# Sinus Tarsi Approach and Osteosynthesis with Cannulated Screws in Calcaneal Fractures with Articular Depression

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#### ABSTRACT

Introduction: Open reduction and internal fixation via an extended lateral approach is the most commonly accepted surgical strategy for managing intra-articular calcaneal fractures with articular depression. However, the high rate of soft tissue complications associated with this technique has led to the development of less invasive alternatives that aim to reduce complications and improve functional outcomes. **Objective**: To evaluate the complications and functional outcomes of calcaneal fracture fixation using the sinus tarsi approach and cannulated screws. **Materials and Methods**: Between June 2016 and June 2022, 14 intra-articular calcaneal fractures with articular depression were treated using the sinus tarsi approach and cannulated screw fixation. Postoperative complications, radiographic outcomes (Gissane angle, Böhler angle, calcaneal length and width), and CT findings (Sanders classification) were assessed, along with functional outcomes using the American Orthopaedic Foot & Ankle Society (AOFAS) score and a self-administered satisfaction questionnaire. **Results**: With a mean follow-up of 19.28 months, the average AOFAS score was 84.14. One superficial infection was reported and successfully treated with oral antibiotics. In two patients, hardware removal was required. Immediate and late postoperative imaging showed no significant differences compared to the contralateral healthy calcaneus. No postoperative articular step-offs greater than 2 mm were observed on CT scans. Eight patients reported being satisfied with the outcome, and six were very satisfied. **Conclusion**: The sinus tarsi approach combined with cannulated screw fixation provides functional and radiographic outcomes comparable to or better than those achieved with the extended lateral approach and lateral plating, with fewer soft tissue complications.

Keywords: Calcaneus; minimally invasive approach; sinus tarsi.

Level of Evidence: IV

Abordaje del seno del tarso y osteosíntesis con tornillos canulados en fracturas de calcáneo con depresión articular

#### RESUMEN

Introducción: La reducción abierta y fijación interna mediante un abordaje lateral amplio representa la estrategia quirúrgica más aceptada para el manejo de las fracturas de calcáneo con depresión articular. Sin embargo, las altas tasas de complicaciones de partes blandas llevaron a desarrollar técnicas menos invasivas que causaron menos complicaciones y lograron mejores resultados funcionales. **Objetivo:** Evaluar las complicaciones y los resultados funcionales de la reducción y osteosíntesis de calcáneo mediante el abordaje del seno del tarso y tornillos canulados. **Materiales y Métodos:** Entre junio de 2016 y junio de 2022, se trataron 14 fracturas de calcáneo con depresión articular por un abordaje del seno del tarso y tornillos canulados. Se evaluaron las complicaciones posoperatorias, los resultados en las radiografías y las tomografías, los resultados funcionales con la escala de la AOFAS y un cuestionario autoadministrado sobre la conformidad. **Resultados:** Con un seguimiento medio de 19.28 meses, el puntaje promedio de la AOFAS fue de 84,14. Hubo una infección superficial tratada con antibiótico por vía oral. En 2 pacientes, fue necesario retirar el material de osteosíntesis. Las imágenes del posoperatorio inmediato y alejado no mostraron diferencias significativas con el calcáneo contralateral sano. No hubo escalones articulares >2 mm en los controles tomográficos posoperatorios. Ocho estaban conformes con el resultado y 6, muy conformes. **Conclusión:** El abordaje del seno del tarso asociado a tornillos canulados asegura iguales o mejores resultados funcionales y en los estudios por imágenes, con menos complicaciones, que el abordaje lateral amplio con una placa lateral.

Palabras clave: Calcáneo; abordaje mínimamente invasivo; seno del tarso. Nivel de Evidencia: IV

Received on September 11<sup>®</sup>, 2024. Accepted after evaluation on March 5<sup>®</sup>, 2025 • Dr. PABLO M. YAPUR • yapur36@hotmail.com

How to cite this article: Yapur PM, Herrera HS, Rofrano Botta MA, Pereira FJ, Paitampoma Álvarez P. Sinus Tarsi Approach and Osteosynthesis with Cannulated Screws in Calcaneal Fractures with Articular Depression. Rev Asoc Argent Ortop Traumatol 2025;90(2):166-176. https://doi.org/10.15417/issn.1852-7434.2025.90.2.2025

#### **INTRODUCTION**

Calcaneal fractures represent 2% of all fractures and 60% of all tarsal fractures. In 75% of cases, there is involvement of the posterolateral articular facet, which is a cause of future morbidity.<sup>1,2</sup>

For decades, their surgical management was considered controversial. A better understanding of the mechanism of injury and fracture morphology has made it possible to classify these injuries, plan treatments, and even predict outcomes.<sup>3-6</sup> This led to the current conception: with surgery, the best functional outcomes can be expected. To achieve this, it is imperative to meet two objectives: restore the body shape (height, width, and length) and the congruence of the posterolateral articular facet of the calcaneus (PLAF).

Open reduction and internal fixation using an extended lateral approach (ELA) has been the most widely accepted surgical strategy in recent decades. This approach provides adequate visualization of the PLAF, facilitates manipulation of the fracture fragments, and allows for the placement of a plate on the lateral aspect of the calcaneus. However, it has high rates of soft tissue complications (11–25%), infections, and sural nerve injuries, which have discouraged its use.<sup>7-9</sup>

A study evaluating 838 patients treated with an ELA and 810 patients treated with a sinus tarsi approach (STA) concluded that complication rates are significantly lower with less invasive techniques.<sup>10</sup>

Minimally invasive techniques aim to reduce and fix the fracture entirely percutaneously or through small approaches, such as the STA.<sup>11</sup> In these techniques, K-wires, specific plates, screws, or a combination of these implants are used as definitive internal fixation.<sup>12</sup> The advantage of reduced trauma to the skin and soft tissues results in lower complication rates. Regardless of the fixation method, minimally invasive techniques have achieved better functional outcomes and fewer complications than those using an ELA.<sup>13</sup>

The objective of our research was to evaluate the complications, as well as the functional and imaging outcomes, of minimally invasive surgery using the STA and cannulated screw osteosynthesis in calcaneal fractures with articular depression (CFAD) (Sanders types II and III).

# **MATERIALS AND METHODS**

The sample consisted of 17 patients with calcaneal fractures, selected through critical, non-probabilistic sampling. The sex distribution was 12 men and 5 women. The average age was 54 years (range 28–76). Patients who underwent open reduction of the PLAF using an STA and internal fixation with cannulated screws between June 2016 and June 2022 were included. The mechanism of injury, comorbidities, associated injuries, average time from injury to surgery, and average hospital stay were assessed.

Inclusion criteria were: Sanders type II and III calcaneal fractures, closed, treated with open reduction (STA) and fixation with cannulated screws, and a follow-up period of more than 12 months.

Exclusion criteria were: open fractures, age under 18 years, previous calcaneal fracture, bilateral calcaneal fracture, previous or acute tarsal fractures, and inability to establish contact for the final remote follow-up.

Imaging evaluations were performed before surgery, in the immediate postoperative period, and in the longterm postoperative period, along with analysis of the healthy contralateral side. For this purpose, radiographs and computed tomography (CT) scans were used.

The radiological evaluation included analysis of lateral foot radiographs, measuring the calcaneal length, Böhler's angle, and Gissane's angle. On axial radiographs of the calcaneus, width was evaluated. Prior to surgery, CT scans were used to classify fractures according to Sanders.<sup>5</sup> Additionally, calcaneocuboid joint involvement was assessed based on Gallino's criteria.<sup>14</sup> Type I is defined as a fracture line extending to the articular surface with minimal displacement; type II is characterized by comminution of the articular cartilage involving less than 50% of the joint; and in type III, the comminution affects more than 50% of the joint and is associated with lateral subluxation.<sup>6</sup>

In the immediate postoperative period, the same radiographic projections and measurements were used as in the preoperative evaluation. A good radiographic reduction was defined as an angular difference of no more than  $5^{\circ}$  compared to the healthy contralateral side. All reductions were also evaluated by CT in the postoperative period, analyzing the quality of PLAF reduction according to Sanders' criteria: anatomic reduction: off-step in PLAF  $\leq 1$ 

mm, near-anatomic reduction: off-step between 1 and 3 mm, approximate reduction: off-step between 3 and 5 mm, reduction failure: off-step >5 mm.<sup>6</sup>

The evaluation in the long-term postoperative period was performed using the same radiographic projections as in the immediate postoperative period. Secondary displacement was considered present when there was a change of more than  $5^{\circ}$  compared to measurements taken immediately postoperatively.

Functional evaluation was conducted using the American Orthopaedic Foot and Ankle Society (AOFAS) hindfoot scale and a questionnaire assessing functional outcomes, based on a 4-item Likert-type scale: very satisfied, satisfied, not satisfied, or dissatisfied.

Postoperative complications were evaluated. Secondary displacements (i.e.,  $>5^{\circ}$  difference in radiographic measurements between the immediate and long-term postoperative periods) were also analyzed. The need for removal of osteosynthesis material was evaluated as an additional complication.

#### **Surgical Technique**

After regional block and anesthetic sedation, the patient is placed in lateral decubitus, with the leg of the limb to be operated on in a leg brace. A hemostatic cuff is placed on the thigh. The leg remains parallel to the floor, as does the longitudinal axis of the foot. The image intensifier is positioned to obtain calcaneal, Broden, and axial profile projections by simply moving the C-arm.

A transfixing Schanz nail is placed in the greater calcaneal tuberosity from lateral to medial, marking the entry point on the profile view, proximal to the plantar cortex. The Schanz nail is oriented perpendicular to the greater tuberosity, and its parallelism to the plantar cortex is assessed in the axial projection (Figure 1A).

The first assistant proceeds to perform traction using the transfixing Schanz nail to correct the deformity. Axial and varus/valgus traction is applied to restore calcaneal anatomy by ligamentotaxis. A first guide pin (for a 6.5/7 mm positioning screw) is then placed parallel to the medial cortex to attach the greater tuberosity to the sustentacular fragment—an anatomical component that is generally stable and undisplaced (Figure 1B).

STA is then performed, and the PLAF is reduced under direct visualization (Figure 2).

The PLAF is fixed with one or two pins, placed from lateral and posterior to anterior and medial, directed toward the sustentaculum tali. These are subsequently replaced with 3.5/4 mm cannulated compression screws (Figure 1C). Finally, the second guide pin (line C) is placed and replaced by a 6.5/7 mm full-thread cannulated screw. This screw runs parallel to the lateral cortex and supports the greater tuberosity with the lesser tuberosity (Figures 1D and 3).

The number and orientation of the 6.5/7 mm screws will depend on the fracture lines. The objective of these screws is to support the greater tuberosity with the calcaneal body and the lesser tuberosity, also creating a "scaffolding" that provides stability to the posterolateral articular facet (Figures 4-6).

#### **Statistical Analysis**

Quantitative variables are described as means, standard deviations, medians, ranges, and percentile ranges, according to their distribution, while qualitative variables are expressed as percentages. Continuous data were compared using Student's t-test for independent samples. A p-value <0.05 was considered statistically significant. The study of linear relationships for categorical variables was performed using Spearman's correlation test; a p-value <0.01 was considered statistically significant. All data were entered into an MS Excel spreadsheet, and statistical calculations were performed using IBM SPSS 23.0.



**Figure 1. A.** Sustentacular fragment (1); greater tuberosity (2) with transfixing Schanz nail (D), positioned parallel to the plantar cortex; depressed posterolateral facet (3); lateral wall of the calcaneus (4). **B.** The dotted line (A) represents the guide pin that will anchor the sustentacular fragment (1) to the greater tuberosity (2). **C.** The depressed posterolateral facet (3) is elevated and temporarily fixed to the sustentacular fragment (1). Line B represents the guide pin for the 3.5 or 4 mm cannulated compression screw. **D.** Line C represents the guide pin for the second 6.5/7 mm positioning screw that will fix the greater tuberosity to the lesser tuberosity.



Figure 2. Sinus tarsi approach. P = fibula; 3 = posterolateral facet of the depressed calcaneus; <math>M = fifth metatarsal.



**Figure 3.** Intraoperative lateral radiographic view of the calcaneus. **A.** Guide pin parallel to the medial cortex, directed toward the sustentaculum tali, with its corresponding 6.5/7 mm cannulated screw. **B.** 3.5/4 mm cannulated screw used for osteosynthesis of the posterolateral articular facet of the calcaneus. **C.** Guide pin and corresponding 6.5/7 mm cannulated screw from the greater tuberosity to the lesser tuberosity. **D.** Transfixing Schanz nail placed parallel to the plantar cortex.



**Figure 4.** Lateral (**A**) and axial (**B**) ankle radiographs, showing preoperative views of the fractured side and the contralateral healthy side.



Figure 5. Lateral (A) and axial (B) ankle radiographs in the late postoperative period, comparing the fractured side with the contralateral healthy side.



Figure 6. Preoperative and immediate postoperative computed tomography scans of the ankle and hindfoot: coronal (A), axial (B), and sagittal (C) views. Anatomical reduction is observed.

### RESULTS

Fourteen patients (14 fractures) met the inclusion criteria. According to the Sanders classification, 10 (71.43%) were type II and 4 (28.57%) were type III. The calcaneocuboid joint was affected in 8 patients (57.14%). According to Gallino's criteria, 4 were type I (28.57%), 3 were type II (21.43%), and one (7.14%) was type III. The fracture was caused by a fall from height in 13 cases (92.86%) and by a motorcycle accident in one case (7.14%). Regarding comorbidities, two patients were diabetic. As for associated injuries, one patient (7.14%) had a fracture of the first lumbar vertebra.

The mean time from injury to surgery was  $7 \pm 3.16$  days. The mean hospital stay was  $1.21 \pm 0.43$  days, and the mean follow-up was 19.28 months (range, 14–26).

Regarding complications, we documented a superficial infection in a diabetic patient, which resolved with oral antibiotic treatment. Removal of osteosynthesis material was necessary in two patients. One had shoe intolerance related to a 7 mm screw. Another had tenosynovitis due to friction between the short peroneal tendon and a 4 mm screw, located near the PLAF. Five patients experienced occasional discomfort from the implants, which did not justify their removal.

The mean Böhler angle showed significant differences between the contralateral healthy calcaneus  $(30.76^\circ \pm 5.71^\circ)$  and the preoperative measurement  $(14.05^\circ \pm 6.60^\circ)$ . However, the differences between the healthy side

 $(30.76^{\circ} \pm 5.71^{\circ})$  and the postoperative values, both immediate  $(29.50^{\circ} \pm 5.96^{\circ})$  and remote  $(29.86^{\circ} \pm 6.51^{\circ})$ , were minimal. The 25th, 50th, and 75th percentiles were also considered. Student's t-tests for independent samples confirmed that there was no statistically significant difference between measurements on the healthy contralateral calcaneus and the immediate postoperative values (95% confidence interval [CI], p = 0.571, d = 0.216) or the remote values (95% CI, p = 0.700, d = 0.147), whereas there were significant differences compared to the preoperative values (95% CI, p < 0.001, d = 2.708).

The mean Gissane angle showed differences between the contralateral healthy calcaneus  $(119.03^\circ \pm 6.99^\circ)$  and the preoperative value  $(110.31^\circ \pm 10.01^\circ)$ . However, the differences between the healthy side  $(119.03^\circ \pm 6.99^\circ)$  and the immediate  $(118.85^\circ \pm 7.54^\circ)$  and remote  $(119.00^\circ \pm 7.43^\circ)$  postoperative values were not statistically significant. Student's t-tests for independent samples confirmed that there was no statistically significant difference between the healthy contralateral calcaneus and the immediate (95% CI, p = 0.948, d = 0.0248) or remote (95% CI, p = 0.992, d = 0.004) postoperative values, while there was a significant difference compared to the preoperative values (95% CI, p = 0.013, d = 1.010).

The mean calcaneal length showed minimal differences between the contralateral healthy calcaneus (77.61  $\pm$  8.25), the preoperative value (76.01  $\pm$  8.47), and the immediate (78.26  $\pm$  8.01) and remote (76.99  $\pm$  7.56) postoperative values. Student's t-tests for independent samples confirmed that there were no statistically significant differences between the healthy contralateral calcaneus and the preoperative value (95% CI, p = 0.617, d = 0.191), the immediate (95% CI, p = 0.835, d = -0.080), or the remote (95% CI, p = 0.836, d = 0.078) postoperative values.

The mean calcaneal width showed differences between the contralateral healthy calcaneus  $(36.94 \pm 4.09)$  and the preoperative value  $(44.13 \pm 9.36)$ . However, the differences between the healthy side  $(36.94 \pm 4.09^{\circ})$  and the immediate  $(39.17 \pm 4.77)$  and remote  $(38.99 \pm 5.16)$  postoperative values were minimal.

Postoperative CT scans revealed 9 anatomic reductions and 5 near-anatomic reductions.

The mean AOFAS score was  $84.14 \pm 11$ , and the median was 86.00 (Table).

Regarding the self-administered survey on functional satisfaction perceived by the patients, the results were: very satisfied (42.90%) and satisfied (57.10%).

AOFAS score		
n	Valid	14
	Lost	0
Mean		84.14
Median		86.00
Mode		82*
Standard deviation		11.00
Range		32.00
Minimum		68.00
Maximum		100.00
Percentiles	25	71.75
	50	86.00
	75	92.00

 
 Table. Functional outcomes according to the AO-FAS score.

\*There are multiple modes. The smallest value is shown.

#### DISCUSSION

The surgical management of displaced intra-articular calcaneal fractures (DIACF) involves achieving two main objectives: restoring the shape of the calcaneus (height, length, and width) and reestablishing the congruence of the posterior facet of the subtalar joint (PLAF). Restoring normal anatomy is associated with better functional outcomes and reduces the need for reinterventions.<sup>15</sup> In this context, open reduction and internal fixation (ORIF) with plates and screws via an extensile lateral approach (ELA) has been the standard treatment for these fractures over the past decades.<sup>16</sup> However, the high rate of complications—including skin dehiscence and necrosis, superficial and deep infections, hematoma formation, and injury to the sural or superficial peroneal nerves—has prompted a reassessment of the safety of this technique and led to the development of less invasive approaches with fewer complications.<sup>17</sup>

The ELA provides excellent visualization of the fracture and allows the surgeon to comfortably reduce and fix the fragments.<sup>1</sup>Atraumatic soft tissue handling and the creation of a full-thickness flap are imperative to minimize complications. Folk et al.<sup>8</sup> reported wound complications in 48 (25%) of 190 patients treated via ELA, with 40 (21%) requiring reoperation. Diabetes and smoking were identified as independent risk factors. In a review of 218 fractures treated using the ELA, Harvey et al.<sup>9</sup> reported an overall wound complication rate of 11%, with 6 patients (2.8%) experiencing sural nerve involvement.

The sinus tarsi approach (STA), which extends 3–5 cm from the lateral malleolus toward the base of the fourth metatarsal, allows wide exposure of the PLAF with minimal dissection. It avoids dislocation of the peroneal tendons and can be extended distally to expose the calcaneocuboid joint. Although the STA significantly reduces complication rates, superficial infections have been reported in up to 14% of cases in some studies, and thus should be considered. Weber et al.<sup>18</sup> compared 24 DIACFs treated with STA and cannulated screws to 26 cases treated via ELA and lateral plating. In the ELA group, complications included delayed wound healing (1 case, 3.85%), hematoma (1 case, 3.85%), sural nerve injury (2 cases, 7.69%), and complex regional pain syndrome (4 cases, 15.4%). The STA group reported no complications. Similarly, Kline et al.<sup>19</sup> observed a significant reduction in wound complications and reoperations in patients treated via STA and recommended its use in cases with high risk of wound problems. Nosewicz et al.<sup>17</sup> conducted a systematic review and meta-analysis of nine studies, comprising 331 fractures treated with STA and 390 with ELA. Minor wound healing complications occurred in 11 cases (4.9%) with STA and in 82 cases (24.9%) with ELA; 71% of these were classified as minor and 29% as major. In our series, only one patient (7.14%) developed a superficial wound infection, which resolved with oral antibiotic therapy. This patient had diabetes. No deep infections, necrosis, wound dehiscence, or sural nerve involvement were recorded.

The fixation capability of cannulated screws may be questioned; however, few studies have clearly established the ideal implant for DIACF. In a cadaveric study, Nelson et al.<sup>20</sup> compared an anatomic lateral plate to cannulated screws in 20 specimens with simulated Sanders IIB fractures and concluded that both methods provided adequate fixation. Similarly, Ni et al.<sup>12</sup> found no clear advantage of plates over cannulated screws. Wang et al.,<sup>21</sup> in a systematic review and meta-analysis of randomized clinical trials, compared both fixation methods regarding function, reduction quality, and complications. Radiological outcomes favored cannulated screws; functional outcomes were comparable, but cannulated screws were associated with fewer soft tissue complications. Guo et al.<sup>22</sup> also compared cannulated screws and anatomic plates via STA and found no significant differences in reduction quality or function, but noted significantly lower costs with screw fixation.<sup>7</sup> If cannulated screws are chosen, the literature does not clearly define the optimal construct. Our aim was to simplify the body fracture by joining the greater tuberosity to the anterior tuberosity with 6.5 or 7 mm cannulated screws, and to provide a supporting scaffold to the posterolateral facet, previously fixed to the sustentaculum tali with one or two 4.5 mm cannulated compression screws. No secondary displacements were observed in our series, which supports the safety of this technique. Furthermore, we consider cannulated screws easier to insert and less aggressive to soft tissues, potentially reducing complications.

Although the ELA offers better fracture exposure and should theoretically yield superior reductions, STA with cannulated screws has been shown to be more reliable in restoring Gissane and Böhler angles. Pitts et al.<sup>23</sup> compared 51 DIACFs treated with STA and cannulated screws to 23 treated with ELA and found no significant differences. Wang et al.<sup>21</sup> argue that cannulated screws ensure better reductions In our series, postoperative Gissane and Böhler angles were not significantly different from the contralateral healthy calcaneus, suggesting that limited exposure does not compromise reduction quality. Sanders et al. recommend CT imaging to evaluate postoperative PLAF reduction and classify outcomes based on the residual step height: reductions are considered anatomic when the step is  $\leq 1$  mm and near-anatomic reductions; no steps >2 mm were recorded. We believe that the visualization of the PLAF provided by the STA is sufficient for adequate reduction.

Regarding functional outcomes, STA combined with cannulated screws has not demonstrated superiority over other techniques. Weber et al.<sup>18</sup> compared 24 STA and cannulated screws with 26 ELA and lateral plate. The AO-FAS score was 82.6 for ELA and 87.2 for STA (p = 0.17). Peng et al.<sup>10</sup> retrospectively analyzed 45 DIACFs (21 cannulated screws vs. 24 plates). The AOFAS score was 80.3 for cannulated screws and 83.6 for plates (p = 0.09). In another retrospective study, Weng et al.<sup>24</sup> compared 78 cannulated screws and 72 plates, with a follow-up of 8.7 years, and found no statistically significant differences between the methods In our series, the mean AOFAS score was 84.14 (range, 67–94). These favorable results are comparable to those reported by most authors. Eight patients in our study were satisfied with the outcome, and six were very satisfied.

Intolerance to osteosynthesis material is a common late complication in operated calcaneal fractures. According to the literature, between 10% and 88% of plates placed via an extended lateral approach (ELA) require removal.<sup>6</sup> However, cannulated screws can also cause symptoms, warranting their removal. Driessen et al.<sup>25</sup> reported removal of 60% of cannulated screws implanted in the greater tuberosity due to local skin irritation. In our series, hardware removal was the most frequent secondary procedure. In one patient, 7.5 mm screws had to be removed due to heel skin irritation. Another patient developed peroneal tendon tenosynovitis caused by friction against the prominent flat head of a 4.5 mm PLAF screw. In both cases, symptoms resolved immediately after implant removal.

We believe cannulated flat-head screws are the best option, as they typically do not require removal if implanted correctly. However, if the screws are excessively long and cause friction, they may be less well tolerated than round-head screws. If removal is necessary, it can usually be performed using a minimally invasive and outpatient approach, avoiding the wide exposures required for plate removal and thus reducing the risk of complications.

Rodemund et al.<sup>26</sup> combined a sinus tarsi approach (STA) with cannulated screws and recommended performing surgery within the first 3 days post-injury, even in the presence of soft tissue edema, without increasing the risk of wound-healing complications. Shams et al.<sup>27</sup> published a prospective case series of fracture reduction and fixation using an STA and cannulated screws. According to these authors, a 91% satisfaction rate and a Maryland score of 85 may be attributable to early surgery (mean, 3.2 days).

Our therapeutic approach favors early surgery; the shorter the interval between injury and surgery, the easier the mobilization and reduction of fracture fragments. In our series, the mean time from injury to surgery was 7.64 days (range, 1-10). We concur on the importance of early surgical intervention, although we acknowledge that such short intervals may be difficult to achieve in our setting.

The limitations of our study include the small sample size and a mean follow-up of 19.28 months, which prevents the evaluation of medium- and long-term complications. As strengths, we highlight the detailed description of the surgical technique, appropriate imaging assessment (radiographs and CT), and statistical analysis of the outcomes.

# CONCLUSIONS

The STA provides adequate exposure of the posterior lateral articular facet (PLAF) with minimal dissection and soft tissue trauma. Internal fixation with cannulated screws is safe, and secondary displacements are rare. With an STA and cannulated screws, imaging and functional outcomes comparable or superior to those achieved with an ELA and lateral plate can be expected, with fewer associated complications.

Conflict of interest: The authors declare no conflicts of interest.

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