# Efficacy of the AOS Galileo™ Telescoping Lag Screw for the Treatment of Intertrochanteric Hip Fractures*

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**ABSTRACT**
*Seventy-nine patients with intertrochanteric hip fractures as classified by the OTA 2007 system underwent fixation using the AOS Galileo lag screw system and ES Nail. Twenty-six patients to date have completed final study follow-up at 21.8 ± 7.9 weeks. Eighteen patients (69%) were females and eight (31%) were males, with an average age of 74.32 ± 12.31 years at date of surgery. At final follow-up 12 (46%) patients returned to their pre-fracture ambulatory status, 14 (54%) had a reduction in ambulatory status, and no patients were confined to a wheelchair. The average collapse in Galileo lag screw length was 4.38 ± 3.0 mm. At final follow-up there was an average of 3.31 ± 1.88 mm of lateral lag screw prominence; however, this value did not increase from the date of surgery. All fractures healed uneventfully, no lag screw cutout occurred, no lateral protrusion occurred and no device failure occurred. The AOS Galileo lag screw has shown promise with regards to IT fracture fixation and will continue to undergo further investigation.*

## INTRODUCTION

Fractures of the hip, or proximal femur, are complex injures due to fracture patterns and the multiple comorbidities that these patients often present with. Ninety percent of hip fractures occur in patients greater than 65 years old, 75% of which are women (Apple 1993). Additionally, 47% of proximal femur fractures occur at the intertrochanteric (IT) region.

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 common and effective method for fracture fixation, as several authors have reported on the effectiveness of long IM nails for the treatment proximal femur fractures (Barquet 2000, Sehat 2005, Hamilton 2004, Wright 2011). Refinements have continually been made to these systems, particularly regarding lag screw designs, in order to improve outcomes.

Both fixed and sliding lag screw mechanisms have been used in conjunction with IM nails for the treatment of IT fractures. These mechanisms are subject to various modes of failure including but not limited to screw cut-out, lateral screw protrusion, and lateral thigh pain. Fixed lag screw mechanisms minimize the possibility of lateral screw protrusion/pain at the cost of increased risk to lag screw cut-out. Sliding lag screw mechanisms are designed to eliminate the possibility of cut-out, but present complications involving lag screw protrusion into the lateral soft tissues (Park 2010). This lateral protrusion can often result in significant lateral thigh pain often requiring local injections and occasionally surgery to remove the screw (Figure 1) (Park 2010).

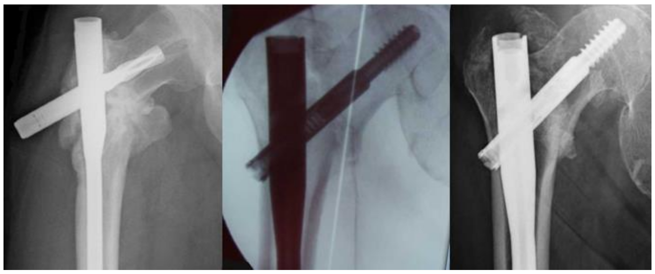

**Figure 1.** *Lateral protrusion of a sliding lag screw requiring removal of compared to the AOS Galileo™ Telescoping Lag Screw with successful post-operative compression.*

The development of telescoping lag screws has aimed to combine the effective qualities of fixed and sliding lag screw mechanisms while preventing the negative side effects of lag screw cut-out, lateral screw protrusion, and lateral thigh pain. Comparison of the telescoping peritrochanteric nail (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 2.68 mm. Cut out through the femoral head did not occur with either fixation system (Schwarzkopf 2011). 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 conducted; 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 device complication rates of 0.07% to 1.1%. These complications such as cutout, back-out, medial perforation of an anti-rotation screw were seen in patients with complex fracture patterns (Kawatani 2011, Takigawa 2014, Wild, 2010).

The present study investigates the telescoping Galileo Lag Screw System (GLS) when used with the Extended-Short (ES) Nail (Advanced Orthopaedic Solutions, Torrance, CA) for IT fracture fixation. The Advanced Orthopaedic Solutions (AOS) Galileo Lag Screw System and AOS ES Nail are both FDA approved devices. The ES Nail, which combines long IM nail size with the distal locking capabilities of both long and short IM nails, has been reported as an effective treatment option for IT fractures of the hip (Wright 2011). The telescoping feature of the Galileo lag screw system can accommodate up to 10mm of decrease in length before the lag screw becomes a fixed/rigid system (Table 1). The Galileo lag screw can also 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).

**Table 1. AOS Galileo Lag Screw Telescoping Capabilities**

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

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 (Cooper 1992), with the incidence of hip fractures in the US predicted to reach 500,000 by 2040 (Cummings 1990). Proximal femoral fractures, particularly those of the IT region, are debilitating injuries that can significantly impact the lifestyle and mortality of patients. The development of telescoping/collapsible lag screws shows promise in regards to fracture fixation and improving patient outcomes following IT fractures potentially decreasing the incidence of lateral thigh pain secondary to lateral lag screw prominence. In this study we analyzed the telescoping capabilities of the AOS Galileo lag screw system until bony union was identified radiographically.

## METHODS

A retrospective analysis of 79 consecutive patients undergoing open reduction and internal fixation (ORIF) for IT/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 2007 system (Marsh 2011). Patients having pathologic fractures and those denied medical clearance for surgery were excluded from the study population. Patients were operated on 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 time period.

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

Fixation of Galileo lag screw to the IM nail: located at the base of the lag screw is a cylindrical sheath. When released, this sheath expands to the portal diameter within the IM nail, thereby fixing the lag screw to the IM nail. This unique property replaces traditional methods of fixation such as inserting a locking screw through the proximal end of the IM nail (Bridle 1991).

Intra-operative lag screw compression: In addition to the post-operative telescoping capabilities of the Galileo lag screw, an option to guide intraoperative telescoping is available. Following final placement and fixation the GLS to the IM nail, traction from the table is gradually released as with any trochanteric nail technique. During this time, accessory handles on the lag screw inserter allow for manual compression of the GLS.

Removal of activation sleeve: Following complete release of table traction and manual compression of the lag screw, the lag screw inserter is again utilized to remove the "activation sleeve." The activation sleeve acts as a block within the telescoping mechanism. Without removal of the activation sleeve, the GLS will act as a solid lag screw. Removal of the activation sleeve allows for the lag screw to telescope and decrease in length as the fracture progresses through the stages of healing; allowing for functional post-operative compression.

All patients underwent 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 intervals of two to four weeks until the fracture was deemed healed based on physical examination, ambulatory status, presence of pain with weight-bearing and radiographic union. Radiographic union was defined as bridging callus formation on 3 or more cortices. At the final study follow up, patients were analyzed 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 measurement software available through PACS systems (Image Information Systems iQ-WEBX; London, UK) (Philips iSITE PACS; Amsterdam, Netherlands). Radiographs were evaluated to determine the length of the Galileo lag screw, TAD at final follow-up and distance of lateral screw prominence.

Method of radiographic assessment in the A/P plane:

1. Radiograph is magnified, making sure to include entirety of the femoral head and GLS
2. The diameter of the GLS (10.5 mm standard) is used to calibrate the radiograph
3. Measurement is taken along length of GLS (base to tip) and recorded
4. The apex of the femoral head is located, which is defined as the point of intersection between the subchondral bone and a line in the center of and parallel to the femoral neck.
5. Measurement is taken from the apex of the femoral head to the center-tip of the GLS and recorded

6. From the most lateral portion of GLS base, a line perpendicular to length of the IM-Nail is drawn from this point to the lateral femoral cortex.

Method of radiographic assessment in the lateral plane:

1. Radiograph is magnified to include entirety of the femoral head and Galileo lag screw
2. The diameter of the Galileo lag screw (10.5mm standard) is used to calibrate the radiograph
3. The apex of the femoral head is located, which is defined as the point of intersection between the subchondral bone and a line in the center of and parallel to the femoral neck.
4. Measurement is taken from the apex of the femoral head to the center-tip of the Galileo lag screw and recorded

The length of the Galileo lag screw is the value recorded following step 3 of assessment in the A/P plane. The TAD is a sum of the values recorded following step 5 of assessment in the A/P plane and step 4 of assessment in the Lateral plane. The distance of lateral screw protrusion is the value recorded following step 6 of assessment in the A/P plane.

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

## RESULTS

To date 79 patients have been operated on, 56 of which are eligible for a final follow-up. Of these 56 eligible patients, 26 have completed final study follow-up. The average time period of final follow-up was 21.8 ± 7.9 weeks. All results/data presented here pertain to the 26 patients which have completed a final study follow-up. Eighteen patients (69%) were females and eight (31%) were males. The average age at date of surgery was 74.32 ± 12.31 years; BMI at date of surgery was 25.09 ± 4.66 kg/m$^2$.

Twenty-three (88.5 %) patients walked without any assistance prior to fracture, one (3.8 %) patient with a cane, and two (7.7 %) patients with a walker. Four (15.4 %) patients had a documented history of osteoporosis. The average time between injury and surgery was 32.5 ± 14.7 hours; the average postoperative stay before discharge was 4.7 ± 3.1 days.

Fractures were classified according the Orthopaedic Traumatology Association 2007 Classification (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.

**Table 2. Fracture Classification (OTA 2007) Group 31-A Femur, proximal trochanteric**

| Subgroup | N | % |
|---|---|---|
| A1.1 | 5 | 19.23 |
| A1.2.1 | 4 | 15.38 |
| A1.2.2 | 2 | 7.69 |
| A1.3.1 | 0 | 0.00 |
| A1.3.2 | 0 | 0.00 |
| A2.1 | 7 | 26.92 |
| A2.2 | 2 | 7.69 |
| A2.3 | 1 | 3.85 |
| A3.1 | 1 | 3.85 |
| A3.2 | 0 | 0.00 |
| A3.3.1 | 3 | 11.54 |
| A3.3.2 | 1 | 3.85 |

At final follow-up 12 (46%) patients had no change from their pre-fracture ambulatory status, six (23%) had a one point reduction, and eight (31%) had a two point reduction in ambulatory status; no patients were confined to a wheelchair (Table 3).

**Table 3. Ambulatory Status Point Interpretation**

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

Seven (27%) patients received a 90 mm lag screw, three (11%) received a 95 mm, eight (31%) received a 100 mm, five (20%) received a 105 mm, and three (11%) received a 110 mm (Table 3). The average decrease in Galileo lag screw length seen at final follow up was 4.38 ± 3.0 mm. The 90 mm lag screw is capable of 9 mm of telescoping; patients in the present study telescoped 55 ± 27.8% of this distance. The 95-120 mm lag screws are capable of 10 mm of telescoping; patients in the present study telescoped 41.7 ± 32.1% of this distance. No device telescoped the full possible distance and began functioning as a solid lag screw.

**Table 4. Lag Screw Distribution**

| Screw Length (mm) | Max Telescoping (mm) | # Implanted |
|---|---|---|
| 85 | 7 | 0 |
| 90 | 9 | 7 |
| 95 | 10 | 3 |
| 100 | 10 | 8 |
| 105 | 10 | 5 |
| 110 | 10 | 3 |
| 115 | 10 | 0 |
| 120 | 10 | 0 |

In addition to the postoperative telescoping capabilities of the Galileo lag screw, manual compression/telescoping of the lag screw is an option during the operative procedure. Following fixation of the lag screw base to the IM nail and release of traction on the patient's leg, the lag screw inserter contains a mechanism that allows for telescoping or shortening of the lag screw at the surgeons discretion. The average intraoperative compression of the Galileo Lag Screw was 0.73 mm (range 0 – 3.99 mm).

At final follow-up 19 (73%) patients had a complaint of pain; any mention of pain to the hip or thigh region was included in this incidence without any further classification based on quality and provocation. The use of steroid injection as a treatment option for lateral thigh pain was indicated in two of the 26 patients.

The tip-to-apex distance (TAD) at final follow-up was 15.15 ± 5.52 mm. Based on operative technique, lateral prominence of the lag screw is inherently present due to lag screw placement. No change in lateral prominence was noted throughout the study, and at final follow-up was measured to be 3.31 ± 1.88 mm (range 0-9.2 mm). All fractures healed uneventfully, no lag screw cutout occurred, and no known device failure occurred.

**DISCUSSION**

This is the first study regarding the AOS Galileo Lag Screw and its effectiveness for treating IT hip fractures. This is the first study to evaluate the in-vivo efficacy of a telescoping or collapsible lag screw for IT hip fractures for devices approved within the US. Thorough review of the literature determined there are two other lag screws indicated 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 (Schwarzkopf 2011). The Targon PF has no evidence of use within the US; multiple publications were found from studies based in Europe and Asia. A 2010 in-vivo study cited an average lag screw collapse of 14.5 mm (range 0.8-28.6 mm) and postoperative complication rate of 0.07% (Wild, 2010). A 2011 in-vivo study cited an average lag screw collapse of 6 mm (range 0-19) and postoperative device complication rate of 0.85% (Kawatani 2011). A 2014 in-vivo study cited an average lag screw collapse of 14.7 mm and postoperative compilation rate of 1.1% (Takigawa 2014). The Targon lag screw has a much larger range of collapse than the AOS Galileo lag screw and has been associated with device complications such as lag screw cutout and back-out.

The present study evaluated four primary outcomes related to the AOS Galileo lag screw: distance of lag screw telescoping/collapse, lateral protrusion/prominence, cutout incidence, and TAD at final follow up.

In the present study, the average distance collapsed by the Galileo lag screw was 4.38 ± 3.0 mm (range 0-9.2 mm). No cutout through the femoral head occurred.

The lateral prominence of the lag screw seen in the current study, 3.31 ± 1.88 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 protrusion will be present in some cases. It is important to note again that no failure of the fixation mechanism occurred, which locks the lag screw base to the IM nail, and no change in the distance of lateral prominence occurred throughout the study.

The TAD at final follow-up, 15.15 ± 5.52 mm, places patients in a low risk category for lag screw cut-out (Baumgaertner 1995). Recalling the ranges of telescoping available for each lag screw (Table 3), it is possible for a telescoping lag screw to eventually become a solid/fixed lag screw. In the present study, no lag screw reached its full collapsible distance and began functioning as a solid lag screw. The AOS Galileo lag screw was purposefully designed to accommodate the respective ranges of telescoping (Table 3) following close evaluation of fracture healing dynamics and functional recovery (Zlowodzki 2008).

Results of these four outcomes allow us to state the following. First, the mechanism which locks the lag screw onto the IM nail is effective and has not failed. This mechanism eliminates the incidence of lateral screw protrusion via distal migration of the screw from fracture healing. Second, this locking mechanism allows for functional collapse/telescoping of the lag screw to take place thereby removing strain from the femoral head and preventing cutout from occurring. Clinical outcomes also point to the AOS Galileo lag screw being an effective treatment option. Steroid injections for pain relief were used in approximately 7.5% of patient's post-op. Approximately 50% of patients returned to their pre-op ambulatory status and no patients were confined to a wheel chair.

To date the AOS Galileo lag screw has shown great promise with respect to IT fracture fixation. Further studies and increasing data collection will eventually allow for correlations between fracture type and lag screw length with the observed distanced telescoped by the Galileo lag screw.

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