Real-World Outcomes for a Dual-Mechanism Digital Treatment for Amblyopia in Older Kids: Analysis from the PUPiL Registry

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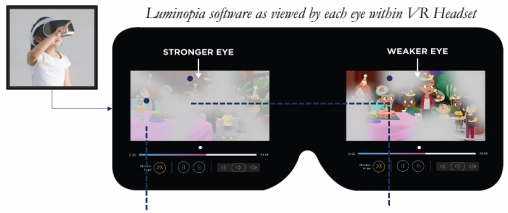
PURPOSE

Evaluate real-world outcomes of a digital amblyopia therapy, Luminopia, in children aged 8-12 years, an age range where traditional amblyopia treatments show limited effectiveness.[1]

BACKGROUND

Dual-Mechanism Digital Treatment: Luminopia

Binocular treatment for at home use, standard dose 1 hr per day, 6 days per week



Luminopia software as viewed by each eye within VR Headset

Contrast reduction to the fellow eye to reduce amblyopic eye suppression

Dichoptic masking complementary across both eyes to encourage binocular vision

Evaluated in Phase 1, 2, 3 trials:

Open-Label Phase 1/2[2] → *Randomized, Controlled* Phase 3[3] → *Retrospective, All-Comers* PUPiL Registry

FDA De Novo Approval for 4 – 7 years with amblyopia associated with anisometropia and/or strabismus[4]

FDA Expansion: 4 to < 13 years via Substantial Equivalence[4]

PUPiL Registry

Patients Using Prescription Luminopia

- Retrospective
- IRB-Approved at 14 US sites
- All aspects of treatment and follow-up at doctor discretion
- Patients with amblyopia, 12+ weeks of Luminopia treatment (NCT06429280)

METHOD

PUPiL COHORT EVALUATED*

- 8- to 12-year-olds with unilateral† anisometropic and/or strabismic amblyopia
- At least one follow-up after initiating treatment

ANALYSIS

- Total change in best-corrected visual acuity (BCVA) for subgroups based on amblyopia severity, type, and prior treatment
- General Linear Models (ANCOVA) used to assess the significance of each predictor on the change in BCVA, adjusting for baseline vision.

*Registry Data submitted up to 3/4/25 | †Unilateral defined as ≥2 lines BCVA of interocular difference

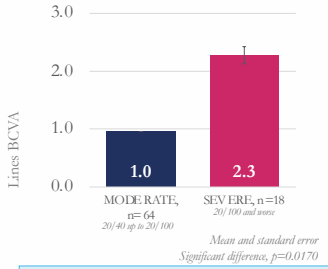
CONCLUSIONS

In these 8 – 12 year old PUPiL Registry patients:

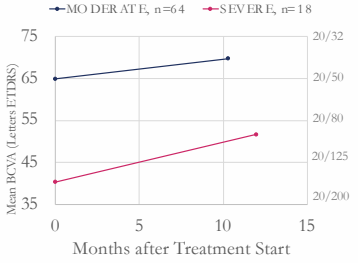
- Clinically significant improvement in vision across a diverse group of children
- Children with poorer vision at treatment start experienced more improvement in BCVA
- A large majority of these children had years of prior treatment, and experienced additional gains after being prescribed Luminopia

RESULTS: In 83 children aged 8 – 12 years

BCVA Change in Registry, By Severity
Unadjusted

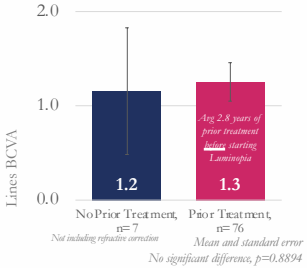


Mean BCVA at First & Last Registry Entry

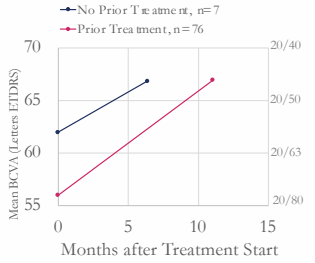


Treatment response was strongest in severe amblyopia (20/100 and worse)

BCVA Change in Registry
Adjusted for baseline BCVA

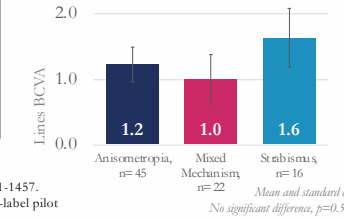


Mean BCVA at First & Last Registry Entry

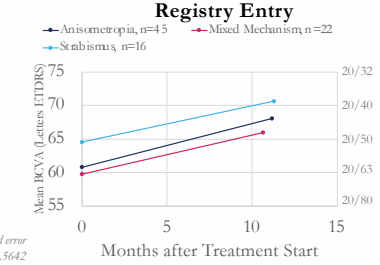


Treatment response was similar regardless of prior treatment history

BCVA Change in Registry, by Type
Adjusted for baseline BCVA



Mean BCVA at First & Last Registry Entry



Treatment response was similar regardless of amblyopia type

Avg Weekly Usage

3.3 hours per week

95% CI: 3.0, 3.7

Measured via treatment software

Avg Treatment Duration

9.2 months on treatment

95% CI: 7.3, 10.8

for those who have completed treatment, 73% (n =61 out of 83)

Top Viewed Shows
in these 8 – 12 year olds

FINANCIAL DISCLOSURES: SH – Employee (Luminopia)

Sources

1.Holmes, J.M., et al., Effect of age on response to amblyopia treatment in children. Arch Ophthalmol, 2011. **129**: p. 1451-1457.
2. Xiao, S., et al., Digital therapeutic improves visual acuity and encourages high adherence in amblyopic children in open-label pilot study. J AAPOS, 2021. **25**: p. 87.e81-87.e86.
3. Xiao, S., et al., Randomized controlled trial of a dichoptic digital therapeutic for amblyopia. Ophthalmology, 2022. **129**: p. 77-85.
4. Luminopia [directions for use]. Cambridge, ma; luminopia, inc. 2025.