OTA HIGHLIGHT PAPER

# Open Reduction and Internal Fixation Compared With ORIF and Primary Subtalar Arthrodesis for Treatment of Sanders Type IV Calcaneal Fractures: A Randomized Multicenter Trial

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**Objectives:** To compare long-term health outcome of Sanders type IV calcaneal fractures treated with open reduction and internal fixation (ORIF) versus ORIF plus primary subtalar arthrodesis (PSTA).

**Design:** Randomized prospective multicenter trial.

**Setting:** Four Level 1 trauma hospitals in Canada.

**Patients:** Thirty-one patients with 31 Sanders IV displaced intra-articular calcaneal fractures.

**Intervention:** Seventeen patients were treated with a standard protocol involving a lateral approach for ORIF. Fourteen patients were treated with a standard protocol involving a lateral approach with ORIF + PSTA.

**Main Outcome Measurements:** Health outcomes were assessed with 4 validated instruments: (1) the Short Form 36 version 2 (SF-36), (2) the Musculoskeletal Functional Assessment Survey, (3) the American Orthopaedic Foot and Ankle Society's Ankle-Hindfoot Scale, and (4) the Visual Analogue Scale.

**Results:** From 2004 to 2011, 26 patients (26 displaced intraarticular calcaneal fractures) were followed for a minimum of 2 years (81% follow-up). No statistical difference was found between the results for ORIF compared with ORIF + PSTA: the mean SF-36 physical component scores were, respectively, 30.2 (SD = 11.4) and 37.8 (SD = 10.4) ($P = 0.10$); the mean Musculoskeletal Functional Assessment Survey scores were 44.2 (SD = 25.6) and 37.9 (SD = 21.5) ($P = 0.50$); the mean Ankle-Hindfoot Scale scores were 62.5 (SD = 19.6) and 65.8 (SD = 19.2), ($P = 0.68$); and the mean Visual Analogue Scale scores were 36.8 (SD = 34.7) and 36.0 (SD = 30.7) ($P = 0.82$).

**Conclusions:** We were unable to demonstrate a significant difference between treating Sanders type IV fractures with either ORIF or ORIF + PSTA. It remains the choice of the surgeon and patient to take into account patient specific factors to determine treatment. However, ORIF + PSTA may be advantageous for both patients with Sanders type IV fractures and the health care system as patients heal quickly. Furthermore, ORIF + PSTA may prevent the need for late secondary subtalar fusion adding to increased costs and lost time from work.

**Key Words:** ORIF, fusion, Sanders IV calcaneal fractures, multicenter trial

**Level of Evidence:** Therapeutic Level II. See Instructions for Authors for a complete description of levels of evidence.

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## INTRODUCTION

The calcaneus is the most commonly fractured tarsal bone and accounts for approximately 2% of all fractures.[1] The mechanism of injury and pathoanatomy has been studied in great detail.[2,3] Most fractures of the calcaneus are intraarticular with involvement of the subtalar joint (and calcaneocuboid joint) in up to 75% of cases.[4] Change in life style because of residual pain and stiffness can cause significant socioeconomic hardship for these otherwise fit individuals and may have associated public cost.[1,5,6]

The literature on management of displaced intraarticular calcaneal fractures (DIACF) is confusing.[7–11] The pendulum has swung from nonoperative treatment[12–14] to open reduction internal fixation (ORIF).[15–17] Older literature[18,19] suggested that delayed primary fusion was satisfactory for severe DIACFs. The early pessimism about operative reduction of these intraarticular fractures began with the inability to predictably produce good results and the high rate of complications associated with surgery.[13,14,18] Also, retrospective cohort studies and randomized controlled trials have failed to show a significant difference between operative and nonoperative treatment.[20–25] A large prospective randomized multicenter trial conducted by the Canadian Orthopaedic Trauma Society with 559 enrolled patients has shown better functional outcome and patient

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satisfaction in an operatively treated group after excluding Workers Compensation Board patients.[9]

Despite carefully planned open reduction and near anatomic reconstruction, there is a group of patients who may proceed to painful subtalar arthritis and need delayed subtalar fusion.[12,17,26] It has been shown by various investigators[1,12,15,27] that the prevalence of poor results after ORIF increases with the severity of comminution.[9] Displaced, Sanders type IV fractures with at least 3 fracture lines across the posterior subtalar facet usually result from high energy injury and have done poorly with both nonoperative and operative management.[7,9] In the large Canadian prospective study,[27] it was shown that 47% of the late fusion group had Sanders type IV fractures and 20 of the available 81 patients with Sanders type IV injury required fusion within 2 years of presentation. They also found that patients with Sanders type IV fractures were 5.5 times more likely to go on to a subtalar fusion when compared with fractures of lesser complexity (Sanders type II). Results with delayed subtalar fusion were good and patient satisfaction was high regardless of initial nonoperative or operative treatment for the fracture.

As a high percentage of patients with Sanders type IV comminuted fractures do poorly with operative reduction,[7,9,27] there is some justification in considering a primary fusion in these patients. In 1991, Sanders suggested that primary subtalar arthrodesis (PSTA) has the advantage of decreasing the overall disability time in patients with type IV DIACFs.[15] With a level I study, we sought to answer the question: does treating Sanders type IV calcaneal fractures with an open reduction and internal fixation result in better long-term outcomes as compared with treating with ORIF + PSTA?

## PATIENTS AND METHODS

This randomized multicenter trial was conducted at 4 level 1 trauma centers with 5 surgeons participating. All surgeons who participated were experienced calcaneal fracture surgeons and were involved in previous large randomized trials.[9,27] Each participating center obtained ethical and research approval independently to be eligible to participate.

### Power and Sample Size Calculation

Using the results of a large Canadian multicenter trial,[9] an a priori power calculation was performed to determine the sample size that would be needed to demonstrate a mean difference of 15 points ± 20 in the primary outcome [Short Form 36 (SF-36)] score between the ORIF and ORIF + PSTA groups. With the use of a 2-tailed hypothesis and taking into account type I and type II errors of 5% ($\alpha$) and 20% ($\beta$), respectively, the required sample size was 29 patients per group and 58 patients total. To account for a 15% anticipated dropout (ie, loss to follow-up, death, voluntary withdrawal) rate, we aimed for an enrollment of 66 patients; 33 in each group. All participant data were analyzed according to the intention-to-treat principle.

### Protocol and Randomization

All patients had isolated Sanders IV DIACFs. Sanders IV calcaneal fractures were defined as highly comminuted fractures with 4 or more articular fragments.[10] All fractures in this study were severe and classified as Sanders type IV (AO/OTA 82-C2); none of the fractures were marginally close to a Sanders type III classification because of the severity of comminution.

All patients who presented with a DIACF to any of the participating institutions were splinted and treated with rest, ice, elevation, and analgesia. A computed tomography (CT) scan of both heels splinted in neutral position was performed on all patients. Any patient demonstrating a Sanders type IV DIACF was considered for inclusion in the study. After obtaining informed consent, eligible patients (Table 1) with Sanders type IV calcaneal fractures were randomized either to undergo ORIF or ORIF + PSTA. Patients and health care providers involved with subsequent patient care were not blinded to the treatment.

A computer-generated random allocation sequence at the central administration site was used to assign patients to the 2 parallel operative treatment groups (ORIF or ORIF + PSTA) at a 1:1 ratio. Bilateral calcaneal fractures were randomized by the patient and not by fracture. Randomization was carried out with the use of sequentially numbered, opaque, sealed envelopes. After 15 patients, a safety analysis was

**TABLE 1.** Inclusion and Exclusion Criteria

| Inclusion Criteria | Exclusion Criteria |
|---|---|
| Patients presenting or referred to the contributing institutions with a Sanders IV DIACF | Medical contraindications to surgery |
| Age 16–59 inclusive | Previous calcaneal pathology (infection, tumor etc) |
| Clear demonstration of at least 3 fracture lines across the posterior subtalar facet, dividing it into at least 4 fragments and the fragments being displaced by at least 2 mm, as seen on the coronal and axial CT scans (classified as Sanders IV) | Previous calcaneal surgery |
| Ability to provide informed consent | Co-existent foot or ipsilateral lower limb injury |
| Available for follow-up for at least 2 years after injury | Open calcaneal fractures |
| | Injury more than 3 weeks old |
| | Head injured patients |
| | Inability to obtain preoperative CT scans or accurately classify the fractures as per Sanders classification system |
| | Inability to comply with advice to diminish smoking after the injury |
| | Patients with metal allergy |
| | Extremely comminuted intraarticular fractures of calcaneus, deemed impossible to reconstruct by the treating surgeon. (nonoperable or mangled foot) |
| | Any concerns either on the part of the treating surgeon or the patient about harvesting autograft needed for fusion |

performed to ensure that patient wellness was not compromised by this study.[28,29]

Demographic data were collected and the patient was enrolled. All patients received the same initial care and the exact timing of intervention was decided by the treating surgeon. Surgery was considered after a minimum period of 6 days and maximum of 3 weeks from injury. Before surgery, patients needed to show minimal swelling, positive "wrinkle sign," and absence of hemorrhagic blisters.[7]

Once these parameters were met and no other contraindications to surgery were present, surgical intervention occurred.

## OPERATIVE TREATMENTS

### Open Reduction and Internal Fixation Group

The patient was anesthetized and positioned laterally on the operating room table and a thigh tourniquet was applied. An extended "L"-shaped lateral approach was used to expose the calcaneus and subtalar joint. A full-thickness soft tissue flap was developed in a subperiosteal fashion, protecting the tendons, nerves, and vessels. The soft tissue flap was retracted out of the field with the help of temporary K-wires placed into the fibula and talus. The fracture was opened laterally and the medial wall of the calcaneus was reduced first and then the surgeon worked laterally. The height and length of the tuberosity was established with manual traction, periosteal elevators, indirect reduction means (mini-distractor), longitudinal Schantz pins, or traction Schantz pins. The tuberosity was pulled out to length, reestablishing medial wall continuity, and the subchondral surface was elevated. Fixation of the posterior facet was achieved by use of lag screws, threaded K-wires (for small osteochondral pieces), and nonlocking plate fixation on the lateral wall of the calcaneus. The reduction was assessed intraoperatively by fluoroscopy. Both intraarticular and extraarticular reconstruction of the calcaneus was ensured clinically and radiologically before closure. Two-layer closure over a surgical drain completed the procedure and the foot was placed in a well-padded splint for comfort. Postoperatively, plain film x-rays (lateral and axial views) and CT scan were performed to confirm reduction of the articular surface.

The splint was left for 48 hours after which the surgical drain was removed and early active and passive motion of the foot and ankle commenced when the wound had sealed. The patients were non-weightbearing for a minimum of 10 weeks.

### Open Reduction and Primary Subtalar Fusion Group

The patient was positioned laterally on the operating room table and a thigh tourniquet was applied.[30] The extended lateral approach was again used in this group to expose the fracture site. Reconstruction of the extraarticular pathoanatomy was undertaken, including restoration of the height of the tuberosity. An attempt at reconstruction of the subtalar articular surface was made and internal fixation was used to maintain this reduction. Then, the subtalar joint was distracted by use of a laminar spreader and the entire subtalar articular cartilage was denuded from both talus and calcaneus. If required, a burr was used. Hindfoot varus was manually corrected, and if necessary (because of severe bone loss in a comminuted Sanders IV fracture), a block bone autograft from the ipsilateral iliac crest or large allograft was placed in the subtalar gap. The fusion was held with partially and fully threaded cannulated 7.3-mm cancellous screws, inserted from the calcaneal tuberosity into the talus. Compression with cancellous screws was used where there was no bone loss but fully threaded screws were used if there was bone loss in these severe Sanders IV fractures. Anatomic position was confirmed clinically and fluoroscopically before closure. A 2-layer closure was used over a surgical drain to complete the procedure and the foot was placed in a well-padded splint for comfort. Postoperatively, plain film x-rays (lateral and axial views) and a CT scan was performed to evaluate the surgical procedure. At 48-hour postoperatively, the drain was removed and the limb was placed in a below knee cast with the ankle in neutral position. The patients were kept non-weightbearing for 6 weeks.

### Outcome Measures

Four validated instruments were used to assess health outcome: (1) the General Health Survey—SF-36 version 2,[31–33] (2) the Musculoskeletal Functional Assessment (MFA),[34] (3) the American Orthopaedic Foot and Ankle Society's Ankle-Hindfoot Scale (AHS),[33] and (4) the Visual Analogue Scale (VAS).[4]

## POSTOPERATIVE REHABILITATION PROTOCOL AND ASSESSMENT

All study patients were followed for a minimum of 2 years with assessments performed at 5 time points: 6 weeks, and 3, 6, 12, and 24 months or longer from the time of surgery. During each follow-up appointment, the patient was evaluated clinically and radiographically. An axial and lateral radiograph was taken at each follow-up visit. The SF-36, VAS, and MFA was used to assess the general health/functional status at 6-, 12-, and 24-month follow-up. As well, the AHS was used at 12- and 24-month follow-up.

### Data Management and Analysis

Questionnaires were reviewed manually for any obvious miscoding before data entry. In addition, any "reverse coding" that needed to be done with selected health outcome questions (eg, the MFA) was implemented before data entry. IBM SPSS Statistics 19.0 for Windows (SPSS, Chicago, IL) was used for data management and statistical analysis. Categorical variables are summarized as frequencies and percentages, and the $\chi^2$ test of association or Fisher exact test were used to compare groups. Normally distributed data are presented as the mean and SD, and differences between groups on continuous variables were computed using an independent measures $t$ test. All statistical tests were 2-sided with a 0.05 significance level.

## RESULTS

From 2004 to 2011, 31 patients with 31 fractures were included in the study. We did not meet our target for patient numbers (66 patients) because of difficulty in recruiting

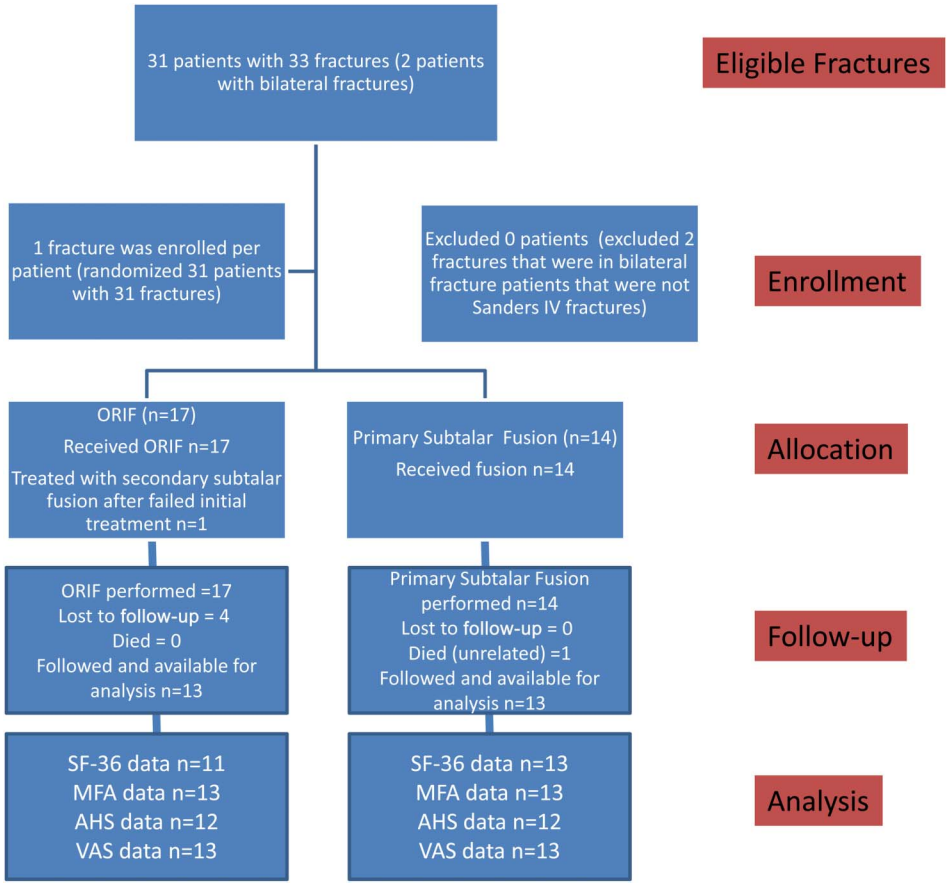


**FIGURE 1.** Patients enrolled in this study (consort diagram). **Editor's note:** A color image accompanies the online version of this article.

patients with this rare fracture. As stated in the Patients and Methods section, we accepted into the study only severe Sanders IV fractures. After 7 years of recruiting from all 4 trauma centers, with roughly half of the target number achieved (31 patients), the study was closed for reasons of practicality.

Seventeen patients received ORIF; 14 received ORIF + PSTA. Twenty-six patients were followed and assessed (81% follow-up) for a minimum of 2 years and a maximum of 7 years. Five patients were lost to follow-up (Fig. 1, Table 2). The comparability of the 2 treatment groups was assessed on the baseline demographic variables of severity of fracture, age, gender, Worker's Compensation Board status, and smoking status (Table 3). The mean postoperative Bohler angle for ORIF was 32.8 degrees (SD = 7.5).

## Outcomes Analysis

Independent samples *t* tests were computed to determine if there was a statistically significant difference between the 2 surgical treatment groups on mean SF-36 physical component scores, mean MFA scores, mean AHS scores, and mean VAS scores at the ≥24-month follow-up period. For each outcome and at each time interval, 95% confidence intervals were also determined.

For each health outcome, we report the mean score with SD for both surgical treatments and the *P* value. No statistical difference was found between the results for ORIF versus ORIF + PSTA: the mean SF-36 physical component scores were 30.2 (SD = 11.4) and 37.8 (SD = 10.4), respectively ($P = 0.10$); the mean MFA scores were 44.2 (SD = 25.6) and 37.9 (SD = 21.5), respectively ($P = 0.50$); the mean AHS scores were 62.5

**TABLE 2.** Analysis of the Patients Enrolled in this Study

| | Randomized (Received Standard Intervention as Allocated) | Did not Receive Standard Intervention as Allocated | Completed Trial, Followed up ≥24 mo | Lost to Follow-up | Patients Died (Unrelated Causes) | ORIF Treated With Secondary Fusion (Analyzed on Intention-to-Treat Basis) |
|---|---|---|---|---|---|---|
| ORIF | 17 | 0 | 13 | 4 | 0 | 1 |
| Primary fusion | 14 | 0 | 13 | 0 | 1 | – |
| Total | 31 | 0 | 26 | 4 | 1 | 1 |

**TABLE 3.** Baseline Characteristics of Included Patients (Complete Study Group)

| Group | No. Patients | Gender | Age, Mean (SD) | Bohler Angle Preoperatively, Mean (SD) | Worker's Compensation Board Patient | Smoker Preoperatively |
|---|---|---|---|---|---|---|
| Open reduction and internal fixation | 17 | 1 female, 16 males | 36 (12.1) | −1.5 (18.4) | 7 | 5 |
| Primary Subtalar Fusion | 14 | 1 female, 13 males | 44 (12.4) | −13.3 (20.4) | 4 | 1 |
| *P* | | – | 0.12 | 0.2 | – | – |

(SD = 19.6) and 65.8 (SD = 19.2), respectively ($P = 0.68$); and the mean VAS scores were 36.8 (SD = 34.7) and 33.9 (SD = 30.7), respectively ($P = 0.82$) (Table 4, Fig. 2).

## DISCUSSION

In our small underpowered randomized trial, we found that there was no statistical difference in general health outcome surveys when treating Sanders type IV calcaneal fractures with ORIF compared with ORIF + PSTA. This trial is the first randomized clinical trial comparing 2 standard surgical treatment options for the Sanders IV calcaneal fracture.

Orthopaedic trauma dogma has always stated that joint reconstruction is crucial for good long-term outcome. However, in this scenario, where the articular cartilage is so badly injured, and there is a high rate of delayed subtalar fusions in comminuted subtypes, primary subtalar fusion seems logical. Although we did not find a statistical significant difference between the 2 treatment modalities, we are cautious to accept our findings because of the possibility of type II error—there may be a difference between the 2 treatment modalities that we were unable to show.

**TABLE 4.** Mean (SD) Outcome Results of 31 Patients With Sanders Type IV Calcaneal Fractures Who Were Randomly Assigned to ORIF or PSF: Complete Study Group

| Assessment (100 = Best Score) | Group (ORIF, n = 17; PSF, n = 14) | 6 mo | 12 mo | ≥24 mo |
|---|---|---|---|---|
| SF-36 physical component | ORIF | 33.1 (7.8) | 30.9 (11.6) | 30.2 (11.4) |
| | PSF | 35.0 (9.1) | 26.3 (8.0) | 37.8 (10.4) |
| | | | | $P = 0.10$ |
| MFA | ORIF | 42.0 (11.2) | 39.7 (28.1) | 44.2 (25.6) |
| | PSF | 41.5 (27.4) | 44.1 (26.0) | 37.9 (21.5) |
| | | | | $P = 0.50$ |
| American Orthopaedic Foot and Ankle Society's AHS | ORIF | – | 64.6 (17.8) | 62.5 (19.6) |
| | PSF | – | 65.7 (12.6) | 65.8 (19.2) |
| | | | | $P = 0.68$ |
| VAS | ORIF | 38.4 (20.2) | 25.3 (20.8) | 36.8 (34.7) |
| | PSF | 38.4 (24.1) | 39.0 (22.8) | 33.9 (30.7) |
| | | | | $P = 0.82$ |

PSF, primary subtalar fusion.

Both treatment groups scored poorly on general health outcome surveys. This reflects the severity of this type of fracture and the detrimental impact it has on a patient's life. This fracture affects all domains of life (physical, emotional, psychologic and financial) and perhaps regardless of which currently available treatment is provided, patients will still be physically challenged. Sanders IV fractures generally produce guarded outcomes. Our previous trial[9] noted that there was only a small difference in results with respect to ORIF compared with nonoperative treatment when looking at the Sanders type IV fractures in particular.

Sanders et al[7,10] discussed treating Sanders IV fractures with ORIF + PSTA but no literature has ever compared ORIF versus ORIF + PSTA. On the SF-36, ORIF + PSTA scored higher than ORIF alone in our study (score of 38 vs. 30; maximum 100) with a *P* value of 0.102, which may suggest a trend if given more power. Our study may be interpreted as a pilot study comparing the 2 treatment modalities and we recommend further investigations of the treatment of Sanders IV type fractures treated with ORIF + PSTA.

Some authors have shown only marginal success with late or secondary subtalar fusions[17,26,37] after nonoperative care of DIACFs. But, secondary subtalar fusions do relatively well[17,26,35,37] after primary operative care of DIACF and can improve a patient's function when it is surgically indicated. In providing a comparable treatment to ORIF for the Sanders IV fracture, PSTA may spare the patient an interim period of pain as a small percentage of ORIF patients (5%–10%) will need a late subtalar fusion.[27] We had 1 patient (of 17 ORIF patients) proceed to a secondary fusion. In offering ORIF + PSTA, we provide a single surgery for definitive treatment. As Potenza et al[36] found in their small series of 6 patients with Sanders type IV fractures treated with PSTA, PSTA would reduce the need for a second surgery and therefore potentially save time and money for both patients and the health care system.

It is interesting to note, our mean SF-36 physical component scores for primary fusion is slightly higher than scores found by Schepers et al[26] for late or secondary fusions (65% initially treated nonoperatively and 35% initially treated operatively). Our ORIF + PSTA SF-36 physical component mean score was 38, whereas Schepers secondary subtalar fusion mean score was 33; maximum score is 100. Although this comparison may not be valid, it suggests patients may function better physically with a primary fusion than a late subtalar fusion. Also, we found that an ORIF + PSTA patient may mobilize more quickly postoperatively (6 weeks non weightbearing) compared to an ORIF patient (minimum of 10 weeks non weightbearing). Certainly, this may be an advantage of PSTA.

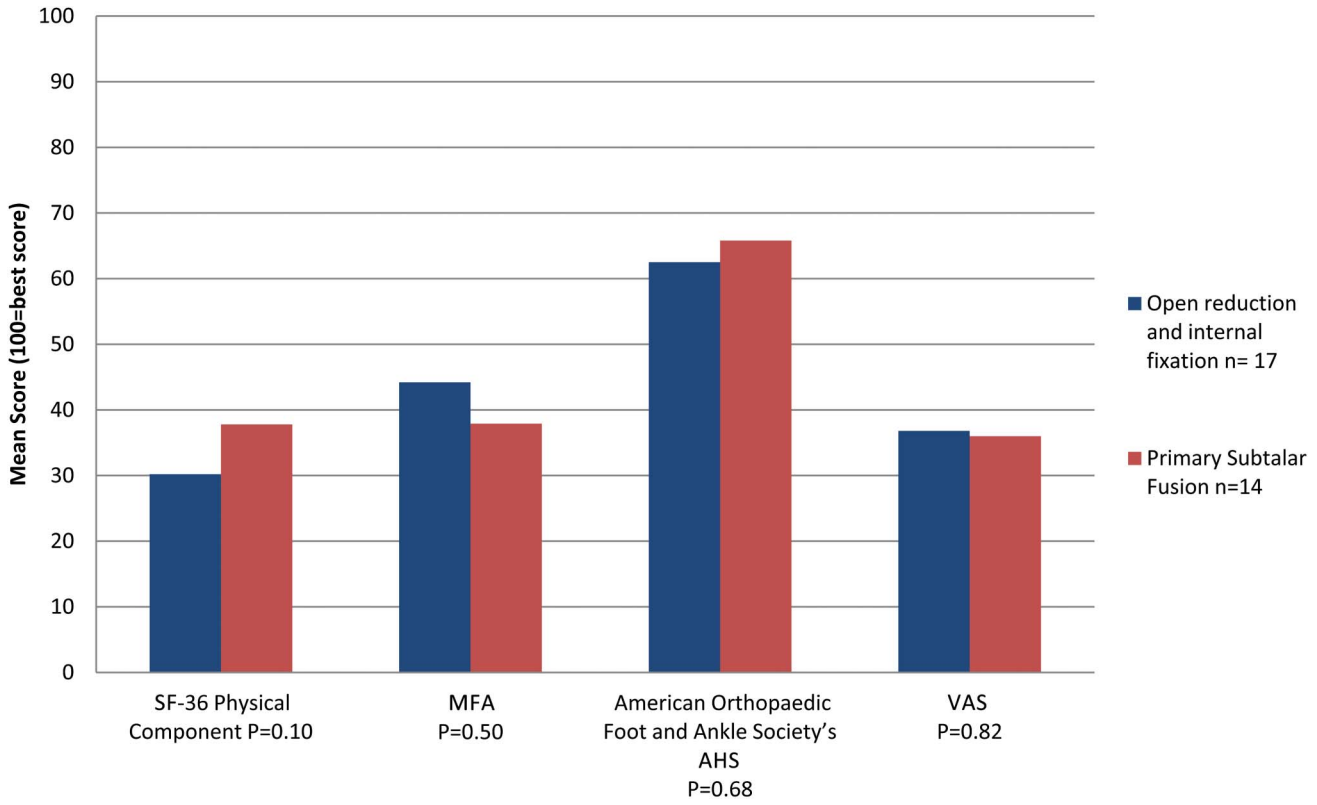


**FIGURE 2.** Outcome results of 31 patients at 24 months or more with Sanders type IV calcaneal fractures who were randomly assigned to open reduction and internal fixation or primary subtalar fusion (complete study group). **Editor's note:** A color image accompanies the online version of this article.

Strengths of our multicenter study include its prospective nature and generalizability. It was also administered by a confident research trial group of experienced surgeons. A review of the literature reveals no randomized trials examining the treatment of Sanders type IV fractures. This study represents a concentrated collection of contemporary data on this unusual and severe Sanders type IV fracture. Furthermore, we achieved a high follow-up rate on our patients, 2 to 7 years postoperatively.

Weaknesses include insufficient number to fulfill recruitment and power justification. This lack of power may not allow us to show a statistical difference between the 2 groups where indeed one may exist. This study also only looked at surgical options as there was no arm of the study to evaluate nonoperative treatment followed by a late subtalar fusion as it became necessary for the patient.

For now, there are many factors that may be weighed into the decision-making process for treatment choice. Until more conclusive results are available, current evidence suggests that it is not so much the best treatment option to fit the fracture, but the best treatment option to fit the patient. When considering surgical options for a severe calcaneal fracture, many patient factors must be taken into account to evaluate a surgical candidate: co morbidities, age, gender, occupation, etc.[9,10,38,39]

In summary, our small, though randomized multicenter trial was unable to demonstrate any significant difference between ORIF compared with ORIF + PSTA for the treatment of isolated Sanders type IV fractures with respect to long-term outcome. ORIF + PSTA however, should be considered for patients with Sanders type IV fractures, and the health care system as they heal at a much more rapid rate, and will not require additional surgery. This must be considered as the choice of treatment may have profound economic effects on the patient. More research is needed to find the best solutions for these difficult fractures.

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