Sterilized by ethylene oxide

Table 5. Number of patients with iritis. All randomized qualified patients.

<table>
<thead>
<tr>
<th>Visit and group</th>
<th>Visit 1</th>
<th>Visit 2</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Q8 = 24 hours</td>
<td>Q8 = 3 days</td>
</tr>
<tr>
<td>Healon® OVD</td>
<td>87</td>
<td>72</td>
</tr>
<tr>
<td>Healon® OVD</td>
<td>87</td>
<td>72</td>
</tr>
<tr>
<td>Healon® OVD</td>
<td>87</td>
<td>72</td>
</tr>
<tr>
<td>Healon® OVD</td>
<td>87</td>
<td>72</td>
</tr>
</tbody>
</table>

* For patient 114 iritis was not assessed on visit 5. It ± 2 days after surgery. Two Healon® OVD events were scored as possibly device related by the investigators.

Table 6. Adverse Events. Number of patients in whom a medical event occurred at least once. All randomized qualified patients.

<table>
<thead>
<tr>
<th>Group</th>
<th>N=187</th>
<th>N=172</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Healon® OVD</td>
<td>Healon® OVD</td>
</tr>
<tr>
<td></td>
<td>Pre-op</td>
<td>Op + 24 hours</td>
</tr>
<tr>
<td></td>
<td>Pre-op</td>
<td>Op + 24 hours</td>
</tr>
<tr>
<td></td>
<td>Pre-op</td>
<td>Op + 24 hours</td>
</tr>
<tr>
<td></td>
<td>Pre-op</td>
<td>Op + 24 hours</td>
</tr>
</tbody>
</table>

The Healon® OVD syringes are terminally steam sterilized and aseptically packaged. A sterile single-use, 25 gauge cannula is included with each syringe.

Preparation and Storage

Refrigerated Healon® OVD should be held at room temperature for approximately 30 minutes before use.

Store between 2° to 8°C (36° to 46°F).

Protections from freezing and exposure to light.

Definition of symbols on cannula, syringe, blister label and carton.

Create, see instructions for use

See instructions for use

Do not reuse

Do not use if the packaging has been opened or damaged

Protect from freezing

Table 7. Endothelial cell counts, changes and percentage change in endothelial cell counts from pre-surgery to 3 months.

<table>
<thead>
<tr>
<th>Visit</th>
<th>N</th>
<th>Pre-op</th>
<th>Op + 24 hours</th>
<th>Op + 7 days</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-op</td>
<td>87</td>
<td>2046 ± 292</td>
<td>2218 ± 380</td>
<td></td>
</tr>
<tr>
<td>Pre-op</td>
<td>87</td>
<td>2046 ± 292</td>
<td>2218 ± 380</td>
<td></td>
</tr>
<tr>
<td>Pre-op</td>
<td>87</td>
<td>2046 ± 292</td>
<td>2218 ± 380</td>
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</tr>
<tr>
<td>Pre-op</td>
<td>87</td>
<td>2046 ± 292</td>
<td>2218 ± 380</td>
<td></td>
</tr>
</tbody>
</table>

How Supplied

The Healon® OVD is a sterile, non-pyrogenic, viscoelastic preparation supplied in disposable 0.6 mL glass syringes. Each mL of the Healon® OVD contains:

- 23 mg sodium hyaluronate 5000
- 8.5 mg sodium chloride
- 0.28 mg sodium hydrogen phosphate dihydrate
- 0.04 mg sodium dihydrogen phosphate dihydrate
- q.s. water for injection

The Healon® OVD is a sterile, non-pyrogenic, viscoelastic preparation supplied in disposable 0.6 mL glass syringes. Each mL of the Healon® OVD contains:

- 23 mg sodium hyaluronate 5000
- 8.5 mg sodium chloride
- 0.28 mg sodium hydrogen phosphate dihydrate
- 0.04 mg sodium dihydrogen phosphate dihydrate
- q.s. water for injection

References


6. Lundberg K, Osterling L. A double-blind, randomized, parallel group study evaluating the safety of a new viscoelastic agent UPG-96 (Healon5® OVD), compared to Healon® OVD in the phacoemulsification with intraocular lens implantation. Pharmaceut&Upjohn Report DR500231

Importance

Perform the procedure before screwing on the plastic rod.

Press the vial completely into the holder so that the needle perforates the membrane.

Remove the plastic rod.

Screw the plastic rod into the blue plunger.

Connect the cannula and check for proper function.

Store at 2 to 8°C (36 to 46°F).

For single use only

Sterile opening technique

Tear off the paper covering.

Bend the plastic backwaords at the central indentation so as to fully expose the white plastic rod.

Dislodge syringe and place onto sterile field.

Instructions

Sodium Hyaluronate

Assembly

Connect the cannula and check for proper function.

Store at 2 to 8°C (36 to 46°F).

For single use only
Sodium Hyaluronate

Product information

Description

The Healon® Ophthalmic Viscosurgical Device (OVD) is a sterile, non-pyrogenic, transparent viscous solution of a highly purified, nonimmunogenic, high molecular weight fraction (average molecular weight 4 million) of sodium hyaluronate dissolved in a non-pyrogenic solution of Na-acetatoxysuccinate and sodium glutamate linked by glycosidic bonds. Sodium hyaluronate is a physiological substance that is widely distributed in the extracellular matrix of connective tissues in both animals and man. For example, it is present in the vitreous and aqueous humor of the eye, the synovial fluid, the skin, and the umbilical cord. Sodium hyaluronate derived from various human or animal tissues do not differ chemically.

The fraction of sodium hyaluronate in the Healon® OVD is reported to be nonantigenic and does not cause inflammatory or foreign body reactions. The graph below represents the flow curve (shear viscosity versus shear rate). The viscosity of the Healon® OVD at rest (at zero shear rate) is about 7 million mPas, with removal technique.

As a result of clinical experience, the following removal techniques (TCT) is one option to ensure efficient removal of the Healon® OVD:

- Use a standard IV tip, 0.3 mm, with effective flow of 20-25 ml/min and vacuum of 200-300 mmHg with a potential maximum setting at 500 mmHg. When using a machine with a periodic pump, use the upper limits of the suggested settings.
- When using a Venturi pump use the lower limits of the suggested settings. Bottle height should be 40-70 cm above eye level.
  1. Start the removal directly after the IOL implantation, while the anterior chamber is still filled with the Healon® OVD and before the IOL has been centered. Go behind the IOL optic without engaging the flow of the IV tip (stop the flow) and then start flow Remove the Healon® OVD from the capsular bag first and ensure that the lens has adequately centered. During removal of the Healon® OVD from the capsular bag, the continuous flow of irrigation fluid keeps the bag inflated and reduces the risk of aspirating the capsular bag. While maintaining continuous flow, remove the tip from behind the optic and place the IV tip on the optic.
  2. Continue the removal by circling the IV tip in a circular motion, then make an additional sweep in the anterior chamber to avoid any attached to the angles.

An alternative technique to remove the Healon® OVD is to create maximum turbulence to make the Healon® OVD and IOL lens of large pieces. This can be accomplished by using the Rock’n Roll technique (described below) with standard IV tip 0.3 mm, with high settings. Flow rates should be 35-50 mPas and vacuum 350-500 mmHg depending on the type of pump. If a periodic pump is used, the vacuum should be set towards the lower limit.

- If a venturi pump is used, the vacuum should be set at 500 mmHg. Bottle height should be 40-70 cm above eye level. Today’s IV tips above 0.3 mm often use linear control. The suggested machine settings cannot be achieved if the surgeon operates with a machine with fully depressed foot pedal.
  1. Start by circling the hand piece in the anterior segment at 90° plane.
  2. Gently nest the IV tip on the anterior surface of the optic. Press on the IOL optic on one side and rotate the IV hand piece directing the flow into the bag. Direct the hand piece port towards the equator of the capsular bag and then stay in this position for a few seconds and then repeat on the other side of the IOL optic until the Healon® OVD is completely removed. Finally sweep the anterior chamber including the angles and repeat step 2 if necessary.

Other removal techniques other than the TCT and Rock’n Roll technique may be used, depending on the surgeon’s preference and/or experience with the OVD. The Healon® OVD is a highly purified fraction extracted from swine tissues which may contain minute amounts of protein. The potential risks associated with the injection of biological material should be considered.

Before instilling phacoemulsification, use irrigation/aspiration to create a fluid-filled space above the lens. This reduces the risk of initial visco-occlusion of the phaco tip or the irrigation line which could cause phaco tip heating.

Pre-existing glaucomas, other causes of compromised outflow, higher preoperative intraocular pressure and complications in surgical procedures may also lead to increased intraocular pressure; consequently, extra care should be taken in patients with these conditions. Prophylactic pressure-lowering treatments should always be considered and especially in cases where the Healon® OVD has to be left in the eye for clinical reasons.

Both the Rock’n Roll technique and “behind the Lens” or the Two Compartment Technique (TCT) were evaluated during the clinical trial. The table below reflects IOPs ≥ 30 mmHg at 5 hours postoperatively in association with removal technique.

<table>
<thead>
<tr>
<th>Table 1.</th>
<th>Patients with IOP ≥ 30 mmHg at 5 Hour Visit by Removal Technique</th>
</tr>
</thead>
<tbody>
<tr>
<td>Healon® N=172</td>
<td>Healon® N=187</td>
</tr>
<tr>
<td>Rock’n Roll</td>
<td>20</td>
</tr>
<tr>
<td>Behind-the-Lens (TCT)</td>
<td>30</td>
</tr>
<tr>
<td>Combination of 1 and 2</td>
<td>30</td>
</tr>
<tr>
<td>Other</td>
<td>30</td>
</tr>
</tbody>
</table>

Contraindications

There are no known contraindications to the use of the Healon® OVD when used as recommended.

As a result of clinical experience, the following removal techniques (TCT) is one option to ensure efficient removal of the Healon® OVD:

There are no known contraindications to the use of the Healon® OVD when used as recommended.

Precautions

Precautions normally considered during ophthalmic surgical procedures should be taken.

Special care should be taken to ensure complete removal of the Healon® OVD from the entire eye including behind the lens and the chamber angles. Complete removal of the Healon® OVD is important to avoid postoperative pupil complications postoperatively. Due to the greater viscosity and higher concentration of sodium hyaluronate in the Healon® OVD, the risk of postoperative pupil retraction (PTX) may be higher with the Healon® OVD even if the same volume of other sodium hyaluronate viscoelastic products, with a viscosity higher than the Healon OVD and the Healon GV OVD. At high shear rates, the viscosity of the Healon® OVD decreases dramatically due to hydroxyapatite, facilitating extraction through a 25G cannula.

Indications

The Healon® OVD is intended for use in anterior segment ophthalmic surgical procedures of the human eye. The Healon® OVD is designed to create and maintain a deep anterior chamber which facilitates manipulation inside the eye with reduced trauma to the corneal endothelial and other ocular tissues. The Healon® OVD can also be used to efficiently separate and control ocular tissues. The Healon® OVD is not designed to have any pharmacological effect.

Contraindications

Do not use if the blister package has been damaged.

If the same volume of other sodium hyaluronate viscoelastic products, with a concentration of sodium hyaluronate in the Healon® OVD, the rise in the pressure peaks postoperatively. Due to the greater viscosity and higher concentration of sodium hyaluronate in the Healon® OVD, the risk of postoperative pupil retraction (PTX) may be higher with the Healon® OVD even if the same volume of other sodium hyaluronate viscoelastic products, with a viscosity higher than the Healon OVD and the Healon GV OVD. At high shear rates, the viscosity of the Healon® OVD decreases dramatically due to hydroxyapatite, facilitating extraction through a 25G cannula.

Sodium hyaluronate solution may appear cloudy or form precipitates when it is repackaged and then frozen. In these instances, this redissolves, resulting in opalescence, between sodium hyaluronate and solutions containing cationic components, e.g., dextran and benzalkonium chloride. Reprocessed ophthalmic viscosurgical preparations should not be used. Do not use if the blister package has been damaged. Do not resterilize.

The Healon® OVD is for single use.

Increased intraocular pressure has been reported after use of sodium hyaluronate solutions. Increased intraocular pressure is likely to occur if the Healon® OVD is not removed as completely as possible. Clinical judgment concerning the use of this product should be considered in cases where thorough removal may not be possible. The precautions noted above should be taken to manage any increased postoperative intraocular pressure and to reduce the likelihood of occurrence of related postoperative complications such as optic neuropathy, papillary stasis and dilation, and iritis.

Rarely, postoperative inflammatory reactions (iritis, hyphema, endophthalmitis) following the use of sodium hyaluronate, as well as incidents of corneal edema and corneal decompensation, have been reported. Their relationship to sodium hyaluronate has not been established.

The intraocular pressure (IOP) was assessed at 5 hours after surgery, since the expected IOP peak time period is 4–6 hours after surgery. The IOP was measured at 24 hours and 7 days post surgery. No anti-glaucoma medication was permitted until after the 5-hour IOP assessment.

Eleven percent of the Healon® OVD patients and 10% of the Healon® OVD patients experienced IOP spikes ≥ 30 mmHg at 5 hours postoperatively.

<table>
<thead>
<tr>
<th>Table 3.</th>
<th>IOP (mmHg) during the study All randomized qualified patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>Group</td>
<td>N=172</td>
</tr>
<tr>
<td>Mean</td>
<td>15.6</td>
</tr>
<tr>
<td>STD</td>
<td>7.7</td>
</tr>
<tr>
<td>Min</td>
<td>0</td>
</tr>
<tr>
<td>Max</td>
<td>107</td>
</tr>
</tbody>
</table>

The specified complications were similar for both groups. All of the complications are commonly seen after cataract surgery. Blurred vision, scratchy sensation, foreign body sensation, itching, burning, tender cornea, corneal edema, represented most of the complications recorded in both groups.

<table>
<thead>
<tr>
<th>Table 4.</th>
<th>Number of patients with complications related to surgery All randomized qualified patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>Visit and group</td>
<td>N=183</td>
</tr>
<tr>
<td>Missing</td>
<td>0</td>
</tr>
</tbody>
</table>

The specified complications were similar for both groups. All of the complications are commonly seen after cataract surgery. Blurred vision, scratchy sensation, foreign body sensation, itching, burning, tender cornea, corneal edema, represented most of the complications recorded in both groups.

The graph below represents the flow curve (shear viscosity versus shear rate). The viscosity of the Healon® OVD at rest (at zero shear rate) is about 7 million mPas, with removal technique.

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There are no known contraindications to the use of the Healon® OVD when used as recommended.

Precautions normally considered during ophthalmic surgical procedures should be taken. Special care should be taken to ensure complete removal of the Healon® OVD from the entire eye including behind the lens and the chamber angles. Complete removal of the Healon® OVD is important to avoid postoperative pupil complications postoperatively. Due to the greater viscosity and higher concentration of sodium hyaluronate in the Healon® OVD, the rise in the postoperative intraocular pressure may be higher with the Healon® OVD if the same volume of other sodium hyaluronate viscoelastic products, with a lower zero shear viscosity, is left in the anterior segment of the eye.