Universiteit
Leiden
The Netherlands

New insights in the treatment of femoral neck fractures

Kalsbeek, J.H.

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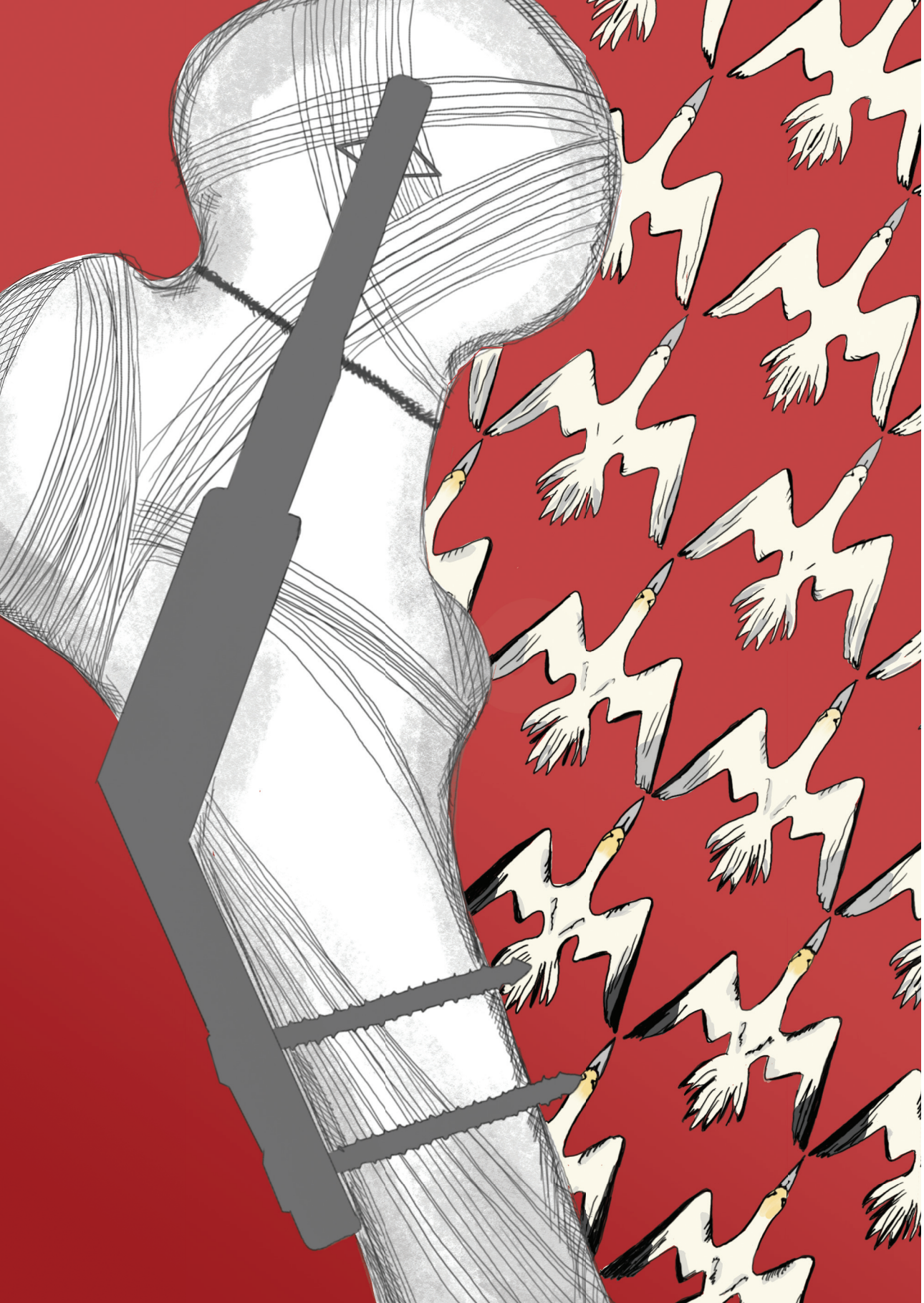

Chapter 5

Displaced femoral neck fractures in patients 60 years of age or younger; results of internal fixation with the Dynamic Locking Blade Plate

J.H. Kalsbeek, A.D.P. van Walsum, J. Vroemen, H.M.J. Janzing,
J.T. Winkelhorst, B.P. Bertelink, W.H. Roerdink

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ABSTRACT

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 1 year. All patients aged ≤60 years with a displaced FNF treated with the DLBP were included. Patients with pathological fractures, concomitant fractures of the lower extremity, symptomatic arthritis, local infection or inflammation, inadequate local tissue coverage, or any mental or neuromuscular disorder were also excluded. Primary outcome measure was failure in fracture healing due to non-union, avascular necrosis or implant failure requiring revision surgery.

Results

In total, 106 consecutive patients (mean age 52 years, range 23–60; 46% [49/106] female) were included. The failure rate was 14 of 106 patients (13.2%, CI 7.1–19.9%). Avascular necrosis occurred in 11 patients (10.4%), non-union 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.

INTRODUCTION

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

The viability of the femoral head after FNF is dependent on preservation of the remaining vascular supply and on revascularisation 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 revascularisation is the vascular ingrowth across the uniting fracture line.[2] The transverse shear and the rotational interfragmentary movement (IFM) caused by poor fracture stabilisation are deleterious to revascularisation as they disrupt angiogenesis in the femoral head.[3] Kumar et al 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 6 weeks.[4] The (re)vascularisation of the femoral head is further compromised when using implants with larger volumes as this may increase the incidence of 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 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 minimalized 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 hemi-arthroplasty (Figure 1).[12-14] Generally, patients aged <60 years are considered to be young patients.[15] 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 30–33% for non-union and 10–16% for AVN in displaced fractures.[16-19] The data received from the FAITH trial show 11.1% non-union and 6.3% AVN and an overall revision rate of 22.3% for displaced FNF.[20] Revision rates of 35%[18] and up to 48%[19] for displaced fractures were reported in two large meta-analyses. More recently, Parker reported a revision rate of 20.7% in patients with

displaced FNF treated with the Targon Femoral Neck plate.[21] A 2015 meta-analysis on the results of internal fixation in patients <60 years old with a displaced FNF reported a revision rate of almost 18%.[15]

Fig. 1a

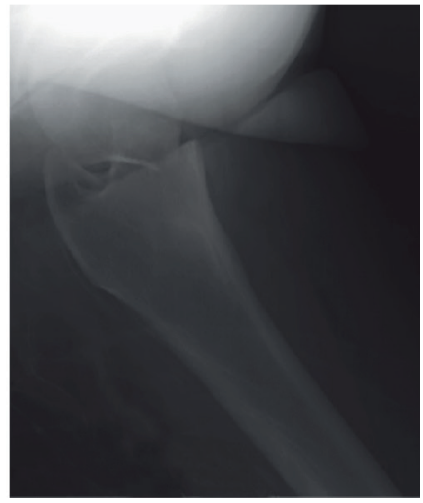

Fig. 1b

Figure 1. a) Anteroposterior and **b)** lateral radiograph of displaced femoral neck fracture in a 57-year-old woman.

The most commonly used implants are multiple parallel (cannulated) screws or sliding hip screw (SHS) devices.[22] It is obvious that not all factors contributing to the failure rate of the FNF are implant-related. Other factors such as primary displacement, posterior comminution, fracture reduction and implant positioning are even more important than implant choice.[23-25]

However, triggered by the poor results of internal fixation achieved with the current implants, we analysed 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). It is characterised by a low implant volume combined with rotational and angular stability while allowing controlled axial compression (Figure 2).

The DLBP was initially tested by two surgeons who participated in the development of the implant. This earlier small pilot study with a follow-up of 2 years reported a failure rate of 8% in 25 patients (mean age 60 years; range 39–75) with undisplaced or displaced FNF.[26] A

larger prospective multicentre study of the DLBP with a follow-up of 1 year demonstrated a failure rate of 4% among 149 patients (mean age 69 years, range 35–101) with an undisplaced FNF.[27] The primary objective of the present study was to determine the failure rate of the DLBP in a larger general population of 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 mobilisation after surgery, and compare these between groups.

Fig. 2a

Fig. 2b

Figure 2. 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.

PATIENTS AND METHODS

Design and cohort

This was a multicentre prospective case series. All patients aged ≤60 years admitted to the participating hospitals with a displaced FNF were treated by internal fixation with a DLBP. In cases where 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 extremity, 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 or complications in postoperative care, were excluded. A displaced FNF was defined as a grade 3 or 4 fracture according to the conventional Garden classification. Following surgery, patients were mobilised by permissive weight-bearing according to pain.

Implant

The DLBP was developed by Baat Medical Engineering in Hengelo, the Netherlands 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 (Figure 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

Figure 3. The Dynamic Locking Blade Plate also known as the Gannet Implant.

stability.[28] The volume of the DLBP inserted 50 mm into the head is 1800 mm^3. The volumes of the DHS and 3 cannulated screws are respectively 2700 mm^3 and 2520 mm^3.[29] 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 with the DLBP. Trainee surgeons were always supervised by a senior consultant. Reduction was performed using closed technique for all the fractures. The surgical technique is described in an earlier published study.[28,30]

Outcomes measurements

Anteriorposterior (AP) and lateral X-rays were assessed by a radiologist and by the treating surgeon for fracture healing and complications. The radiographs were standardized for projection and also for rotation within the pain limits. Follow-up was performed by the authors at 6 weeks, 3 months and 1 year. The primary outcome measure, failure of fixation, is defined as the need for revision surgery because of non-union, AVN or cut out of the implant. Union was defined by an absence of visible margins in the fracture. Non-union was identified by either displacement of the fracture or clearly visible margins of the fracture 1 year postoperatively. AVN was defined according to the Steinberg classification from stage 2 and upward.[31] The Garden Alignment Index was used to evaluate the fracture reduction on the first postoperative X-ray.[32,33] As reported previously, the acceptable range of reduction is a 160–180° angle.[34,35] The impaction at the fracture site was assessed by measuring the degree 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 X-rays; TAD >25 mm is predictive of a higher extrusion rate.[23] The measurements were performed by the authors. Before and 1 year after surgery mobility was assessed by need for walking aids: no walking aids, one crutch, two crutches or a walker.

Statistical analysis

Statistical analysis was performed using SPSS v. 21 (IBM Corp., Armonk, NY, USA) for Windows 7. 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 $p<0.05$.

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 hemi- 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 mental disorder, two had known neuromuscular disease and one had concomitant fractures of the lower extremity. 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 (Figure 4). Seven patients did not have a radiograph after one year. Follow-up after one year through interview by telephone revealed that none of the seven patients underwent revision surgery.

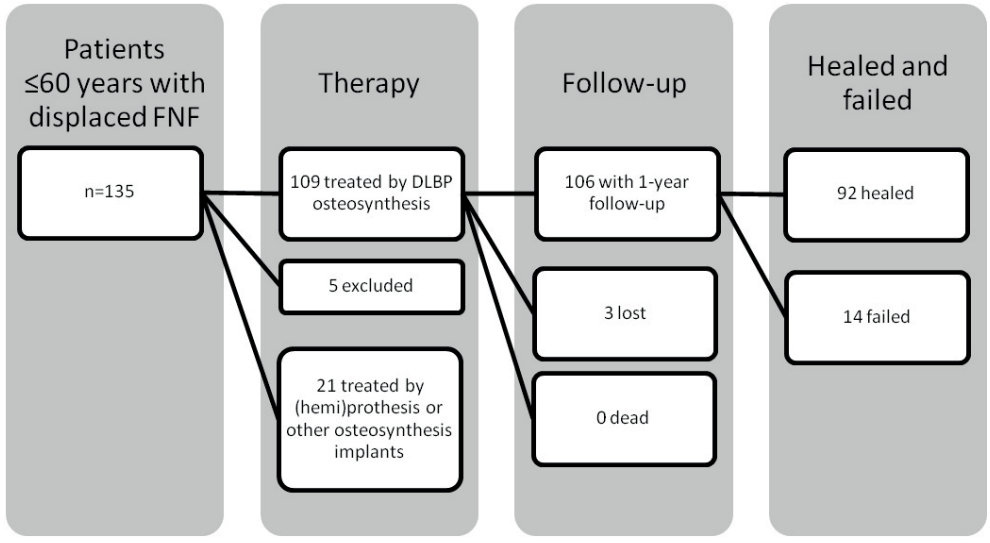

Figure 4. Flowchart of patient population. *DLBP*, dynamic locking blade plate; *FNF*, femoral neck fracture.

Surgery was undertaken by (orthopaedic) trauma surgeons (86%) and trainee surgeons (14%). Follow-up for all included patients was at least 1 year. Mean patient age was 52 years (range 23–60) and 46% (49/106) were female. Of the treated patients, 85% (90/106) were operated within 24 hours and 97% (103/106) within 48 hours. Mean operating time was 44 min (range 15–102). One patient developed a local complication of a deep infection.

One implant-related complication, no expansion of the impaction anchors, was noted in five patients. In one case, 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 (range 9.0–40.0 mm) and mean impaction was 7.1 mm (0–23 mm).

Failure rate for the displaced femoral neck fixated by the DLBP was 14 of 106 patients (13.2%; 95% CI 7.1–19.9%). There were no statistical differences between the healed and failed group in terms of sex, 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 1).

Table 1. Variable characteristics divided in healed and failed fractures

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

*Chi-squared test
†Students *t*-test
TAD, tip–apex distance

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

DISCUSSION

The goals of surgical treatment for displaced FNF are 1) to do no further vascular harm, 2) provide the stability necessary for revascularisation of the femoral head and 3) 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 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 1 year, while the literature gives an incidence of 14.7–22.5% of AVN in young patients and mean impaction of 9.3 mm.[15,17,36-38]

Other possible implant-related factors contributing to the high failure rate of the common implants are the insufficient intrinsic angular and rotational stability.[39,40] The stability of multiple screws is fully dependent on the three-point fixation principle based on precise screw placement and is consequently surgeon-dependent.[40] As the most common implants fail to provide adequate rotational stability, the clinical importance of the prevention of rotational IFM seems to be underestimated.[29] Biomechanical testing demonstrated that a de-centralized 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 physiologic load torque could outrun resistance of the cancellous bone around the implant.[39] 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.[41] 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.[29] The counter-clockwise rotational stability of a lag screw is negligible.[42] Unlike the SHS devices, no torque force at all is exerted on the femoral head on insertion of the DLBP, and therefore it is unnecessary to insert an extra pin or screw in the femoral head to prevent rotation.

Jenkins et al demonstrated by micro-computed tomography 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.[43] The DLBP provides stability by using one single implant in the biomechanical most optimal, rotation-neutral, centre-centre position in the femoral head.[39,43] This contrary to other implants where two, three or even four screws/pins are placed in suboptimal peripheral positions. 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.[44,45]

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 or that the DLBP is capable of stabilising malreduced FNF. It has to be mentioned that the reduction was measured by one observer and an inter- and intra observer 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 decentralised, the holding power of the implant is reduced.[23] 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 non-union (5.6% versus 6–11% in the literature), and cut-out (1.9% versus 9–13.1% in literature) and not a single case of perforation of the femoral head.[15,20,24,36,37] The overall failure rate in 106 young patients (23–60 years old) was 13.2%. These results compare favourably with the literature and with recently published results of new implants.[21]

The strength of this study is its prospective design and the well-defined patient population (young patients with displaced FNF). Despite this specific patient population we had a relatively large patient cohort. The contribution of a variety of (orthopaedic) trauma surgeons from five different hospitals also advocates for treatment by DLBP in general hospitals. Limitations of this study include its relative short follow-up of 1 year and lack of an official mobility score.

CONCLUSION

The DLBP has been developed specifically for the fixation of FNFs and is characterised by a combination of dynamic compression, angular and rotational stability, and low implant volume within the femoral head. Despite the participation of various surgeons in this multicentre study, the DLBP held up its performance as demonstrated in an earlier pilot study. The failure rate of the DLBP for displaced femoral neck fractures (13.2%) in young patients is promising and warrants a randomised controlled trial comparing the DLBP with contemporary implants.

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