

Gel-One® Cross-Linked Hyaluronate

Resistance to Diffusion*

The cross-link bonds between the HA molecules result in a larger molecule. HA products can have different chemical structures which may impact its ability to diffuse through a membrane.

An *in vitro* mesh bag test was conducted to observe how long each HA product remains in the mesh bag. In this study, both water and the HA product are free to move in and out of the Polyethylene terephthalate (PET) mesh bag (Figure 1).

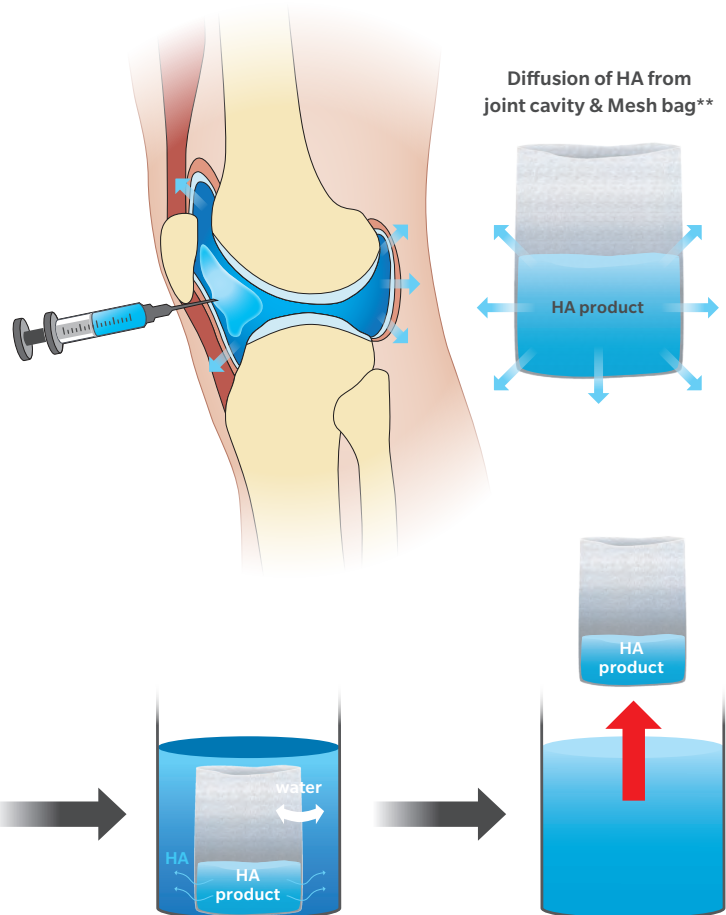


Figure 1: Methodology of PET mesh bag test: demonstrating HA dissolution

The HA samples were placed in the PET mesh bag, the mesh bag was immersed in a beaker containing a concentrated Blue Dextran dye mixed with phosphate buffered saline (PBS) and allowed to sit with gentle mixing. After immersion of the HA in the mesh bag, measurements of the absorption of the Blue Dextran solution remaining in the beaker were taken at 30 min, two hours, six hours and 24 hours. The amount of HA that flowed out of the bag, or the amount of PBS that flowed into the bag, was determined by measuring the absorption of the solution outside of the mesh bag.

Results

The Non Cross-Linked HA (NCL-HA) was observed to completely run out of the bag at two hours. This could possibly be due to the lack of cross-linking, which results in a smaller chemical structure and therefore it more easily flows out of the mesh bag. Monovisc diffused out of the bag completely by the six hour mark (Figure 2).¹ After the six and 24 hour time mark, 38% and 75% respectively, of the total volume of Synvisc/Synvisc-One had diffused outside of the mesh bag (Figure 2).¹ Upon visual inspection, most of the product left in the bag appeared to be the insoluble Hylan B (Figure 3).

Gel-One hyaluronate on the other hand did not flow outside of the mesh bag. The Gel-One structure is able to incorporate fluid from its surrounding environment, increasing the total fluid volume. Conversely, the less cross-linked formulations of HA along with their fluid carriers diffused out of the mesh bag (Figure 3).¹ The Gel-One structure could be the reason for this resistance to diffuse outside of the mesh bag.

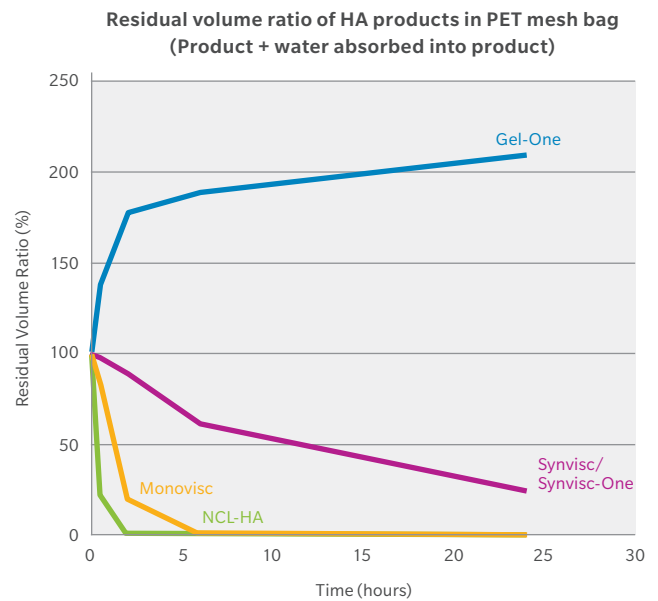


Figure 2: Results of mesh bag test.

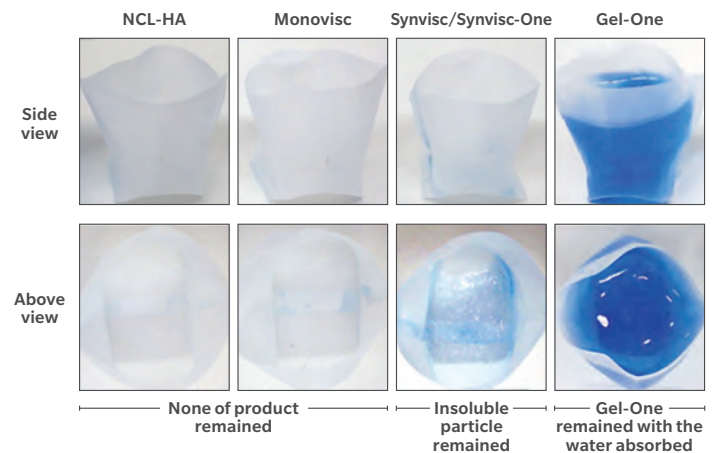


Figure 3: Mesh bags viewed from side and right above after 24 hours

References

1. Data on file at Seikagaku corporation. Rheology
- * Lab testing not necessarily indicative of clinical results
 **In this experiment the mesh bag represents the joint cavity.

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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