Synvisc® lindert Schmerzen effektiv bei Arthrose des oberen Sprunggelenkes

A prospective multi-centre, open study of the safety and efficacy of hylan G-F 20 (Synvisc) in patients with symptomatic ankle (talo-crural) osteoarthritis

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Purpose: To evaluate the safety and efficacy of hylan G-F 20 viscosupplementation in patients with symptomatic osteoarthritis (OA) of the ankle.

Methods: Prospective, multi-center, open study in patients with primary or secondary grade II talocrural OA confirmed by X-ray. At baseline, patients had to score between 50-90 mm on the Patient-completed Ankle OA Pain VAS (0 -100 mm). Patients received one intra-articular injection of 2 ml of hylan G-F 20 and were given an option of a second and final 2 ml injection if their pain remained between 50-90 mm on the VAS after 1, 2 or 3 months. Intra-articular injections were placed in the anteromedial portal of the ankle joint as described for ankle arthroscopy. Patients were followed for 6 months after the final injection. As rescue medication, patients could only take paracetamol up to 4 g per day, except on the day of or the day before a study visit. All treatment emergent adverse events (AEs) were recorded. The primary efficacy endpoint was change from baseline (at final injection) in the Ankle OA Pain VAS at 3 months after the final injection. Secondary endpoints were Ankle OA Pain VAS scores at all other time-points, total Ankle OA Scale, Patient and Physician Global OA Assessment (VAS), and health-related quality of life (SF-36).

Results: Fifty-five patients (33 M; 22 F) were enrolled and received a first injection of hylan G-F 20. Twenty-four patients (44%) received a second injection. The mean age was 41 years (range 19-70). Overall, treatment with hylan G-F 20 was well tolerated. Seventeen patients (31%) had a treatment related AE of the target ankle. All were of mild or moderate intensity, the majority consisting of arthralgia and injection site pain. There was a statistically significant decrease in Ankle OA Pain VAS score from 68.0 mm at Baseline to 33.8 mm at Month 3 ($p<0.001$, paired t-test), which was maintained at 6 months followup. The decrease was statistically significant at all time points. Patients who received only 1 injection demonstrated a greater decrease at 3 months (-42.5 mm) than patients with 2 injections (-23.5 mm). The secondary efficacy endpoints showed similar results. Of the total study population, 29 patients (53%) were responders (i.e. at least a 50% decrease in ankle OA pain) after 3 months. 64% of patients receiving 1 injection were responders after 3 months. The SF-36 questionnaire showed statistically significant improvements for both the physical and mental component scores at 3 and 6 months follow-up.

Conclusions: Treatment of OA of the ankle with intra-articular hylan G-F 20 injections is well tolerated. Treatment with hylan G-F 20 significantly decreases pain which is maintained for up to 6 months.