Original Article

A novel technique for the fixation of inter-trochanteric hip fractures: A telescoping lag screw

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ABSTRACT

One-hundred and three patients with intertrochanteric hip fractures as classified by the OTA 2007 system underwent fixation using the telescoping AOS Galileo lag screw system and ES Nail (a long IM nail). Thirty-one patients (76%) were female and ten (24%) were male, with an average age of 75.70 ± 11.3 years at date of surgery. At final follow-up 21 (53%) patients returned to their pre-fracture ambulatory status, 20 (47%) had a reduction in ambulatory status, and no patients were confined to a wheel chair. The telescoping capability of the AOS Galileo lag screw allowed for a decrease in total length by 3.96 ± 3.04 mm during fracture healing. The TAD distance at final follow-up was 14.09 ± 4.69 mm. Lateral protrusion of the lag screw into soft tissue did not occur. There was one reported incidence of femoral head cutout, which occurred after the lag screw had telescoped its entire distance and began functioning as a rigid non-compressible lag screw. All other fractures healed uneventfully and no device failure occurred. The AOS Galileo telescoping lag screw has shown promise concerning IT fracture fixation and will continue to undergo further investigation.

1. Introduction

Fractures of the hip, or proximal femur, can be complex injuries due to fracture patterns and the multiple comorbidities these patients often present with. Ninety percent of hip fractures occur in patients greater than 65 years old, 75% of which are women.¹ Additionally, 47% of proximal femur fractures occur at the intertrochanteric (IT) region. Projections indicate the number of hip fractures occurring in the world annually will rise from 1.66 million in 1990 to 6.26 million by 2050 with the incidence of hip fractures in the US predicted to reach 500,000 by 2040.^{2,3}

Fractures of the femoral trochanteric region have been subjected to numerous treatment options over the past decades. Intra-medullary (IM) femoral nailing has become a widely used method for fracture fixation, as several authors have reported on their effectiveness for the treatment of proximal femur fractures.^{4–10}

Fixed and sliding lag screws are viable options in conjunction with IM nails for the treatment of IT fractures. These lag screw mechanisms are subject to various complications including but not limited to lag screw cut-out through the femoral head, lateral screw protrusion, and lateral thigh pain. Fixed lag screw mechanisms are designed to decrease the possibility of lateral screw protrusion or pain, at the cost of

increased risk to lag screw cut-out through the femoral head. Sliding lag screw mechanisms are designed to decrease the possibility of cut-out, which predisposes the patient to lag screw protrusion into the lateral soft tissues.¹¹ This lateral protrusion can often result in significant lateral thigh pain often requiring local injections and occasionally surgery to remove the screw (Fig. 1).¹¹

The development of the telescoping lag screws has aimed to combine the advantages of fixed and sliding lag screw mechanisms while minimizing the complications of lag screw cut-out, lateral screw protrusion and lateral thigh pain. Comparison of the telescoping peritrochanteric nail (PTN) (Biomet; Warsaw, IN) with the trochanteric fixation nail (Synthes; West Chester, PA) in cadaver models showed a significant decrease in the distance of lateral screw protrusion by the telescoping lag screw, 0.25mm compared to 2.68mm. Cut-out through the femoral head did not occur with either fixation system.¹² To our knowledge, no in vivo studies of the Biomet PTN are available in the literature. The Targon PF (Aesculap, Tuttlingen, Germany) is a similarly designed telescoping lag screw paired with an IM nail. Multiple studies taking place in Europe and Japan have been reported; however the device is not approved for use in the United States. The Targon lag screw accommodates a greater range of collapse and has been associated with complication rates of 0.07%–1.1%. These complications

Abbreviations: AOS, advanced orthopaedic solutions; GLS, Galileo lag screw; ES nail, extended short nail

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Fig. 1. Lateral protrusion of a sliding lag screw requiring removal (not a patient in this series).

such as cut-out, back-out, and medial perforation of an anti-rotation screw were seen in patients with complex fracture patterns.^{13–15}

The present study investigates the AOS (Advanced Orthopaedic Solutions) telescoping Galileo Lag Screw System (GLS) in use with the Extended-Short Nail (ES Nail) (Advanced Orthopaedic Solutions, Torrance, CA) for IT fracture fixation. The AOS GLS System and ES Nail are both FDA approved devices. The ES Nail is a long IM nail with distal and proximal locking capabilities, and has been reported as an effective treatment option for IT fractures of the hip.⁷ The telescoping feature of the Galileo lag screw system can accommodate up to 10mm of shortening in length before the lag screw becomes a fixed/rigid system (Table 1) (Fig. 2). The Galileo lag screw can be used in conjunction with a Short and Long IM nail; this study only evaluated its use with the ES nail (a long IM nail).

In this study we analyzed the telescoping capabilities of the AOS Galileo lag screw system until bony union was identified radiographically at approximately 6 months of follow-up. The authors received research funding from Advanced Orthopaedic Solutions (Torrance, CA). AOS was involved in preliminary study design. All other aspects of study design, implementation, and manuscript preparation were undertaken solely by the authors.

2. Materials and methods

A retrospective analysis of 103 consecutive patients undergoing open reduction and internal fixation (ORIF) for inter-trochanteric fractures of the proximal femur was conducted. Patients included in the study were those subjected to an IT fracture as classified by the OTA

Table 1
AOS Galileo Lag Screw Telescoping Capabilities.

Lag Screw length (mm)	Distance of Telescope/Collapse (mm)
85	7
90	9
95–120	10

Fig. 2. The Advanced Orthopaedic Solutions telescoping Galileo Lag Screw in comparison with a solid lag screw. The head of the lag screw (pink) telescopes up to 10 mm into the shaft of the screw as the fracture heals. The base of the lag screw (gold) expands within the portal of the IM nail to create a fixed mechanism.

2007 system.¹⁶ Patients having pathologic fractures and those denied medical clearance for surgery were excluded from the study population. Fracture fixation was performed by one of four surgeons from a private orthopaedic practice; surgical procedures took place at a large community based hospital after the patient presented to the emergency department. IRB approval was obtained through the institution at which all surgical procedures were performed. There were no changes to surgical procedures or patient protocols during the study period.

The AOS trochanteric nail is placed in the customary percutaneous technique on a fracture table with use of intraoperative fluoroscopy. The Galileo lag screw is placed utilizing three critical steps of fixation which differentiates it from other lag screws currently available:

- 1) Fixation of GLS to the trochanteric nail: a sheath at the lag screw base expands to the portal diameter within the trochanteric nail, fixing the lag screw to the trochanteric nail.
- 2) Intra-operative lag screw compression: an option to manually adjust the lag screw length, known as intraoperative telescoping, is available during the release of lower extremity traction.
- 3) Removal of activation sleeve: this final step allows the GLS to function as a telescoping screw postoperatively.

All patients received post-operative antibiotic prophylaxis and deep vein thrombosis prophylaxis with low molecular weight heparin. Postoperative weight-bearing status was determined by the operating surgeon on the basis of fracture pattern and fixation. Post operatively, patients were typically admitted to the acute rehabilitation ward for two to three weeks, transferred to a skilled nursing facility or discharged home. Patients were followed up at routine intervals until the fracture was deemed healed based on clinical and radiographic exam. Radiographic union was defined as bridging callus formation on three or more cortices. At the final study follow-up patients were assessed based on their clinical and radiographic presentation.

Patient demographic, radiographic, surgical and clinical data were retrieved manually through electronic medical records (EMR). Radiographic analysis was performed using software available through PACS systems (Image Information Systems iQ-WEBX; London, UK) (Philips iSITE PACS; Amsterdam, Netherlands). Radiographs were

Fig. 3. Anteroposterior radiograph with superimposed arrows indicating measurements. The radiograph is calibrated to the lag screw diameter of 10.5mm (1). Lag screw length is the distance from the base to the tip (2). Anteroposterior measurement of tip-to-apex distance from the tip of the lag screw to the apex of the femoral head (3). Measurement of lateral screw prominence from the lateral base of the GLS to the cortex of the bone, perpendicular to the IM nail (4). Note the lateral view component of tip-to-apex distance measurement is not shown here.

evaluated to determine the length of the Galileo lag screw, tip-to-apex distance (TAD) and distance of lateral screw prominence.

Measures of radiographic assessment were obtained in both the A/P and lateral planes. Each radiograph was calibrated using the known diameter of the GLS (10.5 mm) to obtain measurements. In the A/P plane, the base to tip of the GLS was recorded. From the most lateral portion of GLS base, a line perpendicular to length of the IM-Nail was drawn to the lateral femoral cortex measuring the lateral screw prominence. The TAD was measured from the apex of the femoral head to the tip of the GLS following an established method.¹⁷ (Fig. 3)

These numerical data were analyzed to determine the amount of telescoping that occurred within the Galileo lag screw during fracture healing. Numerical results along with clinical outcomes were taken into consideration to determine the effectiveness of the Galileo lag screw with respect to IT fracture fixation and post-operative patient outcomes.

3. Results

One hundred and three consecutive patients meeting the inclusion criteria were studied following surgical treatment with the AOS GLS and IM nail. Of these 103 patients, 62 did not complete a six month post-op follow-up; 14 have expired. Forty-one (40%) patients have completed final study follow up at 40.0 ± 14.5 weeks. All results/data presented here pertain to the 41 patients that have completed final study follow-up. Thirty-one patients (76%) were females and ten (24%) were males. The average age at date of surgery was 75.70 ± 11.3 years; BMI at date of surgery was 25.09 ± 4.66 kg/m².

Twenty-nine (70.7%) patients walked without any assistance prior

Table 2

Fracture Classification (OTA 2007) Group 31-A Femur, proximal trochanteric.

Subgroup	N	%
A1.1	9	21.95
A1.2.1	7	17.07
A1.2.2	4	9.76
A1.3.1	0	0.00
A1.3.2	2	4.88
A2.1	7	17.07
A2.2	4	9.76
A2.3	2	4.88
A3.1	1	2.44
A3.2	0	0.00
A3.3.1	3	7.32
A3.3.2	2	4.88

to fracture, six (14.6%) patients with a cane, and six (14.6%) patients with a walker. Four (9.8%) patients had a documented history of osteoporosis.

Fractures were classified according the Orthopaedic Traumatology Association 2007 Classification (Marsh 2007). (Table 2) Subgroup A1 are simple two fragment fractures traveling along the intertrochanteric line, through the greater trochanter, or below the lesser trochanter; subgroup A2 are multifragmentary fractures along the intertrochanteric line; subgroup A3 are simple oblique or multifragmentary oblique fractures.

At final follow-up, 22 (53.7%) patients had no change from their pre-fracture ambulatory status, 11 (26.8%) had a one point reduction, and eight (19.5%) had a two point reduction in ambulatory status; no patients were confined to a wheelchair (Table 3).

The average distance telescoped by the GLS postoperatively was 3.96 ± 3.04 mm (Fig. 4). Two devices telescoped the full possible distance and began functioning as a solid lag screw, one of which led to cut out through the femoral head (Fig. 5).

At final follow-up, 16 (39%) patients complained of pain to the hip or thigh. Quality of pain or provoking causes were not included. The use of steroid injection as a treatment option for lateral thigh pain was indicated in two (4.9%) of the 41 patients.

The tip-to-apex distance (TAD) at final follow-up was 14.09 ± 4.69 mm. No change in lateral screw prominence was noted throughout the study, and at final follow-up was measured to be 4.69 ± 1.44 mm (range 2.4–8.2 mm). In one patient (2.4%) cutout through the femoral head occurred after the GLS had telescoped the full distance and began functioning as a rigid non-compressible lag screw. All other fractures healed uneventfully and no known device failure occurred.

4. Discussion

This is the first study regarding the AOS Galileo Lag Screw and its effectiveness for treating IT hip fractures. To our knowledge this is the first study to evaluate the in-vivo efficacy of a telescoping or collapsible lag screw for IT hip fractures approved for use within the US. Thorough review of the literature determined there are two other lag screws available for the treatment of IT and pertrochanteric fractures that have a capability to change in length, the Biomet PTN and the Targon PF. The Biomet PTN has been evaluated in cadaver-based studies only.¹²

Table 3

Ambulatory Status Point Interpretation.

Patient Mobility	Point
No assistance	3
Cane	2
Walker	1
Wheelchair	0

Fig. 4. Anteroposterior radiographs of successful compression of the Advanced Orthopaedic Solutions telescoping Galileo Lag screw from initial placement (a) to 6 month follow-up (b).

Fig. 5. Radiograph of patient in the current series, the Galileo lag screw telescoped its entire distance before functioning as a solid lag screw, which led to cutout through the femoral head.

The Targon PF has not been used in the US to our knowledge; multiple publications were found from studies based in Europe and Asia. The Targon lag screw has a much larger range of collapse than the AOS Galileo lag screw (0.8–28.6 mm observed in the literature) and has been associated with device complications such as lag screw cutout and lateral protrusion.^{14,15}

The present study evaluated four primary variables: distance of lag screw telescoping/collapse, lateral protrusion/prominence of the lag screw, incidence of cutout through the femoral head, and TAD at final follow up.

The average distance collapsed by the Galileo lag screw was 3.96 ± 3.04 mm. One incidence of cutout through the femoral head occurred after the lag screw had telescoped fully and began functioning as a solid lag screw. The lateral prominence of the lag screw seen in the current study, 4.69 ± 1.44 mm, is a product of initial lag screw placement and available lag screw lengths. Since the lag screws come in 5mm increments, an inevitable amount of lateral prominence will be present. It is important to note that no failure of the GLS fixation mechanism occurred, which locks the lag screw base to the IM nail. No change in the distance of lateral prominence/protrusion occurred throughout the study.

The TAD at final follow-up of 14.09 ± 4.70 mm places patients in a low risk category for lag screw cut-out.^{17–19} The AOS Galileo lag screw was purposefully designed to accommodate the respective ranges of telescoping (Table 4) following close evaluation of fracture healing dynamics and functional recovery.²⁰

5. Conclusion

Results of this study show the mechanism that locks the lag screw to the IM nail is effective and has not failed. This mechanism prevents lateral screw protrusion, which typically occurs by distal migration of the lag screw base during fracture healing. Second, the telescoping capability of the lag screw functioned to remove strain from the femoral head and minimize the risk of cutout through the femoral head. Clinical outcomes cited also point to the AOS Galileo lag screw being an effective treatment option.

To date the AOS Galileo lag screw has shown promise with respect

Table 4
Lag Screw Distribution.

Screw length (mm)	Max telescoping (mm)	# of implants
85	7	4
90	9	10
95	10	7
100	10	9
105	10	4
110	10	4
115	10	2
120	10	1

to IT fracture fixation. Further studies and increased data collection will allow for correlations between fracture type and the distance telescoped by the Galileo lag screw.

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