

Gel-One® Cross-Linked Hyaluronate

Cushioning* & Chondroprotection**

Cushioning

As an axial force is applied to HA, its structure reorganizes and the elastic properties dominate. HA's elastic property in healthy synovial fluid protects cartilage by acting as a shock absorber and providing cushioning, when the joint is exposed to an axial force such as jumping¹ (Figure 1). In a laboratory setting, a texture analyzer applies a downward force on a test sample with a probe. The probe measures the amount of resistance or counter force produced by the test sample.

Results

When measured, the texture analyzer reveals that Gel-One hyaluronate produces a greater counter force than Synvisc/Synvisc-One® and the non-cross-linked HA. In this test, Gel-One hyaluronate provided 212% more counter force than Synvisc/Synvisc-One, and 338% more counter force than Non Cross-Linked HA (NCL-HA) (Figure 2). This means that Gel-One hyaluronate compressed less than the other HA materials.²

Counter Force Provided by HA

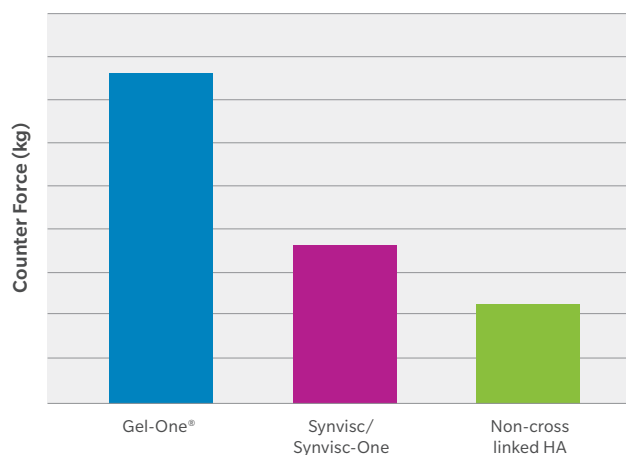


Figure 1: Counter force performance of Gel-One, Synvisc/Synvisc-One, and non-cross linked HA

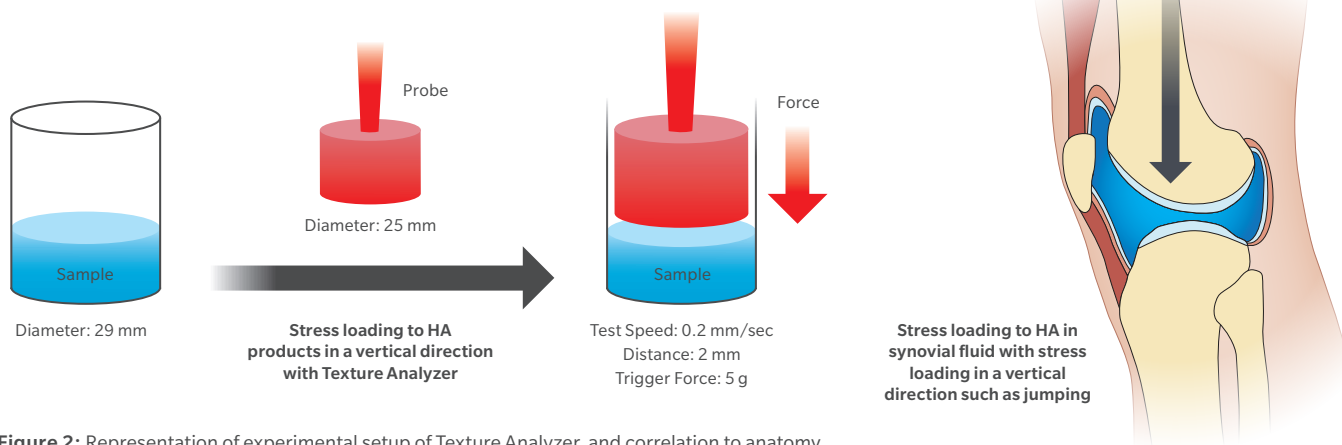


Figure 2: Representation of experimental setup of Texture Analyzer, and correlation to anatomy.

Chondroprotection

It has previously been reported that hyaluronic acid has chondroprotective properties, and can reduce cartilage wear.¹ It is possible that the viscoelastic properties of HA play a role in this function. According to a preclinical animal study, a single injection of Gel-One hyaluronate reduced cartilage wear and showed joint preservation effects.³

In this study, the ACLs of rabbits were surgically transected in order to mimic the pathological condition of OA. This model has been accepted as an arthritis model that produces cartilage degeneration similar to OA in humans.⁴ The rabbits were allowed to develop cartilage degeneration for 4 weeks, at which point animals that did not display abnormalities during observation were allocated into two groups. The experimental group was treated with a single injection of Gel-One hyaluronate, while the control group was treated with a single injection of phosphate buffered saline (PBS).³

Pictures of articular cartilage of the femoral condyle were observed at nine weeks after anterior cruciate ligament transection surgery. The lesions of cartilage wear and destruction were identified using india ink (blue arrow heads). The control group showed a larger percentage of test subjects with mild cartilage degeneration (Grade 1-3; 1 being mild and 3 being severe) than those treated with Gel-One hyaluronate (Figure 3).³

Figure 4 shows a histological image of articular cartilage of the femoral condyles. The Safranin O stain displays glycosaminoglycan (red) and bone and collagen fibers (green). As seen from the macroscopic level, in the Gel-One group cartilage degeneration was less severe compared with that of the control group. Overall, the Gel-One group had less cartilage degradation than the control group (Figure 4).³

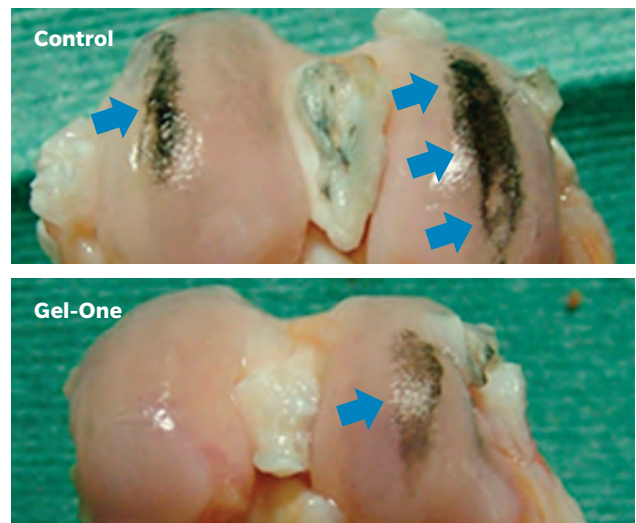


Figure 3: Gross morphological assessment of cartilage degeneration in the rabbit OA model

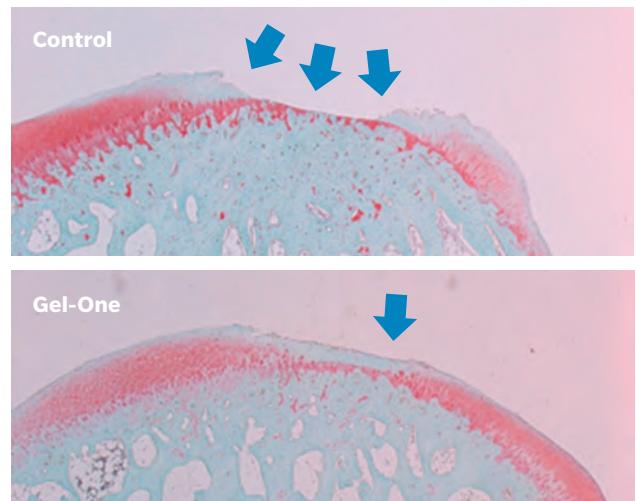


Figure 4: Histological examinations of cartilage degeneration in the rabbit OA model

References

1. Balazs, E. A. Viscoelastic properties of hyaluronic acid and biological lubrication. *UnivMichigan Med Ctr. J.* 1968;255-259. 2. Data on file at Seikagaku corporation. *Rheology* 3. K. Yoshioka *et al.* Pharmacological effects of novel cross-linked hyaluronate, Gel-200, in experimental animal models of osteoarthritis and human cell lines. *Osteoarthritis and Cartilage* 2014; 22:879-887. 4. Yoshioka M, Coutts RD, Amiel D, Hacker SA. Characterization of a model of osteoarthritis in rabbit knee. *Osteoarthritis Cartilage*. 1996;4:87-98.

* Lab testing not necessarily indicative of clinical results

** Animal studies not necessarily indicative of clinical results

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 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 or 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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