A Barbed Proximal Femoral Nailing System for Isolated Intertrochanteric Femur Fractures: Operative Outcomes

Benjamin W. Hoyt, MD[1]; Sarah A. Walsh, PhD[1]; Scott M. Tintle, MD[1]; and Romney C. Andersen, MD[2]

Intertrochanteric femur fractures are associated with high morbidity/mortality, necessitating strategies to limit time under anesthesia, blood loss, and additional trauma while achieving maximal fixation in osteopenic bone. The Orthopedic Designs North America, Inc. Talon DistalFix Femoral Nail System uses deployable barbs to maximize axial and rotational control without distal interlock screws. The purpose of this study was to evaluate perioperative features and postoperative outcomes in patients treated with the DistalFix Femoral Nailing System for isolated intertrochanteric femur fractures. Seventy-one consecutive patients underwent intramedullary fixation for isolated intertrochanteric fractures with the DistalFix system between January 2019–July 2020. Median operative time was 35 (33 – 40) minutes. Median estimated blood loss was 125 (75 – 150) cc. Median fluoroscopy time was 2.4 (2.2 – 2.9) minutes and dosage was 27.1 (18.0 – 35.2) mGy. Union occurred in 98% of patients; none experienced implant cutout, and 81.1% returned to previous mobility. The DistalFix system achieves a high rate of union and return to function while limiting operative risk factors. (Journal of Surgical Orthopaedic Advances 32(1):036–040, 2023)

Key words: hip fracture, intertrochanteric fracture, intramedullary nail, osteoporosis, cost containment, safety

In the United States, an estimated 10.2 million adults have osteoporosis, and an additional 43.4 million have low bone mineral density based on femoral and spine densitometry.[1] These patients are at increased risk of sustaining fractures of the proximal femur, which among all fractures are most strongly associated with high morbidity and mortality, with a one-year mortality rate of 27% While these represent only an estimated 14% of all fractures, this number is expected to rise with increasing life expectancy and older patient populations.[3] Given the increasing frequency of these injuries and the high-risk patient population, there has been substantial interest in optimizing management options, including intramedullary implant design and length.

The benefit of longer or distally locked intramedullary devices is increased biomechanical stability, rotational control, and protection from late periprosthetic femur fractures at the tip of the implant, particularly in severe osteoporotic patients.[4,5] However, these implants are associated with increased operative times and blood loss and do not appear to affect long-term outcomes.[6] The primary cause of increased operative times appears to be the need for incisions to place interlock screws, especially in long stems where the interlocks are placed freehand. Placement of these bolts increase operative time, radiation exposure, and opportunities for hardware complications.[7,8]

Orthopedic Designs North America, Inc. (ODi, Florida, USA) received Substantially Equivalent status for their Talon DistalFix Proximal Femoral Nail in 2011 by the US Food and Drug Administration (FDA). The DistalFix Femoral Nail System uses deployable barb-like talons in both the lag screw and the distal stem to achieve endocortical purchase and maximize cancellous purchase in the femoral head-neck junction. This endocortical fixation achieves axial and rotational control proximally and distally without the need for placing distal interlock screws (Fig. 1).

The theoretic advantages of this system include fewer incisions and decreased blood loss, elimination of mechanical stress risers from drill holes and interlocks, reduced radiation exposure for freehand placement of screws, and shorter operation time.[9,10] In response to these potential benefits, the lead author transitioned to use of this system for all intertrochanteric femur fractures amenable to intramedullary fixation in 2018. The purpose of this study was to evaluate these clinical measures and complications in patients treated with the ODi Talon DistalFix Femoral Nail for isolated intertrochanteric femur fractures. The null hypothesis was that intramedullary fixation with this implant system would produce high rates of stability while limiting operative time, blood loss, and radiation exposure.

Methods

After receiving approval from our Institutional Review Board, the surgery scheduling system was reviewed to identify all patients who presented with an intertrochanteric proximal femur fracture (AO 31A) for which they underwent intramedullary nailing at a Level II regional trauma center between January 2019 and July 2020. Patients who were excluded included two who sustained polytrauma necessitating con-

From [1]USU-Walter Reed Department of Surgery, Walter Reed National Military Medical Center, Bethesda, Maryland; [2]Orthopaedic Surgery, Riverside Regional Medical Center, Newport News, Virginia. Address correspondence to Benjamin W. Hoyt, MD, LT, MC, USN, Teaching Fellow, Uniformed Services University, Orthopaedic Surgeon, WRNMMC, 8901 Wisconsin Ave., Bethesda, MD 20889: email: benjaminwhoyt@gmail.com.

1548-825X/19/3201-0036$22.00/0
DOI: 10.3113/JSOA.2023.0036

FIGURE 1. Plain films demonstrating intertrochanteric femur fractures addressed with (A) DistalFix Femoral Nailing System and (B) long cephalomedullary nail with distal interlock screw fixation.

current procedures at the time of nailing, two with retained implants necessitating removal of an implant at the time of surgery, and three with incomplete medical records. These patients were excluded in order to limit confounding potential of these substantial additional procedures on operative time, blood loss, and radiation exposure, leaving 71 patients (29 male, 42 female) that met these criteria for intra-operative metric analysis. Patient demographics and comorbidities were collected to describe the patient population and injury pattern (Table 1).

Primary intra-operative measures were operative time, estimated blood loss (EBL), radiation time and dosage, and perioperative blood transfusion. Other factors examined were American Society of Anesthesiologists (ASA) status and perioperative mortality, defined as death prior to three-month follow-up, as a postoperative outcome in relation to intra-operative measures.

Postoperative outcomes were assessed for patients treated with the DistalFix femoral nail. To perform this analysis, all patients with available follow-up less than three months were excluded. Of the 71 patients treated with the ODi DistalFix system, 11 died before 3 months, and 7 were either lost to follow up or transitioned to hospice with no plans for follow-up evaluation, leaving 53 total patients for longitudinal analysis. For these remaining 53 patients tip-apex distance (TAD), comorbidities, and DEXA diagnosis of osteoporosis were collected. Outcomes considered included union, defined as radiographic and clinical evidence of osseous union by 15 weeks, complications, pain scores on a visual analog scale (VAS), and change in ambulatory status from pre-injury.

Statistical analysis was performed using RStudio (version 1.3.1073, RStudio, PBC, Boston, Massachusetts, USA), and GraphPad Prism (version 9.0.2, GraphPad software, San Diego, California, USA). Linear and logistic regression were applied to assess relationship between outcomes and patient demographics, fracture type, TAD, reduction quality, or bone density.

Surgical Technique

In accordance with AAOS recommendations, intramedullary fixation for intertrochanteric femur fractures is performed as soon as safely achievable.[11] The patient is positioned supine on a fracture table and the reduction is performed prior to skin prep or incision whenever possible. A small longitudinal incision is made in the lateral thigh and carried down through the iliotibial fascia. The guide pin is introduced through the tip of the greater trochanter and a starting reamer is used to open the proximal femur. A ball-tipped guidewire is then introduced and advanced to the distal metaphysis and then over-reamed to appropriate cortical chatter and both are removed. An appropriately sized long femoral nail is then placed and sunk to the appropriate depth, and the outrigger is used to place a guidewire in the center of the femoral head through a second small incision.

TABLE 1. Summary of patient demographics

Characteristic	n = 71
Sex	
Female	42 (59%)
Male	29 (41%)
Age (years)	82 (71, 87)
ASA status	
2	4 (5.6%)
3	48 (68%)
4	18 (25%)
5	1 (1.4%)
Body Mass Index	
Normal	40 (57%)
Obese	8 (11%)
Overweight	22 (31%)
Unknown	1
Smoker	
No	58 (82%)
Yes	13 (18%)
Mechanism of injury	
Fall from stepladder	1 (1.4%)
Ground level fall	68 (96%)
Motor vehicle collision	1 (1.4%
Pivot while standing	1 (1.4%

Statistics presented: n (%); median interquartile range
American Society of Anesthesiologists

The wire is over-reamed and replaced with a cephalomedullary lag screw. The set screw is then placed and tightened to achieve the desired static stability or controlled compression collapse. Distal locking for the DistalFix is achieved by passing the proprietary driver down the central cannula of the nail and turning the driver clockwise to deploy the distal talons. Cortical contact is registered initially through tactile feedback, and continued deployment progress is then monitored with fluoroscopy until the torque-limiting handle trips or is radiographically indicated to stop. Proximal locking in the femoral head-neck junction is achieved through a similar talon mechanism deployed with a driver inserted into the cephalomedullary lag screw. Patients are permitted to fully weight-bear immediately after surgery.

Results

Median operative time was 35 (33 – 40) minutes, median EBL was 125 (75 – 150) cc, median fluoroscopy time was 2.4 (2.2 – 2.9) minutes and dosage was 27.1 (18.0 – 35.2) mGy (Table 2). In this cohort, patient ASA, EBL, perioperative transfusion, and operative time were not significantly associated with perioperative mortality (p = 0.13, p = 0.41, p = 0.71, p = 0.21, respectively).

Union occurred in 98% of patients by 12 weeks. One patient had not achieved union by 12 weeks and was lost to follow-up before 15 weeks, resulting in final union 98% by 15 weeks. No patients experienced implant cutout, therefore no association could be determined between TAD and implant failure. Mean pain score at final follow-up was 0.8 ± 1.7 with 75% reporting no pain. Of patients, 81.1% were able to return to their previous levels of mobility (Table 3). There was a significant association between age and reported pain at final follow-up, with older patients reporting less pain (p = 0.046).

Discussion

Intertrochanteric femur fractures typically occur in elderly patients with multiple medical comorbidities. Multiple factors, including increasing patient age, frailty, comorbidities, and operative delays may further escalate this risk.[12-14] In the setting of such poor physiologic reserve, surgeons must optimize strategies to limit operative risk. These risks, including time under anesthesia, blood loss, and additional incisions, should be balanced against the necessity to achieve sufficient stability in presumably weak bone to prevent healing complications and allow return to previous function. Use of intramedullary, minimally invasive implants has become increasingly common as it permits reliable fixation, while decreasing operative time, blood loss, and perioperative blood transfusions.[15] This deliberate, efficient approach to time under anesthesia appears to be a factor in reduced risk of perioperative mortality.

Previous reports have sought to clarify ideal implant choice for intertrochanteric fractures. While there is clear support for intramedullary fixation to treat unstable or extensile patterns, there is limited guidance to support any specific intramedullary device.[17-19] In a Cochrane systematic review, there were no important differences in patient outcomes or major complications between designs of proximal femoral nailing systems produced by various manufacturers.[20] The DistalFix system achieves a high rate of union, similar to those reported for other implant systems, and a high return to function while reducing operative risk factors compared to similar fixation constructs. Given this tendency for achieving similar long-term outcomes between implants, the next logical focus may be minimizing perioperative risk for these patients.

In this study population, there was a low estimated blood loss and operative time, as well as a very low rate of blood transfusion necessary on the date of surgery. Patients who sustain extra-capsular hip fractures lose an estimated 2 units of blood from the injury alone and are prone to require transfusions to maintain systemic perfusion.[21] A Cochrane

TABLE 2. Summary of operative measures

Characteristic	n = 71
Operative time (min)	35 (33, 40)
Estimated blood loss (cc)	125 (75, 150)
Fluoroscopy time (min)	2.40 (2.20, 2.90)
Fluoroscopy dose (mGy)	27 (18, 35)

Statistics presented: median interquartile range

TABLE 3. Summary of postoperative outcomes

Characteristic	n = 53
Tip Apex Distance (mm)	13.5 (10.8, 17.2)
Union at 15 weeks	
LOF	1 (1.9%)
Yes	52 (98%)
Decreased mobility from baseline	
No	43 (81%)
Yes	10 (19%)
Pain at final follow-up	
0	39 (75%)
1	3 (5.8%
2	2 (3.8%)
3	0
4	4 (7.7%)
5	2 (3.8%)
6	2 (3.8%)

Statistics presented: n (%); median interquartile range
LOF, leakage of fluids

systematic review of blood transfusion protocols after hip fracture surgery found that the rate of perioperative blood transfusion was 11 to 45% using a restrictive threshold (Hgb < 8 g/dL or symptomatic anemia) and 74 to 100% in more liberal (Hgb < 8 g/dL) transfusion protocols.[22] The findings of the current investigation are comparable to the lower end of this range for restrictive transfusion. As operative time and blood transfusions have both been associated with increased infection risk and other complications postoperatively,[23-26] these factors and the decreased number of incision sites as potential sites of contamination would be expected to contribute at least a theoretical benefit to severe complications such as deep implant infection after surgery.

Removal of distal interlocks may be beneficial for additional reasons including limiting iatrogenic injury and radiation exposure. Placement of distal interlocking screws in a cephalomedullary implant can injure the profunda femoris or superficial femoral artery during drilling or screw insertion.[27,28] The deep vascular structures lie in close proximity to the medial femoral cortex and can be at risk when a short implant is used, particularly when the extremity is internally rotated and adducted for intertrochanteric fracture reduction.[29,30] In this study, no patients were noted to have any neurovascular injury in the postoperative period, which may be in part due to the infrequency of this complication, but also due to the absence of opportunity for iatrogenic injury with this implant system. The absence of distal interlock screws is potentially beneficial with regards to intra-operative radiation exposure for the operative team. In prior studies, authors have observed greatly increased radiation exposure associated with free-hand placement of distal interlocking screws, which may be reduced with alternate techniques.[31,32] Fluoroscopy time in the current patient population was 132 seconds, which is consistent with reports for other cephalomedullary constructs.[33]

There are several limitations to the current study. First, it is a retrospective, observational study, which is limited by the completeness of the electronic medical record, patient follow-up, and potential for bias in reporting. There is no comparison group to compare results against other than historically reported outcomes. Patients treated in this study are not obligated to return to the same hospital system for management, and there is a possibility that patients may have been treated at other facilities, which would not have been reflected in the current study. Similarly, several patients were lost to follow-up or death after discharge, which is a known issue in trauma patients and studies of this population. Second, nearly all surgeries were performed by a single surgeon, which may be prone to bias due to variability in practice, preferences in exposure, and experience with the surgery and implant. Another potential limitation was the chosen outcome measures. There is opportunity for multiple factors to influence operative time, EBL, and fluoroscopy time including fracture complexity, surgeon experience, patient status, or delays obtaining additional tools/equipment—all of which would be difficult to account for in this study design.[34,35] EBL may also be a problematic measurement as it is subject to observer bias, with poor inter-rater reliability.[36,37]

Conclusions

There are several options for intramedullary fixation of proximal femur fractures. This study demonstrates operative metrics and complication profiles for the ODi Talon DistalFix femoral nail. By removing the necessity for distal interlocking screws, this implant system achieves similar fixation and union rates to those reported for other systems while enabling placement of a long protective construct, expeditious operative times, limited blood loss and radiation exposure, and an excellent return to prior functional level. In the absence of clear long-term advantages of any specific device, the DistalFix femoral nail may offer unique advantages to efficiency patient safety and should be considered as a viable alternative to other cephalomedullary implants.

References

1. Wright NC, Looker AC, Saag KG, et al. The recent prevalence of osteoporosis and low bone mass in the United States based on bone mineral density at the femoral neck or lumbar spine. J Bone Mineral Res. 2014;29:2520-2526.
2. Panula J, Pihlajamäki H, Mattila VM, et al. Mortality and cause of death in hip fracture patients aged 65 or older - a population-based study. BMC Musculoskelet Di. 2011;12:105.
3. Burge R, Dawson-Hughes B, Solomon DH, et al. Incidence and economic burden of osteoporosis-related fractures in the United States, 2005–2025. J Bone Miner Res. 2007;22:465-475.
4. Bjørgul K, Reikerås O. Outcome after treatment of complications of Gamma nailing: A prospective study of 554 trochanteric fractures, Acta Orthop. 2009;78:231-235.
5. Sears BR, Ostrum RF, Litsky AS. A mechanical study of gap motion in cadaveric femurs using short and long supracondylar nails. J Orthop Trauma. 2004;18:354-360.
6. Hou Z, Bowen TR, Irgit KS, et al. Treatment of pertrochanteric fractures (OTA 31-A1 and A2): long versus short cephalomedullary nailing., J Orthop Trauma. 2013;27:318-324.
7. Okcu G, Ozkayin N, Okta C, et al. Which implant is better for treating reverse obliquity fractures of the proximal femur: a standard or long nail? Clin Orthop Relat Res. 2013;471:2768-2775.
8. Kanakaris NK, Tosounidis TH, Giannoudis PV. Nailing intertrochanteric hip fractures: short versus long; locked versus nonlocked. J Orthop Trauma. 2015;29:S10-S16.
9. Brophy RH, Bansal A, Rogalski BL, et al. Risk factors for surgical site infections after orthopaedic surgery in the ambulatory surgical center setting. J Am Acad Orthop Sur. 2019;27:e928-e934.
10. Cogbill CL. Operation in the aged: mortality related to concurrent disease, duration of anesthesia, and elective or emergency operation. Arch Surg-Chicago. 1967;94:202-205.
11. Quinn RH, Mooar PA, Murray JN, etv al. Treatment of hip fractures in the elderly. J Am Acad Orthop Surg. 2017;25:e102-e104.
12. Guerra MTE, Viana RD, L. Feil ET, et al, Mortalidade em um ano de pacientes idosos com fratura do quadril tratados cirurgicamente num hospital do Sul do Brasil, Revista Brasileira De Ortopedia. 2017;52:17-23.
13. Turrentine FE, Wang H, Simpson VB, et al. Surgical, risk factors, morbidity, and mortality in elderly patients. J Am Coll Surgeons. 2006;203:865-877.
14. Frost SA, Nguyen ND, Black DA, et al. Risk factors for in-hospital post-hip fracture mortality. Bone. 2011;49:553-558.
15. Kuzyk PRT, Guy P, Kreder HJ, et al. Minimally invasive hip fracture surgery: are outcomes better? J Orthop Trauma. 2009;23:447-453.
16. Elder GM, Harvey, R. Vaidya, P. et al. The effectiveness of orthopaedic trauma theatres in decreasing morbidity and mortality: a study of 701 displaced subcapital hip fractures in two trauma centres. Injury. 205;36:1060-1066.
17. Zhang W-Q, Sun J, Liu C-Y, et al. Comparing the intramedullary nail and extramedullary fixation in treatment of unstable intertrochanteric fractures. Sci Rep-Uk. 2018;8:2321.
18. Duymus TM, Aydogmus S, Ulusoy İ, et al. Comparison of intra- and extramedullary implants in treatment of unstable intertrochanteric fractures. J Clin Orthop Trauma. 2019;10:290-295.

19. Socci AR, Casemyr NE, Leslie MP, et al. Implant options for the treatment of intertrochanteric fractures of the hip: rationale, evidence, and recommendations, Bone Joint J. 2017;99-B:128-133.
20. Queally JM, Harris E, Handoll HH, et al. Intramedullary nails for extracapsular hip fractures in adults. Cochrane Database Syst Rev. 2014;9:CD004961.
21. Smith GH, Tsang J, Molyneux SG, et al. The hidden blood loss after hip fracture. Injury. 2011;42:133-135.
22. Brunskill SJ, Millette SL, Shokoohi A, et al. Red blood cell transfusion for people undergoing hip fracture surgery. Cochrane Database Syst Rev. 2015;4:CD009699.
23. Colman M, Wright A, Gruen G, et al. Prolonged operative time increases infection rate in tibial plateau fractures. Injury. 2013;44:249-252.
24. Lin S, Mauffrey C, Hammerberg EM, et al. Surgical site infection after open reduction and internal fixation of tibial plateau fractures, European J Orthop Surg Traumatol. 2014;24:797-803.
25. Li G, Guo F, Ou Y, et al. Epidemiology and outcomes of surgical site infections following orthopedic surgery. Am J Infect Control. 2013;41:1268-1271.
26. Teng Z, Zhu Y, Liu Y, et al. Restrictive blood transfusion strategies and associated infection in orthopedic patients: a meta-analysis of 8 randomized controlled trials. Sci Rep-Uk. 2015;5:13421.
27. Grimaldi M, Courvoisier A, Tonetti J, et al. Superficial femoral artery injury resulting from intertrochanteric hip fracture fixation by a locked intramedullary nail. Orthop Traumatology Surg Res. 2009;95:380-382.
28. Neubauer T, Grechenig S, Clement H, et al. Risk of extrapelvine vascular injuries in osteosynthesis with gliding hip screws. Arch Orthop Traum Su. 2018;139:339-345.
29. Han CD, Lee YH, Yang KH, et al. Relationship between distal screws and femoral arteries in closed hip nailing on computed tomography angiography. Arch Orthop Traum Su. 2012;133:361-366.
30. Yang KH, Yoon CS, Park HW, et al. Position of the superficial femoral artery in closed hip nailing. Arch Orthop Trauma Surg. 2004;124:169-172.
31. Han B, Shi Z, Fu Y, et al. Comparison of free-hand fluoroscopic guidance and electromagnetic navigation in distal locking of femoral intramedullary nails. Medicine. 2017;96:e7450.
32 Sanders R, Koval KJ, DiPasquale T, et al. Exposure of the orthopaedic surgeon to radiation., J Bone Joint Surg. 1993;75:326-330.
33. Frisch NB, Nahm NJ, Khalil JG, et al. Charters, short versus long cephalomedullary nails for pertrochanteric hip fracture. Orthopedics. 2016;40:83-088.
34. Rashid MS, Aziz S, Haydar S, et al. Intra-operative fluoroscopic radiation exposure in orthopaedic trauma theatre. Eur J Orthop Surg Traumatol. 2018;28:9-14.
35. Quah C, Mehta R, Shivji FS, et al. The effect of surgical experience on the amount of radiation exposure from fluoroscopy during dynamic hip screw fixation, Ann R Coll Surg Engl. 2017;99:198-202.
36. Mooney JF, Barfield WR. Validity of estimates of intraoperative blood loss in pediatric spinal deformity surgery. Spine Deformity. 2013;1:21-24.
37. Budair B, Ahmed U, Hodson J, et al. Are we all guilty of under-estimating intra-operative blood loss during hip fracture surgery? J Orthop. 2017;14:81-84.