Choosing Glaucoma Surgery

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Conflicts of Interests Disclosure

• AAO Foundation – Hoskins Center for Quality and Safety
• American Board of Ophthalmology
• Centers for Disease Control and Prevention
• ARVO Foundation for Eye Research
• University of Michigan
• Duke University / Health System
• Glaucoma Research Fdn
• Private investment
  – Vital Spring Health Technologies
• Consultant and Research funding
  – Genentech
  – Pfizer
  – Novartis
• Intellectual property
  – Statins for glaucoma
  – EMR decision support and data entry
Key Points

• Choosing among conventional surgical options

• Placing new surgeries in context

• Important role of laser trabeculoplasty
Considerations in Choosing Surgery

• Achieve long-term target pressure range
  – Stage / severity of glaucoma
  – Ability of surgery to achieve target range
• Immediacy of pressure reduction
• Minimize complications / side effects
• Minimize patient and MD burden of care
• Consistent with patient lifestyle and needs
• Ability to continue to use medications
“Failure Rate” in Glaucoma Filtering Surgery – Advanced Cases

- Modified “Dose Response” to IOP (PPP, 1992)

<table>
<thead>
<tr>
<th>Mean IOP (mm)</th>
<th>Worse (%)</th>
<th>Follow-up (yrs)</th>
</tr>
</thead>
<tbody>
<tr>
<td>14.4</td>
<td>6</td>
<td>5</td>
</tr>
<tr>
<td>15.0</td>
<td>18</td>
<td>5</td>
</tr>
<tr>
<td>17.3</td>
<td>35</td>
<td>4</td>
</tr>
<tr>
<td>18.1</td>
<td>29</td>
<td>5</td>
</tr>
<tr>
<td>19.1</td>
<td>58</td>
<td>5</td>
</tr>
</tbody>
</table>
Blindness after Filtering Surgery
Parc, et al, AJO, 2001

• 73 eyes from Olmsted County, diagnosed and between 1965 and 1980 and surgery between 1965 and 1998
• Mean pre-op IOP of 27.6 ± 8.5 mm

• Blindness at 10 years was 46 %
• NO difference in IOP (14.0 blind, 15.4 not)
• Difference – degree of initial VF loss
Longer-Term Pressure Results (with Medications) – **Patient** Level

- **Single digits**
  - Full thickness trab with antimetabolite tube “plus”

- **Low –mid teens**
  - Trab w or w/o antimetabolite large plate tube (s)

- **Mid - high teens**
  - Mid size plate tube / trab canaloplasty / trabectome / stenting surgeries
Tube vs Trabeculectomy Study: 5 Year (after cataract or failed trab) Gedde SJ, et al, AJO 2012

IOP of > 17 or not 20% decrease
Also persistent hypotony, reoperation for glaucoma, loss of LP

IOP of > 14
Tube vs Trabeculectomy Study
Ahmed vs Baerveldt 350 Trial
Christakis, et al, Ophthlamology 2011
IOP Control and Medications Needed
Plate Area = Drainage

- Coleman, et al, 1995 – Ahmed
  Prior CYC eyes included
  Eyes without CYC did worse

- Heuer, et al, 1995 Molteno Study

<table>
<thead>
<tr>
<th></th>
<th>Single</th>
<th>Double</th>
</tr>
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<tbody>
<tr>
<td>One-year</td>
<td>55 %</td>
<td>86 %</td>
</tr>
<tr>
<td>Two-years</td>
<td>46 %</td>
<td>71 %</td>
</tr>
</tbody>
</table>
350 vs. 500 Baerveldt

- Life table success
  - 18 mos: 93 % (350) vs. 88 % (500)
  - w/o meds: 14 % (350) vs. 38 % (500)

- Complications
  - choroidals: 16 % (350) vs. 32 % (500)
  - SCH: 3 % (350) vs. 5 % (500)
  - phththisis: 0 % (350) vs. 3 % (500)
Plate Surface Areas

- S3 Ahmed: 96
- Molteno – single: 135
- Molteno – double: 270
- S2 Ahmed: 184
- Baerveldt: 250-425
- 360 Schocket: 1080

- Current Opinion (review)
- Gedde S et al, 2013

- “Increasing the surface area of the end-plate ... is associated with lower levels of IOP and ... fewer adjunctive glaucoma medications.”
## Complications - ABC

*Budenz D et al, Ophthalmology 2011*

Statistically Significant Differences in Red

<table>
<thead>
<tr>
<th>Complication</th>
<th>Ahmed</th>
<th>Baerveldt</th>
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</thead>
<tbody>
<tr>
<td>Tube occlusion</td>
<td>2 %</td>
<td>9 %</td>
</tr>
<tr>
<td>Corneal edema</td>
<td>12</td>
<td>22</td>
</tr>
<tr>
<td>Total early (pts)</td>
<td>43</td>
<td>58</td>
</tr>
<tr>
<td>Reoperations for Complications</td>
<td>5</td>
<td>13</td>
</tr>
<tr>
<td>Total serious (pts)</td>
<td>20</td>
<td>34</td>
</tr>
<tr>
<td>Vision loss (2+ lines)</td>
<td>18</td>
<td>27</td>
</tr>
<tr>
<td>Diplopia (≤ 3 mos)</td>
<td>6</td>
<td>5</td>
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</table>
Key Points

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• Placing new surgeries in context
• Important role of laser trabeculoplasty
Clinical Results - Trabectome for OAG: Mayo

Failure: increase in meds on 2+ consecutive visits, loss to LP, glaucoma op, and IOP top is 21 or less or 20% reduction; bottom is 18 or less AND 20%
Canaloplasty – 3 Year
Grieshaber MC, et al (Stegman R), BJO 2010

<table>
<thead>
<tr>
<th>Description</th>
<th>1 year</th>
<th>2 year</th>
<th>3 year</th>
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<tbody>
<tr>
<td>Kaplan Meier Survival for IOP 21 or less</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>IOP of 18 or less</td>
<td>81%</td>
<td>68%</td>
<td>68%</td>
</tr>
<tr>
<td>Mean pre-op IOP of 45</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Kaplan Meier Survival for IOP of 16 or less</td>
<td></td>
<td></td>
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<tr>
<td>Complete success rates without medications</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean pre-op IOP of 45</td>
<td></td>
<td></td>
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Phacotrab vs Phacocanaloplasty

• Complete success
  – IOP of less than 18 mm
  – No use of glaucoma medications
  – N/S (small sample size)
iStent and Cataract Surgery

- Mild to moderate stage
  - VF or ONH
  - c/d 0.8 or better
  - IOP 24 or better on 1 to 3 medications
- IOP between 22 and 36 after washout
- Randomize 1:1 to cataract surgery alone or with iStent

- 24 month follow-up
- Primary endpoint of 21 mm Hg or less (p=.036)
  - iStent 61%
  - Control 50%
- Secondary endpoint of 20% reduction in IOP (n/s)
  - iStent 53%
  - Control 44%
Multiple iStents

- 53 eyes / 47 pts
- Needed cataract surgery
- IOP either
  - Poor control
  - 3 or more medications
- Nasal region
- 1 to 2 hrs apart
- # based on IKA view of severity
Cypass Micro-stent

- Results from initial safety study (FDA)
- Fenestrated, polyimide, with inserter through Anterior chamber
- 184 patients – 6 mos f/u
  - 91 failed rx
    - 37% mean IOP reduction
    - 1.2 meds mean reduction
  - 93 wanted to reduce rx
    - All stayed below 21 mm Hg
    - 71% reduction in meds
Science of Trabecular Meshwork

• Flow is functionally restricted in Schlemm’s canal as we age

• Majority of outflow resistance is in juxtacanalicular meshwork, but around 30% external to lumen of Schlemm’s canal
  – Dissection surgically in Grant’s lab in 1950’s
  – Excimer directed dissection by Schuman in 1990’s

• Scar tissue is not very permeable to fluid
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Glaucoma Laser Trial

- IOP 1 mm lower than medications
- VF 0.5 to 1.0 db better than meds

- VF Progression

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<thead>
<tr>
<th></th>
<th>Laser</th>
<th>Medicines</th>
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<tbody>
<tr>
<td>7 yrs</td>
<td>43 %</td>
<td>66 %</td>
</tr>
<tr>
<td>9 yrs</td>
<td>74 %</td>
<td>100 %</td>
</tr>
</tbody>
</table>
Systematic Review – SLT
McAlindden C, Eye, 2013

• “In terms of the IOP lowering effect, there is no difference between SLT and ALT.”

• “… no difference between 360 degree SLT and medical therapy.”

• “… no difference between 180 degree and 360 degree SLT.”
Key Points

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Recovery of Visual Field / Vision
Immediate Pressure Lowering

• Trabeculectomy
• Ahmed / Krupin valve
• Venting slits on Baerveldt
• Cyclodestruction
Adverse Outcomes with Surgery
Stein JD, et al, Ophthalmology 2008

- (♦) GDD = glaucoma drainage device
- (■) PT = primary trabeculectomy
- (▲) TS = trabeculectomy with scarring.
Figure 4  Kaplan-Meier curves showing the cumulative probability of failure from any cause in the Ahmed Baerveldt Comparison Study defining inadequate intraocular pressure (IOP) control as ( A ) IOP of more than 17 mmHg or ( B ) IOP of more than 14 mmHg.

Donald L. Budenz, Keith Barton, William J. Feuer, Joyce Schiffman, Vital P. Costa, David G. Godfrey, Yvonne ...

**Treatment Outcomes in the Ahmed Baerveldt Comparison Study after 1 Year of Follow-up**

Ophthalmology Volume 118, Issue 3 2011 443 - 452

http://dx.doi.org/10.1016/j.ophtha.2010.07.016
Initial treatment with medications and initial treatment with trabeculectomy are effective in reducing IOP.
Visual field loss was greater in the Surgery Group during the first 3 years of the Study, but these differences largely disappeared during years 4 and 5 of followup.
Blindness after Filtering Surgery
Parc, et al, AJO, 2001

• 73 eyes from Olmsted County, diagnosed and between 1965 and 1980 and surgery between 1965 and 1998
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Impact of Clinical Trials (AGS)

Panarelli JF, et al. J Glaucoma 2013 (epub)
Canaloplasty – 2 Year Followup

- 107 eyes
- International prospective study
- Enrollment
  - IOP ≥ 16
  - Tmax ≥ 21
- DG = distention grade on U/S
- Visits = 6 month intervals
Impact of Clinical Trials (AGS)
Panarelli J, et al, J Glaucoma 2013 (Epub)

TVT - tube for failed trab
TVT - tube after cataract surgery

- Strongly Disagree
- Disagree
- Neutral
- Agree
- Strongly Agree