Implantable MIGS Devices
Sub-Conjunctival Space

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Disclosure: I have no financial interest in the material covered in this lecture

Alcon: C,L,S
Aeon Astron: S,C
Endo Optiks: C
Glaukos: S
InnFocus: C
iScience: C
Ivantis: C
New World Medical: C
SightSciences: O
Transcend: S
Trabeculectomy! What’s the big deal?
Common Complications from Trabeculectomy

• Endophthalmitis/Blebitis
• Bleb leak
• Hypotony
  – Maculopathy
  – Choroidal Effusions/Hemorrhage
• Bleb Dysaesthesia
• Astigmatism
The Aquasys Xen Gel Stent

• Currently, the only true MIGS device being investigated that is implanted into the subconjunctival space.
• Ab interno implantation
• Soft, compressible implant that is the size of a human hair
• Bypasses the conventional outflow pathway by filtering aqueous into the subconjunctival space.
XEN Materials

- Hydrophilic cylindrical implant of porcine gelatin, cross-linked with glutaraldehyde (to become permanent)
- Hydrates and swells, creating a soft, non-inflammatory drainage channel that is tissue conforming
- 6mm long, with targeted IOP design via Poiseuille’s Law (laminar flow)

\[
\Phi = \frac{dV}{dt} = v\pi R^2 = \frac{\pi R^4}{8\eta} \left(\frac{-\Delta P}{\Delta x}\right) = \frac{\pi R^4 |\Delta P|}{8\eta L}
\]
XEN One-Handed Injector

Pre-loaded, Disposable, “IOL-Like” Inserter

• Inserter Sleeve
  – Longitudinal placement guidance (leaves approx. 1 mm of the implant in the anterior chamber)
  – Needle retracts into sleeve after implantation
  – Acts as a safety mechanism for the angle

• Needle
  – 27 gauge, double beveled needle
  – Provides force to pass through the angle to the SC space
  – Angle of the needle is almost parallel to the conjunctiva
  – Needle’s angle design significantly reduces risk of puncturing the conjunctiva
XEN Placement

1. Conjunctiva Sparing: Ab interno placement

2. Needle bevel exits sclera but stays under conjunctiva

3. Implant positioned with ~2 mm in the subconjunctival space

4. 3 mm intrascleral and 1 mm in the anterior chamber
Video of Xen Implant
Ab Externo Bleb vs. XEN Ab Interno Bleb

**After Trabeculectomy/Express**
- Elevated and focal due to ab externo dissection
- Superficial and Thin Walled Bleb
- Higher potential risk for complications

**After XEN**
- Low lying and diffuse due to ab interno
- Deep intra tenon’s bleb
- Lower potential risk for complications
Current Global Status

• The **XEN Gel Stent** is an investigational device within the U.S.
  – AqueSys is conducting two studies in refractory glaucoma subjects in the U.S. (stand-alone procedure)
    • One study completed enrollment and follow-up is ongoing
    • Second study is currently enrolling subjects

• The **XEN Gel Stent** has obtained the CE Mark in Europe
  – Phase IV studies are ongoing
  – Limited commercial launch underway
Thank You!

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• Subconjunctival Space

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