

**Heyworth BE, Lee JH et al. Hylan Versus Corticosteroid Versus Placebo for Treatment of Basal Joint Arthritis: A Prospective, Randomized, Double-Blinded Clinical Trial. J Hand Surg 2008;33A:40-48.**

Design: Randomized clinical trial

Brief summary of findings:

- 60 patients (8 men, 52 women, mean age 63) with osteoarthritis of the basal thumb joint, enrolled from the 2 senior authors' practices at Columbia University in New York
- Inclusion criteria were age over 40 and a clinical diagnosis of thumb OA: basal joint tenderness, thumb/wrist pain at rest or with activity, joint stiffness, decreased mobility, deformity, instability, and decreased function
- Exclusion criteria were pregnancy, prior surgery on affected thumb or wrist, infection, inflammatory arthritis, or allergy to eggs, feathers, or avian products
- Previous injection was an exclusion criterion if the injection had been in the past 6 months, if 3 or more injections had been given, or if 1 or 2 injections had been given without pain relief or functional improvement
- Patients who had had 1 or 2 injections more than 6 months earlier were included if they had had at least moderate improvement, because they were expected to have another good response to a further injection
- Each patient had 2 injections of 1 ml spaced one week apart, randomized to 3 treatment groups: saline for both injections (n=18), saline for the first injection and betamethasone for the second injection (n=22), or hylan for both injections (n=20)
- Injections were given through an opaque syringe, and outcome evaluations were done by a blinded clinician
- Multiple outcomes were measured at baseline and at 2, 4, 12, and 26 weeks, with the 26 week result being the primary end point of the study
- Pain VAS, DASH (Disability of Arm, Shoulder, Hand), ROM (range of motion), grip strength, patient global assessment of improvement, and 2 measures of pinch strength were used; each patient was also asked to keep a daily diary of use of splints and of NSAIDs
- Few differences were observed between treatment groups for any outcome
- Some differences were recorded within groups; grip strength increased between baseline and 26 weeks for the hylan group, but decreased for the control and steroid groups

Authors' conclusions:

- Current trial does not show superiority of hylan injections to steroid or saline
- Injections were well-tolerated, but because of the small size of the basal joint, it may be more susceptible to inaccurate or extra-articular deposition of injectable material than the knee joint
- Hylan is comparable to steroid, may be a useful alternative to steroid, and can be performed with little or morbidity

Comments:

- Authors show appropriate caution in interpreting their data (no superiority of hylan to steroid or saline), but if hylan is not superior to saline, it is not clear why it should be entertained as an alternative treatment
- Although statistical analysis is well-planned, the execution of the plan and the presentation of the results lack clarity—there need to be estimates of effect size and of uncertainty (i.e., 95% confidence intervals)
- The inclusion and exclusion criteria allowed entry into the trial of patients who had had 1 or 2 previous injections if they had responded positively, but not if they had failed to respond; this will produce a patient population which is biased in favor of responders, who may not represent the population likely to be considered for injection treatment; the number of exclusions for this reason are not specified
- Multiple comparisons are made, but no discussion of adjustment of Type I error is made; since the authors do not conclude that their “statistically significant” p values of 0.05 demonstrate the efficacy of their injections, this does not undermine the conclusions of the study

Assessment: Inadequate for any evidence statement regarding hylan or steroid (likely bias in entry criteria, unclear presentation of precision of results)