

# The lesser trochanter “Sling fixation technique” in proximal intramedullary nailing of unstable intertrochanteric fractures: A polymer-based cerclage wiring

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## ABSTRACT

**Introduction:** Lesser trochanter (LT) fixation to restore the continuity of the posteromedial fragment using a cerclage wire has been reported to provide a more stable reduction in the treatment of unstable femoral neck fractures with LT involvement. However, LT fixation is not commonly performed due to the complications associated with the traditional monofilament cerclage metal wires. In this study, we investigate the clinical and radiological outcomes of a new technique for LT fixation in conjunction with Intramedullary (IM) fixation with nail and screws when compared to isolated IM fixation. The Sling Fixation Technique involves a new wiring technique and the use of a polymer-based cerclage cable characterized by iso-elastic properties that is hypothesized to provide better clinical and radiographic outcomes.

**Patients and methods:** This prospective observational study included 30 patients who underwent proximal IM nailing from July 2019 to April 2020. Thirty consecutive patients (30) were assigned to 2 different treatment groups. Fifteen (15) patients were treated with the IM Nailing and Sling Fixation Technique and 15 with IM nailing only. Patients were comparable for demographic features, fracture pattern, age, gender and associated medical comorbidities. Clinical outcomes were analyzed in terms of time needed to achieve complete weight bearing, Harris hip score (HHS), Barthel Index (BI) and Radiographic Union Scale for Hip (RUSH). The follow-up period was one year.

**Results:** Time for fracture healing and to achieve weight-bearing in the “Sling” group were shown to be significantly shorter than in the IM group. The Sling group showed furthermore better HHS, BI and RUSH scores when compared to the IM group at 1, 3, 6, and 12 months from the surgery. No complications such as wiring breakage, cut-outs, breakage or pullout of the fixation screws were observed; one case of heterotrophic ossification was reported.

**Conclusion:** In cases of unstable intertrochanteric fractures of the proximal femur with lesser trochanter involvement, the Sling fixation technique using an isoelastic polymer-based wire showed superior results in terms of stability and consequently better clinical and radiographic outcomes than IM nailing only.

## 1. Introduction

Intramedullary (IM) fixation with a nail and locking screws has recently become the gold standard management of intertrochanteric fractures of the proximal femur providing short operating time and minimal soft tissue injury.<sup>1,2</sup> However, in unstable intertrochanteric fractures with lesser trochanter (LT) involvement, the use of IM nailing alone may not be enough since anatomical reduction of the

posteromedial fragment is not achieved leading to non-union of the fracture.<sup>3–6</sup> Additionally, the iliopsoas muscle's function is greatly compromised resulting in delayed recovery, groin pain and limited physical mobility post-surgery; both aspects have relevant prognostic consequences on all patients presenting with this type of fracture.

Various techniques have been described in the scientific literature to fix the LT including screw fixation and circumferential wiring,<sup>7–9</sup> nevertheless, these cerclage techniques use traditional monofilament

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metal wires that are associated with breakage, loss of tension, debris, and increased risk of injury to the surgeon.<sup>10–12</sup>

The Sling Fixation Technique is a new surgical technique where traditional IM nailing of the proximal femur is performed in conjunction with fixation of the LT using a polymer-based cerclage wire.

## 2. Patients and methods

We designed a prospective observational study following for one year after surgery a number of thirty consecutive patients undergoing proximal IM nailing between July 2019 to April 2020. The consecutive patients presented with a similar fracture pattern (unstable intertrochanteric fractures with LT involvement), and were then assigned into 2 groups, each group consisted of 15 patients. The control group was treated with IM nailing alone while the second group was treated with IM nailing followed by LT fixation with the Sling technique.

The primary outcomes of the present study were to compare both the clinical results and the radiological outcomes of the Sling Fixation Technique against isolated IM fixation in the treatment of these unstable intertrochanteric fractures. The secondary outcomes were checking any eventual differences in complication and implant failure rates.

The Institutional Review Board approval was obtained (IRB approval number: 2211/2018). The study was conducted according to the criteria set by the Declaration of Helsinki and each subject signed an informed consent before participating in the study.

### 2.1. Demographic features and fracture pattern

Patients were comparable for demographic features, age, body mass index (BMI), American Society of Anesthesiologist (ASA), medical comorbidities, and fracture pattern (Table 1). The demographic inclusion criteria were age between 50 and 85 years, a BMI between 16 and 35 and ASA score between 1 and 4. The radiographic inclusion criteria were an unstable intertrochanteric fracture with LT involvement according to the AO/OTA classification system (31A2.1, 31A2.2, 31A2.3, 31A3.3) but with an intact posterior wall of the LT with proximal and distal fragment extension of no more than 0.5 cm. Patients were assigned to 2 groups: the control group of 15 patients was treated only with IM nailing while the second group of 15 patients was treated with LT fixation using the Sling Technique followed by IM nailing.

The nail used for IM fixation was the same in all patients: long Gamma 3 nail (Stryker, Kalamazoo, MI, USA) with one proximal locking screw and two static distal locking screws.

In the Sling Technique group, following IM nailing, LT fixation was achieved using a polymer-based cerclage wire (SuperCable® Iso-Elastic™ cerclage Kinamed, Camarillo, CA, USA). The main property of this wire that renders it superior to others is its iso-elastic characteristics which allows for a symmetrical distribution of load over the cable and hence the fracture. This has been demonstrated by multiple tests that showed only fiber fusion of the cable and no breakage after one million cycles of loading it with 445 N in direct abrasive contact on a bone plate. The cables also have blunt ends that reduces greatly surgeon's risk of injury and glove perforations. Finally, the system provides a Titanium locking mechanism allowing easy re-tightening of the system.

In order to minimize discrepancies between both groups of the trial, all patients followed the same postoperative rehabilitation protocol and were enrolled into programs encouraging early joint mobility and weight-bearing to promote bone healing.

Postoperative observation indices included surgical duration, intraoperative bleeding, time to reach weight-bearing and fracture healing time. Different indices were used to evaluate the overall clinical picture of the patients at different points during follow-up. Harris hip score (HHS) was used to evaluate hip function<sup>13</sup> and the Barthel Index (BI) was used evaluate clinically patients' autonomy in their daily life.<sup>14</sup> The Radiographic Union Scale for Hip (RUSH) was used for the iconographic evaluation of fracture healing.<sup>15</sup> These evaluations were initially done

**Table 1**

Comparison of basic data between the two groups.

GROUP FEATURES	SLING GROUP (N = 15) <sup>†</sup>	IM GROUP (N = 15) <sup>‡</sup>	P VALUE (95% CI) <sup>§</sup>	t/c2* <sup>¶</sup>
Age (years ± SD <sup>¶</sup> )	79.0 ± 10.5	81.7 ± 6.9	0.402 (0.2–1.1)	0.206
BMI <sup>#</sup> (number ± SD)	23.2 ± 2.65	22.9 ± 2.4	0.137 (0.09–0.86)	0.120
GENDER				
Male	3	4	0.841 (0.18–1.4)	0.830
Female	12	11		
PREOPERATIVE DISEASES				
Hypertension	7	8	0.25 (0.12–0.96)	0.250
Diabetes	6	4	0.724 (0.44–1.25)	0.722
Heart disease	3	4	0.322 (0.28–0.48)	0.230
Others	4	2	0.117 (0.08–0.46)	0.119
ASA GRADING				
II	8	8	0.356 (0.19–0.84)	0.856
III	7	5	0.285 (0.18–1.14)	0.270
IV	0	2	0.379 (0.24–0.92)	0.860
AO CLASSIFICATION				
31 A2.1	5	6	0.860 (0.47–1.21)	0.790
31 A2.2	4	3	0.820 (0.56–1.02)	0.220
31 A2.3	2	3	0.870 (0.49–1.34)	0.800
31 A3.3	4	3	0.820 (0.52–1.28)	0.770

\*t/c2 = Chi-square test.

§ CI = Confidence of Interval.

¶ SD = Standard Deviation.

# BMI = Body Mass Index.

† SLING GROUP = Lesser Trochanter Fixation + Intramedullary fixation group (case group).

‡ IM GROUP = Intramedullary fixation only group (control group).

preoperatively and then at 1, 3, 6, and 12 months after the surgery. A nonunion was diagnosed when the patient had pain on ambulation, inability to bear weight on the affected limb, clinically documented motion between fragments, absent active straight leg raising test, demonstrable telescoping, progressive change of neck-shaft angle on anteroposterior abduction-adduction views on X-ray, radiolucent defect at the fracture site, and a delay of 6 months or more after the initial trauma. Patients without movement, but having pain along with an angulation less than 120° at the intertrochanteric region on antero-posterior X-ray view or patients complaining a painful limping due to lower leg shortening more than 1 cm or with a clinical external/internal rotation more than 20° compared to the other leg and defined as disturbing by the patients were classified as malunion.

### 2.2. "Sling" surgical technique

All surgeries were performed by the same senior surgeon (M.V.). All patients underwent spinal anesthesia and then placed in supine position on a traction table with the affected lower limb firmly placed in a traction boot, the contralateral limb was placed in flexion-abduction to facilitate intraoperative fluoroscopy using the C-arm. Closed reduction maneuvers were attempted no more than 3 times under fluoroscopic control. The surgical site was then prepared and draped using a dedicate transparent adhesive sheet. This draping system has a plastic conical shape bag positioned just under the planned surgical incisions. In order to collect the intraoperative blood loss we used a different method

compared to Algadiem et al.<sup>16</sup>: all the blood that comes out from the patient is therefore kept inside this plastic bag. Every time the surgeon needs to wash the surgical field with NaCl solution, the bag is previously emptied from its bottom where there is a tap to keep the liquid inside the bag. While washing the tap is left open. In case of this procedure is repeated more than once, the total amount of intraoperative bleeding loss is calculated by summing the amount of blood collected in this bag time by time.

The standard IM nail incision above the greater trochanter was distally extended by 4–6 cm, the fascia lata was then incised and the gluteus medius was bluntly split to reach the fracture site. A mini-subvastus approach is then performed to gain visualization of the fracture site. Limb traction is applied to bring the displaced LT fragment approximately to the fracture line's level. At this point, a reduction clamp or a narrow Hohmann retractor is used to obtain temporary anatomical reduction of the LT fragment which is then confirmed under fluoroscopy. To maintain this reduction, the cerclage wire is then introduced. A Deschamps wire passer is inserted in an anteromedial-posterolateral fashion just above the LTa and then the proximal cable is inserted. The Deschamps are then placed distally to the LT and the distal cable is inserted. Both ends of the cable are then locked. The cable is manually pre-tensioned and locked with the use of tensioning cleats. The knob is turned in a clockwise fashion to ensure correct tension. For assessing the tension on the wire, the tensioning cleats are labelled LO and HI where "LO" indicates 360 N, while the "HI" indicates 530 N. The wire tension used will greatly depend on the patient's bone quality and its ability to withstand the cable pressure and should be evaluated clinically and radiographically pre-operatively. The Supercable cerclage is then locked in position by rotating the side lever of the tensioning tool that thrusts the cable locking wedge. This system allows easy re-tightening if necessary. The last step before cutting the cable ends is to slightly de-tension the cable by turning the knob. A second Supercable cable might be used if there is distal diaphyseal extension of the LT fracture requiring additional support (Fig. 1).

Following the LT fixation, a standard IM nailing procedure is performed. At the preference of the surgeon, the cerclage wire placement can also be performed after the IM nailing to directly stabilize the fracture and bring the LT fragment to the level of the fracture line.

Post-operative medical treatment generally consisted of anti-thromboembolic prophylaxis for 1 month and antibiotic treatment with cephalosporins for 24 h post-op.

Patients were directly enrolled in a physical rehabilitation program consisting of passive hip mobilization and progressive weight-bearing by walking with crutches for 2 weeks, after which, all patients were encouraged to perform weight bearing exercises.

### 2.3. Statistical analysis

Statistical analysis was performed using SPSS® statistics software (IBM®, Armonk, New York, USA). Data are expressed as a mean  $\pm$  standard Deviation (SD). The Fisher formula was used to calculate the sample size (95% of CI), while the Cohen's *d* was adopted to calculate the effect size. The *t*-test was used to compare the data collected, and a Chi-square test was used to compare the enumeration data and a  $p < 0.05$  was considered statistically significant. The intra- and inter-observer reliability (absolute agreement) was assessed using intraclass correlation coefficients (ICC) with a two-way mixed effect model.

### 3. Results

All the patients survived to reach the one-year follow-up mark and no patients were lost during follow-up. The 2 groups were considered homogenous since there was no significant difference in terms of age distribution ( $p = 0.402$ ), BMI ( $p = 0.137$ ), gender ( $p = 0.841$ ), ASA grading and AO classification of the fracture (Table 1).

Minimal differences were observed in terms of patient comorbidities: hypertension ( $p = 0.25$ ), diabetes ( $p = 0.724$ ), heart disease ( $p = 0.322$ ) and other diseases ( $p = 0.117$ ).

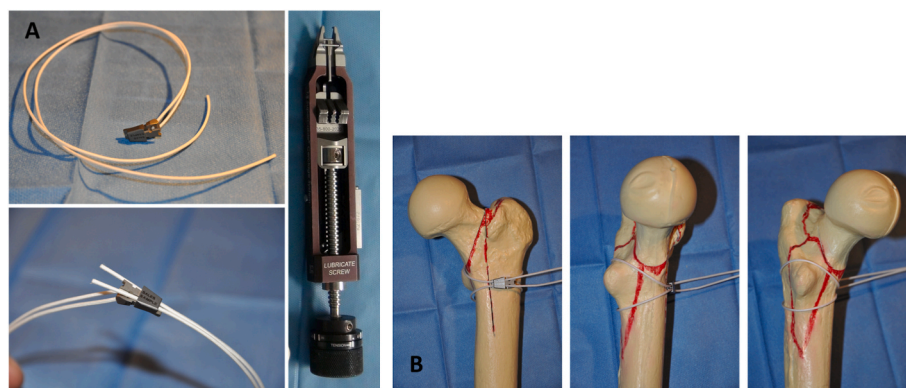
The Sling group showed slightly higher but non-significant intra-operative blood loss ( $p = 0.217$ ) and longer operation time ( $p = 0.067$ ). On the other hand, the Sling group demonstrated significantly shorter times to achieve weight-bearing ( $p = 0.001$ ) and fracture healing ( $p = 0.001$ ) (Table 2).

The HHS, BI and RUSH scores were significantly improved at 3 months after surgery for both groups; although the Sling group showed better improvement in terms of HHS and RUSH score compared to the IM group at every point during the follow-up.

No major surgery related postoperative complications were reported. One case of non-evolving Brooker type 1 heterotopic ossifications was observed at 3 months follow-up in the Sling group. In the IM group, fracture nonunion was seen in one case and was treated with a total hip replacement.

### 4. Discussion

In this study, we describe a new method of treating unstable intertrochanteric fracture using a polymer-based cerclage wire to first achieve LT fixation followed by IM nailing to achieve fixation of the fracture. The clinical and radiological outcomes are reported and compared to treatment with isolated IM nailing. Our results show superiority of the Sling Technique + IM nailing in the treatment of unstable intertrochanteric fractures with LT involvement when compared to IM nailing along. The Sling group when compared to the control



**Fig. 1.** Fig. 1 (A) Supercable® Iso-Elastic™ wire and tensioning tool. (B) Possible patterns of fracture with intact posteromedial wall that is the fundamental requirement for this technique.

"Sling" fashion cerclage with Supercable wire is also represented.

**Table 2**

Surgical factors and follow-up results between “Sling” group and IM group.

GROUP FEATURES (mean ± SD <sup>#</sup> )	SLING GROUP (N = 15) <sup>‡</sup>	IM GROUP (N = 15) <sup>§</sup>	P VALUE (95% CI) <sup>§</sup>	T* 
Operation Time	65 ± 15.6	55 ± 12.9	0.067 (0.24–1.08)	1.768
Intraoperative blood loss (mL)	197.4 ± 16.7	195.4 ± 14.2	0.217 (0.12–0.94)	1.249
Post-op weight bearing time (months)	2.01 ± 0.29	3.33 ± 0.71	0.001 (0.0006–0.02)	7.645
Fracture Healing Time (months)	3.38 ± 0.23	4.37 ± 0.31	0.001 (0.00098–0.038)	24.57
RUSH SCORE <sup>¶</sup>				
1 month post-op	17.2 ± 0.8	13.8 ± 0.7	0.001 (0.00092–0.044)	25.65
3 months post-op	24.7 ± 0.7	22.0 ± 1.2	0.000	16.76
6 months post-op	27.3 ± 0.7	25.3 ± 0.8	0.000	14.37
12 months post-op	28.4 ± 0.8	26.4 ± 0.7	0.000	16.85
HHS <sup>&amp;</sup>				
Preoperative	58.9 ± 6.3	61.7 ± 5.2	0.317 (0.09–0.84)	0.689
1 month post-op	75.7 ± 2.5	72.9 ± 2.5	0.148 (0.06–0.34)	1.750
3 months post-op	87.2 ± 1.4	80.3 ± 1.6	0.001 (0.00095–0.009)	15.03
6 months post-op	88.9 ± 1.3	81.7 ± 1.2	0.001 (0.0087–0.02)	24.33
12 months post-op	97.4 ± 2.3	90.1 ± 3.4	0.001 (0.0098–0.024)	6.209
BI SCORE <sup>§</sup>				
Preoperative	49.8 ± 4.3	47.9 ± 5.2	0.410 (0.126–0.986)	0.423
1 month post-op	53.2 ± 4.4	53.3 ± 3.9	0.227 (0.086–0.748)	1.250
3 months post-op	82.7 ± 2.1	75.4 ± 2.8	0.000	11.03
6 months post-op	88.7 ± 0.7	83.6 ± 3.1	0.000	12.33
12 months post-op	92.3 ± 0.2	89.1 ± 2.6	0.000	16.2

\*T = t-Student test.

<sup>#</sup> SD = Standard Deviation.<sup>§</sup> CI = Confidence of Interval.<sup>‡</sup> SLING GROUP = Lesser Trochanter Fixation + Intramedullary fixation group (case group).<sup>§</sup> IM GROUP = Intramedullary fixation only group (control group).<sup>¶</sup> RUSH = Radiographic Union Scale for Hip (RUSH).<sup>&</sup> HHS = Harris hip score.<sup>§</sup> BI = Barthel Index.

group showed significantly shorter time for fracture healing, time to achieve weight-bearing ( $p = 0.001$ ) and significantly better outcomes in terms of functional recovery and radiographic assessment at 3, 6, and 12 months post-op compared to the IM group ( $p < 0.001$ ) (Fig. 2).

Multiple LT fixation techniques have been previously described in the scientific literature. In a recent study, Gao et al.<sup>17</sup> described cerclage wiring technique to further stabilize intertrochanteric proximal femur fractures (AO/OTA 31-A2.2 and 31-A2.3) used in association with IM fixation. They reported healing time of 14 weeks without any complications such as cable breakage, implant irritation or infection. However, their technique did not consider fixation of the LT.

Wu et al.<sup>18</sup> investigated the biomechanical aspect of fixing the LT using different wiring techniques in conjunction with Dynamic Hip Screw (DHS) system in the treatment of AO/OTA 31-A2.1 unstable intertrochanteric fractures. This study has demonstrated that patients who underwent DHS + LT Fixation have experienced a better prognostic outcome, in comparison to those who underwent only DHS. Among the different fixation techniques used the so-called “candy package” cerclage technique, first described by Lee et al.<sup>19,20</sup> which has shown superiority by exhibiting greater stability and resistance to cut-out failure with minimal displacement of the fragments. Recently, Kim et al.<sup>10</sup> modified the “candy package” and reported a fracture healing time of 16.6 weeks on average in all cases. They reported wire breakage in only two cases and heterotrophic ossification in one case. The authors did not report any other complications.

The “Sling fixation” technique is based on ensuring continuity of the posteromedial fragment and recovery of psoas muscle function after LT fixation. However, a very important aspect for the success of this technique is the continuity of the posterior wall of the LT: proximal and distal fragment extension must be no more than 0.5 cm. A fragment extension that exceeds this limit results in an ineffective fixation yielding an increased risk of non-union and psoas dysfunction. The Sling technique, as the name suggests, involves the passage of the wire in a “sling” fashion. This immediately sets the technique on a pedestal in comparison to other existing techniques, as it eliminates the need of creating a drill hole. On top of that, the use of an iso-elastic polymer-based wire ensures symmetrical load distribution that improves prognosis by establishing long-term dynamic compressive loading across bony fragments. Thus, providing better healing and increased initial construct length. Furthermore, the polymer-based wire furnishes a greater fatigue strength reducing complications such as breakage, fretting wear and metal debris. Finally, these wires are designed with blunt ends which minimize soft tissue irritation and glove tears for the surgeon. Concerns regarding the use of the cerclage wires have arisen particularly due to the potential disruption to the local blood circulation, and the consequent delay in fracture healing. Nevertheless, more benefits have been manifested, thanks to the posteromedial stability, yielding a better fracture union and healing in all patients. Posteromedial stability compensates the lack of support secondary to the unstable fracture. Additionally, preserving the psoas muscle function allows faster functional recovery in most cases especially in the elderly population.

The results of the current study need to be interpreted considering several potential limitations.

The number of treated cases is small, and the patient pool may not provide the exact representation of the general population. However, the incidence of unstable intertrochanteric fractures with displacement of the LT is only about 25% of all femoral neck fractures providing a small number of cases to begin with.<sup>21</sup>

Another limitation of this study was the relatively short follow-up period, even considering that the first-year post-op results are the most crucial in this population due to the early incidence of complications. These patients are still being followed for evaluation of the long-term results of this type of treatment.

## 5. Conclusion

The “Sling fixation” technique using a polymer-based wire providing iso-elastic features showed promising outcomes when put in conjunction with the traditional proximal IM nailing method in the treatment of unstable intertrochanteric fractures with lesser trochanter involvement. Wiring improved the primary stability of the reduction, and the fracture healing time and postoperative weight-bearing time were significantly reduced. It also provided patients’ a faster functional recovery when compared to IM nailing alone.

## Declarations

Ethics approval and consent to participate: IRB approval number: 2211/2018.

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## Author contributions

Marco Villano: Conceptualization, Investigation. Roberto Civinini: Methodology, supervision. Matteo Innocenti: Writing-Original draft preparation, Software. Christian Carulli: Data curation. Alessandro





**Fig. 2.** A) 31A1.3 fracture with the LT fragment that is approximately at the same level of the main fracture line after closed reduction maneuvers. Pre-op and intra-op radiographs. (B) 31A1.3 fracture with distal extension. Pre-op and 1 month post-op radiographs. Two wires were used to fix the LT fragment.

Civinini: Software, Validation. Andrea Cozzi Lepri: Conceptualization, Writing-Original draft preparation, Writing- Reviewing and Editing. Ziad A. Taha.

### Consent for publication

The study was conducted according to the criteria set by the Declaration of Helsinki and each subject signed an informed consent before participating in the study.

### Declaration of competing interest

The authors have no financial disclosures.

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