

Gibson JN, Thomson CE. Arthrodesis or Total Replacement Arthroplasty for Hallux Rigidus: A Randomized Controlled Trial. Foot Ankle Int 2005;26:680-690.

Design: Randomized Clinical Trial

Purpose of study: to compare effectiveness of arthrodesis versus arthroplasty for end stage first MTP joint arthritis

Population/sample size/setting:

- 63 patients (77 feet, 26 men, 37 women, mean age 55) with metatarsophalangeal joint (MTPJ) osteoarthritis treated in a foot and ankle surgery department in Scotland
- All eligible patients had pain on movement of first MTPJ and radiographic evidence of joint arthritis consistent with hallux rigidus, and had had at least 3 months of conservative treatment, including anti-inflammatory medication, orthoses, and shoe modifications
 - o Cheilectomy was excluded as an option by the surgeons based on significant metatarsal head cartilage erosion
- Exclusion criteria were history of systemic joint disease, prior MTPJ surgery, or interphalangeal joint arthritis

Interventions:

- All were scheduled for surgery with either arthroplasty or arthrodesis
- Randomized immediately prior to surgery to arthroplasty (39 feet, 27 patients) or arthrodesis (38 feet, 22 patients), using opaque envelopes
- All operations were performed by Gibson
 - o Arthrodesis was done by fixing the joint with a stainless steel cerclage wire stabilized by a 2 mm Kirschner wire, with a fiberglass cast applied 24 hours after surgery, when the patient was allowed to partially bear weight, and most were discharged after 48 hours
 - o Arthroplasty was done with an unconstrained metatarsal prosthesis made of cobalt chrome and a phalangeal component made from titanium, excising the lateral sesamoid; cement was not used for the joint replacements
 - Feet were kept elevated for 48 hours after surgery, and then patients were allowed to bear weight on the heel; most were discharged at 72 hours
 - After 10 days, the sutures were removed and a standardized course of exercise was begun
- One protocol deviation occurred after first 30 arthroplasties when 5 patients complained of joint pain and x-ray showed radiolucent line around phalangeal components; the remaining 9 arthroplasties were done with cementing of phalangeal component

Outcomes:

- Both groups improved equally in the maximal distance they could walk comfortably from baseline to 24 months

- Pain scores improved in both groups from baseline to 6, 12, and 24 months, but arthrodesis group had larger pain improvements on 100 point VAS (decreased from baseline of 62 to 24 month score of 11 in arthrodesis group; decreased from 60 to 27 in arthroplasty group)
- 6 revisions were done in arthroplasty group for pain and bone resorption; one patient developed reflex sympathetic dystrophy
- 7 of the 22 patients who had arthrodesis developed discharges around their Kirschner wire; Staph aureus was cultured in all cases and a short course of antibiotics resolved the symptoms
- All of the arthrodeses united, although for 6 patients, union was not evident until the 12 month followup
- At 24 months, 1 patient in arthrodesis group and 12 patients in arthroplasty group indicated that they would not have the same surgery again
- Other specialized outcome measurements were done, including measurement of plantar pressure using an insole system with capacitance transducers

Authors' conclusions:

- Both arthrodesis and arthroplasty were beneficial to most patients
- Arthroplasty was superior to arthrodesis in terms of pain and function
- Phalangeal component loosening was frequent in arthroplasty patients and is unacceptably common

Comments:

- It is not clear that the assessment of functional scores such as walking distance was done without awareness of the treatment assignment
- Phalangeal component loosening could only occur in arthroplasty group and cannot be expected to be done blinded, but the decision that revision surgery was necessary could have been influenced by a bias against arthroplasty
- It was reported that arthroplasty costs were twice those for arthrodesis, but the UK system cannot be translated to the US system
- The protocol deviation (cementing the last nine arthroplasties) would be expected to favor the arthroplasty intervention; thus, it seems likely that a bias against arthroplasty on the part of the surgeon would have been a major factor

Assessment: adequate for an evidence statement that first M-P joint arthritis is better treated with arthrodesis than arthroplasty for pain and functional improvement