



# Real-World Vision Gains and Durability of a Binocular, Dual-Mechanism Therapy for Amblyopia: Results from the PUPiL Registry

**Brenda L. Bohnsack, MD, PhD**

**Fatema Ghasia, MD**

**Eric D. Gaier, MD, PhD**

**Shelley Hancock**



# Disclosures/Funding

- Brenda L. Bohnsack: Luminopia (Consultant)
- Fatema Ghasia: None
- Eric D. Gaier: Luminopia (Shareholder, Patents/Royalty)
- Shelley Hancock: Luminopia (Employee)

# Binocular, Dual-Mechanism Therapy: Luminopia

- Dichoptic digital therapeutic software delivered in a head-mounted display
- FDA-cleared for treating amblyopia in 4 to <13 years old children
- Evidence base: Phase 1, 2, 3 clinical trials previously reported
- Currently enrolling: **Patients Using Prescription Luminopia (PUPiL) Registry (NCT06429280)**
- 14 participating sites
- Any amblyopia diagnoses
- 12+ weeks of Luminopia Usage
- All aspects of care at physician discretion
- Retrospectively collecting data on patient demographics and outcomes during and up to a year following treatment



# Assess Outcomes and Durability of BCVA Improvements with Luminopia Treatment

Cohort: Any Registry patient with

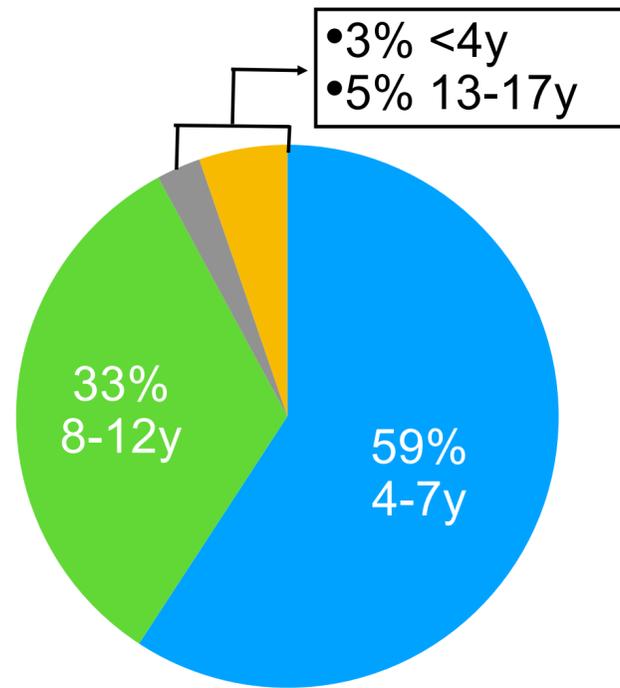
- <18 years of age with anisometropic and/or strabismic amblyopia AND
- >12 weeks of Luminopia AND
- Completed treatment, AND
- >6 weeks post-treatment follow-up

*Note: NO RESTRICTIONS on severity of amblyopia*

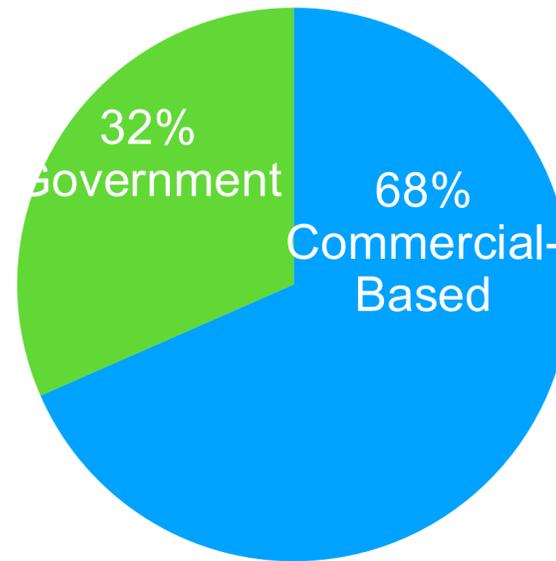
Outcomes Analyzed

- Demographics: Age, Insurance Type, Gender, Prior amblyopia treatment and amblyopia severity (Mild (>20/40), Moderate (20/40 to >20/100), Severe ( $\leq$ 20/100))
- Exam findings: Mean BCVA at baseline, treatment end, and final follow-up
- Amblyopia Recurrence: Loss of 2+ lines from treatment end

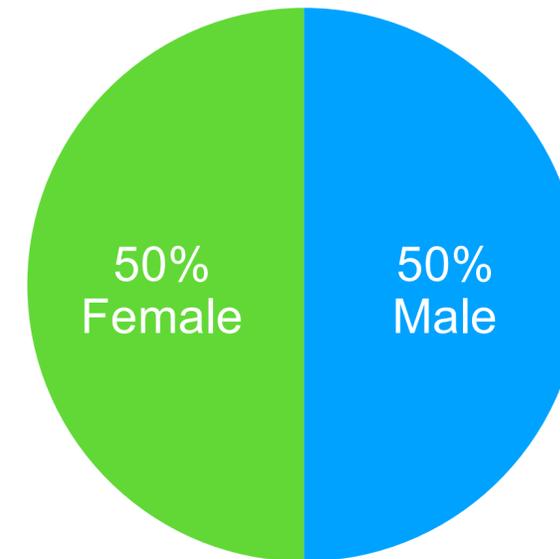
# Luminopia Registry: 76 Children Met Inclusion Criteria



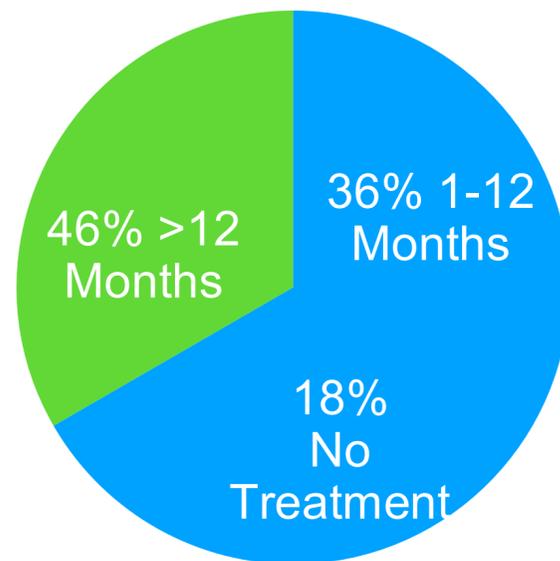
**Age**



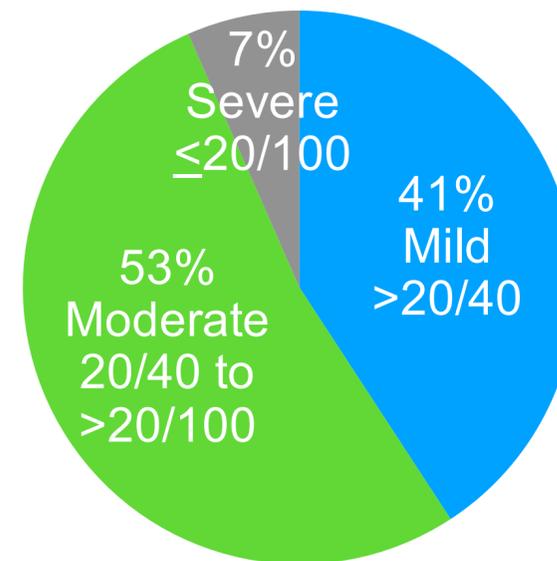
**Insurance**



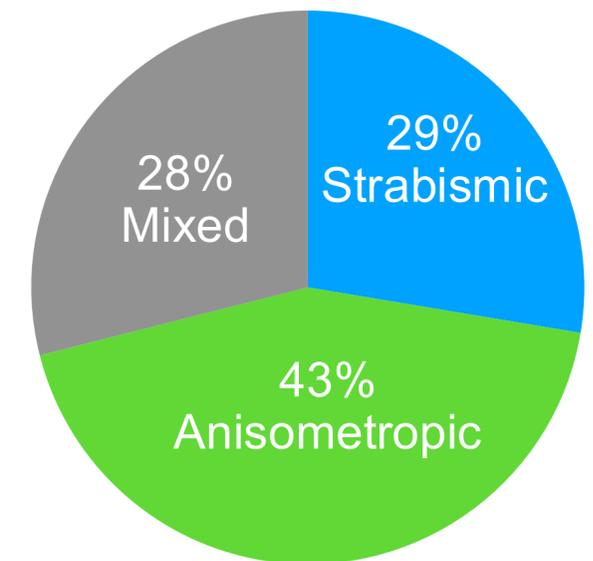
**Gender**



**Prior Treatment**



**Amblyopia Severity**

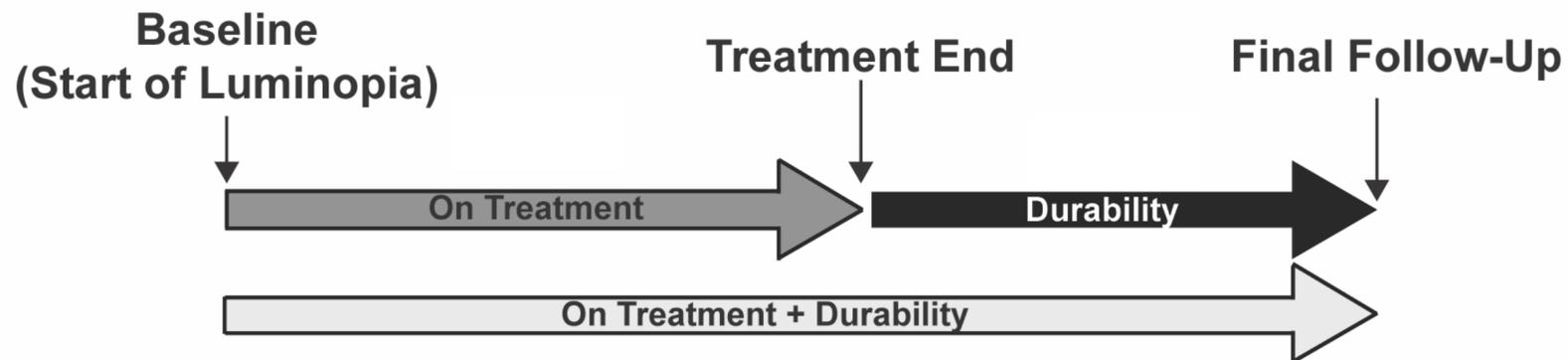


**Amblyopia Type**

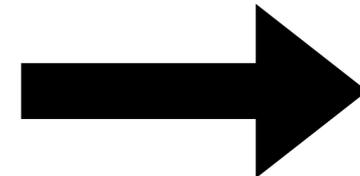
# Luminopia Improved Amblyopic Eye BCVA

Mean “On Treatment” 29.5 ± 12.6 weeks

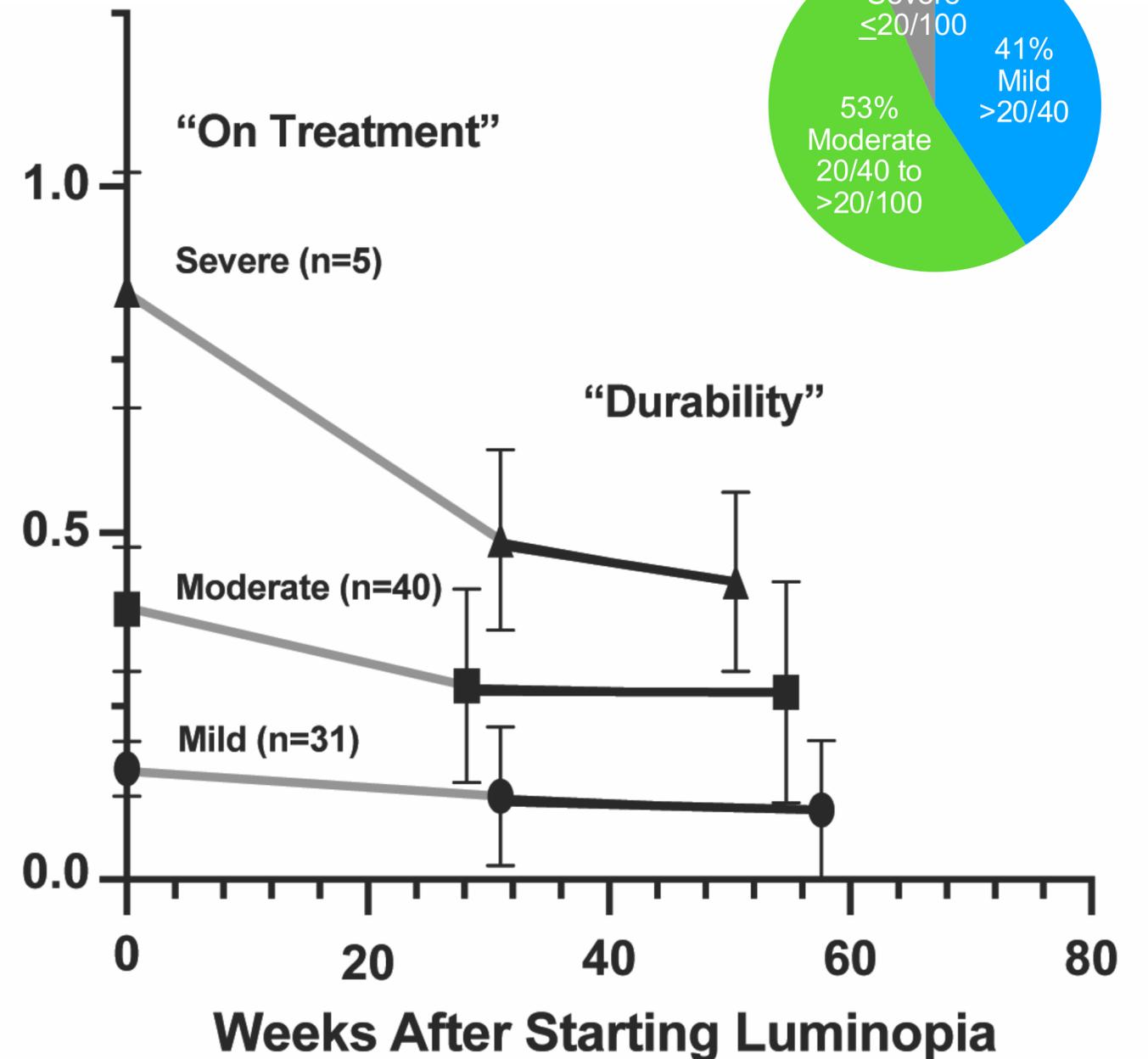
Mean “Durability” 26.1 ± 13.6 weeks



**BCVA Significantly Improved on Treatment ( $p < 0.0001$ ) and was Maintained ( $p < 0.0001$ ) after Discontinuation, across all severity groups**

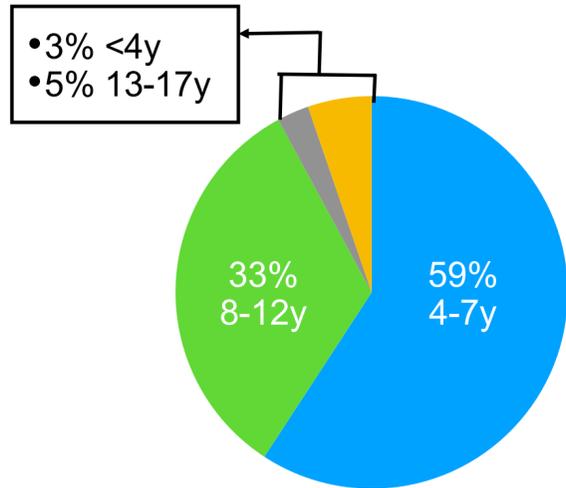


LogMAR BCVA

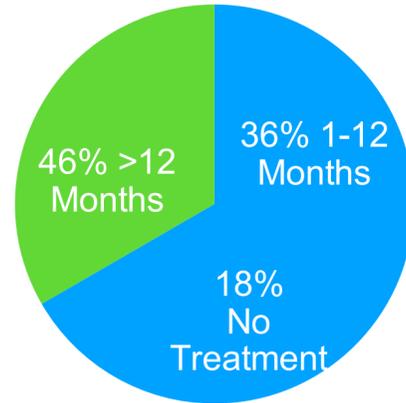


**1% (1/76) Amblyopia recurrence (loss of  $\geq 2$  lines from treatment end)**

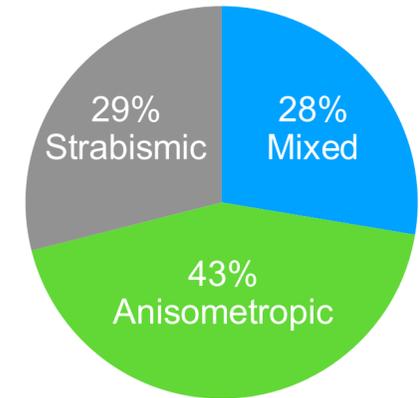
# Consistent Durability Across Subgroups



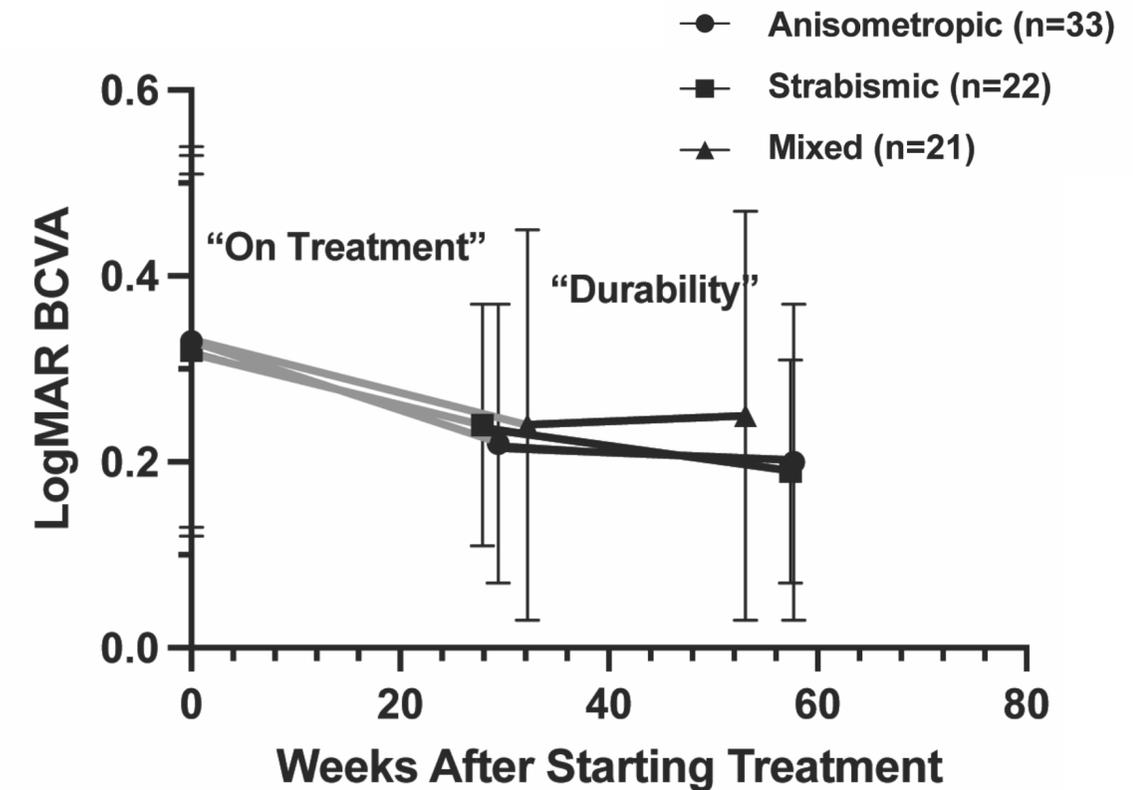
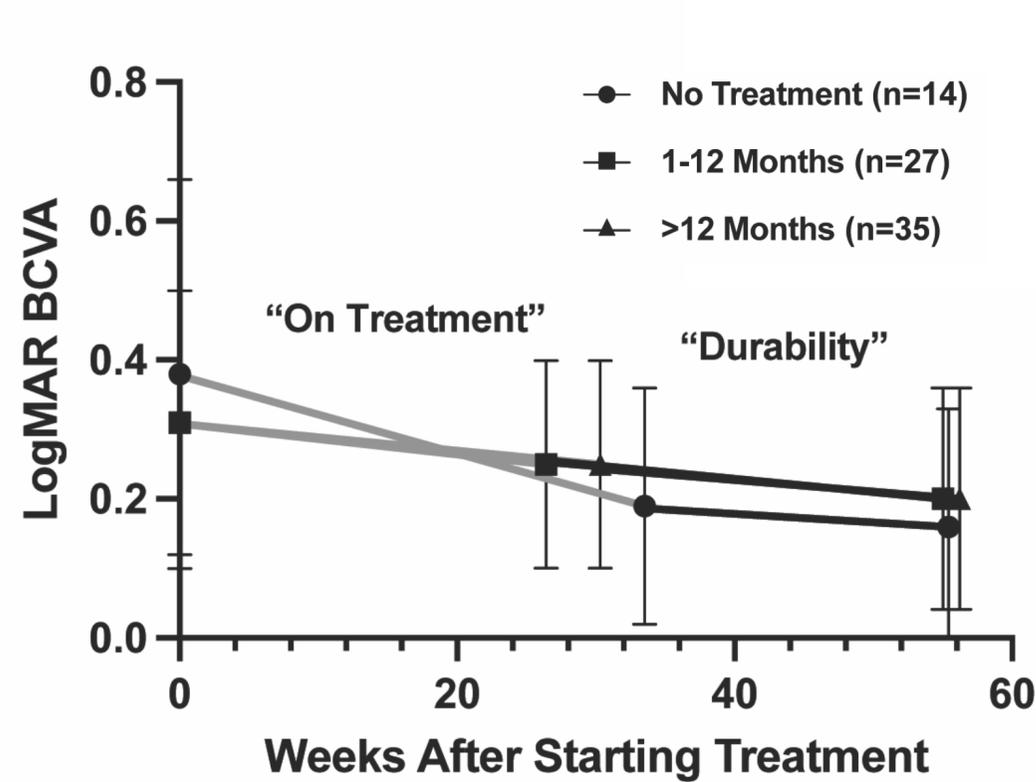
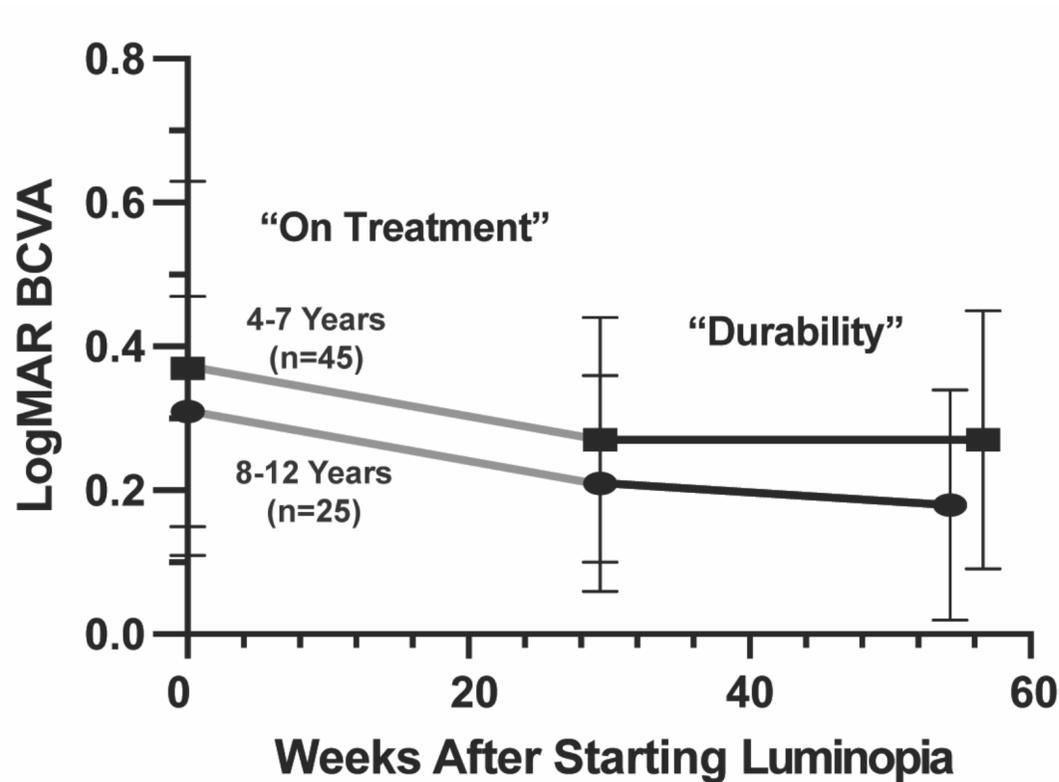
## Age at Treatment Initiation



## History of Prior Treatment



## Amblyopia Type



# PUPiL Registry: Real World Use of Luminopia

- BCVA was maintained after discontinuation of Luminopia in the 76 patients who completed treatment and had final follow >6 weeks after discontinuation
- Average treatment was  $29.5 \pm 12.6$  weeks
- Time off treatment (“Durability”) was  $26.1 \pm 13.6$  weeks
- Amblyopia recurrence was observed in 1% of patients (1 out of 76)
- Lost  $\geq 2$  lines from end of treatment to most recent off-treatment follow-up
- Durability of visual acuity improvement was consistent across amblyopia severity, age of treatment initiation, amblyopia type, and history of prior treatment



# PUPiL Registry: Safety & Limitations

- Safety: Headaches noted in 3 patients (4%)
- Limitations:
  - Retrospective registry with continuing enrollment, only patients who had completed treatment were evaluated
  - 14 sites across US - may not represent all patients on treatment
  - No standardized method of BCVA collection
  - Data queries are at specific time intervals which may not correspond with visits



# Thank You For Your Attention!

