Fixation with Cephalic Intramedullary Nail Versus Sliding Hip Screw for Fractured Lesser Trochanter with Completeness of Lateral Wall

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Research Article

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Abstract

Our study provides references and guidelines, backed by evidence and real world data, in determining if and which certain surgical devices are more applicable to improve the outcome of unstable intertrochanteric fracture treatments.

This retrospective case-crossover study compares the clinical and radiographic outcomes of 177 elderly patients from 2010 to 2014, who underwent procedures for unstable intertrochanteric fractures, specifically, AO/OTA type 31-A1.3 fractures using either the cephalic intramedullary device (Gamma3 IM nail system, Stryker®); or the fixation with sliding hip screws method (Dynamic Hip Screw, DHS, Synthes®).

Clinical outcome conclusions were based on the union rates of the fractures during the patient's one year follow-up. Radiographic conclusions were drawn from various factors, including neck shortening, neck-shaft angle, neck medialization, posterior tilting, callus formation time, Tip-apex distance (TAD), implant failure, and modified TAD, an additional factor further explained in the paper.

The study shows evidence that the cephalic intramedullary device had significantly shorter union time, and significantly reduced rates of lag screw sliding and femoral shortening as well. No significant differences with regard to malunion and cut-out of the lag screw were found. The use of the intramedullary devices led to better clinical and radiographical outcomes for this specific fracture.

Background

The continuous growth of the ageing population has propelled the number of intertrochanteric fractures, particularly in the elderly and patients with osteoporosis. From 2006-2011, 262 to 247 hip fractures were reported per 100,000 people in Taiwan, and these statistics are expected to increase. Hip fractures in patients with osteoporosis often lead to high morbidities, disability rates, and mortality, and all patients who do not receive proper treatments will suffer setbacks in their quality of life including pain, decreased mobility, undergo multiple surgeries, and even motility.

This study will analyze two devices, cephalic intramedullary nails and the dynamic hip screw, which are the two most commonly used devices for hip fractures. Before cephalic intramedullary nails were widely used, the dynamic hip screw was generally considered the golden standard for intertrochanteric fractures (ITF). However, studies have found that the Dynamic Hip Screw's clinical use is limited when used for unstable and reverse oblique ITF, which has led to an increase in the use of cephalic intramedullary nails for these fractures due to lower complication rates, and its less invasive nature enabling postoperative early ambulation.

Studies have proven that the condition of the lateral wall most significantly affects the efficacy of the device used for unstable ITFs, followed by the integrity of the medial and lateral wall of the trochanteric region. While cephalic intramedullary nails have been regarded as more reliable than Dynamic Hip
Screws for unstable ITFs, there is still controversy when encountering fractures with preserved lateral walls. Previous studies have been unable to conclusively determine if intramedullary nails provides better clinical and radiographic outcomes for unstable ITFs with preserved lateral walls 7–10.

The aim of this study is to compare and analyze in-depth the clinical outcomes of elderly patients who have undergone fixations with either cephalic intramedullary nails (Gamma3 IM nail system, Stryker®), or DHS (Dynamic Hip Screw, DHS, Synthes®) to determine which device provided a better clinical and radiographical outcome for unstable ITFs with complete lateral wall (AO/OTA type 31-A1.1.3, according to 2018 AO/OTA classification)11.

Materials And Methods

This study was approved by the Institutional Review Board (IRB) of the authors’ institute (Taipei Veterans General Hospital) as a retrospective study (No. 2021-01-007CC), effectively waiving the informed consent requirement. All procedures performed in this study were in accordance with the ethical standards of the Human Research Protection Center and the Helsinki Declaration.

Patients who were treated for ITFs between January 1, 2010, and June 31, 2014 at the authors’ institute were shortlisted for this study. Inclusion criteria included closed intertrochanteric fracture (ITF) with preserved trochanteric lateral wall (lateral wall > 20.5 mm, AO/OTA type 31-A1.3), while cases with stable type (AO/OTA type 31-A1.1&1.2), incomplete lateral wall (AO/OTA type 31-A2), reverse type (AO/OTA type 31-A3) were excluded. Pathological fractures from metastasis, cases of multiple trauma, and cases with a follow up timeframe shorter than 6 months were also excluded. Within the prescribed timeframe, 995 intertrochanteric femoral fractures were treated, 791 cases were excluded due to multiple trauma (N=95), stable type of intertrochanteric fracture (N=431), follow-up timeframe < 6 months (N=209), type of incomplete lateral wall (<20.5 mm), and subtrochanteric fracture (reverse type, N=55).

Decisions for the type of device used was based on doctors’ personal experience or preference. 177 patients underwent fixation for relatively unstable types of ITFs (AO/OTA 31-A1.3) using Gamma3 (N=85) or DHS (N=92). All the fractures were reduced on a fracture table under fluoroscopic guidance. All operations were performed in the same institution by experienced orthopaedic surgeons. For Gamma3, the femur was reamed to 1 mm greater than the diameter of the nail, and a 130° Gamma3 was applied. All nails were locked distally with one screw. The DHS fixation was performed by using conventional techniques with a four-hole, 135° plate. Operation time was measured as the interval from the start of the reposition to the wound closure.

Clinical and Radiographical Assessment

Clinical and radiographical outcomes were determined by the evidence of bone union. Additionally, post-operative radiographical assessment included: (1) Quality of the fracture reduction as defined according to the three requirements, including over-traction of the reduction (Figure 1A), medial translation of the
proximal fragment (Figure 1B), and tilting of the proximal fragment (Figure 1C). When the reduction achieved all of above 3 factors, a good reduction was recorded. Acceptable and poor reductions were also recorded for qualities respectively conforming to two or none of the requirements. (2) The appearance of bridging callus or continuity of cortical bone, defined as the evidence bone union.\textsuperscript{12} (3) Tip-apex distance (TAD) defined as the distance between the screw tip and apex of the femoral head in plain and lateral radiographs.

In instances where anatomical reduction was not achieved, other radiographic indexes such as overtraction, and shortening of fracture gap, medialization of greater trochanteric (GT) in anteroposterior (AP) view and tilting of displaced fragment in lateral view found in post-operative radiographs (Figure 1), were also included in our analysis.

Failed fixation was defined as fracture non-union or screw cut-outs, requiring re-operation.

**Statistical Assessment**

The Statistical Package for STATA 12.0 software was used for statistical analysis. Comparison of categorical variables were performed using chi-squared tests and Fisher’s exact tests. Normally distributed continuous variables were compared using an independent sample t-test, and a Mann-Whitney test was used for ordinal and continuous data. A value of $P < 0.05$ was taken as statistically significant. A logistic regression model was used to access the factors contributed to the failure rate and odds ratios were also obtained. Receiver operating characteristic (ROC) curve analyses was performed to calculate area under the curve (AUC) to estimate the variable to predict screw cut-out rates for both devices.

**Results**

The demographic data and characteristics were compatible between both Gamma3 and DHS, with the exception of surgery time ($p=0.01$), wound length ($p=0.038$) and length of stay ($p<0.001$). (Table 1)

Additionally, no statistical significance was found between Gamma3 and DHS groups for overall complication rates ($p=0.184$), failure rates ($p=0.667$) and reoperation rates ($p=0.3$). (Table 2) All reoperations cases received total hip arthroplasty surgery due to cut-out (10 cases/ group) and osteonecrosis of femoral head (2 case in Gamma3 and 3 cases in DHS).

When comparing of radiographic outcome for both groups, the mean neck shortening was 1.7 mm for Gamma3, and 14.89 mm for DHS ($P<0.001$), and neck shortening > 1cm occurred in 3 patients for Gamma3, and 19 for DHS ($P<0.001$). Loss of neck-shaft angle was higher (-2.85°) in DHS group. ($P=0.04$)

The mean TAD showed no statistical significance for either group (18.88 mm for Gamma3, and 20.66mm for DHS, $p=0.54$). However, further analysis of the reduction quality in failed cases (N=25) showed a
higher mean distance of over-traction, 7.7 mm, than the non-failure group (P=0.01). In contrast, the medialized GT, tilting of the femoral neck and TAD showed no significant difference. (P= 0.53, P=0.43, and P=0.49). (Table 3)

Our multivariable logistic regression analysis (Table 4) indicated that over-traction (OR= 4.438; confidence interval [CI] =1.377, 14.304) had a significant correlation to screw cut-outs. ROC analysis demonstrated AUC 0.743 (Figure 2), showing that the model had moderate discriminatory power.

Discussion

Fueled by an ageing population and rising cases of osteoporosis, hip fractures are expected to affect more people, and so it is important to understand which treatment plan and which device will be more effective for various patients. If treated poorly, this fracture has a tendency to malunion, resulting in shortening, varus, medialization of the shaft, and external rotation deformity, and as such, it is important to achieve near-anatomic reduction to reduce morbidity and complications.

Recent studies have shown a trend towards using cephalic intramedullary devices over sliding hip screws for intertrochanteric fractures attributed to the improvements in the intramedullary devices’ implant design, and the biomechanical advantages of intramedullary fixation resulting to a lower rate of reoperation than in fixations with the sliding hip screw\textsuperscript{2,13,14}.

Some studies have shown that the sliding hip screw is able to afford satisfactory results for stable types of fractures, such as AO/OTA 31-A1.1 and 31-A1.2 fractures, whereas for severely unstable types of fractures, the cephalic intramedullary device should be the standard treatment for 31-A2.2, 31-A2.3 and 31-A3 fractures. However, proper treatment for the unique fracture type of AO/OTA A1.3 with intact lateral wall remains still controversial\textsuperscript{15,16}. The evidence in this study indicate that when a sliding hip screw is used for relatively unstable fractures (AO/OTA 31-A1.3), in patients with poor bone quality, intra-operative iatrogenic fracture of lateral wall is an issue of concern, and post-operative lateral wall fractures may lead to shortening or medialization of the shaft\textsuperscript{7,17}.

The gamma3 group in this study were shown to be effective for unstable intertrochanteric femoral fractures in the unique fracture pattern of AO/OTA 31-A1.3, fractured lesser trochanter with completeness of lateral walls. Complications were found in 16.4% (14 patients) of the patients in the gamma3 group, including screw cut-outs, aseptic loosening and femoral head necrosis. The DHS group showed no advantages in duration of surgery, wound size, length of hospital stay (LOS) and radiographic parameters such as neck shortening and neck-shaft angle change.

Femoral neck shortening is typically considered a common poor outcome predictor for post-operative recovery, and excessive shortening of over 5mm can lead to weakened gluteus medius strength and hip joint movement limitations\textsuperscript{18}. Randomized studies have demonstrated that cephalic intramedullary nails enabled patients with unstable 31-A2 fractures to return to mobility faster than those treated with sliding
hip screws\textsuperscript{15}. Additionally, while no correlation has been found between the degree of femoral shortening and functional outcome, there were less cases of femoral shortening in patients who were treated with the cephalic intramedullary nails\textsuperscript{19}. The results of our study, that the cephalic intramedullary device leads to a better post-operative recovery, corroborates these studies as well.

The need for cut-outs is considered the most concerning complication following ITF surgery, as its occurrence greatly impacts the patient’s functional outcome, increases the probability for further revision surgeries, and even decreases their life expectancy.\textsuperscript{20} Other studies have shown that poor bone quality, reductions and TAD are correlated with the risk of cut-outs approaching statistical significance.\textsuperscript{21,22} Specifically, they found that a TAD >25mm is an important cut-off value that can predict the need for screw cut-outs in ITF surgical treatments\textsuperscript{23–25}.

Our statistical analysis of TAD alone indicated no significant difference between the two groups for post-operative TAD (18.88 ± 5.9 vs. 20.66 ± 1.22 for Gamma3 and DHS respectively), and also did not reveal a significant enough TAD result to properly analyze and predict cut-outs (P=0.49). We have found that this is because TAD does not take into consideration the reduction quality of the fracture, and as such, post-operative reduction parameters must be taken into consideration.

Our statistical analysis for the reduction quality to predict factors will lead to potential cut-outs, overtraction, medialization and tilting are as follows. (Figure 1) Over-traction is a significant factor that is highly correlated (OR=4.438) with cut-outs for this fracture type. While Bretherton et al. reported that medialization of more than 50\% in the femoral canal group had a higher revision rate (2.1\% vs. 14.3\%, p=0.014) when treated with either the intramedullary nail or sliding hip screw.\textsuperscript{15} our statistical findings did not show significant correlation between medialization and tilting parameters with cut-out (P= 0.148, P=0.657 separately). The concept of reduction parameters should be confirmed by further studies in the future.

There were several limitations in this study. This study was a retrospective and more randomized controlled studies should be considered to conclusively verify our findings. The operations were not performed by a single surgeon, and different operative techniques may impact treatment outcome. Patients' bone quality data were unable to be obtained, and finally, Osteoporosis in the elderly is an uncertain factor for implant failure.

**Conclusion**

Cephalic intramedullary nails and sliding hip screw are both effective devices in treating unstable intertrochanteric femoral fractures with preserved trochanteric lateral wall. However, our study has found that the cephalic intramedullary nail is superior to hip screw in terms of a smaller incision, shorter surgery time, less femoral shortening and length of stay. Furthermore, the reduction parameter of over-traction is a significant factor in potentially predicting implant failure regardless of device in this specific type of fracture.
Declarations

Data Availability

All data generated or analyzed during this study are included in this article.

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|                                | DHS (N = 92) | Gamma nail (N = 85) | P value |
|--------------------------------|--------------|--------------------|---------|
| Age, year                      | 82.71(± 9.28) | 82.08(± 10.9)      | 0.521   |
| Sex                            |              |                    | 0.467   |
| Male                           | 44           | 36                 |         |
| Female                         | 48           | 49                 |         |
| Side                           |              |                    | 0.9376  |
| Right                          | 44           | 42                 |         |
| Left                           | 48           | 43                 |         |
| BMI                            | 21.87(± 3.8) | 22.18(± 3.7)       | 0.46    |
| Follow up month                | 13.7         | 12.3               | 0.37    |
| Surgery time(min)              | 105±(39)     | 85±(27)            | 0.01    |
| Wound(mm)                      | 88.0(± 33)   | 83.86(± 17)        | 0.038   |
| LOS(day)                       | 7.4(± 5.96)  | 6.64(± 3.1)        | < 0.001 |

BMI: Body Mass Index; LOS: Length Of Stay
| Complication               | DHS      | Gamma nail | P value |
|---------------------------|----------|------------|---------|
| Complication              | 18 (14.1%) | 14 (16.4%) | 0.184   |
| Cutout                    | 10 (10.78%) | 10 (11.76%)|         |
| Non-union                 | 4 (4.35%)  | 1 (1.18%)  |         |
| ONFH                      | 3 (3.26%)  | 2 (2.35%)  |         |
| Aseptic loosening         | 1 (1.09%)  | 1 (1.18%)  |         |
| Reoperation in first year | 12 (13.04%) | 7 (8.24%)  | 0.3     |
| Failure                   | 14 (15.22%) | 11 (12.94%)| 0.667   |
| Tip apex distance(mm)     | 20.66 (± 6.2) | 18.88 (± 5.6) | 0.54 |
| Neck shortening(mm)       | 14.89 (± 11.89) | 1.7 (± 3.3) | <0.001 |
| Shortening > 1 cm         | 19        | 3          | <0.001  |
| Neck-shaft angle change   | -2.85°    | -2°        | 0.04    |

ONFH: osteonecrosis of femoral head

*Note:* Failure was defined as non-union of fracture or screw cut-out re-operation was needed.

| Radiographic associated findings                          | Non-failure group (N = 150) | Failure group (N = 25) | P value |
|-----------------------------------------------------------|-----------------------------|------------------------|---------|
| Reduction quality                                         |                             |                        |         |
| Over-traction (mm)                                        | 1.4 (± 0.32)                | 7.7 (± 0.97)           | 0.01    |
| Medialization (mm)                                        | 7 (± 6.2)                   | 10.5 (± 0.44)          | 0.53    |
| Tilting angle (°)                                         | 1.0 (± 0.9)                 | 1.63 (± 1.56)          | 0.43    |
| Tip-apex distance (mm)                                    | 20.05 (± 5.99)              | 19.8 (± 4.92)          | 0.49    |
Table 4
Reduction parameters for radiographic findings of screw cut-outs

| Characteristic         | Odds ratio (95% CI) | P value |
|------------------------|---------------------|---------|
| Over-traction          | 4.438 (1.377, 14.304) | 0.013   |
| Medialization of GT    | 2.284 (0.693, 11.528) | 0.148   |
| Tilting angle          | 0.821 (0.343, 1.966)  | 0.657   |
| Tip-apex distance      | 0.934 (0.851, 1.024)  | 0.147   |

Figures

Figure 1
Measuring methods: (A) Over traction is measured under plain hip radiograph by line A to line B. Line A and B is measured from non-contacted points at the medial trochanteric area, and lines perpendicular to the femoral shaft. (B) Medialization is measured under plain hip radiograph by line C and line D. Line C and D is measured from non-contacted points at the medial trochanteric area, and lines parallel to the femoral shaft. (C) Tilting angle, the value (θ) is measured under hip radiographic lateral view between line E and line F. Line E is parallel to the neck shaft and Line E is parallel to the femur shaft.
Figure 2

Receiver operating characteristic curves for radiographic reduction parameters for the screw cut-out group. TAD: Tip apex distance.