Real-World Treatment Response with Digital Amblyopia Therapy: 12-Week and End-of-Treatment Outcomes from the PUPiL Registry

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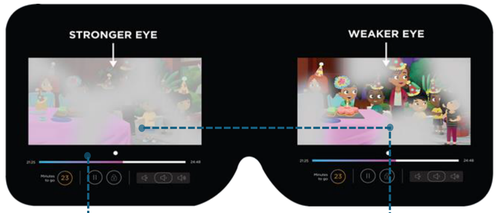
Background

- Luminopia (Figure 1) is an at-home binocular, digital treatment for amblyopia, FDA-cleared to treat patients age 4 – 12 years with anisometropia and/or mild strabismus[1]
- Clinical trials have shown a significant effect after 12 weeks of treatment in multiple trials, but the effect of continued treatment after 12 weeks has not been evaluated
- The PUPiL Reigstry* was established to characterize real-world treatment outcomes for diverse patients in a broad spectrum of amblyopia

Figure 1. View inside Luminopia headset



Contrast reduction to the fellow eye to reduce amblyopic eye suppression

Dichoptic masking complimentary across both eyes to encourage binocular vision

Methods

- PUPiL Cohort Evaluated*, n=83
  - Patients age 4 – 12 years with unilateral (2+ lines interocular difference) anisometropic and/or strabismic amblyopia
  - Follow-up data available at 12 ± 6 weeks of treatment end AND ± 6 weeks of treatment end date
- Outcomes Evaluated
  - % responders (any gain in BCVA) at 12 week follow-up and end of treatment
  - Change in BCVA in the amblyopic eye from baseline (date Luminopia prescribed) to 12 Week follow-up and to treatment end
  - Changes from baseline were tested with paired t-tests, and subgroup differences were evaluated after adjusting for baseline BCVA
  - Treatment usage was objectively measured via software

Table 1. Demographics Table of Cohort

PUPiL Cohort, N	83
Age, years, mean ± SD (min – max)	7.2 ± 1.9 (4 – 11)
Female, n (%)	39 (47)
Government / Medicaid insured, n (%)	35 (42)
Baseline Amblyopic Eye BCVA, logMAR, mean ± SD	0.49 ± 0.18

NCT06429280 | Key Enrollment Criteria include ≥ 12 weeks of Luminopia usage and any amblyopia diagnosis. Data submitted up to 3/4/25 analyzed.

Results

Treatment Response

At 12 weeks: 66% of children (55/83) showed a treatment response

At final visit: 72% of children (60/83) showed a treatment response

First Treatment Day

3.6±1.82 hours per week
Range: 0.22 – 7.32 hours /week

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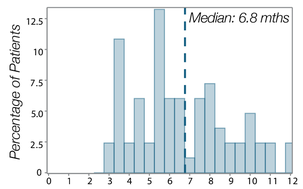
Range: 0.22 – 7.32 hours /week

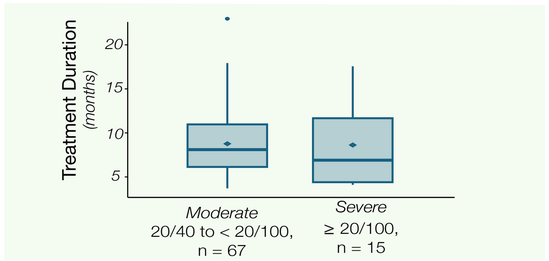
123±83.9 total treatment hours
Range: 6.3 – 375.9 hours

Last Treatment Day

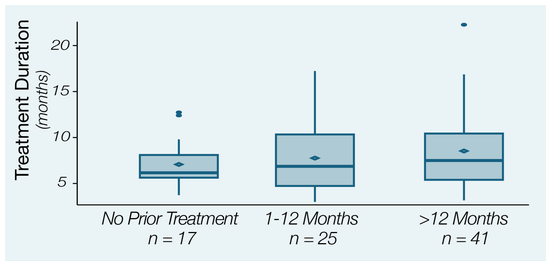


Luminopia Treatment Duration

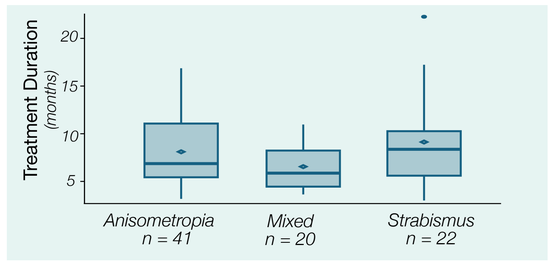
By Severity of Amblyopia



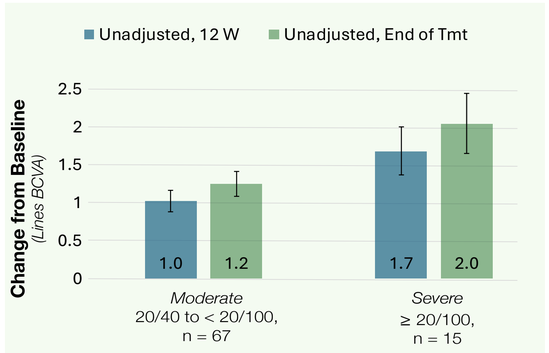
By Prior Treatment
Before Luminopia Rx



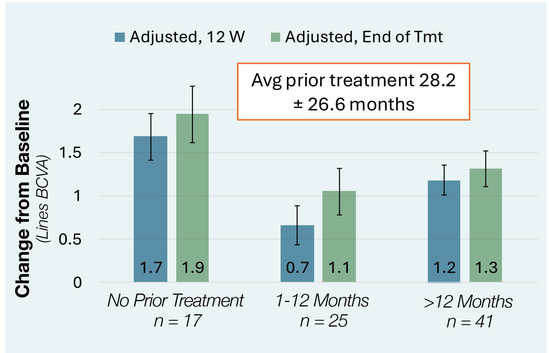
By Amblyopia Type



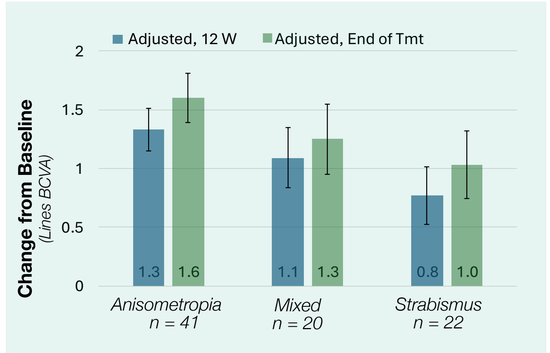
Change in BCVA from Baseline to 12 Weeks and End of Treatment



Children with a larger BCVA deficit showed the greatest improvement (p=.004)



Treatment-naive children experienced a significantly greater improvement at 12 weeks; results were not statistically different between groups at treatment end.
(adjusted, p=0.016 and p=0.11, respectively)



There was no significant difference in treatment outcome based on amblyopia type.
(adjusted p=0.26)

Conclusions

In these PUPiL Registry patients:

- Patients experienced significant gains 12 weeks following treatment initiation, across all subgroups
- Treatment response was greatest in treatment-naïve patients and those with severe amblyopia
- Beyond 12 weeks, there is a more modest but still significant overall improvement, less consistent across the subgroups
- Consistent with other amblyopia treatments, strongest improvement was seen at the beginning of treatment initiation.

Sources

1. Luminopia [directions for use]. Cambridge, ma; luminopia, inc. 2025. 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. Cruz, O.A., et al., Amblyopia preferred practice pattern. Ophthalmology, 2023. 130: p. P136-P178