing was recommended after both treatment modalities. Major post-operative complications were considered to be: deep infection (beneath the fascia lata), congestive heart failure, pulmonary embolus and cerebrovascular accident. Minor complications were: pneumonia, cardiac arrhythmia, urinary tract infection, wound haematoma, superficial wound infection, pressure sores, delirium and deep venous thrombosis.

Definition of end points Major revision of either IF or hemiarthroplasty was the primary end point. Dislocation of an endoprosthesis and closed reduction was not considered to be a major revision. Patients reaching the end point of major revision were still evaluated for the full designated follow-up period. Secondary end points were: mortality and Harris Hip Score at follow-up.

Statistical methods The sample size was calculated with a one-sided 95% Confidence Interval (CI) test for proportions. For normally distributed data, p values were calculated with an independent samples t-test. The two sample Mann-Whitney test was used to calculate significance in non-normally distributed data. The distribution of data was tested for normality with a one-sample Kolmogorov-Smirnov test. For normally distributed data, p-values and 95% confidence intervals were calculated with an independent samples t-test. For non-parametric correlation the Spearman rank coefficient was calculated. Binary Logistic Regression with therapy as a categorical variable was performed. The coefficient of concordance as a measure of agreement on PSS
scoring was calculated with Kendall's W test. P-values < 0.05 were considered to indicate a statistically significant difference. SPSS, version 11.5 (Statistical Package for Social Sciences Incorporated, Chicago IL, USA) was used for data analysis.

Sample size Data from the five comparative studies and eligible case series in Lu-Yao's meta-analysis, which was available in 2000, showed a median revision rate of 35% for IF and 16% for HA at 2 year follow-up. One-year mortality was 28% in both groups combined.

If application of the PSS could achieve a revision rate reduction of 10% (35% to 25%) for IF at 2 year follow-up, one-sided 95% CI analysis with an alpha of 0.05 showed that 70 IF patients [upper limit 95% CI: 0.34] were required for inclusion. Expecting 40% of the total sample to be IF patients, 105 HA patients [upper limit 95% CI: 0.10] were required. The expected amount of HA patients was therefore enough to prove a significant reduction in revision from 16% to 6%. Anticipating a 2 year mortality rate of 30%, at least 70 + 105 + 85 = 250 patients were required.

Data collection and follow-up Case report forms were completed on admission, at operation and upon discharge.

Follow-up was scheduled at 8 weeks, 1 and 2 years after internal fixation and at 1 and 2 years after arthroplasty. At each follow-up interval the Harris Hip Score was documented on the CRF. The Harris Hip Score is based on the assessment of four parameters: no pain is allocated 44 points, optimal function 47 points, absence of deformity 4 points and normal range of motion 5 points of the total score. A maximum of 100 points can be achieved. Plain radiographs in the AP and lateral views of the affected hip were also performed and assessed at each follow-up interval.

Sub-analysis of technique in the internal fixation (IF) group A panel of two independent experts, who were not involved in this study, was instituted for blinded rating of the quality of IF. Digital images of only the pre-, intra- and postoperative radiographs, with patient and institution names removed, were presented to the panel. They were asked to rate fracture reduction and internal fixation separately and to give an overall rating of technique. An adequate or inadequate rating, regardless of their opinion of likely clinical outcome, could be assigned.

Both experts rated fracture reduction and internal fixation according to the treatment specifics stated above. The experts were blinded to each others' findings. A case was
considered a technical failure when both experts rated overall technique as inadequate.

**Institutional Review Board** The study protocol was submitted to the Institutional Review Board (IRB) of each participating clinic. The PSS strategy was considered to be within the limits of existing protocolled medical practice by the IRB and permission was granted to proceed without informed consent in 4 university hospitals and 2 non-university hospitals. Informed consent was deemed necessary in 4 non-university hospitals. Patients were approached at admission by the surgical or orthopaedic registrar on duty for consults in the Emergency Department. Patients consented to be bound by the results of the PSS before the score was completed. The study was conducted in full accordance with the laws and regulations of the Netherlands.

**Results**

**Patient and therapy characteristics** A total of 252 patients were included in 10 participating hospitals in 17 months. In the three hospitals contributing 117 (52%) patients of the total evaluable group all operation codes for femoral neck fracture procedures were retrieved. It appeared that 93% of patients presenting to the Emergency Departments meeting inclusion criteria had indeed been included. No patients refused to abide by their treatment assignment after the PSS score was completed. Twenty-eight patients (11%) were excluded from final analysis due to violation of protocol and dropout, as shown in figure 1. For final analysis 224 patients

<table>
<thead>
<tr>
<th>PSS components:</th>
<th>PSS &lt; 20 (HA)</th>
<th>PSS ≥ 20 (IF)</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>82.67 ± 5.10</td>
<td>77.10 ± 7.14</td>
<td>p &lt; 0.01</td>
</tr>
<tr>
<td>M/F</td>
<td>19 M / 90 F</td>
<td>39 M / 76 F</td>
<td>p = 0.11</td>
</tr>
<tr>
<td>PSS components:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mobility</td>
<td>3.20 ± 1.34</td>
<td>4.74 ± 0.62</td>
<td>p &lt; 0.01</td>
</tr>
<tr>
<td>Accommodation</td>
<td>2.81 ± 1.28</td>
<td>4.89 ± 0.34</td>
<td>p &lt; 0.01</td>
</tr>
<tr>
<td>Bone density</td>
<td>3.06 ± 1.35</td>
<td>4.15 ± 1.28</td>
<td>p &lt; 0.01</td>
</tr>
<tr>
<td>Cognition</td>
<td>2.69 ± 1.66</td>
<td>4.76 ± 0.46</td>
<td>p &lt; 0.01</td>
</tr>
<tr>
<td>Medical condition</td>
<td>3.56 ± 0.67</td>
<td>4.25 ± 0.66</td>
<td>p &lt; 0.01</td>
</tr>
<tr>
<td>Delay to surgery(hours)</td>
<td>34.20 ± 19.80</td>
<td>21.14 ± 16.35</td>
<td>p &lt; 0.01</td>
</tr>
<tr>
<td>Operation time(minutes)</td>
<td>78.80 ± 23.60</td>
<td>65.63 ± 20.80</td>
<td>p &lt; 0.01</td>
</tr>
</tbody>
</table>
Patients presenting with a displaced femoral neck fracture
\( n = 252 \)

- Extracapsular, impacted or pathological fracture \( n = 3 \)

Inclusion criteria met
\( n = 249 \)

PSS scoring error \( n = 5 \)*

Physiologic Status Score applied
\( n = 244 \)

\( < 20 \) points
\( n = 118 \)

- IF performed below threshold
\( n = 6 \)

Hemiarthroplasty
\( n = 112 \)

\( \geq 20 \) points
\( n = 126 \)

- HA performed above threshold
\( n = 10 \)

Internal Fixation
\( n = 116 \)

Dropout during follow-up
\( n = 3 ) *\)

Hemiarthroplasty
\( n = 112 \)

Internal Fixation
\( n = 116 \)

Untraceable new address
\( n = 1 \)

\( n = 109 \)

\( n = 115 \)

* Wrong interpretation of mobility, accommodation or ASA class; † Untraceable new address, refusal to complete follow-up and new ipsilateral hip trauma with acetabular fracture

(166 women, 58 men) were evaluable. IF after closed reduction (PSS \( \geq 20 \)) was performed in 115 patients and hemiarthroplasty (PSS < 20) in 109 patients. The PSS had a significant correlation with age (co-efficient 0.34, \( p < 0.001 \)) as shown in figure 2. Each of the five PSS criteria was significantly lower in the HA group, shown in table 3 along with the basic patient characteristics in each group. Delay to surgery and operation time was longer in HA patients. Operation details and implants are shown in table 4. In the IF group, preferred fracture reduction was achieved in 86% of cases in the AP view and in 84% of cases in the lateral view. The majority (72%) of fractures were treated with Sliding Hip Screws (SHS). The compliance rate with the recommendation to fixate fractures with an angle \( > 50^\circ \) (Pauwels 3 type, 56% of IF group) with a SHS was 70%.
**Figure 2.** Scatter plot of the correlation between PSS and age ($r = 0.34$, $p < 0.001$, $n=224$).

![Scatter plot of PSS vs age](image)

**Table 4.** Operation details

<table>
<thead>
<tr>
<th>PSS $&lt; 20$ (HA) $n = 109$</th>
<th></th>
</tr>
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<tbody>
<tr>
<td><strong>Supine position</strong></td>
<td>33 (30%)</td>
</tr>
<tr>
<td><strong>Lateral position</strong></td>
<td>76 (70%)</td>
</tr>
<tr>
<td><strong>Unipolar head</strong></td>
<td>96 (88%)</td>
</tr>
<tr>
<td><strong>Bipolar head</strong></td>
<td>13 (12%)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>PSS $\geq 20$ (IF) $n = 115$</th>
<th></th>
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</thead>
<tbody>
<tr>
<td><strong>Supine position</strong></td>
<td>115 (100%)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Fracture angle:</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>$&lt; 30^\circ$ (Pauwels 1)</td>
<td>10 (9%)</td>
</tr>
<tr>
<td>$30^\circ - 50^\circ$ (Pauwels 2)</td>
<td>40 (35%)</td>
</tr>
<tr>
<td>$&gt; 50^\circ$ (Pauwels 3)</td>
<td>65 (56%)</td>
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<tr>
<th>Fracture reduction in the AP view</th>
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<tbody>
<tr>
<td>Garden index $&lt; 160^\circ$</td>
<td>16 (14%)</td>
</tr>
<tr>
<td>Garden index $= 160^\circ$</td>
<td>56 (49%)</td>
</tr>
<tr>
<td>Garden index $160^\circ-180^\circ$</td>
<td>43 (37%)</td>
</tr>
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<thead>
<tr>
<th>Fracture reduction in the lateral view</th>
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<tbody>
<tr>
<td>$170^\circ-190^\circ$ (180$^\circ$ = anatomic)</td>
<td>97 (84%)</td>
</tr>
<tr>
<td>$&lt; 170^\circ$ or $&gt; 190^\circ$</td>
<td>18 (16%)</td>
</tr>
</tbody>
</table>

| Cannulated Screws (CS) | 32 (28%) |
| Sliding Hip Screw | 37 (32%) |
| Sliding Hip Screw with antirotational CS | 46 (40%) |
Minor and major postoperative complications developed in 22 (19%) IF and in 31 (28%, p = 0.09) HA patients (table 5). Superficial infection was reported once in the IF group and 4 times in the HA group. Deep infection and a thrombo-embolic event developed in 1 patient in both treatment groups.

**Table 5. Outcome: revision rate, mortality, morbidity and Harris Hip Score**

<table>
<thead>
<tr>
<th></th>
<th>PSS &lt; 20 (HA)</th>
<th>PSS ≥ 20 (IF)</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n = 109</td>
<td>n = 115</td>
<td>[95% Confidence Interval]</td>
</tr>
<tr>
<td>1 year revision rate</td>
<td>3 (3%)</td>
<td>32 (28%)</td>
<td>p &lt; 0.01 [-0.40 to -0.14]</td>
</tr>
<tr>
<td>2 year revision rate</td>
<td>3 (3%)</td>
<td>46 (40%)</td>
<td></td>
</tr>
<tr>
<td>1 year mortality</td>
<td>35 (32%)</td>
<td>10 (9%)</td>
<td>p &lt; 0.01 [0.26 to 0.48]</td>
</tr>
<tr>
<td>2 year mortality</td>
<td>55 (50%)</td>
<td>18 (16%)</td>
<td></td>
</tr>
<tr>
<td>No complications</td>
<td>78 (72%)</td>
<td>93 (81%)</td>
<td></td>
</tr>
<tr>
<td>Minor complications</td>
<td>20 (18%)</td>
<td>18 (16%)</td>
<td>p = 0.09 [-1.95 to 0.07]</td>
</tr>
<tr>
<td>Major complications</td>
<td>11 (10%)</td>
<td>4 (3%)</td>
<td></td>
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| HHS 8 weeks\(^1\)  | 64           |               |
| HHS 1 year\(^1\)   | 72           | 79            | p = 0.02 [1.14 to 14.77]         |
| -pain               | 38           | 39            | p = 1.00 [-3.69 to 5.45]         |
| -function           | 25           | 32            | p < 0.01 [3.54 to 11.16]         |
| HHS 2 year\(^1\)   | 71\(^*\)    | 79            | p < 0.01 [2.37 to 13.39]         |
| -pain               | 39           | 39            | p = 1.00 [-2.96 to 3.36]         |
| -function           | 25           | 33            | p < 0.01 [4.33 to 11.25]         |

HHS 2 year – revised IF: 78\(^*\) \(p = 0.04 [0.61-13.07]\)

\(^1\) The Harris Hip Score is expressed as a mean score.

**PSS scoring agreement** The following coefficients of concordance were calculated between the four raters: Physiologic Status Score 0.88, agreement on therapy 0.92. The concordance for the components of the PSS score were: mobility 0.61, accommodation 0.55, cognition status 0.94, ASA class 0.83. A coefficient above 0.7 is interpreted as good, with 1 representing complete agreement. High concordance was found for therapy decision based on the PSS.

**Outcome** Two years after primary treatment revision had been performed in 46 IF patients (40%; 34% non-union, 6% avascular necrosis) and in 3 HA patients (3%) - see table 5. Figure 3A illustrates the 2 year IF revision rate stratified by PSS group. For IF, the realized outcome of 40% [upper limit 95% CI: 0.48] was 5% above the
meta-analysis 35% revision rate and the expected outcome was not achieved. For HA, the realized outcome of 3% [upper limit 95% CI: 0.06] was significantly below the meta-analysis 16% revision rate and also below the expected outcome of 6%.

Twenty-one primary IF patients were revised to hemiarthroplasty and twenty-five to total hip arthroplasty. Four deep infections (9%) developed after revision to arthroplasty. Mortality after revision (11%) was similar to primary successful IF (16%, p = 0.53, 95% CI: -0.17 to 0.07). The 3 revisions in the HA group consisted of: prosthesis removal due to deep infection, open trochanteric fixation for repeated prosthetic luxation and conversion to total hip arthroplasty due to malpositioning of the prosthesis.

One-year mortality rate in the IF group was 9% and 32% in the HA group (p < 0.01). Two-year mortality was 16% and 50% (p < 0.01) respectively (table 5). Figure 3b illustrates 1 and 2 year mortality stratified by PSS group.

**Figure 3a.** Patients with a PSS ≥ 20 points (IF) in relation to 2 year revision rate (n=115).

**Figure 3b.** PSS in relation to 1 and 2 year mortality (n = 224).
As a result of the PSS selection the Harris Hip Score (HHS) was significantly higher in the primary successful IF group compared to HA (p = 0.02 and p < 0.01 respectively) at 1 and 2-year follow-up. The pain component of the HHS at 1 and 2 year follow-up between successful IF and HA patients was similar (p = 1.00). A higher level of function in the successful IF group was the main reason for the difference in HHS after 1 and 2 years.

After revision of IF, the HHS at 2 year follow-up was higher than in the primary HA group (p < 0.01, 95% CI: 3.27 – 10.00). Again, the difference between the groups was in level of function, not in pain. Compared to successful IF patients, failed IF patients had similar HHS (p = 0.96, 95% CI: -5.50 to 7.50), pain (p = 1.00, 95% CI: -3.43 to 3.34) and function (p = 0.72, 95% CI: -2.67 to 4.68). Figure 4 illustrates the mean Harris Hip Score at 2 year follow-up stratified by PSS group.

**Figure 4.** Mean Harris Hip Score (HHS) at 2 year follow-up. Each bar represents total HHS and is divided into mean Pain score and mean Function plus Range of Motion (ROM) score. Error bars indicate Standard Error of the Mean (SEM) of the total HHS. HA = hemiarthroplasty, IF = internal fixation, successful and failure (n = 151).

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**Logistic Regression** Binary Logistic Regression was performed to determine association between the patient related variables of age, sex, mobility, pre-injury accommodation, bone density, cognition, medical condition, therapy and the outcomes of failure and mortality. Therapy, as determined by the PSS, was the only variable significantly associated with failure; failure was 12 times more likely in the IF group.
Table 6. Subanalysis of failure and technique in relation to age group in the PSS ≥ 20 (internal fixation, IF) and PSS < 20 (hemiarthroplasty, HA) patient groups

<table>
<thead>
<tr>
<th>Age</th>
<th>n</th>
<th>Failure</th>
<th>Non-union</th>
<th>AVN*</th>
<th>TF**</th>
<th>Failure excluding TF**</th>
</tr>
</thead>
<tbody>
<tr>
<td>60-79</td>
<td>70</td>
<td>25 (36%)</td>
<td>20 (29%)</td>
<td>5 (7%)</td>
<td>1</td>
<td>14/59 (24%)†</td>
</tr>
<tr>
<td>&gt; 80</td>
<td>45</td>
<td>21 (47%)</td>
<td>19 (42%)</td>
<td>2 (4%)</td>
<td>4</td>
<td>17/41 (41%)†</td>
</tr>
<tr>
<td>60-90</td>
<td>115</td>
<td>46 (40%)</td>
<td>39 (34%)</td>
<td>7 (6%)</td>
<td>15</td>
<td>31/100 (31%)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Age</th>
<th>n</th>
<th>Failure</th>
<th>Non-union</th>
<th>AVN*</th>
<th>TF**</th>
<th>Failure excluding TF**</th>
</tr>
</thead>
<tbody>
<tr>
<td>60-79</td>
<td>33</td>
<td>1 (3%)</td>
<td>-</td>
<td>-</td>
<td>0</td>
<td>1/75 (1%)</td>
</tr>
<tr>
<td>&gt; 80</td>
<td>76</td>
<td>2 (3%)</td>
<td>-</td>
<td>-</td>
<td>1</td>
<td>1/108 (2%)</td>
</tr>
<tr>
<td>60-90</td>
<td>109</td>
<td>3 (3%)</td>
<td>-</td>
<td>-</td>
<td>1</td>
<td>2/108 (2%)</td>
</tr>
</tbody>
</table>

* Avascular Necrosis, ** Technical failure, † p = 0.03, [95 % CI: 0.04 to 0.40]

[95% CI: 1.3 – 112.67]. In both treatment groups, mortality was significantly associated with a more dependent accommodation status: OR 1.4 [95% CI: 1.02-1.95] and higher ASA class: OR 1.6 [95% CI: 0.99 -2.7].

The logistic and operative technique related variables of institution, delay to surgery, length of operation, fracture reduction in the AP and lateral views, utilized implants and post-operative complications (none, minor and major) were also subjected to Binary Logistic Regression to determine association with failure and mortality. Fracture reduction in varus in the AP view was significantly associated with failure, OR 2.6 [95% CI: 1.3–5.3]. The presence of minor and major postoperative complications was twice as likely to produce failure in both groups, OR 2.00 [95% CI: 1.05-3.70]. The logistic and operative technique variables had no significant association with mortality.

**Sub-analysis of Internal Fixation technique** Both independent experts identified inadequate operative technique on the radiographs of 15 IF patients (14%) of whom 13 also experienced clinical failure, which was unknown to the experts during their analysis. Interobserver agreement on overall technique between the two experts, expressed as the kappa statistic, was 0.65 ± 0,10 indicating good agreement according to Altman. Technical rating was significantly correlated with clinical outcome: Spearman’s correlation co-efficient was 0.41 (p < 0.01).
Excluding these 15 patients with technical failures (TF), the 2 year revision rate in the IF group decreased to 31%, 24% for ages 60-79 and 41% for ages 80 and above - see table 6. The realized outcome excluding TF of 31% [upper limit 95% CI: 0.39] was not significantly below the meta-analysis 35% revision rate. In the subgroup of IF patients aged 60-79 years (n = 59) the realized outcome of 24% [upper limit 95% CI: 0.33] was below expected outcome and therefore significantly below the meta-analysis 35% revision rate.

There was 1 technical failure in the HA group, as stated above. The realized outcome excluding TF for HA decreased to 2% [upper limit 95% CI: 0.04], significantly below the expected outcome of a 6% revision rate.

Discussion
The previously published PSS treatment protocol results were not verified to realize a substantial decrease in revision rate in patients aged 60 to 90 years selected for internal fixation (IF). The selected IF patients were able to tolerate revisional surgery without consequences for mortality or functional outcome. The IF revision rate in these relatively healthy and ambulatory patients was comparable to meta-analysis data. As claimed in the original study, the use of the Physiologic Status Score treatment protocol did realize a decrease in the revision rate of hemiarthroplasty (HA) for displaced femoral neck fracture patients aged 60 to 90 years. Compared to meta-analysis data available at the time of the sample size calculation the revision rate for HA was reduced from 16% to 3% after 2 years.

The original PSS study outcomes among patients from 65 to 85 years old in 1994, showing a 2% revision rate in the IF group and 5% in the HA group when adopting the treatment protocol, could only be reproduced for the HA group in our current multi-center setting. In the same age range as the original study the present results showed a 37% failure rate for IF and a 3% failure rate for HA. In view of the 50% mortality rate in the present study, the original study mortality of 14% after 21 months in the HA group may be suggestive of selection bias. Another possible reasons for the different outcome is the use of exact DXA instead if the poorly reproducible Singh index for bone density measurement. The negative verification in the selected IF patient group emphasizes that the development of a decision-score should follow recognized guidelines and should be validated preferably in different centers.

It remains uncertain whether the threshold of 20 points, as published in the original study, was correct. Analysis of patients with PSS of 20 to 26 showed that the revision
rates (figure 3a) after IF in the present study would not have changed if the threshold had been set at a higher level, although the smaller number of patients in the stratified groups are insufficient. The finding of decrease in age and mortality (figures 2 and 3b) in the range of 19-21 points is suggestive of a threshold of higher physiologic status in this range. Hemiarthroplasty has not been shown to influence mortality. Below 20 points, the PSS is associated with a high (50%) 2-year mortality. If patients with a PSS below 20 had been internally fixated, it is likely in theory that the IF revision rate for these patients, aged 82 years on average, would have been unacceptable and outweighs the potential functional benefit gained from IF. A higher failure rate in the octogenarian IF group was also reported by Barnes. The low revision rate and comparable morbidity support HA in the PSS < 20 group.

The patient's age is adopted in many treatment algorithms for displaced femoral neck fractures\textsuperscript{19,20}, but it often does not represent physiologic age properly. The PSS did have a significant correlation with age, but the mean values of each of the five PSS score components were significantly different in the two treatment groups. Each component therefore appears valid. The factors of mobility, accommodation status, bone density, cognition and past medical history have each been suggested to be associated with clinical outcome.\textsuperscript{8} Logistic regression in this current study refuted their separate association with outcome, but the combination of these 5 individual factors into a single PSS, which determined therapy, was significant in the regression model (Wald statistic: 4.1).

Reliable pre-operative DXA scanning of patients with a displaced femoral neck fracture was performed without additional personnel within the hospitals and did not delay treatment. In our experience, patient discomfort was comparable to plain radiography of the hip. Spine bone density alone was a reliable indicator if hip measurement is not possible (i.e. contralateral endoprosthesis). The correlation ($r=0.44$) of bone density of the lumbar spine and the femoral neck was significant ($p<0.001$) in this study. Another reason for performing DXA scans is compliance with clinical practice guidelines of the Dutch Health Care Quality Institute, which conform to United States guidelines and recommend DXA for all patients sustaining a hip fracture.\textsuperscript{21,22} In the case of osteoporosis, treatment with bifosfonates, calcium and an exercise schedule are evidence-based recommendations, which may help to prevent future fractures from minor trauma.\textsuperscript{21,22}

Rigid attention to surgical technique and infection prevention measures are essential considering the potentially higher morbidity in HA patients.\textsuperscript{4,5,6} Adequate reduction
and fixation are of paramount importance to minimise revisions in IF patients. Complacency to rely more on implant than precise fracture reduction and implant positioning has been shown to produce poor results.\textsuperscript{23} Logistic regression in this study revealed that fracture reduction in the AP view was a significant technical factor associated with failure, which is supported by the literature.\textsuperscript{24,25} In our current study, the technical rating panel identified 13% technical failures even in supervised operations. Delegation of IF for displaced femoral neck fractures to junior inexperienced staff cannot be justified as optimum management. The issue of IF technique is underrated in published studies and meta-analyses. Rating of the pre-, intra- and postoperative radiographs may be inferior to rating operative technique during a theatre session, but the significant correlation ($r=0.44$) of technical rating with clinical outcome appears to justify the method applied in this study.

IF with either cannulated cancellous screws or sliding hip screws (SHS) could be performed according to the study protocol. This recommendation was based on a meta-analysis pooling the data from 25 randomised studies incorporating 4.925 patients, which showed no significant difference between multiple (2-4 cannulated) screws and SHS in relation to clinical outcome.\textsuperscript{26} Although the present study protocol recommended a fixed-angle SHS device for fracture angles $>50$ degrees (Pauwels 3 type fracture),\textsuperscript{27,28} no significant difference in revision rate between SHS and 3 cannulated screws in Pauwels 3 type fractures was found: 35% and 53% respectively ($p = 0.63$). This finding concurred with meta-analysis results.\textsuperscript{26} We recommended using bone cement for endoprosthesis stem insertion based on Cochrane review data, which favoured cementing when regarding pain relief and functional outcome.\textsuperscript{29} Postoperative complications were not significantly different in both groups. A trend towards more major complications in the hemiarthroplasty group was found. No significant difference between IF and arthroplasty was also found in a meta-analysis reporting the incidence of pneumonia (Relative Risk, RR 0.85), thrombo-embolic events (RR 1.15), congestive heart failure (RR 0.89), stroke (RR 0.75) and pressure sores (RR 1.06). Only risk of deep infection (RR 3.85) was significantly higher in arthroplasty patients.\textsuperscript{5}

To minimise the possible selection bias on admission, surgical residents in each participating hospital were instructed to phone about every potential study candidate patient at presentation. In our experience, the availability of a mobile telephone number 24 hours a day for discussion about patient inclusion helped to achieve the reported high inclusion rate.
Before designing this study, a Dutch questionnaire inquiring about indications for either IF or HA showed a large variation. Therefore it would not be possible to design a multi-center randomised study to compare the PSS strategy with current treatment as no uniform current treatment existed. The PSS concept appears a useful guide, but the composition of the score and its implications require refinement. The addition of primary Total Hip Arthroplasty (THA) as a treatment modality for suitable patients also requires further study. We hypothesize that future studies should aim to either randomise by implant (IF vs HA vs THA) within pre-selected groups, based on individual patient characteristics or randomise enough patients representative of all possible subgroups of patients. In the first design the patient's condition is considered first; in the second design there are enough patients enrolled to compare the treatments within the subgroups of patient conditions.

In summary, the PSS treatment protocol does not improve decision-making for femoral neck fracture treatment in a substantial way. The PSS protocol does realize a very low risk of HA revision within 2 years in more frail patients when compared to meta-analysis data. The PSS treatment protocol did not realize a decrease of IF revisions in more healthy and ambulatory patients as previously reported. Revision of appropriate IF is tolerated by active patients aged 60-79 years with a PSS ≥ 20; in this group revision (risk of 1 in 4) does not affect mortality or functional outcome after 2 years. Above 80 years, even in high functional demand patients with a PSS ≥ 20, IF cannot be recommended as the revision risk is nearly 1 in 2.

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References


