Glaucoma Surgery Advances

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Evolution of glaucoma surgery

The changing popularity of filtering procedures:

Elliot’s Trephination 1909 – 1940
Iridencleisis 1940 – 1957
Thermal Sclerostomy (Scheie) 1958 – 1968
Posterior Lip Sclerectomy 1962 – 1968
Trabeculectomy 1968 –

...?... 2013–

after: C. Davis Belcher III, 1992
Glaucoma Surgery Trends

• Evolutionary improvements in trabeculectomy-like procedures
  o Canaloplasty
  o ExPRESS glaucoma filtration device

• Increased use of long-tube shunts
  o Ahmed, Baerveldt GDDs

• New field: “Micro-invasive glaucoma surgery”
  o Ultra-safe, quick procedures with modest IOP lowering
Terminology

• “Minimally invasive glaucoma surgery” introduced by Ike Ahmed at “Cutting Edge” meeting prior to AGS meeting in March, 2011
  Term was used to describe almost all glaucoma surgeries other than trabeculectomy or tube shunt procedures

• “Micro-invasive glaucoma surgery”
  – Hady Saheb and Ike Ahmed clarified their thoughts on this terminology

Micro-Invasive Glaucoma Surgery: MIGS

- Ab interno surgical approach
- Minimal trauma to tissue
- Superior safety and a low complication profile compared with traditional filtering surgery
- At least modest IOP-Lowering efficacy
- Rapid postoperative recovery of patients
- Should not preclude success of future, more aggressive surgical intervention
Patient Profiles: New Procedures

**MIGS-Type Procedures**
Ab-interno Schlemm’s/Suprachoroidal

- Mild-moderate disease
- Open-angle
- Modest IOP target (i.e., 15-16 mm Hg)
- Able to tolerate some meds

**Trab-Type Procedures**
Ex-PRESS

- Moderate-advanced disease
- Progressing normal pressure glaucoma
- Open, or narrow angle
- Low IOP target (i.e., <13 mm Hg)
- Intolerant to most meds
Background

• In the US, there are more than 3 million cataract procedures performed each year.
• More than 650,000 cataract patients have the comorbidity of glaucoma or ocular hypertension.
• Cataract surgery can lower the IOP, but most patients still need to take medications.
The Eye's Conventional Outflow System

POAG

TM the site of resistance?

Trabeculotomy:
- Normal Eye eliminates 50% of R
- GL Eye eliminates all of abnl R

Anterior Chamber
GL 18LN

yes: demonstrated by Grant in 1963
Trabectome
Insulated footplate acts as a guide within Schlemm’s Canal
Trabectome
Intraocular pressure (IOP) timeline before and after surgery (STD = standard deviation).

Brian A. Francis, Don Minckler, Laurie Dustin, Shahem Kawji, Jason Yeh, Arthur Sit, Sameh Mosaed, Murray ...

Combined cataract extraction and trabeculotomy by the internal approach for coexisting cataract and open-angle glaucoma: Initial results

Journal of Cataract & Refractive Surgery Volume 34, Issue 7 2008 1096 - 1103
iStent

Trabecular Micro-Bypass Stent

iStent® is the first ab interno micro-bypass stent for the treatment of glaucoma

- Designed to **restore** continuous physiologic outflow
- **Creates** a patent bypass through the trabecular meshwork to Schlemm’s canal
- **Increases** outflow due to the high presence of collector channels in the lower nasal quadrant
iStent® is the smallest medical device known to be implanted in the human body

- **Length**: 1 mm
- **Height**: 0.33 mm
- **Snorkel**: 0.25 mm x 120 µm (bore diameter)
- **Weight**: 60 µg

- Surgical grade nonferromagnetic titanium
- Heparin-coated to promote self-priming and facilitate outflow
Prospective, randomized, multicenter study:

- iStent + cataract surgery vs. cataract surgery alone
- 240 eyes with cataracts and mild to moderate OAG
- IOP ≤ 24 mmHg on 1 – 3 ocular hypertensive medications
- IOP 22 – 36 mmHg after medication washout

Efficacy endpoints:

- postoperative IOP managed to the same threshold IOP (21 mmHg)
- medication was added when IOP > 21 mmHg

In both groups:

- postoperative IOP managed to the same threshold IOP (21 mmHg)
- medication was added when IOP > 21 mmHg
- Per study design, postop IOP would be expected to be similar in both groups

At 12 months, 73% of iStent subjects with IOP ≤ 21 mm Hg without medication vs. 50% with cataract surgery alone (P<0.001)
2-year F/U study

Craven ER, et al JCRS 2012;38:1339

Total
240 Eyes of 239 Subjects

Stent + Cataract
117 Eyes of 116 Subjects
- n=4 complicated cataract surgery
- n=1 inability to implant stent
- n=1 terminated from study before surgery

Eligible for Continued Study Participation
n=111
- n=5 secondary surgical intervention
- n=1 missed 12 month visit
- n=3 lost to follow-up
- n=4 death

Consistent Cohort
n=98

Cataract Surgery Only
123 Eyes of 123 Subjects
- n=3 complicated cataract surgery
- n=6 terminated from study before surgery

Eligible for Continued Study Participation
n=114
- n=6 secondary surgical intervention
- n=4 lost to follow-up
- n=3 death

Consistent Cohort
n=101
### 2-year F/U study

<table>
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<tr>
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<th>Stent Group n=116</th>
<th>Control Group n=123</th>
<th>P value</th>
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<tbody>
<tr>
<td>IOP ≤21 mm no meds</td>
<td>71(61)</td>
<td>61(50)</td>
<td>.036</td>
</tr>
<tr>
<td>IOP reduction ≥20% no meds</td>
<td>61(53)</td>
<td>54(44)</td>
<td>.090</td>
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</table>
A prospective evaluation of multiple iStent implantations:

- 28 eyes with 2 stents
- 25 eyes with 3 stents

Stents implanted in conjunction with cataract surgery

Evaluation of IOP and medications

Belovay GW, et al JCRS 2012;38:1911
Multiple iStent Therapy
Multiple iStent Therapy

[Graph showing the IOP (mm Hg) over time for 2 and 3 Stents. The graph indicates a decrease in IOP with time, with 3 Stents showing a slightly lower IOP compared to 2 Stents.]
Multiple iStent Therapy
New article

A Novel Schlemm's Canal Scaffold Increases Outflow Facility in a Human Anterior Segment Perfusion Model.

• Measure baseline outflow facility
• Measure outflow facility for a second time after:
  o **Hydrus™** device insertion (experimental eyes)
  o **Sham** procedure (tissue manipulation without device insertion; control eyes)
Hydrus 15 mm Increases Outflow Facility

**C (µL/min/mmHg)**

- **Baseline**
  - Experimental Eyes (n=9)
  - Control Eyes (n=7)

- **Hydrus™ Implant**

- Control

* p<0.05, **p<0.01
Hydrus Microstent

- An ab-interno approach for lowering IOP that targets the eye’s conventional outflow system

- Scaffolding mechanism rebuilds and preserves Schlemm’s canal by dilating tissue and reconstructing outflow channel

- Engineered to re-establish flow to collector channels

- Performed adjunctively with cataract surgery
Hydrus™ Microstent

- Flexible canal “scaffold”
- Composed of biocompatible alloy (Nitinol)
- Scalloped and open design allows aqueous flow
- 3 clock-hour length targets multiple collector channels
Designed to Allow Flow to Multiple Collector Channels
Hydrus™ Microstent in Schlemm’s Canal

(6 - months post-implantation)
Hydrus Surgery Video

- Ab-interno “scaffold” delivery
- Cannula tip opens trabecular meshwork and accesses Schlemm’s canal
- Hydrus dilates and supports canal
Hydrus

- Early European data demonstrate IOPs in the mid-teens at 12 months
- Device is currently available in Europe and is in an FDA investigational device clinical trial (IDE) in the US
Practice

- Should familiarize yourself with intraoperative gonioscopy
- After implantation of the IOL, deepen the AC
- Tilt the patient’s head approximately 30 away from yourself and angle the microscope about 30 towards yourself
- Place a surgical gonioprism on the cornea with nondominant hand and use a Sinskey hook in the dominant hand to approach the angle and mimic the subtle wrist pronation needed for implantation
Summary

• Although trabeculectomy remains the gold standard for incisional glaucoma surgery, the search for a procedure that can effectively and safely lower IOP and improve on these standards continues.

• Majority of the novel procedures seek to avoid bleb formation entirely and rely on augmentation of the physiologic outflow pathways.

• Randomized trials are needed.