

Less wound complications of a sinus tarsi approach compared to an extended lateral approach for the treatment of displaced intraarticular calcaneal fracture

A randomized clinical trial in 64 patients

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Abstract

Background: We conducted a prospective randomized clinical trial to compare the clinical and radiological outcomes of the sinus tarsi and extended lateral approaches for the surgical treatment of displaced intraarticular calcaneal fractures.

Methods: Between January 2009 and January 2014, patients with displaced intraarticular calcaneal fracture were randomly assigned to receive surgical treatment by the sinus tarsi approach or the extended lateral approach using block randomization. We recorded and analyzed data on demographics, time to surgery, wound complications, Böhler angles pre- and postoperatively, and American Orthopedic Foot & Ankle Society score.

Results: Sixty-four patients met the inclusion criteria and were randomly assigned to the 2 groups: 32 patients underwent sinus tarsi approach, and 32 patients the extended lateral approach. Baseline characteristics of both groups were similar. The time to surgery in the sinus tarsi approach group was significantly shorter than in the extended lateral approach group ($P=0.04$). The wound complication rates were 6.3% and 31.2% in the sinus tarsi approach and extended lateral approach groups, respectively, which was significantly different ($P=0.01$). Regarding the clinical outcomes, the groups did not differ significantly on walking visual analogue scale or American Orthopedic Foot & Ankle Society scores at 6 months and 1 year postoperatively. No significant differences existed between groups regarding the Böhler angle at different times and reduction quality of the articular surface and the medial wall.

Conclusion: Compared with the extended lateral approach, the sinus tarsi approach decreased wound complications and preoperative waiting time, and achieved similar functional and radiological outcomes for displaced intraarticular calcaneal fractures.

Abbreviations: AOFAS = the American Orthopedic Foot & Ankle Society, RCT = randomized clinical trial, VAS = visual analogue scale.

Keywords: calcaneus, extended lateral approach, intraarticular fractures, open reduction and internal fixation, percutaneous plate fixation, sinus tarsi approach

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1. Introduction

Calcaneal fracture is a fracture of the calcaneus cause by axial loading when the feet land on the ground in a fall, which is among the most challenging fractures to be treated. Intraarticular calcaneal fracture is the calcaneus fracture with subtalar joint involved, and more commonly in the posterior articular facet. The Sanders classification is often used to categorize the intraarticular calcaneal fracture. There are 4 types based on the fracture location at the posterior articular facet. Type I fracture is nondisplaced fractures with fracture displacement less than 2mm. Type II–IV fractures are displaced intraarticular calcaneal fracture and divided by different articular pieces.^[1] The incidence of calcaneal fractures account for approximately 2% of all fractures, and displaced intraarticular fractures comprise 60% to 75% of calcaneal fractures.^[2]

Open reduction and internal fixation have been considered an appropriate treatment for some patients with a displaced intraarticular calcaneal fracture for decades.^[3,4] The most widely surgical technique is open reduction and internal fixation with plate, using an expanded L-shaped incision on the lateral wall of the heel and with or without bone grafting. The lateral extended is most frequently used because it allows good visibility of the lateral wall of the calcaneus, subtalar joint, and calcaneocuboid

joint.^[5,6] However, wide dissection of soft tissue can also lead to complications such as wound infection, flap or wound-edge necrosis, and nonunion.^[7]

To prevent wound complications and associated problems, a minimally invasive technique, the sinus tarsi approach has become increasingly popular for the treatment of calcaneal fractures. This approach protects blood supply by avoiding wide dissection and can still provide direct visibility of the subtalar joint,^[8–10] and we assumed that this approach was able to reduce the incidence of wound complications. The aim of the present study was to compare the clinical and radiological outcomes between the extended lateral and sinus tarsi approaches for the treatment of displaced intraarticular calcaneal fracture.

2. Material and methods

2.1. Study design and patients

This prospective randomized clinical trial (RCT) was conducted at the Orthopedics Department of PLA Army General Hospital between January 2009 and January 2014. When the study was designed, the sinus tarsi approach was considered superior to nonoperative treatment. The pilot study yielded an estimated rate for wound complications of 32% in the standard extended lateral approach group and 5% in the sinus tarsi approach group, similar to that of other studies (32% and 4.8%, respectively, in 2 reports).^[7,11] We designed the study with an 80% power at the 5% significance level, which indicated that 29 participants were necessary in each group. Considering an approximate loss to follow-up of 10%, we planned to include 64 patients.

Patients who were willing to participate in this study gave informed consent. The inclusion criteria for this trial were as follows: patients between 18 and 60 years of age, who had a displaced intraarticular calcaneal fracture, classified as Sanders type II to IV. The exclusion criteria were as follows: patients with open fracture, nerve or vascular injury in the lower extremity, severe diabetes (blood glucose could not be controlled preoperatively), heavy smokers (more than 20 cigarettes per day), and patients who declined participation in the trial and the assigned treatment algorithm.

This study was approved by the Research and Ethics Committee of PLA Army General Hospital. Block randomization was used and potential participants were graded into 3 blocks according to the Sanders classification.^[1] One researcher in our team who was not involved in the clinical treatment of patients assigned equal number of the 2 groups prior to the recruitment of patients, sealed these assignments in opaque envelopes, and divided these sealed envelopes into 3 blocks according to computer-generated random numbers. The treating surgeons were blinded to the size of each block. The study was registered in Chinese Clinical Trial Registry (ChiCTR-INR-15007601).

2.2. Surgery technique

Patients were placed in the lateral decubitus position and under either epidural or spinal anesthesia. The affected foot was placed in a soft pad, and the axial radiograph was easily obtained transoperatively.

The sinus tarsi approach involved the area from the tip of the fibula to about 4 cm proximal to the cuboid. The peroneal tendon was identified and pulled gently to cephalic direction. The fracture segments of the lateral wall were took down to clearly expose the subtalar joint and the initial fracture line. Reduction

techniques included the use of distraction with a Schanz pin or 4.0-mm K-wire transversely through the tuberosity segments. The traction was directed in a backward, downward, and external-oblique motion, aiming to recover the original fracture line by aligning the interior wall, correcting the varus, shortening deformity, and restoring the Böhler angle. Then, the external segments of the subtalar joint were relocated to reconstruct the joint, and the lateral wall was realigned. A specially designed lateral plate (Acumed, Portland, OR) was used to fix the calcaneus, and it was designed to place screws in 3 main points in the calcaneus (Fig. 1).

A standard extended lateral approach to the calcaneus was used to expose the lateral wall of the calcaneus and subtalar joint. It is important to avoid traction to the flap during dissection. K-wires were used to hold the flap in place after the exposure. Reduction techniques were similar with the standard extended lateral approach. Lateral plates designed for the calcaneus were used for fixation (Fig. 2).

We verify the articular reduction by lateral view, axial view, and Broden view using C-arm intraoperation, lateral view, axial view X-ray, and CT postoperation. We do not use contralateral foot to compare Bohlrs angle as a routine. After the surgery, all participants received routine postoperative care. Nonweight bearing exercises were encouraged as soon as patients recovered from anesthesia. The affected foot was put into a short-leg nonweight bearing cast during 4 to 6 weeks, a sufficient time to ensure wound healing. Partial weight-bearing begins at 4 to 6 weeks postoperatively. Full weight-bearing was allowed at 3 months postoperatively once bone union was evidenced radiographically.

2.3. Outcome assessment

All patients underwent lateral and axial radiographs and CT scan of the injured foot preoperatively and postoperatively and were followed up at 1, 3, and 6 months and at 1 year. The baseline data were recorded, including age, sex, time to surgery, tobacco use, diabetes, and Sanders type.

Preoperatively, all patients were evaluated both clinically and radiologically, as well as postoperatively and at each follow-up. Clinical evaluation included the assessment of wound complications, the visual analogue scale (VAS) score, and the American Orthopedic Foot & Ankle Society (AOFAS) ankle-hindfoot scale. Radiological assessment was performed including the measurements of the Böhler angle and reduction quality of the articular surface and the medial wall.

The primary outcome measure was rate of wound complications, including minor and major complications. The minor complication included the superficial infection involving the skin and subcutaneous tissue and could be cured without reoperation, while the major complication included deep infection involving the internal fixation and wound-edge necrosis. The secondary outcome measures were VAS score, AOFAS, rate of poor reduction, and reduction loss. Poor reduction was defined as displacement of 2 mm, and reduction loss was defined as loss of $\geq 5^\circ$ of the Böhler angle. The functional outcomes were assessed and recorded by an independent surgeon who was blinded to the group allocation.

2.4. Statistics

Statistical analyses were performed using a statistical software package (IBM SPSS Statistics for Windows, Version 20.0; IBM

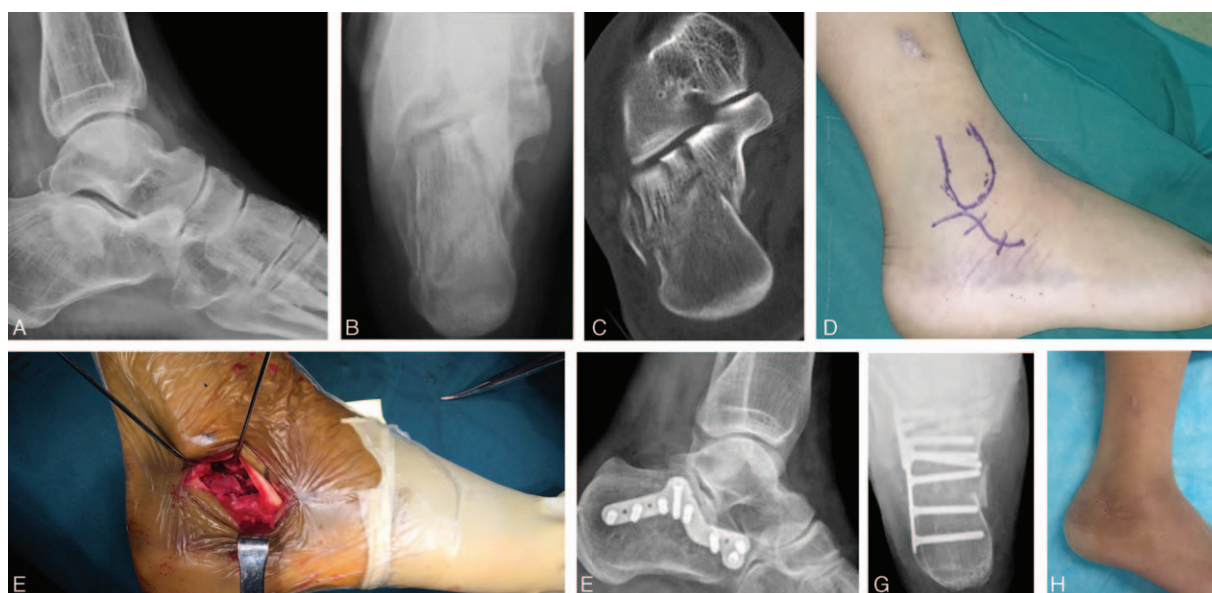


Figure 1. Right calcaneal fracture in a 40-year-old female patient caused by a fall from a height. (A) Preoperative radiograph of lateral view. (B) Preoperative radiograph of axial view preoperation. (C) Computed tomography scan indicated a Sanders type IV fracture preoperatively. (D) Diagram of the sinus tarsi approach. (E) Intraoperative exposure to the subtalar joint. (F) Postoperative radiograph of lateral view. (G) Postoperative radiograph of axial view. (H) Postoperative incision healing of the sinus tarsi approach. (I) Postoperative appearance from the back.

Corp., Armonk, NY). Standard descriptive statistics were calculated including frequencies, percentages, means, and standard deviation. Baseline data differences between the 2 groups were compared with Student *t* test or nonparametric tests. The intention-to-treat strategy was used in the statistical analyses, with 5% as the overall type-I error rate. The primary outcome of wound complication was compared with Fisher exact Chi-square test. The secondary outcomes of poor reduction and reduction loss were compared with Fisher exact Chi-square test, and other secondary outcomes such as VAS, AOFAS, and Böhler angle were compared with a paired *t* test. A *P* value of <0.05 was considered statistically significant.

3. Results

A total of 87 patients were screened for the study (Fig. 3). Twenty-three patients were excluded according to the exclusion criteria and 64 patients met the inclusion criteria and were randomized (32 patients in the sinus tarsi approach the sinus tarsi approach group and 32 patients in the extended lateral approach group). Sixty patients completed the 12-month follow-up (31/32 in the sinus tarsi approach the sinus tarsi approach group and 29/32 in extended lateral approach group). The most frequent cause of withdrawal was poor outcomes and the patients sought treatment at another institution.

Baseline characteristics of the participants were similar between the 2 groups, except for time to surgery (Table 1). Most of the patients were male (73.4%) and middle-aged, and there were no significant differences between the groups with regard to sex and age. There was a large proportion of patients with diabetes (18.8% and 15.6% in the sinus tarsi approach and extended lateral approach groups, respectively) and smokers (25% and 18.8% in the sinus tarsi approach and extended lateral approach groups, respectively), which are the most important factors affecting the blood supply to the skin flap. However, there

was no significant difference between the 2 groups. The time from admission to surgery in the sinus tarsi approach group was averagely significant 4.6 days, which was shorter than that in the extended lateral approach group (averagely 6.9 days, $P=0.04$), which was dependent on the decision of the surgeon and not affected by randomization. The Sanders classification and associated injuries were similar between both groups.

3.1. The primary outcome

The wound complication rate was 6.3% in the sinus tarsi approach group and 31.2% in the extended lateral approach group, with a significant statistical difference ($P=0.01$). Of these, 7 patients had superficial infections (2 in the sinus tarsi approach group and 5 in the extended lateral approach group), 1 had a deep infection in the extended lateral approach the sinus tarsi approach group and 4 in the extended lateral approach group had wound-edge necrosis. The 5 patients with deep infections and skin necrosis underwent reoperation in the extended lateral approach group.

3.2. The secondary outcome

As for the clinical outcomes (Table 2), there were no significant differences between the 2 groups on either walking VAS or AOFAS at 6 months postoperatively and 1 year postoperatively. The Böhler angle in the 2 groups did not differ significantly at different follow-up time points, and neither did the reduction quality of the articular surface and the medial wall (Table 3). Further, the groups did not differ in the reduction loss at 1 year (50% in the sinus tarsi approach group vs 43.8% in the extended lateral approach group, $P=0.62$).

No unintended harm occurred in any of the patients and groups.



Figure 2. Right calcaneal fracture in a 43-year-old male patient caused by a fall from a height. (A) Preoperative radiograph of lateral view. (B) Preoperative radiograph of axial view preoperation. (C) Computed tomography scan indicated a Sanders type III fracture preoperatively. (D) Diagram of the extended lateral approach. (E) Intraoperative exposure to the subtalar joint. (F) Postoperative radiograph of lateral view. (G) Postoperative radiograph of axial view. (H) Postoperative incision healing of the extended lateral approach. (I) Postoperative appearance from the back.

4. Discussion

This study compared the short-term clinical outcomes of the extended lateral and sinus tarsi approaches for the treatment of displaced intraarticular calcaneal fracture. Compared with the extended lateral approach, our results indicate that the sinus tarsi approach had fewer wound complications and similar functional and radiological outcomes. In addition to these findings, the sinus tarsi approach apparently contributed to lessening the waiting time to surgery.

We found a statistically significant difference in the incidence of wound complications between the 2 groups in favor of the sinus tarsi approach. This result is similar to a recent RCT reported by Xia et al,^[12] which is the 1st RCT to compare the extended lateral approach and sinus tarsi approach for the treatment of

intraarticular calcaneal fracture indexed in PubMed. The differences between our research and study by Xia et al were the incision method and plate placement. They made another rear incision to create a lateral channel to install the plate, that is, they used a sinus tarsi approach plus a mini-longitudinal approach. Conversely, we only performed a single incision of the tarsal sinus.

A retrospective study to compare the outcomes of intraarticular calcaneus fractures treated with an extended approach versus the sinus tarsi approach was reported in 2013.^[13] In the minimally invasive group, they used large cannulated screws to fixate calcaneal fracture. Clinical results were similar between the 2 groups and the minimally invasive approach had a significantly lower incidence of wound complications and secondary surgeries, which was consistent with our results.

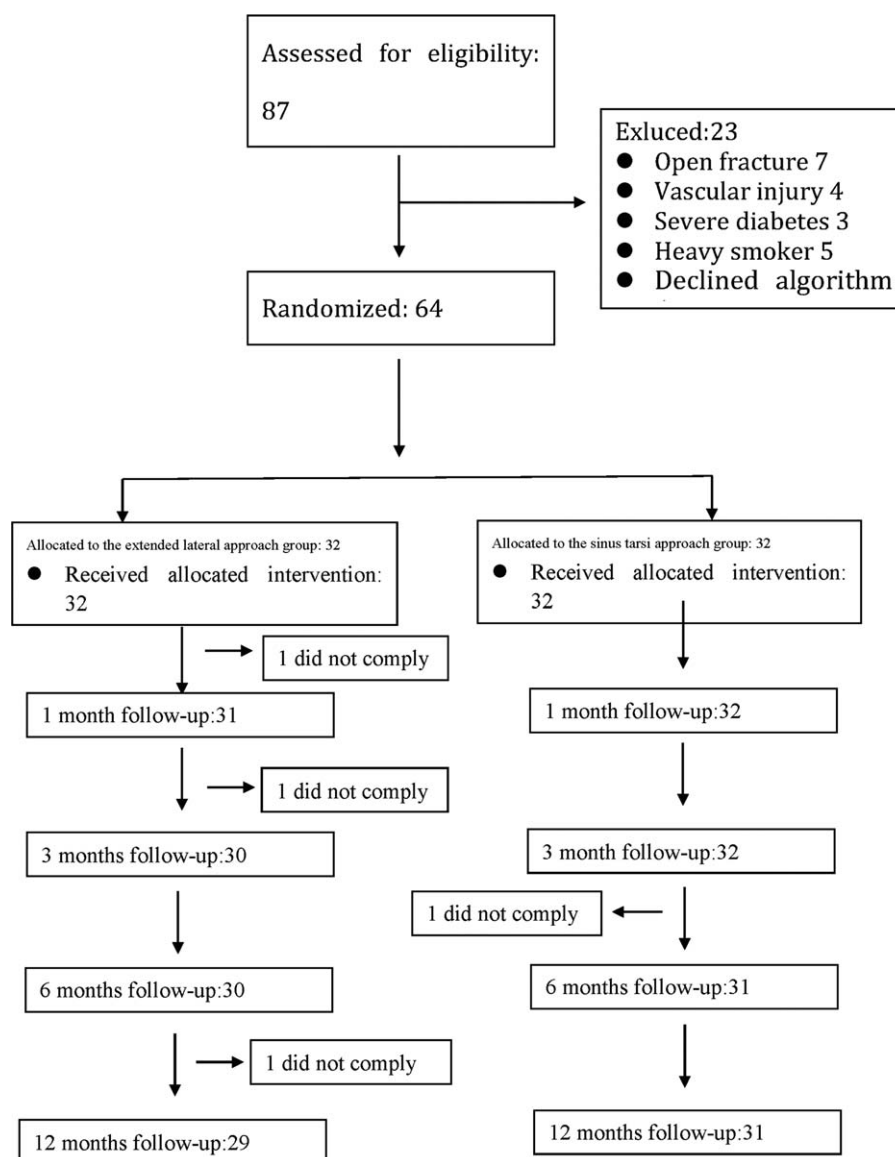


Figure 3. Trial profile. Consolidated Standards of Reporting Trials (CONSORT) flow diagram.

The wound healing process associated with the extended lateral approach depends on the soft tissue covering the lateral wall, which is mainly supplied by the lateral calcaneal artery and is particularly thin and vulnerable.^[14,15] That is why the incidence of wound complications after calcaneal fracture is high compared with other lower extremity fractures.^[16,17] The extended lateral approach should be safely undertaken until the wrinkle sign is positive, that is, if skin wrinkling is seen and no pitting edema is evident.^[18] In our study, the mean time to surgery for the extended lateral approach was 6.9 days. The sinus tarsi approach required less demanding skin conditions because of fewer traumas to the flap. The mean time to surgery for the sinus tarsi approach was 4.6 days.

Various minimally invasive approaches have been developed to minimize the wound complication rate.^[11,19–22] The sinus tarsi approach was most commonly used because it provided exposure of the posterior facet directly.^[8–11,13,23] Zhang et al compared 2 minimally invasive approaches in a recent RCT and found that the wound complication rate was 12.5% in the sinus tarsi group,

which was higher than the 2.9% rate in the minimally longitudinal approach.^[23] In our study, 6.3% of patients in the sinus tarsi group had a superficial infection, which was similar to that in Kline study (6%).^[13] Xia et al^[12] reported no wound complication in the sinus tarsi approach.

Biomechanical study indicated that a measure of 1 to 2mm of incongruity in the posterior facet produced significant unloading of the depressed fragment, with a redistribution of the overall pattern of pressure distribution to parts of the facet that were previously unloaded, and associated with an adverse effect on functional outcome.^[23,24] In this study, we compared the lately postoperative outcomes (walking VAS and AOFAS at 6 and 12 months postoperation) and found no significant difference between the 2 groups. According to the radiographic data, the Böhler angle and the reduction quality were similar between both groups, and there was no significant difference in the maintenance of the Böhler angle, which may contribute to similar lately functional outcomes.

Our study had several limitations. First, treatment could not be masked, and the nonblinded nature of the study may have

Table 1**Baseline characteristics of the patients.**

	The sinus tarsi approach group	The extended lateral approach group	P
Age, years	40 ± 9	41 ± 9	0.90
Gender (female%)	25%	28%	0.78
Time to surgery, days	4.6 ± 1.2	6.9 ± 1.7	0.04
Tobacco, %	25%	18.8%	0.55
Diabetes, %	18.8%	15.6%	0.74
Associated injuries	34.4%	37.5%	0.79
Sanders classification			0.81
Type II	16	17	
Type III	11	11	
Type IV	5	4	

Table 2**Clinical outcomes of the patients.**

	The sinus tarsi approach group	The extended lateral approach group	P
Walking VAS			
6 months postoperation, °	2.5 ± 0.5	2.6 ± 0.5	0.64
12 months postoperation, °	1.5 ± 0.7	1.8 ± 0.9	0.16
AOFAS			
6 months postoperation, °	78.1 ± 8.7	77.3 ± 9.4	0.73
12 months postoperation, °	79.8 ± 7.9	79.3 ± 8.2	0.82

AOFAS = the American Orthopedic Foot & Ankle Society, VAS = visual analogue scale.

Table 3**Radiological assessment outcomes of the patients.**

	The sinus tarsi approach group	The extended lateral approach group	P
The Böhler angle			
Before operation, °	0.8 ± 1.8	1.5 ± 2.1	0.17
Postoperation, °	27.7 ± 2.9	28.3 ± 4.2	0.54
6 months postoperation, °	25.0 ± 3.3	26.3 ± 4.1	0.18
12 months postoperation, °	23.4 ± 3.5	24.9 ± 4.4	0.74
Poor reduction, %	9.4%	6.2%	0.64
Reduction loss, %	50%	43.8%	0.62

affected the patient's response. Second, 26.4% of patients were excluded from this study because of the specific inclusion and exclusion criteria, and it is possible that the sample is not representative of the average calcaneal fracture patient. Third, as the sample number in this trial was small, it may have weakened the statistical power of the final results.

In conclusion, compared with extended lateral approach, the sinus tarsi approach was associated with a decrease in the number of wound complications and shorter waiting time before surgery, and achieved similar functional and radiological outcomes for the treatment of displaced intraarticular calcaneal fractures. We recommended application of this incision for the treatment of displaced intraarticular fractures.

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