

Operative Versus Nonoperative Treatment of Displaced Intra-Articular Calcaneal Fractures

A Prospective, Randomized, Controlled Multicenter Trial

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Background: We conducted a prospective, randomized, controlled multicenter trial to compare operative with nonoperative treatment of displaced intra-articular calcaneal fractures.

Methods: Eighty-two patients who presented to five trauma centers from 1994 to 1998 with an intra-articular calcaneal fracture with ≥ 2 mm of displacement (as verified by computed tomography) were randomized to operative or nonoperative treatment. Independent observers followed the two groups radiographically and clinically at one year and eight to twelve years. The primary outcome measures were a visual analog scale (VAS) for pain and function and the self-administered Short Form (SF)-36 general health outcome questionnaire. The secondary outcome measures were residual pain evaluated with a VAS, the American Orthopaedic Foot & Ankle Society (AOFAS) scale, and the Olerud-Molander (OM) scale.

Results: Forty-two patients in the operative treatment group and forty in the nonoperative group were included. The two groups were comparable with respect to age, sex, and fracture types. Seventy-six patients were available for follow-up at one year and fifty-eight at eight to twelve years. The primary and secondary outcome measures did not differ significantly between the two treatment groups at one year of follow-up. At eight to twelve years of follow-up, there was a trend toward better scores on the patient-reported primary VAS score for pain and function ($p = 0.07$) and the physical component of the SF-36 ($p = 0.06$) in the operative group. The prevalence of radiographically evident posttraumatic subtalar arthritis was lower in the operative group (risk reduction, 41%).

Conclusions: Operative treatment was not superior in managing displaced intra-articular calcaneal fractures at one year of follow-up but appeared to have some benefits at eight to twelve years. Operative treatment was associated with a higher risk of complications but a reduced prevalence of posttraumatic arthritis evident on follow-up radiographs.

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

Calcaneal fractures are the most common tarsal fractures¹⁻³, and approximately 75% are intra-articular⁴⁻⁶. Comminuted displaced fractures, male sex, and heavy manual labor are associated with poor outcomes⁷⁻⁹. The optimal management of displaced intra-articular calcaneal fractures remains a

matter of debate despite advancements in diagnosis by means of imaging and in surgical techniques. In a systematic review of randomized trials, Gougoulas et al.⁷ emphasized that it is unclear whether general health outcome measures, injury-specific scores, and radiographic parameters are better after operative

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A commentary by Alastair Younger, MB, ChB, MSc, ChM, FRCS, is linked to the online version of this article at jbjs.org.

TABLE I Demographic Data

	Operative Group (N = 42)	Nonoperative Group (N = 40)	P Value
Sex	29 M, 13 F	30 M, 10 F	0.34
Age* (yr)	49 ± 14 (24 to 76)	48 ± 13 (20 to 72)	0.81
Sanders fracture type ⁸ (no.)			0.18
2A	13	11	
2B	4	9	
2C	3	2	
3AB	7	8	
3AC	7	5	
3BC	3	2	
4ABC	5	3	
Preop. Böhler angle* (deg)	11 ± 12 (-20 to 40)	11 ± 10 (-10 to 30)	0.97
Work-related injury compensation (no.)	0	2	

*The values are given as the mean and the standard deviation, with the range in parentheses.

compared with nonoperative treatment and whether the benefits of surgery outweigh the risks. They concluded that further studies in the form of carefully designed large-scale trials comparing operative and nonoperative treatment are needed, similar to the conclusions in other published reviews¹⁰⁻¹³.

The aim of the present prospective, randomized, controlled multicenter trial was to evaluate residual pain, functional outcome, and quality of life after operative compared with nonoperative treatment of displaced intra-articular calcaneal fractures. Our hypothesis was that operative treatment would yield superior improvements in pain, functional outcome, and quality of life.

Material and Methods

The trial was conducted from 1994 to 1998 and was registered at Clinicaltrials.gov (NCT01615744). It was conducted in accordance with the ethical principles of the Declaration of Helsinki and was approved by the local ethical committee at the Karolinska Institute. All patients who participated gave informed consent.

Seven senior trauma orthopaedic surgeons at five emergency hospitals in Stockholm were recruited. The catchment area was approximately 1 million inhabitants. All centers used the same study protocol.

Patients presenting with an intra-articular calcaneal fracture with ≥2 mm of displacement, as verified by axial and coronal computed tomography (CT) scans, were considered for inclusion. Exclusion criteria included peripheral neurovascular disease, an open fracture, uncontrolled diabetes mellitus, and medical contraindications to surgery. Demographic data were obtained from the patients.

Operative and Nonoperative Treatment

Operative treatment was performed by senior trauma surgeons who were experienced in managing displaced intra-articular calcaneal fractures and whose experience and caseloads with respect to these fractures were comparable. Surgery was performed within two weeks after injury, once the local soft-tissue swelling had subsided, and included open reduction with use of the lateral extensile approach as described by Benirschke and Sangeorzan¹⁴ and manipulation of the fragments as described by Soeur and Remy¹⁵ to achieve anatomic reduction. The fracture was then fixed with screws (n = 2), reconstruction plates (n = 29), or calcaneal plates (n = 11). Bone graft was used in four cases (10%). Postoperative radiographs and CT scans were used to evaluate the quality of the fracture reduction. Six weeks of non-weight-bearing was recommended for patients in both treatment arms; ankle range-of-motion exercises were allowed during

this period. Subsequently, the patients were allowed full weight-bearing and participated in a standardized physiotherapy regimen.

Nonoperative treatment included rest, elevation, and non-weight-bearing. Early ankle range-of-motion exercises were encouraged as tolerated. Weight-bearing was allowed after six to eight weeks. No patients were managed with impulse compression therapy.

Sample Size, Randomization, and Blinding

When the study was designed, the operative treatment was considered superior to nonoperative treatment. A power analysis was therefore performed on the basis of a 30% improvement in the primary outcome measures with operative treatment. It was estimated that seventy-nine patients would be required to attain a power of 80% with a p value of <0.05 and a confidence interval (CI) of 95%. During the patient inclusion period and the following year, it became evident that we would need a larger sample size to prove the superiority of the operative treatment. However, the high infection rate following operative treatment limited our enthusiasm for expanding the trial.

Block randomization was utilized. An equal number of operative and nonoperative interventions (fifty each) were assigned prior to the recruitment of patients, and sealed opaque envelopes containing these assignments were prepared. The envelopes were divided randomly into five groups and sent to the participating centers; the treating surgeons were blinded to the size of each block. When a patient with a CT-verified displaced intra-articular calcaneal fracture presented and was deemed eligible for the trial, he or she was given full information about the study and was randomized by choosing an envelope. No stratification was performed. The randomization took place before further classification of the fracture was performed.

Outcome Measures

Clinical review of the patients in both groups was performed by the treating surgeon at two weeks, eight weeks, three months, and six months. At one year and at eight to twelve years (mean, ten years) after injury, the patients were evaluated by one of two unbiased surgeons who had not been involved in the treatment.

At the one-year and eight to twelve-year follow-up visits, the patient and surgeon completed various outcome instruments. The two primary outcome measures were the visual analog scale (VAS) score for pain and function devised and tested by Hildebrand et al.¹⁶ (where 0 indicates the worst outcome and 100 indicates the best outcome) and the Short Form (SF)-36, which is a self-administered general health outcome questionnaire with physical and mental health components. The secondary outcome measures were VAS scores for pain at rest and during weight-bearing (where 0 indicates no pain and

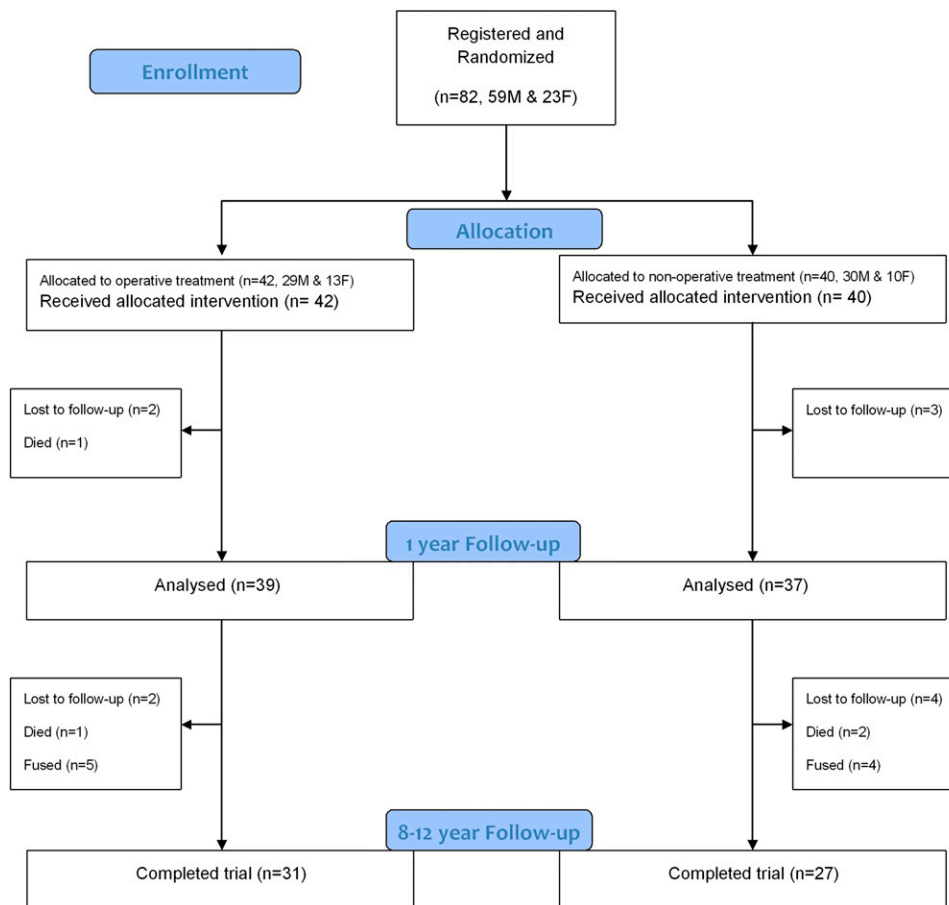


Fig. 1
Flow of patients through the study.

10 indicates the worst pain), the American Orthopaedic Foot & Ankle Society (AOFAS) ankle-hindfoot scale, and the Olerud-Molander (OM) scale.

A clinical examination was also performed during each evaluation to measure the range of motion of the ankle and subtalar joints and the length and width of the hindfoot. The contralateral, nonfractured foot was used for comparison. Shoe problems, complications and the outcome of their treatment, and work-related injury compensation status were documented. Radiographic follow-up with axial and coronal CT scans was performed at the one and three-year visits.

Statistical Analysis

Outcomes were analyzed on the basis of the intention-to-treat principle. The mean, standard deviation, and 95% CI were calculated for each variable of interest. Only bivariate comparisons were made; multivariate analysis was not performed. The Mann-Whitney test was used for the comparison of all outcome indices between the two groups, and a two-sample t test was used for the comparison of the Böhler angles. A p value of <0.05 was considered significant.

Source of Funding

No external funding was received for the study.

Results

Patient Flow and Baseline Data

Eighty-two patients were recruited; forty-two (twenty-nine men and thirteen women) were randomized to the operative group and underwent surgery, and forty (thirty men and ten

women) were assigned to the nonoperative group and treated nonoperatively. Three patients in the operative group and two patients in the nonoperative group had bilateral fractures. No demographic differences between the two groups were observed with respect to age or fracture type (Table I), suggesting integrity of the randomization process. All patients received the type of treatment to which they had been allocated (Fig. 1).

The preoperative radiographs and CT scans were evaluated by the senior radiologists at the centers where the patients had surgery. The Böhler angle was measured at the intersection of two lines drawn from the posterosuperior aspect of the calcaneal tuberosity to the highest point of the posterior articular facet and to the anterior process of the calcaneus. The preoperative Böhler angles are given in Table I, and the postoperative angles ranged from 0° to 40° (mean and standard deviation, 26° ± 9°).

Operative Treatment

Postoperative axial and coronal CT scans were evaluated by the local senior radiologists. The scans revealed that the fractures in twenty-four (57%) of the forty-two patients had been reduced to <2 mm of displacement, eleven (26%) had been reduced to 2 to 5 mm, and four (10%) had been reduced to >5 mm. The CT scans of the remaining three patients were unavailable for review.

TABLE II Primary Outcomes at One Year

	Operative Group*	Nonoperative Group*	P Value
VAS pain and function scoring by patients	56.9 ± 26.4 (48.6-65.2)	54.8 ± 23.7 (47.1-62.4)	0.71
VAS pain and function scoring by surgeon	66.1 ± 25.6 (58.0-74.1)	66.9 ± 22.6 (59.6-74.2)	0.90
SF-36 physical	48.0 ± 20.8 (41.5-54.5)	42.5 ± 21.4 (35.6-49.4)	0.40
SF-36 mental	52.5 ± 23.3 (45.2-59.8)	50.5 ± 21.9 (43.5-57.5)	0.70

*The values are given as the mean and the standard deviation, with the 95% CI in parentheses.

TABLE III Secondary Outcomes at One Year

	Operative Group*	Nonoperative Group*	P Value
VAS pain at rest	0.6 ± 1.1 (0.25-0.95)	0.4 ± 0.7 (0.17-0.63)	0.57
VAS pain during weight-bearing	2.3 ± 2.1 (1.64-2.96)	2.6 ± 1.6 (2.08-3.12)	0.74
AOFAS	75.5 ± 14.2 (71.0-79.9)	72.4 ± 14.9 (67.5-77.2)	0.50
OM	62.2 ± 24.2 (54.5-69.8)	60.9 ± 22.8 (53.5-68.2)	0.44

*The values are given as the mean and the standard deviation, with the 95% CI in parentheses.

TABLE IV Primary Outcomes at Eight to Twelve Years

	Operative Group*	Nonoperative Group*	P Value
VAS pain and function scoring by patients	72.0 ± 21.7 (64.4-79.6)	61.0 ± 24.4 (51.3-70.6)	0.07
VAS pain and function scoring by surgeon	80.0 ± 20.3 (72.8-87.1)	73.0 ± 24.0 (63.5-82.5)	0.25
SF-36 physical	47.6 ± 9.8 (44.1-51.0)	40.8 ± 11.9 (36.1-45.5)	0.06
SF-36 mental	49.8 ± 9.9 (46.3-53.3)	51.0 ± 10.3 (46.9-55.1)	0.66

*The values are given as the mean and the standard deviation, with the 95% CI in parentheses.

Postoperative complications during the first twelve weeks included superficial wound infections, treated successfully with dressing and antibiotics, in eight patients (19%); a chronic MRSA (methicillin-resistant *Staphylococcus aureus*) infection, treated with amputation, in one patient (2%); and a deep infection and fistula, treated with implant removal and antibiotics, in one patient (2%). One patient developed compartment syndrome and was treated with foot fasciotomy.

Thirty-nine patients were available at one year of follow-up, and thirty-one were available at eight to twelve years (mean, ten years) (Fig. 1).

Nonoperative Treatment

One patient developed compartment syndrome and was treated with foot fasciotomy. Two patients had severe symptoms in the foot after nonoperative treatment and retired from their employment; these were the only patients in either group who had work-related injury compensation.

Thirty-seven patients were available at one year of follow-up, and twenty-seven were available at eight to twelve years (mean, ten years) (Fig. 1).

Primary and Secondary Outcome Measures

At one year of follow-up, no significant differences were found between the two groups with respect to the primary outcome measures (VAS pain and function score and SF-36 score) or the secondary measures (VAS pain at rest and during weight-bearing, AOFAS score, and OM score) (Tables II and III). Nine (23%) of thirty-nine patients in the operative group and seven (19%) of thirty-seven in the nonoperative group had difficulty using their previous shoes and needed orthopaedic shoes.

At one year of follow-up, the axial and coronal CT scans revealed that twelve patients in the operative group and twenty in the nonoperative group had signs of subtalar arthritis, characterized by diminished joint space, sclerosis,

TABLE V Secondary Outcomes at Eight to Twelve Years

	Operative Group*	Nonoperative Group*	P Value
VAS pain at rest	0.8 ± 1.7 (0.2-1.4)	0.8 ± 1.0 (0.4-1.2)	0.90
VAS pain during weight-bearing	2.1 ± 1.4 (1.6-2.6)	1.7 ± 1.1 (1.3-2.1)	0.24
AOFAS	81.0 ± 21.2 (73.5-88.4)	77.2 ± 15.5 (71.1-83.3)	0.36
OM	83.2 ± 21.0 (75.8-90.6)	76.3 ± 23.0 (67.2-85.4)	0.24

*The values are given as the mean and the standard deviation, with the 95% CI in parentheses.

osteophytes, and subchondral cysts. Calculation of the relative risk (RR) of developing radiographically evident subtalar arthritis indicated that operative treatment reduced the risk by 41%.

At eight to twelve years (mean, ten years) of follow-up, the primary VAS score for pain and function reported by the patients and the physical component of the SF-36 were higher in the operative group ($p = 0.07$ and 0.06 , respectively) (Table IV). The secondary outcome measures did not differ significantly between the two groups (Table V). Only one of the patients with bilateral fractures was available for follow-up at this time point. Ten (24%) of the patients in the operative group had undergone implant removal. Five (12%) of the patients in the operative group and four (10%) of the patients in the nonoperative group had undergone subtalar arthrodesis.

Discussion

There is an apparent trend among orthopaedic surgeons toward managing displaced intra-articular calcaneal fractures with open reduction and internal fixation (with or without bone graft), despite the lack of evidence that operative treatment is superior to nonoperative treatment and has benefits that outweigh its risks⁷. When we began the present trial in the early 1990s, we were convinced of the superiority of operative treatment of such fractures; however, the results of the trial have refuted this hypothesis.

The reasons that operative treatment failed to demonstrate better results could be multifactorial. First, the cohort size could have been insufficient to demonstrate a difference in the outcome measures between the two treatments. At eight to twelve years of follow-up, two important primary outcome measures (the VAS pain and function score reported by the patient and the SF-36 component indicating physical status) were obviously better in the operative group but the differences did not reach significance. Another possible reason involves the complex pathoanatomy of displaced intra-articular calcaneal fractures, as the subtalar joint has a unique motion pattern in relation to the adjacent talonavicular and calcaneocuboid joints. Any residual displacement might lead to a disturbance of the motion pattern among these three joints¹⁷ with subsequent pain and walking difficulty. A third possibility involves the associated joint-surface injury and soft-tissue trauma sustained at the time of injury. Aggressive exposure and osseous reduc-

tion may be required to achieve proper alignment during surgery, potentially adding new trauma to the original injury¹⁸.

Anatomic reduction and restoration of the Böhler angle are essential elements of the surgical treatment of displaced intra-articular calcaneal fractures. Intraoperative fracture visualization with a standard image intensifier or a CT scan may be necessary to achieve these goals. Surgeons usually rely on visual and radiographic evaluation to assess anatomic reduction and achievement of good subtalar motion when determining the accuracy of their surgical reduction. Buckley et al.¹⁹⁻²¹ and others²² reported better functional results and less pain when Böhler angle restoration and anatomic reduction were achieved. On the other hand, Ibrahim et al.²³ and Kennedy et al.²⁴ found no association between radiographically measured restoration of the angle and clinical outcome. In the present study, at least 36% of the surgically treated patients had a residual subtalar displacement of ≥ 2 mm. Other authors^{19,22,25} reported a greater proportion of patients in whom subtalar reduction was < 2 mm and better final results compared with our study.

Minimally invasive techniques such as closed, limited-open, and arthroscopic-assisted reduction with percutaneous or external fixation have been advocated for these fractures to reduce the surgical trauma²⁶⁻²⁸. DeWall et al.²⁶ compared open reduction and internal fixation with use of a lateral extensile approach with percutaneous reduction and found comparable results for the two surgical approaches, with significantly fewer wound complications in the percutaneous group.

We used a VAS pain and function score¹⁶ and the SF-36 general health outcome form as the primary outcome measures. We did not perform assessments with these measures during the period of fracture-healing. At one year of follow-up, the results of operative and nonoperative treatment were comparable (Table II). At eight to twelve years of follow-up, operative treatment yielded a better mean patient-reported primary VAS score for pain and function, although this did not reach significance ($p = 0.07$) (Table IV). Moreover, the mean VAS score for pain and function was better at eight to twelve years of follow-up compared with one year, probably indicating an improvement in the evaluated parameters during the study period.

The SF-36 form is a well-validated instrument for the assessment of quality of life (including both physical and

mental aspects) in patients who have undergone foot and ankle surgery²⁹⁻³¹. Robb et al.³² reported a higher SF-36 score after operative compared with nonoperative treatment of calcaneal fractures, whereas Buckley et al.¹⁹ and Kennedy et al.²⁴ found no significant difference between the two treatments. In the present study, the SF-36 scores in the two treatment groups were comparable at one year of follow-up (Table II). At eight to twelve years of follow-up, operative treatment resulted in a trend toward a higher mean SF-36 physical component ($p = 0.06$) (Table IV). However, the mean SF-36 scores in the present study were generally lower than those in a previous study¹⁹. This might be due to greater residual fracture displacement in the patients in our study as well as possible cultural and expectation-level differences between the patients in the two studies.

As secondary outcome measures, we used a VAS to evaluate the residual pain at rest and during weight-bearing, and we used the AOFAS and OM scores to evaluate the functional outcome. The residual pain at rest and during weight-bearing did not differ significantly between the operative and nonoperative treatment groups at either one or eight to twelve years of follow-up (Tables III and V). This agrees with the findings of a recent meta-analysis of current evidence by Jiang et al.¹⁵ and a Cochrane report by Bridgman et al.¹¹. Other investigators^{19,20,22} found better VAS pain scores only in certain subgroups, such as patients with no residual subtalar displacement or those who did not receive Workers' Compensation. The mean VAS pain score in the present study also improved slightly at eight to twelve years of follow-up compared with one year.

The AOFAS score is a widely used outcome measure in patients with foot and ankle conditions³³. However, debate exists regarding its limited validity and responsiveness. We chose to include this score because it was a common and well-known outcome index when we designed the trial in the early 1990s. According to the two most recent meta-analyses^{7,13}, it is unclear whether the AOFAS score improves after operative compared with nonoperative treatment of displaced intra-articular calcaneal fractures. In the present study, no significant difference between the two groups was found at either one or eight to twelve years of follow-up (Tables III and V). Rammelt et al.³⁴ reported a higher mean AOFAS score after percutaneous arthroscopically-assisted reduction and screw fixation of selected Sanders type-II calcaneal fractures compared with that reported in the present study, possibly as a result of the less traumatic percutaneous technique.

The OM score is typically used to evaluate residual symptoms and functional outcome after ankle fractures³⁵. The results at both one and eight to twelve years were comparable after operative and nonoperative treatment (Tables III and V). The postoperative residual fracture displacement and complications may have contributed to a lower score in the operative group, resulting in an outcome that was not significantly better than that in the nonoperative group.

The issue of work-related injury compensation after displaced intra-articular calcaneal fractures has gained impor-

tance. In a previous study, men who had a severely displaced fracture and received this type of compensation had poorer results and a higher risk of subtalar arthrodesis if they were treated nonoperatively¹⁹. In the present study, only two patients had such compensation; both were in the nonoperative group and retired because of the injury. Therefore, no stratification of the results according to work-related injury compensation status was performed. Compensation systems vary among countries; furthermore, the validity of the outcome scores for patients receiving such compensation has not been documented.

The list of complications following operative treatment of calcaneal fractures is lengthy^{13,18}. Howard et al.¹⁸ found that VAS pain scores were lower and SF-36 scores were higher in patients without complications regardless of the treatment group. In that study, no differences existed between the operative and nonoperative groups. When patients with complications were included, VAS pain scores but not SF-36 scores were better in the operative treatment group. The present study revealed a risk reduction of 41% for radiographically evident subtalar arthritis after operative compared with nonoperative treatment. However, that reduction did not result in a significant difference in the measured outcomes. This might indicate a discrepancy between the radiographic changes and the clinical outcome. Furthermore, the risk of arthrodesis at the end of the present trial was not higher in the nonoperative group (four patients, 10%) compared with the operative group (five patients, 12%). Radnay et al.³⁶ studied the outcome of patients with a displaced intra-articular calcaneal fracture that eventually required arthrodesis; patients who had initially been treated operatively had superior results compared with those who had initially been treated nonoperatively. This might have been due to the comparatively better preservation of the calcaneal geometry after operative treatment. We have the same impression and believe that the arthrodesis surgical technique is less demanding when the arthrodesis follows operative treatment of such a fracture compared with nonoperative treatment.

A meta-analysis of previous studies has shown a clear advantage of operative treatment of displaced intra-articular calcaneal fractures with respect to shoe wear. In that meta-analysis, patients could use the same shoes as before the injury¹³. This was not the case in the present study, in which nine (23%) of thirty-nine patients in the operative group and seven (19%) of thirty-seven in the nonoperative group had difficulty with shoe wear and needed special shoes. Howard et al.¹⁸ also reported a comparable prevalence of shoe-wear problems after operative and nonoperative treatment of such fractures.

Wound infections and problems leading to implant removal have also been reported after operative treatment. The prevalence of these problems in the present study was rather high compared with those in other studies^{13,18}. The increasing problem of nosocomial and antibiotic-resistant infections such as MRSA in clinical practice makes this aspect of the management of these fractures of crucial importance.

The present study has some limitations. The sample size was relatively small. However, compared with other published

randomized controlled trials⁷, the number of included patients and the extent of drop-out make the present study valuable. Another limitation is our inability to report the number of patients excluded from the study, as this information was not documented by some of the participating centers. However, we estimate that no more than ten patients were excluded. These limitations are counterbalanced by the strengths of the study, which was a prospective randomized multicenter trial with long-term follow-up.

In conclusion, the results of this study showed comparable outcomes following operative and nonoperative treatment of displaced intra-articular calcaneal fractures at one year of follow-up. There was a trend toward a better VAS pain and function score reported by the patients and a better physical component of the SF-36 score in the operative treatment group at eight to twelve years of follow-up. The risk of complications was higher with operative treatment. The prevalence of radiographically documented posttraumatic subtalar arthritis was higher, but the need for secondary

subtalar arthrodesis was not increased, following nonoperative treatment. ■

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