

Synvisc® kann Post-Arthroskopie-Schmerzen über 52 Wochen lindern

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Multicentre, prospective, open study to evaluate the safety and efficacy of hylan G-F 20 in knee osteoarthritis subjects presenting with pain following arthroscopic meniscectomy.

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The aim of the study was to evaluate the safety and efficacy of viscosupplementation with hylan G-F 20 in patients with mild to moderate osteoarthritis (OA) presenting with persistent knee pain 4-12 weeks after arthroscopic meniscectomy. A prospective, multi-centre, open study was carried out in patients with pain due to OA of the knee, not resolved by simple analgesics, 4-12 weeks after undergoing arthroscopic meniscectomy. To be eligible, patients had to score ≥ 50 mm and ≤ 90 mm on both walking pain and patient global assessment visual analogue scales (VAS; 0-100 mm) at baseline and be radiologically diagnosed pre-operatively with OA grade I or II on the Kellgren-Lawrence scale, with $< 50\%$ joint space narrowing. Patients received three intra-articular, 2 ml injections of hylan G-F 20 in the target knee with an interval of 1 week between injections, and were followed for 52 weeks. The primary efficacy endpoint was the change from baseline in the walking pain VAS score at 26 weeks. Secondary outcome measures were the walking pain VAS scores at all other time points, the WOMAC Index at all time points, and patient and physician global assessment at all time points. The safety of the treatment was assessed using adverse event (AE) reports. A total of 62 patients (mean age 55.4 years, 52% male) were enrolled. The mean walking pain VAS score decreased by 36.8 mm from baseline at 26 weeks ($P < 0.0001$), and also showed statistically significant decreases ($P < 0.0001$) at all other time points. The change in WOMAC total and subscale scores from baseline were statistically significant ($P < 0.0001$) at all time points, as were the decreases in the physician and patient global assessment VAS scores. There were 18 target knee AEs (mostly pain and/or swelling and/or effusion) in 12 patients (19%) considered to be at least possibly related to treatment. The majority of these (78%) were mild or moderate in intensity. One patient (1.6%) experienced a serious adverse event (synovitis) in the target knee that was considered possibly related to study treatment. Hylan G-F 20 provides effective pain relief and improves stiffness and physical function in patients with mild to moderate OA presenting with persistent osteoarthritic pain 4-12 weeks after arthroscopic meniscectomy. Symptomatic efficacy was maximised at 12 weeks and maintained at 26 and 52 weeks. The type (pain and/or swelling and/or effusion) and the intensity (mostly mild/moderate) of AEs reported in this study are similar to those reported in other trials in different patient populations, but the incidence was higher (19%). The risk/benefit of hylan G-F 20 in this particular population of patients is favourable.

