ABSTRACT

The Long Trochanteric Fixation Nail (LTFN) is a titanium alloy cephalomedullary nail indicated for treatment of proximal femur fractures, including intertrochanteric and subtrochanteric varieties. Between 03/01/2002, and 10/01/2003, 211 consecutive fractures classified either as “intertrochanteric” or “subtrochanteric” were treated surgically at involved study centers. Fifty of these fractures were identified as being unstable intertrochanteric or subtrochanteric fractures treated with the LTFN and were selected as the study population, including 14 intertrochanteric fractures with reverse obliquity (AO Type 31-A3) and 29 with subtrochanteric extension. At average 11–month follow-up, mean Functional Recovery Score was 85. At average 9–month radiographic follow-up, 37 of 38 hips for which complete radiographic data sets were available healed, for a union rate of 97%. There were no cut-out failures of the helical blade providing proximal fixation for the implant. We recommend the LTFN for treatment of subtrochanteric fractures and unstable intertrochanteric fractures, including those with reverse obliquity.

INTRODUCTION

Küntscher introduced intramedullary fixation of femoral shaft fractures in 1940, and indications for intramedullary instrumentation of the femur have continued to expand as designs have evolved. Current second–generation, cephalomedullary nails permit purchase in the femoral neck and head for proximal fixation as well as providing distal locking capacity for axial and torsional control. We report our initial experience with the use of the Long Trochanteric Fixation Nail (LTFN, Synthes, Paoli, PA), a second–generation cephalomedullary implant, for the treatment of subtrochanteric and unstable intertrochanteric fractures.

MATERIALS AND METHODS

Approval for this study was obtained from our Institutional Review Board. Between 03/01/2002, and 10/01/2003, 211 intertrochanteric and subtrochanteric fractures of the proximal femur underwent operative treatment at one of two Level One Trauma Centers involved in this study. Of these fractures, 53 were treated with the Long Trochanteric Fixation Nail (LTFN, Synthes, Paoli, PA). Fifty of those fractures treated with the LTFN were classified as either subtrochanteric or unstable intertrochanteric fractures according to the Orthopaedic Trauma Association (OTA) system. This subset of 50 fractures in 50 patients constituted the subject population for this study.

Subjects included 28 males and 22 females with a mean age of 68 years (range, 18–93 years). Preoperatively, 24 (60%) of patients were community ambulators without limitation, and an additional 7 (18%) had only minor limitations, requiring use of a cane. Mechanism of injury qualified as low energy in the majority of patients (62%), with the predominant etiology being a fall from standing height. Pathologic fractures were observed in two patients, and the remainder of patients experienced high–energy mechanisms including: fall from a height ≥10 feet (6 patients), motor vehicle accident (5 patients), pedestrian versus motor vehicle (2 patients), gunshot wound (1 patient), downhill skiing (1 patient) and downhill sledding (1 patient).

All fractures were classified using the OTA comprehensive system of fracture classification and for purposes of historical comparison, intertrochanteric fractures were classified according to the system of Kyle and colleagues, and subtrochanteric fractures according to the system of Seinsheimer. There were 29 subtrochanteric fractures and 14 intertrochanteric fractures with reverse obliquity.

In 46 cases (92%) use of the LTFN represented the index procedure, and in 4 cases the LTFN was used to revise a pro-
procedure that had used an alternative means of fixation (Figure 1).

**Surgical Technique**

In each case, antegrade intramedullary nail insertion was performed according to established guidelines for use of the LTFN. Patients are positioned supine on a fracture table with the application of axial traction to the injured extremity. A 2 – 3 cm incision is made along the lateral thigh immediately proximal to the palpable prominence of the greater trochanter. The insertion point for the nail is slightly lateral to the tip of the greater trochanter and requires the use of an 17 mm cannulated reamer to accommodate the large proximal diameter of the nail. The helical blade is inserted through a separate lateral thigh incision, the exact location of which is determined with the use of an aiming arm that attaches to the nail insertion handle. Standard freehand technique with fluoroscopic guidance is used to place distal interlocking screws.

Supplemental fixation (cerclage wire) was used in one case. Autogenous bone grafting was used in one case (revision of a pathologic fracture).

**Clinical Evaluation**

Clinical follow-up was accomplished through a combination of retrospective chart review and phone survey using the Functional Recovery Score (FRS) as described by Zuckerman and Koval. The FRS is a validated functional outcomes instrument that can be administered either by phone or as mailed survey. It consists of three subscales that evaluate respectively mobility, basic activities of daily living and instrumental activities of daily living, using standardized, scripted questions. Each subscale is differentially weighted, with the basic activities scale receiving the highest weight. Clinical results were also analyzed according to estimated intraoperative blood loss, operative time, length of hospital stay, preoperative ambulatory status and presence of subjective postoperative limp.

**Radiographic Evaluation**

Fractures were judged to be completely healed when osseous consolidation could be observed in two planes on plain radiographs and pain – free ambulation was possible. In order to evaluate the accuracy of device placement and mechanical performance of the device, radiographic results were also analyzed according to tip – apex distance, amount of translation of the helical blade and the degree of varus collapse at the time of final radiographic follow-up.

**Postoperative Treatment**

Postoperatively, 32 patients (64%) were made weight – bearing as tolerated, 10 patients (20%) were made partial weight – bearing and 8 patients (16%) were made toe – touch weight – bearing.

**Statistical Evaluation**

A two – tailed independent t – test was used for comparison of continuous variables. A p – value of 0.05 was chosen to determine statistical significance.

**Results**

Six patients died of medically – related causes prior to study inception. Four of these deaths occurred in the acute postoperative period, precluding the possibility of complete radiographic follow-up for these patients. An additional 8 patients had incomplete radiographic data sets, leaving 38 patients available for radiographic follow – up. Two patients refused participation in the phone survey, and an additional 6 patients could not be located, leaving 36 patients available for complete clinical review.

By OTA classification, fractures included 10 (31-A2), 14 (31-A3), 9 (32-A1), 6 (32-A2), 1 (32-A3), 8 (32-B1), 1 (32-B3) and 1 (32-C2). All intertrochanteric fractures were unstable by Kyle classification, with 5 Type III and 4 Type IV fractures. According to the Seinsheimer classification, there was 1 Type I, 2 Type IIA’s, 8 Type IIB’s, 3 Type IIC’s, 11 Type IIIA’s, 1 Type IIIB, 1 Type IV and 2 Type V’s. There were 29 subtrochanteric fractures and 14 fractures with reverse obliquity (OTA 31-A3.1, 31-A3.2 and 31-A3.3).

With a mean duration of radiographic follow – up of 9 months (range, 3 to 33 months), 97% of fractures went on to union (Figure 2A – C). In the one case that went on to non-union, immediate postoperative radiographs revealed a signifi-
cant malreduction with the proximal fragment flexed 20° and the nail insertion point in the greater trochanter situated more posteriorly than is typically indicated. This case was revised at 7 months after the index procedure with open reduction and internal fixation using a 95° blade plate and autogenous bone graft. The patient went on to fail the revision procedure and subsequently required a second revision procedure.

Mean tip – apex distance was 25 mm (range, 13 – 48 mm). There were no instances of cutout of the helical blade. Mean amount of varus collapse was 2° (range, 0° – 10°). Mean amount of subsidence of the helical blade was 4 mm (range 0 mm to 12 mm). Unstable intertrochanteric fractures experienced more (p = 0.02) subsidence of the helical blade than other fracture patterns. Neither fractures with reverse obliquity nor Seinsheimer Type IIIA subtrochanteric fracture patterns experienced significantly more varus collapse or subsidence of the helical blade than other fracture patterns. The tip – apex distance for the one nonunion in the series was 48 mm, although the mode of failure was not cutout of the helical blade.

With an average clinical follow – up of 11 months (range, 6 – 22 months), mean total FRS was 87. Mean subscore for Basic Activities of Daily Living was 96, for the Instrumental Activities of Daily Living subscale 80 and for the Mobility subscale was 80. Seven (19%) of patients had the subjective impression that they ambulated with a limp. The FRS did not vary significantly when analyzed by general fracture type (unstable intertrochanteric without reverse obliquity, unstable intertrochanteric with reverse obliquity and subtrochanteric).

There were no device failures involving cutout of the helical blade or fractures of the intramedullary nail. There were 3 instances of broken distal interlocking screws, all through the distal static hole. In two of these cases, two distal interlocking screws had been placed and in one case a single interlocking screw had been placed through the static interlocking slot. Two of these fractures exhibited a fracture pattern with reverse obliquity and one was a Seinsheimer Type IIIA subtrochanteric fracture.

Average time from injury to fixation was 2 days. Mean surgical time was 95 minutes. Mean estimated blood loss was 326 mL. Length of hospital stay was on average 8 days.

All nails were 11 mm in diameter with a 130° helical blade – nail angle. The most commonly used nail length was 40 cm (28%), and the most commonly used helical blade length was 95 mm (20%). One (20%), two (72%) or three (8%) distal interlocking screws were placed in each case, according to the discretion of the treating surgeon. Cases in which an 11 mm nail could be passed easily, or when preoperative radiographs demonstrated a narrow intramedullary canal, were reamed prior to nail insertion. Nails were inserted without intramedullary reaming in 31 cases (62%). Six cases (12%) required open reduction secondary to inability to achieve satisfactory alignment via closed manipulation.

**COMPLICATIONS**

One patient had a symptomatic distal interlocking screw with medial prominence, necessitating screw removal. There was one deep infection in a case that involved revision of a subtrochanteric nonunion from a dynamic compression screw to an LTFN. The patient required multiple operative debridements and long – term intravenous antibiotic therapy. The patient had healed without signs or symptoms of recurrent infection at the time of most recent follow – up. Overall four patients (11%) required reoperation: one revision ORIF for nonunion, two removals of distal interlocking screws (one secondary to postoperative discomfort and one for dynamization) and one irrigation and debridement for infection.

**DISCUSSION**

We report our results of the use of a long, second – generation cephalomedullary nail to treat subtrochanteric and unstable intertrochanteric fractures in a predominantly elderly subject group. Our population comprised a high percentage of fractures with reverse obliquity (28%) and subtrochanteric fractures with medial comminution (34%). The cases selected for review were chosen based upon fracture pattern, as we were interested in the performance of this device in fractures that historically have proven challenging for nail – plate, screw – plate and intramedullary devices. Nonunion rates associated with the use of nail – plate and screw – plate devices for subtrochanteric and unstable intertrochanteric fractures have been reported to be as high as 37%,9-14 Multiple cadaveric studies have shown intramedullary devices to provide substantially stronger and more rigid fixation of subtrochanteric and unstable intertrochanteric fractures than extramedullary devices.15-18 The biomechanics of intramedullary fixation in the context of a destabilized medial cortex are optimized by medialization of the fulcrum point and resultant reduction of the bending moment with respect to proximal fixation.17

First generation locking nails permitted treatment of low subtrochanteric fractures, but despite the use of “reverse” techniques, these devices did not provide the purchase necessary for adequate fixation of subtrochanteric and unstable intertrochanteric fractures.19 The Zickel intramedullary device, first reported in 1967, attempted to address inadequacies present in these and other fixation devices by incorporating a large, triflanged Smith – Peterson nail that locked through the proximal portion of the device into the femoral neck.20 The lack of distal locking capacity, however, limited axial and torsional control. As a result, the use of supplemental fixation was often necessary to avoid axial collapse and rotational malunion of the distal fracture segment.21,22

The Russell – Taylor reconstruction nail (RTRN, Smith and Nephew, Memphis, TN), introduced around 1988, addressed the deficiencies of the Zickel device and represented the first cephalomedullary, second – generation locking nail that provided both proximal fixation into the femoral head and neck and distal locking capability for axial and torsional control.23,24 The RTRN offered proximal fixation through the use of two large lag screws that passed through the reinforced, proximal portion of the nail at a fixed angle. Use of the RTRN, however, was plagued by technical challenges, many of which...
seemed to derive from the use of two parallel screws to obtain proximal fixation.25,26

Reports on the use of the RTRN to treat subtrochanteric and unstable intertrochanteric fractures cite nonunion rates ranging from 0% to 8%, but are typically small series, comprising less than 10 patients, and look primarily at younger populations with high energy injuries.23,25-29 In a subset of patients over the age of 60 years, Carvamos and colleagues reported a 31% rate of wound infection and a 23% reoperation rate, and concluded that the RTRN may not be an ideal implant in an elderly population.28 Kang and colleagues reported an 8% nonunion rate and a 37% reoperation rate following the use of the RTRN in complex fractures of the proximal femur.26 French and colleagues reported an impressive 100% union rate in a series of 45 patients with subtrochanteric fractures.27 However, the mean age in their series was 39.5 years, all patients were made non weight–bearing postoperatively and a 13% rate of intraoperative complications was observed.

The use of short cephalomedullary nails, such as the short Gamma Nail (Stryker, Kalamazoo, MI) and the Intramedullary Hip Screw (IMHS, Smith and Nephew, Memphis, TN) to treat unstable intertrochanteric fractures has been associated with nonunion rates as high as 11%.30-32 Furthermore, the incidence of intraoperative complications has been reported to be as high as 14%, including such devastating occurrences as femoral shaft fracture at the tip of the device.31 Radford and colleagues reported an 11% incidence of shaft fracture with the use of the short Gamma Nail.32

The long Gamma Nail (Stryker, Kalamazoo, MI) emerged following the introduction of the short Gamma Nail, expanding the indications of the device, and has performed well in the treatment of subtrochanteric fractures.9,33-36 In biomechanical testing by Roberts and colleagues, the long Gamma Nail with its 17 mm proximal segment and single, stout, 12 mm proximal lag screw, was shown to be superior to three less substantial cephalomedullary designs with respect to minimization of rotational, shearing and axial fracture site motion.37 Each of the other designs had smaller proximal segment diameters and two smaller screws, rather than a single, large proximal screw for fixation in the femoral neck.

The long Trochanteric Fixation Nail became available in the United States in 2001. The proximal helical blade represents the most significant departure from previous cephalomedullary design elements. The helical shape of the blade theoretically enhances rotational control of head and neck fragments, while leaving a smaller footprint than conventional lag screw designs.

The long Trochanteric Fixation Nail performed well in our series. With respect to technical placement, the mean tip–apex distance of 25 mm – while at the upper limit of acceptable – was within the target range reported by Baumgaertner and colleagues, and did not vary significantly between fracture patterns.7,8 The mean operative time of 95 minutes and intraoperative blood loss of 326 mL compares favorably with previously reported values.10,27,28,35,38,39

There were no fractures of the nail or helical blade component. There was a significant difference in the amount of sliding of the helical blade observed in the unstable intertrochanteric fracture patterns versus that observed in other fracture patterns (7 mm versus 3 mm), indicating proper functioning of the proximal aspect of the device in fractures expected to experience some degree of collapse. The overall amount of helical blade subsidence was small, however, well below that reported by Kim and colleagues to be associated with increased postoperative discomfort.30

With respect to functional outcomes, as might be expected, we observed a decreasing trend in subscale scores with increasing complexity of tasks that make up each subscale. Our population was slightly younger than that in which the Functional Recovery Score of Zuckerman and Koval was validated, which may have skewed the mean score.5,6 We found no difference in functional scores when stratified by general fracture pattern (unstable intertrochanteric without reverse obliquity, unstable intertrochanteric with reverse obliquity and subtrochanteric).

New implants must undergo critical evaluation as they are introduced into the orthopaedic surgeon’s armamentarium. The LTFN performed well in this series of challenging fractures from both functional and radiographic perspectives. The union rates observed in this series compare favorably with union rates reported for other intramedullary devices used to treat subtrochanteric and unstable intertrochanteric fractures. We can recommend the use of the long Trochanteric Fixation Nail for treatment of subtrochanteric and unstable intertrochanteric fractures, including such challenging fracture patterns as intertrochanteric fractures with reverse obliquity and subtrochanteric fractures with extensive medial comminution.