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New insights in the treatment of femoral neck fractures

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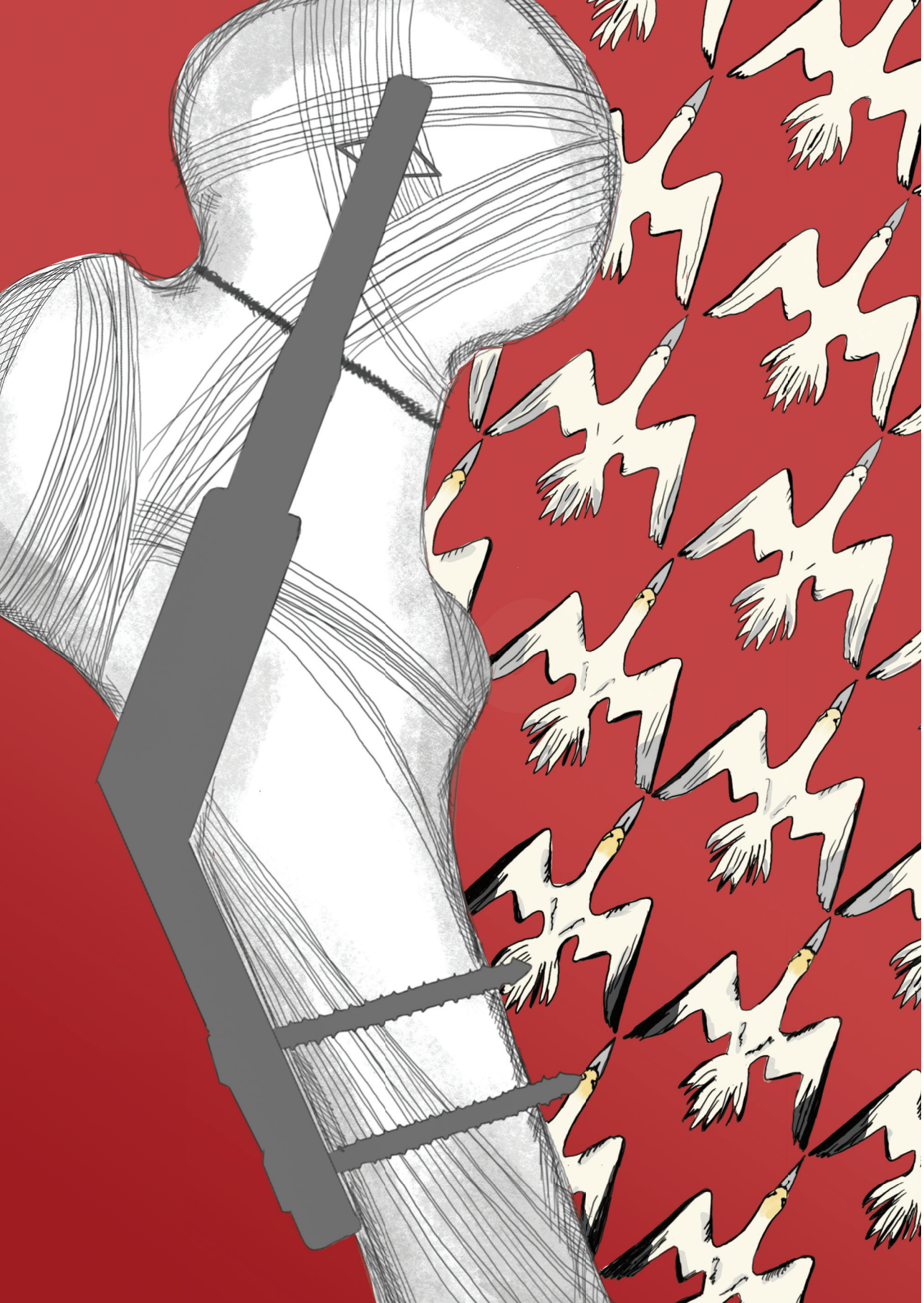
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Chapter 6

The Dynamic Locking Blade Plate: Seven-year follow-up results of 389 patients with a femoral neck fracture

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ABSTRACT

Purpose

This study aimed to investigate the long-term outcomes of patients with a femoral neck fracture (FNF), treated with the Dynamic Locking Blade Plate (DLBP).

Methods

Retrospective analysis of prospectively collected data of a multicentre cohort of hip fracture patients was conducted, regarding the long-term incidence of revision surgery after DLBP. Implant failure was evaluated using Kaplan-Meier and Cox regression analysis. Secondary outcomes were the indication for revision surgery, complications, time to revision surgery, rate of elective removal of the implant, potential predictors for revision surgery and mortality.

Results

Median follow-up of 389 included patients was 98 months; 20.6% underwent revision surgery; 28.8% after treatment of a displaced FNF (dFNF) and 10.0% with a undisplaced FNF (uFNF). 5.7% (n=22) of the patients had operation related complications and 32.9% (n=128) deceased during follow-up. Median time to revision surgery was 13 (dFNF) and 18 months (uFNF). 15.7% of the DLBPs were electively removed. In the multivariate Cox regression analysis, female gender (hazard ratio 2.1, 95% CI 1.2–3.7) and a TAD >25mm (hazard ratio 2.9, 95% CI 1.7–5) were significant predictors for revision surgery in patients with dFNF.

Conclusion

This study is the first long-term follow-up study on the outcome of the DLBP. The DLBP demonstrated positive long-term results in the treatment of FNF.

INTRODUCTION

The treatment of femoral neck fractures (FNFs) has been discussed extensively for many decades. The two main surgical treatment options are internal fixation and (hemi) arthroplasty. However, both treatments know potential disadvantages and complications. Arthroplasty of the hip is associated with dislocation, pulmonary embolism, cement induced syndrome, limited implant survival and severe morbidity due to infection^{1,2}, Internal fixation is associated with high failure rates (10–49%) due to non-union, avascular necrosis (AVN) of the femoral head and cut-out of the implant.³

To improve the outcome of head preserving treatment of FNFs, the Dynamic Locking Blade Plate (DLBP) was developed, a fixed angle device characterized by its excellent rotation stability, low implant volume and simple operation technique.⁴⁻⁶ The DLBP demonstrated good results in treatment of FNF, with 4% failure rate at one year in a prospective multicentre cohort study of 172 patients with undisplaced FNFs (uFNF).⁵ Another prospective cohort study of 106 young patients with displaced FNFs (dFNF) demonstrated a failure rate of 13.2% after one year.⁶ A randomised controlled trial comparing the DLBP with the Dynamic Hip Screw is ongoing at this moment.⁷

The follow-up of these studies was limited because most of the complication occur within one year. Yet some FNFs are still revised after one year.^{8,9} Kelly et al. found a mean time to revision of 1.3 years (range 73 days – 4.9 years) within a cohort of FNFs treated with a sliding hip screw with a mean follow-up time of 8.2 years (range 6.7–10.1).¹⁰ Mean time to AVN varies between 16–18.8 months with a total range of 3–60 months.¹¹⁻¹³ Patients may also suffer from posttraumatic osteoarthritis (PTOA) which can present years after the initial trauma. In 35% of patients treated for FNF, PTOA is found to be the indication for subsequent total hip arthroplasty.¹⁴

The aim of this study was to investigate the long-term outcomes of patients with an FNF, treated with the DLBP. More specifically, the need for and type of revision surgery were evaluated, as were complication and mortality rates in patients with a minimum of seven years follow-up.

PATIENTS AND METHODS

Design and cohort

Retrospective analysis of prospectively documented data of a multicentre cohort including 468 adult patients treated with the DLBP between 2010–2014 was conducted. In this cohort all consecutive patients of any age with a uFNF, patients with a dFNF of ≤65 years and

patients between 65 and 75 years who were not dependent on walking aids and who were not admitted in a nursing home prior to the fracture were included. Their prospectively registered data including clinical outcomes up to one year have been published previously.^{5, 6} For the present study, all patients with an FNF from this cohort with a minimum follow-up of seven years, or shorter if the endpoint (revision surgery or death) was reached before seven years of follow up, were eligible. Patients who met any of the following criteria were excluded in this study:

- Pathological fracture
- Ipsilateral or contralateral fracture(s) of the lower extremity
- Symptomatic osteoarthritis or radiographic osteoarthritis grade III or IV¹⁵
- Previous surgery of the ipsilateral hip
- Patients who were wheelchair-bound in their pre-injury situation
- Patients who were not mentally competent to take a survey

Study outcome parameters

The main study outcome parameter was the incidence of revision surgery, defined as any reoperation due to failure of treatment (cut-out of the implant, AVN, non-union, or PTOA), such as conversion to (total) hip arthroplasty, girdle stone, core decompression, vascular fibular graft, valgus (intertrochanteric) osteotomy. Elective removal of the DLBP after union of the fracture was not considered as revision surgery.

Secondary outcome parameters were the indications for revision surgery (AVN, non-union, cut-out of the implant, PTOA), operation related complications such as bleeding or infection and general hospital complications such as delirium and pneumonia, time to revision surgery, elective removal of the DLBP, and mortality. AVN was defined as stage 2 necrosis and upward, according to the Steinberg classification.¹⁶ Our definition of non-union was based on the Radiographic Union Score for Hip (RUSH).¹⁷ Non-union was defined as a visible fracture line on the radiograph, absence of cortical bridging or bridging trabeculae over the fracture site in combination with persisting pain in the hip or the inability to bear weight for at least 9 months after surgery or sooner if revision surgery was performed because it was no longer expected that fracture healing would occur. PTOA was defined as having symptoms of OA including pain, stiffness of the joint with or without radiologic findings of OA in absence of AVN, non-union or cut-out of the implant.

Other data registered in the database were age, gender, fracture displacement, posterior tilt of the femoral head, time to surgery, operation time, reduction of the fracture, Tip-Apex-Distance (TAD), postoperative complications, mortality and revision rate and indication for revision at one year. Fracture displacement was assessed according to the Garden classification with uFNF defined as Garden type 1 & 2 and dFNF as Garden type 3 & 4.¹⁸ The Garden

Alignment Index was used to evaluate the fracture reduction on the first postoperative radiograph.¹⁹ The acceptable range of reduction is a 160 to 180° angle.^{20,21} Posterior tilt was measured using the posterior tilt measurement according to Palm et al.²²

Study procedure

If patients were eligible for the present study, outcome data additional to their one-year follow-up data were collected from the medical records. If information on the presence or absence of revision surgery during at least seven years, and if applicable peri-operative information of the revision surgery, could not be found in the records, the patient was contacted by telephone. If information on the primary outcome could not be retrieved the patient was excluded. Seven years follow-up was chosen because time between implantation of a DLBP in the last included patient and the start of data collection was seven years.

Statistical analysis

Statistical analysis was performed using SPSS Statistics 28 software (IBM Corp., Armonk, New York) for Windows 10 Home (Microsoft, Redmond, Washington). The data was analysed in subgroups of patients with uFNF and dFNF. Results are presented as frequency and percentage for categorical data and mean (standard deviation) or median (range) for continuous data. Difference in revision rate between the groups with uFNF and dFNF was evaluated using Kaplan-Meier survival curves and compared with the log-rank test. Kaplan-Meier analysis was also used to compare revision surgery rates between subgroups of patients with various indications for revision surgery (AVN, non-union, cut-out of the implant, posttraumatic OA). Potential predictors for revision surgery (female gender, operation performed by a surgical resident, TAD>25mm, age>65 years, inadequate reduction for dFNF and posterior tilt >20° in uFNF) were assessed using univariable and multivariable Cox proportional hazards regression analysis, separately for the uFNF and dFNF groups. Statistical significance was set at $p<0.05$.

Ethical approval

This study was conducted in compliance with the declaration of Helsinki (2008) and the principles of good clinical practice (GCP). According to the institutional Medical Research Ethics Committee, this study did not meet the criteria of the Dutch Medical Research Involving Human Subjects Act (WMO), so that ethical approval was not needed.

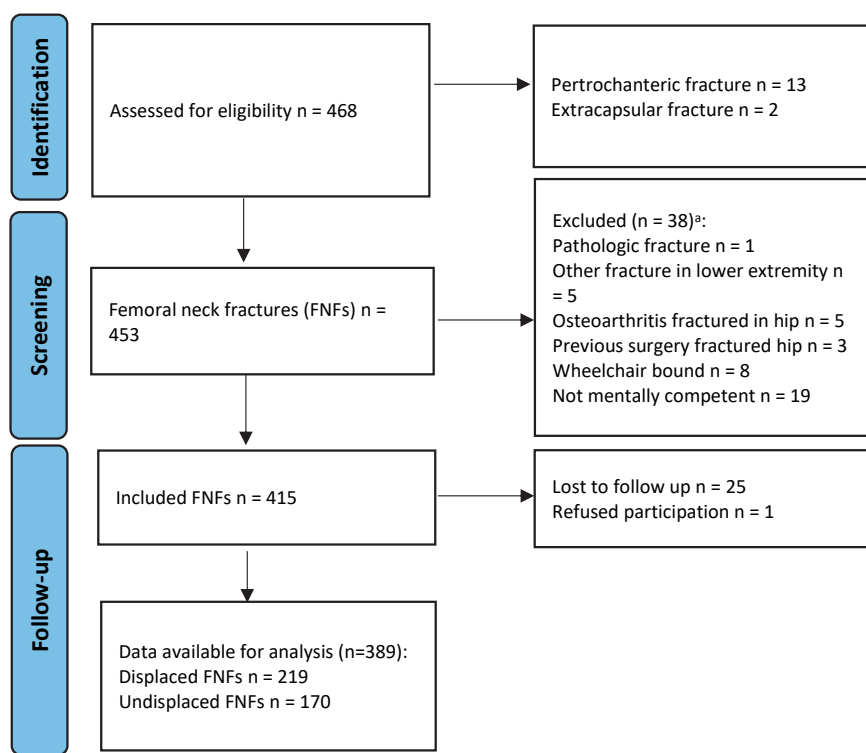


Figure 1. STROBE flow diagram

^a Some patients met multiple exclusion criteria

RESULTS

Seventy-nine of the 468 patients in the cohort were excluded, leaving 389 patients eligible for analysis (219 with dFNF and 170 with uFNF). Reasons for exclusion are presented in Figure 1. The characteristics of the study population are presented in Table 1. Median follow-up was 98 months (range 0–150) and similar in both dFNF and uFNF. Of the 389 patients, 80 patients (20.6%) underwent revision surgery, 63 of the 219 patients with a dFNF (28.8%) and 17 of the 170 patients with a uFNF (10.0%). The rate of revision surgery was higher for the dFNF group than for the uFNF group (Figure 2; log-rank test $p < 0.001$).

Twenty-two patients (5.7%) had an operation related complications and 41 patients (10.5%) had one or more general hospital complications. Detailed information about complications can be found in Tables 2 and 3. Almost one third of all patients ($n = 128$, 32.9%) died during follow up. There were three instances of in-hospital deaths; one patient died after a cardiac event, another patient experienced a fatal pneumonia and the third patient expired due to heart failure secondary to a pneumonia.

Table 1. Demographic and clinical characteristics of 389 included patients

Variable	Total n=389	Displaced FNF n=219	Undisplaced FNF n=170
Mean age, in years (SD)	65.8 (13.3)	62.8 (12.2)	69.7 (13.7)
Male, n (%)	169 (43.4)	106 (48.4)	63 (37.1)
Mean operation time, in minutes (SD) ^a	43.1 (18.7)	43.9 (19.5)	42.0 (17.7)
Operating physician, n (%) ^b			
Surgeon	328 (84.8)	183 (83.6)	145 (86.3)
Surgical resident	59 (15.2)	36 (16.4)	23 (13.7)
Time to surgery, n (%)			
within 24 hours	321 (82.9)	187 (85.8)	134 (79.3)
within 48 hours	362 (93.5)	206 (94.5)	156 (92.3)
Mean TAD, in mm (SD) ^c	21.4 (6.9)	21.6 (7.2)	20.1(6.5)
Mean posterior tilt, in degrees (SD)	13.8 (9.8)	N/A	13.8 (9.8)
Inadequate reduction, n (%)	48 (12.9)	29 (13.8)	19 (11.8)
Median follow-up, in months (range)	98 (0–150)	99 (0–150)	98 (0–150)

^a N=9 missing.^b N=2 missing.^c N=21 missing.

FNF = femoral neck fracture; SD = standard deviation; TAD = Tip-Apex-Distance; N/A= not applicable.

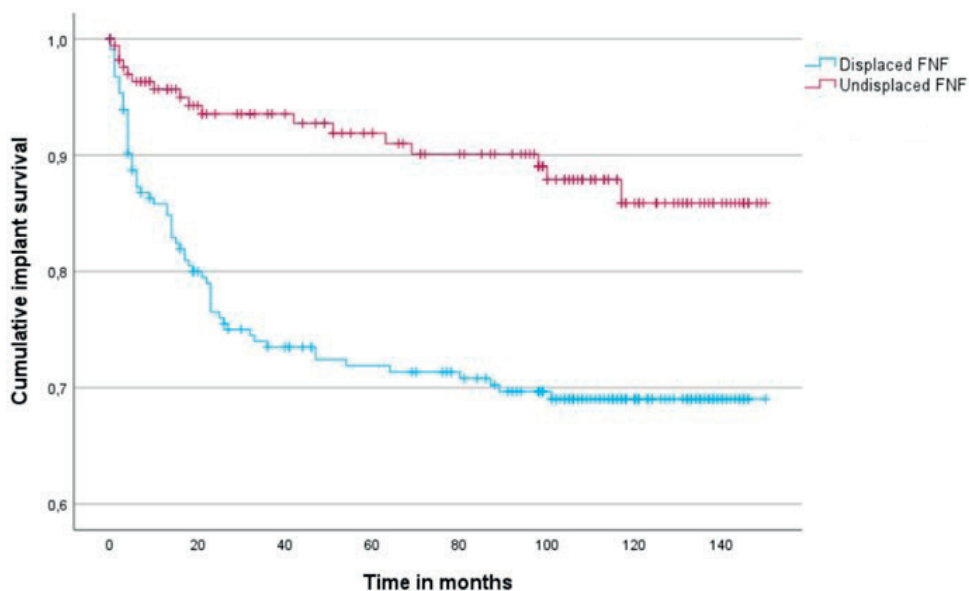
**Figure 2.** Kaplan–Meier curves for time to revision surgery in patients with displaced FNF and undisplaced FNF. Log-rank test, $p < 0.001$.

Table 2. General complications in 389 femoral neck fracture patients

Complication	n
Urinary retention	4
Urinary tract infection	2
Delirium	19
Pneumonia	7
Ileus	2
Hypertension	1
Electrolyte disturbance	2
Decubitus	1
Cardiac event	6
Anaemia	1
Alcohol withdrawal seizure	1
Renal dysfunction	1
Heart failure	1
Total	48

Table 3. Perioperative complications in 389 femoral neck fracture patients

Complications	n
Wings of implant did not expand (partially)	9
Piece of drill head remained in femoral head	1
Fracture Related Infection	3
Gauze remained in wound	1
Device malfunction	1
Postoperative bleeding	6
Blade measured too short and was revised in a second operation	1
Total	22

The type and indications for revision surgery for dFNF and uFNF are presented in Table 4. Although the difference in indications for revision surgery did not reach statistical significance, dFNFs seemed to be more often revised due to AVN than uFNFs (46.0% vs. 29.4% $p=0.22$), while uFNFs seemed to more often need revision due to PTOA (47.1% vs. 25.4%, $p=0.08$). Figure 3 shows the Kaplan Meier curve for time to revision surgery per indication for revision for dFNF and uFNF together. Median time to revision for PTOA was 32 months and respectively 1, 4 and 14 months for cut-out, non-union and AVN (log rank test, $p<0.001$). In three patients treatment failed (two cut-out, one AVN), yet no revision was performed because the patients could not be operated; two patients had severe lung disease and one patient was 90 years old and had a poor clinical condition. Sixty-one (15.7%) DLBPs were electively removed after union.

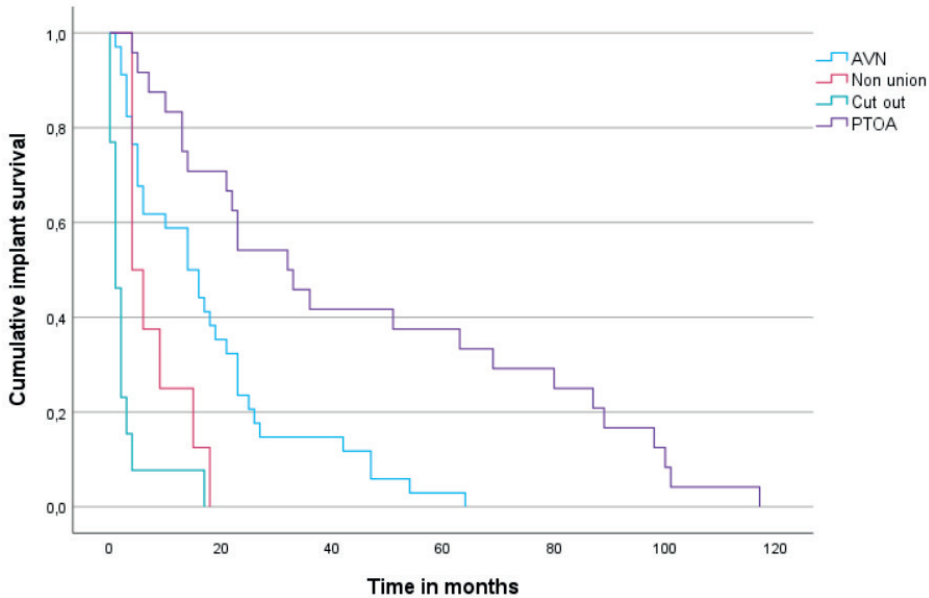


Figure 3. Kaplan–Meier curves for time to revision surgery by indication for revision. Log-rank $p < 0.001$. AVN=avascular necrosis, PTOA=Posttraumatic osteoarthritis.

Table 4. Type and indication for revision surgery after treatment with the Dynamic Locking Blade Plate

Revision type	Total n=80	Displaced FNF n=63	Undisplaced FNF n=17	p-value
Total hip arthroplasty, n (%)	74 (92.5)	58 (92.1)	16 (94.1)	0.78
Hemiarthroplasty, n (%)	6 (7.5)	5 (7.9)	1 (5.9)	
Indication				
Avascular necrosis, n (%)	34 (42.5)	29 (46.0)	5 (29.4)	0.22
Non-union, n (%)	8 (10.0)	7 (11.1)	1 (5.9)	0.52
Cut out, n (%)	13 (16.3)	10 (15.9)	3 (17.6)	0.86
Posttraumatic osteoarthritis, n (%)	24 (30.0)	16 (25.4)	8 (47.1)	0.08

^a One patient in the displaced FNF group was revised abroad, the indication for revision could not be determined. FNF = femoral neck fracture

The multivariable Cox proportional hazards regression analysis did not identify any predictors for revision surgery in the uFNF group (Table 5). Female gender (hazard ratio 1.99, 95% CI 1.14–3.49) and a TAD >25 mm (hazard ratio 2.66, 95% CI 1.52–4.67) were statistically significant predictors for revision surgery in patients with dFNF. Notable was that fracture reduction was not a significant predictor for revision surgery in the dFNF group. Yet in a multivariate analysis, fracture reduction was a significant predictor for AVN after dFNF (HR 2.90, CI 95% 1.20–7.01, Table 6). None of the other characteristics were predictors for AVN.

Table 5 Predictors for revision surgery of femoral neck fractures (FNF) treated with the Dynamic Locking Blade Plate: uni- and multi-variable Cox regression analyses

		Univariable analysis		Multivariable analysis	
Displaced FNF		Hazard ratio (95% CI)	p-value	Hazard ratio	p-value
Gender	Male	Reference			
	Female	1.70 (1.02–2.83)	0.04	1.99 (1.14–3.49)	0.02
Surgeon	Surgeon	Reference			
	Surgical resident	1.06 (0.55–2.02)	0.87	1.04 (0.53–2.04)	0.91
TAD	≤25 mm	Reference			
	>25 mm	2.20 (1.31–3.69)	0.03	2.66 (1.52–4.67)	<0.001
Age	≤65 years	Reference			
	66–75 years	1.50 (0.89–2.57)	0.13	1.33 (0.76–2.33)	0.32
	>75 years	1.28 (0.56–2.90)	0.56	1.47 (0.64–3.38)	0.36
Reduction	Adequate reduction	Reference			
	Inadequate reduction	1.75 (0.93–3.29)	0.83	1.53	0.22
Undisplaced FNF					
Gender	Male	Reference			
	Female	2.71 (0.78–9.44)	0.12	2.79 (0.78–10.02)	0.12
Surgeon	Surgeon	Reference			
	Surgical resident	2.76 (0.97–7.87)	0.06	2.30 (0.76–6.95)	0.14
TAD	<25 mm	Reference			
	≥25 mm	1.16 (0.38–3.54)	0.80	1.64 (0.51–5.23)	0.41
Age	≤65 years	Reference			
	66–75 years	2.08 (0.67–6.49)	0.21	1.85 (0.58–5.97)	0.30
	>75 years	1.40 (0.42–4.68)	0.59	1.45 (0.43–4.91)	0.55
Posterior tilt	≤20°	Reference			
	>20°	1.80 (0.68–4.72)	0.24	1.87 (0.70–5.01)	0.22

DISCUSSION

In this study we evaluated the revision rate of FNF treated with the DLBP during a minimum follow-up of seven years. The revision rate was 10.0% in uFNF and 28.8% in dFNF. Long-term results of large prospective multicentre cohorts of patients with FNF are rare in literature. There are only few studies investigating outcomes of more than 100 patients with FNFs treated with IF, with a follow-up of at least five years.^{23–27} All of these studies concerned treatment with cannulated screws or pins. The rates of revision surgery presented in these studies range from similar to our results to much higher percentages, 31.3–45.6% in dFNF and 10.7–19.0% in uFNF. We have not been able to find any large, long-term studies of

Table 6. Independent predictors for avascular necrosis of the femoral head (AVN) of patients with displaced femoral neck fractures (FNF) treated with the Dynamic Locking Blade Plate: uni- and multi-variable Cox regressions

		Univariable analysis		Multivariable analysis	
Displaced FNF		Hazard ratio (95% CI)	p-value	Hazard ratio	p-value
Gender	Male	Reference			
	Female	1.50 (0.72–3.15)	0.28	1.45 (0.64–3.28)	0.38
Surgeon	Surgeon	Reference			
	Surgical resident	1.30 (0.53–3.19)	0.57	1.44 (0.56–3.74)	0.45
TAD	≤25 mm	Reference			
	>25 mm	1.73 (0.78–3.82)	0.18	1.77 (0.75–4.20)	0.20
Age	≤65 years	Reference			
	66–75 years	1.01 (0.44–2.34)	0.98	0.85 (0.35–2.10)	0.72
	>75 years	1.44 (0.48–4.30)	0.51	1.79 (0.58–5.50)	0.31
Reduction	Adequate reduction	Reference			
	Inadequate reduction	2.89 (1.27–6.55)	0.01	2.90 (1.20–7.01)	0.02

FNF treated with a DHS. However, studies with a short (i.e. 12 to 24-month) follow-up have shown revision rates of 24–41% in dFNF and 9.8–16.3%.^{9, 28–29} Low implant volume and high angular and rotational stability may attribute to improved stability of the fracture-implant complex and subsequent lower revision rates. However, it also could be that these five studies included predominantly older people, with an average age of 77–82 years for patients with a dFNF and 79–81 years for patients with a uFNF, compared to 63 and 70 years respectively in our study.^{23–27} These age differences render comparison of results and interpretation of findings of these studies difficult.

In concordance with earlier findings in literature, dFNFs were revised more often than uFNFs (28.8% vs 10.0%). These numbers are higher than previously reported revision rates of the DLBP with a follow-up of one year.^{5,6} In our cohort the median time to revision surgery was 13 months for dFNF and 18 for uFNF. Other studies also found a median time to revision surgery of more than one year.^{10–13} Figure 2 demonstrates dFNF were revised more often in the first 24 months. This might be due to the specific indications for revision. We found that 46% of the dFNFs needed revision surgery because of AVN, in comparison to 29.4% of uFNF. UFNFs were more often revised because of PTOA (25.4% vs 47.1%). Although this difference is not significant, probably because of the low rate of revisions in the uFNF group, the results present a trend regarding the different indications for revision surgery in dFNFs and uFNFs. Figure 3 shows that AVN was revised at an earlier stage than PTOA. Median time until revision for AVN was 14 months and 32 months for PTOA. Thirty percent of all

revisions were due to PTOA. These numbers are corresponding with the 35–38% described in literature.^{14,30} However, there is no other literature describing time to PTOA and overall incidence of PTOA after FNF.

We could not find any independent predictors for revision surgery in uFNFs. This might be due to a lack of statistical power with only 17 revisions in the undisplaced fracture group of 170 patients. The inherent stability of an undisplaced fracture and the preservation of a significant portion of vascularization in these fractures will probably be the main factors that attribute to low revision rates. Female gender and a TAD >25 mm showed to be independent predictors for revision surgery in displaced hip fractures and increased the risk respectively 2.0 and 2.7 times. A recent meta-analysis provided an overview of predictors for revision of internally fixated dFNFs and also identified female gender as a predictor for revision surgery (OR 1.78, 95% CI 1.26–2.52).³¹ TAD was not associated with a higher risk of revision surgery in this systematic review. However only one included study in this review described TAD as a possible predictor and interestingly, this study utilized the same population as the current study with one year follow-up.⁶ TAD is widely described as a predictor for failure after fixated extracapsular fractures but not for intracapsular FNFs.³² On the other hand, reduction of the fracture has been widely described in literature as a predictor for revision surgery after internal fixation of FNFs.³¹ However, based on our data, fracture reduction did not emerge as a significant predictor. Fracture reduction has a large influence on the vascularisation of the femoral head and therefore on the risk of AVN. Due to the long follow-up of this study a rather large amount of patients with dFNFs were revised because of PTOA (25.4%). The follow-up in the studies included in the meta-analysis of Kalsbeek et al. was 24 months at most versus a median follow-up of 98 months in this study. Possibly these patients are mainly revised due to AVN and therefore reduction has more influence on the revision rate. We could not retrieve information on the proportion of FNFs that needed revision because of AVN in the studies included in the meta-analysis. To test the hypothesis that reduction of the fracture is a predictor for AVN we performed a multivariable Cox regression analysis on our data (Table 6). Fracture reduction was a predictor for AVN in dFNF (HR 2.90, CI 95% 1.20–7.01). This indicates that reduction of the fracture is essential to ensure viable vascularisation to the femoral head and prevent AVN.

PTOA may occur due to the fact that a fractured hip, even with optimal reduction, will never fully regain its original anatomical integrity. Due to these (little) biomechanical changes the load distribution through the hip differs and accelerates decline of joint cartilage. Furthermore, a decreased vascularisation of the femoral head and cartilage after an FNF in elderly patients could impair the ability to slow this increased degeneration.

Strengths of this study are its large cohort, its prospective inclusion of the patients, long follow-up and the small percentage of patients lost to follow-up. A small part of the data

was collected retrospectively. This causes limitations inherent to a retrospective set-up. Furthermore, we studied a young population with FNFs whereas most other studies will show a higher average age of their study population. This age difference renders comparison between groups difficult. Other limitations are the absence of a valid functional outcome and the lack of registration of more possible predictors for revision surgery, such as smoking [31].

CONCLUSION

This study is the first long-term follow-up study on the outcome of the DLBP and first large long-term cohort study of FNFs with a relatively young population. Although study populations differ throughout literature and are not exactly comparable to our patients cohort, the DLBP demonstrated positive long-term results in the treatment of FNFs, with an overall 7-year revision rate of 20.6%, a revision rate of 28.8% for dFNF, and 10.0% for uFNF. Our study identified female gender and a TAD >25 mm as predictors for revision in dFNF.

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