## Glaucoma Clinical Trials

**Classic clinical trials: The Big 6**

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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!
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
- Protocol: 1 eye assigned to tx, the other to no tx
- Treatment target: 20% IOP reduction and IOP < 24

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

- **Ocular Hypertension Treatment Study**
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Ocular Hypertension Treatment Study

Objective: Efficacy of medical treatment in preventing/delaying onset of POAG in OHTN

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'Normal visual fields and optic nerve head'
Glaucoma Clinical Trials

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new risk factor (abb.)
cup-disc ratio
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Findings:

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

Central Corneal Thickness
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

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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 < #, POAG risk 3x than if CCT > #
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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
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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 surprising?
Because previous studies had found either no association between diabetes and glaucoma, or that diabetes was associated with an increased risk of glaucoma.
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? 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
Glaucoma Clinical Trials

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  - Objective: Compare immediate treatment vs observation in newly-diagnosed OAG/NTG
  - Protocol: 1 eye assigned to treatment + betaxolol, the other to no treatment
Glaucoma Clinical Trials

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Glaucoma Clinical Trials

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  - Objective: Compare immediate treatment vs observation in newly-diagnosed OAG/NTG
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  - Findings:
    - Significantly more progression in untreated eyes than in treated eyes

Percentages:
Glaucoma Clinical Trials

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  - Objective: Compare immediate treatment vs observation in newly-diagnosed OAG/NTG
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    - Significantly more progression in untreated eyes (62%) than in treated eyes (45%)
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    - Significantly more progression in untreated eyes (62%) than in treated eyes (45%)
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    - ALT + betaxolol had little IOP-lowering effect on eyes for which the baseline IOP was # or less
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Glaucoma Clinical Trials

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    - ALT + betaxolol had little IOP-lowering effect on eyes for which the baseline IOP was 15 or less
    - 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
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What does this imply about managing NTG?

That such pts likely need medical tx with something other than a \(\beta\)-blocker, or they may require incisional surgery
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- Progression occurred later in treated eyes
- ALT + betaxolol had little IOP-lowering effect on eyes for which the baseline IOP was 15 or less
- 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

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.

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.

Caveat emptor.
Collaborative Initial Glaucoma Treatment Study

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

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

- Objective: Compare efficacy of medicine vs surgery as initial treatment for POAG
- Subs: ~600 pts (1200 eyes) w/ new diagnosis POAG
- Protocol: 1 eye received tx 1, the other a trab Glaucoma Clinical Trials tx 2
Collaborative Initial Glaucoma Treatment Study

- Objective: Compare efficacy of medicine vs surgery as initial treatment for POAG
- Subs: ~600 pts (1200 eyes) w/ new diagnosis POAG
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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
- Protocol: 1 eye received meds, the other trab

Findings:
- IOP reduction better in trab tx group (45% vs 38%)
Collaborative Initial Glaucoma Treatment Study

- Objective: Compare efficacy of medicine vs surgery as initial treatment for POAG
- Subs: ~600 pts (1200 eyes) w/ new diagnosis POAG
- Protocol: 1 eye received meds, the other a trab

Findings:
- IOP reduction better in Trab group (45% vs 38%)
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- Subs: ~600 pts (1200 eyes) w/ new diagnosis POAG
- Protocol: 1 eye received meds, the other a trab

Findings:
- IOP reduction better in Trab group (45% vs 38%)
- Cataracts more common in group
Collaborative Initial Glaucoma Treatment Study

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- Protocol: 1 eye received meds, the other a trab

Findings:
- IOP reduction better in Trab group (45% vs 38%)
- Cataracts more common in Trab group
- After 5 years, VF loss worse in which group?
Collaborative Initial Glaucoma Treatment Study

Objective: Compare efficacy of medicine vs surgery as initial treatment for POAG

Subs: ~600 pts (1200 eyes) w/ new diagnosis POAG

Protocol: 1 eye received meds, the other a trab

Findings:
- IOP reduction better in Trab group (45% vs 38%)
- Cataracts more common in Trab group
- After 5 years, VF loss equal between groups
Collaborative Initial Glaucoma Treatment Study

- Objective: Compare efficacy of medicine vs surgery as initial treatment for POAG
- Subs: ~600 pts (1200 eyes) w/ new diagnosis POAG
- Protocol: 1 eye received Meds, the other a trab
- Findings:
  - IOP reduction better in Trab group (45% vs 38%)
  - Cataracts more common in Trab group
  - After 5 years, VF loss equal between groups
- 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 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
- Protocol: 1 eye assigned to ALT, other to T.5
  - Other meds added to either eye as needed
Glaucoma Clinical Trials

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  - **Objective:** Compare efficacy/safety of ALT vs T.5 for initial treatment of POAG
  - **Subs:** ~270 pts (540 eyes) w/ new diagnosis POAG
  - **Protocol:** 1 eye assigned to ALT, other to T.5
    - Other meds added to either eye as needed
  - **Findings:**
    - ALT v T.5 IOP 1-2 better, needed fewer additional meds
Glaucoma Clinical Trials

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  - **Objective:** Compare efficacy/safety of ALT vs T.5 for initial treatment of POAG
  - **Subs:** ~270 pts (540 eyes) w/ new diagnosis POAG
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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
  - Protocol: 1 eye assigned to ALT, other to $T.5$
    - Other meds added to either eye as needed
  - Findings:
    - ALT IOP 1-2 better, needed fewer additional meds
    - No difference in VF/VA at 2 years, **but**…
    - ALT had better VF at 7 and 9 years
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  - Note: Study preceded Xalatan, CAI, as well as SLT, so implications are somewhat dated
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  - **Findings:**
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    - ALT had better VF at 7 and 9 years
  - **Note:** Study preceded Xalatan, CAI, \( \alpha_2 \) 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)
Advanced Glaucoma Intervention Study

- Two objectives:
  1) Compare ALT (A) vs trab (T) as first surgery in advanced POAG
  2) Determine relation between IOP and VF loss
Advanced Glaucoma Intervention Study

- Two objectives:
  1) Compare ALT (A) vs trab (T) as first surgery in advanced POAG
  2) Determine relation between IOP and VF loss

- Subs: 789 eyes w/ advanced OAG refractory to MTMT (maximum tolerated medical management)
Advanced Glaucoma Intervention Study

- Two objectives:
  1) Compare ALT (A) vs trab (T) as first surgery in advanced POAG
  2) Determine relation between IOP and VF loss
- Subs: 789 eyes w/ advanced OAG refractory to MTMT
- Protocol: half assigned to tx order ATT, other half to TAT
Advanced Glaucoma Intervention Study

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  1) Compare ALT (A) vs trab (T) as first surgery in advanced POAG
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2) Determine relation between IOP and VF loss

Subs: 789 eyes w/ advanced OAG refractory to MTMT

Protocol: half assigned to tx order ATT, other half to TAT

Findings:
- IOP control better in treatment order ATT
Advanced Glaucoma Intervention Study

- Two objectives:
  1) Compare ALT (A) vs trab (T) as first surgery in advanced POAG
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Glaucoma Clinical Trials

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Collaborative Normal-Tension Glaucoma Study

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

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- Subjects: 70 patients (140 eyes) with normal IOP and VF loss
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%
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What one topical hypotensive was used?

**Meds**
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  - 12% of treated eyes progressed anyway
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Glaucoma Clinical Trials
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ouch! ouch?
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Glaucoma Clinical Trials

- Tube versus Trabeculectomy (TVT) Study
  - Objective: Compare the safety/efficacy of tube shunt and trab in eyes with a history of
Glaucoma Clinical Trials

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  - Objective: Compare the safety/efficacy of tube shunt and trab in eyes with a history of prior ocular surgery and/or cataract surgery, with IOP too high (18-40) on MTMT surgery.
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Glaucoma Clinical Trials

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

Is the Baerveldt a valved or nonvalved device?
- Nonvalved

What intra-op maneuver is commonly performed—and was required by the TVT protocol—to reduce the risk of overfiltration?
- The drainage tube was tied off with a suture, to be cut later.

After what biological event would the drainage-tube suture be lysed?
- 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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Protocol: Eyes randomly assigned to tube or trab; medications added as needed for IOP control.

Findings:
- Good IOP control in both groups (no statistical difference).
- The tube group needed more medications than the trab group.
- Higher failure and post-op complication rates in the trab group.

Baerveldt, Ahmed, Molteno

What are tube shunt devices made of?
- The majority are made of silicone (a few models are polypropylene).
- Do they show up on CT/X-rays? Depends. Silicone is radiolucent; however, some devices are made of barium-impregnated silicone in order to render them radio-opaque and thus visible.
- Are they MRI-safe? Yes.

Higher failure, post-op complication rates in the Trab group.
Tube versus Trabeculectomy (TVT) Study

Objective: Compare the safety/efficacy of tube shunt and trabeculectomy in eyes with a history of prior ocular surgery.

Subjects: 212 eyes with a history of previous trabeculectomy and/or cataract surgery, with IOP too high (18-40) on MTMT.

Protocol: Eyes randomly assigned to tube or trabeculectomy; medications added as needed for IOP control.

Findings:
- Good IOP control in both groups (no statistical difference).
- Tube group needed more medications than the Trab group.
- Higher failure and post-op complication rates in the Trab group.

Baerveldt, Ahmed, and Molteno are the three tube-shunt brands most often used in the US; Baerveldt was employed in the TVT study.

What are tube shunt devices made of? The majority are made of silicone (a few models are polypropylene).

Higher failure, post-op complication rates in Trab group.
Glaucoma Clinical Trials

Tube versus Trabeculectomy (TVT) Study

Objective: Compare the safety/efficacy of tube shunt and trab in eyes with a history of prior ocular surgery

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

Protocol: Eyes randomly assigned to tube or trab; meds added as needed for IOP control

Findings:

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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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Do they show up on CT/X-rays?

- Depends. Silicone is radiolucent; however, some devices are made of barium-impregnated silicone in order to render them radio-opaque and thus visible.

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

- Yes
Glaucoma Clinical Trials

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- Baerveldt
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**Baerveldt** — used in the TVT study.

**Is the Baerveldt a valved or nonvalved device?**

- Nonvalved

**What intra-op maneuver is commonly performed—and was required by the TVT protocol—to reduce the risk of overfiltration?**

- The drainage tube was tied off with a suture, to be cut later.

**After what biological event would this suture likely be lysed?**

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

**What are tube shunt devices made of?**

- The majority are made of silicone (a few models are polypropylene).

**Do they show up on CT/X-rays?**

- Depends. Silicone is radiolucent; however, some devices are made of barium-impregnated silicone in order to render them radio-opaque and thus visible.

**Are tube shunts MRI-safe; i.e., are they non-ferrous?**

- Yes
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**Glaucoma Clinical Trials**

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- Are tube shunts MRI-safe; ie, are they non-ferrous?
  - Yes
Glaucoma Clinical Trials

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**Baerveldt—used in the TVT study**

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**AhmedMolteno**

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

- Yes

---

**There is a different class of glaucoma surgical device (ie, not tube shunts), some members of which are made of ferrous material. What is that class?**

- It is the class of devices implanted during some forms of 'minimally invasive glaucoma surgery' (MIGS); eg, the EX-PRESS glaucoma filtration device is made of stainless steel.
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Glaucoma Clinical Trials

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- **There is a different class of glaucoma surgical device (ie, not tube shunts), some members of which are made of ferrous material. What is that class?**
  - It is the class of devices implanted during some forms of ‘minimally invasive glaucoma surgery’ (MIGS); eg, the EX-PRESS glaucoma filtration device is made of stainless steel.

- **Is the EX-PRESS device MRI safe?**
  - Yes. 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.
Tube versus Trabeculectomy (TVT) Study

Objective: Compare the safety/efficacy of tube shunt and trab in eyes with a history of prior ocular surgery.

Subjects: 212 eyes with history of previous trab and/or cataract surgery, with IOP too high (18-40) on MTMT.

Protocol: Eyes randomly assigned to tube or trab; meds added as needed for IOP control.

Findings:
- Good IOP control in both groups (no statistical difference).
- Tube group needed more meds than Trab group.
- Higher failure, post-op complication rates in Trab group.

Glaucoma Clinical Trials

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

Is the Baerveldt a valved or nonvalved device?
- Nonvalved

What intra-op maneuver is commonly performed—and required by the TVT protocol—to reduce the risk of overfiltration?
- The drainage tube was tied off with a suture, to be cut later. 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.

What are tube shunt devices made of?
- The majority are made of silicone (a few models are polypropylene).

Do they show up on CT/X-rays?
- Depends. Silicone is radiolucent; however, some devices are made of barium-impregnated silicone in order to render them radio-opaque and thus visible.

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

There is a different class of glaucoma surgical device (ie, not tube shunts), some members of which are made of ferrous material. What is that class?
- It is the class of devices implanted during some forms of ‘minimally invasive glaucoma surgery’ (MIGS); eg, the EX-PRESS glaucoma filtration device is made of stainless steel.

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

- Baerveldt—used in the TVT study
- Ahmed
- Molteno

What does it mean to say a tube shunt is valved?

- It means the device is intentionally constructed to provide some resistance to filtration (ie, to the egress of aqueous into the device)
- Nonvalved devices are at increased risk for overfiltration, with subsequent hypotony

After what biological event would the drainage-tube suture be lysed?

- 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.
Tube versus Trabeculectomy (TVT) Study

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

- **Baerveldt**—used in the TVT study

**Question:** Is the Baerveldt a valved or nonvalved device?

- **Nonvalved**

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- The drainage tube was tied off with a suture, to be cut later.

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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**

**Question:** What does it mean to say a tube shunt is valved?

- It means the device is intentionally constructed to provide some resistance to filtration (ie, to the egress of aqueous into the device)

**Question:** Nonvalved devices are at increased risk for what post-op complication?

- Overfiltration, with subsequent hypotony
Tube versus Trabeculectomy (TVT) Study

Objective: Compare the safety/efficacy of tube shunt and trabeculectomy in eyes with a history of prior ocular surgery.

Subjects: 212 eyes with a history of previous trabeculectomy and/or cataract surgery, with IOP too high (18-40) on maximal therapy and medications (MTMT).

Protocol: Eyes randomly assigned to tube or trabeculectomy; medications added as needed for IOP control.

Findings:
- Good IOP control in both groups (no statistical difference).
- The tube group needed more medications than the trabeculectomy group.
- Higher failure and post-op complication rates in the trabeculectomy group.

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What does it mean to say a tube shunt is valved?
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Nonvalved devices are at increased risk for what post-op complication?
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Higher failure, post-op complication rates in Trab group
Tube versus Trabeculectomy (TVT) Study

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What does it mean to say a tube shunt is valved?

It means the device is intentionally constructed to provide some resistance to filtration (ie, to the egress of aqueous into the device). Nonvalved devices are at increased risk for overfiltration, with subsequent hypotony, which is a bad thing.
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Objective: Compare the safety/efficacy of tube shunt and trabeculectomy in eyes with a history of prior ocular surgery.

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What intra-op maneuver is commonly performed—and was required by the TVT protocol—to reduce the risk of overfiltration?
The drainage tube was tied off with a suture, to be cut later.

After what biological event would the drainage-tube suture be lysed?
After the Tenon's capsule and conjunctiva overlying the drainage device had scarred sufficiently to offer some (but not too much!) resistance to aqueous filtration; this scarring process is called encapsulation.

What does it mean to say a tube shunt is nonvalved?
It means the device is intentionally constructed to provide no (or minimal) resistance to filtration (i.e., to the egress of aqueous into the device).

Nonvalved devices are at increased risk for what post-op complication?
Overfiltration, with subsequent hypotony.
Tube versus Trabeculectomy (TVT) Study

Objective: Compare the safety/efficacy of tube shunt and trab in eyes with a history of prior ocular surgery.

Subjects: 212 eyes with history of previous trab and/or cataract surgery, with IOP too high (18-40) on MTMT.

Protocol: Eyes randomly assigned to tube or trab; meds added as needed for IOP control.

Findings:
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Glaucoma Clinical Trials

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Glaucoma Clinical Trials

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  **Subjects:** 212 eyes with a history of previous trabeculectomy and/or cataract surgery, with IOP too high (18-40) on MTMT.

  **Protocol:** Eyes randomly assigned to tube or trabeculectomy; medications added as needed for IOP control.

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**Is the Baerveldt a valved or nonvalved device?**

- Nonvalved

**What intra-op maneuver is commonly performed—and was required by the TVT protocol—to reduce the risk of overfiltration?**

- The drainage tube was tied off with a suture, to be cut later.

  This maneuver is performed to prevent excessive drainage of aqueous humor post-surgery. The suture is lysed after the Tenon's capsule and conjunctiva overlying the drainage device have scarred sufficiently to offer some resistance to aqueous filtration. This process is known as **encapsulation**.
Tube versus Trabeculectomy (TVT) Study

Objective: Compare the safety/efficacy of tube shunt and trabeculectomy in eyes with a history of prior ocular surgery.

Subjects: 212 eyes with a history of previous trabeculectomy and/or cataract surgery, with IOP too high (18-40) on MTMT.

Protocol: Eyes randomly assigned to tube or trabeculectomy; medications added as needed for IOP control.

Findings:
- Good IOP control in both groups (no statistical difference).
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Tube versus Trabeculectomy (TVT) Study

Objective: Compare the safety/efficacy of tube shunt and trab in eyes with a history of prior ocular surgery.

Subjects: 212 eyes with a history of previous trab and/or cataract surgery, with IOP too high (18-40) on MTMT.

Protocol: Eyes randomly assigned to tube or trab; meds added as needed for IOP control.

Findings:
- Good IOP control in both groups (no statistical difference).
- Tube group needed more meds than Trab group.
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Glaucoma Clinical Trials

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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**Tube versus Trabeculectomy (TVT) Study**

**Objective:** Compare the safety/efficacy of tube shunt and trab in eyes with a history of prior ocular surgery.

**Subjects:** 212 eyes with history of previous trab and/or cataract surgery, with IOP too high (18-40) on MTMT.

**Protocol:** Eyes randomly assigned to tube or trab; medications added as needed for IOP control.

**Findings:**
- Good IOP control in both groups (no statistical difference).
- Tube group needed more medications than the trab group.
- Higher failure and post-op complication rates in the trab group.

**Glaucoma Clinical Trials**

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Findings:
- Good IOP control in both groups (no statistical difference).
- Tube group needed more medications than the Trab group.
- Higher failure, post-op complication rates in the Trab group.

Speaking of the TVT protocol: Was mitomycin-C (MMC) employed in the trab arm of the TVT study? Yes.

What were the MMC parameters (strength; duration of exposure)? 0.4 mg/mL x 4 minutes was employed for all trab eyes.

Why is this 'one size fits all' approach to MMC dosing a source of controversy? 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 0.4 mg/mL x 4 minutes for all patients.

Why is this a problem for the study? Some experts have questioned whether suboptimal MMC dosing might have inflated the complication/failure rate in the Trab arm of the study.
Tube versus Trabeculectomy (TVT) Study

Objective: Compare the safety/efficacy of tube shunt and trabeculectomy in eyes with a history of prior ocular surgery.

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

What about the relative efficacy/safety of tube vs trab in virgin eyes? This is the subject of the Primary Tube vs Trab Study.
Tube versus Trabeculectomy (TVT) Study

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Glaucoma Clinical Trials

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