

# AZR-MD-001 Opens Meibomian Glands and Improves Meibum and Tear Quality, Resulting in Increased Lens Wear Time in Patients With CLD

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## INTRODUCTION

- Contact lens discomfort (CLD) is a common problem for contact lens wearers and practitioners due to discontinuation of lens use (estimated between 12% and 51% of wearers<sup>1</sup>), with 31%–58% of wearers considered symptomatic.<sup>2</sup>
- CLD is defined as "a condition characterized by episodic persistent adverse ocular sensations related to contact lens wear, either with or without visual disturbance, resulting from reduced compatibility between the contact lens and the ocular environment, which can lead to decreased wearing time and discontinuation of contact lens wear."<sup>3</sup>
- AZR-MD-001 is an ophthalmic keratolytic, keratostatic, and lipogenic ointment containing selenium sulfide shown to improve signs and symptoms of meibomian gland dysfunction (MGD).<sup>4</sup>
- This study evaluated if AZR-MD-001 used twice a week can make meibomian glands functional and improve comfortable wear time in patients with CLD and signs of MGD, allowing patients to wear their contact lenses as desired.

## DEMOGRAPHICS

- All participants reported wearing soft lenses, with the majority using daily disposable lenses (49/67, 73%). Additional baseline characteristics are presented (Table 1).

TABLE 1. DEMOGRAPHIC AND BASELINE CHARACTERISTICS OF PARTICIPANTS

		AZR-MD-001 (n=34)	VEHICLE (n=33)	OVERALL (N=67)
Age (years)	Mean (SD)	46.7 (12.8)	49.4 (14.3)	48.0 (13.5)
	Median (min, max)	47.5 (18, 76)	51 (18, 72)	48 (18, 76)
Sex, n (%)	Female	29 (85%)	26 (79%)	55 (82%)
	Male	5 (15%)	7 (21%)	12 (18%)
Race, n (%)	White	26 (76%)	26 (79%)	52 (78%)
	Asian	8 (24%)	7 (21%)	15 (22%)
Number of MGYS*	Mean (SD)	2.8 (0.8)	3.0 (0.6)	2.9 (0.7)
MGS score*	Mean (SD)	8.4 (1.7)	8.7 (1.6)	8.6 (1.6)
TBUT (seconds)*	Mean (SD)	6.3 (2.2)	5.5 (1.6)	5.9 (1.9)
Comfortable CL wear time (hours)*	Mean (SD)	6.6 (2.4)	5.4 (2.4)	6.0 (2.4)

Percentages may not add to 100% due to rounding. Characteristics captured at the baseline visit and reported for the safety population (all participants who were dispensed study medication), unless specified otherwise.  
\*Reported for intent-to-treat population (all patients randomized).  
CL, contact lens; MGS, Meibomian Gland Secretion; MGYS, Meibomian Glands Yielding Liquid Secretion; SD, standard deviation; TBUT, Tear Break-up Time.

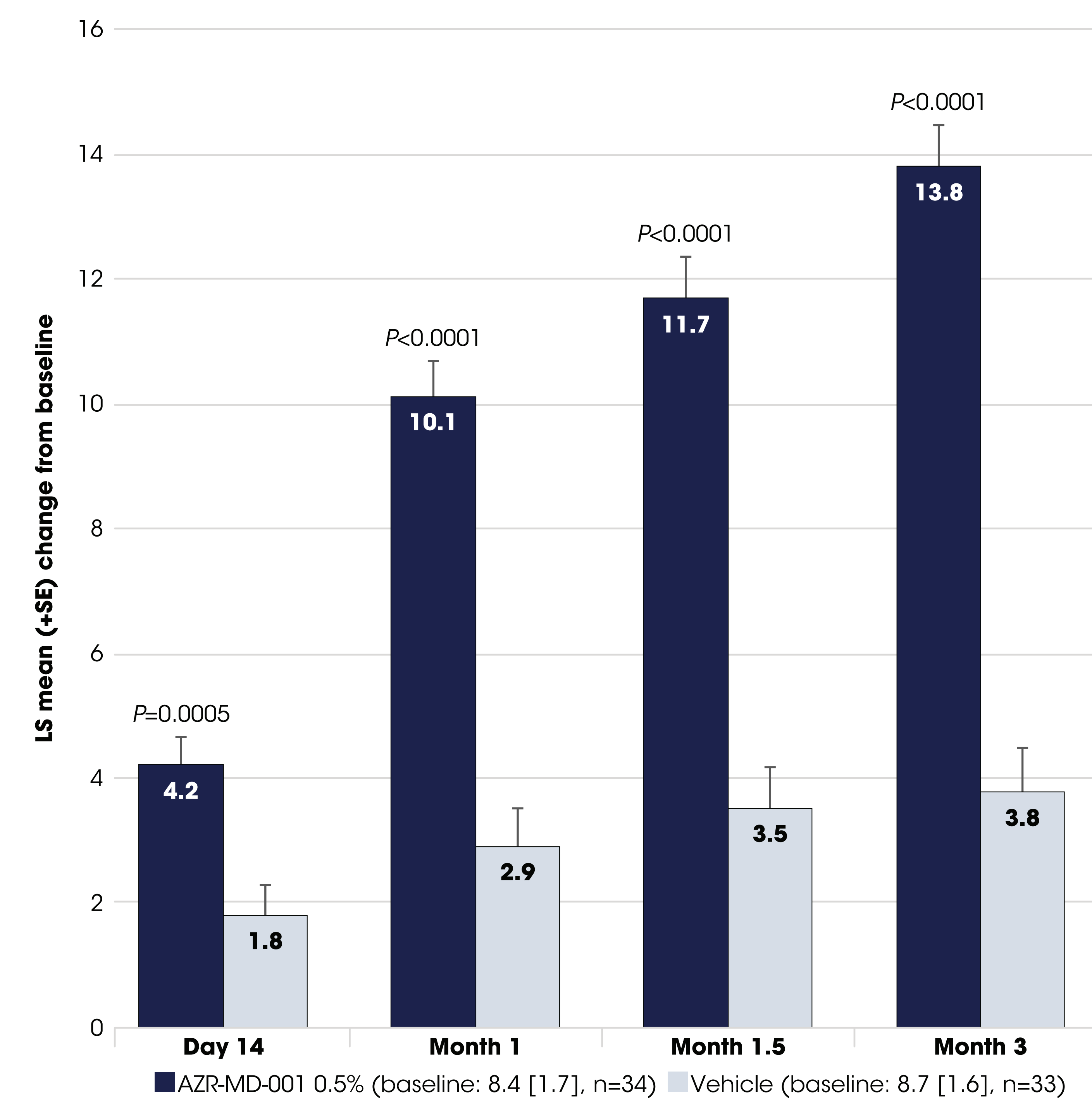
## METHODS

- Study design:** Phase 2, multicenter, parallel-group, double-masked, vehicle-controlled, randomized trial (NCT05548491)
- Eligible patients:** Adults (≥18 years) who had evidence of MGD (Meibomian Gland Secretion [MGS] score of ≤12 for 15 glands of the lower lid) in both eyes at baseline; had a history of wearing soft contact lenses for ≥6 months, including ≥3 weeks before the baseline visit and wore or attempted to wear lenses ≥4 times a week before the baseline visit; answered "No" to "Are you able to comfortably wear your lenses as long as you want?"; self-reported history of contact lens dryness/intolerance in the 6 months preceding baseline; and had a Contact Lens Dry Eye Questionnaire-8 (CLDEQ-8) score of >12 at baseline
  - Contact lenses were to be used during the study and were removed for scheduled visits, as well as 15 minutes before dosing.
- Treatment:** Patients randomized (1:1) to AZR-MD-001 0.5% or vehicle applied to the lower eyelid just before bedtime twice weekly
  - No conventional treatments were allowed during the study.
- 6 scheduled visits:** Screening, randomization/baseline, Day 14, Month 1, Month 1.5, and Month 3
- Primary efficacy endpoints:** Hierarchical order: Change from baseline to Month 3 versus vehicle in (1) Meibomian Glands Yielding Liquid Secretion (MGYS), (2) CLDEQ-8 total score, and (3) CLDEQ-8 fluctuating vision items
- Secondary efficacy endpoints:** Change from baseline versus vehicle in MGS score (key secondary), tear break-up time (TBUT; additional secondary) post lens removal, and comfortable contact lens wear time (key secondary); comfortable wear time responder rate (exploratory)
- Change from baseline analysis:** Evaluated using an analysis of covariance model with continuous baseline endpoint score as a covariate and treatment and baseline MGS score category (<6 or ≥6 and ≤12) as factors
- Responder rate analysis:** Evaluated using a Cochran-Mantel-Haenszel test controlling for baseline MGS score category (<6 or ≥6 and ≤12)

## RESULTS

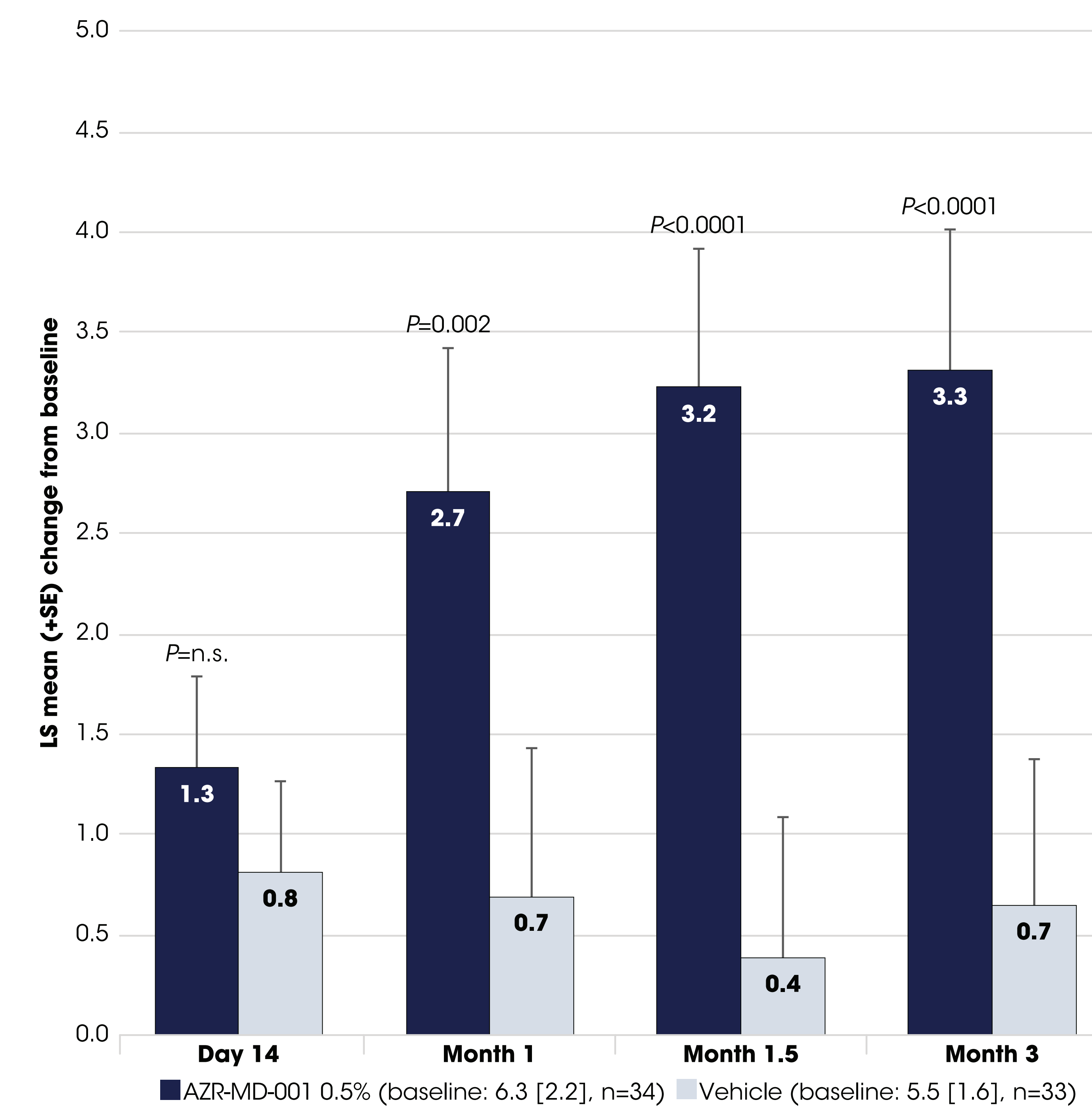
- AZR-MD-001 0.5% met the primary endpoint for MGYS change from baseline to Month 3 versus vehicle, did not meet statistical significance for CLDEQ-8 change from baseline to Month 3 versus vehicle for total or fluctuating vision item scores, and demonstrated good safety and tolerability. (Please see poster 6584 - B0271 for primary efficacy and safety results.)
- At Month 3, AZR-MD-001 0.5% significantly improved signs MGS (Figure 1) and TBUT (Figure 2), and lens wear time (Figure 3) versus vehicle.
- Improvements over vehicle were first seen on Day 14 in MGS score (Figure 1) and at Month 1 for TBUT (Figure 2) and comfortable contact lens wear time (Figure 3).
- At baseline, all patients were unable to comfortably wear contact lenses as desired, and by Month 3, significantly more patients treated with AZR-MD-001 than vehicle were able to wear them as long as desired (Figure 4).
- Please see other ARVO 2024 posters for additional efficacy results (2971 - A0130; 2669 - B0505).

FIGURE 1. MEAN CHANGE FROM BASELINE IN MGS SCORE OVER TIME (ITT)



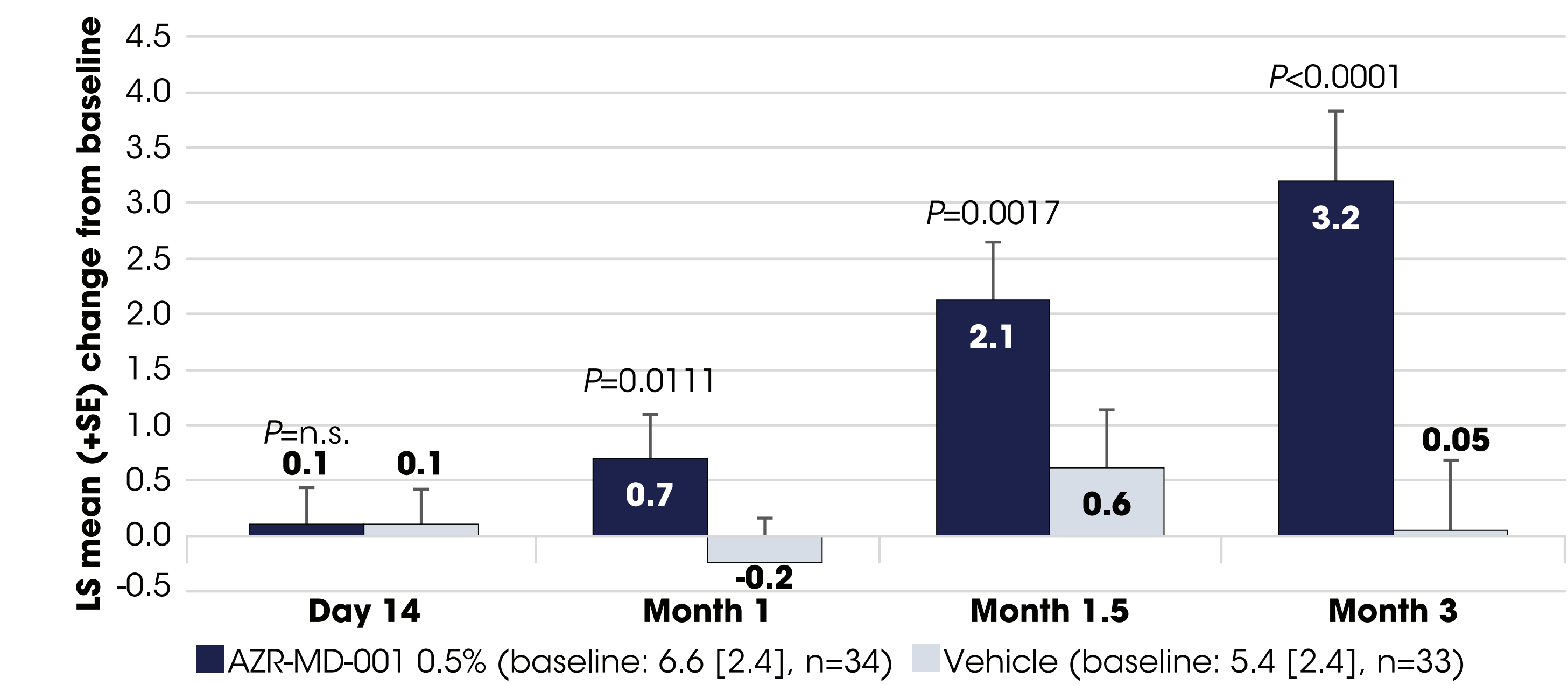
ITT, intent-to-treat (all patients randomized); LS, least squares; MGS, Meibomian Gland Secretion (higher scores are better); SE, standard error.

FIGURE 2. MEAN CHANGE FROM BASELINE IN TBUT (SECONDS) OVER TIME (ITT)



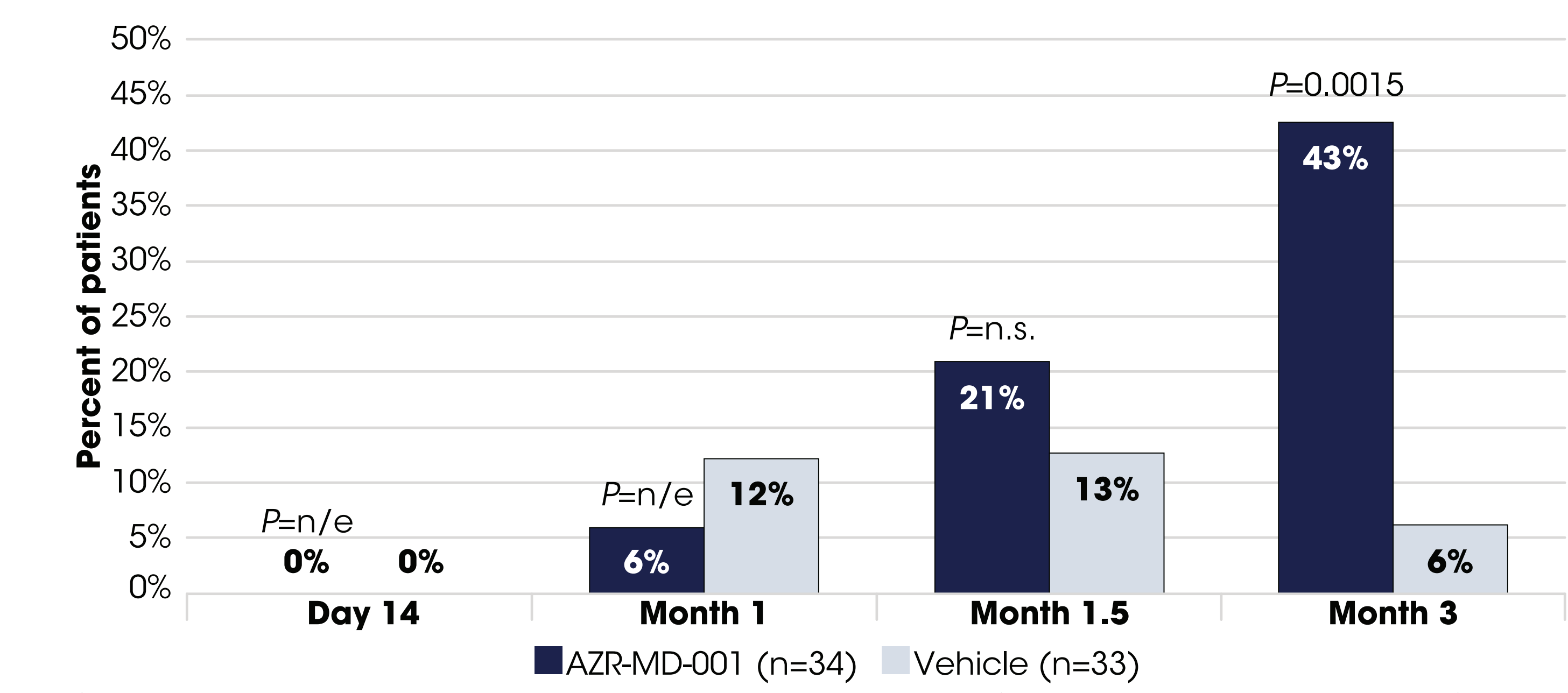
ITT, intent-to-treat (all patients randomized); LS, least squares; n.s., not significant versus vehicle; SE, standard error; TBUT, Tear Break-up Time (longer time is better).

FIGURE 3. MEAN CHANGE FROM BASELINE IN HOURS OF COMFORTABLE LENS WEAR TIME (ITT)



ITT, intent-to-treat (all patients randomized); LS, least squares; n.s., not significant versus vehicle; SE, standard error.

FIGURE 4. COMFORTABLE LENS WEAR RESPONDER RATES\* OVER TIME (ITT)



\*Contact lens wear time responders are patients who answered "Yes" to "Are you able to comfortably wear your lenses as long as you want?" ITT, intent-to-treat (all patients randomized); n/e, not estimable; n.s., not significant versus vehicle.

## CONCLUSION

- Compared to vehicle, AZR-MD-001 significantly improved meibum and tear film quality, resulting in significantly longer comfortable wear time, starting as early as after 8 doses of treatment, in patients with CLD and signs of MGD.

## Contact

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## References

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