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

Financial Disclosures

- Consultant
  - Alcon
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  - Ocular Therapeutix
  - Omerus
  - Powervision
  - Presbyopia Therapies
  - Shire
  - TearScience

Is the CCI “Self-Sealing”?
### Incidence of Leak Rates

<table>
<thead>
<tr>
<th>Leak Rate</th>
<th>Reference</th>
<th>Publication</th>
</tr>
</thead>
<tbody>
<tr>
<td>12%</td>
<td>Chee</td>
<td>Int. Oph. 2005</td>
</tr>
<tr>
<td>50%</td>
<td>Herretes et. al.</td>
<td>AJO 2005</td>
</tr>
<tr>
<td>67%</td>
<td>Masket et. al.</td>
<td>JCRS 2013</td>
</tr>
<tr>
<td>85%</td>
<td>Mifflin et. al.</td>
<td>JCRS 2012</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%*


### Endophthalmitis and Wound Leaks

**Cohort study of 27 cases of endophthalmitis at a single institution**

Trevin Wallin, MD, Jared Parker, MD, Yan Jin, MD, Gus Kefalopoulos, MD, Randall J. Olson, MD

*J Cataract Refract Surg 2005; 31:735–741*

"Postoperative contamination is a problem with sutureless incisions..."

"Our greatest association was a leaky wound on the first postoperative day... with a 44-fold increased risk...”

**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
Inflated Porcine Anterior Chamber

Inflated porcine anterior chamber imaged with prototype swept source intrasurgical OCT. Credit: Carrasco-Zevallos O, Kuo AN, Toth CA, Izatt JA (Duke University)

Deflated Porcine Anterior Chamber

Same porcine anterior chamber deflated by gaping wound. Imaged with prototype swept source intrasurgical OCT. Note that en face view (top right) is not very different inflated or deflated. Credit: Carrasco-Zevallos O, Kuo AN, Toth CA, Izatt JA (Duke University)

Dislocated Accommodating IOL

Patient-Induced Wound Trauma

Courtesy of Alan Robin, MD
Prevents fluid egress from clear corneal incisions
- Soft, flexible, and lubricious
- 100% synthetic and biocompatible

The first and only FDA approved ophthalmic sealant

How it Works

It’s not a glue!
- The ReSure Sealant binds to de-epithelialized tissue via ‘lock & key’
- Lid movement sloughs the hydrogel off as the epithelium regenerates.
- Hydrolysis occurs in approximately seven days.

Pivotal Clinical Trial
- 487 patients (488 eyes) enrolled at 24 clinical sites in the U.S.
- Following cataract surgery, a wound challenge test was conducted using an Ocular Force Gauge (OFG):
  - If no leak observed up to 1 ozf: screen failure
  - If leak observed ≤ 1 ozf: randomized 5:3 into study using ReSure Sealant or sutures, respectively
- Following device application, a second wound challenge test was conducted using the OFG:
  - If leak observed ≤ 1 ozf: primary endpoint failure
  - If no leak observed up to 1 ozf: successful prevention of fluid egress

Pivotal Study Results

Leak Rates Prior to Device Placement
- 50.0% (244/488)
- 76.0% (371/488)

Per Protocol Leak Rate Results
- 4.1%
- 34.1%

*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 astigmatism
  - Corneal edema
  - Asymmetry
  - Pain
  - BCVA

Adverse Event Rates

<table>
<thead>
<tr>
<th>Parameters</th>
<th>ReSure n=304</th>
<th>Suture n=183</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Subjects with AE(s) related to study device</td>
<td>5 (1.6%)</td>
<td>56 (30.6%)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Subjects with at least one AE</td>
<td>69 (22.7%)</td>
<td>83 (45.4%)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Subjects with no AEs</td>
<td>235 (77.3%)</td>
<td>100 (54.6%)</td>
<td>&lt;0.0001</td>
</tr>
</tbody>
</table>

Stromal Hydration

- Excessive stromal hydration may not be optimal for favorable outcomes:
  - Induced wound gape allowing bacterial invasion
  - Variability of post-op wound architecture and integrity
  - Tissue trauma/Descemet’s membrane detachment
  - Persistent corneal edema with loss of BCVA
  - Increased surgical time

- Results at 24 hours without stromal hydration¹:
  - Better BCVA*
  - Less edema*
  - Less corneal staining/erosion*

*All statistically significant compared to stromal hydration

Additional Benefits over Sutures

- Previously been considered the gold standard, however, are an antiquated technology with disadvantages:
  - Inflicts trauma on cornea
  - Possible nidus for infection, inflammation, and neovascularization
  - May induce corneal astigmatism
  - Sutures leak 34.1% of the time with minimal to mild touch pressure¹
  - 87.5% of suture patients require device removal within 3 years due to AEs including astigmatism and degradation²

Hydrated vs. Non-hydrated Incisions

Leak Rate Results

<table>
<thead>
<tr>
<th>Incisions</th>
<th>ReSure Sealant</th>
<th>Suture</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline IOP</td>
<td>15.7 ± 3.06</td>
<td>15.2 ± 2.80</td>
</tr>
<tr>
<td>IOP day-1</td>
<td>18.5 ± 5.40</td>
<td>18.4 ± 6.23</td>
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Stromal hydration did not appear to influence leak rates in sealant patients.

Instructional Overview

Mix thoroughly for 5 seconds

Place two drops of diluent in the blue deposit

Thoroughly dry incision and surrounding tissue

Device Components

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

Standard Cataract Surgery

Thoroughly dry incision and surrounding tissue
‘Premium’ Cataract Surgery
Acrysof ReStor

Complex Cataract Surgery
MST capsule retractors

Combined Cataract/Glaucoma Surgery
iStent

Cataract Surgery/Iridodialysis Repair
Clinical Use in Cataract Surgery

Standard Cataract Surgery
- Incisions up to 3.5 mm
- Suture replacement
- Leaky wounds
- Visible internal/external gape
- Irregular/asymmetric wounds
- High myopes
- Corneal ectasia (keratoconus)
- Phaco burn
- Patients at risk for eye trauma:
  - Mentally disabled
  - Patients in assisted living
  - Elderly

Previous Ocular Surgery
- Post-refractive
  - RK
  - LASIK
  - PRK
- Post-glaucoma filtering
  - Trabeculectomy
  - Tube shunt

High-Risk Cataract Patients
- MRSA
- Monocular
- Diabetic
- Immunocompromised
- Undergoing chemotherapy
- Long-term systemic steroids

Premium Cataract Patients
- Toric
- Multifocal
- Accommodating
- Femtosecond

Complex Cataract Patients
- Small Pupil
  - Iris hooks
  - Malyugin Ring
- Capsular tension rings
- Dense Cataract
- Lens explant/exchange

Combination Cataract Patients
- MIGS
- Pars Plana Vitrectomy

*Temporary dry surface must be achieved at the time of application
HOW DO I GET IT?

www.resuresealant.com

THANK YOU!

Duke University Eye Center

Duke Albert Eye Research Institute