The observed mean percent changes in ECC from preoperative to three months postoperative (p<0.0001, 1-sided t-test, d = 5%). Healon EndoCoat® OVD demonstrated non-inferiority compared to Viscoat® OVD in corneal endothelial cell count (ECC) from preoperative to three months postoperative for the Intent To Treat (ITT) primary analysis population where missing values were imputed using the last observation carried forward method. The observed mean percent changes in ECC from preoperative to three months postoperative for the Safety Population also showed statistically significant differences in favor of Healon EndoCoat® OVD compared to Viscoat® OVD (p=0.0003). Reports of inflammatory cells diminished over time to minimal levels by the one-month visit in both viscoelastic groups. Early postoperative incidence rates of corneal, epithelial and stromal inflammatory cells in the anterior chamber were the most reported form of inflammation for both groups and within the range of what would typically be reported. In the early postoperative period, the majority of subjects in both groups were reported as “none” at all postoperative visits. Early postoperative rates of IOP spikes were much lower than would typically be expected to occur in any clinical trial setting (nearly all spikes were ≤ 10 mmHg). Early postoperative rates of IOP spikes were much lower than would typically be expected to occur in any clinical trial setting (nearly all spikes were ≤ 10 mmHg). Early postoperative rates of IOP spikes were much lower than would typically be expected to occur in any clinical trial setting (nearly all spikes were ≤ 10 mmHg). Early postoperative rates of IOP spikes were much lower than would typically be expected to occur in any clinical trial setting (nearly all spikes were ≤ 10 mmHg). Early postoperative rates of IOP spikes were much lower than would typically be expected to occur in any clinical trial setting (nearly all spikes were ≤ 10 mmHg).

### Viscoelastic Comparative Study

**Safety Population**

- **Visit:** 1 Day
  - **Healon EndoCoat® OVD:** 199
  - **Viscoat® OVD:** 199
  - **Difference:** 0
- **Visit:** 1 Week
  - **Healon EndoCoat® OVD:** 199
  - **Viscoat® OVD:** 199
  - **Difference:** 0
- **Visit:** 1 Month
  - **Healon EndoCoat® OVD:** 199
  - **Viscoat® OVD:** 199
  - **Difference:** 0

### Foot-Operative IOV Spike Rate Over Time

**Safety Population**

<table>
<thead>
<tr>
<th>Time</th>
<th>Healon EndoCoat® OVD</th>
<th>Viscoat® OVD</th>
<th>Difference</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Day</td>
<td>1.0 (2)</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>1 Week</td>
<td>0</td>
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<td></td>
</tr>
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### Foot-Operative OVD Spike Rate Over Time

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</table>

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**Healon® Assembly Instructions**

1. **Stylist opening technique**
   - Tear off the paper covering. Bend the plastic backwashes to the central indentation so as to fully expose the white plastic rod. Remove syringe and place on sterile field.

2. **Assembly**
   - Press the valve completely into the holder so that the needle performs the assembly. Important:
     - Perforate the membrane before screwing on the plastic rod.

3. **Remove the plastic rod.**

4. **Screw the plastic rod into the blue plunger:**
   - Connect the cannula.

5. **Check for proper function.**

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**Symbols Used On Sterile Packaging**

- **Cannula Instructions For Use:**
  - Caution.
  - Do Not Use If Package Is Broken Or Damaged.
  - Do Not Reuse.
  - Catalogue Number.
  - Batch Code.
  - OVD Product of USA
  - Date of Manufacture (YYYY-MM-DD: year-month-day).
  - USE BY (YYYY-MM-DD: year-month-day).
  - Protect From Light.
  - Protect From Freezing.

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**Temperature Limitations:**

- ** Leakage.**

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**Revision Date:** 11/2014

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The diaphragm is punctured, the physician should be aware of this potential problem. Express a small amount of air from the choroidal space to the anterior chamber for less than 6 days and protects corneal endothelial cells and other ocular structures. The precautions are recommended:

- It has a high molecular weight.
- It does not cause inflammatory or foreign body reactions.
- It has a high stability.
- It is neutral.
- It is non-irritating and non-pyrogenic.
- It has a low viscosity and can be injected with a small volume.
- It is non-toxic and does not cause any systemic or local adverse effects.
- It is non-cytotoxic and does not interfere with the healing process.
- It is non-antigenic and does not cause any immune response.
- It is non-profibrinogenic and does not promote fibrin formation.
- It is non-fibrinolytic and does not interfere with the fibrinolytic system.
- It is non-mutagenic and does not cause any genotoxic effects.
- It is non-sensitizing and does not cause any allergic reactions.
- It is non-carcinogenic and does not cause any tumorigenic effects.
- It is non-toxic and does not cause any toxic effects.
- It is non-haemolytic and does not cause any haemolytic effects.
- It is non-coagulative and does not cause any coagulative effects.
- It is non-vesicant and does not cause any vesicant effects.
- It is non-vasoactive and does not cause any vasoactive effects.
- It is non-pharmacological and does not cause any pharmacological effects.
- It is non-hyperosmotic and does not cause any hyperosmotic effects.
- It is non-hypoosmotic and does not cause any hypoosmotic effects.
- It is non-hypertonic and does not cause any hypertonic effects.
- It is non-hypotonic and does not cause any hypotonic effects.
- It is non-ionic and does not cause any ionic effects.
- It is non-proteinogenic and does not cause any proteinogenic effects.
- It is non-carbohydrogenic and does not cause any carbohydrategenic effects.
- It is non-fatogenic and does not cause any fatogenic effects.
- It is non-lipogenic and does not cause any lipogenic effects.
- It is non-glucogenic and does not cause any glucogenic effects.
- It is non-lysogenic and does not cause any lysogenic effects.
- It is non-bacteriocidal and does not cause any bacteriocidal effects.
- It is non-phagocytotic and does not cause any phagocytotic effects.
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