A Case-based Approach to Caring for the Glaucoma Patient: Advances in Glaucoma Surgery

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Financial Disclosure
I have the following financial interests or relationships to disclose:
- Abbott Medical Optics: P,S;
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- Glaukos Corporation: C.S;P
- New World Medical: P;C
- IVANTIS: C;
- ClarVista Medical C, O, P
- OASIS Medical, Inc.: P;
- Shire
- Aerie Pharma
- Regeneron: S;
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- ShapeTech LLC: O,P
- NEI S

Outline
- How to choose which MIGS device to use
- Novel Ophthalmic Knife (Goniotomy)
- Conclusions

The TVT Mentality
- Tubes are worse than Trabs (More meds)
- Trabs are worse than Tubes (More failure)
- Have you ever considered that many of our trials are geared towards identifying which intervention is less harmful? Perhaps it is time for a change?
MIGS: A Case-based Approach

- How do you decide which MIGS to use?
  - Inflow:
    - Endocyclophotocoagulation
    - Therapeutic Ultrasound (Ultrasound Circular Cylco-Coagulation)
    - Iridex CPC (micropulse)
  - Outflow:
    - iStent
    - Hydrus
    - Suprachoroidal (CyPASS)
    - Trabectome
    - GATT
    - Trab 360 Vico360
    - Kahook Dual Blade
    - XEN (MIGS-PLUS)

What are the data points that help us decide?

- Disease status (ONH, VF, OCT)
- Change over time (Slow/Rapid)
- Age (Health Status)
- IOP (Current/Goal)
- Previous Surgery (CE/Trab/GDD)

Choosing the best option(s)

Case #1

- 56 year old male with history of moderate POAG for 10 years and visually significant cataract
- HVF stable for 3 years and current IOP is 16mmHg on PGA and CAI and main goal is to decrease dependence on medication due to intolerance
- Discussion regarding combining CE with MIGS
- What is the best option?
Case #1
- Disease status ➔ Moderate
- Change over time ➔ Stable
- Age ➔ Young and healthy
- IOP ➔ Goal in mid-teens (major goal to dec. meds)
- Previous Surgery ➔ None

CE + iStent
- iStent has been our work horse for mild disease when main goal is to decrease medications
- Superior safety profile with very modest IOP lowering
- Options remain (Trab/GDD)
- Using iStent less every month

Case #2
- 67 year old female with 15 year history of moderate glaucoma and h/o CE 5 years ago
- Failed medications, laser and ExPRESS in past and now has Ahmed implanted with IOP of 18mmHg
- Slight worsening of NS over 1 year
- Goal IOP is 15mmHg
- What is your best MIGS option?

Case #2
- Disease status ➔ Moderate
- Change over time ➔ slow progression
- Age ➔ older and healthy
- IOP ➔ Goal in mid-teens
- Previous Surgery ➔ Ahmed Drainage Device
Standalone ECP

- ECP is ideal in cases with previous GDD implantation where the device is still functioning but goal IOP not achieved
- Good choice prior to committing the patient to a second GDD
- 360 degree treatment
- Options remain for second GDD if needed

Case #3

- 73 year old female with history of LTG for 20 years
- Current IOP is 18mmHg and goal is 12mmHg on MTMT
- Visually significant cataract
- Disease worsening significantly over 8 months
- What is your best option?

Case #3

- Disease status → Advanced
- Change over time → rapid progression
- Age → older and healthy
- IOP → Goal below teens
- Previous Surgery → none
**CE + XEN**

- This patient has advanced disease that is progressing over a short period of time
- Failed medications and goal IOP is low
- Risk/Benefit of more aggressive approach
- CE + XEN more likely to achieve lower pressure with benefits of an ab interno approach
- This will replace ExPRESS in my practice

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**Case Study: Pseudophakic Glaucoma**

- Patient NMS is a 45 year old AA male with 3 year history of POAG and bilateral cataract extraction two years ago
- He has been using latanoprost in both eyes with IOP of 18mmHg in both eyes (Goal is 14mmHg in both eyes)
- He has not refilled his drops in 6 months and has an advancing nasal step
- He admits that remembering to put drops in has been difficult and he has already failed laser trabecuoplasty
- What should be the next step?

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**Goniotomy is making a comeback!**
Genesis of the idea:

- We needed a way to collect TM strips for imaging
- Peeling/stripping did not work well
- 20-30 iterations (focused on ramp)
- Final design worked really well in the lab
- Decision was made to develop for the OR

Design Features

1. Pointed Tip
   Pierce TM
2. Ramp
   Elevates & stretches TM
3. Dual Blades
   Parallel incisions in TM
4. Foot Plate/Heel
   Prevents damage to the anterior wall of the canal

The Ramp is Critical:

- Placing the TM on stretch allows for a more precise cut
- Attempts at incising the tissue on both sides of the TM without elevating and stretching the tissue failed in the past
- As the KDB moves forward, the TM is elevated and cutting occurs above the plane of where the TM usually rests

KDB PRE-CLINICAL DATA
KDB CLINICAL DATA

KDB User Survey
Results to Date in All Patients

<table>
<thead>
<tr>
<th></th>
<th>Pre-Op (n=120)</th>
<th>Day 1 (n=120)</th>
<th>Week 1 (n=120)</th>
<th>Month 1 (n=120)</th>
<th>Month 3 (n=115)</th>
<th>Month 6 (n=90)</th>
<th>Month 9 (n=89)</th>
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</thead>
<tbody>
<tr>
<td>IOP (mm Hg)</td>
<td>18.7 ± 6.7</td>
<td>13.0 ± 6.5</td>
<td>14.2 ± 4.3</td>
<td>13.5 ± 3.9</td>
<td>12.3 ± 2.5</td>
<td>12.0 ± 4.2</td>
<td></td>
</tr>
<tr>
<td>Mean IOP difference</td>
<td>REFERENCE</td>
<td>-5.7 (P&lt;0.001*)</td>
<td>-4.2 (P&lt;0.001*)</td>
<td>-5.2 (P&lt;0.001*)</td>
<td>-5.8 (P&lt;0.001*)</td>
<td>-5.5 (P&lt;0.001*)</td>
<td></td>
</tr>
<tr>
<td>Mean Meds</td>
<td>1.8 ± 1.3</td>
<td>0.7 ± 1.1</td>
<td>0.9 ± 1.1</td>
<td>1.0 ± 1.1</td>
<td>1.0 ± 1.1</td>
<td>0.7 ± 0.8</td>
<td></td>
</tr>
<tr>
<td>Mean Difference</td>
<td>REFERENCE</td>
<td>-1.1 (P&lt;0.001*)</td>
<td>-0.9 (P&lt;0.001*)</td>
<td>-0.8 (P&lt;0.001*)</td>
<td>-1.1 (P&lt;0.001)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Mean Models (α of 0.05) were used for analysis with adjustment for multiple comparisons.
** Bonferroni adjustment at α of 0.05.

IOP lowering by ~5.0mmHg and ~80% of patients were off of at least 1 med

KDB User Survey
CE+KDB 9 months follow up

<table>
<thead>
<tr>
<th></th>
<th>Pre-Op (n=72)</th>
<th>Day 1 (n=72)</th>
<th>Week 1 (n=72)</th>
<th>Month 1 (n=72)</th>
<th>Month 3 (n=58)</th>
<th>Month 6 (n=57)</th>
<th>Month 9 (n=25)</th>
</tr>
</thead>
<tbody>
<tr>
<td>IOP (mm Hg)</td>
<td>17.4 ± 5.2</td>
<td>13.3 ± 3.9</td>
<td>13.4 ± 4.8</td>
<td>12.6 ± 3.4</td>
<td>12.7 ± 2.3</td>
<td>12.4 ± 3.4</td>
<td></td>
</tr>
<tr>
<td>Mean IOP difference</td>
<td>REFERENCE</td>
<td>-4.1 (P&lt;0.001*)</td>
<td>-4.0 (P&lt;0.001*)</td>
<td>-3.8 (P&lt;0.001*)</td>
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<tr>
<td>Mean Difference</td>
<td>REFERENCE</td>
<td>-1.2 (P&lt;0.001*)</td>
<td>-0.9 (P&lt;0.001*)</td>
<td>-0.9 (P&lt;0.001*)</td>
<td>-0.7 (P=0.002**)</td>
<td>-1.0 (P=0.003***)</td>
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ROBUST IOP LOWERING THROUGH 9 MONTHS
KDB Adverse Events in User Survey

- Hyphema has been seen in ~40% of patients intra-operatively to date
- Hemorrhage entry into the anterior chamber indicates a patent distal outflow system when AC pressure drops below venous pressure and is seen with all MIGS angle procedures
- Hyphema resolution has been rapid with only 9% exhibiting heme at day 1 postoperatively (mostly micro-hyphema) and 3.5% at week one
- AEs such as iridodialysis and cyclodialysis caused by improper device use have been rare
- One patient required additional glaucoma surgery for uncontrolled IOP

KDB Surgical Technique

Pre-Operative Regimen

- Treat like standard cataract when combined Phaco+KDB
  - Standard cataract preoperative drops
  - May use Miostat to constrict pupil if KDB done after phaco and better visualization of the angle is desired (recommended if new to angle surgery)

- For stand-alone KDB
  - Standard pre-operative drops (Steroid, Antibiotic, NSAID)
  - No dilation drops
  - Use Pilocarpine 1-2% q5m x 3 to constrict pupil or use Miostat at the beginning of the case to constrict the pupil

Post-Operative Regimen

- Treat with steroids and antibiotics as per routine:
  - For combined Phaco-KDB, standard cataract post-operative drops
  - For stand-alone KDB, steroids/antibiotics per surgeon judgment
  - Stop all glaucoma drops and restart as needed
  - May use pilocarpine 1-2% qid for 2-4 weeks to help keep angle open during the early post-operative follow up
  - Stop pilocarpine at 2-4 weeks and restart glaucoma medications as needed
Dr. Berdahl Performing KDB Case

Fluid Wave Post TM Removal with KDB

TM Removal Post KDB

Postop Gonio

Courtesy of Dr. Leonard Seibold

Courtesy of Dr. Leonard Seibold

Courtesy of Leonard Seibold, MD
Tissue Collection and Treatment Post GATT Procedure

- Incisional angle procedures have been associated with tissue overgrowth leading to increased IOP
- Drs. Grover and Fellman were able to collect this tissue from a patient post GATT
- Analysis took place by Drs. Ammar and Kahook and revealed fibrosis with basement membrane deposition
- KDB can assist with tissue collection for studies and enhanced diagnostic capabilities

Case Study: Pseudophakic Glaucoma

- Standalone MIGS procedures are an excellent option prior to trab/tube in patients where poor adherence to medications is a major contributor to progression of disease
- Laser trabeculoplasty would have been an option but has significantly less efficacy in pseudophakic patients and often fails early
- The decision was made to perform KDB as a standalone procedure and IOP is 15mmHg 6 months out of surgery off of all medications
Bypassing Trabecular Meshwork

What will you be hearing about more soon?

Conclusions

- We have many options now beyond Trab/GDD (mild-severe)
**Simplifying Choices**

- ECP Dual Blade
- Combined-MIGS
- Trab/GDD
- Hydrus/CyPASS

**Conclusions**

- We have many options now beyond Trab/GDD (mild-severe)
- Must take into consideration several factors before deciding on best approach (involve the patient in the decision)
- Standalone angle procedures work well for mild to moderate disease with higher teen goal (KDB data are promising to date)
- Standalone outflow procedures can work well for severe disease
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- Standalone outflow procedures can work well for severe disease
- Newer devices like XEN and InnFocus Microshunt may occupy the space between MIGS and traditional Trab/ExPRESS (TBD)
- Possibility of combining lower risk inflow/outflow procedures could be the next advancement

Thank You