Injury, Int. J. Care Injured 48 (2017) 1575–1578

Contents lists available at ScienceDirect

Injury

journal homepage: www.elsevier.com/locate/injury

Full length article

The learning curve with a new cephalomedullary femoral nail

N.F. Fine*, S.A. Sexton, D.H. Williams

Royal Cornwall Hospital, Truro, Cornwall, UK

ARTICLE INFO

Keywords:
Hip fracture
Femoral fracture
Cephalomedullary nail

ABSTRACT

Introduction: The Cephalomedullary Nail (CMN) (Zimmer, Warsaw) was introduced in 2010 as part of a multicenter trial to evaluate its performance. At one year the CMN had results in keeping with other intramedullary devices with good union rates and low complication rates. In the second and third years of use an increased rate of implant failure was observed, towards the higher end of the 1–5% nail breakage rate seen in other studies. This study aims to evaluate if there any common features in this cohort of patients.

Materials and methods: This is a retrospective cohort study looking at patients who underwent femoral fracture fixation using the cephalomedullary nail between January 2011 and June 2014. The primary outcome measure was implant failure; secondary outcomes were; fracture reduction and bisphosphonate use.

Results: 201 patients were included (135 female, 66 male) with an average age of 81 years. Ten (5%) nail breakages occurred in the study period at an average of 39 weeks (24–92); 9 were 125° nails 1 was a 130° nail and all fractured at the lag screw junction.

Conclusions: Implant failure is a recognised complication of intramedullary nailing in cases of non-union. The increased rate of implant failure in our department required a change to a 130° CMN implant and a 3.2 mm diameter guide wire for placement of the lag screw. We continue to monitor this difficult group of patients very closely.

Introduction

Over 75,000 proximal femoral fractures occur in the UK each year [1]. Extra capsular proximal femoral fractures are managed operatively with either a dynamic hip screw (DHS) or a cephalomedullary device. While DHS fixation remains the gold standard for comminuted AO 31-A2 fractures [2] cephalomedullary nails are generally reserved for unstable AO 31-A3 intertrochanteric and sub trochanteric fractures [8], showing better preservation of reduction [3–5] and post-operative mobility [6] in comparison studies with DHS fixation of these fractures.

A new cephalomedullary device, the Cephalomedullary Nail (CMN) (Zimmer, Warsaw), was introduced to the trauma implant market in 2010. This new nail has a smaller (15.5 mm) proximal diameter to minimise the amount of bone resected to implant the nail, an anatomical bow to better match the shape of the femur and an anterior bevel on a 'clothespin' tip to reduce the risk of fracture at the tip of the implant.

A multicenter trial at five centres across four countries was set up, in parallel to general commercial release of the CMN, to evaluate the introductory period. The study was noted by the local Research and Development department and did not require approval of the National Research Ethics Service (NRES). Preliminary results of this trial at the 12-month mark were in line with the published data from trials using other intramedullary devices [3–5,7–10]. Twenty-seven (87%) of 31 cases that had reached the 12-month point showed callus visible across 3 cortices on two orthogonal x-ray films. Two (2.6%) of the lag screws from 77 of the patients operated had cut out and one nail (1.3%) had broken at the lag screw hole. Recognised complications with any intramedullary femoral fixation include lag screw cut out, nonunion and implant breakage [11]; the latter more likely to occur with non-union of the fracture as the metalwork is subject to additional dynamic stresses.

As a contributor to this preliminary report, our centre reported an increased number of nail breakages, both within the study group and in those patients who had not met the inclusion criteria for the study. This paper reports the number of nail failures across a consecutive series of patients with this new implant and assesses factors common to those patients where the Cephalomedullary nail failed. Essentially this is a report of the learning curve across a busy department using this new trauma implant.

* Corresponding author.
E-mail address: nfine@nhs.net (N.F. Fine).

http://dx.doi.org/10.1016/j.injury.2017.05.030

Materials and methods

This is a retrospective cohort study analysing prospectively collected data from a consecutive series of patients undergoing femoral fracture fixation using the cephalomedullary nail. The study period includes the first patient from December 2010, through a period when changes were introduced to June 2014, which affords a minimum of 12-months follow up for every patient who had a cephalomedullary nail implanted. The series includes those nails implanted prophylactically for imminent pathological fracture and those patients with a pathological fracture.

All data was collected prospectively on an electronic patient record that captured details of the operation and the clinical follow up; paper records were cross checked where necessary and electronic pre-operative, post-operative and follow up x-ray films assessed by two members of the research team. The database was also cross checked with data collected in the National Hip Fracture Database.

All operations were performed by a consultant, staff grade surgeon or registrar trainee in orthopaedic surgery. In our department trauma surgery is performed by general orthopaedic surgeons populating an on call trauma rota system. The consultant surgeons undertaking the procedure were experienced in intramedullary fixation of femoral fractures and more junior members of the team were supervised by a consultant.

The nail design requires a trochanteric entry point through a muscle splitting operative approach. Closed reduction with a minimally invasive technique was used where possible; open reduction, with or without cabling used depending upon the severity of the fracture. Use of a short or long CMN implant was decided by the operating surgeon. All patients received a single shot of antibiotics at induction and thromboprophylaxis prescribed following a risk assessment in line with hospital policy.

The CMN implant is available with one of three angles for hip screw insertion: a 125, 130 or 135° nail. From December 2010 until September 2011 both the 125 and 130° nail were available; the operating surgeon choosing which to use. This choice was made either pre- or intra-operatively by analysing the contralateral, uninjured hip and deciding the best fit for that patient for their natural neck shaft angle.

Stock was rationalised to only the 125° nail in October 2011. After concern over number of nail breakages the 125° nail was removed and replaced by the 130° nail, the middle choice, in July 2013. Twenty nails were performed when both implants were available, 125 when only the 125 ° nail was on the shelf and 56 after the change to the 130 ° nail was made.

In the absence of a validated scoring system, the adequacy of reduction of each intraoperative radiograph was retrospectively assessed by the research team. Anteroposterior (AP) plane, lateral plane and rotational alignment was assessed on two planes from the saved image intensifier films. Each plane of reduction was scored one if adequately reduced and zero if not, leading to a possible total of 3 points for an adequately reduced fracture in all three planes.

Thirty-six (18%) patients died during the study period. 63 (31%) patients were followed up in clinic, with a median follow up of 14 weeks (6–71 range).

Statistical analysis was performed using the Statistical Package for Social Sciences version 11 (SPSS, Chicago, Illinois, USA). The Chi-squared test was used to compare categorical variables.

Results

Table 1 shows the demographics of the study population. There were 201 CMN implants used in 201 patients during the 42-month

Table 1
Demographics of patients involved and nails used over the study period.

		Group A (broken nail) (n = 10)	Group B (intact nail) (n = 191)
Male: female		2:8	64:127
Age: median (range)		76 (63–86) years	74 (52–87) years
Diabetes		2 (20%)	23 (12%)
Smoking history		0 (0%)	21 (11%)
Bisphosphonate use on admission		3 (30%)	19 (10%)
Bisphosphonate use post treatment		8 (80%)	99 (52%)
AO fracture classification	31-A1	0	3 (1.5%)
	31-A2	1 (10%)	43 (23%)
	31-A3	4 (40%)	104 (55%)
	31-B2	0	1 (0.5%)
	32-A1	1 (10%)	13 (7%)
	32-A2	0	5 (3%)
	32-A3	2 (20%)	11 (6%)
	32-B1	2 (20%)	6 (3%)
	32-B2	0	1 (0.5%)
	32-C1	0	1 (0.5%)
	Impending	0	3 (2%)
Implant length	Long	7 (70%)	142 (74%)
	Short	3 (30%)	49 (26%)
Lag Screw Angle (degrees)	125	9 (90%)	116 (60.73%)
	130	1 (10%)	74 (38.74%)
	135	0	1 (0.53%)
Nail diameter (mm)	10	2 (20%)	24 (12%)
	11.5	3 (30%)	67 (35%)
	13	3 (30%)	89 (46%)
	14.5	2 (20%)	14 (7%)
Guide wire diameter (mm)	3.0 mm	9 (90%)	137 (72%)
	3.2 mm	1 (10%)	54 (28%)