Safety and Efficacy of Dextenza® Intracanalicular Implant for Postoperative Control of Inflammation after Vitrectomy

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Financial Disclosures

- Ocular Therapeutilx
  - Consultant, speaker, investigator
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  - Consultant, speaker, investigator
- Allergan
  - Consultant, investigator
- Regeneron
  - Consultant, investigator
- Novartis
  - Consultant, investigator
• In a pilot study, **Dextenza® Intracanalicular Implant** was safe and efficacious in providing control of postoperative pain and inflammation

• **Dropless vitrectomy** surgery is possible with Dextenza® Intracanalicular Implant
Background: Vitrectomy Surgery Postoperative Management

- Positioning for Air/Gas Bubble
Background: Vitrectomy Surgery Postoperative Management

- Positioning for Air/Gas Bubble
- Topical anti-inflammatory steroids, Antibiotics
Postoperative Management: Traditional

- Pain and inflammation
  - Topical therapy
    - Dose 4x/day
Postoperative Management: Alternatives

- Pain and inflammation
  - Periocular steroid
    - IOP
    - ?Dose/Duration
Postoperative Management: Alternatives

- Pain and inflammation
  - Intraocular steroid
  - IOP
  - Risky in gas/air-filled eye
  - Snowglobe effect
What Is Dextenza®?

- Dexamethasone 0.4 mg ophthalmic insert
- Placed in canaliculus thru punctum
- Implanted in office or operating room
- Drug delivery for 30 days
- Approved for pain and inflammation after ocular surgery
What about Dextenza® for retinal surgery?

- No interruption in positioning
- Consistent dosing
- Ideal for elderly patients (difficulty with drops)
Pilot Study for Vitrectomy Surgery

- Single Center
  - Retina Associates of Florida, Tampa, FL

- Single Surgeon
  - Ivan J. Suñer, MD, MBA

- Dropless Regimen
  - Dextenza®, subconj antibx (Ancef)
Methods

- **Entry Criteria**
  - Pars Plana Vitrectomy not including Retinal Detachment

- **Procedure**
  - 25-Gauge PPV with air/gas tamponade
  - Dextenza® Implant in-office or intraoperative
  - Subconjunctival Cefazolin intraoperative
Methods

- Exam at 1 day, 1 week, and 1 month

- Primary Endpoint
  - Pain/Inflammation Requiring Topical Steroids

- Secondary Endpoints
  - Vision
  - Retinal thickness (SD-OCT)
  - IOP (Tonopen)
# Results

## Patient Demographics

<table>
<thead>
<tr>
<th>Gender</th>
<th>10 Female: 10 Male</th>
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<tbody>
<tr>
<td>Age</td>
<td>69.5 Years</td>
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## Diagnosis

<table>
<thead>
<tr>
<th>Diagnosis</th>
<th>Count</th>
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<tbody>
<tr>
<td>Epiretinal Membrane</td>
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<tr>
<td>Macular Hole</td>
<td>3</td>
</tr>
<tr>
<td>Vitreous Opacities</td>
<td>3</td>
</tr>
<tr>
<td>Silicone Oil Removal</td>
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</tr>
<tr>
<td>Vitreomacular Traction</td>
<td>1</td>
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</tbody>
</table>
Dextenza® Insertion in Operating Room
Results: Pain/Inflammation

- Pain/Inflammation Requiring Topical Steroids
  - 2/20 (10%) required topical steroids
    - both were combined Phaco-Vitrectomy
    - 2/6 (33%) combined Phaco-Vitrectomy
Results: Vision

- Mean Vision Improvement at 1 month
  - +12 letters
  - Preop 20/80, Postop 20/40
Results: IOP

- Mean IOP change at 1 month
  - +3.8 mmHg

- IOP > 20 mmHg
  - 1/20 (0 >25 mmHg)

- IOP Meds
  - 0/20
Results: OCT

- Mean OCT change at 1 month
  - -98 microns
  - Mean CFT baseline: 390 microns
  - Mean CFT 1 month: 292 microns

- CFT > 350 microns
  - 20% (4/20); all less than preop CFT
Limitations

- Small study
- Retrospective
- No control group
Conclusions: Dropless Retinal Surgery Is Possible

- Dextenza® safe and effective in control of pain and inflammation after retinal surgery
- 10% required supplemental steroids
- No significant IOP rise/OCT worsening
- 7/7 Patients having 2nd eye surgery preferred over topical drop regimen
Thank You