

Agren PH, Wretenberg P, Sayed-Noor AS. Operative versus nonoperative treatment of displaced intra-articular calcaneal fractures: a prospective, randomized, controlled multicenter trial. JBJS Am 2013;95(15):1351-7.

Design: Randomized clinical trial

Study question: Is there a difference in outcomes between operative and nonoperative treatment of displaced intra-articular calcaneal fractures?

Population/sample size/setting:

- 82 patients (23 women, 59 men) treated for calcaneal fractures at five emergency hospitals in Stockholm
- Eligibility criteria were an intra-articular calcaneal fracture with at least 2 mm displacement as verified by axial and coronal CT scans
- Exclusion criteria were peripheral vascular disease, an open fracture, uncontrolled diabetes, and medical contraindications to surgery

Interventions:

- Randomization was to operative (n=42) or nonoperative (n=40) treatment of the fractures
- Six weeks of non-weight-bearing was recommended for all patients, but range of motion exercises were allowed
- Operative treatment was done within two weeks of injury, after the soft-tissue swelling had subsided, and consisted of open reduction with the use of the lateral extensile approach and manipulation of the fracture fragments to achieve anatomic reduction
 - o Fracture fixation was done with screws (n=2), reconstruction plates (n=29), or calcaneal plates (n=11); bone graft was used in 4 cases
- Nonoperative treatment was rest, elevation, and non-weight-bearing with early range of motion exercises; no patient had impulse compression therapy

Outcomes:

- Followup evaluations were done by the treating surgeon at 2 weeks, 8 weeks, 3 months, and 6 months
- At 1 year and again at 8 to 12 years (average 10 years), followup evaluations were done by a surgeon not involved in the treatment
- The two primary outcome measures were a 100 point pain/function VAS and the SF-36
 - o The 100 point pain/function VAS asks the patient 12 items about pain frequency and severity, difficulties walking on level ground, uneven ground,

- and inclines, running, standing for long periods of time, and limping; the worst score is 0 and the best score is 100
- The assessing surgeon has 3 items for the patient's pain, gait, and overall result of the fractured calcaneus; the worst score is 0 and the best score is 100
 - Secondary outcomes included VAS pain at rest and during weight-bearing, the American Orthopedic Foot and Ankle Society (AOFAS) hindfoot score, and the Olerud-Molander scale
 - The Olerud-Molander scale recapitulates most of the items on the 100 point pain/function VAS
 - In the operated patients, postoperative axial and coronal CT scans revealed that 57% of the fractures had been reduced to less than 2 mm of displacement, 26% were reduced to 2-5 mm of displacement, 10% to more than 5 mm of displacement, and the remaining 7% were not available for review
 - Postoperative complications in the first 12 weeks included superficial wound infections treated successfully with dressing and antibiotics in 8 patients' a chronic MRSA infection led to amputation in one patient, a deep infection and fistula was treated with implant removal and antibiotics on one patient and one patient had a compartment syndrome treated with fasciotomy
 - In the non-operated patients, one had a compartment syndrome treated with fasciotomy; two patients, who were the only workers' compensation patients in the study, had severe foot symptoms and retired from their employment
 - At 1 year of followup, there were no group differences in the VAS pain/function scores on either the patient or the surgeon scoring; the SF-36 physical and mental scores also did not differ between groups
 - Similarly, the secondary outcomes at one year did not differ between groups
 - At one year, 12 of the operated group and 30 of the nonoperated group had CT evidence of subtalar arthritis with diminished joint space, sclerosis, osteophytes, and subchondral cysts
 - At the 8 to 12 year followup, there was a trend towards better VAS pain/function scoring by patients in the operated group, which was not statistically significant ($p=0.07$); the same was true of the physical scale of the SF-36 ($p=0.06$)
 - At the 8 to 12 year followup, there were no differences on the secondary outcomes between the two groups

Authors' conclusions:

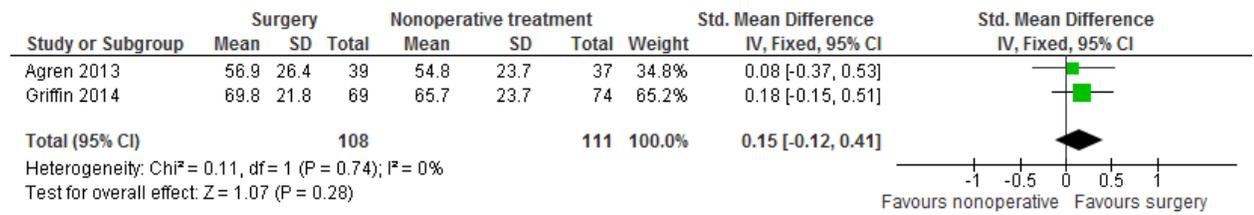
- Operative treatment of intra-articular calcaneal fractures was not superior to nonoperative treatment for reasons which could be multifactorial
 - There may have been too few patients to show a difference
 - The complex anatomy of these fractures could be a factor
 - The associated joint surface and soft tissue trauma could be a factor

- Although the CT scans suggested that operative treatment reduces the risk of subtalar arthritis by 41%, but this did not correlate with the measured outcomes, and secondary subtalar arthrodesis was not required
- Operative complications such as wound infection may be a problem for operative management of these fractures
- There was a trend toward better pain/function VAS scores at the later followup, but there were more complications with operative treatment

Comments:

- The primary outcomes were taken from a scoring system proposed by Hildebrand 1996, but the allocation of points among the items of the patient and physician scales is not clear; both scales add up to 100 maximum points, but there are 12 patient items and only 3 physician items
- Because of the presence of hardware, the radiographic analysis of subtalar arthrodesis could not be blinded
- Although the trend toward better 8-12 year outcomes in the operated group does not rise to the level of evidence, it does present problems toward an interpretation that the study is evidence of a lack of effectiveness of operative treatment
 - o Table IV, showing the primary outcome data at 8-12 years, shows an 11 point difference in the patient-reported pain/function VAS, but does not show confidence intervals for the difference
 - o However, these confidence intervals can be calculated from the sample sizes in Figure 1 at the end of the study, and from the standard deviations of the VAS scores; the 95% CI is from 22.9 points in favor of operative treatment to 0.9 points in favor of nonoperative treatment; an important difference in favor of operative treatment cannot be excluded
- No clear conclusion in either direction is supported by the results, but it is justified to infer that the effectiveness of surgical reduction of intra-articular calcaneal fractures is not established
- There are often fractures of the malleoli or other bones when the calcaneus is fractured, and nothing can be inferred about whether more complicated fractures should be managed operatively or nonoperatively
- A separate randomized trial of operative versus nonoperative treatment of calcaneal fractures (Griffin 2014) had similar patient selection criteria and used a comparable pain/function outcome at two years of followup, and the two studies can be combined to yield an estimate of treatment effect with a standardized mean difference (SMD) of 0.15 SD, with a confidence interval from 0.12 SD in favor of nonoperative treatment to 0.41 SD in favor of surgery
- A SMD of 0.20 to 0.50 is considered a small difference; a SMD of 0.50 to 0.80 is a moderate difference, and a SMD of 0.8 or more is considered a large difference; the

combined estimate from the two studies would fall short of even a small difference, but a small to moderate difference cannot be ruled out



- A previous Cochrane review of the same topic (Bruce 2013) was inconclusive with respect to the effect of surgery, but relied on a 2002 study which was methodologically of lower quality than either Agren or Griffin; the estimated effect size was of similar magnitude with respect to a combined VAS score at 3 years, and its relevance to current practice is uncertain.

Assessment: A methodologically high quality study which is not adequate by itself for evidence against operative treatment of calcaneal intra-articular displaced fractures due to limitations of sample size, but, in combination with a comparable study, does yield good evidence that the pain and functional difference between surgical and nonoperative treatment at one to two years is small and likely not to be clinically important. A clinically significant difference in favor of surgery at 8 or more years in preventing subtalar arthritis requiring arthrodesis cannot be ruled out.

References:

Bruce J, Sutherland A. Surgical versus conservative interventions for displaced intra-articular calcaneal fractures. Cochrane Database of Systematic Reviews 2013, Issue 1. Art. No.: CD008628

Hildebrand KA, Buckley RE, et al. Functional outcome measures after displaced intra-articular calcaneal fractures. JBJS Br. 1996;78B:119-23.

Griffin D, Parsons N, et al. Operative versus non-operative treatment for closed, displaced, intra-articular fractures of the calcaneus: randomised controlled trial. BMJ 2014;349:g4483.