Achieving Success in Today’s World of Glaucoma Surgery

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Disclosures

New World Medical, C

Aerie Pharmaceuticals, S
Disease Stage?

POAG?

Assess Risk for Subconjunctival Fibrosis

Filtration Surgery

HIGH

ECP
Trabeculectomy
MMC Sponge Application versus Injection
• 82 consecutive patients randomized to MMC injection vs. sponges and followed for 3 years post-operatively

• Primary Outcome
  • Surgical Success = IOP > 5 and < 21 mm Hg, IOP reduction ≥ 20%, no loss of NLP, no re-op

• Secondary Outcomes
  • IOP, # gtts, BCVA, Complications, Endothelial Cell Count Changes, Bleb Appearance

• Similar cumulative probabilities of success at 3-years (72.2% vs. 65.1% in injection versus sponge groups, P=.30)
• Similar post-op IOPs (15.3±3.7 vs. 16.4±3.5, respectively, P=0.54)
• More diffuse, less vascularized, and more shallow blebs in injection group

• Retrospective review of 30 eyes of 28 NTG patients with follow-up of 50.3±30.8 mos after trabeculectomy

• Mean pre-op IOP = 13.3±1.4 mmHg

• Mean post-op IOP = 8.6±2.9 mmHg

Treatment Outcomes in the Primary Tube Versus Trabeculectomy Study after 1 Year of Follow-up

Steven J. Gedde, MD,1 William J. Feuer, MS,1 Wei Shi, MS,1 Kin Sheng Lim, MD,2 Keith Barton, MD,3 Saurabh Goyal, MD,4 Iqbal I.K. Ahmed, MD,5 James Brandt, MD,6 for the Primary Tube Versus Trabeculectomy Study Group*

Aqueous Shunts
- Cumulative proportion failing, $p = .01$
  - AGV $\rightarrow$ 49%
  - BGI $\rightarrow$ 37%

Pooled AVB-ABC Study, IOP Results

- Mean IOPs, p<.001
  - AGV: $31.2 \pm 10.9 \rightarrow 15.8 \pm 5.2$
  - BGI: $31.8 \pm 11.8 \rightarrow 13.2 \pm 4.8$
Pooled AVB-ABC Study, Reasons for Failure

<table>
<thead>
<tr>
<th>Reason for Failure</th>
<th>Ahmed</th>
<th>Baerveldt</th>
<th>P Value</th>
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<tbody>
<tr>
<td>Overall outcome</td>
<td></td>
<td></td>
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<tr>
<td>Success</td>
<td>137 (51%)</td>
<td>156 (63%)</td>
<td>.007</td>
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<tr>
<td>Failure</td>
<td>130 (49%)</td>
<td>91 (37%)</td>
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<tr>
<td>Reasons for failure</td>
<td></td>
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<tr>
<td>Hypotony</td>
<td>1 (0.4%)</td>
<td>11 (4%)</td>
<td>.002</td>
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<tr>
<td>High intraocular pressure</td>
<td>112 (42%)</td>
<td>56 (23%)</td>
<td>&lt;.001</td>
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<tr>
<td>Severe vision loss</td>
<td>13 (4.9%)</td>
<td>18 (7%)</td>
<td>.25</td>
</tr>
<tr>
<td>Explantation</td>
<td>4 (2%)</td>
<td>6 (2%)</td>
<td>.53</td>
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Risk-Reward
• 47 cases tx’d with timolol/dorzolamide once IOP > 10mm Hg (group 1) vs. 47 cases tx’d with stepwise gtt therapy once IOP > goal (group 2)

• 63.2% vs. 33.3% success rates, respectively, P=0.008, at 1-year

Effect of Early Treatment with Aqueous Suppressants on Ahmed Glaucoma Valve Implantation Outcomes

Mohammad Pakravan, MD,1 Shahram Salehi Rad, MD,1 Shahin Yazdani, MD,1 Elaham Ghahari, MD,1 Mehdi Yaseri, PhD2

MicroInvasive Glaucoma Surgery
MIGS Definition

Ab interno microincision
Minimal trauma
Modest Efficacy
High Safety Profile
Rapid Recovery

Visualization is Key!
iStent Inject

- FDA approved for combination with cataract surgery in mild to moderate stages of primary open-angle glaucoma in June 2018

SSED, available at FDA.gov.

Hydrus Microstent

For Old Time’s Sake
MIGS Efficacy Outcome Measures

1) Percentage of subjects achieving $\geq 20\%$ reduction in unmedicated mean diurnal IOP (MDIOP) versus baseline
   • Medication washout at baseline AND at 2-year follow-up visit

2) Mean unmedicated IOP reduction
MIGS Efficacy Summary – Outcome 1, 24 mo

Proportion with MDIOP Decrease ≥ 20% from baseline (%)

- iStent Inject (n=387)
- Cypass (n=374)
- Hydrus (n=369)
- Phaco/IOL (n=118, 131, 187)
MIGS Efficacy Summary – Outcome 2, 24mo

IOP Reduction from Baseline (mmHg)

- iStent Inject (n=387): 7.0±4.0
- Cypass (n=374): 7.4±4.4
- Hydrus (n=369): 7.6±4.1
- Phaco/IOL (n=118, 131, 187): 5.4, 5.4, 5.3
Cypass & Endothelial Health

Statistically Significant Difference in ECD between Cypass and Control at Months 48 and 60

Month 48

Month 60
Cypass & Endothelial Health

Statistically Significant Difference in ECL between CyPass and Control at Months 48 and 60

Month Post Implantation

Percent Change

-45% -40% -35% -30% -25% -20% -15% -10% -5%

3 6 12 24 36 48 60

N= 209 65 210 64 206 66 212 67 11 5 116 33 162 40

p=0.0001 p=0.0032

CyPass Control
August 14, 2019

Dear Colleagues,

Today, Alcon announced an expansion, including recall, of all versions of the CyPass MicroStent.

The recall is related to a regulatory issue in specific lots of the device. Specifically, the affected lots are 306301 and 306302, which were manufactured on September 20, 2018.

It is important to note that the CyPass MicroStent has already been approved by the FDA for the treatment of POAG.

Please refer to the recall notice for specific details.

Sincerely,

[Signature]

Additional Information:

Example of CyPass MicroStent Position

- Collar
- Retention ring
- 3 rings
- 1 ring

Product Information:

- CyPass MicroStent
- FDA Approval
- Regulatory Notice
Recommendations

• If more than 1 ring visible and corneal decompensation $\rightarrow$ trim proximal end

• Do not attempt removal/repositioning

• If no clinical sequelae to > 1 ring $\rightarrow$ monitor
Kahook Dual Blade

Courtesy of Leo Seibold, MD
University of Colorado
SC = Canal of Schlemm
TM = Trabecular Meshwork
SS = Scleral Spur

Source: NWM Sponsored Study at Univ. of Colorado
• Retrospective Review of standalone KDB goniotomy (n=32) vs. KDB/Phaco (n=165)
• Success = IOP reduction ≥ 20% and/or reduction of 1 gtt
• At 12 mo
  • 68.8% and 71.8% success rates (84.6% in PXF)
  • IOP/gtt reductions
    • $20.4 \pm 1.3$ on $3.1 \pm 0.2$ gtt → $14.1 \pm 0.9$ on $2.3 \pm 0.4$ gtt (p<.01)
    • $16.7 \pm 0.4$ on $1.9 \pm 0.1$ gtt → $13.8 \pm 0.4$ on $1.5 \pm 1.1$ gtt (p<.01)

Reduction in Intraocular Pressure after Cataract Extraction: The Ocular Hypertension Treatment Study

- Average 16.5% IOP reduction
- 39.7% with postoperative IOP reduction >20%
Gonioscopy-assisted Transluminal Trabeculotomy: An Ab Interno Circumferential Trabeculotomy: 24 Months Follow-up

Davinder S. Grover, MD, MPH,* Oluwatosin Smith, MD,* Ronald L. Fellman, MD,* David G. Godfrey, MD,* Aditi Gupta, MD,* Ildamaris Montes de Oca, MD;† and William J. Feuer, MS‡

- Retrospective review of 198 adult patients with ≥ 18 months follow-up
- POAG
  - Mean IOP decrease = 9.2 mm Hg (37.3%) at 24 months
- SOAG
  - Mean IOP decrease = 14.1 mm Hg (49.8%) at 24 months
- 9-13% incidence of hyphema

GATT Results – Advanced Disease

Endoscopic Cyclophotocoagulation

• Endoscopically-guided ablation of ciliary processes

• 810nm diode laser probe combined with video camera and light source

• Developed in 1992 by Uram
Operating Room Logistics
ECP Technique
One-site Versus Two-site Endoscopic Cyclophotocoagulation

Malik Y. Kahook, MD, Kira L. Lathrop, MAMS, and Robert J. Noecker, MD

• 1-Site ECP (n=15)
  • 23.6±3.89 → 16.00±2.77 mmHg at 6mo

• 2-Site ECP (n=25)
  • 24.48±8.99 → 13.00±3.09 mmHg at 6mo

• P=0.03 for IOP difference between 1-site and 2-site ECP

ECP Complications

• 5824 eyes, 5.2 years follow-up
  • Cataract (24.5%)
  • Post-operative IOP spike (14.5%)
  • Intraocular hemorrhage (3.8%)
  • CME with vision loss (1.0%)
  • Serous choroidal effusion (0.4%)
  • Retinal detachment (0.3%)
  • Hypotony/phthisis (0.1%)
  • Choroidal hemorrhage (0.1%)

Xen Gel Stent
• 76.3% (n=65) with ≥ 20% IOP lowering from baseline on same or fewer medications

• Mean diurnal IOP reduction = 6.4 ± 1.1 mm Hg

• Efficacy independent of age, ethnicity, gender, and baseline IOP

• AEs through month 12 classified as mild/moderate and self-resolved

• 32.3% required needling within 12 months

Future Questions to Consider

• Preferential Bleb Morphology with MMC injection associated with better long-term outcomes?

• Differential MIGS Efficacy Based on:
  • Age? Duration of Disease? Topical Meds?

• Will suprachoroidal devices make a comeback?
Thank you
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