Original Article • Journal of Southeast Asian Orthopaedics Vol 46 No 2 (2022) 10-16

Journal of Southeast Asian Orthopaedics
ISSN 2821-9848 (Print)
ISSN 2821-9864 (Online)
https://doi.org/10.56929/jseaortho.v46i2.156 https://jseaortho.org

Comparison of Dynamic Versus Static Lag Screw Modes for Short Cephalomedullary Nails in the Treatment of Unstable Intertrochanteric Fractures: A Randomized Controlled Trial

Naruepol Ruangsillapanan, MD, Tana Rattanakitkoson, MD, Teerayut Ittimongkonkul, MD

Department of Orthopedic Surgery, Maharat Nakhon Ratchasima Hospital, Nakhon Ratchasima, Thailand

Purpose: To compare the static locked and sliding proximal lag screw modes of short cephalomedullary nail in the treatment of unstable intertrochanteric fractures.
Methods: Ninety-four patients (age>60 years) with low energy unstable intertrochanteric fractures were randomized for treatment into two groups. They were treated with static and sliding proximal lag screw modes of short cephalomedullary nail. The pre-operative variables, operative time, fluoroscopy time, blood loss, tip apex distance, and reduction quality were recorded for each patient. Post-operative follow-ups were undertaken every other week until bone union or implant failure occurred. Plain anteroposterior and lateral radiographs (both hip) were obtained at all visits. Ipsilateral leg length discrepancy (LLD), radiographic union score for hip complications, and fixation failure were recorded.
Results: The mean follow-up time was 16.7 months (range 12–24). The mean bone union times of static locked (n=35) and sliding proximal (n=34) screw mode groups were 12.4 weeks and more than 11.2 weeks, respectively; the difference was not significant (p=0.213). The ipsilateral LLD of the sliding proximal (mean 4 mm) and static locked (mean 2 mm) screw mode groups showed a statistically significant difference (p<0.001). Post-operative complications (lag screw perforated to hip joint, lag screw cutout from the femoral head, and excessive inferolateral lag screw sliding) developed in 8.82% patients in sliding proximal group, whereas, no complications were reported in the static locked group.
Conclusions: Treatment of unstable intertrochanteric fracture using static locked proximal lag screw mode of cephalomedullary nail showed some advantages over sliding proximal lag screw in terms of less complication and ipsilateral LLD; however, the bone union times were not different. Therefore, a static locked proximal screw mode is preferable over sliding proximal screw mode in treating unstable intertrochanteric fractures.

Keywords: unstable intertrochanteric fracture, cephalomedullary nail, dynamic proximal screw mode, static proximal screw mode, union times

Article history:
Received: April 17, 2022 Revised: May 30, 2022
Accepted: July 2, 2022
Correspondence to: Naruepol Ruangsillapanan, MD
Department of Orthopedic Surgery, Maharat Nakhon Ratchasima Hospital, Nakhon Ratchasima, Thailand
E-mail: Naruepol.ru@cpird.in.th

Intertrochanteric fractures are fragility hip fractures in older adults[1]. Incidences of hip fracture, a significant cause of morbidity and mortality in older adults, are markedly increasing due to an increase in aging population. The treatment goal is the rapid recovery of the patient by performing emergency surgeries.

Cephalomedullary nails are used as the standard treatment for unstable intertrochanteric fracture because their construct is more robust, in biomechanic principle, than that of the sliding extramedullary hip screws[2-4]. Various nail designs are available nowadays. The two significant modes of the proximal locking system are always sliding proximal lock mode (e.g., proximal femoral nail antirotation (PFNA)) and static/dynamic proximal lock mode (e.g., InterTAN Gamma3 nail and Zimmer natural nail). Many factors, such as the implant design, poor reduction quality, and poor tip apex distance (TAD) lead to implant failure[5-7]. Some previous studies emphasized the use of proximal screw locking system. The biomechanical study conducted by Kuzyk PR et al.[8] revealed a significant reduction in axial and lateral stiffness while using the dynamic lag screw mode on unstable intertrochanteric fracture saw bone model. Clinical studies[1] have shown that the implant failure rates are more in procedures that use sliding proximal screw systems (as in PFNA) compared to that uses static proximal screw lock systems (Gamma3 nail). A biomechanical study revealed the superiority of the proximal femoral nail (InterTAN) over PFNA in the treatment of intertrochanteric fracture[9]. A study recommended cement augmentation of PFNA to increase pullout strength at the blade-bone interface to reduce implant failure in osteoporotic bone conditions[10]. Cement augmentation needs high technical demand; increased treatment cost and cement complications are the other issues associated with cement augmentation. Intertrochanteric fractures occur in the metaphyseal region of the bone. Therefore, this type of fracture undergoes metaphyseal fracture-healing process without a compression force to promote the healing[11]. The Static locked proximal screw mode may be the better treatment option for unstable intertrochanteric fracture cases in which a sliding proximal screw mode with cemented augmentation is not used. No clinical study directly compared the sliding and static proximal screw modes in terms of bone union time and post-operative complications. The present study aimed to compare the outcomes and complications of the static locked proximal lag screw mode and sliding proximal lag screw mode in short cephalomedullary nails to treat unstable intertrochanteric fractures.

METHODS

Selection of patients

Patients (age>60 years, n=94) diagnosed with unstable intertrochanteric fractures, from July 2019 to December 2021, were included in this study. The Ethics Committee of the Hospital approved the study. The inclusion criteria for the participants of the study were: 1. Patients with low energy intertrochanteric fracture 2. Age>60 years 3. Those with unstable intertrochanteric fracture (AO Foundation/Orthopaedic Trauma Association (AO/OTA) classification 31A2.2,31A2.3) 4. Those who could walk independently before the occurrence of hip fracture. The exclusion criteria were: patients with 1. multiple fractures 2. open fracture 3. pathological fracture 4. active life-threatening medical condition 5. iatrogenic intra-operative fracture (Fig 1).

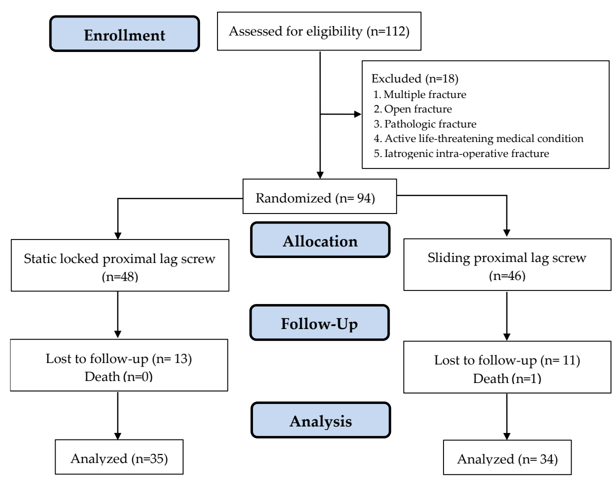

Fig. 1. CONSORT flow diagram.

Ninety-four patients, enrolled in the study, were randomized for treatment into two groups: the static locked proximal lag screw mode group (n=47) and the sliding proximal lag screw mode group (n=47); randomization was done using a block of four with sealed envelopes. Sealed envelopes were opened after the surgeon locked the set screw and decided whether to loosen back the sliding screw or not. The demographic data of the patients is shown in Table 1.

Table 1 Baseline characteristics of the participants.

	Sliding group	Static group	p-value
Patient, n	34	35	
Gender, n (%)			0.080
Men	7 (20.59)	14 (40.00)	
Women	27 (79.41)	21 (60.00)	
Age, mean±SD	77.17±8.39	80.22±9.33	0.147
BMI, kg/m^2±SD	23.13±2.67	25.57±3.54	0.354
Side, n (%)			0.819
Right	17 (51.52)	19 (54.29)	
Left	16 (48.48)	16 (45.71)	
AO/OTA classification			0.726
31A2.2	18 (52.94)	20 (57.14)	
31A2.3	16 (47.06)	15 (42.86)	

BMI, body mass index; SD, standard deviation; AO/OTA, AO Foundation/Orthopaedic Trauma Association

Procedure

The surgery was performed according to standard protocols with a close reduction under fluoroscopic guidance; the reduction quality was assessed using Baumgaertner criteria[3]. After the traditional sterile techniques, an experienced orthopedic surgeon performed the surgery. Zimmer's natural nails (ZNN) are solid short (215 mm) titanium cephalomedullary nails (dynamic/static mode) with a lower mediolateral curvature (4°), 10 mm diameter, 15.5 mm proximal head, and 130° caput-collum-diaphyseal angle. The set screw was fully tightened onto the lag screw so that linear movement of the lag screw is prevented by friction. The cephalomedullary nail lag screw was then inserted into the femoral neck, and fluoroscopy was performed to check good TADs in both antero-posterior (AP) and lateral views; set screw was inserted and tightened in static locked proximal lag screw mode group. For the dynamic proximal screw mode group, the captured set screwdriver was rotated one-quarter counterclockwise (as per the ZNN instruction leaflet) to allow the lag screw for sliding after tightened set screw. The surgeon confirmed that the set screw is still engaged in the groove by checking whether it is possible to turn the lag screw with the lag screw inserter. At the last step, one static distal screw was locked in both groups. The surgery time, blood loss, and intra-operative complications were recorded. The same early rehabilitation protocol was followed for patients in both the groups, post-operatively. Plain AP and lateral hip radiographs were obtained on the first post-operative day to analyze the reduction quality and TAD.

The patient had undergone follow-up visits every other week until a bony union or implant failure reported post-operatively. Plain AP and lateral hip radiographs were obtained at each visit to evaluate the healing of the bone using the radiographic union score for the hip[12] until a solid union (score>18) is noted. Ipsilateral leg length discrepancy (LLD) from inferolateral screw sliding back was measured using the base of lesser trochanter and inter-teardrop line as the reference[13]. Complications[14-16], such as infection, lateral hip pain, and fixation failures were recorded by a blinded assessor during early post-operative follow-ups.

Sample size and statistical analysis

The sample size was detected based on the calculation for non-inferiority trials (with a power of $1-\beta=0.90$ and $a=0.01$), to detect a difference in deviation from non-inferiority limit of two weeks bone union time (primary outcome) with standard deviation = 2.2 (required sample size n = 64) similar to a study conducted by Mustafa Seyhan et al.[17] A sample size of 94 was chosen for this study to compensate for 30% possible dropouts during COVID-19 pandemic. The statistical analysis was performed using the STATA version14 (Stata Corp., College Station, Texas, USA), and data were expressed as mean ± standard deviation. Categorical variables were analyzed using chi-square or Fisher exact test.

RESULTS

No statistically significant difference was found in the demographic data (age, gender, body mass index, and fracture type according to AO/OTA classification) of patients in both the groups. All enrolled patients were operated on by experienceed trauma surgeons. An open reduction was performed in 10% in the static locked proximal screw mode group and 2 of 34 patients in the sliding proximal screw mode group. Baumgaertner criteria were used to assess the reduction quality in both groups. No statistically significant difference (p=0.670) was found in the reduction quality of both the groups. TAD in both groups had no statistically significant difference (p=0.199) (Table 2). The peri-operative data, such as operative time, blood loss, fluoroscopy time, intra-operative complication, and length of hospital stay were not different for both the groups.

Table 2 Intra- and post-operative variables in both the groups.

	Sliding group (N=34)	Static group (N=35)	p-value
Blood loss (ml)	119±26	115±24	0.345
Fluoroscopic times (s)	54.64±13	53.7±10	0.648
Operative time (s)	63.98±12.45	62.91±8.97	0.722
TAD; mean±SD	21.93±6.53	20.31±4.14	0.199
Baumgaertner criteria			0.670
Poor	3 (8.82)	2 (4.44)	
Acceptable	20 (58.82)	15 (55.56)	
Good	11 (32.35)	18 (40.00)	

The data was expressed as mean ± standard deviation and number (%). Baumgaertner classification: for accuracy of reduction, TAD=Tip apex distance was determined by measuring the distance from the tip of the lag screw to the apex of the femoral head on both AP and lateral radiographs

Twelve patients, each from the static lock and dynamic proximal lag screw mode groups, were lost to be followed up, and one patient from the dynamic proximal lag screw mode group died in the first year. Total 69 patients were analyzed in this study, 35 in the static locked and 34 in the dynamic proximal lag screw mode group. The mean follow-up time was 16.7 months (range; 12 – 24 months). The mean bone union time of patients in the static locked proximal screw mode group (12.4 weeks) was more than that of the dynamic proximal screw mode group (11.2 weeks); however, this difference was not statistically significant (p= 0.213). A statistically significant difference (p< 0.001) was noted in the ipsilateral LLDs of dynamic proximal lag screw mode group (mean 4 mm) and statically locked proximal lag screw mode group (mean 2 mm), which were assessed at the early post-operative and bone union times. However, a 2 mm difference does not affect in clinical outcomes and patients with <2 cm LLD did not consider their short leg to be a problem in any way[18] (Table 3).

Table 3 Clinical outcome.

	Sliding (N=34)	Static (N=35)	p-value
Union times (weeks); mean±S	11.27±1.7	12.04±3.11	0.213
Ipsilateral LLD; median (min, max)	4 (0,12)	2 (0,6)	<0.001
Complication (percentage)			0.114
Yes	3 (8.82%)	0	
No	31 (91.18%)	35 (100%)	

LLD; leg length discrepancy

Complications were developed in patients of dynamic proximal screw group; 3 of 34 patients (8.82%) had lag screw perforated to hip joint (Baumgaert: acceptable, TAD 23 mm) (Fig. 2), lag screw cutout from femoral head (Baumgaertner: acceptable, TAD 24 mm), and excessive infero-lateral lag screw sliding with lateral hip pain (Fig. 3) (Baumgaertner: acceptable, TAD 23 mm). All three patients were operated to remove the nails, and two of these three patients had undergone total hip replacement. However, no complications were reported in patients in static lock proximal screw group.

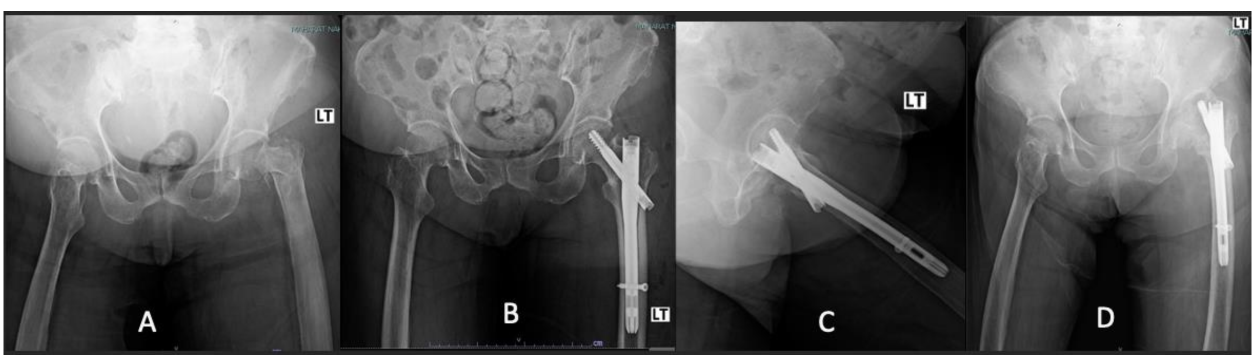

Fig. 2. (A) Low energy left intertrochanteric fracture in a 72-year-old woman.
(B, C) post-operative film showing AP and lateral view.
(D) 14 weeks post-operative film showing lag screw cutout.

N. Ruangsillapanan et al. / Journal of Southeast Asian Orthopaedics Vol 46 No 2 (2022) 10-16

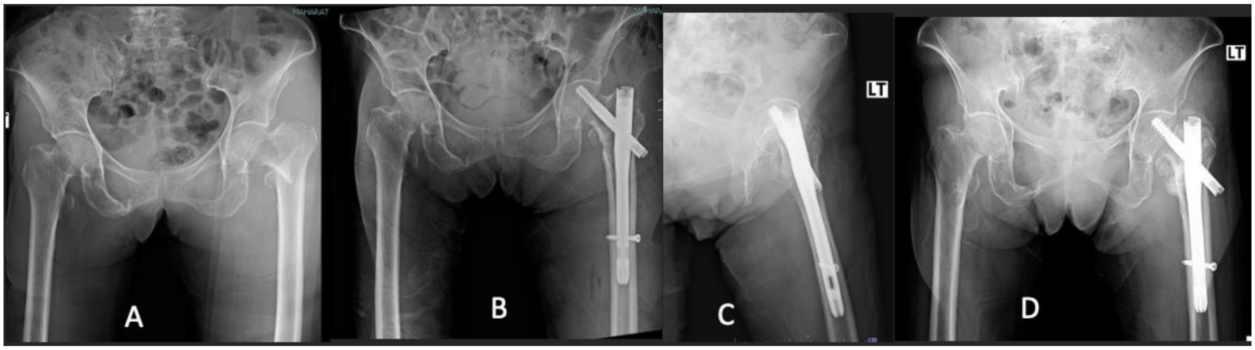

Fig. 3. (A) Low energy left intertrochanteric fracture in an 82-year-old woman.
(B, C) post-operative film, AP and lateral view.
(D) 12 weeks post-operative film showing lag screw sliding back.

DISCUSSION

In a study conducted by Mustafa Seyhan et al., the bone union times in the PFNA and InterTAN groups were 9.79±2.2 and 9.91±3.86 weeks, respectively. However, in our study, the bone union times in static locked proximal and sliding proximal lag screw groups were 12.04±3.11 and 11.27±1.7 weeks, respectively. Ipsilateral LLDs showed a statistically significant difference in post-operative and final follow-up period; however, there was no difference in the clinical outcomes.

Some previous studies reported that sliding helical blade in PFNA has more implant failure. J.J. Lieut al. reported that treatment of intertrochanteric fracture with PFNA has implant failure in 7.03%. I. Kempf et al. treated 121 cases of intertrochanteric fracture using Gamma nail and the bone union occurred in 2.7 months (10.8 weeks) on average; no hardware failure or breaking of the locking screws reported. In our study, the use of sliding proximal lag screw reported an implant failure in 8.82% (3 of 34) patients; one has lag screw perforated to hip joint (Baumgaertner: acceptable, TAD 23 mm), one had a lag screw cutout (Baumgaertner: acceptable, TAD 24 mm), and one lag screw excessive inferolateral lag screw sliding (Baumgaertner: acceptable, TAD 23 mm) with lateral hip pain as reported by Young-soo shin et al.[19] The study showed a higher rate of lateral hip pain in ZNN with dynamic mode, compared with no complication in static mode. The present study showed a similar result to the previous research implying that a dynamic proximal screw system without cement augmentation may not be suitable for osteoporotic unstable intertrochanteric fracture.

To summarize, our study results showed no significant inter-group differences in bone union time, surgery time, fluoroscopy time, and blood loss. However, ipsilateral LLD and development of complications were significantly different in both groups. The dynamic proximal screws mode group showed a higher incidence of complication and ipsilateral LLD than the static proximal screw mode group, even though there were no significant inter-group differences in TAD. Baumgaertner criteria demonstrated implant position and fracture reduction quality in both groups. We also found that cut-out, penetrated screw, and posterolateral screw sliding cases have good screw position within the femoral head measured with TAD and are acceptable in reduction quality.

The strength of our study is that we used a single design cephalomedullary nail in different techniques, such as static locked proximal screw and sliding proximal screw. For this reason, there is no confounding factor in implant design.

This study has some limitations. Due to COVID-19 pandemic, many patients were lost to be followed up and some had delayed follow-ups; therefore, only a small population was available for calculation. It did not report clinical outcome in terms of specific clinical scores. Implant failure caused in dynamic proximal screw mode could be a main focus for future research.

CONCLUSION

To conclude, in treating unstable intertrochanteric fracture with cephalomedullary nail, static locked proximal lag screw mode shows some advantages over dynamic proximal lag screw mode in terms of fewer complications and less ipsilateral LLD with a statistical difference; however, bone union times are not different. The static locked proximal screw is a preferable option with less unpredictable complications. It could economize the cost of cement used for treating unstable intertrochanteric fracture compared to the cost of dynamic proximal screw mode without cemented augmentation.

REFERENCES

1. Yaozeng X, Dechun G, Huilin Y, et al. Comparative study of trochanteric fracture treated with the proximal femoral nail antirotation and the third generation of gamma nail. Injury 2010;41:1234-8.
2. Kempf I, Grosse A, Taglang G, E. et al. Gamma nail in the treatment of closed trochanteric fractures. Results and indications of 121 cases. Orthop Traumatol Surg Res 2014;100:75-83.
3. Chang SM, Zhang YQ, Ma Z, et al. Fracture reduction with positive medial cortical support: a key element in stability reconstruction for the unstable pertrochanteric hip fractures. Arch Orthop Trauma Surg 2015;135:811-8.
4. Socci AR, Casemyr NE, Leslie MP, et al. Implant options for treating intertrochanteric fractures of the hip: rationale, evidence, and recommendations. Bone Joint J 2017;99-B:128-33.
5. Kashigar A, Vincent A, Gunton MJ, et al. Predictors of failure for cephalomedullary nailing of proximal femoral fractures. Bone Joint J 2014;96-B:1029-34.
6. Mao W, Ni H, Li L, et al. Comparison of Baumgaertner and chang reduction quality criteria for the assessment of trochanteric fractures. Bone Joint Res 2019;8:502-8.
7. Baumgaertner MR, Curtin SL, Lindskog DM, et al. The value of the tip- apex distance in predicting failure of fixation of peritrochanteric fractures of the hip. J Bone Joint Surg Am 1995; 77:1058-64.
8. Kuzyk PR, Shah S, Zdero R, et al. A biomechanical comparison of static versus dynamic lag screw modes for cephalomedullary nails used to fix unstable peritrochanteric fractures. J Trauma Acute Care Surg. 2012;72: E65-70.
9. Huang Y, Zhang C, Luo Y. A comparative biomechanical study of proximal femoral nail (InterTAN) and proximal femoral nail antirotation for intertrochanteric fractures. Int Orthop 2013;37:2465-73.
10. Kammerlander C, Hem ES, Klopfer T, et al. Cement augmentation of the Proximal Femoral Nail Antirotation (PFNA) - A multicentre randomized controlled trial. Injury 2018;49: 1436-44.
11. Chen WT, Han DC, Zhang PX, et al. A special healing pattern in stable metaphyseal fractures. Acta Orthop 2015;86:238-42.
12. Frank T, Osterhoff G, Sprague S, et al. The Radiographic Union Score for Hip (RUSH) identifies radiographic nonunion of femoral neck fractures. Clin Orthop Relat Res 2016;474: 1396-404.
13. Meermans G, Malik A, Witt J, et al. Preoperative Radiographic Assessment of Limb-length Discrepancy in Total Hip Arthroplasty. Clin Orthop Relat Res 2011; 469:1677–82.
14. Takigami I, Ohnishi K, Ito Y, et al. Acetabular perforation after medial migration of the helical blade. J Orthop Trauma 2011;25:e86-9.
15. Liu W, Zhou D, Liu F, et al. Mechanical complications of intertrochanteric hip fractures treated with trochanteric femoral nails. J Trauma Acute Care Surg 2013;75:304-10.
16. Liu JJ, Shan LC, Deng BY, et al. Reason and treatment of failure of proximal femoral nail antirotation internal fixation for femoral intertrochanteric fractures of senile patients. Genet Mol Res 20147;13:5949-56.

17. Seyhan M, Turkmen I, Unay K, et al. Do PFNA devices and Intertan nails both have the same effects in the treatment of trochanteric fractures? A prospective clinical study. J Orthop Sci 2015; 20:1053-61.

18. Gross RH. Leg length discrepancy: how much is too much?. Orthopedics 1978;1:307-10.

19. Shin Y-S, Chae J-E, Kang T-W, et al. Prospective randomized study comparing two cephalomedullary nails for elderly intertrochanteric fractures: Zimmer natural nail versus proximal femoral nail antirotation II. Injury 2017;48:1550-7.