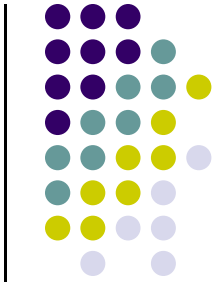
Glaucoma Clinical Trials



Classic clinical trials: The Big 6

Study Name	*Key Contribution*
?	Looked at efficacy of treating glaucoma **before** it appears
?	Looked at efficacy of treating glaucoma **after** it has appeared
?	Compared incisional surgery vs meds as initial glaucoma treatment
?	Compared laser surgery vs meds as initial glaucoma treatment
?	Compared laser vs incisional surgery in advanced glaucoma
?	Evaluated role of IOP in NTG

Glaucoma Clinical Trials

Classic clinical trials: The Big 6

Study Name	*Key Contribution*
Ocular Hypertension Treatment Trial (OHTS)	Looked at efficacy of treating glaucoma **before** it appears
Early Manifest Glaucoma Trial (EMGT)	Looked at efficacy of treating glaucoma **after** it has appeared
Collaborative Initial Glaucoma Treatment Study (CIGTS)	Compared incisional surgery vs meds as initial glaucoma treatment
Glaucoma Laser Trial (GLT)	Compared laser surgery vs meds as initial glaucoma treatment
Advanced Glaucoma Intervention Study (AGIS)	Compared laser vs incisional surgery in advanced glaucoma
Collaborative Normal -Tension Glaucoma Study	Evaluated role of IOP in NTG

Glaucoma Clinical Trials

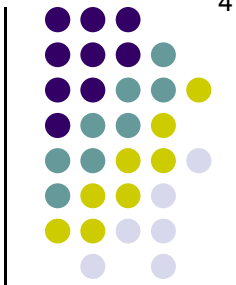
Classic clinical trials: The Big 6

Study Name	*Key Contribution*
Ocular Hypertension Treatment Trial (OHTS)	Looked at efficacy of treating glaucoma **before** it appears
Early Manifest Glaucoma Trial (EMGT)	Looked at efficacy of treating glaucoma **after** it has appeared

We'll also take a look at the ***Tube vs Trab (TVT) Study***, although it remains to be seen whether this study will be influential enough to muscle its way into the Big 6!

Glaucoma Laser Trial (GLT)	Compared laser surgery vs meds as initial glaucoma treatment
Advanced Glaucoma Intervention Study (AGIS)	Compared laser vs incisional surgery in advanced glaucoma
Collaborative Normal -Tension Glaucoma Study	Evaluated role of IOP in NTG

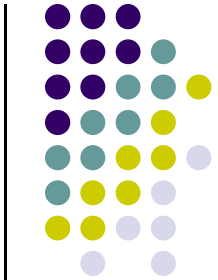
Glaucoma Clinical Trials



- **Ocular Hypertension Treatment Study**
  - Objective: Efficacy of medical treatment in preventing/delaying onset of POAG in OHTN

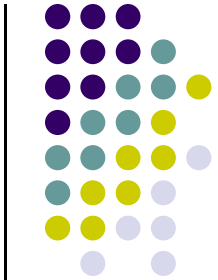
Primary open-angle glaucoma *Ocular hypertension*

Glaucoma Clinical Trials



- **Ocular Hypertension Treatment Study**
  - Objective: Efficacy of medical treatment in preventing/delaying onset of POAG in OHTN
  - Subs: ~1600 patients with IOP # to #, nl abb. & diff abb.

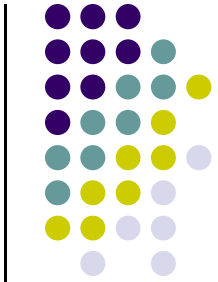
Glaucoma Clinical Trials



- **Ocular Hypertension Treatment Study**
  - Objective: Efficacy of medical treatment in preventing/delaying onset of POAG in OHTN
  - Subs: ~1600 patients with IOP 24-32, nl VF & ONH

'Normal visual fields and optic nerve head'

Glaucoma Clinical Trials



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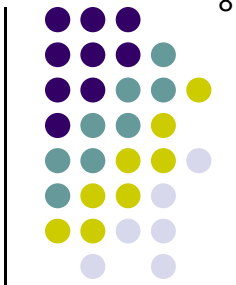
    - Treatment target: % IOP reduction *and* IOP < #

Glaucoma Clinical Trials



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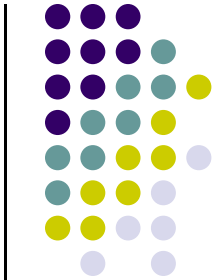
Glaucoma Clinical Trials



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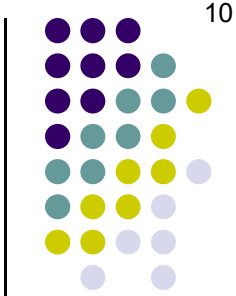
    - Treatment target: 20% IOP reduction *and* IOP < 24
  - Findings:
    - At 5 years, [%] of untreated eyes developed POAG, vs [%] of treated eyes

Glaucoma Clinical Trials



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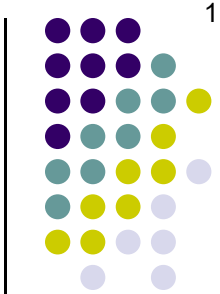
Glaucoma Clinical Trials



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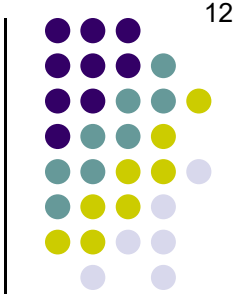
    - At 5 years, 9.5% of untreated eyes developed POAG, vs 4.4% of treated eyes
    - new risk factor (abb.) is a significant and independent predictor of POAG, even after adjusting for IOP, age, CDR

cup-disc ratio

Glaucoma Clinical Trials



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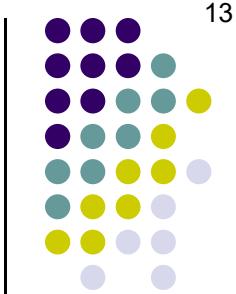
    - CCT is a significant and independent predictor of POAG, even after adjusting for IOP, age, CDR

***C**entral*
***C**orneal*
***T**hickness*

Glaucoma Clinical Trials



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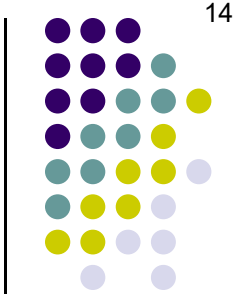
      - If CCT < # , POAG risk 3x than if CCT > #

Glaucoma Clinical Trials



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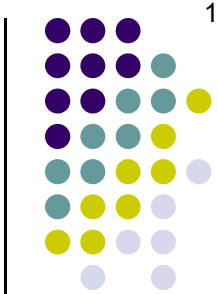
  - Findings:
    - At 5 years, 9.5% of untreated eyes developed POAG, vs 4.4% of treated eyes
    - CCT is a significant and independent predictor of POAG, even after adjusting for IOP, age, CDR
      - If CCT < 555, POAG risk 3x than if CCT > 588

Glaucoma Clinical Trials



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  - **Findings**:

There was another finding that was surprising and controversial. What was it?

vs

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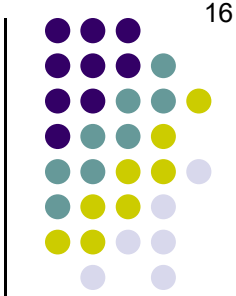
Glaucoma Clinical Trials



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That [common clinical condition] was associated with a **reduced** risk of developing glaucoma

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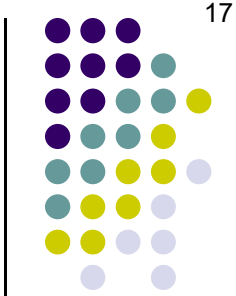
Glaucoma Clinical Trials



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That diabetes was associated with a **reduced** risk of developing glaucoma

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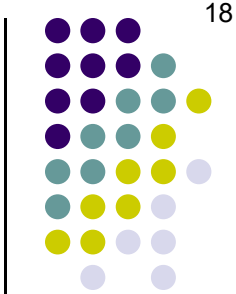
Glaucoma Clinical Trials



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Why was this finding surprising?

    - C… …G, even after adjusting for IOP, age, CDR
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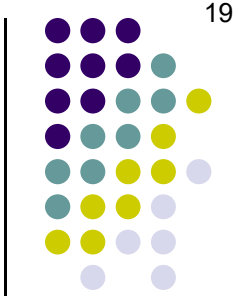
Glaucoma Clinical Trials



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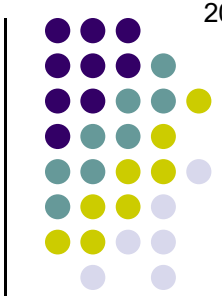
  - **Findings**:

*There was another finding that was **surprising** and controversial. What was it?*
That diabetes was associated with a **reduced** risk of developing glaucoma

Why was this finding surprising?
Because previous studies had found either no association between diabetes and glaucoma, or that diabetes was associated with an **increased** risk of glaucoma

    - C… vs … G, even after adjusting for IOP, age, CDR
      - If CCT < 555, POAG risk 3x than if CCT > 588

Glaucoma Clinical Trials



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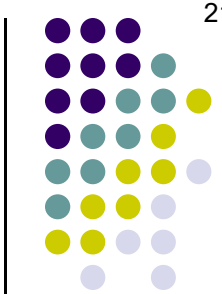
There was another finding that was surprising and ***controversial****. What was it?*
That diabetes was associated with a **reduced** risk of developing glaucoma

Why was this finding controversial?

Glaucoma Clinical Trials



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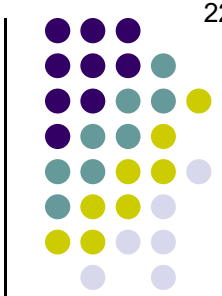
    - Treatment target: 20% IOP reduction *and* IOP < 24
  - **Findings**:

There was another finding that was surprising and ***controversial****. What was it?*
That diabetes was associated with a **reduced** risk of developing glaucoma

Why was this finding controversial?
The OHTS exclusion criteria included the presence of retinopathy, including diabetic retinopathy. Because of this, the diabetic cohort that participated in the OHTS is not representative of the diabetic population as a whole. Thus, any conclusions derived from the OHTS regarding the relationship between diabetes and glaucoma are tentative at best.



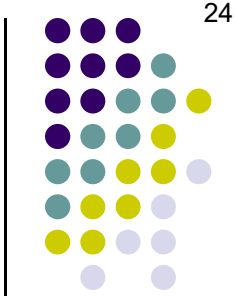
Glaucoma Clinical Trials

- **Early Manifest Glaucoma Trial**
  - Objective: Compare immediate treatment vs observation in newly-diagnosed OAG/NTG

normal-tension glaucoma

Glaucoma Clinical Trials

- **Early Manifest Glaucoma Trial**
  - Objective: Compare immediate treatment vs observation in newly-diagnosed OAG/NTG
  - Protocol: 1 eye assigned to treatment + treatment, the other to no treatment



Glaucoma Clinical Trials

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  - Protocol: 1 eye assigned to ALT + betaxolol, the other to no treatment

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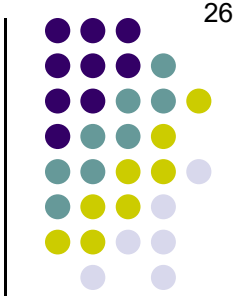
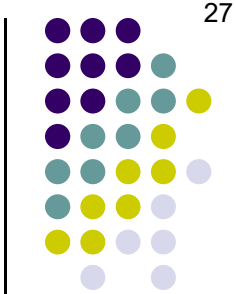
- **Early Manifest Glaucoma Trial**
  - Objective: Compare immediate treatment vs observation in newly-diagnosed OAG/NTG
  - Protocol: 1 eye assigned to ALT + betaxolol, the other to no treatment
  - Findings:
    - Significantly more progression in untreated eyes % than in treated eyes %

Glaucoma Clinical Trials



- **Early Manifest Glaucoma Trial**
  - Objective: Compare immediate treatment vs observation in newly-diagnosed OAG/NTG
  - Protocol: 1 eye assigned to ALT + betaxolol, the other to no treatment
  - Findings:
    - Significantly more progression in untreated eyes (62%) than in treated eyes (45%)

Glaucoma Clinical Trials



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Glaucoma Clinical Trials

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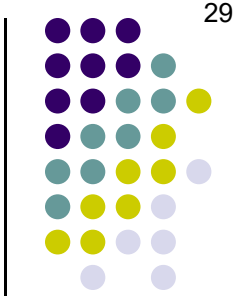

Glaucoma Clinical Trials

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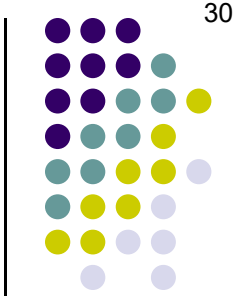

Glaucoma Clinical Trials

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    - Every 1 mmHg decrease in IOP from baseline to the first follow-up visit was associated with a ~% reduction in risk of glaucoma progression

Glaucoma Clinical Trials

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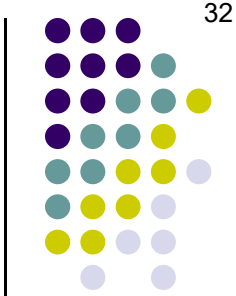
Glaucoma Clinical Trials



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What does this imply about managing NTG?

Glaucoma Clinical Trials

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What does this imply about managing NTG?
That such pts likely need medical tx with something other than a β blocker, or they may require incisional surgery

Glaucoma Clinical Trials

- **Early Manifest Glaucoma Trial**
  - Objective: Compare immediate treatment vs
  - Note: This info is straight from the BCSC *Glaucoma* book, and thus must be borne in mind while taking the OKAP, WQE and Boards. That said, be aware that some glaucoma experts dismiss it, arguing that the number of pts in the EMGT with IOP ≤15 was too small to support such conclusions. Caveat emptor.
  - e
  - Findings:
    - Significantly more progression in untreated eyes (62%)
    - *What does this imply about managing NTG?* That such pts likely need medical tx with something other than a β blocker, or they may require incisional surgery
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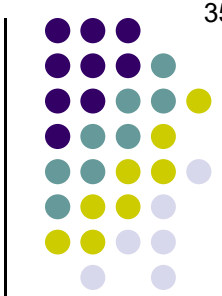
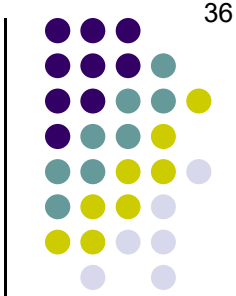
    - Every 1 mmHg decrease in IOP from baseline to the first follow-up visit was associated with a ~10% reduction in risk of glaucoma progression

Glaucoma Clinical Trials



- **Collaborative Initial Glaucoma Treatment Study**
  - Objective: Compare efficacy of medicine vs surgery as initial treatment for POAG

Glaucoma Clinical Trials



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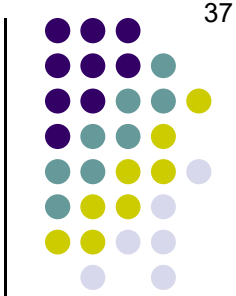
  - Objective: Compare efficacy of medicine vs surgery as initial treatment for POAG
  - Subs: ~600 pts (1200 eyes) w/ new diagnosis POAG

Glaucoma Clinical Trials



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  - Objective: Compare efficacy of medicine vs surgery as initial treatment for POAG
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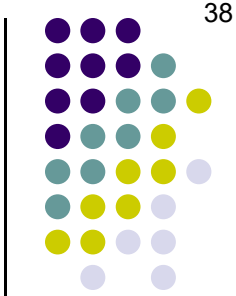
  - Protocol: 1 eye received tx 1 , the other a tx 2

Glaucoma Clinical Trials



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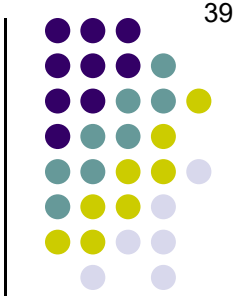
Glaucoma Clinical Trials



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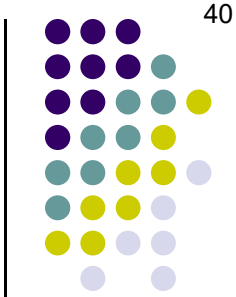
  - Findings:
    - IOP reduction better in tx group (45% vs 38%)

Glaucoma Clinical Trials



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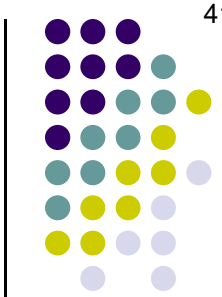
Glaucoma Clinical Trials



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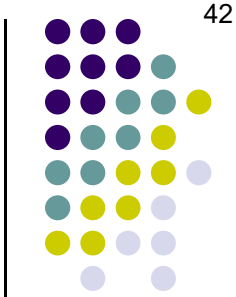
Glaucoma Clinical Trials



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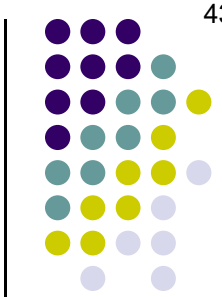
Glaucoma Clinical Trials



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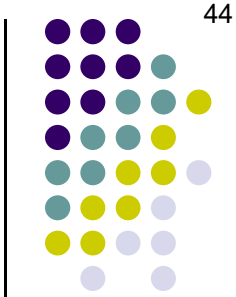
    - After 5 years, VF loss

worse in which group?

Glaucoma Clinical Trials



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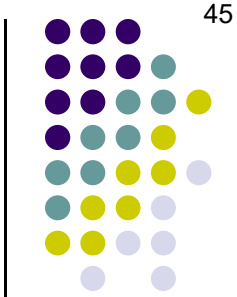
Glaucoma Clinical Trials



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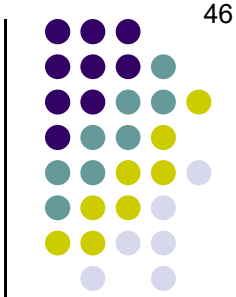
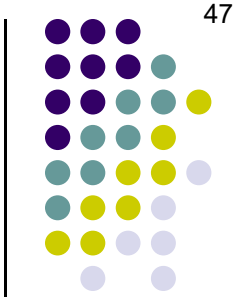
    - NOTE: Findings do *not* warrant surgery as initial tx

Glaucoma Clinical Trials



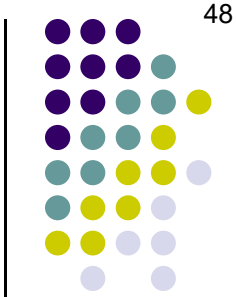
- **Glaucoma Laser Trial**
  - Objective: Compare efficacy/safety of ALT vs $T_{.5}$ for initial treatment of POAG *(Timolol 0.5%)*

Glaucoma Clinical Trials



- **Glaucoma Laser Trial**
  - Objective: Compare efficacy/safety of ALT vs $T_{.5}$ for initial treatment of POAG
  - Subs: ~270 pts (540 eyes) w/ new diagnosis POAG

Glaucoma Clinical Trials



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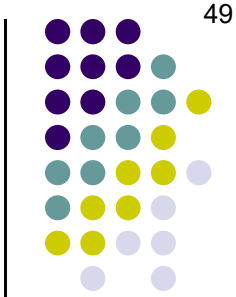
Glaucoma Clinical Trials



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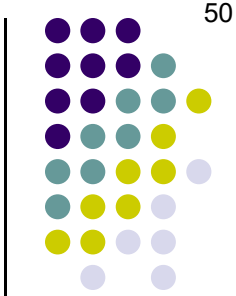
Glaucoma Clinical Trials



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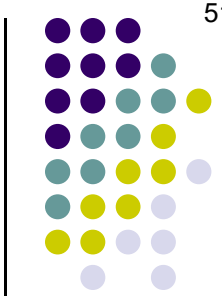
Glaucoma Clinical Trials



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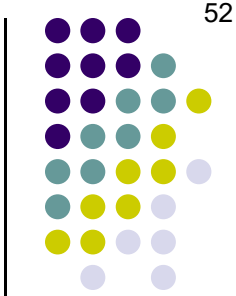
    - No difference in VF/VA at 2 years, **but**…
    - ALT v $T_{.5}$ had better VF at 7 and 9 years

Glaucoma Clinical Trials



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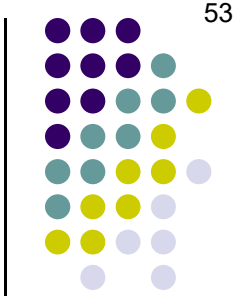
Glaucoma Clinical Trials



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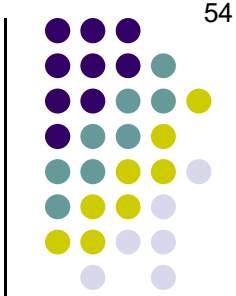
  - Note: Study preceded drug, drug, drug, as well as not ALT, so implications are somewhat dated

Glaucoma Clinical Trials



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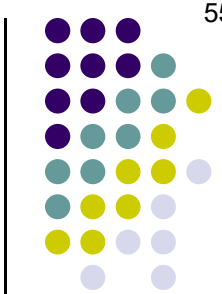
  - Note: Study preceded Xalatan, CAI, α_2 agonists, as well as SLT , so implications are somewhat dated

Carbonic anhydrase inhibitors

(Selective laser trabeculoplasty)

Glaucoma Clinical Trials

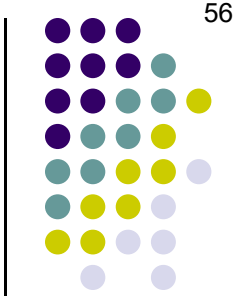


- **Advanced Glaucoma Intervention Study**
  - Two objectives:

    1) Compare ALT (*A*) vs trab (*T*) as first surgery in advanced POAG

    2) *(You come up with the second objective)*

Glaucoma Clinical Trials



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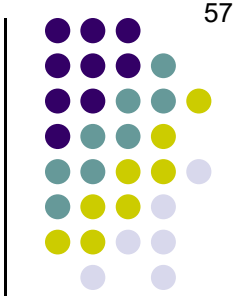
    1) Compare ALT (*A*) vs trab (*T*) as first surgery in advanced POAG

    2) Determine relation between IOP and VF loss

Glaucoma Clinical Trials



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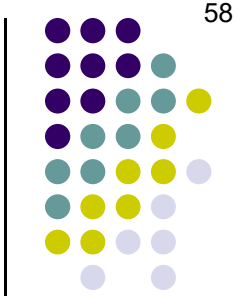
  - Subs: 789 eyes w/ advanced OAG refractory to MTMT

(maximum tolerated medical management)

Glaucoma Clinical Trials



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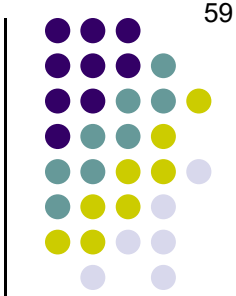
Glaucoma Clinical Trials



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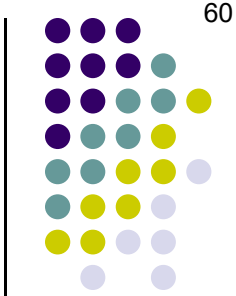
Glaucoma Clinical Trials



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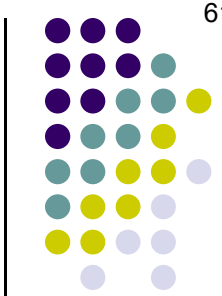
treatment order

Glaucoma Clinical Trials



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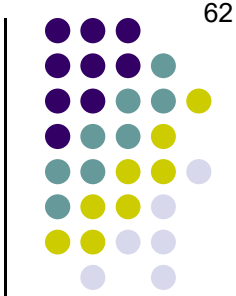
Glaucoma Clinical Trials



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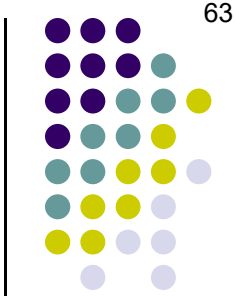
Glaucoma Clinical Trials



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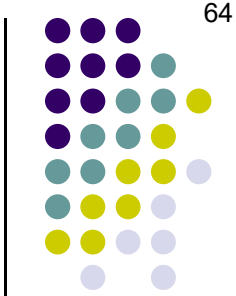
Glaucoma Clinical Trials



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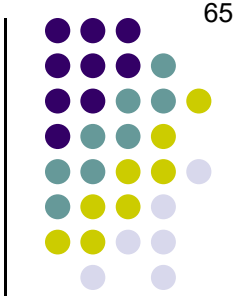
Glaucoma Clinical Trials



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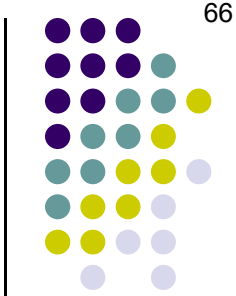
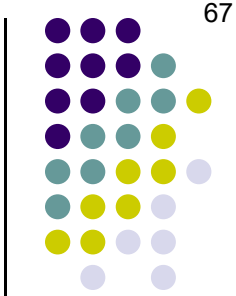
Glaucoma Clinical Trials



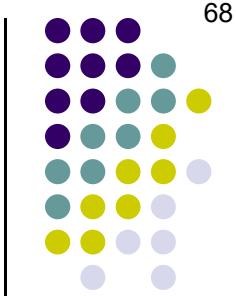
- **Collaborative Normal-Tension Glaucoma Study**
  - Objective: Determine whether IOP is involved in the pathogenesis of NTG

Glaucoma Clinical Trials



- **Collaborative Normal-Tension Glaucoma Study**
  - Objective: Determine whether IOP is involved in the pathogenesis of NTG
  - Subjects: 70 patients (140 eyes) with normal IOP and VF loss

Glaucoma Clinical Trials



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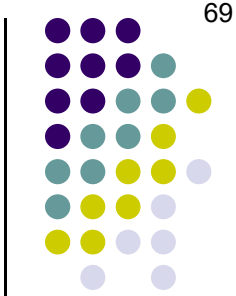
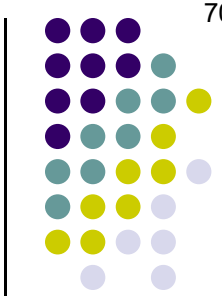
  - Objective: Determine whether IOP is involved in the pathogenesis of NTG
  - Subjects: 70 patients (140 eyes) with normal IOP and VF loss
  - Protocol: 1 eye assigned to tx, the other to no tx
    - Tx: 3 modalities as needed to lower IOP %

Glaucoma Clinical Trials



- **Collaborative Normal-Tension Glaucoma Study**
  - Objective: Determine whether IOP is involved in the pathogenesis of NTG
  - Subjects: 70 patients (140 eyes) with normal IOP and VF loss
  - Protocol: 1 eye assigned to tx, the other to no tx
    - Tx: Meds/ALT/surgery as needed to lower IOP 30%

Glaucoma Clinical Trials



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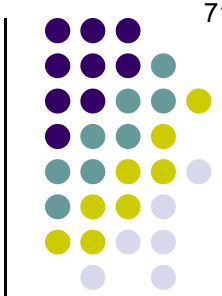
What one topical hypotensive was used?

Glaucoma Clinical Trials



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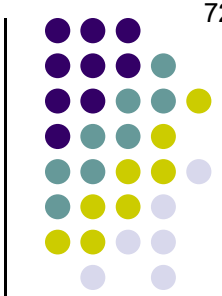
Glaucoma Clinical Trials



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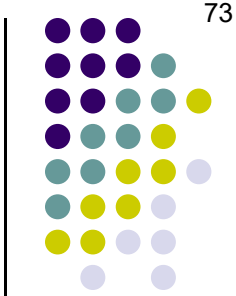
Glaucoma Clinical Trials



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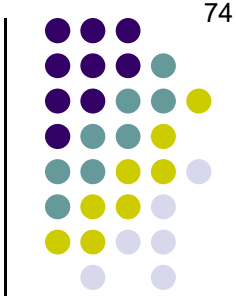
Glaucoma Clinical Trials



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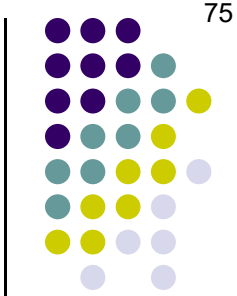
Glaucoma Clinical Trials



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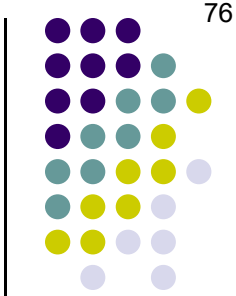
Glaucoma Clinical Trials



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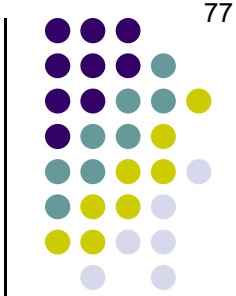
Glaucoma Clinical Trials



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Several risk factors for progression were identified, including:
-- gender
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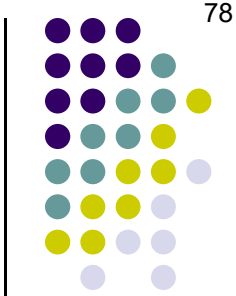
Glaucoma Clinical Trials



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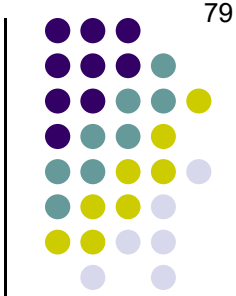

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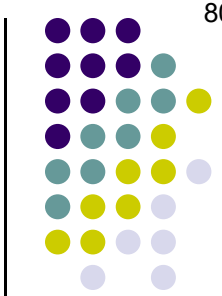
Glaucoma Clinical Trials



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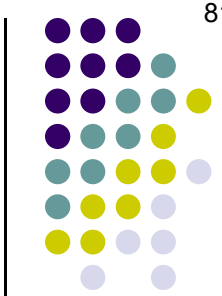

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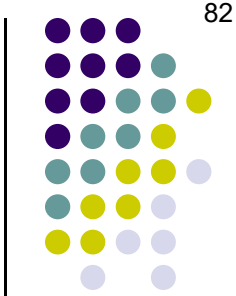
Glaucoma Clinical Trials



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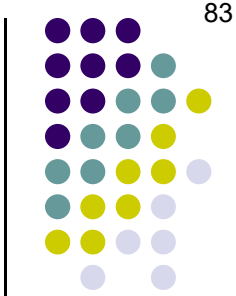

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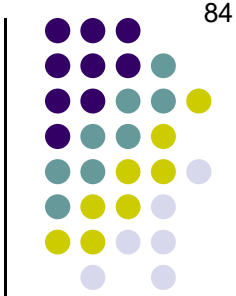
  - Objective: Compare the safety/efficacy of tube shunt and trab in eyes with a history of three words

Glaucoma Clinical Trials



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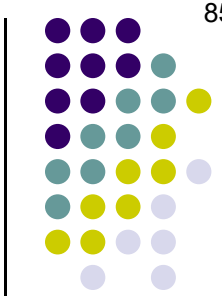
Glaucoma Clinical Trials



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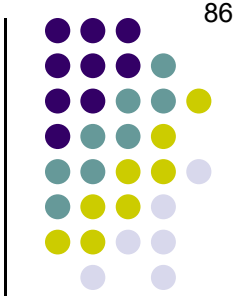
  - Subjects: 212 eyes w/ hx of previous surg. and/or surgery surgery, w/ IOP too high (18-40) on MTMT

Glaucoma Clinical Trials



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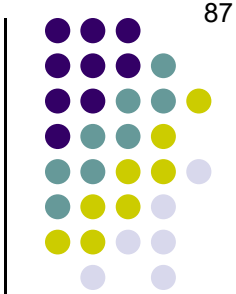
Glaucoma Clinical Trials



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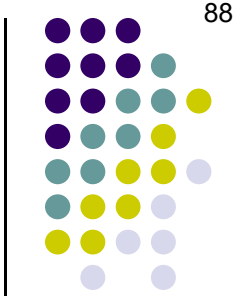
Glaucoma Clinical Trials



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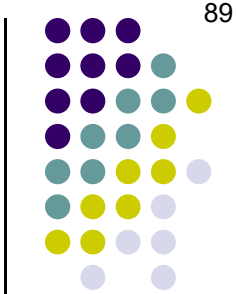
  - Findings:
    - IOP outcome: Good vs poor control; which treatment (if either) yielded better IOP control?

Glaucoma Clinical Trials



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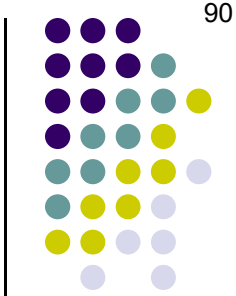
Glaucoma Clinical Trials



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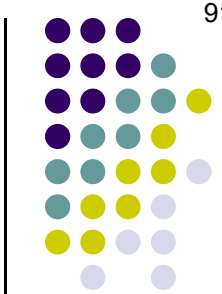
Glaucoma Clinical Trials



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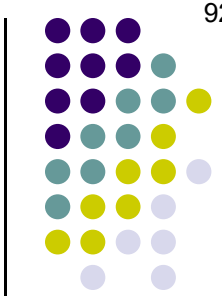
Glaucoma Clinical Trials



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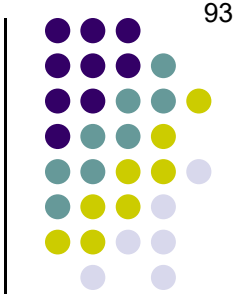
Glaucoma Clinical Trials



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Glaucoma Clinical Trials

- **Tube** versus Trabeculectomy (TVT) Study

Which three tube-shunt brands are most often used in the US, and which one was employed in the TVT study?

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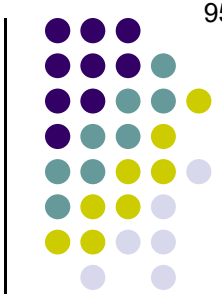
Glaucoma Clinical Trials



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Ahmed
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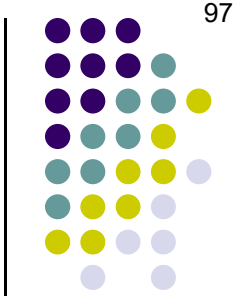

- **Tube** versus Trabeculectomy (TVT) Study

Which three tub *in the TVT study*
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What are tube shunt devices made of?
The majority are made of silicone (a few models are polypropylene)

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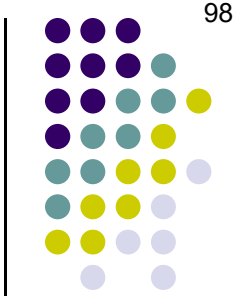

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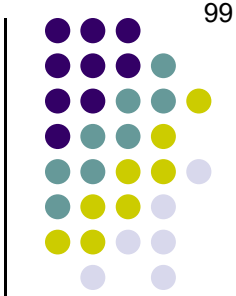

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Are tube shunts MRI-safe; ie, are they non-ferrous?

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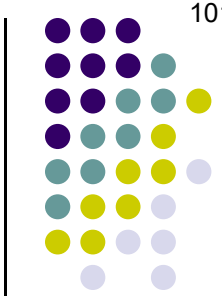

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Are tube shunts MRI-safe; ie, are they non-ferrous?
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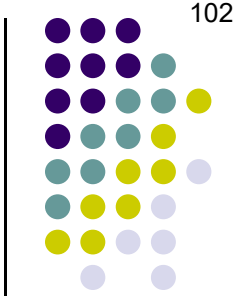
- Higher failure, post-op complication rates in Trab group

Glaucoma Clinical Trials



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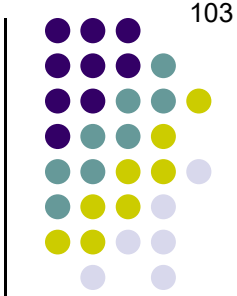

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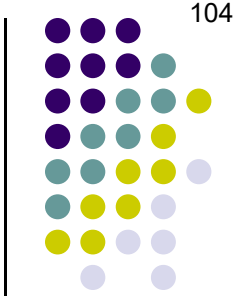

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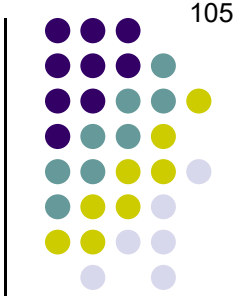

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Is the EX-PRESS device MRI safe?
It is, provided the MRI strength is 3T or less, although the manufacturer advises avoiding MRI of the head during the first few weeks after implantation if possible. (For further safety info concerning this or other MIGS devices, see the manufacturer's info.) The point is, be prepared to receive calls from providers on your MIGS pt's health-care team asking whether that 'glaucoma thing' you put in their eye is MRI safe.

Glaucoma Clinical Trials

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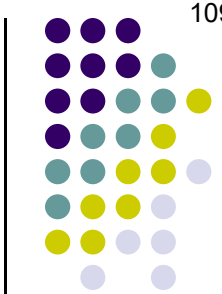

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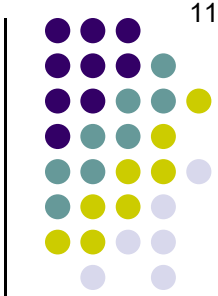

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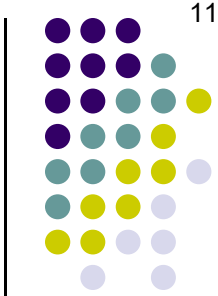

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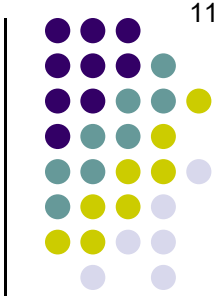

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After the Tenon's capsule and conj overlying the drainage device had scarred sufficiently to offer some (but not too much!) resistance to aqueous filtration; this scarring process is called *encapsulation*

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Why is this 'one size fits all' approach to MMC dosing a source of controversy?

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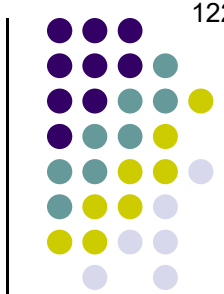

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Most surgeons titrate MMC dosing on an individual-patient basis. For example, most feel that a young African-American eye likely requires more intense MMC dosing than does the eye of an elderly Caucasian. The TVT study population ranged in age from 32 to 85, and included white, African-American and Latino patients. Left to their own devices, it is highly unlikely that the TVT surgeons would have elected MMC 0.4mg/mL x 4 minutes for **all** patients.

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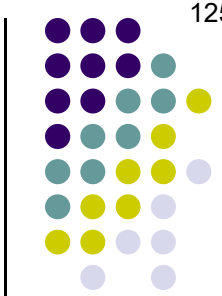
Glaucoma Clinical Trials



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Very important! Remember, the TVT study concerned eyes with a history of previous surgery, not 'virgin' eyes!

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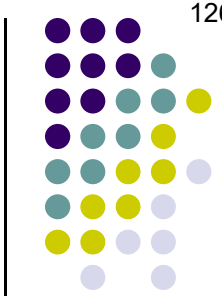

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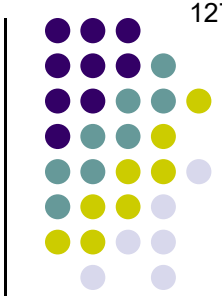

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This is the subject of the ***Primary*** **Tube vs Trabeculectomy Study**