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Early Minimally Invasive Percutaneous Fixation of Displaced Intra-Articular Calcaneal Fractures With a Percutaneous Angle Stable Device

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ABSTRACT

The Minimally Invasive Reduction and Osteosynthesis System® (MIROS) is a percutaneous angle stable device for the treatment of fractures. The aim of the present study was to evaluate the clinical and radiographic results of an early minimally invasive osteosynthesis with the MIROS device. A total of 40 consecutive patients were treated for an intra-articular fracture of the calcaneus. We evaluated the clinical and radiographic outcomes after treatment of intra-articular calcaneal fractures with the MIROS hardware. Soft tissue damage was noted. The patients completed the American Orthopaedic Foot and Ankle Society survey at 12 and 24 months and underwent radiologic evaluations. A statistically significant association between the American Orthopaedic Foot and Ankle Society score and type of soft tissue lesion. A Sanders type II, III, and IV fracture was found in 15, 20, and 15 of 50 fractures, respectively. Postoperatively, restoration of the posterior facet was reached in 13 of 15, 18 of 20, and 11 of 15 with a type II, III, and IV fracture, respectively. The American Orthopaedic Foot and Ankle Society scale mean score was 85 at the final follow-up visit. No significant association was found between the score and the preoperative variables ($p > .09$), although patients with bilateral fractures had a significantly lower score. The MIROS device for early treatment of intra-articular calcaneus fractures resulted in excellent clinic and radiologic results. The standardized technique we have reported, with the elastic wires acting as a girder for the fractured and displace subtalar joint and the collapsed lateral calcaneal wall, has permitted early weightbearing with positive stimuli for the bone healing. The drainage effect of the percutaneous wires likely prevented compartment syndrome when applied within the first hours after the trauma.

The calcaneus is the most commonly fractured tarsal bone, accounting for 75% of displaced intra-articular fractures (1). The treatment of complex intra-articular calcaneal fractures is still controversial (2). Evidence from previous studies has shown that anatomic restoration of the calcaneal shape and joint congruity is associated with higher functional scores (3–6), a lower incidence of post-traumatic subtalar arthritis, and a lower rate of secondary subtalar fusion (7) when treating these fractures. When performing open reduction and internal fixation, a frequent complication has been soft tissue trauma with disturbance of wound healing and necrosis, in particular over the lateral calcaneal wall exposed during surgery (8). The rate of skin necrosis has varied from 2% to 11%, with the soft tissue infection rate ranging from 1.3% to 7% after an extended lateral approach, with reported wound complications in 25% of patients (3,6,8–10).

To overcome the soft tissue problems in the treatment of complex calcaneus fractures, some investigators have proposed minimally invasive reduction and fixation (5,11,12). Compared with open procedures, minimally invasive techniques can guarantee good reduction with fewer complications. The Minimally Invasive Reduction and Osteosynthesis System® (MIROS; Technovare Europa Trading, Anagni, Frosinone, Italy) is a recently introduced angle stable device for the treatment of fractures. It has shown good results in osteosynthesis of complex proximal humerus fractures in the elderly with severe osteoporosis (14). To achieve the best results, timing is an important factor, with surgery ideally performed within 3 to 5 days, especially in percutaneous or minimally invasive procedures (13). It allows for correction of angular displacement and fixation of fracture fragments using elastic Kirschner wires locked in a metallic clip placed externally to the skin.

In our department, in the previous 4 years, we have used the MIROS device to treat displaced intra-articular calcaneus fractures in

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43 consecutive patients, 10 of whom had bilateral fractures, for a total of 53 fractures. The aim of the present prospective cohort study was to evaluate the clinical and radiographic results of early minimally invasive osteosynthesis of the calcaneum using the MIROS device.

Patients and Methods

From January 1, 2008 to December 31, 2011, all patients admitted with a diagnosis of unilateral or bilateral displaced intra-articular fractures of the calcaneus were considered for inclusion in the present study. The included Current Procedural Terminology diagnostic codes were 825.0 and 825.1 (2012 "International Classification of Diseases, 9th Revision, Clinical Modification" diagnosis code). The inclusion criteria were the diagnosis of a closed or open displaced intra-articular fracture of the calcaneus (posterior articular facet step-off of >2 mm, significant shortening, loss of height, and widening of the calcaneus [i.e., decreased Böhler's and Gissane's angles], valgus deviation >10°, varus deviation >5°) of Sanders type II, III, or IV; recovery of the patient within 12 hours from the time of trauma; and patient age 18 years or older.

The exclusion criteria included a history of previous fractures or surgeries in the affected lower limb, a previous diagnosis of neurologic or vascular diseases affecting the lower extremities, and/or local vascular or neural complications associated with the injury.

All patients admitted to the hospital with a diagnosis of a calcaneal fracture were examined by 1 of 2 of us (A.B., S.C.), who first classified the soft tissue damage in accordance with the classification system of Tscherne and Oestern (15). In the emergency department, all patients underwent standard radiographic assessment, including the calcaneus lateral, axial, and Brodén views at 20° and 40°, and bilateral computed tomography for fracture classification and preoperative planning (16). The fractures were classified using the Sanders (4) scale, with the letters A, B, and C denoting the location of the fracture lines within the posterior facet. Type A represents a lateral fracture line, type B a fracture line through the middle of the facet, and type C a medial fracture line adjacent to the sustentaculum tali. The 2 of us (A.B., S.C.) involved in classifying the soft tissue damage and the fracture pattern were trained by repeating the evaluation 3 times per fracture.

After hospitalization, the study participants gave their informed consent for inclusion in the present study and for the operation, which was performed 6 to 12 hours (after the recovery) in 36 patients (83.72%) and in 7 patients within 4 days, always by the same 2 surgeons (A.B., P.C.). The fitness for surgery was assessed using the American Society of Anesthesiologists grade (17). Of the 43 patients, 26 (60.47%) were American Society of Anesthesiologists grade I, 10 (23.25%) grade II, and 4 (9.30%) were grade III. The duration of surgery and the fluoroscopic time were recorded.

The study participants underwent clinical evaluation with standard radiographs at 3, 6, and 12 weeks postoperatively. At 12 and 24 months postoperatively, the patients were assessed by the same 2 examiners (A.B., S.C.), and the American Orthopaedic Foot and Ankle Society (AOFAS) ankle hindfoot scale (18,19) was administered to quantify the functional outcomes. The scale measures the intensity of pain, function (including restraint of activities and the need for support with an orthosis), maximum walking distance, abnormality of gait, sagittal mobility (flexion and extension), hindfoot mobility (inversion and eversion), the anteroposterior and varus–valgus stability of the ankle and hindfoot, and alignment of the foot and ankle. The scores for each item were summed, providing a total from 0 to 100. Total scores of 90 to 100 were classified as excellent, from 80 to 89 as good, and from 70 to 79 as fair; a total score less than 70 was considered a poor result.

At the final follow-up evaluation, a clinical assessment was performed (A.B. or S.C.) and a full radiographic assessment completed, including standard views, hindfoot alignment view (20), lateral and dorsoplantar weightbearing radiographs (21), and a 20° Brodén view (16). The 2 examiners (A.B., S.C.) judged (3 times each for each measurement) the reduction of the calcaneal shape considering the Böhler tuberosity joint angle (in angular degrees), the crucial Gissane angle (in angular degrees), and the height and width of the calcaneus (in millimeters) (20).

Standard Operative Technique

After a carbocaine lower limb block, the patient was placed in a lateral decubitus position. No tourniquet was used. For antibiotic prophylaxis, 2 g of cefazolin was administered intravenously 30 minutes preoperatively and at 3 and 12 hours postoperatively. Before inserting the Kirschner wires, attempts were made to reduce the fracture by manipulation. A lateral incision of 2 cm was made as an access entry point for insertion of a periosteal elevator (Fig. 1). The elevator was moved to the lower posterior articular surface, and the articular fragment was elevated into anatomic configuration. Next, 1 wire was inserted from the same direction of the major axis of the calcaneus, parallel to the reduced posterior facet, and pulled until the cuboid, because the purchase in the calcaneus alone might be not sufficient. The same procedure is used with a second wire, parallel to the first. If necessary, additional elevation of the articular posterior facet can be done using the 2 wires as elevators, with the cuboid as a fulcrum. In this configuration, the 2 wires act as an inferior girder for the depressed articular fragment, and correction of Böhler's angle is obtained (Fig. 2). Reduction of the posterior facet should be checked on the Brodén radiographic views, and reduction of the calcaneus can be verified from the lateral radiographic views. The first 2 wires can then be locked in the pin and clip fixator. Next, the heel was compressed to impact the lateral wall, reduce the calcaneal width, and prevent lateral impingement of the peronei tendons. Acting on the lateral wall, 2 wires were introduced and pulled until reaching the sustentaculum tali, which will usually not have been dislocated in most calcaneal fractures because of its attached ligaments. The other 2 wires will act as 2 lateral girders to sustain the collapsed wall. The second 2 wires can now be locked in the metallic clip (Fig. 3). Additional fragments can be fixed with other wires, which should be positioned conically into the talus and cuboid and bent to lock them in 1 of the 2 metallic clips or in an additional metallic clip. As an alternative, bone fragments that could cause lateral or medial impingement can be percutaneously removed by osteotomy. Finally, 2 or more metallic clips were fastened with connecting wires to improve the stability of the whole system (Fig. 3).

Postoperative Care

Postoperatively, a simple dressing was applied without a cast. Physical therapy with passive and active range of motion at the ankle, subtalar, and midtarsal joints was initiated the day after surgery under the supervision of a physiotherapist. The patients were encouraged to perform their exercises at least 30 minutes twice a day, in addition to isotonic and isometric exercises of the leg. The patients were allowed to walk with 2 crutches 2 days after surgery but were instructed to remain non-weightbearing. Partial weightbearing was begun in the fourth postoperative week and increased to full weightbearing at the eighth postoperative week. The pins were removed once the fracture was considered healed, usually 70 days after surgery, without any anesthesia in an outpatient procedure. The fracture was considered healed when the lines of the fracture were not visible on standard radiographs. In addition, fracture stability and healing were consistently evaluated by testing the inversion, eversion, flexion, and extension of the ankle under fluoroscopy. This was performed by the 2 surgeons involved in evaluating the clinical and radiologic assessments.

Statistical Analysis

The statistical analysis was performed using Statistical Package for Social Sciences software, version 16.0 (SPSS, Chicago, IL). The intra- and interobserver agreement was determined using the κ statistic, with the level of significance set a priori at $p < .01$. Interpretation of the κ statistic was performed as described by Landis and Koch (22). Agreement was considered excellent if the κ statistic was from 0.81 to 1.0, high if it was 0.61 to 0.80, moderate if 0.41 to 0.60, fair if 0.21 to 0.40, and poor if 0.20 or less (22). Fisher's exact test was used to compare the proportions and Student's t test for average values. Student's t test, paired, was used for average values.

We defined statistical significance at the 5% ($p \leq .05$) level. Multiple regression analysis was performed to identify potential associations between dependent variables

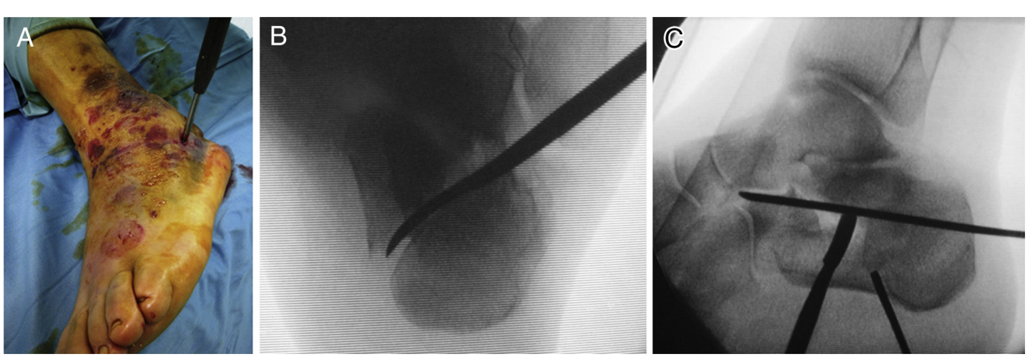

Fig. 1. (*A* and *B*) The periosteal elevator was inserted through a 2-cm incision in the lateral aspect of the calcaneus to reduce the posterior facet. (*C*) The first elastic wire was inserted to stabilize the articular fragment.

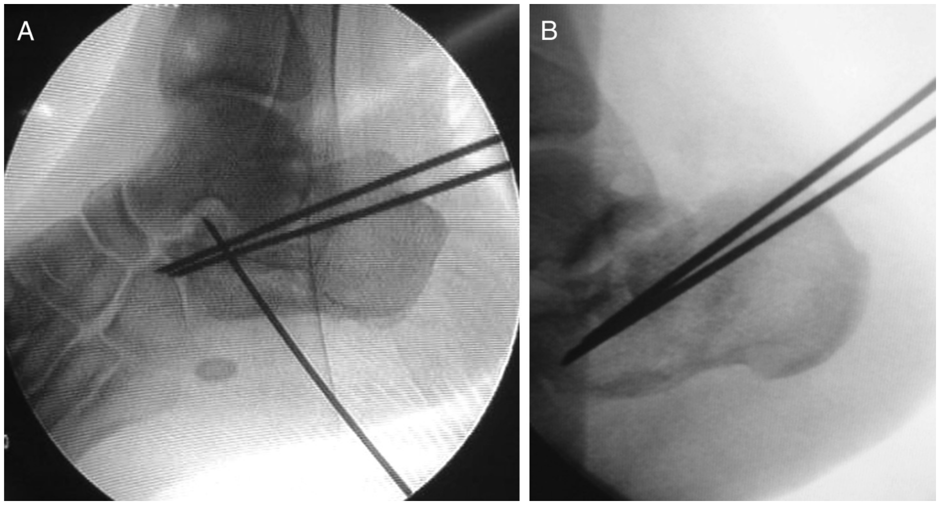

Fig. 2. (*A* and *B*) Additional elevation of the articular posterior facet can be accomplished using the 2 wires as elevators, with the cuboid as a fulcrum. The 2 wires act as an inferior girder for the depressed articular fragment.

(AOFAS score, Böhler's angle, Gissane's angle, calcaneal height, and calcaneal width) and independent variables (classification of soft tissue injury, type of fracture).

Results

A total of 43 consecutive patients met the inclusion criteria and agreed to participate in the study. Of the 43 patients, 3 (6.97%) did not attend the final assessment visit; thus, 40 patients (50 fractures) were included in the analysis. Of the 40 patients, 35 (87.5%) were male and 5 (12.5%) were female; the overall mean age was 46 ± 17 (range 28 to 70) years. A concomitant fracture or additional fracture was present in 16 patients (40%). The cause of the fracture was a fall from varying heights in 35 patients (87.5%) and a motor vehicle accident in 5 patients (12.5%). These and other demographic data are listed in Table 1.

In 42 fractures (84%), the soft tissue lesion was classified as 1° or 2°; in 8 fractures (16%), it was classified as 3° (Fig. 4*A*). No significant association was found between the AOFAS score and the type of soft tissue lesion at both 12 ($p = .72$) and 24 ($p = .79$) months.

No delay occurred in surgical treatment for patients with severe soft tissue lesions. The mean operative time was 47.3 ± 20 (range 35 to 100) minutes. The mean fluoroscopy time was 96 ± 53 (range 32 to 225) seconds. To achieve satisfactory fixation of the fragments, 4 to 6 wires were used with 2 or 3 external metallic clips.

Sanders type II fractures were diagnosed in 15 cases (40.0%), type III fractures in 20 (30.0%), and type IV fractures in 15 (30.0%; Table 2). Postoperatively, restoration of the posterior facet was reached in 13 type II fractures (86.6%), 18 type III fractures (90%), and 11 type IV fractures (73.3%). The radiographic parameters (Böhler's tuberosity joint angle, crucial Gissane's angle, height and width of the calcaneus) were comparable to the contralateral side on the weightbearing radiographs in all but 1 case. In patients with bilateral fractures, the calcaneus with the better postoperative radiographic result was considered as the basis for comparison. These and other data are listed in Table 3. The patient with an unsatisfactory radiographic outcome underwent subtalar fusion.

Böhler's angle showed a mean improvement of 17° ± 6° (range 5° to 22°; $p = .017$). At the final follow-up visit, the mean improvement was 24° ± 14° (range 10° to 38°), with respect to the mean of 26° on the contralateral side ($p = .72$).

No complications related to surgery were observed.

In the evaluation of the soft tissue lesions, the interobserver κ value ranged from 0.85 to 0.89. The intraobserver κ value ranged from 0.85 to 0.9 (excellent intra- and interobserver value). In the evaluation of the fracture pattern, the interobserver κ value ranged from 0.78 to 0.84. The intraobserver κ value ranged from 0.8 to 0.87 (excellent intra- and interobserver value). The patients were discharged after a mean of 3 ± 3 (range 1 to 10) days after surgery.

At 1 year of follow-up, the AOFAS mean scale was 88 ± 9 (range 72 to 100). At the final follow-up visit, the AOFAS mean scale was 85 ± 11 (range 70 to 100; $p = .33$; Table 4). No significant association was found between the AOFAS score, Böhler's angle, Gissane's angle, calcaneal height, and calcaneal width with the preoperative variables ($p \geq .09$ to $\leq .059$). Patients with bilateral fractures had a significantly lower AOFAS score at 12 months postoperatively (mean 78 ± 4, range 72 to 80, $p = .036$) and 24 months postoperatively (mean 73 ± 5, range 68 to 80, $p = .032$). All but 1 patient had a stable plantigrade foot,

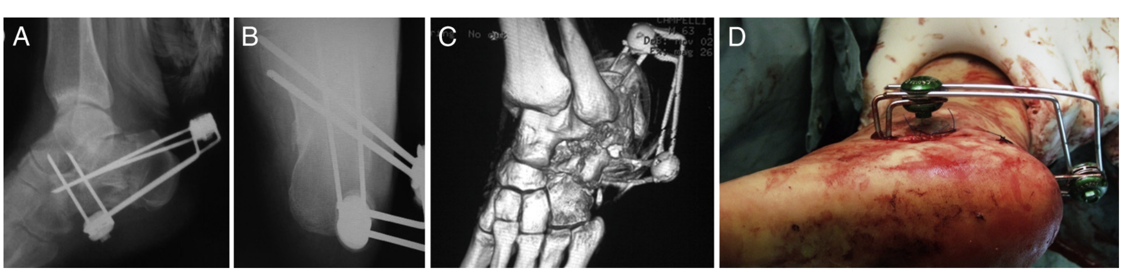

Fig. 3. (*A* to *C*) Two elastic wires were introduced and pulled to the sustentaculum tali through the lateral wall. These other 2 wires acted as 2 lateral girders to sustain the collapsed wall. The final construct of the Minimally Invasive Reduction and Osteosynthesis System® (MIROS) was then obtained, with 4 wires and 2 metallic clips. (*D*) Photograph taken after implantation of the MIROS, showing the external part of the system.

Table 1
Demographic profile of study group (N = 40)

Characteristic	Frequency Count (%) or Mean ± SD
Sex	
Male	35 (87.5)
Female	5 (12.5)
Side	
Right	24 (60)
Left	16 (40)
Mean age (y)	46 (2.5)
Body mass index (kg/m^2)	
<20	28 to 70, SD = 19
20 to 25	15 (37.5)
25 to 30	17 (42.5)
>30	7 (17.5)

Abbreviation: SD, standard deviation.

without chronic swelling. One patient developed very restricted motion in the subtalar joint with chronic pain. The eversion and inversion of the foot was a mean of 39° ± 15° (range 15° to 60°), with ankle motion comparable to the contralateral side.

Independently of the preoperative variables, 18 of the 50 ankles (36%) developed arthritic changes in the lower ankle, with 3 with sinus tarsi syndrome, which were treated with steroid injections. The patients returned to work activities within 10 weeks after surgery in all cases, except for the patient who underwent subtalar fusion, who received Worker's Compensation and did not return to work.

The power calculation detected a significant difference in the total AOFAS scale score of 76 ± 8.3 at the first evaluation and 86.8 ± 8 at the final follow-up visit. From these differences, and assuming a 2-tailed α value of 0.05 (sensitivity 95%) and β value of 0.95 (study power 95%), we determined that at least 35 patients would be required at the follow-up evaluation (G3 power analysis program; Softpedia, Bucharest, Romania).

Discussion

In the present case series, joint depression and tongue-type fractures of all grades of severity (Sanders type II, III and IV fracture found in 15, 20, and 15 of 50 fractures) were treated using the same protocol and the MIROS device. Both extra- and intra-articular anatomy were restored in most cases, with an excellent AOFAS mean score and satisfactory radiologic evaluations at 1 and 2 years of follow-up. The protocol we have adopted uses the principles of minimally invasive reduction and percutaneous fixation that have emerged in published studies (11–13,23), with carefully performed semiopen reduction and percutaneous fixation as an effective method for complex displaced intra-articular fractures of the calcaneus, and we have used a new fixation device of percutaneous wires with particular elasticity that permits a modular construct locked in a metallic clip. Previously, this method has shown clear advantages with respect to classic percutaneous pinning in the upper limb (14). In complex fractures of the calcaneus, this system has been able to ensure a stable intracalcaneal girder in the major axis of the calcaneus to support the achieved reduction of the posterior facet, with precocious weightbearing owing to the elasticity and the angular stability of the wires. This concept of an intrafracture girder is totally different from that of plates, in which the stability of the fragments is achieved laterally owing to compression of the plate in the lateral wall of the calcaneus and to the support of the lateral to medial screws.

An important characteristic of the study design was the precocious treatment, performed within 6 to 12 hours in 36 of the 40 patients (90%) and in the remaining 4 patients within 4 days. It is well known that percutaneous techniques should be used as soon as possible after injury. In contrast, for open reduction and, in particular, using the lateral extensile approach, an interval of 5 to 9 days between the trauma and surgery has been advised to prevent complications with wound healing (4,24,25). In our series, even those cases with a grade 3 soft tissue lesion according to the Tscherne and Oestern (15) classification were treated as an emergency, with no related complications. The lateral extensile approach, which has been the most widely used (4,24), has also been associated with serious complications, with the most common being wound dehiscence. Abidi and Gruen (24) reported a 32% rate of wound healing problems. Sanders (4) reported 5 free flaps and 3 amputations in 120 patients. Schuler et al (25) noted that the better the radiological result after surgery, the greater the soft tissue tension, with a greater risk of wound dehiscence. We believe that a clear advantage of percutaneous pinning is that it works as a drainage point for the fracture site (Fig. 4), resulting in a lower local compartmental pressure, with approximately 10% of patients with calcaneal fractures developing compartment syndromes of the foot (26,27).

Several studies have shown that early postoperative weightbearing can result in better outcomes (28–30). Prolonged nonweightbearing can cause osteoporosis and joint stiffness (28), and it can shorten the time to the occurrence of subtalar arthritis (30). The subtalar joint has a key role in inversion and eversion of the hindfoot. The range of motion of this joint has been well established (31), and most of the patients with calcaneal fractures are young or middle-age males. The early weightbearing leads to early molding on the subtalar surface, which helps the congruity of the subtalar joint, with the probable outcome of less development of post-traumatic subtalar arthritis (32). The standard amount of non-weightbearing after open reduction and internal fixation with locking plates is 9 weeks (30), and for closed reduction and percutaneous pinning, the period increases to 11 weeks (23). With the MIROS device, partial weightbearing began at the fourth postoperative weeks and was increased to full weightbearing at the eighth postoperative week. This system allows precocious weightbearing owing to the stable configuration of the assembly, with up to four 2.5-mm elastic wires locked together in 2 metallic stainless steel clips. In addition, the wires provide a stable

Fig. 4. A case with severe soft tissue damage (Tscherne and Oestern grade 3). Photographs showing (*A*) the preoperative aspect, (*B*) the view 3 days after surgery, and (*C*) the view 12 days after surgery.

Table 2
Fracture distribution using the Sanders classification system (N = 50 fractures in 40 patients)

Sanders Classification	No. of Fractures (%)
Type IIA	5 (10)
Type IIB	8 (16)
Type IIC	2 (4)
Type IIIAC	3 (6)
Type IIIAB	15 (30)
Type IIIBC	2 (4)
Type IV	15 (30)

fulcrum in the uninjured cuboid bone, permitting a much faster recovery with respect to what has been reported in published studies. The assessment of functional outcome in our study showed good to excellent AOFAS scores, comparable to those obtained with open reduction and internal fixation (21,24,29,30). We believe that this excellent functional result, despite an articular reconstruction that cannot be as anatomical compared with that achieved with open reduction, is the consequence of less postoperative swelling, less periarticular scarring, and an improved range of motion.

The present study had several limitations that need to be assessed. First, the study cohort was relatively small, but a power calculation analysis was performed with a minimum of 35 patients. In addition, we lacked a comparison group, although in the discussion section, our results were compared with those of other studies. A related limitation was that the radiographic parameters were compared with the contralateral side, which was also injured in 10 patients. In those cases, the calcaneus with the better postoperative radiographic result was considered as the basis for comparison. Second, we adopted this treatment method from 2008, and we only had a mean follow-up of 2 years. Regardless, from a recent systematic review of the published data (33), a minimum of 2 years follow-up is required to assess the outcome of calcaneal fractures. However, a longer follow-up period is needed, especially to assess arthritic changes in the subtalar joint, which is one of the most common complications, with subtalar fusion often needed independently of the operative treatment (34). Third, the clinical and radiographic evaluations were performed by the authors involved in the study, with the surgeons measuring their own results, and thus a related potential bias. Finally, the identification of cases using the "International Classification of Diseases," 9th or 10th revision, or Current Procedural Terminology codes relies on the accuracy of the input data, which varies from surgeon to surgeon and could have been miscoded. Nonetheless, our entire reimbursement process, insurance company, and government identification of the disease burden hinges on these codes. We realize some bias could be inherent in using such codes.

Table 3
Preoperative and postoperative radiologic assessment of study group and comparison with contralateral side at the final follow-up visit

Parameter	Study Group (N = 50 fractures in 40 consecutive patients)			
	Anderson Fracture Type II	Anderson Fracture Type III	Anderson Fracture Type IV	Contralateral (*p* value)
Böhler's angle (°)				
Postoperative	29 ± 5.4	26 ± 5.1	25 ± 3.2	
2-y Follow-up visit	28 ± 4.8	24.9 ± 2.7	24.5 ± 3.6	29.1 ± 9 (.06)
Gissane's angle (°)				
Postoperative	125.7 ± 8	124.6 ± 5.2	126 ± 9	
2-y Follow-up visit	117.5 ± 3.4	119.6 ± 7.5	124 ± 8.1	122 ± 9 (.18)
Calcaneal height				
Postoperative	44.1 ± 5.1	43.8 ± 3.2	43.3 ± 6.2	
2-y Follow-up visit	43.6 ± 4.3	43 ± 4.5	42.9 ± 5.7	44 ± 7 (.059)
Calcaneal width				
Postoperative	48.1 ± 7.6	48.9 ± 8.3	49.1 ± 7.4	
2-y Follow-up visit	47.9 ± 7.4	48.5 ± 5.2	48.9 ± 9.3	46.8 ± 6 (.66)

Data presented as mean ± standard deviation.

Table 4
AOFAS clinical assessment of the study group at 12 and 24 months of follow-up (N = ??)

Follow-up Duration (mo)	AOFAS Scale Score for Study Group (N = 50 fractures in 40 consecutive patients)		
	Anderson Fracture Type II	Anderson Fracture Type III	Anderson Fracture Type IV
12	85 ± 9	90 ± 8	87 ± 9
24	82 ± 7	86 ± 10	85 ± 10

Abbreviation: AOFAS, American Orthopaedic Foot and Ankle Society.
Data presented as mean ± standard deviation.

In conclusion, the MIROS device for the early treatment of intra-articular calcaneus fractures has been shown to give excellent clinic and radiologic results in a cohort of 40 patients, 10 of whom had bilateral fractures. The standardized technique we have reported, with the elastic wires acting as a girder for the fractured and displace subtalar joint and the collapsed lateral calcaneal wall, permitted early weightbearing with positive stimuli for the bone healing. The drainage effect of the percutaneous wires likely prevented compartmental syndrome when applied in the first hours after the trauma.

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