My glaucoma patient is continuing to progress. What’s new and best?

An Update on Glaucoma Surgery
Michael Chaglasian, OD, FAFAO
Illinois Eye Institute
Illinois College of Optometry
mchaglas@ico.edu

Here’s the situation:
- 57 yo, W, F
- -7.50 Myopia
- Good Medical Health
- CCT= 562, 571
- GAT: 19-23 / 18-23 mmHg
  - Pre-Treatment 26/31; 12 months ago
- Current Meds:
  - PGA qhs OU
  - Fixed Combination OU
- Target IOP OD:
  - ≤ 12 mmHg

Selective Laser Trabeculoplasty
1. Is SLT more effective (IOP reduction) than ALT?
2. Is SLT better than medical therapy?
3. Is SLT repeatable?
4. Do topical medications affect SLT?
5. How good is SLT on maximal topical therapy?
6. Does SLT work on nocturnal IOP elevation?
7. Does SLT work after cataract surgery?
8. Cost effectiveness vs. medical therapy?

Is SLT better than ALT?
- Conclusions:
  - Laser trabeculoplasty is successful in lowering intraocular pressure for patients with open angle glaucoma.
  - At this time, there is no literature establishing the superiority of any particular form of laser trabeculoplasty.

Is it better than medical therapy?
- Conclusions:
  - IOP reduction was similar in both arms after 9 to 12-months follow-up.
  - These results support the option of SLT as a safe and effective initial therapy in open-angle glaucoma or ocular hypertension.
  - SLT may be the best or most preferred treatment option for some patients

Is SLT repeatable?
- Conclusions:
  - “We found that a repeat 360-degree SLT provided additional IOP reduction, which was not as marked as that with the first treatment (~20%)”
  - Overall, poorly studied.
  - Generally yes, to a very modest extent (~2 mmHg)
Repeat SLT

- 45 eyes/25 subjects
- Avg 28 m post 1st Tx @ 24 m
- 29% > 20% IOP lowering
- 39% > 15% lowering
- Repeat Tx was less effective than initial

Do top topical medications affect SLT?

- Conclusions:
  - Topical medications do not adversely, nor favorably, affect SLT success.
  - Success rate of 67% at 6 months.
- Factors:
  - Pigmentation of the anterior chamber angle, class of antiglaucoma medications, diabetes, sex, corneal thickness, pseudophakia, diagnosis, washout of eye drops, and previous argon laser trabeculoplasty treatment are not associated with SLT treatment efficacy.

How good is SLT with topical maximal therapy?

- SLT with ≥ 3 mmHg Reduction
  - 30% Non Responders
  - 70% Responders

Somewhat

Does SLT work on nocturnal IOP?

Yes!

Does SLT work after cataract surgery?

- Conclusions:
  - SLT response was delayed in pseudophakic compared to phakic patients.
  - while the long-term effectiveness of SLT is the same in both groups.

Yes!

Does SLT work after cataract surgery?

- Results:
  - There were no significant differences in the IOP lowering effects between the two methods at any time point during the follow-up period (12m)
  - Mean IOP reduction:
    - 75% subjects ≥ 15% dec. from base.
    - Approx. 3-4 mmHg
Is SLT more cost effective?

- Conclusions:
  - Prostaglandin analogs and LTP are both cost-effective options for the management of newly diagnosed mild open-angle glaucoma.
  - Assuming optimal medication adherence, PGAs confer greater value compared with LTP.
  - However, when assuming more realistic levels of medication adherence (making them 25% less effective), then at current prices for PGAs ($330/yr), LTP may be a more cost-effective alternative.

Why not just do a CE/Phaco.?

- Cataract Extraction
  - Generally only appropriate for early stage OHTN glaucoma that is not progressing (or ACG)
  - Much less effect for moderate glaucoma
  - Can reduce use of topical medications
  - Is not long lasting.

Data from OHTS:
- ~ 3-4 mmHg lower
- mean of -16% lower
- ~ 36 months (at least)

Traditional Options

- Trabeculectomy with anti-metabolite (MMC)
  - Bleb forming procedure
  - Risk of bleb leak related complications
  - Long established procedure with vast experience

- Glaucoma Drainage Device
  - External reservoir, moderately invasive
  - Baerveldt, Ahmed
  - Typical role is following failed procedures

Incisional Glaucoma Surgery

Traditional filtering or glaucoma drainage devices remain the surgery of choice for patients with advanced glaucoma.

EX-PRESS Glaucoma Filtration Device

- E-Shunt
  - Stainless steel implant into angle
  - still a bleb forming procedure
  - Generally good outcomes, about on par with standard trabeculectomy
  - Fewer complications

FDA Approved

Ex-Press mini-shunt

Alcon
An Update on Glaucoma Surgery

Conclusions:
• Mean intraocular pressures, medication use, and surgical success were similar at 2 years after treatment with the EX-PRESS device and trabeculectomy.
• Vision recovery between groups was also similar throughout the study, although return to baseline vision was more rapid in the EX-PRESS group.
• Intraocular pressure variation was lower during the early postoperative period, and postoperative complications were less common after EX-PRESS implantation compared with trabeculectomy.

What’s New Surgically?
MIGS
Micro Invasive Glaucoma Surgery
Why?
• An unmet need for surgical intervention for mild to moderate glaucoma patients with coexisting cataract.
• MIGS combined with cataract surgery will have an increasing role in managing these patients

Newest Surgical Procedures
• MIGS
  — Micro Invasive Glaucoma Surgery
• Emerging category of devices and procedures
  — Alternative to multiple medications
  — Often combined with cataract extraction
  — Differing definitions and can be grouped into two categories

Methods of lowering IOP with MIGS
1. Schlemm’s canal
   (Trabectome - NeoMedix; iStent - Glaukos)
2. Supraciliary space
   (none FDA-approved, Cypass – Transcend; Supra – Glaukos both in trials)
3. Subconjunctival space
   (none FDA-approved, Aquesys XEN)
4. Intra-Canalicular
   (Hydrus MicroShunt)

MIGS: ab interno
(from inside)

Only Two are Currently FDA Approved:
• iStent trabecular micro-bypass
• Trabectome

iStent
• iStent: Trabecular Micro-Bypass Stent
  — Glaukos Corp.
  — FDA Approved 2012 for:
  • Mild to Moderate Glaucoma in patients who need cataract surgery
  • No Bleb is formed
    — Few complications
  • Relatively Easy to perform
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**iStent**

- iStent safely improves outflow by creating a patent bypass between the anterior chamber and Schlemm’s canal.
- iStent is surgical-grade nonferromagnetic titanium micro-bypass stent preloaded in a single-use sterile inserter.

**iStent: Two Year Data**

- OAG patients to have CE alone or with single iStent
- Results:
  - 61% in iStent had ≤21 mmHg vs. 50%  
  - Note 1 yr data was 68%  
  - IOP similar at first (~17), but then 1mmHG higher in CE alone  
  - iStent group had fewer medications

**iStent Inject**

- targets uveoscleral outflow
- "is a lot easier to use"

**Trabectome**

- FDA approval in 2004, is an ab interno technique that involves the removal of the nasal 60º to 100º of the trabecular meshwork, leaving the inner wall of Schlemm canal intact to preserve collector channel drainage.
- The Trabectome offers surgeons the opportunity to combine surgical cataract and glaucoma treatment with relatively favorable risk profiles while sparing the conjunctiva

**Trabectome (NeoMedix):**

- A thermal cautery device with irrigation and aspiration
- Used to ablate a 2- to 4-clock hour segment of TM and SC
- less traumatic and safer than trabeculectomy surgery
- Is combined with CE
- Modest IOP lowering

M. Chaglasian, OD
Other Procedures in Clinical Trials

Not FDA Approved

CyPass Micro-Stent (Transcend Medical)
- Supraciliary microstent that increases uveoscleral outflow.
- It is implanted through a clear corneal incision and can be combined with cataract surgery.
- CE Mark approval
- Several international clinical trials – US timeline ~2018

Hydrus Microstent
- Is an intra-canalicular device.
- Presently, a 2-year prospective, randomized, controlled trial is underway the safety and efficacy of the Hydrus implanted in conjunction with phacoemulsification.

XEN Gel Stent
- Minimally invasive sub-conjunctival approach bypasses all potential aqueous outflow obstructions.
- Soft gelatin material minimizes complications related to synthetic materials for the patient’s future care.

http://www.ivantisinc.com/hydrus-microstent.php
http://www.aquesys.com/xen.aspx

09.09.2015 | Investors
Allergan to Acquire Glaucoma Treatment Company AqueSys to Add Minimally Invasive Implantable Shunt to Eye Care Offering
- Acquisition adds global rights to XEN45, a minimally invasive “best in class” implantable shunt for glaucoma – XEN45 approved in global markets; late stage development in the US – bolsters Allergan's position in the glaucoma market.