Operative Compared with Nonoperative Treatment of Displaced Intra-Articular Calcaneal Fractures

A Prospective, Randomized, Controlled Multicenter Trial

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Background: Open reduction and internal fixation is the treatment of choice for displaced intra-articular calcaneal fractures at many orthopaedic trauma centers. The purpose of this study was to determine whether open reduction and internal fixation of displaced intra-articular calcaneal fractures results in better general and disease-specific health outcomes at two years after the injury compared with those after nonoperative management.

Methods: Patients at four trauma centers were randomized to operative or nonoperative care. A standard protocol, involving a lateral approach and rigid internal fixation, was used for operative care. Nonoperative treatment involved no attempt at closed reduction, and the patients were treated only with ice, elevation, and rest. All fractures were classified, and the quality of the reduction was measured. Validated outcome measures included the Short Form-36 (SF-36, a general health survey) and a visual analog scale (a disease-specific scale).

Results: Between April 1991 and December 1997, 512 patients with a calcaneal fracture were treated. Of those patients, 424 with 471 displaced intra-articular calcaneal fractures were enrolled in the study. Three hundred and nine patients (73%) were followed and assessed for a minimum of two years and a maximum of eight years of follow-up. The outcomes after nonoperative treatment were not found to be different from those after operative treatment; the score on the SF-36 was 64.7 and 68.7, respectively ($p = 0.13$), and the score on the visual analog scale was 64.3 and 68.6, respectively ($p = 0.12$). However, the patients who were not receiving Workers' Compensation and were managed operatively had significantly higher satisfaction scores ($p = 0.001$). Women who were managed operatively scored significantly higher on the SF-36 than did women who were managed nonoperatively ($p = 0.015$). Patients who were not receiving Workers' Compensation and were younger (less than twenty-nine years old), had a moderately lower Böhler angle (0° to 14°), a comminuted fracture, a light workload, or an anatomic reduction or a step-off of ≤2 mm after surgical reduction ($p = 0.04$) scored significantly higher on the scoring scales after surgery compared with those who were treated nonoperatively.

Conclusions: Without stratification of the groups, the functional results after nonoperative care of displaced intra-articular calcaneal fractures were equivalent to those after operative care. However, after unmasking the data by removal of the patients who were receiving Workers' Compensation, the outcomes were significantly better in some groups of surgically treated patients.

Controversy remains with regard to whether displaced intra-articular calcaneal fractures should be treated operatively or nonoperatively[1-5]. Historically, displaced intra-articular calcaneal fractures were treated nonoperatively, as predictable operative reduction and fixation were not possible[2,3,6]. Operative reduction became more popular as fracture care improved[7-10]. Reviews on this subject, however, have failed to demonstrate indisputable superior results of a single approach to the treatment of displaced intra-articular calcaneal fractures[5,9,11-13]. Historical cohort studies[4,14,15] have suggested that open and closed treatment provide nearly equal results. Kundel et al.[15] pointed out that gait may be somewhat better after sur-

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gical treatment. A radiographic review[16] demonstrated little association between treatment and outcome but showed a high prevalence of hardware in the subtalar joint after surgery.

Few prospective, randomized trials have been done in this field of orthopaedic surgery. Parmar et al.[17], in a study of fifty-six patients who had been randomized by date of birth to either operative or nonoperative care, demonstrated that there was no difference between the groups at one year of follow-up. In a study by O'Farrell et al.[18], twelve patients were assigned, without randomization, to operative care and twelve were assigned to nonoperative care. After fifteen months of follow-up, the patients who had been managed operatively had returned to work sooner and walked better than those who had been managed nonoperatively. Thordarson and Krieger[13] randomized thirty patients to operative or nonoperative treatment and noted that the operatively treated patients had higher functional scores one year after treatment. These investigations demonstrated problems with the study design, patient-selection bias, susceptibility bias, nonresponse bias, and lack of stratification. The number of patients in the studies was small, and the duration of follow-up was short. In a meta-analysis published in 2000, Randle et al.[19] stated that "there is a trend for surgically treated patients to have better outcomes; however, the strength of evidence for recommending operative treatment is weak." They concluded that, before a strong recommendation could be made for operative treatment, a randomized trial with controls and validated outcomes was needed[19].

The present multicenter, prospective, randomized controlled trial was designed by the Canadian Orthopaedic Trauma Society. At the inception of the study, the members of the Society thought that a displaced intra-articular calcaneal fracture was amenable to either operative or nonoperative care.

The primary question addressed by this study was: (1) Does open reduction and internal fixation of displaced intra-articular calcaneal fractures result in better outcomes, as measured by general and disease-specific health-outcome measures at two years after the injury, compared with those after nonoperative management? Secondary questions included: (2) Is the outcome after open reduction and internal fixation of displaced intra-articular calcaneal fractures associated with the findings on the postoperative computerized tomography scan and the clinical results? (3) Does open reduction and internal fixation affect the outcome as determined with use of patient-oriented scoring scales? (4) Are radiographic classifications predictive of the functional outcome in patients with a displaced intra-articular calcaneal fracture?

Materials and Methods

Fourteen surgeons in seven centers were recruited to participate in this multicenter, prospective, randomized controlled trial, which was conducted between April 1991 and December 1997. Each hospital approved the study through its local university medical ethics review board. Informed consent was obtained from each patient. Each surgeon was required to recruit a minimum of twenty patients and follow them for a minimum of two years. Three centers were unable to meet the rigors of this study, and no data from these excluded centers were included. This left six surgeons from four centers, including the Calgary General Hospital in Calgary, Alberta; the Royal Columbia Hospital in New Westminster, British Columbia; the Royal Victoria Hospital in Halifax, Nova Scotia; and the Victoria Hospital in London, Ontario. Inclusion criteria mandated that the patients be between fifteen and sixty-eight years old and had to have been seen or referred to the participating institutions because of an intra-articular calcaneal fracture that was displaced >2 mm from anatomic position as demonstrated by axial and coronal computerized tomography scanning of the posterior facet. Exclusion criteria included medical contraindications to surgery, a previous calcaneal abnormality (an infection or a tumor), a previous calcaneal injury, a coexistent foot injury, an extra-articular fracture, an open calcaneal fracture, an injury that had occurred more than fourteen days before presentation, or a head injury.

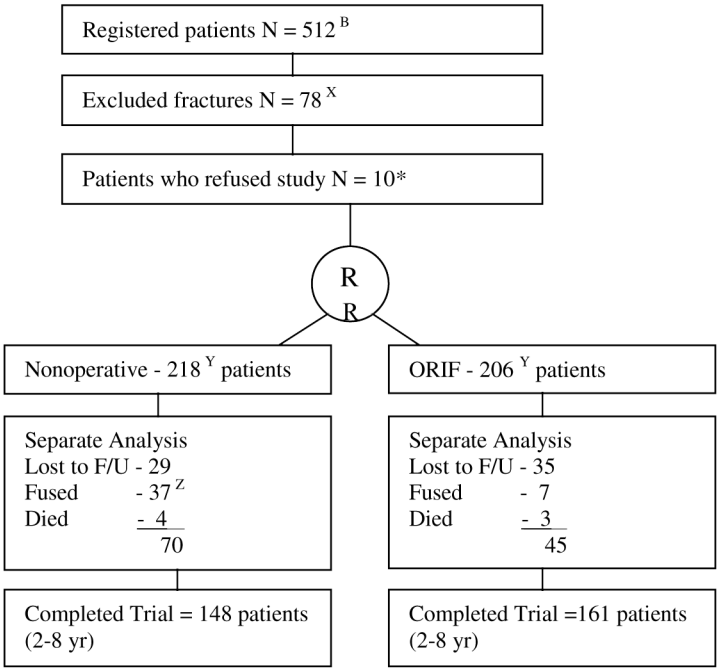
Protocol

Patients were randomized with use of random number tables after they were deemed eligible to enter the study (Fig. 1). The prerandomized design[20] was used for this particular study because it reduced important obstacles to participation in the prospective trial and minimized open discussion of uncertainty and other problems with the attainment of informed consent. This randomization design maximized the physician-patient relationship. Patients, not fractures, were randomized. Patients with a bilateral fracture were randomized by the individual and not by the fracture. All centers followed the random number assignments. Random numbers were generated at the site of the principal investigator, with a central administration site sending random number assignments to study centers involved in the ongoing study.

Sample Size

The target sample size was projected on the basis of determinations of fracture audits performed at the surgical centers in 1991. Historical data and historical outcome scoring were so scarce (neither the Short-Form-36 [SF-36] nor validated outcome measures had been published) in the literature that a difference in scores of 20 points between groups was arbitrarily chosen to represent a clinically relevant difference on a 100-point scoring scale. A standard deviation of 40 was chosen. A power analysis, with a power of 90% and an alpha of 0.05, determined that a sample size of eighty-six patients per group was needed. It was anticipated initially that 10% to 15% of the patients would drop out or not fully meet the criteria for long-term follow-up and that 100 patients per group would be required. An interim analysis at one year demonstrated that the difference between groups was small, and thus the original difference (20 points) indicating a clinically relevant finding between groups was adjusted to 10 points on a 100-point scoring scale. A resultant recalculation of sample size showed that 436 patients would be required to demonstrate a difference between groups. If there was a difference of 10% between groups, we would have had a 90% chance of cor-

	Randomized (received standard intervention as allocated)	Did not receive Standard intervention as allocated	Completed Trial, Followed Up	Lost to Follow-Up	Treated with Arthrodesis	Patients Died	Total Withdrawn
Nonoperative	218	0	148	24	37 [Z]	4	70
ORIF	206	0	161	35	7	3	45
TOTALS	**424**	**0**	**309**	**64**	**45**	**7**	**115**



B - 47 bilateral cases
Total 559 calcanei

Excluded #'s

[X] - Open #	21
Extraarticular #	14
"beak" #	4
too old for study	16
delayed entry into study	4
non compliance with protocol initiation (head injury)	9
too young for study	4
non displaced #	3
medically unwell	1
#D/L	2
	78

* These 10 patients were excluded because of "loss of confidence in surgeon and the open discussion of uncertainty with being involved in a randomized trial."
R - Randomization
[Y] - All patients received intervention as allocated
[Z] - 1 person had 2 fusions

Fig. 1

Analysis of the patients enrolled in the study. ORIF = open reduction and internal fixation, F/U = follow-up, and D/L = fracture dislocation.

rectly detecting it (a type-II error) at a p value of <0.05. Given the number of significant findings, and the initial power calculation, post hoc power tests were not done. When an odds ratio exceeds 2 and the confidence interval includes the null value, it may be suggested that the sample size within that stratum was not sufficiently large to render the point estimate significantly different from null[21]. Patients were enrolled on an intention-to-treat basis. After interim analysis was complete, the study was continued until completion without alteration of the protocol.

TABLE I Outcome Results of 424 Patients with a Displaced Intra-Articular Calcaneal Fracture Who Were Randomly Assigned to Operative or Nonoperative Treatment (Complete Study Group)

Group	No. of Patients	Mean Score on Short Form-36	Mean Score on Visual Analog Scale	No. of Patients Treated with Arthrodesis
Nonoperative treatment	218	64.7	64.3	37
Operative treatment	206	68.7	68.6	7
P value		0.13	0.12	0.001

Intervention

The patients who were treated nonoperatively had no attempt at closed reduction and were treated only with ice, elevation, and rest. A predetermined standard protocol for operative treatment, which involved an extended lateral approach with open reduction and application of a plate, screw, or wire fixation, was used at all sites. Bone-grafting (autograft) was left to the discretion of the surgeon. After six weeks of non-weight-bearing, all patients began a standardized physiotherapy regimen with full weight-bearing. No patients were treated with a cast.

Demographic data were obtained from the patients as they entered the study, and they were followed routinely at two to four weeks; at six, twelve, twenty-six, and fifty-two weeks; and at two years. At the one-year and two-year follow-up examinations, the patients completed a self-administered general health-outcome form (the SF-36[22]) and rated the outcome with a visual analog scale (a disease-specific scale)[23]. Patients who required assistance with the forms because of illiteracy or a language barrier were helped by nurses involved in the study. As patients were followed through the study to the two-year end point, data were also collected with regard to the time from injury to the patient's return to work, the capability to perform normal work, complications, and the need for repeat surgery. Computerized tomography scans were performed preoperatively, postoperatively, and at two years postoperatively. One of us (R.B.) reviewed all of the computerized tomography scans to measure the quality of the reduction. The quality of the reduction of the fracture of the posterior facet was measured as (1) anatomic, (2) a step-off of ≤2 mm, or (3) a comminuted reduction (a step-off or gap of >2 mm after reduction). The reduction of the medial and the lateral wall and impingement of the peroneal tendon were not evaluated. All fractures were classified with use of the classification systems of Sanders[9], Essex-Lopresti[24], Crosby and Fitzgibbons[25], and the Orthopaedic Trauma Association[26].

Management and Analysis of the Data

The patient questionnaires were reviewed manually for consistency and appropriate codes prior to data entry. The data were entered into Epi Info software (version 6.01; USD, Stone Mountain, Georgia); a sample of the data was double-entered, and discrepancies were resolved. The data were analyzed with use of SPSS software (version 10.0 for personal computers; SPSS, Chicago, Illinois), and Stata software (Stata, College Station, Texas)[27]. The data analysis focused on the study objectives through descriptive techniques (frequencies) and bivariate comparisons to examine differences according to the variable of interest (for example, the scores on the SF-36 and visual analog scale). The analysis was performed with the scores on the SF-36 and visual analog scale as categorical as well as continuous variables. In order to determine the magnitude of the relationship between variables, as opposed to just the association, the categorical results are presented. The scores on the SF-36 and visual analog scale were dichotomized at the mean on the basis of the complete sample. Bivariate analysis included chi-square techniques, calculation of relative risks, and comparisons of means. When there was a gradient in the data, the Mantel-Haenszel test for linear trend was used. Bivariate analysis with use of odds ratios and relative risk ratios was used to determine whether there were differences between strata for the independent variables and the treatment.

The initial bivariate analysis revealed some significant differences associated with the scores on the SF-36 and visual analog scale. Variables that were found to be significant, or clinically relevant, in the bivariate analysis were eligible for evaluation in the bivariate logistic regression. All independent variables were recoded as categorical for use of interpretation and informativeness, although in so doing there is some loss of precision[28]. Variables were eliminated from the bivariate regression if they did not distinguish between the patients who scored above and those who scored below the mean on the SF-36 and visual analog scale variables. The dependent outcome variable was patient satisfaction as measured by the SF-36 and visual-analog-scale scores.

Logistic regression analysis was used to derive estimates of the increase in the odds of higher scores for satisfaction associated with different independent risk factors. The odds ratio or exponential of beta can be interpreted as the independent increase (>1.0) or decrease (<1.0) in risk according to the presence or absence of that independent variable. To determine the impact of two or more independent risk factors on the outcome, the odds ratios can be multiplied together (as is shown in the Results section).

To address the study objectives, which were to determine which patients were best served by which treatment methodology, bivariate logistic regression was carried out in the following manner: (1) the variable of interest was entered into the equation (for example, age, gender, Böhler angle, status with regard to Workers' Compensation, and workload);

(2) the variable of interest was then entered with the treatment variable (operative versus nonoperative), and (3) the variable of interest, the treatment variable, and then the interaction between them were entered into the regression.

Interaction terms that were found to be significant were noted. The selection of the variables to be included was made on the basis of the findings of previous studies and the results of the bivariate analysis. A p value of <0.05 was considered significant. The specific impact of the independent variable on the scores of the SF-36 or the visual analog scale can be interpreted from the exponential of beta as the increase (or decrease) in the odds with the presence of the factor, with all else held constant.

Results

Five hundred and twelve patients with 559 calcaneal fractures were registered in the study (Fig. 1). Seventy-eight patients who had an ineligible fracture and ten patients who refused to participate in the study or refused the treatment options presented to them were excluded. Thus, 424 patients (471 fractures) were enrolled in the study. Two hundred and eighteen patients (262 fractures) were managed nonoperatively, and 206 patients (249 fractures) were managed operatively. A separate analysis of the patients who did not complete the trial (seventy who were managed nonoperatively and forty-five who were managed operatively) was performed (Fig. 1). Specifically, patients who needed a delayed subtalar arthrodesis because of posttraumatic arthritis were analyzed in a separate group because normal management had failed and reconstructive surgery was required[29]. Three hundred and nine patients (371 fractures) who were followed for a minimum of two years and a maximum of eight years (average, three years) were analyzed in the study.

The age of the patients at the time of the injury was a mean (and standard deviation) of 40 ± 11 years (range, fifteen to sixty-eight years). Over 60% of the participants were between thirty and forty-nine years old. One hundred and fifty-seven patients (37%) had a work-related injury and were receiving Workers' Compensation. Information on the Böhler angle was available for 375 patients. The initial Böhler angle was an average (and standard deviation) of 1.6° ± 14.6° (range, –56° to 36°). The Böhler angle was –9° to 0° for ninety-six patients (26%), 1° to 9° for eighty-two (22%), and 10° to 19° for eighty-nine patients (24%). The average measurement of the Böhler angle in the normal foot of the patients was 30° (range, 18° to 40°).

No significant differences between the operative and nonoperative groups were detected with regard to the age at the time of the injury (forty-one versus thirty-nine years, respectively; $p = 0.61$); Böhler angle (1.3° versus 1.9°, respectively; $p = 0.77$); classification according to the systems of Crosby and Fitzgibbons ($p = 0.13$), Sanders ($p = 0.62$), or Essex-Lopresti ($p = 0.30$); male gender (90% in both groups; $p = 0.82$); workload ($p = 0.59$); or Workers' Compensation status (36% versus 39%, respectively; $p = 0.54$). There were forty-three females and 381 males. One hundred and fifty seven patients (37%) had a work-related injury.

Three hundred and ten patients (73%) were treated at one center by the senior one of us (R.B.). The fracture was on the left side in 185 patients, on the right side in 192 patients, and was bilateral in forty-seven patients. Injuries other than the calcaneal fracture were identified in 133 patients. Thirteen (10%) of them had an accompanying spinal injury.

Sixty-four patients who had been lost to follow-up were tracked by nurses involved in the study. No known complications or problems had developed when they were last seen. The early results in the two groups were comparable[30].

A combination of subchondral interfragmental screws and one-third tubular plates were used in 175 patients (85%). Plates alone were used in thirteen patients (6%), screws alone in twelve (6%), and Kirschner wires alone in two (1%). Bone-grafting was used in fifty-three patients (26%). Postoperative computerized tomography scans showed that screws were very near or in the subtalar or calcaneocuboid joint in eleven feet (5%). Two patients needed repeat operations for hardware removal as the screws had penetrated the posterior facet of the subtalar joint. No other adverse outcomes from the screws were found near or in the subtalar or calcaneocuboid joint. None of these patients subsequently required subtalar arthrodesis. Wound complications included eleven deep infections (5%) and thirty-six superficial wound sloughs (17%) in the operative group.

Table I demonstrates the overall results for the main

TABLE II Quality of the Reduction of a Displaced Intra-Articular Calcaneal Fracture in 156 Operatively Treated Patients Who Had a Validated Score on the Visual Analog Scale*

Quality of Reduction†	No. *(%)* of Patients	Mean Score on Visual Analog Scale†	Standard Deviation§
Anatomic reduction	49 (31.4)	72.9	22.0
Step-off of ≤2 mm	78 (50.2)	69.5	24.2
Comminuted reduction	29 (18.6)	67.3	22.7

*All operative patients including those receiving Workers' Compensation. †A step-off of ≤2 mm indicated an imperfect reduction, and a comminuted reduction was a step-off or a gap of >2 mm in the joint surface after reduction. †The difference was not significant ($p = 0.56$). §The average standard deviation was 23.2.

TABLE III Overall Logistic Regression Model of the Scores on the Short Form-36 (SF-36) and the Visual Analog Scale for Patients with a Displaced Intra-Articular Calcaneal Fracture Evaluated with Respect to Operative Compared with Nonoperative Intervention

	SF-36 (N = 286)		Visual Analog Scale (N = 326)	
Variable	Exponential of Beta (Odds Ratio)	95% Confidence Interval	Exponential of Beta (Odds Ratio)	95% Confidence Interval
Böhler angle				
–56° to –1°	1.00	Baseline		
0° to 14°	1.61	0.86-3.00		
15° to 36°	2.95	1.30-6.68		
Arthrodesis				
Yes	1.00	Baseline	1.00	Baseline
No	20.34	2.52-164.73	3.34	1.17-9.67
Receiving Workers' Compensation				
Yes	1.00	Baseline	1.00	Baseline
No	8.09	4.48-14.60	6.12	3.71-10.11
Involvement of injury				
Bilateral	1.00	Baseline		
Unilateral	2.14	1.19-3.83		

study question for the complete study group. Table II demonstrates the outcome results associated with the quality of the reduction in the operative treatment group. Multiple logistic regression analysis of the whole group suggested that the independent predictors of satisfaction include a Böhler angle of 15° to 36°, no subsequent arthrodesis, a non-work-related injury, and a unilateral injury (Table III). Patients who present with these characteristics are more likely to score above the mean on the SF-36 than are those with a lower Böhler angle or those who require arthrodesis or who have multiple injuries. (Multiple logistic regression suggests that the independent predictors of satisfaction include a Böhler angle of 15° to 36° [odds ratio of 2.95] and a patient who is not receiving Workers' Compensation injury [odds ratio of 8.09] [Table III]. Thus, a patient who presents with a Böhler angle of 15° to 36° and is not receiving Workers' Compensation is 2.95 × 8.09 = 23.86 times more likely to score above the mean on the SF-36 than are those with a lower Böhler angle who are receiving Workers' Compensation.)

Bivariate Results for Nonoperative Treatment

For the patients who had nonoperative treatment, the scores for satisfaction did not differ with regard to age, gender, score according to the system of Crosby and Fitzgibbons, workload, or bilaterality of the injury. However, the scores for satisfaction were significantly higher among those who had a Böhler angle between 15° and 36° ($p = 0.01$), had a moderate tongue-type fracture according to the Essex-Lopresti classification ($p = 0.035$), or were not receiving Workers' Compensation ($p = 0.001$) (Table IV). When the analysis was restricted to the fifty-three patients who were receiving Workers' Compensation and were managed nonoperatively, no significant difference was detected with respect to any variable. When the analysis was restricted to the 111 patients who were not receiving Workers' Compensation and were managed nonoperatively, the satisfaction scores were significantly higher for those who were between fifty and sixty-five years old ($p < 0.014$) and for those with a Böhler angle of 15° to 36° ($p < 0.044$). No significant difference was noted with respect to gender, classification according to the systems of Crosby and Fitzgibbons or Essex-Lopresti, workload, or bilateral or unilateral injury.

Bivariate Results for Operative Treatment

For those who received surgical intervention, no significant differences in the SF-36 scores were detected with respect to age or classification according to the systems of Crosby and Fitzgibbons or Essex-Lopresti. However, patients who were female ($p = 0.015$), had a Böhler angle of 15° to 36° ($p = 0.014$), had a light workload ($p = 0.001$), were not receiving Workers' Compensation ($p = 0.001$), or had an initial anatomic reduction (compared with a mild step-off or a comminuted reduction) ($p = 0.012$), and who had a single calcaneal fracture ($p = 0.02$) had significantly higher SF-36 scores (Table IV). When the analysis was restricted to the sixty-five patients who were receiving Workers' Compensation and were managed surgically, no significant difference in the SF-36 scores was detected in relation to any demographic category.

Bivariate Comparisons by Strata

In order to refine the analysis for useful clinical decision-making, the strata within each variable were compared for the increased or decreased likelihood of higher satisfaction scores depending on treatment. The sample size across some strata was small, and the results must be interpreted with caution. In general, an increase or decrease in risk of ≥2.0 (a relative risk of 2.0) would be considered clinically important[21].

TABLE IV Comparison of Patient Outcomes According to Satisfaction Scores on the Short Form-36 with Respect to Operative or Nonoperative Intervention for Complete Study Group*

Variable	Nonoperative Treatment		Operative Treatment	
	Percentage (No.) of Patients Who Scored Above Mean (N = 164)	P Value†	Percentage (No.) of Patients Who Scored Above Mean (N = 160)	P Value†
Age-group (*yr*)		0.195		0.095
15-19	0 (0)		100.0 (3)	
20-29	40.7 (11)		75.0 (18)	
30-39	48.9 (23)		46.0 (23)	
40-49	44.9 (22)		56.6 (30)	
50-65	31.7 (26)		56.7 (17)	
Gender		0.798		**0.015**
Male	50.3 (74)		53.1 (76)	
Female	47.1 (8)		**83.3 (15)**	
Böhler angle		**0.010**		**0.014**
–56° to –1°	39.6 (21)		41.9 (18)	
0° to 14°	46.4 (32)		61.5 (40)	
15° to 36°	**69.7 (23)**		**70.8 (17)**	
Classification of Crosby and Fitzgibbons		0.160		0.184
Displaced	60.6 (20)		69.6 (16)	
Comminuted	46.9 (60)		54.7 (75)	
Classification of Essex-Lopresti		**0.035**		0.893
Tongue type, moderate	**77.8 (7)**		42.9 (3)	
Tongue type, severe	57.5 (23)		59.0 (23)	
Joint, moderate	47.6 (10)		58.3 (7)	
Joint, severe	44.0 (40)		56.4 (57)	
Classification of Sanders		0.838		0.064‡
Type I	25.0 (2)		33.3 (1)	
Type II	55.8 (29)		66.7 (32)	
Type III	53.0 (44)		59.5 (47)	
Type IV	31.8 (7)		35.5 (11)	
Workload		0.658		**0.001**
Light	47.4 (9)		**87.0 (20)**	
Moderate	28.0 (57)		74.5 (35)	
Heavy	47.9 (45)		40.4 (36)	
Receiving Workers' Compensation		**0.001**		**0.001**
Yes	28.3 (15)		24.2 (16)	
No	**60.4 (67)**		**78.9 (75)**	
Quality of reduction				**0.012**
Anatomic			**68.1 (32)**	
Mild step			53.2 (42)	
Comminuted			51.7 (15)	
Involvement of injury		0.326		**0.020**
Unilateral	51.7 (74)		**59.9 (85)**	
Bilateral	40.0 (8)		31.6 (6)	

*Scores in bold type correspond with p value in bold type. †Chi square analysis. ‡A trend to significance was detected.

Complete Study Population

Patients who were between twenty and twenty-nine years old were 2.37 times (relative risk, 2.37; 95% confidence interval, 1.11 to 5.07) more likely to have high scores on the SF-36 after surgery than were those who had been treated nonoperatively. Women were 3.18 times (relative risk, 3.18; 95% confidence interval, 1.03 to 9.79) more likely to have high scores on the SF-36 after surgery than were those who had received nonoperative treatment. Among patients who had a light workload, those who had surgery were four times (relative risk, 4.04; 95% confidence interval, 1.29 to 12.59) more likely to report high scores on the SF-36. Among the patients who were not receiving Workers' Compensation, those who had surgery were 1.88 times (relative risk, 1.88; 95% confidence interval, 1.20 to 2.96) more likely to have high scores for satisfaction. Bivariate analysis failed to identify any predictors of higher satisfaction among the patients who were receiving Workers' Compensation. Furthermore, when the variables were modeled with use of univariate linear regression, there were no significant variables related to satisfaction scores.

TABLE V Scores on the Short Form-36 for 267 Patients Who Were Not Receiving Workers' Compensation*

Variable	Odds Ratio	95% Confidence Interval	Relative Risk	95% Confidence Interval
Age-group *(yr)*				
20-29	20.0	1.79-944.53	**9.14**	**1.30-64.34**
30-39	2.63	0.71-10.03	1.87†	0.85-4.12†
40-49	2.14	0.63-7.47	1.71†	0.78-3.79†
50-65	0.84	0.21-3.38	0.88	0.37-2.11
Gender				
Male	2.09	1.01-4.38	**1.69**	**1.03–2.78**
Female	6.00	1.0-43.2	**3.19**	**1.05-9.71**
Böhler angle				
–56° to –1°	2.42	0.70-8.55	1.69	0.84-3.39
0° to 14°	4.53	1.36-17.38	**3.12**	**1.28-7.62**
15° to 36°	2.5	0.37-28.3	2.13†	0.49-9.29†
Classification of Crosby and Fitzgibbons				
Displaced	3.27	0.49-36.4	2.55	0.61-10.67
Comminuted	2.53	1.21-5.34	**1.9**	**1.16-3.10**
Classification of Essex-Lopresti				
Tongue type, moderate	0.67	0.02-58.78	0.75	0.10-5.54
Tongue type, severe		Undefined (0's)		
Joint, moderate	2.07	0.31-16.35	1.57	0.54-4.59
Joint, severe	2.42	1.04-5.70	**1.81**	**1.06-3.08**
Classification of Sanders				
Type I	5.0	0.03-469	1.67	0.40-6.97
Type II	3.75	0.99-17.32	**2.74**	**1.01-7.44**
Type III	2.36	0.89-6.34	1.85†	0.96-3.55†
Type IV	1.03	0.14-7.04	1.02	0.36-2.91
Workload				
Light	10.0	1.54-105.85	**5.26**	**1.32-20.97**
Moderate	2.93	0.94-9.36	2.17	1.0-4.17
Heavy	1.29	0.46-3.66	1.19	0.62-2.28
Involvement of injury				
Unilateral	2.88	1.37-6.11	**2.16**	**1.28-3.65**
Bilateral	0.86	0.12-6.08	0.92	0.39-2.17

*Values reflect the increase or decrease in satisfaction for operative compared with nonoperative treatment with respect to the odds ratio and relative risk comparisons. Values in bold type represent a significant association with higher scores for satisfaction. †It is possible that the sample size is too small.

TABLE VI Quality of the Reduction of Displaced Intra-Articular Calcaneal Fractures and Resulting Outcome According to Two Validated Scoring Scales*

Quality of Initial Reduction	No. of Patients Receiving Workers' Compensation	Score on Visual Analog Scale†	Score on Short Form-36†	No. of Patients Not Receiving Workers' Compensation	Score on Visual Analog Scale†	Score on Short Form-36†
Anatomic	17	62.7 (19.6)	56.1 (20.7)	31	79.7 (20.8)	80.1 (16.5)
Mild step or gap of ≤2 mm	43	53.3 (22.7)	54.1 (17.6)	44	81.1 (20.7)	79.5 (17.9)
Comminuted reduction‡	71	50.9 (22.8)	53.7 (19.7)	139	71.6 (26.5)	70.1 (23.9)
Total	131	131	131	214	214	214
P value		0.15	0.90		0.04	0.01

*Some numbers may be different from total because of incomplete data accrual or bilateral involvement. †The values are given as the mean with the standard deviation in parentheses. ‡A reduction with a step or gap of >2 mm or fractures managed nonoperatively.

Bivariate Analysis for Patients Who Were Not Receiving Workers' Compensation (Table V)

Age-group; gender; Böhler angle; score according to the classification systems of Crosby and Fitzgibbons, Essex-Lopresti, and Sanders; workload; and bilaterality were all prognostic and predictive of satisfaction scores in patients who were not receiving Workers' Compensation. Surgery improved the outcome. Women who had surgery scored significantly higher on the SF-36 than did women who had not had surgery. Patients who had been treated operatively and were between twenty and twenty-nine years old or who had a Böhler angle of between 0° and 14°, a comminuted fracture, an Essex-Lopresti classification of a severely involved joint and/or a Type-II classification according to the system of Sanders, or who had a light-to-moderate workload scored significantly higher on the SF-36 compared with those who had been treated nonoperatively. Univariate logistic regression was used to evaluate whether there was a significant relationship between satisfaction and treatment with respect to age, gender, Sanders classification, Böhler angle, classification according to the system of Crosby and Fitzgibbons, workload, and status with regard to Workers' Compensation. The results suggested that surgery was significantly associated with higher scores for satisfaction among women ($p < 0.05$, odds ratio of 4.9) and among all patients who were not receiving Workers' Compensation ($p < 0.035$, odds ratio of 9.5).

The results of the two tests of outcome, the scores on the SF-36 and the visual analog scale, were analyzed in the same fashion. The findings were very similar. Analysis of the outcome, as measured with the visual analog scale, for only the patients who were receiving Workers' Compensation demonstrated no significant difference between those managed operatively and those managed nonoperatively. However, when the patients who were not receiving Workers' Compensation were included, the relative risks were much higher as a whole, with the patients who had been managed operatively demonstrating a better long-term outcome.

The quality of the reduction in the operatively treated patients was not found to be significant ($p = 0.56$) (Table II). However, when patients receiving Workers' Compensation were stratified from those who were not receiving Workers' Compensation and all fracture reductions were reviewed, the patients who were not receiving Workers' Compensation had a significantly better result with a better quality of reduction on both scoring scales ($p = 0.01$ for the SF-36, and $p = 0.04$ for the visual analog score) (Table VI). The patients receiving Workers' Compensation did not score on either scoring scale as well as those who were not receiving Workers' Compensation regardless of the quality of the reduction when the computerized tomography scans were read. The patients who had a comminuted reduction were included with those who had had nonoperative care. All of those fractures had a step-off or gap of >2 mm or comminution.

As noted in Table VI, a significant difference in outcome was detected when patients who were not receiving Workers' Compensation and had a mild step-off or gap of ≤2 mm were compared with those who had had a comminuted reduction or a step-off or gap of >2 mm ($p = 0.01$).

Discussion

Patient-oriented functional outcome was the focus of many clinical trials during the 1990s[22,23,31]. The Short Form-36 (SF-36)[22], a standardized general health survey, and the disease-specific visual-analog-scale score[23] are two examples of validated patient-oriented functional outcome tools. They provide both general and disease-specific outcomes to lessen assessment bias. Additionally, consensus articles on clinical trials have provided guidelines to improve study design, encouraging clinicians to evaluate patient care through standardized methodologies[32-36]. The controversy over the preferred treatment of displaced intra-articular calcaneal fractures is a good impetus for the development of a randomized, prospective, controlled, multicenter clinical trial.

Recent retrospective and small prospective studies have suggested that operative care of displaced intra-articular calcaneal fractures had a clear advantage over nonoperative care[9,11-13].

A meta-analysis, however, published in the year 2000[19], demonstrated that there was no level-I evidence that enabled a surgeon to decide upon optimal treatment for a displaced intra-articular calcaneal fracture.

Our prospective, randomized, controlled trial suggests that anatomic or near anatomic reduction provides a positive effect on outcome. To our knowledge, this is one of the few studies in the literature on calcaneal fractures that strongly suggests that a better reduction provides a better long-term outcome following an intra-articular fracture. In a previous clinical matched-cohort study[14], Buckley and Meek hinted that a better reduction, as measured by computerized tomography scanning, may result in a better patient outcome. They demonstrated that anatomically reduced calcaneal fractures had a better clinical score than their matched nonoperatively treated counterparts. In contrast, the displaced intra-articular calcaneal fractures that had a small residual step-off left in the joint after reduction were not substantially better than their matched nonoperatively treated counterparts.

Randomized, controlled trials that involve surgery are especially difficult to perform. We started off with twice the number of surgeons who completed the study. The rigors of a properly conducted randomized, controlled trial are such that study center compliance, surgeon requirements, and patient follow-up are difficult to attain. Certain standards[34] for sample size and statistical power were maintained, but unfortunately there was little written on the subject in 1991 when this study was initiated. We proceeded to validate a disease-specific outcome measure for calcaneal fractures[23]. This measure was then used in combination with the SF-36[22] to provide a high standard for clinical outcomes. The Outcome Scoring Scale of the American Foot and Ankle Society had not been published when this study was initiated nor was the validated Musculoskeletal Functional Assessments scale published. It was especially interesting to note that, as this particular study was being conducted, the clinical outcomes after operative and nonoperative care were so similar that we had to revise our projection for the number of patients needed to complete the study. With our present "negative" study, it is projected that we would need over 1200 patients per group to demonstrate small differences between operative and nonoperative treatment. However, stratification of demographic types revealed that characteristics such as age, gender, bilaterality, workload, Böhler angle, classification schemes, and the quality of the reduction can influence the results regardless of whether surgery is recommended. Patients who are younger, female, have a light or moderate workload involving the foot, and especially those who are not receiving Workers' Compensation do well with operative care. A larger Böhler angle seen on presentation (before surgery)[37] is prognostic of better results with operative care. We also found that it was apparently not possible to salvage a more severely injured foot (a lower Böhler angle on initial presentation) with operative care.

Regardless of treatment, patients who received Workers' Compensation scored significantly lower than those who were not receiving Workers' Compensation (Table IV). Patients receiving Workers' Compensation remain a challenge on the basis of both life satisfaction and injury measures. Quality of life scores such as the SF-36 may be limited in their ability to distinguish good surgical candidates and those better served by nonoperative treatment. The use of the SF-36 score in this case may not reflect patient satisfaction with recovery after operative or nonoperative treatment but may speak to the profile of the patient receiving Workers' Compensation.

The present study, because of its design and sample size, is of higher power than any comparable study done in the past[19]. Despite being a "negative" study, its prospective nature allows for stratification and development of high relative risk values and noteworthy 95% confidence intervals. Also, the characteristics of generalizability are an important consideration of a multicenter study such as this one. No difference was detected between treatment centers in relation to the scores or the quality of the reduction. However, we suspect that there is a learning curve with the treatment of this fracture, and we recommend that the fracture be treated by experienced surgeons with careful selection of patients.

Previous classification schemes such as those of Sanders[9], Essex-Lopresti[24], and Crosby and Fitzgibbons[25] have all been touted as being clinically useful, but this has not been proven in the literature. We found that the Böhler angle, or the loss thereof, is prognostic[37]. The most common classification used, the Sanders classification[9], received a vote of confidence from this study as patients with less comminution (a Sanders Type-II fracture) were 2.74 times more likely to score above the mean on the SF-36 scoring scale when treated operatively (Table V). This finding provides evidence that the fracture was not only the result of lower-energy trauma but was also easier to fix and more reliably reduced. The fractures with a higher (Type-IV) Sanders classification demonstrated no difference in results with respect to operative or nonoperative treatment. The other classification schemes, those of Crosby and Fitzgibbons and Essex-Lopresti, also showed trends indicating their usefulness in prognostication (Table V).

Patients who have a light or moderate workload before the injury are generally thought to have better outcomes with operative care[38]. Sixty-four percent of our patients returned to the same occupation after the injury. A light or moderate workload is usually possible after recovery from a displaced intra-articular calcaneal fracture; however, a heavy workload is often not possible after such a fracture, leading to patient dissatisfaction regardless of treatment type. This may be an important reason why patients receiving Workers' Compensation (often those who have a heavy workload) are often dissatisfied regardless of the treatment type.

The rate of wound complications (superficial and deep infections and wound sloughs) in this study was 16%, which is similar to that in many studies in the literature[12,15,39-41]. Certainly, we think that patients who are noncompliant in the initial management of soft-tissue swelling or who are smokers are not good surgical candidates. Soft-tissue management is extremely important, and early surgery (in the first few days) is not recommended. The surgeons in the study believed that,

if there was one area in which data collection could have been improved, it was in the area of patient profile and personality type. For example, our study was limited by a lack of information with regard to smoking status, alcohol use, body-mass index, and social or family support—all variables that may impact healing.

A difficult scenario unfolded within this trial with regard to patients who had failure of early treatment in either arm of the study and required a subtalar arthrodesis to treat severe, persistent pain within two years after the injury. We believed that the need for intervention in the form of an arthrodesis was important and that these patients should be analyzed separately[29]. The fact that they were removed from the final analysis and analyzed separately as patients in whom treatment failed in either the operative or nonoperative arm of the study does not invalidate the findings of this particular study. However, a nonoperatively treated patient is 5.5 times more likely than an operatively treated patient to need a subtalar arthrodesis[29].

This prospective, randomized trial demonstrated that nonoperative care is reasonable for selected individuals, while the need for a late subtalar arthrodesis can be predicted on the basis of demographic criteria such as Workers' Compensation involvement, a heavy workload, and a lower Böhler angle in a high proportion of male patients. When each of these features is combined with nonoperative care, the rate of arthrodesis is higher[29]. Perhaps this group should have an immediate arthrodesis rather than open reduction and internal fixation or nonoperative treatment. A randomized, controlled trial to investigate the treatment of high-energy injuries (Sanders Type-IV fractures) with open reduction and internal fixation or with a primary subtalar arthrodesis is required.

The present study has some limitations. We analyzed the differences within treatment arms to determine if outcomes depended upon treatment. A large number of bivariate comparisons were made between the operative and nonoperative groups to determine the magnitude of the association (odds ratio or relative risk) between scores and treatment. When a large number of comparisons are made, some of the findings may be significant by chance. If the magnitude of the association is large (a relative risk of >2.0), we can be reassured that the possibility of finding this result by chance alone is reduced. In the stratified analysis, many of the strata had small cell sizes and our power was reduced. In instances in which the relative risk is large (approaching 2.0) and the confidence intervals are wide (for example, the age-group variable among patients who were not receiving Workers' Compensation), we lacked the power to determine a significant difference between groups. We analyzed patients on a "total" SF-36 score and not with use of subscores. The latter technique may be more appropriate. Finally, as noted above, information on smoking status, personality type, and body-mass index was not collected.

In summary, this prospective, randomized, controlled multicenter trial demonstrated that operative treatment as a whole provides no improvement over nonoperative treatment of displaced intra-articular calcaneal fractures. However, careful stratification of the patient population and clinical outcome information distinguishes certain features that support surgical care for displaced intra-articular calcaneal fractures. Statistical analysis demonstrated that women, patients who were not receiving Workers' Compensation, younger males, patients with a higher Böhler angle, patients with a lighter workload, and those with a single, simple displaced intra-articular calcaneal fracture have better results after operative treatment than after nonoperative treatment. Anatomic or near anatomic reductions enhance outcomes while comminuted reductions or fractures without reduction produce long-term outcomes that are less satisfactory. Nonoperative care more commonly leads to late arthrodesis. The best patients to treat nonoperatively are those who are fifty years old or more, males, and those who are receiving Workers' Compensation and have an occupation involving a heavy workload. The results after a higher-energy fracture (a lower Böhler angle and more comminution) are not as good as those after a low-energy injury. ■

NOTE: The authors thank Bonnie Sobchak, the study coordinator, and the many Canadian orthopaedists who referred patients for the purposes of this study.

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In support of their research or preparation of this manuscript, one or more of the authors received grants or outside funding from the Orthopaedic Trauma Association and the Workers' Compensation Board of Alberta. None of the authors received payments or other benefits or a commitment or agreement to provide such benefits from a commercial entity. No commercial entity paid or directed, or agreed to pay or direct, any benefits to any research fund, foundation, educational institution, or other charitable or nonprofit organization with which the authors are affiliated or associated.

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