Displaced femoral neck fractures in patients 60 years of age or younger: results of internal fixation with the dynamic locking blade plate

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Aims

The objective of this study was to investigate bone healing after internal fixation of displaced femoral neck fractures (FNFs) with the Dynamic Locking Blade Plate (DLBP) in a young patient population treated by various orthopaedic (trauma) surgeons.

Patients and Methods

We present a multicentre prospective case series with a follow-up of one year. All patients aged ≤ 60 years with a displaced FNF treated with the DLBP between 1st August 2010 and December 2014 were included. Patients with pathological fractures, concomitant fractures of the lower limb, symptomatic arthritis, local infection or inflammation, inadequate local tissue coverage, or any mental or neuromuscular disorder were excluded. Primary outcome measure was failure in fracture healing due to nonunion, avascular necrosis, or implant failure requiring revision surgery.

Results

In total, 106 consecutive patients (mean age 52 years, range 23 to 60; 46% (49/106) female) were included. The failure rate was 14 of 106 patients (13.2%, 95% confidence interval (CI) 7.1 to 19.9). Avascular necrosis occurred in 11 patients (10.4%), nonunion in six (5.6%), and loss of fixation in two (1.9%).

Conclusion

The rate of fracture healing after DLBP fixation of displaced femoral neck fracture in young patients is promising and warrants further investigation by a randomized trial to compare the performance against other contemporary methods of fixation.

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The biology of the fracture healing of femoral neck fractures (FNF) is characterized by its specific type of bone healing and the vascularity of the femoral neck and head. These biological features place the FNF apart from most other fractures, including the intertrochanteric fractures of the hip. Awareness of the biological characteristics of the FNFs is prerequisite in their operative treatment.

The viability of the femoral head after FNF is dependent on preservation of the remaining vascular supply and on revascularization and repair of the necrotic areas before collapse of the necrotic bone segment can occur.[1-4] To preserve the remaining blood supply to the displaced femoral head, accurate reduction and stable fixation is critical in any attempt to salvage the femoral head.[1] An important source of revascularization is the vascular ingrowth across the uniting fracture line.[2] The transverse shear and the rotational interfragmentary movement (IFM) caused by poor fracture stabilization are deleterious to revascularization as they disrupt angiogenesis in the femoral head.[3,4] stated that decreased or absent vascularity of the femoral head is seen in approximately 75% of FNFs, whereas 80% of femoral heads with initial vascular compromise seem to regain blood flow within six weeks. The (re)vascularization of the femoral head is further compromised when using implants with larger volumes, as this may increase the incidence of avascular necrosis (AVN).[5,6]

Bone healing of FNF is determined by the anatomical fact that the intracapsular portion of the neck has essentially no cambium layer in its fibrous covering to participate in external callus formation.[7] The cells in the cambium

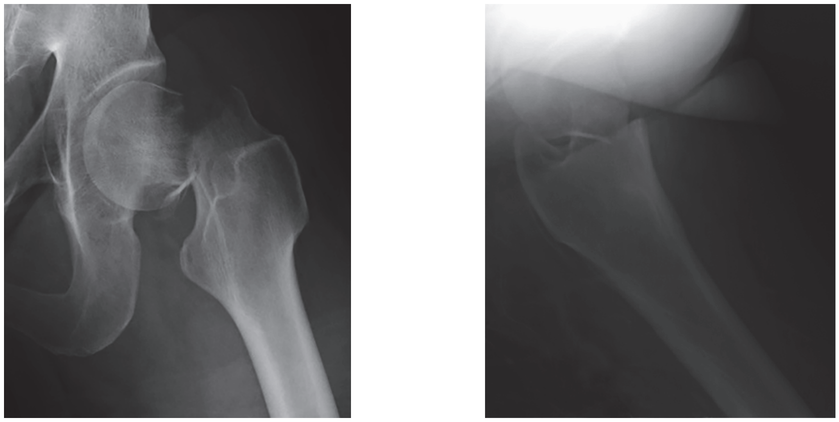

Fig. 1a Fig. 1b

a) Anteroposterior and b) lateral radiograph of displaced femoral neck fracture in a 57-year-old woman.

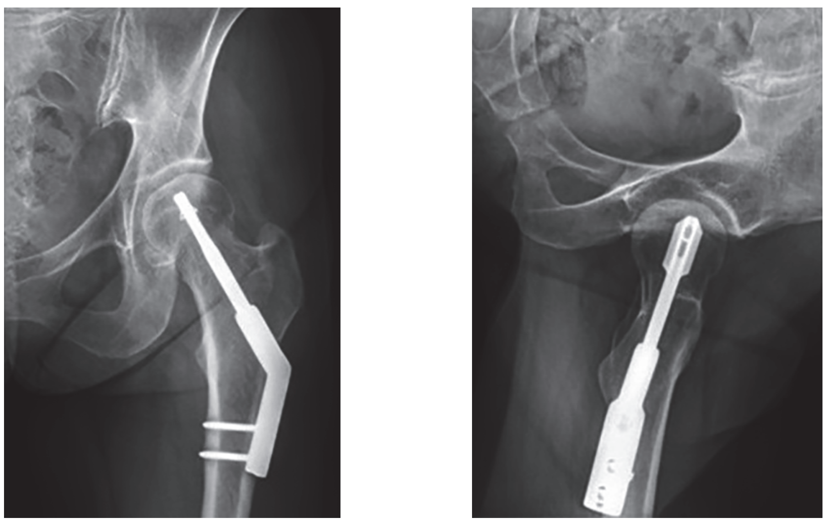

Fig. 2a Fig. 2b

a) Anteroposterior and b) lateral radiograph of the patient in figure 1 following treatment using the dynamic locking blade plate with union of the fracture line.

layer of the periosteum are highly proliferative and osteogenic, and respond to mechanical stimulation.[8] Unlike diaphyseal, but similar to scaphoid fractures, FNFs cannot heal by periosteal (external) callus formation; hence, healing is by primary osteonal reconstruction.[9,10] Primary bone healing requires anatomical reduction and a stable fixation. In the context of fixation of FNF the term, 'stable' means that the transverse shear and rotational IFM are minimized within the strain tolerance of 2% while allowing controlled axial IFM.[11]

The consensus is that young patients with displaced FNF are treated by internal fixation, whereas elderly patients are treated by total or hemiarthroplasty (Fig. 1).[12-15] Generally, patients aged < 60 years are considered to be young patients.[16] However, treatment of a displaced FNF by internal fixation remains controversial because of the high failure rate encountered after internal fixation. Overall, the literature gives an incidence of between 30% and 33% for nonunion, and between 10% and 16% for AVN in displaced fractures.[17-20] The data received from the FAITH trial of 350 patients show 11.1% nonunion and 6.3% AVN, and an overall revision rate of 22.3% for displaced FNF.[21] Revision rates of 35%[19]and up to 48%[20] for displaced fractures were reported in two large meta-analyses. More recently, Parker et al[22] reported a revision rate of 20.7% in 320 patients with displaced FNF treated with the Targon femoral neck plate (TFN; Aesculap, B. Braun, Tuttlingen, Germany). A 2015 meta-analysis[16] on the results of internal fixation in patients < 60 years old with a displaced FNF reported a revision rate of almost 18%.

The most commonly used implants are multiple parallel (cannulated) screws or sliding hip screw (SHS) devices.[23] It

Fig. 3

Dynamic locking blade plate with impaction anchors

is obvious that not all factors contributing to the failure rate of the FNF are related to the implant. Other factors such as primary displacement, posterior comminution, fracture reduction, and implant positioning are even more important than implant choice.[24-26]

However, triggered by the poor results of internal fixation achieved with the current implants, we analyzed the possible biological, surgical, and implant-related factors contributing to the high failure rate, and formulated features of a new implant tailored to the fixation of FNF. We then developed this new implant with the working name ‘Dynamic Locking Blade Plate’ (DLBP, Baat Medical, Hengelo, Netherlands). It is characterized by a low implant volume combined with rotational and angular stability while allowing controlled axial compression (Fig. 2).

The DLBP was initially tested by two surgeons (WHR, ADPW) who participated in the development of the implant. This earlier small pilot study with a follow-up of two years reported a failure rate of 8% in 25 patients (mean age 60 years; 39 to 75) with undisplaced or displaced FNF.[27] A larger prospective multicentre study of the DLBP with a follow-up of one year demonstrated a failure rate of 4% among 149 patients (mean age 69 years, 35 to 101) with an undisplaced FNF.[28] The primary objective of the present study was to determine the failure rate of the DLBP in a general population of previously unreported patients aged < 60 years of age with a displaced FNF and treated by various orthopaedic (trauma) surgeons and surgical trainees. Secondary objectives were to determine complication rates, radiographic outcome, and mobilization after surgery, and compare these between groups.

Patients and Methods

Design and cohort. This was a multicentre prospective case series. After review, no ethical approval was deemed necessary.

All patients aged ≤ 60 years admitted to the participating hospitals with a displaced FNF were treated by internal fixation with a DLBP. In the event that the on-call surgeon was unfamiliar with the DLBP or the patient chose otherwise following informed consent, patients were treated with an arthroplasty or an implant other than the DLBP (e.g. cannulated hip screws or SHS).

All patients aged ≤ 60 years of age or younger treated by the DLBP were included, while all patients treated with an arthroplasty or any implant other than the DLBP were excluded. Pathological fractures, concomitant fractures of the lower limb, symptomatic arthritis, local infection or inflammation, inadequate local tissue coverage, or any mental or neuromuscular disorder, which would create an unacceptable risk of fixation failure, complications or evaluation postoperatively, were excluded.

A displaced FNF was defined, by an independent radiologist, as a grade 3 or 4 fracture according to the conventional Garden classification.[29] Following surgery, patients were mobilized by permissive weight-bearing according to their preference determined by pain.

Implant. The DLBP was developed by Baat Medical, and is now marketed as the ‘Gannet’. The DLBP consists of a two-hole standard 135° barrelled side-plate combined with a low-volume cannulated locking blade (Fig. 3). The side plate provides angular stability and allows controlled dynamic axial compression of the fracture. Two side wings at the tip of the blade provide rotationally stable fixation of the locking blade in the femoral head. The expandable impaction anchors lock the blade in the femoral head and prevent perforation and backing out of the implant and further augment the rotational stability.[30] The volume of the DLBP inserted 50 mm into the head is 1800 mm^3. The volumes of the DHS and three cannulated screws are respectively 2700 mm^3 and 2520 mm^3.[31]

Surgery was undertaken by general orthopaedic and trauma (orthopaedic) surgeons. All participating surgeons were trained in the use of the DLBP, and the first surgical procedure was undertaken under the supervision of a surgeon with wide experience of the DLBP. Trainee surgeons were always supervised by a senior consultant. Reduction was performed using a closed technique for all the fractures. The surgical technique is described in an earlier published study.[30,32]

Outcomes measurements. Anteroposterior (AP) and lateral radiographs were assessed by an independent radiologist and by the treating surgeon (WHR, ADPW, JPAMV, HMJJ, TW, BPB) for fracture healing and complications. The radiographs were standardized for projection and for rotation within the pain limits. Follow-up was performed by the authors at six weeks, three months, and one year. The primary outcome measure, failure of fixation, is

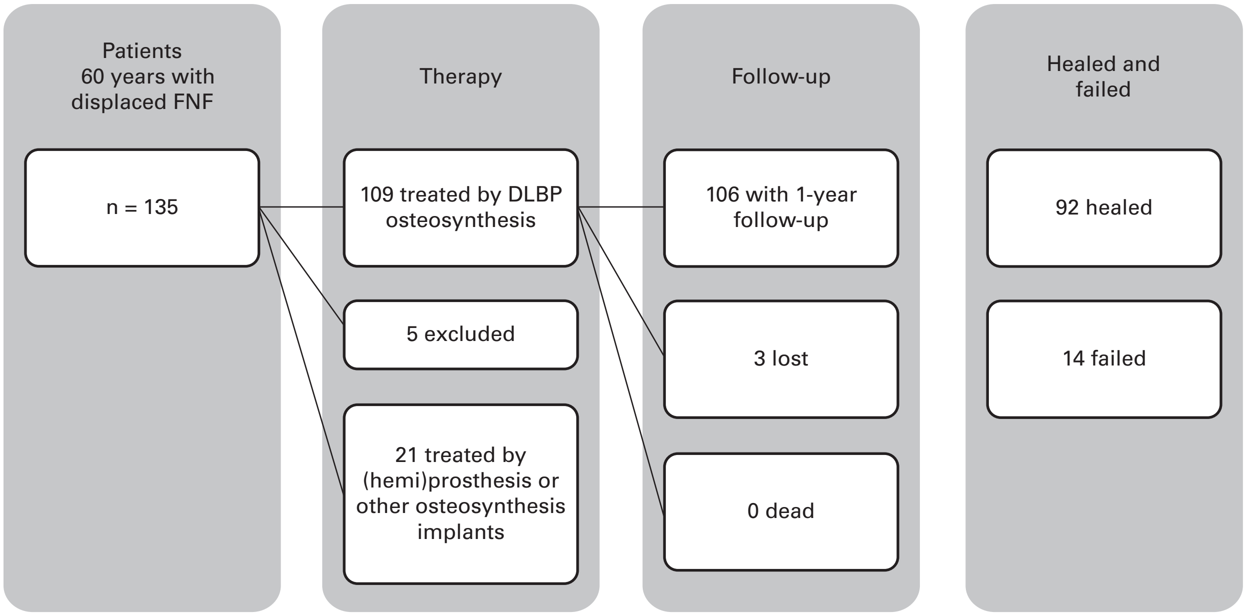

Fig. 4

Flowchart of patient population. DLBP, dynamic locking blade plate; FNF, femoral neck fracture.

defined as the need for revision surgery because of nonunion, AVN, or cut-out of the implant. Union was defined by an absence of radiologically visible margins in the fracture. Nonunion was identified by either displacement of the fracture or clearly visible margins of the fracture one year postoperatively. AVN was defined according to the Steinberg classification from stage 2 and upward.[33] The Garden Alignment Index was used to evaluate the fracture reduction on the first postoperative radiograph.[34,35] As reported previously, the acceptable range of reduction is a 160 to180° angle.[36,37] The impaction at the fracture site was assessed by measuring the extent of telescoping of the lag screw with correction for magnification in millimetres. The position of the locking blade in the femoral head, as a predictor of implant cut-out, was assessed by the corrected tip-apex distance (TAD) on the first postoperative radiographs; TAD > 25 mm is predictive of a higher extrusion rate.[24] The radiological measurements were performed by the authors (WHR, ADPW, JPAMV, HMJJ, TW). Before and one year after surgery, mobility was assessed by need for walking aids: no walking aids, one crutch, two crutches, or a walking frame.

Statistical analysis. Statistical analysis was performed using SPSS v. 2 software (IBM Corp., Armonk, New York) for Windows 7 (Microsoft, Redmond, Washington). The primary analysis was descriptive. Frequencies and percentages are reported for categorical data, and means and ranges for continuous data are presented. Mean differences between groups (healed *versus* failed) were compared using Student's *t*-test and chi-squared test. Statistical significance was defined as a p-value < 0.05.

Results

One level 1 community trauma centre and four level 2 community teaching hospitals participated in the study. Between 1 August 2010 and 31 December 2014, 135 consecutive patients aged ≤ 60 years with a displaced FNF were admitted to these hospitals. Of these, 21 patients were treated by devices other than the DLBP: eight chose a hemiarthroplasty or total hip arthroplasty following informed consent, and 13 were treated by other implants than the DLBP because the on-call surgeon was unfamiliar with the DLBP. The remaining 114 patients were treated with the DLBP, and of these five were excluded: two had a psychological disorder, two had known neuromuscular disease, and one had concomitant fractures of the lower limb. The fracture healed in four of these five patients. Thus, of the 135 patients with a displaced FNF, 109 were included in the study. None of the patients died within the follow-up period and only three were lost to follow-up (Fig. 4). Seven patients did not have a radiograph obtained after one year. Follow-up after one year by telephone interview revealed that none of the seven patients underwent revision surgery.

Surgery was undertaken by (orthopaedic) trauma surgeons 30 (86%) and trainee surgeons 5 (14%). Follow-up for all included patients was at least one year. For the 106 patients completing the study, their mean age was 52 years (23 to 60) 49 (46%) were female. Of the treated patients, 90 (85%) were operated within 24 hours and 103 (97%) within 48 hours. Mean operating time was 44 minutes (15 to 102). One patient developed a local complication of a deep infection. The patient was successfully treated with single debridement and 30

Table I. Variable characteristics divided in healed and failed fractures

	Healed	Failed	p-value
Female, n (%)	40 (43.5)	9 (64.3)	0.163*
Mean age, yrs (SD)	51.5 (8.4)	53.1 (6.1)	0.474†
TAD > 25 mm, n (%)	22 (23.9)	4 (28.6)	0.742†
Malreduction, n (%)	11 (12.0)	2 (14.3)	0.681*

*chi-squared test
†Student's *t*-test
TAD, tip-apex distance

Gentamicin beads (Septopal) were placed into the wound. Before surgery the patient received 1 gram of Kefzol iv. After 16 days the Gentamicin beads were removed and replaced with resolvable Gentamicin sponges (Garacol). Full functional recovery was achieved and the DLBP was not removed.

One implant-related complication, failure of the expansion of the impaction anchors, was noted in five patients. In one patient, the insufficient expansion of the anchors was accompanied by a high TAD of 29 mm, resulting in implant extrusion and loss of fixation. Loss of fixation was not seen in any of the other four cases. There were no perforations or backing out of the implant, and no breakage of blades, plates, or screws occurred. Overall, mean TAD was 22.0 mm (9.0 to 40.0) and mean impaction was 7.1 mm (0 to 23).

Failure rate for the displaced femoral neck secured by the DLBP was 14 of 106 patients (13.2%; 95% confidence interval (CI) 7.1 to 19.9). There were no statistical differences between the healed and failed group in terms of gender, age, or TAD. In the group of healed fractures, 11 (12.0%) fractures were inadequately reduced, while there were two (14.3%) malreductions in the failed patient group (Table I).

AVN was the most common complication. In the 14 failed fractures, bone healing was complicated by: AVN in 11 patients (10.4%), nonunion in six (5.6%), and loss of fixation in two (1.9%). Four patients had a combination of complications. Three of the six nonunions were combined with AVN and one patient suffered a combination of nonunion, AVN, and cut-out. In all of the 14 failed cases, revision surgery was performed by total hip arthroplasty. All patients, except one who required a walking frame, were free of walking aids before surgery. Only five patients did not recover to the preinjury mobility grade. Elective implant removal after fracture healing, for possible implant-related complaints, such as pain and irritation around the plate, or on patient's request, was performed in 18 (17%).

Discussion

The goals of surgical treatment for displaced FNF are 1) to do no further vascular harm, 2) to provide the stability necessary for revascularization of the femoral head and 3) to provide the stability necessary for primary bone healing. The DLBP was designed to be compatible with FNF biology and is a low-volume, dynamic implant providing angular and rotational stability. In this study, DLBP fixation of displaced FNF led to failure caused by AVN in 11 (10.4%) of patients. The viability and stability of the DLBP is also apparent from the low degree of fracture impaction, with a mean of 7.1 mm after one year, while the literature gives an incidence of between 14.7% and 22.5% for AVN in young patients and mean impaction of 9.3 mm.[16,18,38-40]

Other possible implant-related factors contributing to the high failure rate of the common implants are the insufficient intrinsic angular and rotational stability.[41,42] The stability of multiple screws is fully dependent on the three-point fixation principle based on precise screw placement and is consequently surgeon-dependent.[42] As the most common implants fail to provide adequate rotational stability, the clinical importance of the prevention of rotational IFM seems to be underestimated.[30] Biomechanical testing demonstrated that a decentralized position of a lag screw by only 3 mm in the femoral head can result in rotation of the femoral head around the lag screw, as the physiological load torque could overwhelm the resistance of the cancellous bone around the implant.[41] This rotation initiates a reaction whereby the stability of cancellous bone fails rapidly after the first trabeculae are fractured and that may lead to a cut out of the implant.[43] Resistance of the bone-implant interface depends on the design of the implant. Biomechanical analysis showed that the rotational stability of the DLBP proved to be three times higher than that of SHS.[30] The counter-clockwise rotational stability of a lag screw is negligible.[44] Unlike the SHS devices, no torque force at all is exerted on the femoral head on insertion of the DLBP, and it is therefore unnecessary to insert an extra pin or screw in the femoral head to prevent rotation.

Jenkins et al[45] demonstrated by micro-CT that greatest density and trabecular thickness was found in the centre of the head and the weakest area was the apex and peripheral areas of the head. The DLBP provides stability by using one single implant in the biomechanical most optimal, rotation-neutral, centre-centre position in the femoral head.[41,45] This is contrary to other implants where two, three, or even four screws/pins are placed in suboptimal peripheral positions.[46,47] It was also shown that two or more parallel angular stable screws may be complicated by the so called 'Z effect' (or reverse 'Z effect'), in which the lag screws migrate in opposite directions during physiological loading, which can lead to perforation.[46,47]

Irrespective of the implant used, the single most important step in surgical treatment of displaced FNF is fracture reduction. Surprisingly, in this study, there was almost no difference in failure rates between reduced and malreduced FNFs, indicating that either the number of malreduced fractures was too low to influence our analysis or that the DLBP is capable of stabilizing malreduced FNFs. We acknowledge that each reduction was measured by one observer and an inter and intraobserver variation has to be taken into account.

The second most important technical step is the central and deep positioning of the implant in the femoral head. If the insertion into the femoral head is too shallow and/or too decentralized, the holding power of the implant is reduced.[24] However, in this study, a TAD > 25 mm did not contribute to failure by cut-out. Again, this could be due to the study being underpowered or to the improved holding strength of the DLBP. The stability of the DLBP was demonstrated by a low rate of nonunion (5.6% *versus* between 6% and 11% in the literature) and cut-out (1.9% *versus* between 9% and 13.1% in literature), and not a single case of perforation of the femoral head.[16,21,25,38,39] The overall failure rate in our 106 young patients was 13.2% (14/106). These results compare favourably with the literature and with recently published results of new implants.[22]

The strength of this study is its prospective design and the well-defined young patient population with displaced FNFs. The contribution by a variety of (orthopaedic) trauma surgeons from five different hospitals suggests the findings may have general applicability. Limitations of this study include its relative short follow-up of one year and the lack of a recognized mobility score.

In conclusion, the DLBP has been developed specifically for the fixation of FNFs and is characterized by a combination of dynamic compression, angular and rotational stability, and low implant volume within the femoral head. The DLBP, in this broader study, maintained the performance as demonstrated in an earlier pilot study.[27] The failure rate of the DLBP for displaced femoral neck fractures (13.2%) in young patients is promising and warrants a randomized controlled trial comparing the DLBP with contemporary implants.

Take home message:

- The Dynamic Locking Blade Plate (DLBP) an implant for fixation of femoral neck fractures.

- Rate of fracture healing after DLBP fixation of displaced femoral neck fractures in young patients is promising.

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