Ayhan FF, Ustun N. The evaluation of efficacy and tolerability of Hylan G-F 20 in bilateral thumb base osteoarthritis: 6 months follow-up. Clin Rheumatol 2009;28:535-541.

Design: Randomized clinical trial

Population/sample size/setting:

- 33 right-handed women (mean age 62.6) treated for bilateral thumb OA at a university division of hand rehabilitation in Ankara, Turkey
- Eligibility criteria were thumb base of Eaton stage 1-4, with pain VAS> 40 on a 100 mm scale, failure of NSAID, PS, steroid injection, and splinting, but with no injection in the past 6 months or pain medication in past 2 weeks
- Exclusion criteria included pregnancy, prior surgery of thumb or wrist, history of infection or inflammatory arthritis of the affected joint

Main outcome measures:

- Every patient received an injection (without fluoroscopy) at the bases of both thumbs; the randomization was which thumb received which injection
- The experimental injection was 1 ml of hyaluronic acid (Hylan G-F 20); the control injection was 1 ml of saline
- Under Eaton classification, there were 19 patients with stage 1, 8 with stage 2, 1 with stage 3, and 5 with stage 4, symmetrically bilateral
- Follow-up visits were scheduled 6 weeks and 6 months after the injections
- Several outcomes were measured at follow-up: pain VAS, Dreiser index, and 3 modes of pinch-grip testing
- Dreiser index asks the patient to assess difficulty of 10 activities of daily living (turn a key in a lock, cut cloth with scissors, tie a knot, fasten buttons, write with hand, accept handshake, etc)
- Pinch strength measurements were pulp to pulp (distal index finger with distal thumb), tripod (distal thumb, index, and middle fingers), and key pinch (thumb with radial aspect of index finger)
- Pain VAS scores for hylan group decreased significantly between baseline and the 6 month follow-up, but did not decrease significantly for the control group at the 6 month follow-up
- Improvement of Dreiser functional scores was slower than for pain; improvement for the hylan group was seen at 6 months, but not at 6 weeks; in the control group, no functional improvement was observed
- Pinch strength improvements were recorded in the hylan group between baseline and 6 months; for the control group, no improvements in pinch strength were observed

Authors' conclusions:

- A single intra-articular injection of hylan was effective on pain and function at 26 weeks of follow-up for thumb base OA
- Precise injection into the joint space could not be confirmed, and this may have limited the effectiveness of the injections

- Intra-articular hylan should be considered prior to surgery in thumb OA patients, but further large trials are needed

Comments:

- The results are presented graphically rather than in tables; therefore, the numerical scores for the outcomes are not precisely reported
- However, because non-parametric testing was used, the numerical values of the scores, if reported, would not have allowed confidence intervals to be calculated and reported
- There were 4 dropouts among the patients with grade 4 disease because of knee surgery; it is not clear why these exclusions were necessary, unless there was reason to believe that the knee surgery would have altered the measurements of hand function
- The results are reported as before-after score differences (baseline to 6 weeks, baseline to 6 months); however, because each patient received an injection in each thumb, each patient would have available a hylan-saline difference score at 6 weeks and at 6 months; this would have been valuable, but does not seem to have been reported
- If the guideline were to list hylan as a treatment option, it will be necessary to identify it as off-label use, since FDA labeling is only for knee OA

Assessment: Adequate for an evidence statement that intra-articular OA is more effective than saline for thumb OA pain and function at 6 months