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ORIGINAL STUDY

Outcome after short intramedullary nail fixation of unstable proximal femoral fractures

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In this study we assess the clinical and radiological outcomes after surgical fixation of unstable, extra-capsular fractures of the proximal femur using two designs of short intramedullary nail. We reviewed 158 patients of which 131 had fixation using the Intra Medullary Hip Screw (IMHS original Richards Compression Hip Screw design) and 27 with the original design Proximal Femoral Nail (PFN Synthes). Outcome measures including non-union, peri-implant fracture, post-operative function and mortality were similar between groups. Proximal screw cut-out and consequently re-operation rate were significantly higher for the PFN. A number of variables may predispose a patient to develop screw cut-out including gender, experience of surgeon, fracture pattern, implant design and tip-apex distance. As such a multivariable logistic regression model was used to investigate the independent effects of these variables on proximal screw cut-out. Only tip-apex distance was found to have a significant association with proximal screw cut-out and differences between implant designs could be accounted for by surgical technique rather than implant design. The results of this study suggest that both implants have similar post-operative outcome measures and complication rates when implanted correctly.

Keywords : hip fracture ; intra-medullary nail ; outcomes ; elderly ; implant failure.

INTRODUCTION

Hip fracture is the most common, serious injury to occur in the elderly (*9*). The surgical management of this injury is frequently complicated by fracture comminution and osteoporotic bone (*8*). Revision surgery after failure of primary fixation has high associated morbidity and mortality (*12,23*). The dynamic hip screw (DHS®) has become the standard fixation device for stable, extra-capsular hip fractures and is the benchmark to which other methods of hip fracture fixation are compared (*18,22*). However, failure of fixation is more common in unstable trochanteric and subtrochanteric fractures (*6,8,10,14*). Common mechanisms of failure include : screw cut-out, plate pull-off and fatigue failure in cases of delayed union (*24*). Cephalocondylic intramedullary nails were developed as an alternative to the DHS. Examples include the Gamma® nail (Stryker), the intramedullary hip screw (IMHS®, Smith & Nephew)

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and the proximal femoral nail (PFN, Synthes). The theoretical biomechanical advantages of such implants over screw/plate fixation are attributed to a reduced distance between the hip joint and the implant. This diminishes the bending moment across the implant/fracture construct and allows the load to be transferred directly to the femoral shaft, bypassing the calcar femorale (*7*). These characteristics offer theoretical advantages in the setting of unstable fractures ; however any potential clinical benefit has yet to be demonstrated (*18*). Despite these theoretical advantages, cephalocondylic nails have been associated with a number of complications including peri-implant fracture, thigh pain and increased technical difficulty (*16,18,19*).

Implants

IMHS – First introduced in 1995, the IMHS (original Richards CHS nail, Smith & Nephew) is a 210 mm long nail with a 4° proximal valgus angulation to facilitate a greater trochanter entry point (fig 1). A single lag screw is used for proximal fixation and 4.5 mm distal locking screws are used for rotational stability. There are four options of nail diameter (10, 12, 14 and 16 mm) and two options of neck-shaft angle (130 and 135°). The IMHS has a unique sleeve held by a set screw which passes through the intramedullary nail and over the lag screw. The sleeve helps prevent rotation, while allowing the lag screw to slide.

PFN – The PFN was introduced in 1998 and was developed by the AO/ASIF group for the treatment of unstable proximal femoral fractures (fig 2). It features a 240 mm long nail with 6° proximal valgus angulation and a 130° neck-shaft angle. Two proximal screws are used for fixation into the femoral head and neck. The larger self-tapping 11 mm femoral neck screw is the load-bearing screw. The smaller, more proximal 6.5 mm self-tapping hip pin is inserted to provide rotational stability and as it has no theoretical load bearing function it is recommended to be inserted 15-20 mm shorter than the femoral neck screw (not exceeding the line between the tip of the femoral neck screw and the top of the IM nail). Outcome results of the PFN are reported to be generally favourable with a relatively low incidence of complications and implant failure (*2,18,21*). However, there is concern that the biomechanical properties of the PFN may predispose to cut-out of the proximal screw(s) (*20,23*). It is has been hypothesised that during weight-bearing the proximal hip pin becomes load-bearing and so may lead to cut-out of the screw due to its narrow diameter (*20*).

Fig. 1. — Intramedullary hip screw (IMHS®, Smith and Nephew).

Much controversy continues to exist regarding the ideal implant for osteosynthesis of unstable, proximal femoral fractures. The aim of this study was to report patient outcomes after operative treatment of unstable, extra-capsular fractures of the proximal femur using the IMHS/PFN short intramedullary nails. We also investigated differences in outcome between these implant designs.

Fig. 2. — Proximal femoral nail (PFN®, Synthes)

PATIENTS AND METHODS

Data collection – All patients admitted to our acute trauma unit as a result of a fracture of the proximal femur are entered into the Scottish Hip Fracture Audit database (*22*). This is a national, prospective audit that collects data relating to patients aged 50 years and above admitted to hospital after sustaining a hip fracture. Using this database we were able to identify all individuals who had undergone short, intramedullary nail fixation for unstable extra-capsular fractures of the proximal femur at our institution. Hospital medical records, operative records and radiographs were then reviewed to obtain additional relevant information not entered into the original dataset.

A standard core dataset was collected by a dedicated audit co-ordinator during the patient's acute stay, 120 days and 1 year post-injury. Recorded case-mix data included : age ; gender ; American Society of Anesthesiologists (ASA) grade (used as a surrogate measure of patient co-morbidity) ; pre-fracture mobility ; pre-fracture residence and fracture type. Process data collected included : type of surgery ; length of hospital stay and discharge destination. Outcome data included mobility status, living circumstances, complications and mortality. The following surgical details were also recorded retrospectively : grade of surgeon ; duration of procedure and intra-operative complications. Haemoglobin levels were measured pre-operatively and at 24 hours post-operatively unless clinically indicated. All post-operative complications were recorded. Review data at day 120 were collected by telephone interview with the patient/immediate carers for those patients that attended the fracture clinic at a different date. Deaths and re-operations within 12 months of the primary fracture were also recorded from patient clinical case-notes.

Radiographs were taken post-operatively and repeated at fracture clinic review at 12 months post-injury or sooner if clinically indicated. Patients/carers were advised to contact the fracture clinic if any problems arose in the period between discharge and scheduled fracture clinic follow-up. Pre-operative radiographs were used to classify fracture pattern. All patients entered into the study had sustained subtrochanteric or comminuted intertrochanteric fractures (3 fragments or more). For simplicity, fractures were grouped according to pattern and stability based upon Jensen's modification of Evans' classification (*11,12*). We used three separate groupings to simplify the association between fracture pattern and outcome : (1) comminuted intertrochanteric fracture with an intact calcar (Type III) ; (2) comminuted intertrochanteric fracture with separation of the calcar (Type IV and V) and (3) subtrochanteric fractures. The position of the proximal screw within the femoral head was assessed using antero-posterior and lateral radiographs using Baumgaertner's tip-apex distance method (*3*). For the PFN, tip-apex distance was based on the position of the inferior femoral neck screw.

Surgery was performed according to standard recommended surgical techniques for both implants using a fracture table with closed fracture reduction under image-intensifier control. Routine anti-thrombotic prophylaxis was given (unless contra-indicated) for a total of six weeks after surgery and all patients received prophylactic peri-operative antibiotics. Post-operative care and rehabilitation was standardised for both groups. All patients were encouraged to walk full weight-bearing as able on the first post-operative day under physiotherapist supervision.

A total of 158 patients were identified who underwent IMHS or PFN fixation of a unilateral, unstable, extra-capsular fracture of the proximal femur between March 1999 and December 2004. The cohort consisted of 41 (26%) males and 117 (74%) females. The mean age was 78 years (range : 45-102 years, SD ± 11 years).

IMHS was used in 131/158 (83%) individuals and PFN in 27 (17%). This difference was accounted for primarily by the availability of implant sets within the trauma theatre (as only one PFN set was available at any time). All 8 surgeons (4 consultant grade and 4 non-consultant grade) used both implants. There was no significant difference in implant use between surgeon grades (table I, $p = 0.67$).

Statistical analysis was performed using SPSS version 16.0 software (SPSS Inc, Chicago, Illinois, USA). Categorical data were compared using the chi-squared test. The Mann-Whitney and t-tests were used to analyse continuous data as appropriate. As several factors may contribute to the risk of developing proximal screw cut-out, a multivariable logistic regression model was used to determine whether implant design was an independent risk factor for proximal screw cut-out.

RESULTS

A summary of patient case-mix variables is documented in table I. Individuals in both treatment groups were similarly matched for : age ; ASA score ; gender ; fracture type ; grade of operating surgeon ; pre-fracture residence ; and pre-fracture mobility.

Table II documents outcome after surgery for both implants. Mortality at 30 days, 120 days and 1 year post-fracture was similar, $p > 0.05$. Length of

Table I. — Patient case-mix variables and surgeon grade by implant type

	Variable	Implant type		
		IMHS	PFN	
ASA Score	1-2	29/131 (22%)	5/27 (19%)	*p = 0.68*
	3	71/131 (54%)	16/27 (59%)	*p = 0.63*
	4-5	31/131 (24%)	6/27 (22%)	*p = 0.87*
Fracture pattern	3 part intertrochanteric fracture - calcar intact	35/131 (27%)	8/27 (30%)	*p = 0.92*
	3-4 part intertrochanteric with calcar fracture	62/131 (47%)	14/27 (51%)	*p = 0.67*
	Subtrochanteric fracture	34/131 (26%)	5/27 (19%)	*p = 0.42*
Gender	Male 41 (26%)	33/131 (25%)	8/27 (30%)	*p = 0.63*
	Female 117 (74%)	98/131 (75%)	19/27 (70%)	
Age (mean)		77.3 years	80.4 years	*p = 0.17*
Pre-fracture	Own home	85/131 (65%)	18/27 (67%)	*p = 0.86*
	Sheltered/residential home	13/131 (10%)	2/27 (7%)	*p = 0.69*
Residence	Nursing home	18/131 (14%)	6/27 (22%)	*p = 0.26*
	Long term hospital care	6/131 (4%)	0/27 (0%)	*p = 0.26*
	Acute hospital ward	9/131 (7%)	1/27 (4%)	*p = 0.54*
Pre-fracture Mobility	Walked without aids	60/131 (46%)	10/27 (37%)	*p = 0.40*
	Walked with 1 aid	28/131 (21%)	7/27 (26%)	*p = 0.60*
	Walked with 2 aids	6/131 (4.5%)	3/27 (11%)	*p = 0.18*
	Walked with frame	31/131 (24%)	7/27 (26%)	*p = 0.96*
	Bed bound	6/131 (4.5%)	0/27 (0%)	*p = 0.26*
Surgeon Grade	Junior	62/131 (47%)	14/27 (52%)	*p = 0.67*
	Consultant	69/131 (53%)	13/27 (48%)	

PFN – Proximal femoral nail.
IMHS – Intramedullary hip screw.

Table II. — Clinical outcomes by implant type (41 men (26%) and 117 women (74%)

	Outcome variable	Implant type		
		IMHS	PFN	
Mortality	30 days	8%	7%	*p = 0.98*
	120 days	18%	19%	*p = 0.98*
	1 year	31%	33%	*p = 0.78*
Median inpatient stay		23 days	23 days	*p = 0.94*
Residence at 120 days	Own home	63/131 (48%)	11/27 (42%)	*p = 0.49*
	Sheltered/residential home	8/131 (6%)	1/27 (4%)	*p = 0.62*
	Nursing home	21/131 (16%)	6/27 (23%)	*p = 0.44*
	Long term hospital care	4/131 (3%)	2/27 (8%)	*p = 0.28*
	Acute hospital ward	2/131 (2%)	0/27 (0%)	*p = 0.52*
	Orthopaedic rehabilitation unit	9/131 (7%)	1/27 (4%)	*p = 0.54*
	Died	24/131 (18%)	5/27 (19%)	*p = 0.98*
Mobility at 120 days	Walked without aids	16/131 (12%)	4/27 (15%)	*p = 0.71*
	Walked with 1 aid	23/131 (18%)	3/27 (11%)	*p = 0.41*
	Walked with 2 aids	11/131 (8%)	3/27 (11%)	*p = 0.65*
	Walked with frame	43/131 (33%)	9/27 (33%)	*p = 0.96*
	Bed bound	13/131 (10%)	3/27 (11%)	*p = 0.85*
	Died	24/131 (18%)	5/27 (19%)	*p = 0.95*

PFN – Proximal femoral nail.
IMHS – Intramedullary hip screw.
"p" values in **bold** text represent significance at $p < 0.05$.

hospital stay, place of residence and mobility at 120 days post-fracture did not differ significantly between treatment groups. Mean operative time (100 mins (range : 50-165 mins) for the IMHS versus 116 mins, (range : 40-215 mins) for the PFN ($p = 0.88$)) and mean blood loss (3.6 g/dl versus 3.9 g/dl ($p = 0.58$)) were also similar.

Tables III and IV list post-operative complications and reason for any re-operation by implant design by 12 months follow-up. Re-operation for post-operative complications was relatively high, affecting 15/158 (9%) of the total patient cohort. Reasons for this are now discussed in greater detail.

Peri-implant fracture – Despite concerns in the orthopaedic literature, peri-implant fracture was a rare complication affecting only 3/158 (2%) individuals. Two cases occurred in the IMHS cohort and one in the PFN cohort, $p > 0.05$. One individual from the IMHS group required revision surgery while the other 2 cases were successfully managed non-operatively. These fractures were late complications secondary to further falls and none occurred intra-operatively.

Thigh pain – Persistent thigh pain was reported from one patient in the IMHS cohort. All investigations including a radioisotope-labelled white cell scan were normal. There was no radiographic evidence of implant failure and no further surgery was indicated.

Non-union – Two patients (1.5%), (both from the IMHS cohort) developed non-union. The first case occurred subsequent to a subtrochanteric fracture which subsequently united following iliac bone grafting and dynamisation of the implant. The other case occurred subsequent to a comminuted intertrochanteric fracture which required revision to a total hip replacement. All fractures in the PFN cohort progressed to radiological union.

Implant cut-out – It is clear that both the incidence of proximal screw cut-out (15% vs. 3%)

Table III. — Post-operative complications by implant type

Post-operative Complication	*Implant*				Significance (p) *
	IMHS		PFN		
	(number and percentage)				
Proximal screw cut-out	4/131	*3%*	4/27	*15%*	*0.01*
Superficial infection	8/131	*6%*	1/27	*4%*	
Deep infection	2/131	*1.5%*	0/27	*0%*	
Fracture of distal locking screws	4/131	*3%*	0/27	*0%*	
Peri-implant fracture	2/131	*1.5%*	1/27	*4%*	
Nail fatigue fracture	1/131	*1%*	0/27	*0%*	
Non-union	2/131	*1.5%*	0/27	*0%*	
Symptomatic malunion	0/131	*0%*	1/27	*4%*	*0.03*
Myositis ossificans	0/131	*0%*	1/27	*4%*	*0.03*
Thigh pain	1/131	*1%*	0/27	*0%*	

PFN – Proximal femoral nail.
IMHS – Intramedullary hip screw.
* "p" values only listed if $p < 0.05$.

and re-operation (22% vs. 7%) were significantly higher for the PFN than for the IMHS. The number of re-operations was significantly higher in the PFN group due principally to a relatively higher rate of cut-out of the proximal screw(s). A number of variables may predispose a patient to develop cut-out of the proximal screw after intramedullary nail fixation, including fracture type, grade of operating surgeon, implant design, gender and tip-apex distance. We therefore constructed a multivariable logistic regression model to investigate the independent effect of these variables on the risk of proximal screw cut-out.

Of all the variables entered into the multivariable logistic regression model, only TAD was found to have a significant association with cut-out of the proximal screw. This variable was used to divide the treatment cohorts into those with a TAD less or greater than 25 mm. Although TAD is directly transferable as a concept to the single lag screw of the IMHS, the PFN has 2 proximal screws and so by design the femoral neck screw tends to be placed lower in the femoral head (and thus may increase tip-apex distance). We did however decide to use TAD as measured from the femoral neck screw to assess whether this is a valid predictor of screw cut-out when using the PFN. When the tip-apex distance was observed to be less than 25 mm the cut-out rate for both implants was extremely low at 1% for the IMHS and 0% for the PFN ($p = 0.67$). However, if we look at the cut-out rate for those implants where the tip-apex distance was greater than 25 mm, we observe a much higher failure rate of 2% for the IMHS and 15% for the PFN ($p = 0.03$). As we can see, TAD has an important effect upon our interpretation of the results. The apparent significant difference in the incidence of cut-out between the implants is eliminated when we exclude those implants with poorly positioned proximal screws. When entered into the multivariable logistic regression model, TAD greater than 25 mm was strongly associated with increased cut-out of the proximal screw. All other variables entered into the model including gender ; fracture pattern ; ASA score ; surgeon grade and importantly implant design had no significant association with proximal screw cut-out.

DISCUSSION

Unstable fractures of the proximal femur represent a significant challenge to the trauma surgeon. Surgical fixation is often technically difficult and poor surgical technique may lead to failure of

Table IV. — Type of re-operation by implant

IMPLANT			
Intramedullary Hip Screw (n = 131)		Proximal Femoral Nail (n = 27)	
Revision to total hip arthroplasty	2/131 (1.5%)*	Revision to total hip arthroplasty	2 (7%)*
Revision to hemiarthroplasty	1/131 (1%)*	Removal proximal screw	2 (7%)*
Revision to dynamic hip screw	1/131 (1%)*	Replace proximal screw	1 (4%)
Girdlestone arthroplasty	1/131 (1%)	Reposition of distal screw	1 (4%)
Secondary wound closure	1/131 (1%)		
Embolisation of pseudoaneurysm	1/131 (1%)		
Autologous bone grafting of non-union and dynamisation of nail	1/131 (1%)		
Drainage of deep abscess	1/131 (1%)		
Total	9/131 (7%)		6/27 (22%)

* procedure performed due to implant cut-out.

primary fixation (*3,24*). Both the IMHS and the PFN have had favourable outcomes for the treatment of such fractures published in the orthopaedic literature, however this is the first study to directly compare outcomes between these implants (*18*).

The general complication rate, blood loss, duration of surgical procedure, length of hospital stay and mortality were similar between treatment groups and comparable to other published series (*18*). Functional outcome measures including residential and ambulatory status again showed no significant difference between treatment groups. The non-union rate for IMHS in our series was 1% and 0% for PFN, which is within the 0-3% range reported in the orthopaedic literature (*4,5,16*). The incidence of late peri-implant femoral fracture was also low (2%, n = 3) and there were no episodes of intra-operative fracture. This is one of the major concerns with short design intra-medullary femoral nails (*18*).

The most significant post-operative complication in this series was cut-out of the proximal screw(s) from the femoral head. This is an important complication as it may cause rapid damage to the articular surface of the acetabulum necessitating potentially complex revision surgery which has a high associated morbidity and mortality (*23*). A potential concern with the PFN relates to the biomechanical properties of most proximal anti-rotation screws and the possible "knife-effect" which may predispose to cut-out of the proximal screw(s) (*20*). The overall incidence of proximal screw cut-out rate was 8/158 (5%) which compares favourably to that reported in the literature (*4,5,15,16,18*). However, when we analyse the outcomes of each implant individually the PFN would appear to have a significantly higher cut-out rate compared to the IMHS (15% vs. 3%, $p = 0.01$). This is also somewhat higher than the rates reported in the orthopaedic literature (*5,9*). A number of variables may predispose an individual patient to develop screw cut-out including gender (due to risk of osteoporosis), fracture pattern, ASA grade, surgeon grade and tip-apex distance. When these variables were controlled for by means of a logistic regression model, implant design was not found to influence the rate of proximal screw cut-out. TAD however was found to be highly predictive of proximal screw cut-out. When TAD was greater than 25 mm the PFN performed extremely poorly with 4/6 (67%) implants suffering cut-out. The IMHS cohort also had a significantly higher cut-out rate (3/16, 19%) when TAD was greater that 25 mm, however this was significantly less than that of the PFN, $p = 0.03$. Our findings that the PFN has an extremely high failure rate when the TAD exceeds 25 mm is one which merits both further biomechanical and clinical study, and reinforces the need for accurate placement of the implant. The PFN femoral neck screw should follow the same course as the IMHS (and not be placed somewhat lower as usually recommended) and the anti-rotation screw should not exceed the line between tip of neck screw and tip of IM nail.

CONCLUSIONS

The results of this study indicate that both the IMHS and PFN have similar, favourable post-operative clinical and radiological outcomes and are comparable in terms of post-operative complications. However, optimal positioning of the proximal screw(s) within the femoral head is of crucial importance, particularly with the PFN and should be obtained at all times. A surgeon may treat the demanding unstable proximal femoral fracture with either implant so long as he is aware that outcome is more dependant on surgical technique than the type of fixation used.

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