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Research Article

# Evaluating Clinical Outcomes of the New Femoral Neck System (Depuy Synthes) for Femoral Neck Fractures

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## ABSTRACT

**Introduction:** The recently introduced Femoral Neck System (FNS) (DePuy Synthes, Zuchwil, Switzerland) is developed for dynamic fixation with rotational stability of a fracture of the femoral neck (FNF). The aim of this study is to evaluate early implant outcomes and the rate of implant failure within 6 months of follow up.

**Methods:** For this cohort study data was extracted from a prospective hip fracture database. Patients receiving a FNS in a level II trauma teaching hospital between 1 January 2018 and 13 May 2021 were included. Follow-up duration was at least 6 months.

**Result:** A total of 81 patients were included, with a median age of 67 years. Patients were most frequently female (45/81) and had most frequently an ASA score of 1 and 2 (52/81). The FNFs were non-displaced fractures in 61 patients and in 9 patients Pauwels type I, in 42 patients type II and in 30 patients type III. Time to surgery was 17 hours (IQR 10–21) and surgery time was 34 minutes (IQR 28–41). In 6 patients avascular necrosis of the femoral head was diagnosed after six months of follow-up. No significant baseline differences were found between patients who developed AVN and patients without this complication.

**Conclusion:** Early results appear to show that the FNS can be a safe alternative for dynamic osteosynthesis with rotational stability of a FNF using a smaller incision and shorter surgery time.

## INTRODUCTION

Femoral Neck Fractures (FNFs) account for approximately 50% of all hip fractures [1]. Based on the patient's age, associated comorbidities and fracture characteristics of the FNF, optimal surgical treatment is determined. FNFs in young patients are preferably treated with internal fixation to preserve the femoral head [2]. Dynamic Hip Screw (DHS) (in combination with an antirotation screw) could be the treatment of choice for these patients since it seems to provide more stability than Cannulated Hip Screws (CHS) [3-5]. For older patients with non-displaced FNFs both CHS and DHS can be considered [6,7]. However, especially in older patients osteosynthesis of FNFs is associated with higher complication rates than with hip (hemi) arthroplasty. Reported complications are Avascular Necrosis (AVN) of the femoral head and non-union of the FNF. These result in relatively high revision rates and therefore Hip Arthroplasty (HA) is the treatment of choice for displaced FNFs in elderly fragile patients [8]. However, for displaced fractures in young patients and non-displaced

FNFs in fragile patients internal fixation has advantages. This type of fixation is associated with a shorter surgery time, reduced blood loss and less risk of infection [9]. The Femoral Neck System (FNS) (DePuy Synthes, Zuchwil, Switzerland) was recently introduced to dynamically fixate FNFs and combine angular stability with a minimally invasive surgical technique (Figure A)[10]. Previously, biomechanical studies in human cadaveric femora appeared to show that the FNS has significantly higher overall construct stability than CHS and has comparable construct stability compared to DHS [3]. The minimally invasive surgical technique using the FNS may reduce blood loss, muscle damage and postoperative pain [10]. Previous clinical studies that assessed clinical outcomes of FNS either included a limited number of (young) patients or had short follow-up duration. The aim of this study is to evaluate early implant outcomes and the rate of implant failure within 6 months of follow up.

Figure A: Femoral Neck system [10].

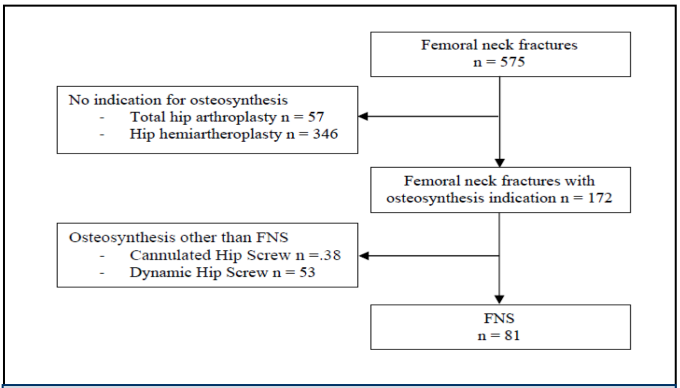


Figure A: Femoral Neck system [10].

## PATIENTS AND METHODS

**Study design, setting and participants**

In this cohort study all consecutively admitted patients between 1 January 2018 and 13 May 2021 in a level II trauma teaching hospital located in Rotterdam, the Netherlands, were screened for eligibility [11]. Inclusion criteria were a non-pathological FNF for which osteosynthesis was indicated. The decision for femoral head preserving surgery and dynamic fixation was made in shared decision making with the patient. Fixation methods other than FNS were excluded. Follow-up duration was at least six months.

**Perioperative variables**

Baseline were extracted from patients' charts. The American Society of Anesthesiologist (ASA) score was used to provide insight in the extent of comorbidities of a patient. The Charlson Comorbidity Index (CCI) was calculated to estimate the frailty of the patient based on several comorbidities [12]. Fractures were categorized using the Garden classification for dislocation and Pauwels classification for the angle of the fracture, measured on preoperartive hip X-ray and intraoperative fluoroscopy [13]. Time to surgery was measured as hours between admission and start of surgery. Surgery time was the time needed to perform the surgery measured in minutes.

Surgical perioperative conditions were standardized according to the hospital protocol. All surgeries were performed in laminar airflow theatres. Cefazolin (Kefzol) 1–3grams was administered intravenously 20-30 minutes pre-operatively as antibiotic prophylaxis. After training by one of the surgical specialists of Depuy Synthes eventually seven senior trauma surgeons and two surgical residents directly supervised by a senior trauma surgeon performed all surgeries. Estimated blood loss was extracted from patients' medical charts and hemoglobin loss was used as a proxy of perioperative blood loss (measured as the difference between the preoperative hemoglobin level and the lowest postoperative hemoglobin level (in g/dL) [14].

Postoperative hematomas were diagnosed by physical examination, where a blue/purple discoloration (ecchymosis) and swelling of the skin surrounding the incision was used as a clinical definition. Surgical Site Infections (SSI) were diagnosed based on the classification system of the United States Centers for Disease Control and Prevention of surgical site infections (CDC criteria) [15]. Admission duration was the number of days a patient was admitted at the hospital. During follow-up, union of the fracture was assessed using X-ray of the hip at the outpatient clinic, following local hospital protocol at six weeks, three months and six months. If AVN of the femoral neck was suspected an independent trauma surgeon assessed the X-rays and the patients were discussed in the multidisciplinary team for the best following treatment options.

**Statistical analysis**

Data was stored in a cloud-based clinical data management platform (Castor EDC; Amsterdam; The Netherlands). Categorical variables are presented as frequencies and percentages, whereas continuous variables are presented as means with a Standard Deviation (SD) in case of normal distribution, or as median with an Interquartile Range (IQR) in case of skewed distribution. To provide more insight in which patients were prone to developing AVN of the femoral neck univariable analysis was performed with a significance level of 5%, $p<0.05$, using Stata version 14.0 (StataCorp, Collega Station, Texas, USA). No correction or substitution for missing data or loss to follow-up was performed.

## RESULTS

A total of n=575 FNFs were screened for eligibility, of which n=172 had an indication for osteosynthesis. Eventually n=81 patients received an FNS (Figure B). Baseline characteristics are presented in Table 1. The median age of the patients was 67years (IQR 56–77). Patients were most frequently female (45/81) and had most frequently an ASA score of 1 and 2 (52/81). FNFs were most frequently non-displaced (61/81). In 9 patient the FNF was Pauwels type I, in 42 Pauwels type II and in 30 Pauwels type III.

Table 1: Baseline characteristics of 81 included patients.

| Factor | Overall (81) | Successful osteosynthesis (75) | AVN of femoral neck (6) | p-value |
|---|---|---|---|---|
| | n / known n (%) | n / known n (%) | n / known n (%) | |
| **Age**(years)(median (IQR)) | 67 (56 – 77) | 66 (55 – 78) | 74 (63 – 76) | 0.487^ |
| **Female gender** | 45/ 81 (56) | 42 / 75 (56) | 3 / 6 (50) | 0.776* |
| **ASA score** | | | | |
| 1 | 11 / 81 (14) | 10 / 75 (13) | 1 / 6 (17) | 0.819* |
| 2 | 41 / 81 (50) | 40 / 75 (53) | 1 / 6 (17) | 0.084* |
| 3 | 28 / 81 (35) | 24 / 75 (32) | 4 / 6 (66) | 0.086* |
| 4 | 1 / 81 (1) | 1 / 75 (2) | 0 / 6 (0) | 0.776* |
| **CCI** (median(IQR)) | 3 (2 – 4) | 3 (1 – 4) | 3 ( 2 – 4) | 0.770^ |
| **Non-displaced fracture** | 61 / 81 (75) | 56 / 75 (75) | 5 / 6 (83) | 0.636* |
| **Displaced fracture** | 20 / 81 (25) | 19 / 75 (25) | 1 / 6 (17) | 0.636* |
| **Garden classification** | | | | |
| Type 1 | 33 / 81 (41) | 31 / 75 (42) | 2 / 6 (33) | 0.701* |
| Type 2 | 28 / 81 (34) | 25 / 75 (33) | 3 / 6 (50) | 0.409* |
| Type 3 | 16 / 81 (20) | 16 / 75 (21) | 0 / 6 (0) | 0.207* |
| Type 4 | 4 / 81 (5) | 3 / 75 (4) | 1 / 6 (17) | 0.168* |
| **Pauwels classification** | | | | |
| Type 1 | 9 / 81 (11) | 9 / 75 (12) | 0 / 6 (0) | 0.368* |
| Type 2 | 42 / 81 (52) | 40 / 75 (53) | 2 / 6 (33) | 0.345* |
| Type 3 | 30 / 81 (37) | 26 / 75 (35) | 4 / 6 (67) | 0.118* |
| **Preoperative Hb** (mmol/L)(mean±SD) | 8.4 ± 0.9 | 8.4 ± 0.9 | 8.8 ± 0.5 | 0.241^ |
| **Preoperative GFR** (mL/min/1.73m$^2$) (median(IQR)) | 80 (70 – 90) | 81 (71 – 90) | 71 (59 – 90) | 0.437^ |
| **Walking aid preoperative** | | | | |
| None | 69 / 81 (85) | 64 / 75 (85) | 5 / 6 (83) | 0.894* |
| Walking cane | 3 / 81 (4) | 3 / 75 (4) | 0 / 6 (0) | 0.618* |
| Rollator | 9 / 81 (11) | 8 / 75 (11) | 1 / 6 (17) | 0.653* |
| **Residential status** | | | | |
| Home | 77 / 81 (95) | 71 / 75 (95) | 6 / 6 (100) | 0.562* |
| Semi-independent nursing home | 1 / 81 (1) | 1 / 75 (1) | 0 / 6 (0) | 0.776* |
| Nursing home | 3 / 81 (4) | 3 / 75 (4) | 0 / 6 (0) | 0.618* |

Wilcoxon rank-sum test, Pearson's chi-squared test, AVN: Avascular Necrosis; ASA: American Society of Anesthesiologists; Hb: Hemoglobin; GFR: Glomerular Filtration Rate; BMI: Body Mass Index; CCI: Charlson Comorbidity Index

Perioperative characteristics and clinical outcomes were presented in Table 2. Median time to surgery was 17 hours (IQR 10–21). Median surgery time was 34 minutes (IQR 28–41). Median perioperative blood loss was 60mL (IQR 50–100) and Δhemoglobin was 0.7 (IQR 0.4–1.1)mmol/L. One patient needed packed cell supplementation due to postoperative anemia. Median admission duration was 4 days (IQR 3–6). No surgical site infections were diagnosed.

AVN of the femoral head was diagnosed in 6 patients after six months follow-up. No significant baseline or perioperative differences were found between patients who developed AVN and patients without this complication.

Table 2: Surgical characteristics of 81 included patients.

| Factor | Overall (81) | Succesful osteosynthesis (75) | AVN of femoral neck (6) | p-value |
|---|---|---|---|---|
| | n / known n (%) | n / known n (%) | n / known n (%) | |
| **Time to surgery**(hours) (median(IQR)) | 17 (10 – 21) | 17 (7 – 21) | 18 (18 – 20) | 0.366^ |
| **Anesthesia**(spinal) | 70 / 81 (86) | 64 / 75 (85) | 6 / 6 (100) | 0.313* |
| **Surgery time**(min) (median(IQR)) | 34 (28 – 41) | 34 (28 – 42) | 29 (25 – 34) | 0.395" |
| **Blood loss**(mL)(median (IQR)) | 63 (50 – 100) | 75 (50 – 100) | 50 (50 – 50) | 0.406^ |
| **Δ Hb**(mmol/L)(median (IQR)) | 0.7 (0.4 – 1.1) | 0.7 (0.4 – 1.1) | 0.8 (0.6 – 1.1) | 0.347^ |
| **Packed cell supplementation** | 1 / 81 (1) | 1 / 75 (1) | 0 / 6 (0) | 0.776* |
| **Hematoma** | 2 / 81 (2) | 2 / 75 (3) | 0 / 6 (0) | 0.685* |
| **Surgical site infection** | 0 / 81 (0) | 0 / 75 (0) | 0 / 6 (0) | - |
| **VAS pain postoperative day 1** (mean±SD) | 3 ± 1 | 3 ± 2 | 4 ± 1 | 0.132" |
| **Admission duration** (days)(median(IQR)) | 4 (3 – 6) | 4 (2 – 5) | 6 (4 – 8) | 0.074^ |
| **Mobility at discharge** | | | | |
| Walking cane/crutch | 33 / 80 (41) | 30 / 74 (41) | 3 / 6 (50) | 0.631* |
| Rollator | 39 / 80 (49) | 37 / 74 (50) | 2 / 6 (33) | 0.450* |
| Wheelchair/person | 8 / 80 (10) | 7 / 74 (9) | 1 / 6 (17) | 0.562* |

^ Wilcoxon rank-sum test, *Pearson's chi-squared test, "Student's t-test

AVN: Avascular Necrosis; Hb: Haemoglobin; VAS: Visual Analogue Scale.

## DISCUSSION

The purpose of this study was to describe clinical outcomes of the FNS implant in a large patient cohort. During follow-up of 6 months n=6 patients (7%) developed AVN or cut out of the femoral head. Previous studies have assessed the biomechanical characteristics of the FNS in human cadaveric femora [3,16]. These studies concluded that FNS has significantly higher overall construct stability than Cannulated Hip Screws (CHS, DePuy Synthes) or Hansson Pins and comparable construct stability to the Dynamic Hip Screw (in combination with an antirotation screw)(DHS, DePuy Synthes) [3,16]. Few clinical studies have been performed to assess clinical outcomes after FNS implant. These studies however either included a limited number of (young) patients or had short follow-up duration [9,17-19]. Zhou et al. compared FNS (n=30) with CHS (n=30) in patients younger than 65years of age and a Pauwels type III FNF. In this study no AVN of the femoral head was diagnosed. Also no difference in surgical time (FNS 43minutes (SD±5) and CHS 41minutes (SD±5)) or admission duration (FNS 5days (SD±1)) and CHS 5days (SD±2)) were found. However, Zhou et al. did find more blood loss in patients receiving FNS compared to patients receiving CHS (100±5 versus 30±9, $p<0.001$). However the clinical relevance of the 70cc difference in blood loss could be questioned, in their study no patients received packed cell supplementation [18]. Our study found a comparable amount of perioperative blood loss to the cohort of Zhou et al., except for one patient, who did receive packed cell supplementation.

Hu et al. also compared the FNS (n=20) with CHS (n=24) in patients younger than 60 years of age. They concluded that after FNS implant less femoral head shortening and screw cut-out was found compared to the use of CHS. Hu et al. diagnosed one patient (5%) with AVN after FNS implant after one year follow-up [17]. Previous meta-analysis showed that the incidence of AVN of the femoral head in young patients after osteosynthesis of FNFs was 14.3%, but wide ranges have been reported [20]. In our cohort an incidence of 8% AVN of the femoral neck was found after six months of follow-up. The higher incidence of AVN of the femoral neck in our cohort compared to the study of Hu et al. could be explained by lower bone mineral density (BMD) in older patients compared to the young patients in the cohort of Hu et al [17]. Lower BMD not only leads to decreased stability and a higher chance of femoral neck shortening after osteosynthesis, but also explains why FNFs in older patients are frequently frailty fractures that occur after low-impact trauma [17,19]. In young patients FNFs are usually caused by high-energy trauma, such as falls from height or high speed traffic accidents [17,20] . It is possible that decreased stability of osteosynthesis, in our cohort FNS, due to lower BMD led to higher incidence of AVN of the femoral head in older patients.

Two clinical studies evaluated the clinical outcomes of FNS implant in older patients [9,19]. Nibe et al. compared FNS with CHS and Hansson Pins and found comparable blood loss but shorter surgery time in patients receiving FNS (42minutes ±13 versus 53minutes ±21, p=0.032)[19]. In our study cohort surgery time was shorter than in the cohort of Nibe et al. (34min (IQR 28–42)). The mean surgery time is shorter compared to the mean DHS and CHS surgery times reported in literature, showing a mean surgery time of 66–111 minutes for DHS and 47–62 minutes for CHS [21,22]. An explanation for the shorter surgery time of the FNS could be the small incision, less dissection and surgical steps necessary for positioning the FNS implant. Besides costs and efficiency, surgery time could be a determinant for surgical site infections, perioperative blood loss, longer anesthesia and overall higher rates of postoperative complications [9,11,23].

Vasquez et al. compared a limited number of patients after the use of CHS, DHS and FNS and found no revision surgery after FNS placement in older patients [9]. Their results are comparable to the results of Nibe et al. Both studies however included limited number of patients after FNS placement, n=27 and n=15 respectively [9,19]. The limited number of included patients can explain the differences in incidence of AVN between these two studies and our results [24].

## STRENGTHS AND LIMITATIONS

Data used in this study was extracted from a large and comprehensive prospective hip fracture database with real time registration of patients (FAMMI)[25]. This however could not have prevented potential selection bias and treatment bias since the indication for femoral head preserving surgery and dynamic fixation was decided by the group of orthopedic trauma surgeons in shared decision making with the patient. The present study is not the first study presenting early clinical outcomes and implantation of the FNS, but in contrast to previous literature this study was conducted in a relatively large patient cohort.

## CONCLUSION

In this cohort study AVN of the femoral head occurred in n=6 patients (7%) after FNS placement. The AVN percentage seems to be lower than previously reported incidences of AVN of the femoral head in other types of osteosynthesis of FNFs [20]. It appears the FNS could be a safe alternative for dynamic osteosynthesis with rotational stability of FNFs with smaller dissection and shorter surgery time compared to other dynamic implants. Nevertheless, long-term follow-up is needed to evaluate long-term clinical outcomes as well as comparison of clinical outcomes of the FNS with other dynamic implants after FNF.

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