

**Saltzman CL, Hillis SL, et al. Motion versus fixed distraction of the joint in the treatment of ankle osteoarthritis: a prospective randomized controlled trial. J Orthop Trauma. 2012;26(3):129-34.**

Design: randomized clinical trial

Study question: In patients with ankle osteoarthritis who are being treated with distraction, are there differences in outcome between fixed distractors which allow no ankle motion and hinged distractors which allow for some ankle motion?

Population/sample size/setting:

- 36 patients (12 men, 24 women, mean age 42) treated for ankle osteoarthritis at the University of Iowa
- Eligibility criteria were skeletally maturity with age under 60, symptomatic isolated unilateral Kellgren-Lawrence grade 3 or 4 OA with failure of at least one year of nonoperative treatment with NSAIDs and unloading treatments such as braces and walkers, but with capacity to main extremity non-weight-bearing with the use of walking aids
- Exclusion criteria were findings suggesting inflammatory arthritis, crystal deposition disease, fibromyalgia, diabetes, peripheral neuropathy, complex regional pain syndrome, or previous infection of the ankle region, contralateral ankle OA, presence of other symptomatic joints in the ipsilateral lower extremity, and ankle/hindfoot malalignment

Interventions:

- All patients had arthroscopic ankle joint lavage with removal of osteophytes and placement of a circumferential fixator secured with 5 mm half-pins and a crossing wire tensioned to 110 to 130 pounds, and was left in place for 12 weeks before being removed
  - o After fixator removal, all patients had a removable below-the-knee Velcro-strapped rocker-bottom boot for one month, when weight-bearing was allowed; over a period of 6 months, the patient gradually progressed to full weight bearing
- Randomization was to either a fixed (n=18) or a motion distractor (n=18), using envelopes which were opened after the arthroscopy had been performed
  - o The fixed group had distraction rods without hinges
  - o The motion group had a distraction rod with hinges and an unhinged posterior rod which could be detached during motion therapy, and this group was instructed in passive dorsiflexion and plantar flexion of the ankle 3 times per day with 20 repetitions each for weeks 2 through 12

## Outcomes:

- Followup was done at 1 week, 26 weeks, 52 weeks, and 104 weeks after fixator removal
- The primary outcome was the change in the overall Ankle Osteoarthritis Scale (AOS) at 52 and at 104 weeks
  - o Secondary outcomes were ankle range of motion on flexion-extension films, the pain and disability AOS subscale scores, and the SF-36 physical component scores
- In the motion group, no patients were lost to followup; one patient had conversion to an arthrodesis between weeks 52 and 104, leaving 17 patients in the analysis
- In the fixed group, 3 were lost to followup and 3 discontinued the intervention to have arthrodesis, leaving 12 patients in the analysis
- The mean AOS scores were similar at baseline (63.14 in the motion group and 62.77 in the fixed group), but the values at 52 and 104 weeks favored the motion group
  - o At 52 weeks, the mean AOS scores for the motion and fixed groups were 33.09 and 54.69 respectively
  - o At 104 weeks, the mean AOS scores were 26.61 and 48.78 respectively
- The ankle range of motion on the flexion-extension films were similar between groups
- Adverse events were common but were not related to treatment group
  - o Any redness, increasing pain, warmth, drainage, or swelling around a pin was classified as a probable infection and treated with oral cephalexin for 7 days
    - There were 43 such treated episodes of presumed infection in 19 of the 36 patients
  - o Signs of infection persisted in 4 patients, leading to pin removal; 2 of these patients were thought to have acute osteomyelitis and treated with 6 weeks of intravenous antibiotics
  - o 2 patients had residual numbness in the area of the medial calcaneal branch of the tibial nerve

## Authors' conclusions:

- Treatment with a hinged motion distractor led to better AOS scores than treatment with a fixed distractor at 52 and 104 weeks
- Even though there were a total of 7 patients in the fixed group without data for analysis at 104 weeks, the missing data were probably missing at random and not related to any unobserved outcomes that occurred after the patients were lost to followup
- Many of the presumed infections were probably related to other causes, such as skin irritation, rather than to true infection

- Ankle distraction is not for patients who want a rapid and easy resolution of ankle OA symptoms, since treatment entails three months in the distractor followed by a gradual resumption of weight bearing; results may not be seen until one year has elapsed after the operation to place the distractor

Comments:

- The authors analyzed only the patients who remained in the study and did not have arthrodesis, even though these patients probably could have had ascertainment of the AOS scores
- The assumption of data missing at random is more in the nature of a conjecture than based on solid evidence, since the study is too small to allow for an adequately powered test of that assumption
- However, the analysis is not likely to create a significant bias to inflate the benefits of motion distraction, since the 3 arthrodeses in the fixed group could reasonably be classified as treatment failures, whose inclusion in the analysis would not have improved the outcomes of the fixed group in comparison with the motion group
- The high rate of apparent infection and the lengthy duration of the distraction placement could present obstacles to its widespread acceptance in patients with OA, but if this option is chosen, the use of a hinged distractor which allows for ankle motion is likely to improve ankle function at the end of one and two years

Assessment: Adequate for some evidence that when an external distractor is used to treat ankle osteoarthritis in patients under 60, a hinged device which allows for ankle flexion and extension is to be preferred over a fixed distractor which allows for no ankle motion