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# Outcomes of TFN-Advanced™ Proximal Nail System (TFNA) for AO Type 31-A1/A2/A3 Intertrochanteric Fractures: A Retrospective Review of 100 Cases with Minimum 2-Year Follow-Up

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## Abstract

**Purpose:** Hip fractures are a growing concern for healthy systems worldwide. Several fixation modalities have been developed for the fixation of AO type 31-A1/A2/A3 fractures. The TFN-AdvancedTM Proximal Nail System (TFNA) is a novel fixation device that aims to build on success of previous generation nails. Currently, there is a paucity of literature regarding the outcomes of this implant. The aim of this study was to present our experience using the TFNA implant over a 2-year minimum follow-up.

**Methods:** We retrospectively reviewed patients above the age of 65 who underwent closed reduction and internal fixation (CRIF) for AO type 31-A1/A2/A3 intertrochanteric fractures, with the TFNA nail between January 2017 and June 2018. The minimum follow-up time in our study was 2 years. Radiological evaluation was performed during follow up visits to evaluate for post-operative complications.

**Results:** Following exclusions, the final study population consisted of 100 patients. The mean follow-up was 30.8 months (range 24–44, SD 5.1). During the follow-up period, 6% of the patients (n=6) experienced orthopedic complications. The rate of peri-prosthetic fracture in our study was 2% (n=2), the rate of peri-prosthetic infection was 2% (n=2) and the cut-out rate was 1% (n=1). No cases of mal-union or non-union were observed. Revisions were required in 4% of patients (n=4).

**Conclusion:** The low rates of complications reported in our study support the implementation of TFN-A as a fixation device for AO type 31-A1/A2/A3 intertrochanteric fractures undergoing CRIF. Additional follow-up is required in the long-term.

**Keywords:** Intertrochanteric Fracture; Pertrochanteric Fracture; TFNA Nail

**Abbreviations:** AVN: Avascular Necrosis; CRIF: Closed Reduction and Internal Fixation; SD: Standard Deviation; ROC: Radius of Curvatures; PFN: Proximal Femoral Nail; PFN: Proximal Femoral Nail; Rcts: Randomized Control Trials.

## Introduction

Hip fractures are a growing concern for health systems around the world and have proven to be a significant cause of morbidity and mortality worldwide [1]. It is estimated

that the annual number of hip fractures worldwide will rise to over 6 million by the year 2050 Cooper C, et al. [2]. Intertrochanteric fractures represent the second most common proximal femur fracture (after femoral neck fractures) [3] and their optimal management thus remains a critical aspect of fracture care. The mainstay of management for intertrochanteric fractures involves intramedullary fixation. Common implant related complications include peri prosthetic fracture, cut-out, avascular necrosis (AVN), non-union and infection [4-6].

Several fixation methods have been developed for AO type 31-A1/A2/A3 hip fractures. The TFN-AdvancedTM Proximal Nail System (TFNA) is a novel fixation device that is synthesized from a Ti-15Mo (TiMo) titanium alloy material, intended to offer a step-up from its contemporary fixation modalities. The novelty of the TFNA nail stems from the titanium alloy's refined strength, along with the nail's proximal geometry, which is intended to better fit the anatomic bow of the femur. The novel Ti-15Mo (TiMo) titanium alloy used in the TFNa has a lower tensile strength in smooth tensile testing compared with the Ti-6Al-4v (TAV) titanium alloy found in other cephalomedullary nails [7] .The TFNA additionally includes 2 types of short nails, sized 170 mm and 235 mm.

Data on this implant in a clinical setting is limited. To our knowledge, there has only been one other study to present its results with the TFNA nail [8], which was limited by a small number of cases (n = 34). Further investigation is therefore warranted to evaluate whether this implant may offer an advantage over its contemporaries. The aim of this study was to present our experience using the TFNA implant over a 2-year minimum follow-up. We hypothesize that patients undergoing Closed reduction and internal fixation for intertrochanteric fractures with the use of the TFNA nail will have good clinical results.

## Methods

Institutional research ethics board approval was obtained for this retrospective study. A search of our institutional database was performed to identify patients who underwent closed reduction and internal fixation (CRIF) for AO type 31-A1/A2/A3 intertrochanteric fractures, with the TFNA nail between January 2017 and June 2018. Excluded from our study were patients younger than 65 years, patients with a pathological fracture, patients who underwent revision surgery with a TFNA nail and patients who did not meet the minimum 2-year follow-up period required.

Data was gathered from the patients' electronic medical records and included baseline patient characteristics such as age, gender and comorbidities. All patients underwent CRIF within 48 hours of presentation to our level 1 trauma center. Patients were operated under general or regional anesthesia and positioned supine on a fracture (Tables 1-3). Fracture reduction with rotational restoration was completed under fluoroscopy. The procedure was performed according to the standard protocol using the manufacturer's instructions. Briefly, the nail was inserted using a minimally invasive technique through the medial border of the greater trochanter after obtaining good, closed reduction using image intensifier C-arm. A blade/screw was placed into the femoral neck using image intensifier C-arm. Due to the financial issues, we have limited the use of blades implants to patients over the age of 85.

Operational data such as the surgeons' level of experience, duration of surgery, decreased hemoglobin levels, together with data on other hospitalisation characteristics and any intraoperative and postoperative complications were retrieved from the medical files.

Postoperative management included early mobilization, full-weight bearing, and thrombo prophylactic treatment with enoxaparin. Patients were routinely examined at our outpatient clinic at 3 weeks, 6 weeks, 3 months, 6 months and one year postoperatively. Radiological evaluation of AP and axial films were performed by senior surgeon. Malunion was defined by more than 10 degrees of varus or valgus compared with the unaffected hip and more than 10 mm of shortening. Nonunion was defined by either no callus or with callus that did not bridge the fracture site at least 15 weeks after the fracture [9].

## Statistical Analysis

Continuous variables are presented as mean and standard deviation (SD). Ordinal variables are presented as medians and Interquartile range. Quantitative variables are presented as absolute and relative frequencies.

## Results

Between January 2017 and June 2018, 167 patients with Intertrochanteric fractures underwent CRIF with TFNA nail at our center. Twenty-one patients were lost to follow-up, a further 39 patients had incomplete records, and 7 patients were younger than 65 years, leaving a total of 100 patients. There were 71 females (71%), the average age at the time of surgery was 82.9 years (range 65-102, SD 8.3) (Table 1).

Thirty- one patients (31%) sustained a 31A1 fracture, 50 patients (50 %) a 31A2 fracture, 19 patients (19%) a 31A3 fracture. Ninety short nails were used. Seventeen of them were 170 mm long (17%), and 79 of them were 235 mm long (79%). In addition, 34 blade pegs were used and 66

screw pegs were used. The average time of surgery was 61.6 minutes (range 31-164, SD= 27.1). Fifty-one surgeries (51%) were performed by fellowship trained trauma surgeons and 49% surgeries were performed by an unsupervised resident who had completed his third year of residency. The average intraoperative blood loss was 2.5 g/dl.

| **Age, average (SD)** | | **82.9 (8.3)** |
|---|---|---|
| Gender, n (%) | Female | 71 (71) |
| | Male | 29 (29) |
| ASA Score, n (%) | 1 | 4 (3.4) |
| | 2 | 36 (30.2) |
| | 3 | 38 (31.9) |
| | 4 | 6 (5) |
| Body mass index, average (SD) | | 25.3 (5.8) |
| Age-adjusted Charlson co-morbidity index, average (SD) | | 5.8 (2.6) |
| Osteoporosis diagnosis prior to fracture, n (%) | | 18 (18) |

**Table 1:** Patients' demographics.

The average tip to apex distance (TAD) was found to be 2.1 cm (range 0.89-3.5, SD 0.6). Radiographic data on the anterior–posterior and axial pegs are presented in Table 2.

| **Fracture configuration, n (%)** | **31A1** | **31 (31)** |
|---|---|---|
| | 31A2 | 50 (50) |
| | 31A3 | 19 (19) |
| Nail length, n (%) | Short | 17 (17) |
| | Medium | 79 (79) |
| | Long | 4 (4) |
| Blood loss, Hb (gr/dl), average (SD) | | 2.5 (1.4) |
| Surgical length, min, average (SD) | | 61.6 (27.1) |
| Surgeon experience, n (%) | Resident | 49 (49) |
| | Attending | 51 (51) |
| Neck fixation, n (%) | Screw | 66 (66) |
| | Blade | 34 (34) |
| AP PEG, n (%) | Inferior | 1 (1) |
| | Middle | 78 (78.8) |
| | Superior | 20 (20.2) |
| Axial PEG, n (%) | Anterior | 26 (26.5) |
| | Middle | 72 (73.5) |
| Tip axial difference (cm), average (SD) | | 2.1 (0.6) |
| Cerclage, n (%) | | 1 (1) |

**Table 2:** Surgical features.

The mean follow-up duration was 30.8 months (range 24–44, SD 5.1). During the first year of follow up, 19 patients died from unrelated reasons concerning the surgery.

During the follow up time, 6 patients (6%) experienced orthopedic complications. Two patients sustained a periprosthetic fracture, one cut out was noticed 3 months

post-operative and 2 patients experienced a peri-prosthetic infection. No cases of non-union or malunion were noticed. Revisions were required in 4 patients.

Lastly, forty-two patients experienced non-orthopaedic complications (Table 3).

| Non-orthopaedic complications, n (%) | Infectious disease | 12 (28.6) |
|---|---|---|
| | Renal | 9 (21.4) |
| | Cardiovascular | 8 (19) |
| | Delirium | 5(11.9) |
| | Pulmonary | 5 (11.9) |
| | Pulmonary embolism | 2 (4.8) |
| | Transfusion adverse effect | 1 (2.4) |
| Orthopaedic complications, n (% of surgeries) | Periprosthetic fracture | 2 (2) |
| | Grater trochanter fracture | 1 (1) |
| | Surgical site infection | 2 (2) |
| | Cut-out | 1 (1) |
| Revisions, n (%) | | 4 (4) |
| Length of follow-up (months), average (SD)& | | 30.8 (5.1) |

**Table 3:** Post-operative complications.

## Discussion

Intramedullary fixation represents the gold standard in the management of intertrochanteric fractures. Despite the various implants introduced over the years that have presented good outcomes, the optimal fixation device for intertrochanteric fractures currently remains a topic of debate. The TFNA is a recently introduced nail made from titanium alloy, that aims to build upon the success of previous generation cephalomedullary nails. This titanium alloy material is thought to enhance the nail's strength. This is supported by a recent biomechanical study that evaluated fatigue strength, showing that the TFNA nail was 24% stronger than the Gamma-3 nail and 47% stronger than the Intertan nail. In addition, the proximal diameter of the TFNA nail is 15.66, a reduction from its previous generation TFN nail's diameter of 17mm. This modified proximal geometry is intended to allow the implant to better fit the anatomic bow of the femur, compared to previous cephalomedullary implants. Its proximal design is furthermore believed to reduce lateral impingement and improve reduction quality. Previous studies postulated that the helical blade theoretically enhances local bone quality via impaction, removes less bone than a lag screw, and touts greater surface area to resist superior cut-out [10].

The optimal nail demonstrates considerable amounts of strength so that the fracture may able heal. There is a challenging trade-off however, which is that as strength (ie large diameter) is added to a nail, it comes at the expense of disrupting patient anatomy. Hence, the rationale for decreasing the radius of a nail is to more closely resemble the femoral anterior bow and improve the anatomic fit of the nail [11,12]. This principle was investigated in a biomechanical study by Yuan et al. that examined the ease of the nail insertion process between nails with different radius of curvatures (ROC) designs. The TFNA with a ROC of 1.0 m was compared to its contemporary implant, the proximal femoral nail (PFN) with a ROC of 1.5. As the 1.0-m bow TFNA demonstrated significantly ease of insertion compared to the 1.5-m bow nail, their study in part supported the use of a modality with a lessened proximal diameter.

Theoretically, the make-up of the TFNA nail should thus offer surgeons a fixation option with enhanced strength and ease of insertion. As this is a newer nail, little is known on its performance in a clinical setting. The aim in this study was to present our experience and results with the TFNA implant over a minimum 2-year follow-up.

Gamma nail and the proximal femoral nail (PFN) represent two of the most common methods for fixation of intertrochanteric fractures. Both have demonstrated excellent outcomes and relatively low rates of complications following fixation [4,13]. Cheng, et al. [14] conducted a meta-analysis of 36 randomized control trials (RCTs) that compared 8 surgical interventions for intertrochanteric fractures, amongst which, the gamma nail and PFN were included. Notably, the authors found no significant difference among the 8 surgical procedures in complications. As there is currently no optimal nail for reducing complications

following intertrochanteric fractures, the TFNA has the potential to be a superior alternative in this regard.

Unsay, et al. [8] presented a descriptive review of 34 cases from their institution that were treated with the TFN-A implant over a minimum 2-year follow-up. Their study reported no cases of implant cut-out or anterior cortical impingement. One significant result was the presence of 4 cases in their study of cement augmentation with retrograde filling, a finding that warrants further investigation. While their study presented promising results, it was limited by the very small sample size.

Cut-out is a significant complication that must be given significant consideration. The reported rates of cut-out range from 4-8% following intramedullary fixation. Our present study presents a cut-out rate of 1 %, consistent with the rates presented in the literature using intramedullary fixation [5,6,15].

We achieved high success rates with this device with a rate of 2% for periprosthetic fractures and no cases of malunion and nonunion. As expected, due to the minimally invasive nature of the technique, the infection rate in our study was extremely low (2%), comparable to those reported by other studies [16-19].

The results of our study support the implementation of TFNA implant in the management of intertrochanteric fractures. As our rates of complications were consistent with those presented in the literature, our findings suggest that the TFNA nail is at the very least as good at managing intertrochanteric fractures compared with its contemporary modalities. Our experience should prompt further investigations with longer follow-up times and future comparative studies.

The following study presents with several limitations. As this was not a comparative study, it is thus unclear whether this implant is superior to its contemporaries. Nonetheless, considering the favorable outcomes presented in this study, future comparative investigations are warranted. In addition, the difference in experience levels of the surgeons in both groups might have affected the outcomes.

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