

**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.**

Design: Randomized clinical trial

Study question: In patients with closed, displaced, intra-articular calcaneal fractures, does operative care lead to better outcomes than nonoperative care?

Population/sample size/setting:

- 151 patients (127 men, 24 women, mean age 46.5 ) treated for closed, displaced, intra-articular calcaneal fractures at 22 specialty hospitals in the UK
- Eligibility criteria were a recent (less than 3 weeks) closed, intra-articular, displaced (at least 2 mm) calcaneal fracture
- Exclusions were gross deformity of the hindfoot with such severe calcaneal varus as to cause the patient to walk on the tip of the fibula, or to embed the tip of the fibula in the lateral wall of the calcaneus; other leg injuries sufficient to affect functional outcome measures, peripheral vascular disease or other medical reasons not to operate, or inability to adhere to treatment plans

Interventions:

- Randomization was to either operative (n=73) or nonoperative (n=71) treatment
- Initial management for all patients was bed rest, analgesia, elevation of the foot, and application of ice
- Operative treatment consisted of open reduction and internal fixation with an extensile lateral approach with inter-fragmentary screws and a neutralization plate, considered the standard of care in the US and the UK
  - o Postoperative care entailed six weeks of non-weight-bearing in a splint, followed by six weeks of partial weight bearing, but with early active mobilization of the ankle and subtalar joints, managed by a standardized physical therapy program
- Nonoperative treatment began with gentle mobilization of the ankle and subtalar joints and the fitting of a removable splint; the weight-bearing and PT regimen was the same as for the operated patients

Outcomes:

- The primary outcome was the Kerr-Atkins calcaneal fracture score
  - o This is measured on a 100 point scale in which a score of 80-100 represents minimal pain or minor restrictions in walking ability (occasional use of a

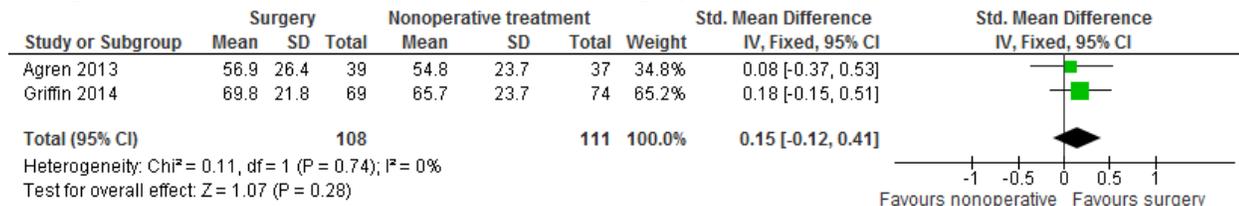
- walking stick); 60-80 represents moderate pain, restricted walking, and more than occasional use of a walking stick
  - A minimal clinically important difference of 15 points was the primary outcome and was measured 2 years after the injury
- There were some secondary outcomes, such as the SF-36 and EuroQol EQ-SD for quality of life, as well as the American Orthopedic Foot and Ankle Society (AOFAS)
- Followup questionnaires were sent at 6, 12, and 18 months, but the two year score on the Kerr-Atkins scale remained of primary interest
  - A physical therapist blinded to treatment status by the patient wearing thin socks did some gait and range of motion measurements at two years as well
- 51 of the operated patients had followup CT scans to show the accuracy of fracture reduction; there was no more than a 2 mm displacement in 40 patients, a residual step of more than 2 mm in 7 patients, and a residual step greater than 2 mm and poor alignment of the calcaneal body in 4 patients
- The mean Kerr-Atkins scores at 2 years were nearly equal in the operated group (69.8) and nonoperated group (65.7); the mean difference, adjusted for baseline score, age, sex, and severity variables, was 0.0, with 95% confidence intervals from 7.1 in favor of operative treatment to 7.0 points in favor of non-operative treatment
- The secondary outcomes and the gait scores assessed by the blinded physical therapist also did not differ between groups
- There were significantly more complications in the operated group (17/73) than in the nonoperated group (3/78)
  - Surgical site infection (n=14) was the most common complication, requiring remedial surgery in 5 cases
  - 3 more reoperations were required to remove painful screws and plates
  - There were 3 cases of subtalar arthritis requiring arthrodesis in the group which was not operated on; no patients in the operated group had arthrodesis for subtalar arthritis
- An as-treated analysis was done to supplement the intention-to-treat analysis, since there were 8 crossovers; the results did not change any conclusions

#### Authors' conclusions:

- Surgical treatment does not improve the outcomes of closed, displaced calcaneal fractures compared with nonoperative treatment, and leads to an increase in serious complications
- Later followup could reveal differences in rates of progression of arthritis and the need for late subtalar surgery; a five year followup is being planned for this purpose
- The confidence intervals for the treatment benefit exclude a treatment effect of 10 points, and the study was large enough to detect this difference if it exists

#### Comments:

- The outcome scale used in the study was described by Kerr 1996, and allocates 36 points for pain at rest and with activity, 25 points for working ability, 25 points for walking ability, and 14 points for the use of walking aids
- A separate randomized study (Agren 2013) of nonoperative versus operative treatment used a pain/function scale which also combines pain and function and also is weighted toward function, and used similar patient selection criteria, making it possible to combine the estimates 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
- Calcaneal fractures are often accompanied by other fractures and various levels of soft tissue injury, and there is insufficient information to rule out the possibility of subgroups of patients who would have better outcomes with than without surgery, since the sample size is still too small to identify statistical interactions and treatment effect modifiers
- 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, in combination with a second comparable study, yields good evidence that the difference between surgical and nonoperative treatment of most calcaneal fractures is unlikely to be clinically important at one to two years after injury. Longer term differences with respect to subtalar arthritis, requiring later arthrodesis, cannot be ruled out.

References:

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.

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

Kerr PS, Prothero DL, Atkins RM. Assessing outcome following calcaneal fracture: a rational scoring system. *Injury* 1996;27:35-8.