

Comparing NGENUITY vs Conventional Microscope in a New

Hydrus User

Study Protocol

NCT05529966

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### **Comparing NGENUITY vs conventional microscope in a new Hydrus user**

**Design:** Prospective, masked study involving two new glaucoma Fellows learning to implant the Hydrus stent with supervision by single Attending. The fellows will alternate performing the surgeries (N=32) utilizing NGENUITY vs Zeiss Lumera conventional microscope.

**Hypothesis:** Hydrus cases using the NGENUITY will take less time, have fewer misdirected attempts, safer outcomes, and superior teaching value due to its better visualization of angle anatomy (higher resolution, improved depth of focus)

### **Key Endpoints:**

**Primary:** Total Hydrus time (time of cannula in /out), # of attempts (piercing TM)

**Secondary:** Other efficiency & efficacy endpoints: # of attempts entering/reentering AC, # of times readjusting focus/microscope, rate of intraoperative adverse events, posture, and previously utilized Fellow and Attending questionnaire

**Exploratory:** Safety outcomes at POD#1 and POM#1

**Statistical Considerations:** N= 32, descriptive qualitative stats

### **Inclusion Criteria:**

- Patients with mild to moderate primary open angle glaucoma as defined by AGS with visually significant cataract undergoing uncomplicated cataract surgery and Hydrus microstent
- Patient is amenable to being a Fellow's case
- Either eye or both eyes may participate

### **Exclusion Criteria:**

- Lack of patient cooperation severely affecting ability to place stent with any visualization technique
- Angle abnormalities including PAS in nasal quadrant
- Unable to properly visualize the angle due to complicated cataract surgery