Clinical Summary

Publications

Product	***Gel-One*® Cross-linked Hyaluronate (*Gel-One* Hyaluronate)**
Authors	V. Strand, H.S.B. Baraf, P.T. Lavin, S. Lim, H. Hosokawa
Title	A multicenter, randomized controlled trial comparing a single intra-articular injection of Gel-200 (*Gel-One*® Cross-linked Hyaluronate), a new cross-linked formulation of hyaluronic acid, to phosphate buffered saline for treatment of osteoarthritis of the knee
Language	English
Journal	Osteoarthritis and Cartilage 20 (2012) pp. 350-356

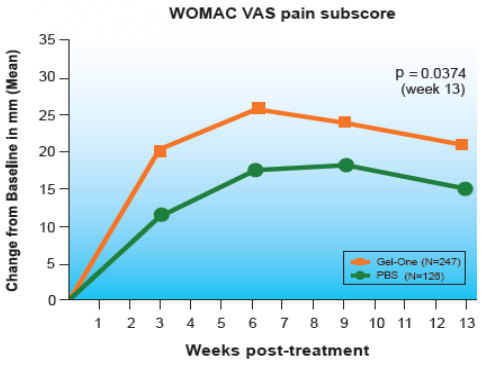
Methodology

A study was conducted to compare the safety and efficacy of *Gel-One* Hyaluronate with phosphate buffered saline (PBS) in the treatment of osteoarthritis (OA) of the knee. *Gel-One* Hyaluronate is a sterile, clear, viscoelastic hydrogel composed of crosslinked hyaluronate, which is a derivative of a highly purified sodium hyaluronate. *Gel-One* Hyaluronate is indicated for the treatment of pain in OA of the knee in patients who have failed to respond adequately to non-pharmacologic therapy, non-steroidal anti-inflammatory drugs (NSAIDs) or simple analgesics (e.g., acetaminophen). Currently, there are five intra-articular hyaluronic acid (IA-HA) products offered in the United States, ranging from single injection treatment (Hylan G-F 20) to multi injection (3-5 injections) treatment. Past studies have shown that IA-HA injections are effective in relieving pain due to OA. This report summarizes the efficacy of *Gel-One* Hyaluronate in human subjects as compared with PBS. In a double-blind, multi-center RCT, the safety and effectiveness of a single injection of *Gel-One* Hyaluronate were demonstrated by treating patients with either *Gel-One* Hyaluronate or PBS in a 2:1 randomization ratio, with the majority of patients receiving *Gel-One* Hyaluronate. In the publication (and clinical study), *Gel-One* Hyaluronate was referred to as Gel-200. The primary measure of effectiveness was Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) by 100 mm Visual Analog Scale (VAS).

Results

The results indicate that a single intra-articular injection of *Gel-One* Hyaluronate is effective at week 13 and safely relieves pain associated with OA of the knee. Neither allergic reactions nor pseudosepsis were reported during this trial.

Measurements were taken at weeks 3, 6, 9, and 13 and included WOMAC pain subscores, Total WOMAC score, and WOMAC physical function subscores. No significant differences between *Gel-One* Hyaluronate and the PBS control were observed in the incidence of AEs related to the study treatment or overall. The below figure summarizes the results of the WOMAC Pain Subscore.



Key Take-Aways

1. At week 13, a statistically significant advantage of 6.39mm in the WOMAC pain subscore was observed for *Gel-One* Hyaluronate. Furthermore, the study showed a favorable safety profile for *Gel-One* Hyaluronate.
2. On average, patients in the *Gel-One* Hyaluronate study group experienced average pain relief of 39.3% (27.8 mm) from baseline[1].

1. Gel-One Patient Information

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