Gel-One® Cross-Linked Hyaluronate

A recently published subgroup analysis of a multicenter, randomized controlled trial with a focus on a subgroup of patients with non-posttraumatic OA, K-L score 2 or 3, WOMAC pain during walking (A1), WOMAC pain subscores of 40 to 80 mm, and ≥3 months' duration of OA pain showed statistically significant mean improvements from baseline in WOMAC pain subscores in patients treated with a single injection of Gel-One over patients treated with Phosphate Buffered Saline (PBS) and compared to results for competitive products published in other studies.

Primary Outcomes: Safety and Efficacy[1,2]

Harmful events for the Gel-One treatment group were predominantly mild or moderate and transient in nature. No device-related serious adverse events were reported. The incidences of TEAEs were similar in the Gel-One and the PBS treatment groups.[1]

In a subgroup analysis of a Gel-One Hyaluronate multicenter, randomized controlled trial, pain relief was assessed at weeks 3, 6, 12, 18, and 26 demonstrating statistically significant mean improvements from baseline over 26 weeks (P=0.032) as well as at 26 weeks (P=0.019) compared with a single injection of Phosphate Buffered Saline control (PBS). The treatment differences and mean changes from baseline were -4.5 mm over 26 weeks and -6.2 mm at 26 weeks on 100-mm VAS in WOMAC pain subscores.[2] This was the largest treatment difference at week 26 reported among the other IA-HA products, in separate studies.[3,4,5]**

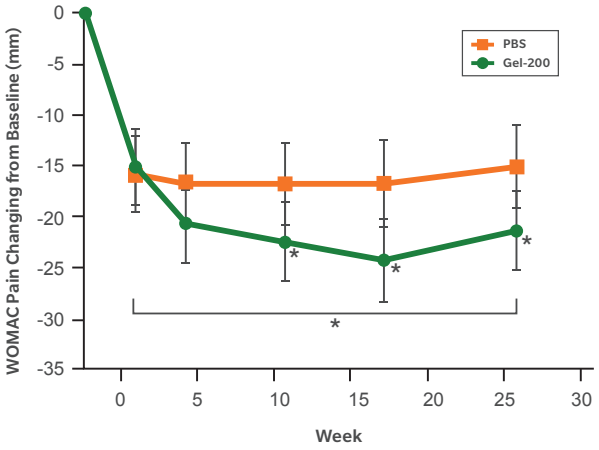

Figure 1. Change from baseline in Western Ontario and McMaster Universities Arthritis Index (WOMAC) pain subscores.
*$P < 0.05$

Secondary Outcomes[2]:

Gel-One demonstrated efficacy in WOMAC stiffness subscores, total scores, and physician global assessment. In separate studies**, no other IA-HA products showed statistically significant differences over PBS treatment except in WOMAC pain subscores when evaluating similar patient populations.[3,4,6,7,8]

Figure 2. Change from baseline in Western Ontario and McMaster

Measurements	Difference (mm)	95% CI	*P*
WOMAC function	-5.0	-10.1, 0.1	0.056
WOMAC stiffness	-6.6	-12.2, -0.9	0.023
WOMAC total	-5.4	-10.4, -0.4	0.036
Physician global evaluation	-7.3	-13.1, -1.6	0.013
Patient global evaluation	-5.1	-10.7, .06	0.078

WOMAC = Western Ontario and McMaster Universities Arthritis Index.

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**Results in separate studies may vary based on the procedures used in the separate studies.

References

1. Gel-One® Summary of Safety and Effectiveness Data (SSED)
2. Takamura J, Seo T, Strand V (2019) A Single Intra-Articular Injection of Gel-200 for Treatment of Symptomatic Osteoarthritis of the Knee Is More Effective than Phosphate Buffered Saline at 6 Months: A Subgroup Analysis of a Multicenter, Randomized Controlled Trial. Cartilage 10:417–422
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4. Altman RD, Rosen JE, Bloch DA, Hatoum HT, Korner P. A double-blind, randomized, saline-controlled study of the efficacy and safety of EUFLEXXA® for treatment of painful osteoarthritis of the knee, with an open-label safety extension (the FLEXX trial). Semin Arthritis Rheum. 2009;39:1-9.
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8. Food and Drug Administration. Summary of Safety and Effectiveness Data (SSED); MONOVISC™–P090031. 2014 [cited 2018 Jan 24]. Available from: https://www.accessdata.fda.gov/cdrh_docs/pdf9/P090031b.pdf.

Important Safety Information

Before using Gel-One Hyaluronate, ask your patients if they are allergic to hyaluronan products, cinnamon, or products from birds such as feathers, eggs, and poultry. Gel-One Hyaluronate is only for injection into the knee, performed by a doctor or other qualified health care professional. Gel-One Hyaluronate injection should not be used in the presence of a skin disease or infection around the area where the injection will be given. Gel-One Hyaluronate has not been tested to show pain relief in joints other than the knee and for conditions other than OA. Gel-One Hyaluronate has not been tested in patients who are pregnant, mothers who are nursing, or anyone under the age of 21. Strenuous or pro-longed weight-bearing activities after treatment are not recommended. The effectiveness of repeat treatment cycles of Gel-One Hyaluronate has not been established. The side effects most commonly seen after injection of Gel-One Hyaluronate in the clinical trial were knee pain, swelling, and/or knee effusion. These reactions are generally mild and do not last long. For complete instructions for use, see the package insert and visit www.zimmerbiomet.com.

Gel-One Hyaluronate is indicated for the treatment of pain in osteoarthritis (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.

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