Sanders DW, Tieszer C, et al.Operative versus nonoperative treatment of unstable lateral malleolar fractures: a randomized multicenter trial. J Orthop Trauma. 2012;26(3):129-34.

Design: randomized clinical trial

Purpose of study: to compare the effectiveness of surgical and nonoperative treatment of isolated unstable fractures of the lateral malleolus

Population/sample size/setting:

- 81 patients (41 men, 40 women, mean age 41) treated for acute fractures of the lateral malleolus at the University of Ontario
- Entry criteria were skeletal maturity but age under 65 with isolated Weber B fractures, with no evidence of talar shift on x-rays of the injury and with a positive external rotation test
    - A positive stress examination was defined as an increase in the medial clear space (MCS, the interval between the medial edge of the talar dome and the lateral edge of the medial malleolus) of 1 mm or more when an external manual stress was placed on the foot as the tibia was stabilized; an absolute MCS of 5 mm or more was also a criterion for a positive stress examination
- Patients with fracture of the medial malleolus were excluded

Interventions:

- Patients were randomized to operative treatment (n=41) or nonoperative treatment (n=40)
    - Operative treatment consisted of open reduction and internal fixation of the fracture within two weeks of injury using direct reduction with lag screw fixation followed by splinting in neutral dorsiflexion for 2 weeks, followed by early mobilization and protected weight bearing in a removable cast until the 6 week visit
    - Nonoperative treatment consisted of a plaster or fiberglass cast or brace with protected weight bearing (using crutches) for 6 weeks; these patients were reviewed 1 or 2 weeks after randomization to ensure appropriate cast or brace fit
- In all patients, cast and brace treatment was terminated at 6 weeks and full weight bearing was encouraged following instruction from a physical therapist regarding mobilization exercises

Outcomes:

- Followup was done at 6, 12, 24, and 52 weeks

- The principal outcome was the physical component score (PCS) of the SF-36 and the joint-specific Olerud-Molander assessment (OMA) of ankle function
- There was a difference in mean total SF-36 scores between men (59.78) and women (42.76) at baseline
- There was no statistically significant difference between operated and nonoperated groups at any of the followup time points for the PCS or OMA scores
- There were some radiographic differences between groups at followup
    - At 12 weeks, delayed union was defined as lack of bridging callus on 3 of 4 cortices
    - At 24 weeks, nonunion was defined as lack of cortical bridging or a visible fracture line
    - 8 patients in the non-operated group, compared to none in the operated group, met the definition of delayed union or nonunion
    - All patients eventually achieved union within 12 months of fracture
    - Radiographic misalignment, manifested as a MCS of 5 mm or more, was seen in 8 non-operated patients but in only 1 operated patient
        - 1 patient with misalignment crossed over from non-operated treatment to surgery 2 weeks after enrollment; the others did not require surgery
        - The operated patient with misalignment had a second operation 7 months after surgery
- Infection was recorded in 6 operated patients, 1 requiring irrigation and debridement and delayed removal of hardware; 3 patients were treated with antibiotics for possible cellulitis
- 5 patients in the operated group required removal of hardware and 2 additional patients had broken screws not requiring removal

Authors' conclusions:

- In this study, 81 patients with isolated fibular fractures and positive stress examinations had comparable functional outcomes whether treated operatively or nonoperatively
- The differences in radiographic alignment and rates of achievement of fracture union are of uncertain functional significance, but could be of concern in nonoperated patients
- Even though the misalignment was slight, the risk of development of arthritis is unknown
- Older and less active patients can be treated safely with immobilization, and in younger patients, the observed risk of misalignment supports a consideration of operative treatment

Comments :

- There is not a Table I displaying baseline balance of characteristics (such as age and sex), which is a limitation, but not necessarily a fatal flaw, since the main outcome variables of PCS and OMA are balanced at baseline
- The method of characterizing Weber B fractures as unstable, using the stress test described in the methods, appears to be fairly novel but also appears to be gaining widespread use, and could be used to clarify the classification of these fractures
- Presumably, most Weber B fractures, involving rupture of the anterior inferior tibiofibular ligament and a spiral or oblique fracture of the fibula, are stable and generally do well with 6 weeks of immobilization and limited weight bearing; it is this subset of potentially unstable fractures whose management is a matter of controversy and prompted the study to be undertaken
- The conclusion that age is a consideration in treatment of the fracture is reasonable but is based on clinical judgment rather than on a presentation of data in the study

Assessment: adequate for some evidence that in the setting of Weber B fractures of the ankle, in which there is a positive manual external rotation stress examination, in which there is a widening of the radiographic interval between the medial edge of the talar dome and the lateral edge of the medial malleolus upon external rotation of the foot, there are equally good functional outcomes and equally prompt recoveries with operative and with nonoperative treatment. This conclusion should be qualified to note that radiographic malalignment of uncertain functional importance is more often observed with nonoperative treatment, and that younger patients and more active patients warrant consideration of operative treatment