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Intramedullary Nailing of Humerus Fractures Using an Implant System with Internal Distal Locking and Avoiding Distal Incisions: Operative and Clinical Outcomes

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There is limited evidence to guide implant selection for humeral shaft fractures. The objective of this study was to evaluate operative differences, early outcomes, and complications associated with use of an intramedullary nailing (IMN) system without distal interlock screws and compare this to a standard humeral nailing system. We evaluated 49 consecutive patients who underwent IMN for humeral shaft fracture between 2015–2018. Patients were grouped based on implant; Stryker T2 Nail (n = 37), or ODI Talon DistalFix (n = 12), which achieves distal interference with an endocortical barb mechanism. Operative time using the T2 nail was significantly longer than DistalFix nails (90 vs. 64 minutes, p < 0.05). With the numbers available, there was no significant difference in estimated blood loss for both systems (114 vs. 97 ml, respectively; p = 0.6). Neurologic complications occurred in eight versus one patient in the T2 and DistalFix cohort, respectively. These findings may support increased shifts to implant systems that bypass distal interlocking systems for cost savings and patient/surgeon safety. (Journal of Surgical Orthopaedic Advances 31(1):012–016, 2022)

Key words: humeral shaft fracture, intermedullary nail, interlock, bar bed nail, operative efficiency

Humeral shaft fractures are a relatively common injury pattern, representing 3–8% of fractures and occurring in 57,000 to 70,000 persons in the United States per year.[1-4] These injuries most often occur as a result of blunt trauma, particularly mechanical falls and motor vehicle collisions (MVCs). It is anticipated that with the continually aging population and increasing number of survivable MVCs, the incidence of these fractures will increase.[5] Historically, most diaphyseal and metadiaphyseal humeral shaft fractures were managed conservatively due to the high rates of union and equivocal long-term outcomes associated with Sarmiento-style functional bracing techniques.[6-8] However, nonunion rates may be higher in comminuted, short oblique/transverse, and more proximal fracture patterns.[9,10] Additionally, these strategies impose a 3–5 month period of non-weightbearing, which may delay return to work for young, active patients, limit mobility in elderly patients, and delay rehabilitation in polytraumatized patients.[11-13] In one recent randomized control trial comparing nonoperative versus operative treatment, 30% of patients randomized to the functional bracing group crossed over to surgical intervention to expedite recovery.[7] As internal fixation permits early return to weight bearing on the injured extremity with union rates of 90 to 97%, there has been increasing interest in improved techniques to stabilize these fractures while minimizing intraoperative risks.[13-15]

There is some controversy with regards to fixation strategy, as no well-designed randomized control trials have demonstrated substantial differences in union, neurovascular injury, or infection rates between plate osteosynthesis and intramedullary nailing for the humeral shaft.[13,16] Rigid plate fixation is associated with improved shoulder outcomes and lower reoperation rates and represents the gold standard for operative management of the humerus. Plate fixation also permits compression across the fracture site, which enhances stability of the construct and has been associated with prevention of nonunion.[17] However, it necessitates a large operative exposure. By contrast, intramedullary fixation can be accomplished quickly, with decreased soft tissue disruption, and with less operative assistance.[18] However, it may be challenging to achieve appropriate compression with current intramedullary implants and these devices represent a greater material cost that may dissuade surgeons from use.[19,20]

One major challenge of all intramedullary fixation is placement of distal cortical interlocking screws to maintain length and rotation. Placement of these bolts in both the upper and lower extremity increase operative time, radiation exposure, and opportunities for hardware complications.[21,22] For humeral shaft fractures, freehand positioning of distal

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locking screws is further encumbered by a slick periosteal surface and narrow nail holes.[23] While these additional steps may represent limited increases in time and irradiation for experienced trauma surgeons, they are compounded for patients who perform intramedullary humeral fixation with less frequency. Finally, placement of distal interlock screws introduces increased risk of iatrogenic injury to adjacent neurovascular structures. While no important structure lies in close proximity to the more common anterior to posterior screw trajectories, a lateral to medial screw or skiving of an anterior to posterior drill may endanger the radial and ulnar nerves, which lie within 4 mm of the lateral to medial drill path.[21,24]

Orthopedic Designs North America, Inc. (ODI, Florida, USA) received Substantially Equivalent status for their Talon DistalFix Humeral Nail in February 2018 by the US Food and Drug Administration (FDA). Their distal interlock system deploys talon-like hooks from within the terminal device to achieve endocortical fixation, eliminating the need for distal cortical screws. Proposed advantages to this system include fewer incisions, elimination of mechanical stress risers from drill holes, reduced radiation exposure, and shorter operation time, which in turn is associated with decreased costs and decreased perioperative infection and mortality in the Orthopaedic trauma patient.[25-27]

Based on these purported benefits, we began using the Talon DistalFix nail system for intramedullary fixation of humeral shaft fractures at our institution in 2018. The purpose of this study was to evaluate the operative characteristics and early postoperative complications associated with its use and compare this to our results using intramedullary fixation with distal interlocking screws.

Methods

After receiving approval from our Institutional Review Board, the surgery scheduling system was reviewed to identify all patients who presented with a proximal third or diaphyseal humeral shaft fracture for which they underwent intramedullary nailing at a Level II regional trauma center between April 2015 and November 2018. We excluded four patients for multi-system trauma necessitating concurrent procedures at the time of intramedullary fixation to limit confounding potential on the estimated operative time, leaving 49 patients (25 male, 24 female) that met these criteria for analysis.

We distinguished patient cohorts based on which intramedullary nailing system was used--Stryker T2 or ODI Talon DistalFix. The T2 proximal humeral nail (Stryker Inc, USA) is an anodized titanium alloy stem with available diameters ranging from 7 to 9 mm and a length ranging from 140 to 320 mm. The distal locking system consists of locking or non-locking screws in a variety of lengths. The ODI Talon DistalFix is available in diameters ranging from 8 to 10 mm and a length ranging from 165 to 315 mm. The distal locking system employs sharp "talon" like barbs that deploy to a maximum span of 22 mm to engage the inner osseous cortex.

We collected patient demographics and comorbidities to describe the patient population (Table 1). Concurrent injuries, laterality, and time from injury to fixation were used to illustrate injury characteristics (Table 2). We also collected nail diameter and number of interlock screws utilized. Thirty-seven patients underwent operative fixation with a Stryker T2 nail and 12 patients underwent fixation with an ODI Talon DistalFix nail.

Our primary outcome measures were operative time, estimated blood loss (EBL), and perioperative complications. Contingency tables and Chi-square test were used to determine potential differences in comparing outcomes between treatment groups. T-tests were used to evaluate for group differences in operative time and EBL.

Surgical Technique

Our standard technique is to perform intramedullary fixation for the humeral shaft with the patient in a beach-chair position. The patient is prepped and draped in a sterile fashion with the injured limb secured in a mechanical arm holder. A longitudinal incision is made along the anterolateral aspect of the acromion and carried down to the humeral head in line with the fibers through the deltoid, subdeltoid bursa, fascia, and rotator cuff tendon. A guidewire is then placed between the greater tuberosity and sulcus, centered with the medullary canal, and advanced across the reduced fracture site. The proximal humerus and canal is then reamed to cortical chatter and a nail is selected with diameter 1mm less than the reamer.

The nail is then inserted completely, the guide wire is removed, and the nail is proximally locked. Both nailing systems use a proximal interlock target guide handle, which permits insertion through a small skin incision and direct tissue protection sleeve contact with the osseous surface.

TABLE 1. Patient demographics and comorbidities

	Total (n = 49)	Stryker T2 Cohort (n = 37)	Talon Distal-Fix Cohort (n =12)
Demographics			
Age (years)	58 +/- 24	54 +/- 24	67 +/- 21
Male Sex (%)	24 (49)	17 (46)	7 (58)
BMI	28 +/- 7	28 +/- 7	27 +/- 6
Race			
African American/ Black (%)	19 (39)	15 (41)	4 (33)
Caucasian (%)	29 (59)	22 (59)	7 (58)
Hispanic (%)	1 (2)	0 (0)	1 (8)
Comorbidities			
Diabetes (%)	7 (14)	4 (11)	3 (25)
Hypertension (%)	14 (29)	10 (27)	4 (33)
COPD (%)	1 (2)	1 (3)	0 (0)
Cancer (%)	7 (14)	6 (16)	1 (8)

BMI, body mass index; COPD, chronic obstructive pulmonary disease

TABLE 2. Injury characteristics

	Total (n = 49)	Stryker T2 Cohort (n = 37)	Talon Distal-Fix Cohort (n =12)
Fracture Laterality (Right)	24 (49)		
Time to Operation (days)			
< 1	5 (10)	4 (11)	1 (8)
1–5	33 (67)	24 (65)	9 (75)
> 5	11 (22)	9 (24.3)	2 (17)
Mechanism of Injury			
Mechanical Fall	30 (61)	21 (57)	9 (75)
MVC	10 (20)	10 (27)	0 (0)
Pedestrian Struck	5 (10)	5 (13)	0 (0)
GSW	3 (6)	0 (0)	3 (25)
Other	1 (2)	1 (3)	0 (0)

MVC, motor vehicle collision; GSW, gunshot wound

Distal locking for the Stryker T2 system (Fig. 1) was accomplished with one to three bolts placed freehand using the perfect circle technique as described by Krettek et al.[28] The number of distal screws was determined by the operative surgeon based on the clinical impression of the fracture pattern, bone quality, and patient goals. Distal locking for the ODI Talon DistalFix (Fig. 2) was 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. Prior to skin closure for both implants, wounds are copiously irrigated and the rotator cuff is then closed in layers with o Vicryl suture.

Results

Mean operative time was 89.6 (95% confidence interval [CI] 74.9–103.5) minutes for Stryker T2 nails and 63.8 minutes (95% CI 56.4–71.3) minutes for ODI Talon DistalFix nails [Table 3, Fig. 3]. Mean EBL was 114 (95% CI: 90–138) mL and 96.67 ml (95% CI: 62.89–130.45mL) for Stryker T2 nails and ODI Talon DistalFix nails, respectively. Non-union occurred in three patients in the Stryker group and none in the ODI group ($p = 0.55$).

Complications

Of those treated, six patients (16.2%) in the Stryker T2 nail group were lost to follow-up (n = 3) or died (n = 3) prior to osseous union, leaving a total 43 patients for analysis of com-

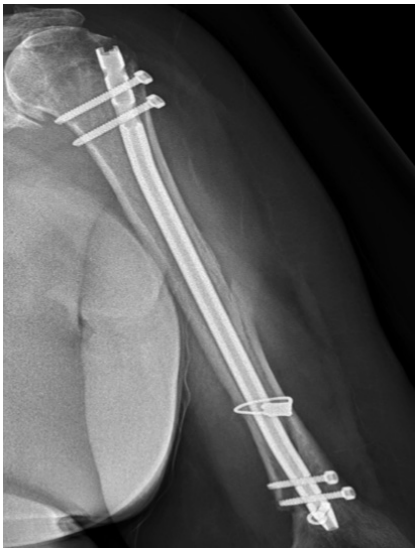

FIGURE 1. Plain film demonstrating placement of Stryker nail, with two proximal and three distal interlock screws.

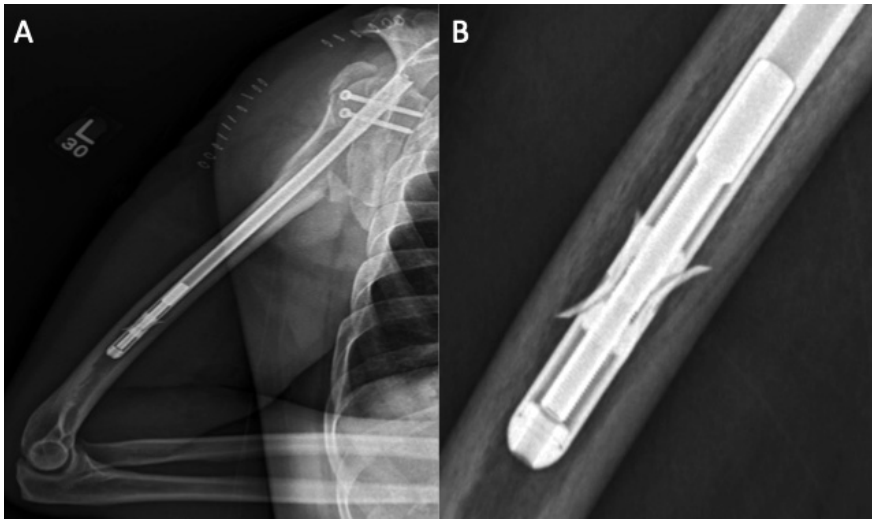

FIGURE 2. Plain film demonstrating placement of ODI Talon DistalFix nail (A), with deployed internal distal talon locking system (B).

TABLE 3. Primary operative outcomes and intraoperative features/complications

	Total (n = 49)	Stryker T2 Cohort (n = 37)	Talon DistalFix Cohort (n =12)
Operative Time (min)	83 ± 39	90 ± 43*	64 ± 13*
Estimated Blood Loss (mL)	111 ± 19	114 ± 71	97 ± 60
Median nail diameter (mm)	8	8	8
Number Proximal Interlock Screws (%)			
1		3 (8)	0 (0)
2		30 (81)	9 (75)
3		3 (8)	3 (25)
Undocumented		1 (3)	0 (0)
Number Distal Interlock Screws (%)			
1		32 (86)	0 (0)
2		3 (8)	0 (0)
3		1 (3)	0 (0)
Undocumented		1 (3)	0 (0)
Intraoperative Complications (%)			
Cable fixation		3 (8)	0 (0)
Additional dissection		4 (11)	0 (0)

* $p < 0.05$

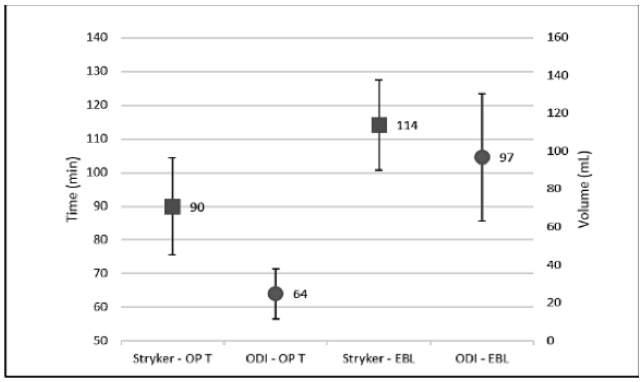

FIGURE 3. Histogram demonstrating operative duration and estimated blood loss for the Stryker T2 and ODI Talon DistalFix intramedullary nailing systems; OPT, operative time; EBL, estimated blood loss.

plications (Table 4). Superficial wound infection responding to local wound care and antibiotics occurred in two patients in the Stryker nail group at the distal interlock incisions. No deep infections occurred in either group. Eight patients in the Stryker group and one patient in the ODI group experienced symptoms of nerve injury including numbness, tingling, or motor dysfunction ($p = 0.17$). No patients displayed clinical signs and symptoms of impingement or rotator cuff tears, nor significant differences in range of motion or muscle strength at the shoulder and elbow joints.

Radiographic evidence of proximal screw back-out occurred in two patients in the Stryker group and three patients in the ODI group. Of these, one patient in the Stryker group underwent a revision surgery for removal of the hardware. Two patients from the Stryker group underwent nail removal and revision fixation for broken hardware; one patient from the ODI group was scheduled for nail removal due to proximal screw and nail migration but cancelled the procedure. Delayed union based on lack of radiographic evidence of callus formation at 6 weeks occurred in five patients in the Stryker group and three patients in the ODI group. All patients diagnosed with delayed union were treated with bone stimulation/radiofrequency therapy and went on to osseous union.

Discussion

In modern Orthopaedic trauma surgery, increasing emphasis has been placed on delivering high quality and safe care while limiting costs to the patient and trauma system.[29] Efficient utilization of the operating room is an important component of this paradigm as it enables increased capacity for patient care, decreases risk for surgical site infection, limits time under anesthesia for fragile trauma patients, and decreases costs. Previous studies have demonstrated an association with duration of Orthopaedic and other surgeries and increased risk of infection.[30] Similarly, in the trauma setting, a deliberate, efficient approach to time under anesthesia appears to be a factor in reduced risk of perioperative mortality.[31] From a system-based economic perspective, time in the operating room incurs a cost of 16 to 36 USD per minute, supporting that inefficiency in the operating room contributes to driving healthcare and payer costs upwards.[27] It is therefore incumbent on Orthopaedic traumatologists to approach operative decision making based on system and patient costs and the value of care delivered, rather than direct material costs.

Operative fixation of the humerus enables faster time to weight bearing, quicker return to work, decreased opiate usage, and improved polytrauma rehabilitation compared to non-operative management.[11-13] In appropriately selected patients, these benefits outweigh the cost and inherent risks of this intervention. However, when selecting intramedullary implants, there is limited guidance to support any specific device. In this study, we observed a substantial decrease in operative times associated with use of an intramedullary nailing system that removes the necessity for distal interlocking screws. This relative decrease of 26 minutes per case corresponds to cost savings, decreased exposure to general anesthesia, and potential for other benefits. Additionally, as the most commonly wasted implants are incorrectly measured or dropped screws, the use of these implants further increases cost saving potential.[32]

TABLE 4. Postoperative complications

	Total (n = 43)	Stryker T2 Cohort (n = 31)	Talon Distal-Fix Cohort (n =12)
Non-Union (%)	3 (7)	3 (10)	0 (0)
Delayed Union (%)	8 (19)	5 (16)	3 (25)
Removal of Implants (%)	2 (5)	2 (7)	0 (0)
Proximal Screw Migration/Failure (%)	5 (12)	2 (7)	3 (25)
Distal Screw Migration/Failure (%)	2 (5)	2 (7)	0 (0)
Nerve Injury (%)	9 (21)	8 (26)	1 (8)
Superficial Wound Infection (%)	2 (5)	2 (7)	0 (0)

Surgical incisions are inherently opportunities for injury to the patient through injury to neurovascular structures, wound healing, or infection. In our series, all superficial surgical site infections were associated with distal interlock incisions. Similarly, only one patient in the ODI group versus eight in the Stryker group experienced nerve injury symptoms. Drilling for the interlocks through small incisions places the radial neve at risk.[24] This may be avoided in part with careful dissection and a soft tissue protector, but it is inherent to the use of distal interlocking screws. While this risk cannot be entirely avoided, given that nerve compression may occur at the fracture site,[21] increasing utilization of this or similar systems may reduce the overall frequency of this complication associated with operative fixation. Additionally, while not measured in this study, intraoperative radiation exposure would be expected to be decreased given the absence of screw placement. 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.[33,34] We anticipate that a similar decrease would be found in our cohort, improving occupational radiation safety for providers regularly performing these procedures. We would also expect this difference to be more marked for surgeons with less experience placing intramedullary humeral nails.

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. 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. Another potential limitation was our outcome measures. There is opportunity for multiple factors to influence operative time including fracture complexity, patient status, difficulty of managing the soft tissue envelope, or delays obtaining additional tools/equipment—all of which would be difficult to account for in this study design. EBL may also be a problematic outcome measure as it is subject to massive observer bias and is difficult to estimate with precision. This and the small incisions used for intramedullary nailing likely account for the inability to observe any meaningful differences in EBL between groups. Last, the ODI Talon DistalFix intramedullary nailing system is relatively new and we have performed comparably few cases given its short period of use. A larger sample size is likely warranted in the future to better to ensure the lack of significant differences in complication profile is not secondary to type II error.

Conclusions

There are several options for intramedullary fixation of diaphyseal and proximal metadiaphyseal humeral shaft

fractures. In this study, we presented operative metrics and complication profiles for two fixation systems that differ primarily in the mode of achieving distal cortical fixation. By removing the necessity for distal interlocking screws, the ODI Talon DistalFix enables faster operative times and fewer incisions, which may portend advantages in terms of health and economic outcomes. Using this system, Orthopaedic surgeons can expect a high rate of union with limited complications, similar to traditional intramedullary nailing techniques.

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