

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



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RETINA ASSOCIATES  
OF FLORIDA, P.A.

# Financial Disclosures

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- **Ocular Therapeutix**
  - Consultant, speaker, investigator
- **Genentech**
  - Consultant, speaker, investigator
- **Allergan**
  - Consultant, investigator
- **Regeneron**
  - Consultant, investigator
- **Novartis**
  - Consultant, investigator



# Summary Slide

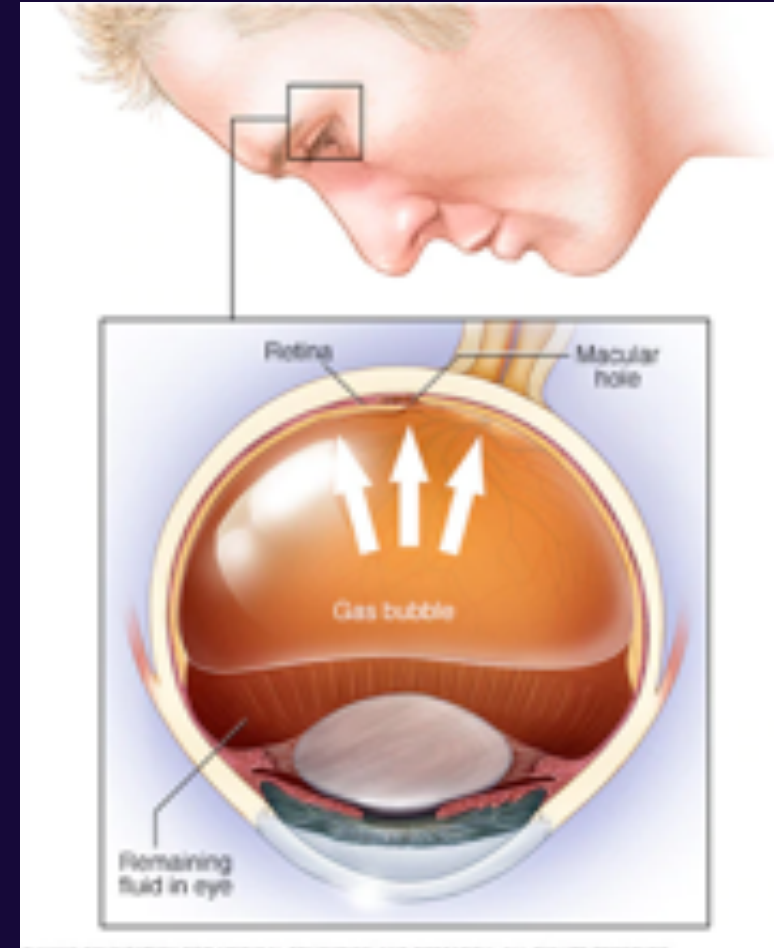
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- In a pilot study, Dextenza<sup>®</sup> Intracanalicular Implant was safe and efficacious in providing control of postoperative pain and inflammation
- Dropleess vitrectomy surgery is possible with Dextenza<sup>®</sup> Intracanalicular Implant



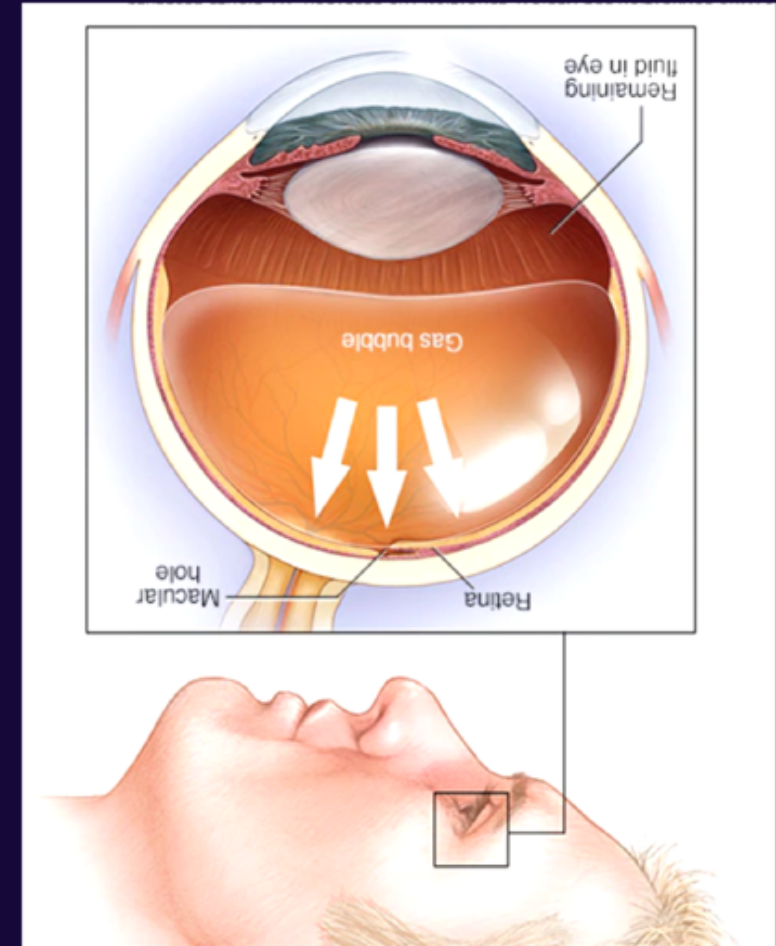
# Background: Vitrectomy Surgery Postoperative Management

- 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



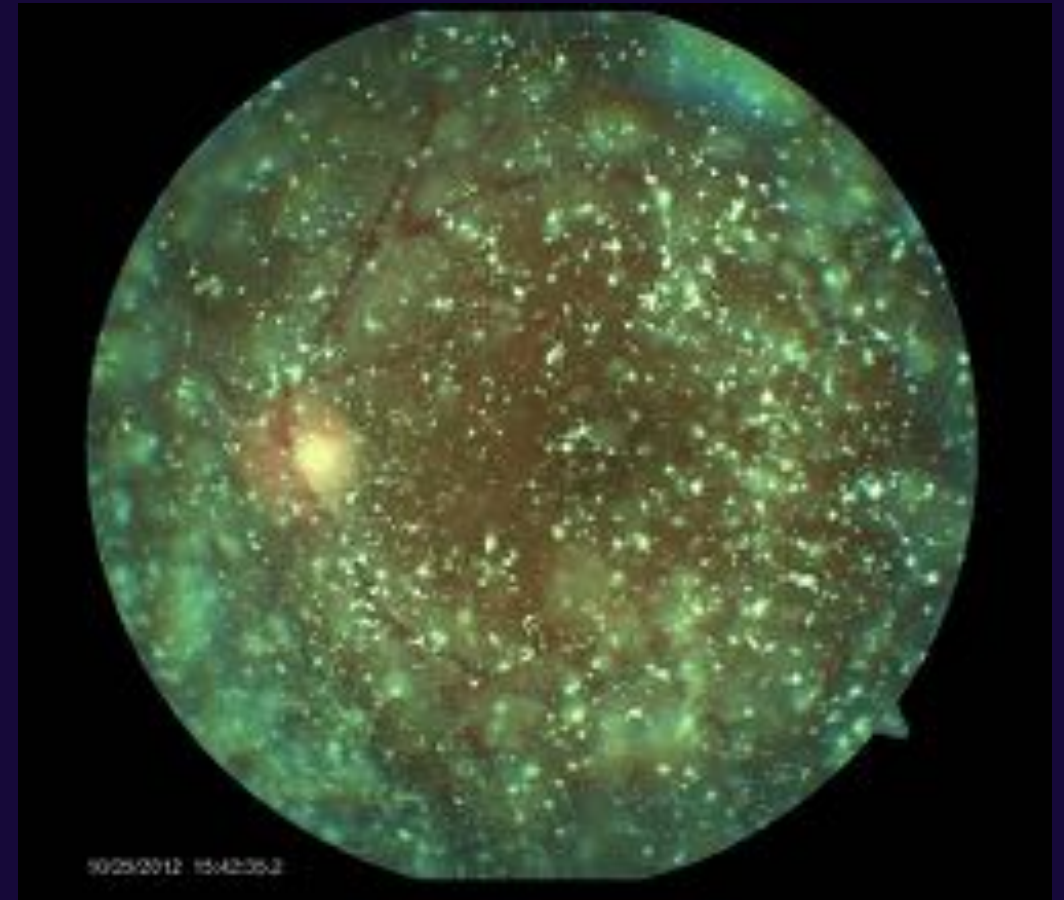
# Postoperative Management: Alternatives

- 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





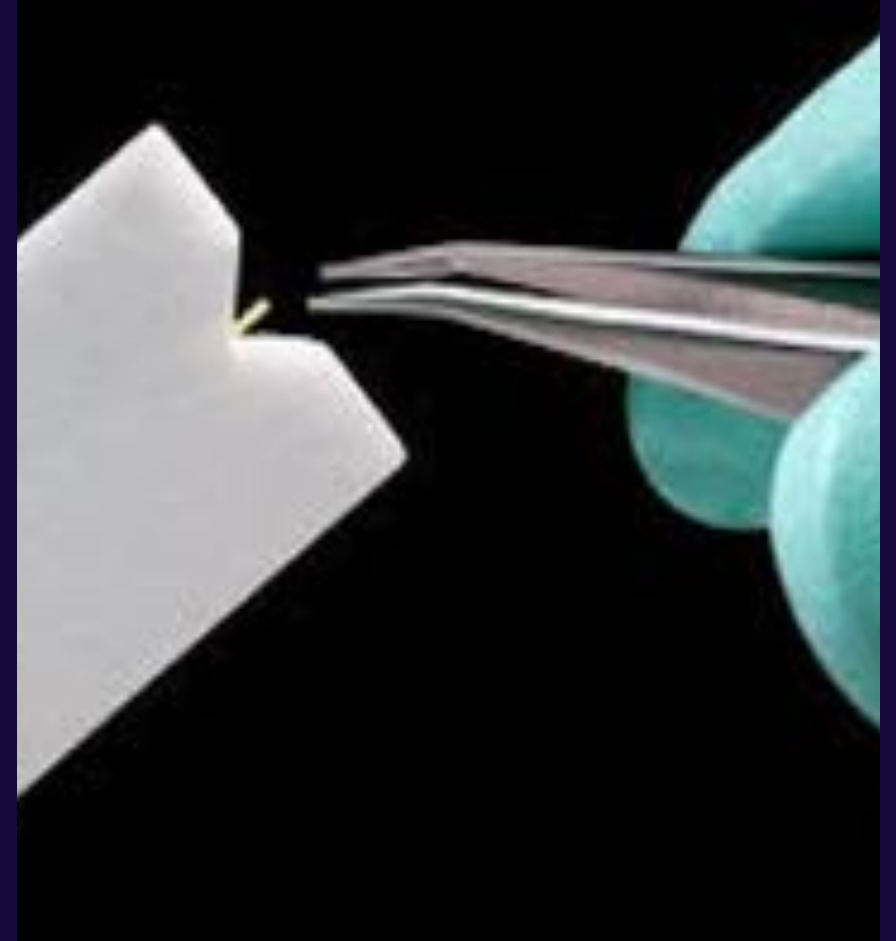
# What Is Dextenza®?

- 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

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- Single Center
  - Retina Associates of Florida, Tampa, FL
- Single Surgeon
  - Ivan J. Suñer, MD, MBA
- Droplless Regimen
  - Dextenza®, subconj antibx (Ancef)



# Methods

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- 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

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- 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

<u>Patient Demographics</u>	
<u>Gender</u>	10 Female: 10 Male
<u>Age</u>	69.5 Years
<u>Diagnosis</u>	
Epiretinal Membrane	11
Macular Hole	3
Vitreous Opacities	3
Silicone Oil Removal	2
Vitreomacular Traction	1



# Dextenza® Insertion in Operating Room

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*Dextenza Placement  
in Operating Room*



# Results: Pain/Inflammation

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





# Results: Vision

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



# Results: IOP

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- Mean IOP change at 1 month
  - +3.8 mmHg
- IOP > 20 mmHg
  - 1/20 (0 >25 mmHg)
- IOP Meds
  - 0/20



# Results: OCT

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- 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

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- Small study
- Retrospective
- No control group



# Conclusions: Dropleless Retinal Surgery Is Possible

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- 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 2<sup>nd</sup> eye surgery preferred over topical drop regimen



# Thank You

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Diseases and Surgery of the Retina and Macula