Gel-One® Cross-Linked Hyaluronate

Durability: Resistance to Deformation*

Durability is defined as the ability of a material to resist deformation (force) and to return to its original state following deformation. Materials that are more durable are more resistant to deformation, and last longer. In synovial fluid, naturally occurring HA changes its macromolecular structure during exposure to force (shear stress loading), such as walking or running, and reverts back to its natural state once the force is removed. The structure of Gel-One hyaluronate demonstrates similar characteristics that allow it to change its structure when an external force is added, and to return to its original structure when the external force is removed (Figure 1).[1] Materials such as HA that exhibit this behavior are called viscoelastic.

A material's viscoelasticity can be measured by temporarily applying a force (shear stress loading) to the material, removing it, and then measuring the resulting strain on the product. Materials with a higher viscoelasticity will exhibit less strain than those with a lower viscoelasticity.

In this test, a parallel plate rheometer was used to apply force (shear stress loading) to the samples of Gel-One, Synvisc/Synvisc-One, Monovisc, and a non commercially available Non-Cross-Linked HA (NCL-HA) prepared to standards outlined in the Japanese Pharmacopoeia (Figure 2). The resulting strain was measured.

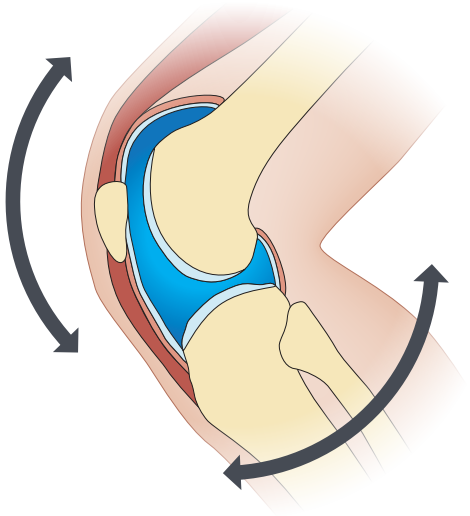


Figure 1: Shear stress loading of the knee joint includes bending, stretching and rotation

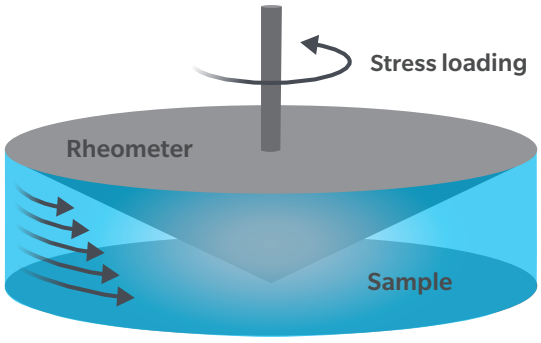


Figure 2: Rheometer measures strain of an HA product after force (shear stress loading) is applied to it.

Results

Gel-One hyaluronate's unique cross-linked structure demonstrated the greatest viscoelasticity, and therefore the greatest durability, or resistance to deformation, of the HA materials tested. The structure of Gel-One recovered even after receiving repeated stress loading.[1] On the other hand, the Synvisc/Synvisc-One failed to recover to its original state after the first stress loading and continued to fail to regain its original state after each subsequent loading (Figure 3).

Gel-One hyaluronate also demonstrated greater viscoelasticity than NCL-HA, Monovisc, and Synvisc/Synvisc-One. In this test Monovisc and NCL-HA lack the ability to recover even after only single stress load, meaning that these products experienced immediate deformation from the time the first stress was applied (Figure 4).

Figure 3: Viscoelasticity of Gel-One in repeated stress loading Compared to Synvisc/Synvisc-One

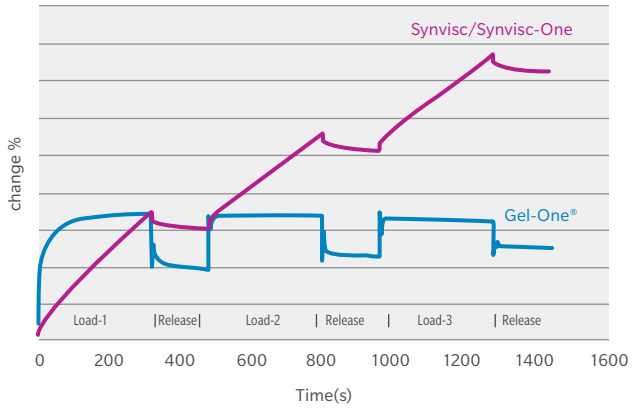
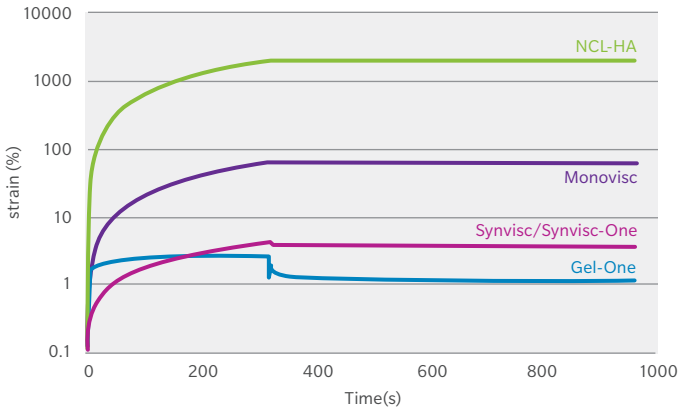


Figure 4: Viscoelastic Response After a Single Stress Loading



References

1. Data on file at Seikagaku corportion. Rheology
* Lab testing 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.

Disclaimers

ZIMMER BIOMET
Your progress. Our promise.™