MIGS in Glaucoma

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• Aerie – C/L
• Allergan – C/L
• Alcon – C/L
• Bausch & Lomb – C/L
• Cosider Therapeutics - C
• EyePoint – C
• Sight Sciences – C
• Mediprint – C
• Visux – C
• Sun – C/L
• Reemex – L
• Reichert - C
• B&L – C/L
• Glaukos – L
• Horizon – C
• Zeiss – C/L
• J&J – C/L
• LKC – C/L

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WHY MIGS
More than 90% of patients are nonadherent to their ocular medication dosing regimens, and nearly 50% discontinue taking their medications before 6 months.


Prospective, multicenter trial evaluating four ocular surface metrics 3 months post-implantation.

- n=47 eyes
- Other ocular health metrics improved as well:
  - 49% longer time to tear break-up (TBUT) (p<0.0001)
  - Significantly reduced corneal/conjunctival staining (Oxford Schema) (p<0.0001)
  - Trend toward less hyperemia (Efron Score)

Interventional Glaucoma

Conservative
Aggressive

MIGS

Minimally or Micro Invasive Glaucoma Surgery (MIGS)

Procedures that have an ab-interno approach, are minimally traumatic, with at least modest efficacy, extremely high safety and rapid recovery.

Cataract surgery alone......

may be the most common glaucoma surgery today.
Case 1:
69-year-old, Caucasian female referred for a cataract evaluation and opinion on her glaucoma. She states she is not taking her drop everyday because they burn and irritate her eyes. She states her vision seems blurry all the time.

Ocular History
• POHX: Primary Open Angle Glaucoma OU
• FHX: Father – glaucoma
• Previous Treatment Regimen: None
• Current Treatment Regimen:
  • Latanoprost qd OU
• IOP max
  • OD: 25 mm Hg
  • OS: 25mm Hg

69-year-old, Caucasian female referred for a cataract evaluation and opinion on her glaucoma. She states she is not taking her drop everyday because they burn and irritate her eyes. She states her vision seems blurry all the time.

Medical History
• PMHX: Hyperlipidemia, Hypertension
• All Medications: Atorvastatin, Norvasc
• Allergies: NKDA
Minimally or Micro Invasive Glaucoma Surgery (MIGS)

<table>
<thead>
<tr>
<th>Method: Lateral</th>
<th>Type</th>
<th>Neodymium:YAG</th>
<th>Type</th>
<th>Combination</th>
<th>Type</th>
</tr>
</thead>
<tbody>
<tr>
<td>Biplane</td>
<td>ILM</td>
<td>Less aggressive</td>
<td>Type</td>
<td>Internal</td>
<td>ECP</td>
</tr>
<tr>
<td>Diode</td>
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</tr>
</tbody>
</table>

Types of Stents:
- Cypass
- iStent
- Hydrus
- OMNI
- ABiC
- OMNI/GATT
- Trabectome

- Suprachoroidal Stents
  - Cypass
  - iStent Supra

- Subconjunctival Stents
  - Xen
  - InnFocus Micro

- Cilioablative Stents
  - Micropulse
  - ECP
Ideal Patient Candidate

Trabecular Meshwork Bypass Stents and Schlemm Canal Microstent

23

Trabecular Microbypass Stent
(iStent Inject W)

24


25
Schlemm Canal Microstent (Hydrus)

HORIZON Trial – 4 Year Update

<table>
<thead>
<tr>
<th>48 Months</th>
<th>Cataract Only (n=187)</th>
</tr>
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<tbody>
<tr>
<td>Baseline IOP (mm Hg)</td>
<td>25.5 (+/- 3.0)</td>
</tr>
<tr>
<td>48 months</td>
<td>16.9 (+/- 3.0)</td>
</tr>
<tr>
<td>5 years</td>
<td>15.6 (+/- 3.2)</td>
</tr>
<tr>
<td>1 year post-op need</td>
<td>32.9%</td>
</tr>
<tr>
<td>2 or 3 year post-op need</td>
<td>54.5%</td>
</tr>
</tbody>
</table>

5 Year Update – 56% patient's remain medication-free and 61% reduction in risk to need further surgery
HORIZON Trial – AAO 2021

Microstent lowers the rate of visual field loss by:

47% vs cataract surgery alone

Aqueous Angiography
Before and After Stenting
Alex Huang, MD, PhD

Ideal Patient Candidate

Excisional Goniotomy and Ab Interno Trabeculotomy + Viscocanalostomy
Excisional Goniotomy
(Kahook Dual Blade)

AS-OCT image after KDB treatment. Arrows indicate area of TM removal revealing minimal residual leaflets. (Source: Nate Radcliffe)

Cataract Surgery plus Goniotomy 12-Month Outcomes

<table>
<thead>
<tr>
<th></th>
<th>1 Day</th>
<th>1 Wk</th>
<th>1 Mo.</th>
<th>3 Mo.</th>
<th>6 Mo.</th>
<th>12 Mo.</th>
</tr>
</thead>
<tbody>
<tr>
<td>% of pts ≥ 20% IOP reduction from baseline</td>
<td>54.4%</td>
<td>57.8%</td>
<td>55.1%</td>
<td>67.4%</td>
<td>60.9%</td>
<td>57.7%</td>
</tr>
<tr>
<td>% of pts using ≥ 1 fewer medications from baseline</td>
<td>56.5%</td>
<td>64.4%</td>
<td>63.3%</td>
<td>60.5%</td>
<td>60.9%</td>
<td>63.5%</td>
</tr>
</tbody>
</table>

12 Mo.
% of eyes ≥ 20% IOP reduction from baseline | 15.4%  |
% of eyes using ≥ 1 fewer medications from baseline | 84.6%  |

12 Mo.
% of eyes ≥ 20% IOP reduction from baseline | 100%   |
% of eyes using ≥ 1 fewer medications from baseline | 42.3%  |

Patients (n=26) with baseline IOP ≤ 16.5 mmHg

86% of eyes (majority moderate to severe) avoided the need for more invasive glaucoma surgery during the post-operative period.
Transluminal Viscoelastic Delivery
Trabeculotomy (ab interno)

- Treats all 3 points of resistance
- Stand-alone or combined with CE
- Titratable
- 7.3mmHg mean IOP reduction from 23.7mmHg mean medicated baseline
- Mean 12-month IOP of 15.7mmHg


Canaloplasty and Trabeculotomy with the OMNI System in Pseudophakic Patients with Open-Angle Glaucoma: The ROMEO Study

Endocyclophotocoagulation (ECP)
- Treats inflow
- Uses a laser endoscope containing three fiber groupings: light source (illuminate), image guide (visualize), diode laser (treat)
- Direct visualization
- Precise delivery to the ciliary processes
- No damage to the underlying ciliary body and surrounding tissue
11/25/21

Case 2:

Ocular History

• POHX: Primary Open Angle Glaucoma OS>OD

• FHX: – Father – glaucoma, age-related macular degeneration

• Previous Treatment Regimen:   None

• Current Treatment Regimen:   – bimatoprost 0.01% qd OU

   – dorzolamide/timolol bid OS

   – brimonidine 0.1% bid OS

• IOP max

   – OD: 25 mm Hg

   – OS: 25 mm Hg

Medical History

• PMHX:  Nothing of significance

• All Medications:  None

• Allergies: Penicillin

• CH

   OD:  10.5

   OS:  7.5

41

42

43
Ideal Patient Candidate

Subconjunctival Stent (XEN)

Subconjunctival Stent (Xen)

Xen 45 Gel Stent: US Pivotal Clinical Trial

<table>
<thead>
<tr>
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<th>Baseline</th>
<th>12 month</th>
</tr>
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<tbody>
<tr>
<td>Medicated IOP</td>
<td>25.1 (3.7)</td>
<td>15.9 (5.2)</td>
</tr>
<tr>
<td>Glaucoma Meds</td>
<td>3.5 (1.0)</td>
<td>1.7 (1.5)</td>
</tr>
</tbody>
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76.3% of patients reported a mean diurnal IOP reduction of ≥ 20% from medicated baseline at 12 months
Postoperative Adverse Events

Hypotony 16 (24.6%)
(IOP < 6 mmHg at any time)
- Anterior chamber shallow with peripheral irido-corneal touch 1 (1.5%)
- Anterior chamber fill 1 (1.5%)

Bleb Needling 21 (32.3%)

Ab Externo

US Multicenter Pivotal Trial:
Trabecular Microbypass Stent x 3
(Stent Infinite)
Three-stent, standalone procedure
- Three wide-flange stents preloaded in injector system, to facilitate placement across ~6 clock hrs. of Schlemm’s canal

Trial enrolled patients with open angle glaucoma with uncontrolled IOP
- Unresponsive to maximum tolerated medical therapy
- Uncontrolled by medical therapy and prior failed ≥ 1 conventional incisional glaucoma or cilioablative procedure

Enrollment completed Oct 2019
- US IDE, open-label, prospective, single-arm pivotal study
- 72 subjects across 15 investigational sites
- 12-month follow-up
Pivotal Trial: 12-Month Outcomes

- Mean of 3.1 hypotensive medications at baseline
- History of 2 failed prior glaucoma surgeries
- 76% of subjects achieved 20% or greater reduction in mean diurnal IOP from baseline on same or lower ocular hypotensive medication burden
- 50% of subjects achieved 30% or greater reduction in mean diurnal IOP from baseline
- In addition, 32% mean reduction in medication burden from baseline
- No explants, infections, device-related interventions or hypotony

Post-operative Considerations with MIGS
1. Stopping GLC Meds
2. IOP Spikes
3. Hyphema
4. Hypotony
5. Establish New Baselines

Stopping Glaucoma Medications

Severity of the Glaucoma
Preoperative IOP vs Postoperative IOP
IOP progression was occurring

New baseline would carry and likely on med in tandem with MIGS
PAS to Stents

US Pivotal iStent Inject Trial
1.8% @ 24 months

HORIZON Trial
13% @ 48 months

Hyphema

IOP Spikes
Ocular Hypotony – Is it a Concern with MIGS?

Hypotony – An IOP below which the eye does not maintain its normal shape and may subsequently lose vision. Definitions vary slightly – IOP< 5 or 6

Episceral Venous Pressure and its role

Establish New Baselines

In Conclusion...

- Glaucoma is both a **medical** and **surgical** disease – Key to success is collaboration
- Trends in treatment aim to **balance** effectiveness and safety
- MIGS procedures allow for **interventional glaucoma**
Thank You!

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