A New Alternative for Wound Sealing in Cataract Surgery

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Modern Cataract Surgery

- ~3.3 million cataract surgeries per year in US
- < 3.5 mm clear corneal incision (CCI) preferred technique
- More difficult to construct and slower to heal than scleral incisions
- Numerous complications still exist that underscore the need for better wound closure

CCI Integrity

- Stability of self-sealing CCIs has been questioned
  - Low IOP in immediate post-op period (30 mins)
    - 20.5% of patients with IOP ≤ 5 mmHg*
  - Gaping
    - 9-12% of wounds at postoperative day 1**

Financial Disclosure

Consultant
- Alcon
- Bausch & Lomb
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- Ocular Systems Inc.
- Ocular Therapeutix
- Omerus
- Powervision
- Shire
- TearScience

**CCI Integrity**

IOP = 40 mm Hg

IOP = 14 mm Hg

IOP = 5 mm Hg


**External Manipulation**

- **IOP rises with normal daily activities**
- **Wound integrity and safety can be compromised with external pressure or manipulation**
  - Touching, rubbing, forced blinking, incorrect drop use

Iatrogenic Trauma From Eyedrops

Courtesy of Alan Robin, MD
Iatrogenic Trauma From Eyedrops
Courtesy of Alan Robin, MD

Is the CCI “Self-Sealing”?
- Proper wound construction is a topic of discussion/concern
- Most surgeons do not routinely test for wound leaks
  - Incidence of leaks underappreciated
- Only a few studies of intra-op incision leakage
  - These studies demonstrate CCIs do leak
  - “Self-sealing” of main incisions overestimated

<table>
<thead>
<tr>
<th>Leak Rate (n (%))</th>
<th>Reference/ Source</th>
</tr>
</thead>
<tbody>
<tr>
<td>50%</td>
<td>Herretes S et al</td>
</tr>
<tr>
<td>75%</td>
<td>ReSure Pivotal Study*</td>
</tr>
<tr>
<td>85%</td>
<td>Mifflin MD et al</td>
</tr>
</tbody>
</table>

Options for Incision Closure
- Stromal hydration
  - Standard of care
  - Not a definitive closure technique
  - Transient effect
  - Wound leak rates of 50 – 85%*

Why are leaks important?
- Incompetent wounds allow fluid into/out of incision*
- May result in sight-threatening events
  - Hypotony
  - Corneal decompensation
  - Epithelial downgrowth
- May compromise refractive outcome
  - IOLs subject to movement due to leaks

Options for Incision Closure

- **Suture**
  - Only current option for definitive closure
  - Disadvantages set high threshold for use
    - Inflicts trauma on cornea
    - Wound leak rates of 24%*
    - Subconjunctival hemorrhage
    - Provides possible nidus for infection, inflammation, and neovascularization
    - Induced corneal astigmatism
    - Need for removal adds additional visit
    - Requires suturing skill suturing AND increased OR time

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**Indication for Use**

ReSure Sealant is indicated for intraoperative management of clear corneal incisions (up to 3.5mm) with a demonstrated wound leak for which a temporary dry surface can be achieved, in order to prevent postoperative fluid egress from such incisions following cataract surgery with intraocular lens (IOL) placement in adults.

**Product Overview:**

- Prevents fluid egress from clear corneal incisions
- Soft and lubricious surface barrier
- 100% synthetic and biocompatible hydrogel
- Contains a visualization aid for ease of application
- Gently sloughs off in the tears during re-epithelialization
- Material hydrolysis occurs in approximately 7 days.

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“The FDA has approved gels like ReSure for sealing small incisions in other parts of the body, but this is a first-of-its kind for the eye”

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**Now FDA Approved**
**Device Components**

- Mixing Tray
- Diluent Dropper

Poly(ethylene glycol) (PEG)
Trilysine, FD&C Blue
Water and buffer salts

**Preparation and Application**

- Thoroughly dry the incision and surrounding tissue.
- Add two drops of diluent to the blue deposit.
- Mix the solutions for up to 5 seconds.
- Use the provided applicators to apply the material over the entirety of the incision.

**ReSure Sealant Pivotal Study**

- **Purpose:**
  - To evaluate the ReSure Sealant against sutures* for prevention of wound leaks from clear corneal incisions within the first 7 days following cataract surgery.

- **Methods:**
  - 487 subjects (488 eyes) enrolled at 24 sites in a prospective, parallel arm, controlled multicenter trial.
  - Uncomplicated cataract surgery with ≤3.5 mm CCIs.
  - Subjects with a demonstrated wound leak were randomized to an ocular sealant or suture and evaluated for 28 days post procedure.

*10-0 nylon sutures applied with 3-1-1 technique and buried knot

**Pivotal Study Results**

**Leak Rates Prior to Device Placement**

<table>
<thead>
<tr>
<th>Leak Type</th>
<th>ReSure Sealant (n=304)</th>
<th>Suture (n=183)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Spontaneous leak</td>
<td>4.1%</td>
<td>34.1%</td>
</tr>
<tr>
<td>Spontaneous or w/ minimal touch</td>
<td>50.0% (244/488)</td>
<td></td>
</tr>
</tbody>
</table>

*ReSure Sealant US Pivotal Clinical Trial, Ocular Therapeutix, data on file.*
Pivotal Study Results

- 94.1% of sealant cases were rated ‘easy’ or ‘very easy’ to use.
- No safety concerns were reported.
- Patients were comfortable overall.
- No significant differences in:
  - Surgically induced corneal astigmatism
  - Anterior chamber inflammation
  - Manifest refraction
  - Corneal edema
  - Asymmetry
  - Pain
  - BCVA

Summary

- A high percentage of clear corneal incisions exhibited some level of wound leakage after cataract surgery and before any intervention.
- Wounds should be carefully evaluated in the immediate post-operative period, and further preventative measures should be taken to manage wound leaks.
- In this trial, the ocular sealant demonstrated superiority over sutures for prevention of wound leaks with significantly fewer adverse events than sutures.
- The ocular sealant is safe and effective for its intended use in prevention of fluid egress.

References: