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Clinical Outcomes of Intermediate-Length Cephalomedullary Nails for Intertrochanteric Femur Fracture Repair in Older Adults

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ABSTRACT

Introduction. Hip fracture is a major cause of morbidity and mortality in older adults. Intertrochanteric hip fractures often are treated surgically using cephalomedullary nails (CMN), in either a short or long length. Their outcomes are documented in the literature; however, outcomes of the intermediate-length CMN have not been well described.

Methods. A retrospective review was conducted of older adults with intertrochanteric hip fractures that were treated with cephalomedullary nail fixation using an intermediate-length (235 mm Synthes Trochanteric Fixation® nail or 240 mm Stryker Gamma 3®) nail. Outcome data were collected during the inpatient stay and 16 months post-operatively.

Results. Seventy-seven patients met inclusion criteria and were reviewed during inpatient stay; however, only 42 had documented post-operative outcomes. Of those, two patients died post-discharge and were not included in the 16-month follow-up. Comparison of results to published literature suggested that intermediate-length nails are comparable to short-length nails with regard to time in the operating room and estimated blood loss. The rate of blood transfusion was lower and length of hospital stay was shorter than in comparable studies of both short- and long-length nails. There were no post-operative peri-prosthetic fractures in the 16-month follow-up. This rate was lower than published rates for short and long nails. The hardware failure rate (3/42, 7.1%) of intermediate-length nails was higher than comparison studies of both short- and long-length nails.

Conclusion. Patient outcomes for intermediate-length nails were similar to outcomes of shorter length nails. Utilization of the intermediate-length nail appears to be an effective treatment option for repair of intertrochanteric femur fractures. However, direct comparison is difficult since peri-prosthetic fracture rate may increase over time and nail length and hardware failure are not defined consistently in the literature. Further study is needed with a larger sample size followed over a longer period of time to confirm our findings.

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INTRODUCTION

Hip fractures are recognized as a cause of significant morbidity and mortality in older adults.[1-6] Due to the increasing older adult population in the United States,[7] the incidence of hip fracture is expected to double by the year 2050.[8] Over the average lifespan of 80 years, approximately 10% of women and 6% of men in the U.S. will experience a hip fracture, with incidence increasing to 30% of women and 20% of men sustaining hip fractures by the age of 90.[9] About 300,000 older adults are hospitalized with hip fractures in the U.S. each year, half of which are intertrochanteric fractures.[9,10] Given the epidemiologic significance of hip fractures in the older adult population and its subsequent impact to the health care system, it is important that researchers continue investigating efficient and effective methods of hip fracture repair.

Historically, intertrochanteric (IT) hip fractures were treated primarily with sliding hip screws (SHS), but after the introduction of the cephalomedullary nail (CMN) in the 1980s, the CMN quickly became the most common method of repair among orthopaedic surgeons in the U.S.[11-14] When originally brought to market, CMNs possessed theoretical improved fracture fixation biomechanics compared to the SHS,[15] as well as the advantages of percutaneous insertion, which include less surgical exposure and blood loss,[16-22] as well as earlier rehabilitation.[21,23] However, the first generation of short-length nail implants was associated with a significantly increased risk of peri-prosthetic femoral shaft fracture as compared to SHS.[24-26] As a result, a new "long" nail was introduced to decrease stress concentration at the proximal femoral diaphysis and provide diaphyseal interference fit to the construct.[27]

Initial comparative studies of short vs. long CMN implants revealed a lower post-operative peri-prosthetic fracture rate in the longer length CMN implants compared to the original, short-length nails.[17] However, by the early 2000s, the increased risk of peri-prosthetic femoral shaft fractures associated with CMN devices was decreasing[10] as new nail modifications were introduced. Nails became smaller in diameter, transitioned from stainless steel to titanium, and were constructed to mimic more closely the anatomical anterior bow of the femur. The size of the distal interlocking screws also was decreased.[28]

In addition to improvements in design over the years, multiple orthopaedic device companies have introduced CMN devices to market. The Depuy Synthes and Stryker companies occupy a significant share of the CMN market in the U.S.[29] Short nails are a fixed length, but long nails vary in length (typically 20 mm increments) as required by the patient's femur length. Each company's product information categorizes nail lengths into either a short or long category (Table 1).

Table 1. Description of manufacturer nail length product specifications.

Manufacturer	Short Nail	Long Nail
Depuy Synthes (Trochanteric Fixation Nail – TFN®)[30]	170 mm 235 mm	300 mm - 460 mm in 20 mm increments
Stryker (Gamma3®)[31]	170 mm 180mm	240 – 480 mm in 20 mm increments

The distinction between short nails and long nails is confusing in that Synthes categorizes their 235 mm nail as "short" and Stryker categorizes their 240 mm nail as "long". The selection of nail implant length for a specific patient is based on many factors including fracture location and stability, surgeon preference, and implant availability at the treatment facility or location.[32]

A number of research studies comparing surgical and post-operative outcomes between short- and long-length nails have been published, suggesting advantages and disadvantages of each type.[16,17,20,32-36] Advantages of short nails compared to long nails include a less technically demanding procedure, shorter operative time, less blood loss, decreased transfusion rates and lower hospital costs.[16,20,32-34] The advantage of the long nail compared to the short nail is a stronger construct with a decreased stress concentration in the proximal femoral diaphysis leading to lower risk of peri-prosthetic fracture post-operatively.[17,35]

A number of published studies have compared surgical and post-operative outcomes of short and long CMNs. However, many of these studies only designate the implant selected as either 'short' or 'long' (designated by manufacturer) without specifying the exact nail implant length.[16,28,33,36] To date, no studies have been found documenting outcomes when specifically using the longest length "short" nail (Synthes TFN® 235 mm) or the shortest length "long" nail (Stryker Gamma 3® 240 mm). For the purpose of this study, "intermediate-length" was defined as either a 235 or 240 mm nail.

The purpose of this study was twofold: to describe surgical and post-operative outcomes of older adult patients undergoing intertrochanteric (IT) fracture repair utilizing an "intermediate-length" cephalomedullary nail (CMN); and to compare findings with outcomes previously published in the literature for short- and long-length nails.

METHODS

A retrospective chart review was conducted involving a case series of older adult patients who sustained an intertrochanteric hip fracture repaired with an intermediate-length (Synthes 235 mm or Stryker 240 mm) CMN. All procedures were performed between January 1, 2015 and December 31, 2015 by two fellowship trained, board certified orthopaedic traumatologists at a single, tertiary care hospital in the mid-western United States. All patients were followed post-operatively at a single outpatient facility. Institutional review board approval was obtained from participating institutions.

Pertinent information included patient age at time of surgery, mechanism of injury, pre-operative hemoglobin, post-operative hemoglobin, type and length of nail, operative duration, hospital length of stay, discharge destination, and post-operative complications (wound infection, transfusions, non-union, femoral head osteonecrosis, hardware failure, and death). Hardware failure was defined as femoral head cutout, blade/screw backout, nail failure, and distal screw backout/breakage. Successful fracture healing was defined as radiographic verification of fracture union or release of patient from follow-up by surgeon. All patients > 90 years old at the time of surgery were recorded as age 90 to increase anonymity in this limited patient population. The information collected was stratified and compared to published outcomes of short- and long-length CMNs in similar patient populations (Stryker Gamma 2/3 or Synthes TFN nails[28,33,34]) to characterize efficacy of intermediate-length CMNs. Authors reviewed similarly designed retrospective studies[28,33,34] in the literature comparing post-operative outcomes of short nails and long nails to serve as benchmarks for outcomes in this study.

Inclusion criteria were: (1) diagnosis of intertrochanteric femur fracture treated surgical repair (CPT code 27245; treatment of intertrochanteric hip fracture with intramedullary nail), (2) age 65 or greater, and (3) fracture fixation with an intermediate-length CMN. Exclusion criteria were: (1) subtrochanteric fracture, (2) isolated fracture of the greater or lesser trochanter, (3) pathologic fracture, (4) no documented follow-up during 16 months post-operative period, and (5) revision of previous hip surgery.

A search of patient databases at the hospital and outpatient clinic was conducted identifying 135 potential subjects for further screening. Fifty-eight patients were excluded because of age less than 65 years (29 cases), nail length different from that specified (23 cases), and different fracture type or location than specified (s cases), leaving 77 patients for further study. Only inpatient data were available for an additional 33 patients who were lost to follow-up during the post-operative period. Additionally, two patients died in the post-operative period before the 16-month follow-up period. Therefore, 42 subjects were followed during both the inpatient and outpatient periods.

RESULTS

A total of 77 patients met inclusion criteria (Table 2). Average age at the time of surgery was 82.5 years and 31% were over the age of 89. Most patients were female (67.5%) and a fall from standing height was the mechanism of injury for 76 of 77 patients (98.7%). Of these patients, 25 (32.5%) fractures were repaired surgically using a Stryker Gamma® 240 mm intermediate-length nail and 52 (67.5%) were repaired using a Synthes TFN® 235 mm intermediate-length nail. All nails were locked distally.

The patient age, type of nail utilized, and in-patient surgical outcomes in the current study were compared with three studies in the literature, all documented outcomes of short- and long-length nails (Table 3). Dunn et al.[33] published a systematic review, pooling data from four studies (1276 patients). Guo et al.[34] conducted a retrospective study of 178 patients at one institution and Kleweno et al.[28] performed a retrospective study of 559 patients at three trauma centers over a six-year period. The mean age of our study cohort was comparable to the average age of patients in these comparison studies. The mean operation time for placement of an intermediate nail in our study was 50 minutes. The mean pre-operative hemoglobin was 11.8 gm/dl, while the mean post-operative hemoglobin was 8.9 gm/dl. Mean estimated blood loss was 94.0 ml. The mean post-operative hemoglobin (Day #1; gm/dl) was 8.9 (1.6). Twenty (26%) patients required post-operative packed red blood cell transfusion; with a mean of 1.3 units. During the hospital stay, 2 of the 77

patients (2.6%) suffered a superficial wound infection. No patients suffered deep infection or peri-prosthetic fracture during their hospital stay. Two (2.6%) patients expired during the hospital stay. The comparison studies did not report post-operative hemoglobin (Day #1), mean transfusion units, superficial wound infection, and in-hospital mortality.

Table 2. Population demographics and clinical characteristics.

Total	**N = 77**
Mean age, in years	82.5
Frequency (%) of patients age over 89	24 (31)
Fall detail, frequency (%)	
Standing height fall	76 (98.7)
> Standing height fall	1 (1.3)
Primary diagnosis (ICD), frequency (%)	
S72.141A (intertrochanteric fracture, right)	20 (26.0)
S72.142A (intertrochanteric fracture, left)	57 (74.0)
Type of nail used (%)	
Stryker Gamma 3® (240 mm)	25 (32.5)
Synthes TFN® (235 mm)	52 (67.5)

Post-operative outcome data were collected up to 16 months following surgery (Table 4). Though 77 patients met our inclusion criteria, 2 patients died after discharge and 33 were lost to follow-up before fracture union was documented. Of the remaining 42 patients, 1 (2.4%) had fracture nonunion and 3 (7.1%) had hardware failure, defined as either blade/screw backout (two patients) or femoral head cutout (one patient). There were no occurrences of peri-prosthetic fracture, deep infection, or femoral head osteonecrosis during the 16-month post-operative period.

Comparison to Published Literature. Tables 2 - 4 compare outcomes from the current study to similar published studies in the literature.[28,33,34] Studies were chosen to compare patient population, patient age, and type of nail studied.[28,33,34] Our study had a smaller sample size, but mean patient age was comparable. The current study included Synthes TFN and Stryker Gamma 3 nails, which is similar to the comparison studies. Dunn[33] and Kleweno[28] included an earlier version of the Gamma nail (Gamma 2) in addition to including the Gamma 3 nail.

Inpatient surgical outcomes are compared in Table 3. Operating room time (mean 50 minutes) was most comparable to short-length nails in all three comparison studies. The hospital length of stay (LOS) in the current study was shorter than both the short and long nails in all comparison studies. Estimated blood loss (EBL) was reported by Guo et al.[34] for long nails only; Dunn et al.[33] reported EBL for long and short nails. The current study result of 94 ml (mean) is comparable to the short nail reported by Dunn et al.[33] The percentage of patients requiring a blood transfusion in the current study (26%) was lower than in the Dunn et al.[33] study (41% for short nails, 50% for long nails) and in the Guo et al.[34] study (57% for long nails).

Regarding post-operative complications (Table 4), there were three patients in the current study (7.1%) who had "hardware failure" (blade/screw backout or femoral head cutout). This rate was slightly higher than the comparison studies at 0% - 3.5%.[28,33,34] There were no peri-prosthetic fractures following surgery in the current study. In the comparison studies, the peri-prosthetic fracture rate for short nails ranged from 0.98%[34] to 2.7%[28] and the rate for long nails ranged from 0.95%[33] to 1.50%[28].

Table 3. Comparison of patient age and surgical outcomes.

		Comparison Studies					
	Current Study (intermediate)	Dunn[33] (short)	Dunn (long)	Guo[34] (short)	Guo (long)	Kleweno[28] (short)	Kleweno (long)
	N = 77	N = 438	N = 838	N = 102	N = 76	N = 219	N = 340
Type of Nail	Stryker Gamma 3 or Synthes TFN	Stryker Gamma 3 or Synthes TFN	Stryker Gamma 2, 3, or Synthes TFN	Stryker Gamma 3	Stryker Gamma 3	Stryker Gamma 3 or Synthes TFN	Stryker Gamma 2, 3, or Synthes TFN
Length of Nail (mm)	235 or 240 mm	NR		180	320-360	NR	
	Mean (SD)	**Mean**	**Mean**	**Mean**	**Mean**	**Mean**	**Mean**
Mean Age	82.5	82	79	82.7	78.9	84	
OR Time (min)	50 (9.7)	47	66	44	59	51	70
Pre-Op Hemoglobin (gm/dl)	11.8 (1.7)	NR		11	10.9	NR	
Estimated Blood Loss (ml)	94.0 (45.1)	96.7	135.2	NR	127.8	NR	
Patient receiving transfusion packed red blood cells	20 (26%)	41%	50%	NR	57%	NR	
Hospital Length of Stay (days)	4.4	7		7.3		12.9	12.7

TFN - trochanteric fixation nail
NR - not reported

Table 4. Comparison of post-operative outcomes.

		Comparison Studies					
	Current Study (intermediate)	**Dunn[33] (short)**	**Dunn (long)**	**Guo[34] (short)**	**Guo (long)**	**Kleweno[28] (short)**	**Kleweno (long)**
Type of nail	Stryker Gamma 3 or Synthes TFN	Stryker Gamma 3 or Synthes TFN	Stryker Gamma 2, 3, or Synthes TFN	Stryker Gamma 3	Stryker Gamma 3	Stryker Gamma 3 or Synthes TFN	Stryker Gamma 2, 3, or Synthes TFN
Length of nail (mm)	235 or 240 mm	NR		180	320-360	NR	
	N=42	N=438	N=838	N=102	N=76	N=219	N=340
Peri-prosthetic fracture	0 (0.0%)	1.60%	0.95%	0.98%	1.31%	2.70%	1.50%
Follow-up period in months	16	mean 18		mean 21		median 30	
Nonunion	1 (2.4)	0.23%	0.60%	0.98%	0%	0%	1.47%
Deep infection	0 (0.0)	NR		0.98%	1.31%	NR	
Femoral head osteonecrosis, %	0 (0.0)	NR		NR		NR	
Hardware failure (total), %	3 (7.1)	NR		0.98%	0%	3.20%	3.50%
Blade/screw backout, %	2 (4.8)	NR		NR		NR	
Femoral head cutout, %	1 (2.4)	NR		NR		2%	3%

*NR - not reported

DISCUSSION

Our surgical outcome data for intermediate-length nails are comparable to published outcome data for short nails in regard to operative time and estimated blood loss. Our hospital length of stay and transfusion rate was considerably shorter than both short and long nails in all comparison studies. The differences in hospital length of stay and transfusion rate are not characteristic of the implant, but rather more a function of post-operative management.

In the outpatient follow-up period, three patients (7.1%) had "hardware failure" (blade/screw backout or femoral head cutout). This rate was slightly higher than comparison studies, however, a determination of significance is uncertain due to our small sample size.[28,33,34] Moreover, direct comparison of "hardware failure" is difficult as there is inconsistency in the literature as to how "failure" is operationally defined.

Another important post-surgical outcome is peri-prosthetic fracture following surgery. In our study, no cases of peri-prosthetic fracture were noted in the 16-month follow-up period. In comparison studies, the peri-prosthetic fracture rate for all nail lengths was higher, ranging from 0.95% to 2.70%. There is some evidence, however, that peri-prosthetic fractures may increase over time.[37] Lindvall et al.[37] published a retrospective cohort study of 609 patients followed over a five-year period after fracture repair with short and long nails. They noted that fractures steadily increased during the period reaching nearly 10% in five years. Additional follow-up time would be required to compare incidence of peri-prosthetic fracture rates for the intermediate-length nail. Finally, one patient (2.4%) had fracture nonunion. On a percentage basis, our rate of nonunion was higher than in comparison studies. However, direct comparison of complication rates is problematic due to our small sample size.

While costs associated with use of the different length nails were not considered in this study, it would be an important area for future study and consideration. Complication rates have dropped significantly to a statistically comparable rate for both short and long nails,[28] and review of recent literature[28,34,38,39] suggested that there is little advantage using one nail length over the other for stable, intertrochanteric fractures. It will be important to consider the cost-effectiveness of using longer length nails when taking into consideration the higher cost of hospitalization (longer OR time, higher EBL and transfusion rates) associated with use of the longer nail.[32,33]

Study Limitations. This study was limited by small sample size and relatively short (16 month) length of follow-up time compared to other studies. It is possible that occult non-unions may have been present, however, post-operative outcome data were collected as documented in the patient record. A longer follow-up period will be necessary to compare complication rates accurately. The study was also limited to two treating surgeons in one facility in the mid-western United States. Comparison of our outcomes to previously published literature was limited by failure of these studies to define basic parameters such as length of the nails implanted and the meaning of terms such as "hardware failure" in those studies.

Statistical comparison to published studies was not achievable, but it was possible to compare the outcomes to evaluate performance. In our study, outcomes of the intermediate-length nail were most comparable to outcomes of the short-length nail in other studies with respect to OR time and EBL. Rates of nonunion and hardware failure were slightly higher in our small population. Our peri-prosthetic fracture rate was lower than in comparison studies. However, our follow-up period was limited to 16 months.

CONCLUSION

This case series was an important first step in describing surgical and post-operative patient outcomes of the intermediate-length nail. Results of this case series suggested post-operative outcomes for intermediate-length nails are similar to outcomes of the shorter-length nails. Comparisons of outcomes indicated that the intermediate-length nail is an effective treatment option for surgical repair of intertrochanteric femur fractures. Further study is needed with a larger sample size and longer follow-up period to determine statistical significance. With increasing emphasis being placed on economy in healthcare, it is important to identify methods of hip fracture repair that are not only efficient and effective, but also financially prudent. Therefore, further research also should be conducted taking the cost of each nail into account to determine which length provides the best outcomes and the smallest financial burden.

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