

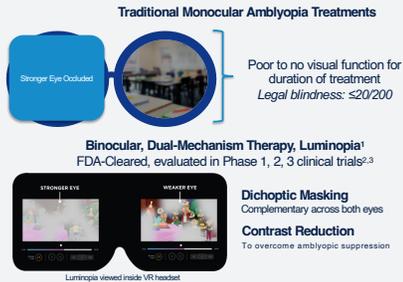
Real-World Effectiveness of a Binocular Dual-Mechanism Therapy in Severe Amblyopia: Analysis from the PUPiL Registry

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Purpose

- Evaluate the real-world effectiveness of Binocular, Dual-Mechanism Therapy (Luminopia) for the management of severe amblyopia (BCVA $\leq 20/100$) using the PUPiL Registry



Methods

- PUPiL Registry⁴ patients selected for analysis:
- Amblyopic eye BCVA of $\geq 20/100$ and worse at time of Luminopia prescription, "baseline"
- Real-World Outcomes Evaluated:
 - Primary Outcomes: Mean Change from Baseline to last registry observation submitted from 11/1/23 - 3/4/25, and treatment usage metrics
 - Linear Mixed Effect model evaluating predictors of improvement in BCVA
 - Sub-analysis of patients with BCVA $< 20/200$ at baseline

Results: Demographics

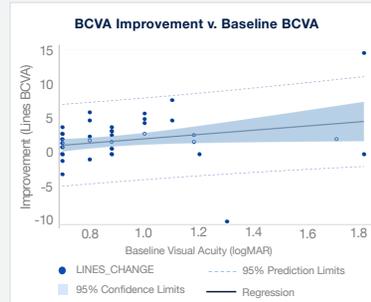
Patients with 20/100 and worse		N=59
Gender	Female, n (%)	21 (36)
	Male, n (%)	38 (64)
Age Category	4 - 7 years, n (%)	33 (56)
	8 - 12 years, n (%)	20 (34)
Amblyopia Type	Anisometropic, n (%)	23 (39)
	Mixed, n (%)	13 (22)
	Strabismic, n (%)	12 (20)
	Deprivation, n (%)	11 (19)
Previous Treatment	Yes, n (%)	50 (85)
	Mean Duration of Previous Treatment(s), months (sSD)	31±25
Treatment Prescribed at Baseline	No, n (%)	9 (15)
	Luminopia only ¹ , n (%)	49 (83)
	Luminopia + Patching, n (%)	6 (10)
	Luminopia + Patching + Atropine, n (%)	4 (7)
Amblyopia Severity	20/100 - 20/200, n (%)	50 (85)
	$> 20/200$, n (%)	9 (15)

Results: Primary Outcomes

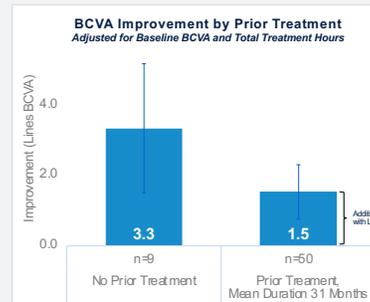


Results: Linear Mixed Effect Model

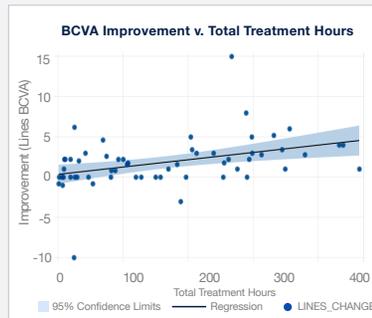
Patients with worse BCVA at baseline gained more lines BCVA during treatment



Treatment naive patients had more gains than those with prior amblyopia treatment



Significant relationship between hours of treatment completed and BCVA improvement



Non-Significant Predictors

- Age (F-value: 0.54, p=0.5875)
- Concurrent Treatments (F-value: 0.32, p=0.5734)
- Amblyopia Type (F-value: 0.25, p=0.8590)

Limitations

- Real world data has inherent variability
 - No standardized method of BCVA collection
 - No pre-determined follow-up schedule
- No control group
- Patient with < 12 weeks not included in the PUPiL Registry

Results: Amblyopia $< 20/200$

Beyond inclusion criteria of prospective clinical trials with Luminopia to date.



Conclusion

Among these Real-World Registry Patients:

- Luminopia demonstrated meaningful BCVA improvements in patients with severe amblyopia
- Patients with worse BCVA, more Luminopia treatment hours, and no prior amblyopia treatment gained more lines BCVA
- Improvement was seen regardless of age, concurrent treatment, and amblyopia type
- Very severe amblyopia ($< 20/200$) showed substantial gains
- No serious events were reported

Sources

- Luminopia LBL-0001 Rev. E, April 2025. Luminopia is indicated for improvement in visual acuity in patients age 4 to < 13 associated with anisometropia and/or mild strabismus
- Xiao S, Gaier ED, Wu HC, et al. Digital therapeutic improves visual acuity and encourages high adherence in amblyopic children in open-label pilot study. J AAPOS. 2021;25(2):87.e1-87.e6. doi:10.1016/j.jaapos.2020.11.022
- Xiao S, Angjelli E, Wu H C, Gaier E D, Gomez S, Travers D A, Binenbaum G, Langer R, Hunter D G, Repka M X, & Luminopia Pivotal Trial Group (2022). Randomized Controlled Trial of a Dichoptic Digital Therapeutic for Amblyopia. Ophthalmology. 129(1), 77-85. https://doi.org/10.1016/j.ophtha.2021.09.001
- NCT06429280. Enrollment Criteria include undergoing at least 12 weeks of Luminopia treatment and diagnosis of amblyopia.



Disclosures:

- Maanasa Indaram: Luminopia (Travel Grant); Glaukos: Code C (Consultant/Contractor)
- Eric D. Gaier: Luminopia: Code E (Employment); Luminopia: Code I (Personal Financial Interest); Luminopia: Code P (Patent)
- Fatema Ghasia: Code N (No Commercial Relationship)
- Euna Koo: Code N (No Commercial Relationship)
- Courtney Kraus: Code N (No Commercial Relationship)
- Whitney Stuard Sambhariya: Code N (No Commercial Relationship)
- Shelley Hancock: Luminopia: Code E (Employment); Luminopia: Code I (Personal Financial Interest)