

Lid, Conjunctival, and Corneal Outcomes Following Treatment With AZR-MD-001 0.5% vs. Vehicle in Contact Lens Wearers With Meibomian Gland Dysfunction and Dry Eye: The ARIES Phase 2b Study

Yair Alster¹, Charles Bosworth¹

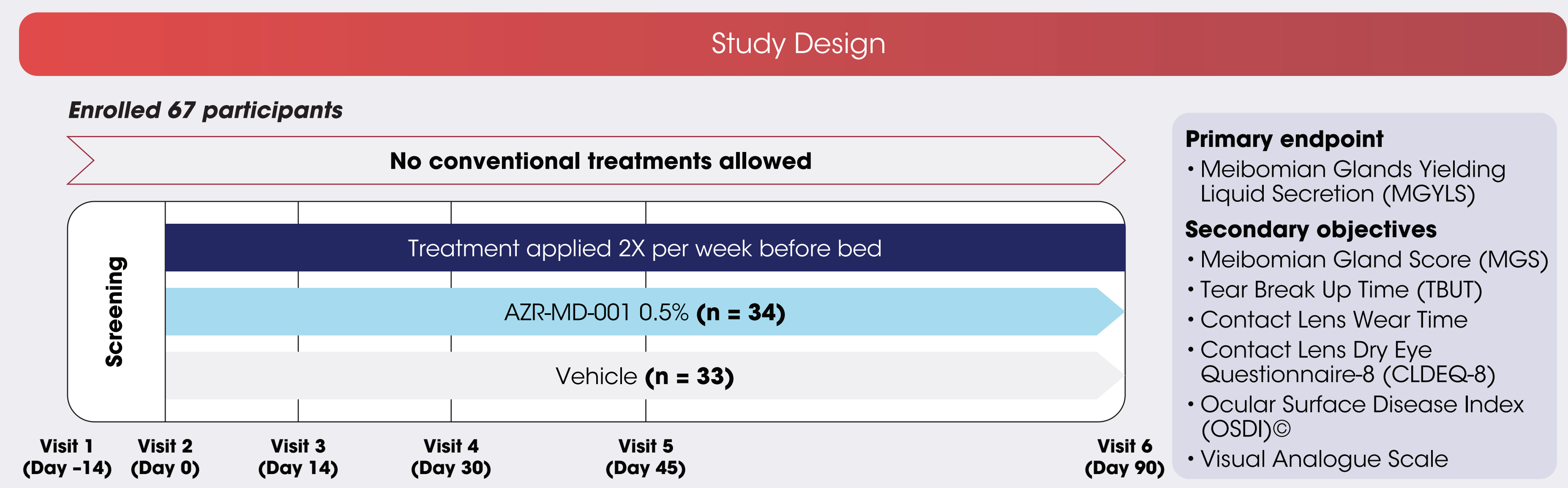
¹Azura Ophthalmics Ltd., Tel Aviv, Israel

Poster presented at the ARVO Annual Meeting, May 3-7, 2026 (Denver, Colorado, USA)

BACKGROUND

- Signs of Meibomian Gland Dysfunction (MGD) and symptoms of Dry Eye Disease (DED) can result in an inability to comfortably wear contact lenses (CL) as desired¹
- Lid margin, corneal, and conjunctival signs have been linked to the severity of CL discomfort associated with underlying DED^{2,3}
- AZR-MD-001 (AZR) 0.5% is a keratolytic ophthalmic ointment utilized in previous clinical trials in patients with DED and MGD (NCT03972501, NCT03652051) demonstrating increased gland opening and meibum expression and improvement in CL comfortable wear time^{4,5}
- Data analysis from a phase 2b study (ARIES) were undertaken to identify impacts of treatment with AZR 0.5% on signs in the lid, conjunctiva, and cornea compared to vehicle

METHODS



- This phase 2b study was a multicenter, parallel-group, double-masked, vehicle-controlled, randomized trial (NCT05548491)
- Eligible participants included adults (≥18 years) who had evidence of MGD (Meibomian Gland Secretion [MGS] score of ≤12; 0-45 scale) at baseline, had a history of wearing soft contact lenses for ≥6 months, and were unable to comfortably wear lenses as long as they desired
- Participants were randomized (1:1) to AZR or vehicle applied to the lower eyelid twice weekly before bedtime
- Scheduled visits included screening, randomization/baseline, Day 14, Month 1, Month 1.5, and Month 3
- Endpoints included eyelid erythema, eyelid margin erythema, eyelid edema, eyelid margin edema, conjunctival hyperemia, subconjunctival hemorrhage, conjunctival edema, corneal edema, and superficial punctate keratitis (SPK)
 - Items were rated on a scale of none, trace, mild, moderate, or severe
- Analyses included shift tables and a statistical comparison across groups for the mean percent change from baseline to each time point to identify changes in these parameters in those treated with AZR or vehicle
 - The difference in distribution between groups (P-values) were generated utilizing a Cochran-Mantel-Haenszel test controlling for baseline value
 - The difference between groups in improvement of at least one classification from baseline was completed using Fischer's exact test

RESULTS

- For participant demographics see ARVO poster #1752 - 0514

TABLE 1. P-VALUES FOR OCULAR OUTCOMES AT MONTH 3

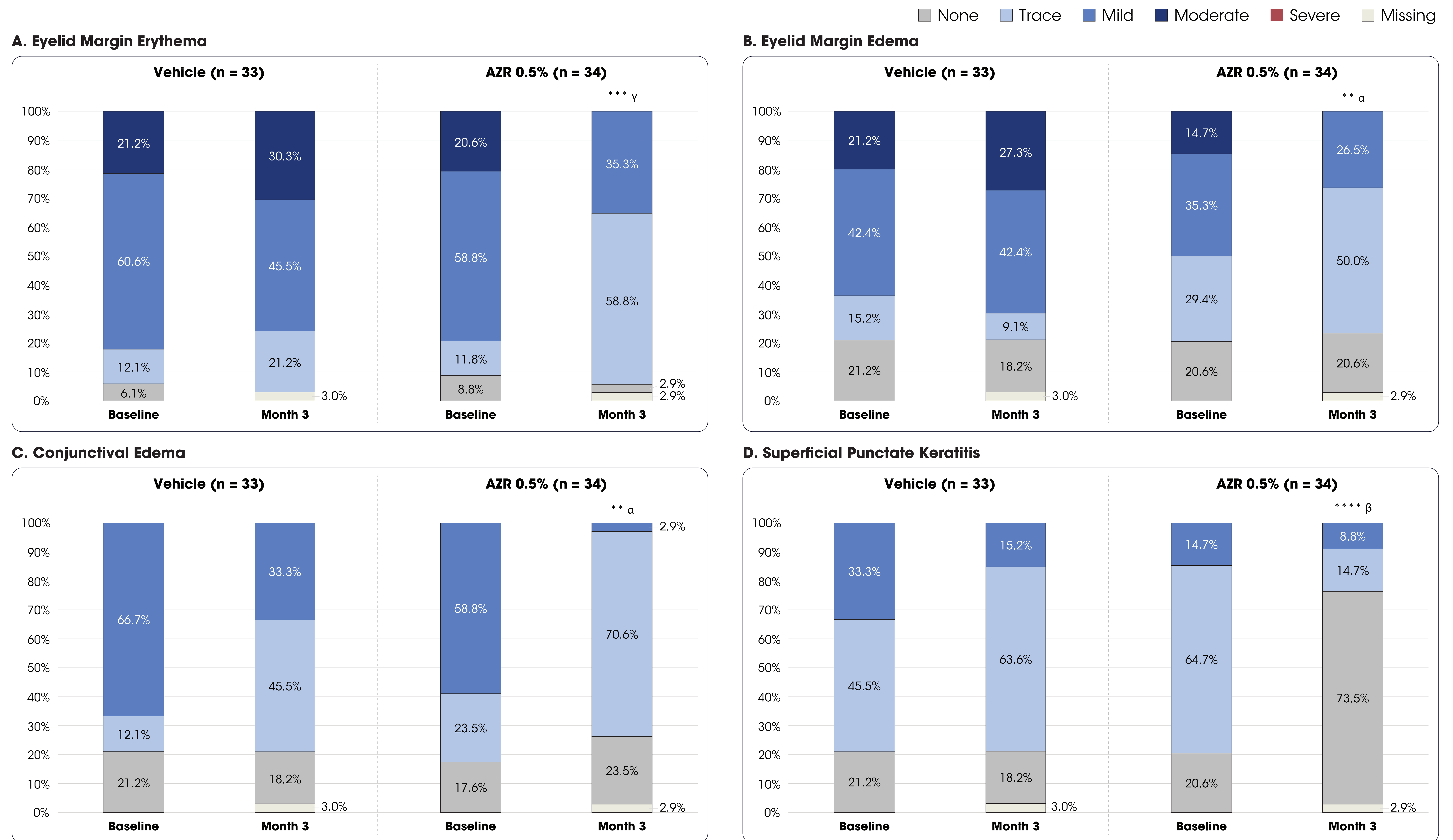
P-values indicate statistically significant differences between AZR-MD-001 0.5% and vehicle

	Difference in Distribution (AZR 0.5% vs. Vehicle)*	Proportion of Participants Achieving ≥1 Grade Improvement		
		AZR 0.5% (n/n)	Vehicle (n/n)	P-Values
Eyelid	P-Values			
Eyelid Erythema	0.0894	14.71% (5/34)	6.06% (2/33)	0.4266
Eyelid Margin Erythema	0.0004	50.00% (17/34)	12.12% (4/33)	0.0012
Eyelid Edema	0.0334	17.65% (6/34)	6.06% (2/33)	0.2576
Eyelid Margin Edema	0.0001	35.29% (12/34)	9.09% (3/33)	0.0169
Conjunctiva				
Conjunctival Hyperemia	0.0043	44.12% (15/34)	21.21% (7/33)	0.0664
Subconjunctival Hemorrhage	0.3173	5.88% (2/34)	3.03% (1/33)	1.0
Conjunctival Edema	0.0022	58.82% (20/34)	30.30% (10/33)	0.0253
Cornea				
Corneal Edema	Non-estimable	0.00% (0/34)	6.06% (2/33)	0.2385
Superficial Punctate Keratopathy	<0.0001	58.82% (20/34)	24.24% (8/33)	0.0057

*See Figure 1. A-D for values

RESULTS (CONT.)

FIGURE 1. PRESENCE AND SEVERITY OF OCULAR OUTCOMES AT BASELINE AND MONTH 3 BY TREATMENT GROUP



SUMMARY

- Improvements in eyelid margin erythema, eyelid margin edema, conjunctival edema, and SPK were observed for participants treated with AZR compared to vehicle over three months of treatment
- These findings indicate that treatment of the obstructions of the meibomian glands by AZR also plays an important role in improving the health of the lid, cornea, and conjunctiva
- Further prospective studies are warranted to confirm these findings

AZR-MD-001 is an investigational product that has not been approved by the FDA.

Contact

Yair Alster, MD | Azura Ophthalmics Ltd., Tel Aviv, Israel | Yair.alster@azurophthalmics.com

References

1. Nichols JJ, et al. Invest Ophthalmol Vis Sci. 2013 Oct 18;54(11):TF057-TF0513. 2. Song H, et al. J Ophthalmol. 2017;2017:1247138. 3. Azar AE, et al. Eye (Lond). 2026 Jan;40(1):139-146. 4. Downie LE, et al. Ocul Surf. 2025 Jan;35:15-24. 5. Stapleton F, et al. Ocul Surf. 2025 Oct;38:431-439.

Acknowledgements

Funding for the study was provided by Azura Ophthalmics Ltd. Medical writing and poster layout were provided by Assisi Consulting, LLC and the Medicine Group, LLC, which were funded by Azura Ophthalmics Ltd. in accordance with Good Publication Practice Guidelines.

Disclosures

Y. Alster: E, P, S; Azura Ophthalmics Ltd.
C. Bosworth: E, P, S; Azura Ophthalmics Ltd.
E: Employee, P: Patent, S: Stock.

