

AZR-MD-001 0.5% Significantly Improves Meibomian Glands Yielding Liquid Secretions With Clinically Meaningful Benefit Across the Dry Eye Disease Spectrum

Kelly K. Nichols¹, Lyndon Jones², Julie Schallhorn³, Kaleb Abbott⁴, Marc T. Gleeson⁵, Yair Alster⁵, Charles Bosworth⁵

¹The University of Alabama at Birmingham School of Optometry, Birmingham AL, USA; ²Centre for Ocular Research and Education, University of Waterloo, Waterloo, ON, Canada; ³University of California San Francisco School of Medicine, San Francisco, CA, USA; ⁴University of Colorado Anschutz Medical Campus School of Medicine, Aurora, CO, USA; ⁵Azura Ophthalmics Ltd., Tel Aviv, Israel

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

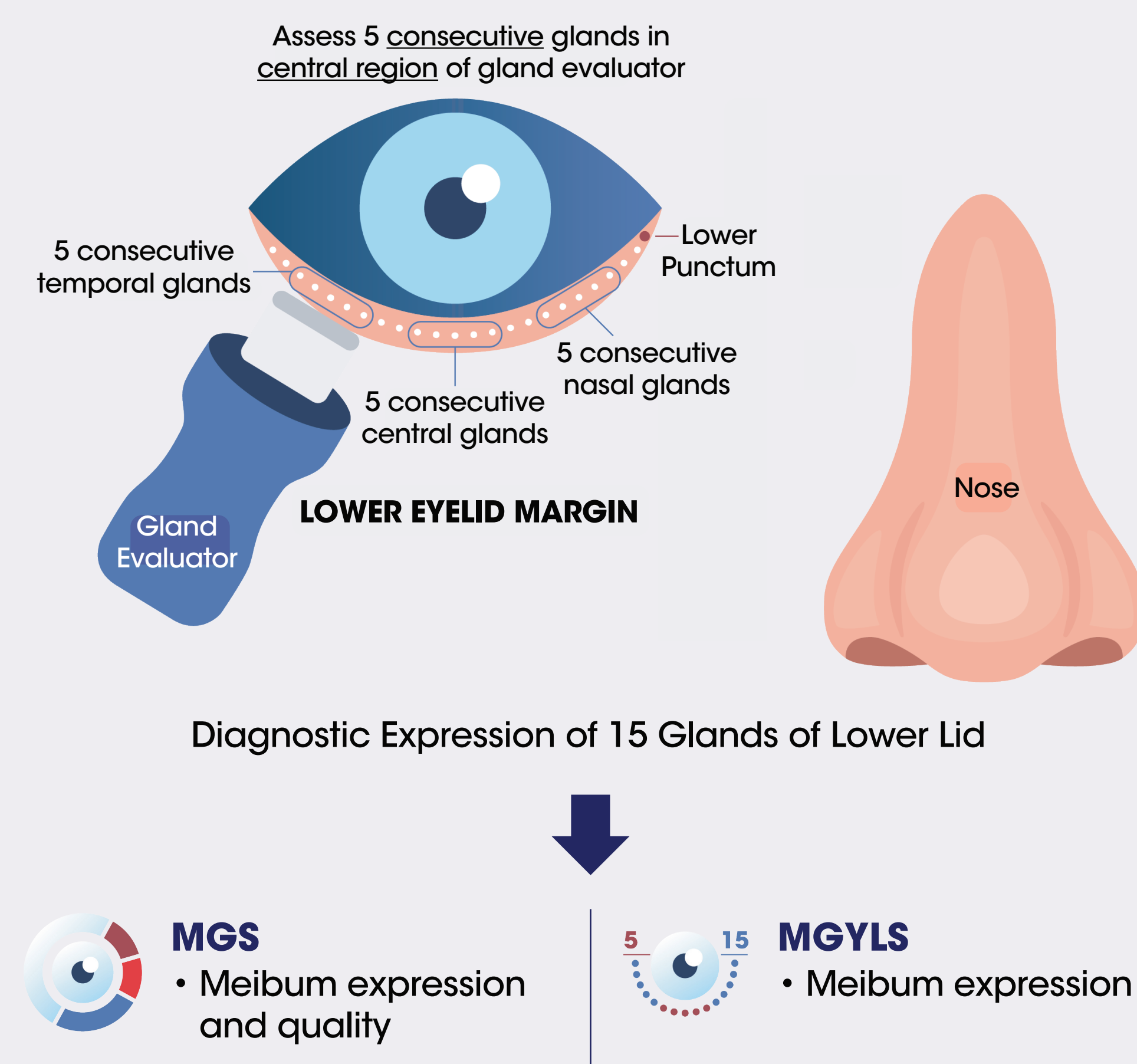
BACKGROUND

- AZR-MD-001 (AZR) 0.5% is an investigational keratolytic ophthalmic ointment that has demonstrated efficacy in opening meibomian glands and improving signs and symptoms of dry eye disease (DED) in previous clinical trials^{1,2,3}
- Research has demonstrated that a decrease in the number of meibomian glands expressing liquid secretions in the lower eyelid is associated with symptoms of DED⁴
- Exploratory analyses were performed using pooled data from 791 participants across three double-masked, vehicle-controlled, multi-center clinical trials (ARIES, CELESTIAL, and ASTRO) to evaluate if increasing the number of open glands expressing liquid meibum in participants with baseline dysfunctional meibomian glands was associated with improvements in the signs and symptoms of DED
- Additional analyses were performed to determine if participants treated with AZR 0.5% are more likely to have an increase in a meaningful number of open glands that would affect downstream signs and symptoms of DED compared to those treated with vehicle

METHODS

- Main inclusion criteria included adults (≥ 18 years of age) with a total OSDI between 13-34 (mild to moderate), and a presence of MGD defined by a Meibomian Gland Secretion Score (MGS) of ≤ 12
- In all three studies, during each visit researchers evaluated the number of open glands using the Meibomian Glands Yielding Liquid Secretion (MGYLS) scoring system
- A Meibomian Gland Evaluator (MGE™, Johnson & Johnson) was utilized to evaluate the number of open glands secreting meibum out of 15 glands along the lower eyelid margin (5 glands in each of the temporal, central, and nasal regions; see **Figure 1**)

FIGURE 1. GLAND EVALUATOR METHODS

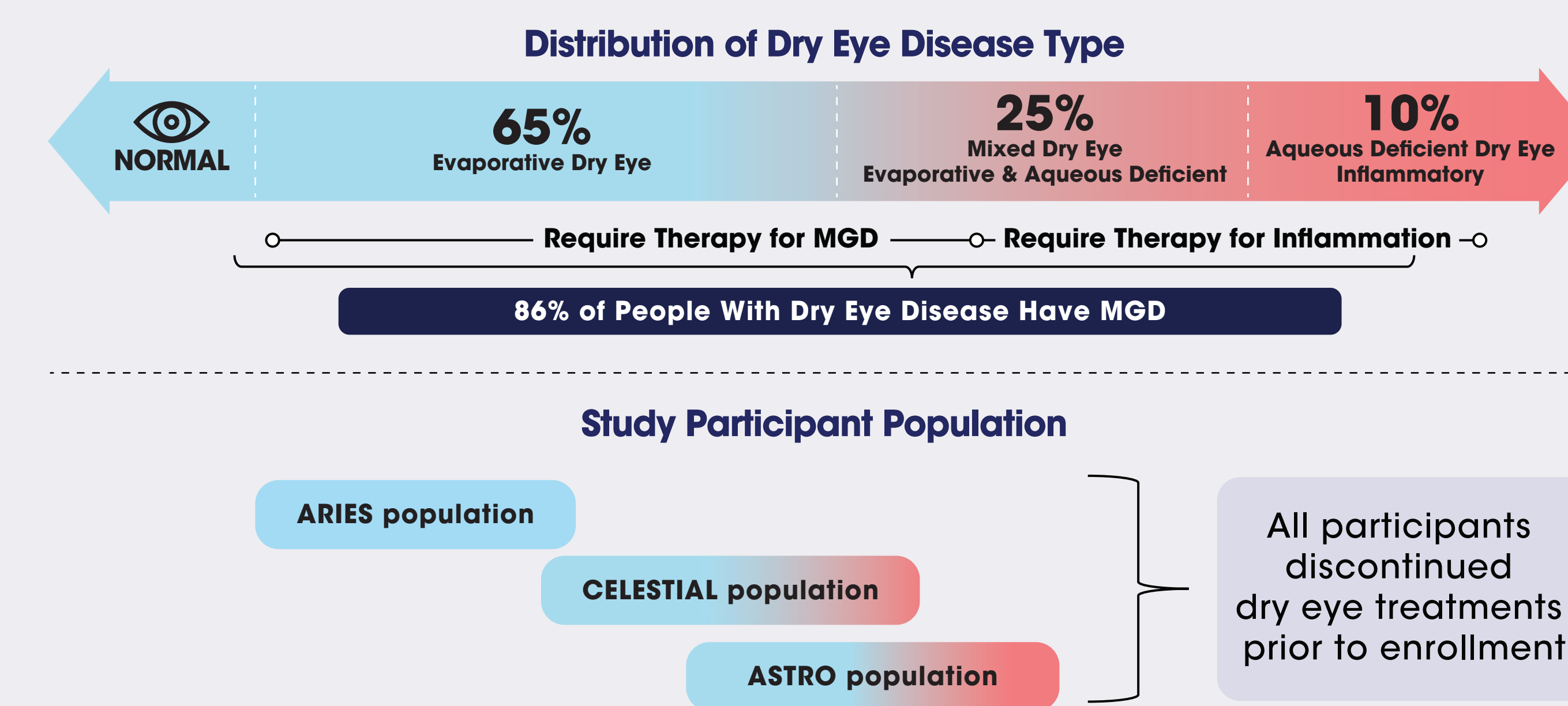


MGS was evaluated by visual appearance of meibum quality upon gland expression, including secretion and quality. MGYLS was evaluated by identifying the number of meibomian glands yielding liquid secretion upon gland expression. MGS, meibomian gland score; MGYLS, meibomian gland yielding liquid secretions.

STUDY POPULATIONS

- All three studies included participants with MGD and DED that spanned the MGD-related DED spectrum, from pure MGD to mixed evaporative and inflammatory disease (**Figure 2**)
- Participants in these studies had dysfunctional meibomian glands (MGD) with an average of only 2/15 (13%) measured glands yielding liquid secretions at baseline^{1,2,3}
 - The ARIES trial (AZR n=33, vehicle n=32, NCT03972501) enrolled participants with early MGD who wore contact lenses daily, but due to their underlying MGD/DED related symptoms, could not wear their contact lenses as long as desired¹
 - The CELESTIAL trial (AZR n=82, vehicle n=80, NCT03652051) enrolled DED participants with early to moderate MGD²
 - The ASTRO trial (long term safety, AZR n=282, vehicle n=280, NCT06329791) enrolled participants with MGD and mixed evaporative and inflammatory DED (See ARVO poster 1750 - 0512)
 - See **Figure 2** for the distribution of DED types

FIGURE 2. DISTRIBUTION OF DED TYPE IN THE GENERAL POPULATION⁵ AND AZR TRIAL PARTICIPANTS



DED, dry eye disease; MGD, meibomian gland dysfunction.

ANALYSES

- In each of the three studies and in the combined pooled data, a sensitivity analysis was performed to determine the optimal increase in the number of open glands that would most positively affect downstream DED signs and symptoms
- The analysis was performed using all participants combined, irrespective of treatment assignment. For each threshold, the analysis determined whether those above a tested threshold of open glands (responders) had better improvement in downstream signs and symptoms of DED compared to those below the tested threshold (non-responders)
- Following determination of the optimal increase in the number of open glands, additional responder analyses comparing AZR 0.5% to vehicle were performed in each of the three studies and the combined pooled data set to determine whether AZR 0.5% had an advantage compared to vehicle in achieving such threshold

STUDY OUTCOMES

- Sign outcomes for all studies:
 - Corneal fluorescein staining
 - Corneal fluorescein staining clearance (score of 0)
 - Tear Break-Up Time (TBUT)

- Symptom outcomes for all studies:
 - Total Ocular Surface Disease Index (OSDI)
 - OSDI subscales (ocular symptoms, vision-related function, environmental triggers)
 - Standardized Patient Evaluation of Eye Dryness (SPEED)
 - Average Visual Analogue Scale (VAS)
 - VAS Subscales (dryness, itch, discomfort)

- Symptom outcomes for the ARIES trial population only:
 - Comfortable contact lens wear time (minutes)
 - The ability to wear lenses as long as desired

RESULTS

- In general, increasing the number of open glands was associated with a significant reduction in the signs and symptoms of DED. The analyses further showed that an increase in at least 3 more open glands (improvement of ≥ 3 MGYLS) from baseline to Month 3 was identified as statistically meaningful across the most DED signs and symptoms measured in all 3 studies and the combined data set (**Table 1**)
- In each of the three studies as well as in the pooled data set of 791 participants, participants treated with AZR 0.5% achieved a statistically significantly larger increase of ≥ 3 open glands from baseline compared to vehicle (P -values of <0.0001 , 0.006 , 0.0424 and <0.0001 in ARIES, CELESTIAL, ASTRO and pooled data, respectively; **Figure 3**)

TABLE 1. SIGNS AND SYMPTOM OUTCOMES OF DED FOR MGYLS ≥ 3 OR < 3 IMPROVEMENT

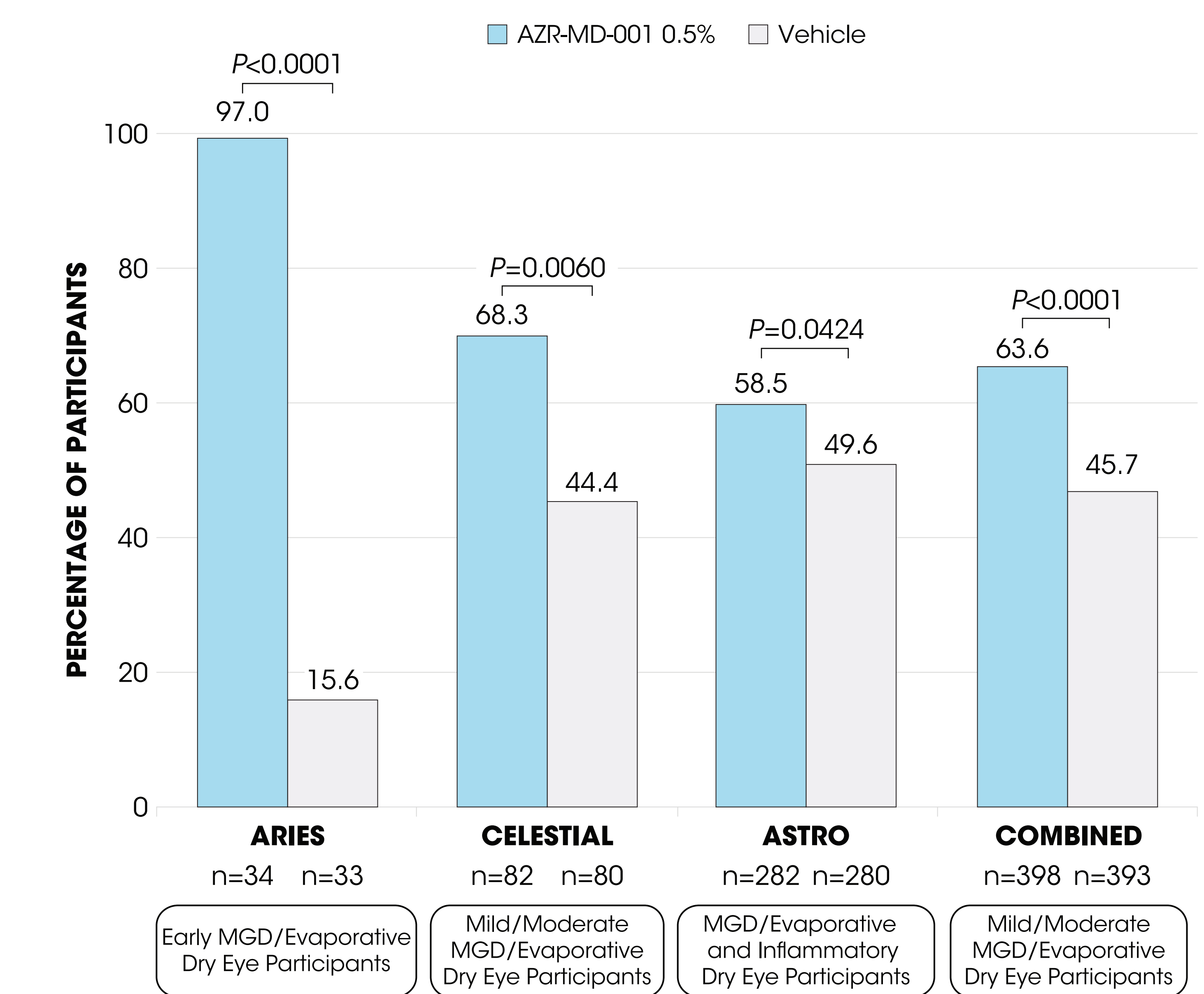
Signs	Difference in Endpoint Between Groups (≥ 3 minus < 3)	P-value
Tear Break-Up Time	0.85	$P < 0.0001$
Corneal Fluorescein Staining	-0.20	$P = 0.0012$
Corneal Fluorescein Staining Score = 0	11.9%	$P = 0.0004$
Symptoms		
Total OSDI	-2.83	$P = 0.0053$
OSDI Ocular Symptoms	-2.16	$P = 0.035$
OSDI Vision-Related Function	-2.77	$P = 0.0256$
OSDI Environmental Triggers	-5.18	$P = 0.0015$
Total SPEED	-1.0	$P = 0.0045$
VAS (Average)	-2.42	$P = 0.0548$
VAS Eye Dryness	-4.9	$P = 0.0085$
VAS Ocular Discomfort	-2.9	$P = 0.0854$
VAS Itching	-3.2	$P = 0.0438$
Comfortable Wear Time (Minutes)*	210.6	$P < 0.0001$
Ability to Wear Lenses As Long As Desired (Yes)*	37%	$P = 0.0005$

n=791. *ARIES study outcomes only. CLD, contact lens disorder; MGYLS, Meibomian Gland Yielding Liquid Secretion; OSDI, Ocular Surface Disease Index; SPEED, Standardized Patient Evaluation of Eye Dryness; VAS, Visual Analogue Scale

SUMMARY

- Across the MGD-related DED spectrum, data suggests that increasing the number of open glands by 3 or more glands in the lower eyelid was associated with significant improvement in important signs and symptoms of DED. This threshold determination was confirmed across three different MGD populations and in a combined data set of 791 participants
 - An increase in 3 or more glands expressing meibum out of 15 measured on the lower lid may be considered as guidance for identifying a therapeutic effect on MGD and DED-related symptoms in clinical practice and clinical studies
- A statistically significantly greater proportion of participants treated with AZR 0.5% achieved an improvement of at least 3 open glands (increase of ≥ 3 MGYLS) over 3 months of treatment compared to vehicle, supporting the effectiveness of AZR 0.5% in treating obstructive MGD and improving multiple signs and symptoms across the MGD-related DED spectrum

FIGURE 3. PERCENTAGE OF PARTICIPANTS ACHIEVING AN INCREASE OF ≥ 3 MGYLS



MGD, meibomian gland dysfunction; MGYLS, meibomian gland yielding liquid secretions.

Contact

Charles Bosworth, PhD | Azura Ophthalmics Ltd. | Charles.bosworth@azuraophthalmics.com

References

1. Watson SL, et al. *Ocul Surf*. 2023 Jul;29:537-546. 2. Downie LE, et al. *Ocul Surf*. 2025 Jan;35:15-24. 3. Stapleton F, et al. *Ocul Surf*. 2025 Oct;38:431-439. 4. Korb DR, Blackie CA. *Cornea*. 2008 Dec;27(10):1142-1147. 5. Lemp MA, et al. *Cornea*. 2012 May;31(5):472-478.

Acknowledgements

Funding for the studies 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

K. Nichols: C: Abbvie, Alcon, Azura Ophthalmics Ltd., Bausch+Lomb, Bruder, Calvary, Cloudbreak, Dompe, Glaukos, Harrow, Kendrion Biopharma, Oyster Point Pharma/Viatris, Santec, Sight Sciences, Sydnexis, Tarsus, Thea, Topcon, Truera, Visus/Tenpoint, R: Science Based Health, TearScience.

L. Jones: C: Alcon, AVTRMed, Azura Ophthalmics, CooperVision, Ophthecs, F: 3N Eyecare, Alcon, Avizor, Azura Ophthalmics, Bausch + Lomb, CooperVision, Essilor, Euclid, Hoya, I-Med Pharma, Integral Biosystems, J&J Vision, MaculMira, Menicon, Myoptechs, Novartis, Ophthecs, Pteryon Therapeutics, Scope Ophthalmics, SightGloss, Topcon, Visioneering, I: Al4Eyes, R: Alcon, Bausch + Lomb, CooperVision, Ophthecs, Scope Ophthalmics, S: TFOS.

J. Schallhorn: C: Zeiss, Johnson & Johnson, Oculus, Vanda Pharmaceuticals, ViaLase, Forsight V6, Elios, Tarsus, Glaukos, Harrow, Novus Vision, Neurotrigger, Long Bridge, Greenman, Emmecell, Jellisee, E: Journey 1.

K. Abbott: C: AbbVie, Alcon, Azura Ophthalmics Ltd., Bausch+Lomb, Dompe, Harrow, Lenz, SunSnap Kids, Tarsus.

M. Gleeson: E, P, S: Azura Ophthalmics Ltd.

Y. Alster: E, P, S: Azura Ophthalmics Ltd.

C. Bosworth: E, P, S: Azura Ophthalmics Ltd.

C: Consultant or Honoraria. **E:** Employment. **P:** Patent. **R:** Research funding/support. **S:** Stock.

