

# AZR-MD-001 Efficacy in the Treatment of Contact Lens Discomfort: A Phase 2 Trial

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## PURPOSE

- 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>
- CLD is commonly associated with meibomian gland dysfunction (MGD) characterized by obstructed glands and poor meibum secretion quality.<sup>1</sup>
- AZR-MD-001 is an ophthalmic keratolytic, keratostatic, and lipogenic ointment containing selenium sulfide and has been shown to improve signs and symptoms of MGD.<sup>4</sup>
- This study investigated whether treating the underlying cause of MGD with AZR-MD-001 can open meibomian glands and improve meibum quality in patients with concomitant CLD and signs of MGD, and subsequently whether AZR-MD-001 can improve symptoms and wear time of CLD in patients who continue to wear their contact lenses.

## DEMOGRAPHICS

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

**TABLE 1. DEMOGRAPHIC AND BASELINE CHARACTERISTICS OF PARTICIPANTS**

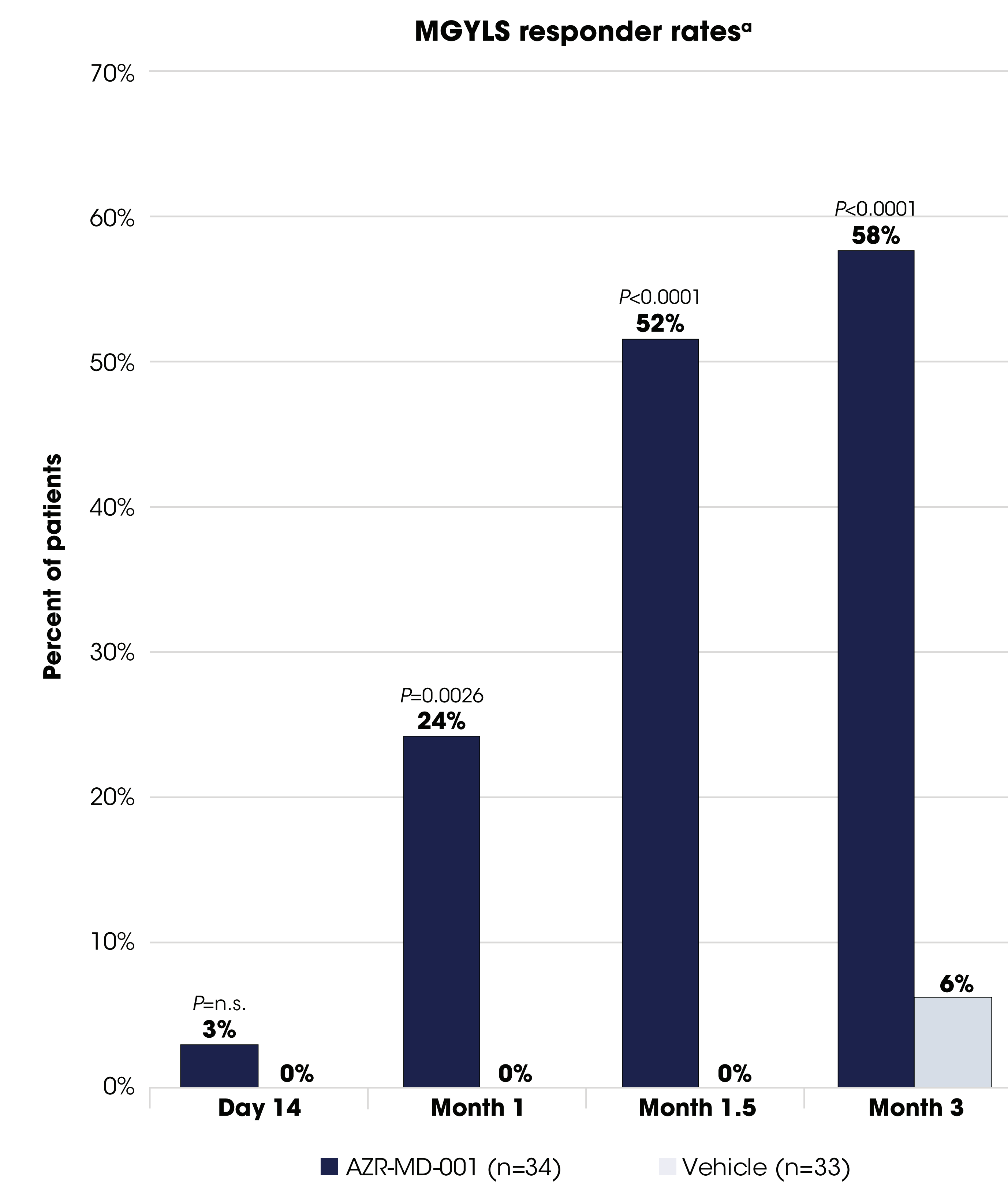
		AZR-MD-001 (n=34)	VEHICLE (n=33)	OVERALL (N=67)
Age (years)	Mean (SD)	46.7 (12.8)	49.4 (14.3)	48.0 (13.5)
	Median (min, max)	47.5 (18, 76)	51 (18, 72)	48 (18, 76)
Sex, n (%)	Female	29 (85)	26 (79)	55 (82)
	Male	5 (15)	7 (21)	12 (18)
Race, n (%)	White	26 (76)	26 (79)	52 (78)
	Asian	8 (24)	7 (21)	15 (22)
Number of MGYSL*	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 wear time (hours)*	Mean (SE)	6.6 (2.4)	5.4 (2.4)	6.6 (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 ITT population (all randomized patients).  
MGS, Meibomian Gland Secretion; MGYSL, Meibomian Glands Yielding Liquid Secretion; SD, standard deviation; TBUT, tear break-up time.

## RESULTS

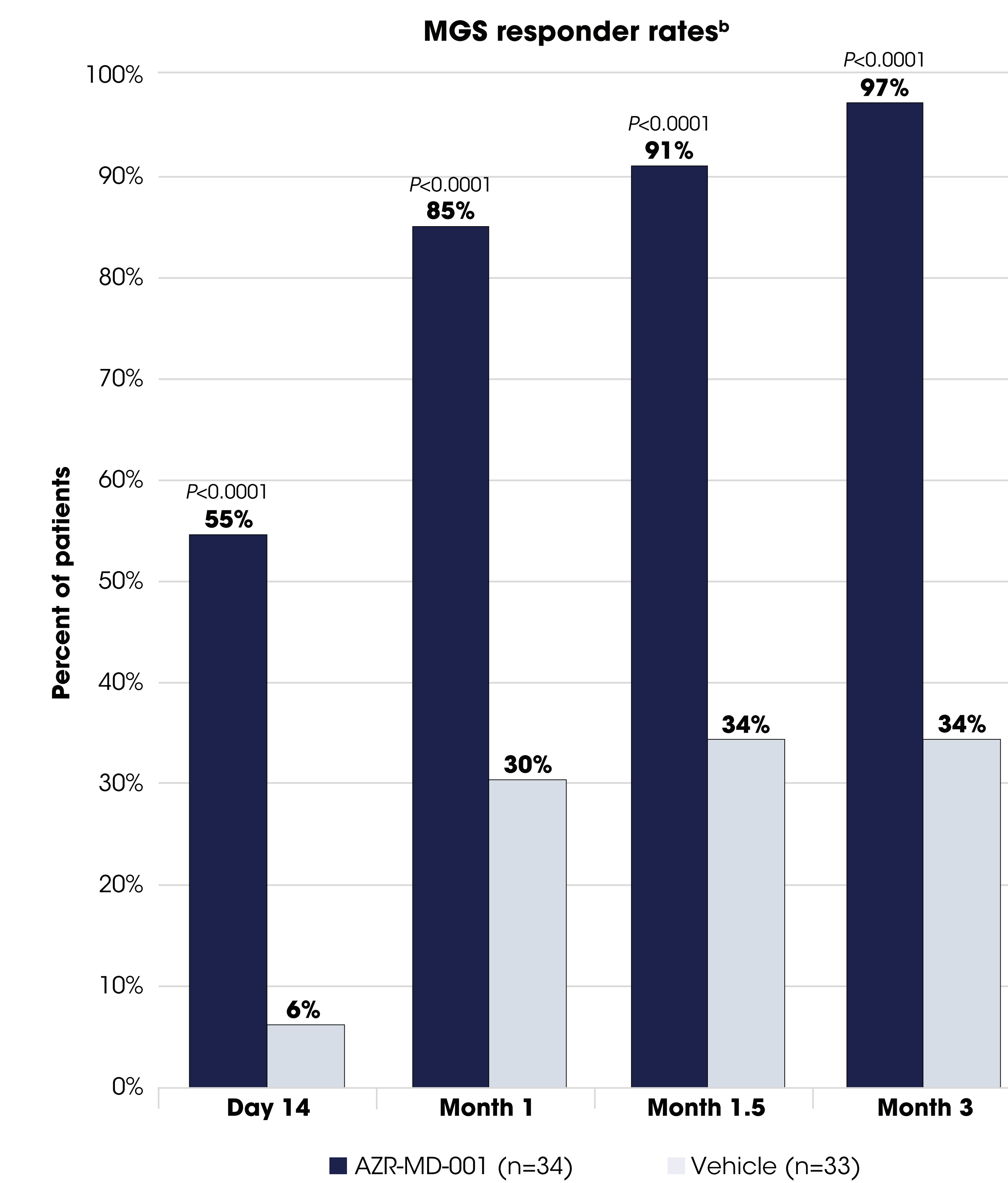
- The percentage of patients with MGYSL response increased throughout the study, with AZR-MD-001 resulting in more patients with a clinically meaningful improvement in the number of MGYSL than vehicle in Months 1 through 3 (**Figure 1**). Please see poster 6584-B0271 for primary efficacy and safety results.
- Starting at Day 14, in 55% of patients treated with AZR-MD-001, meibum secretion quality normalized (MGS >12), which increased to 97% of patients by Month 3 and was statistically significant versus vehicle at all time points (**Figure 2**).
- At Month 3, 43% of patients treated with AZR-MD-001 were able to wear their contact lenses comfortably for as long as desired, which was statistically significant versus vehicle (**Figure 3**).
- At Month 3, patients treated with AZR-MD-001 were able to wear their contact lenses comfortably for an additional 3.2 hours on average versus 3 minutes in patients receiving vehicle (P<0.0001) (**Figure 4**).
- Please see other ARVO 2024 posters for additional efficacy results (2677 – B0513, 2669 – B0505).

**FIGURE 1. MEIBOMIAN GLAND FUNCTIONAL IMPROVEMENTS OVER TIME (ITT)**



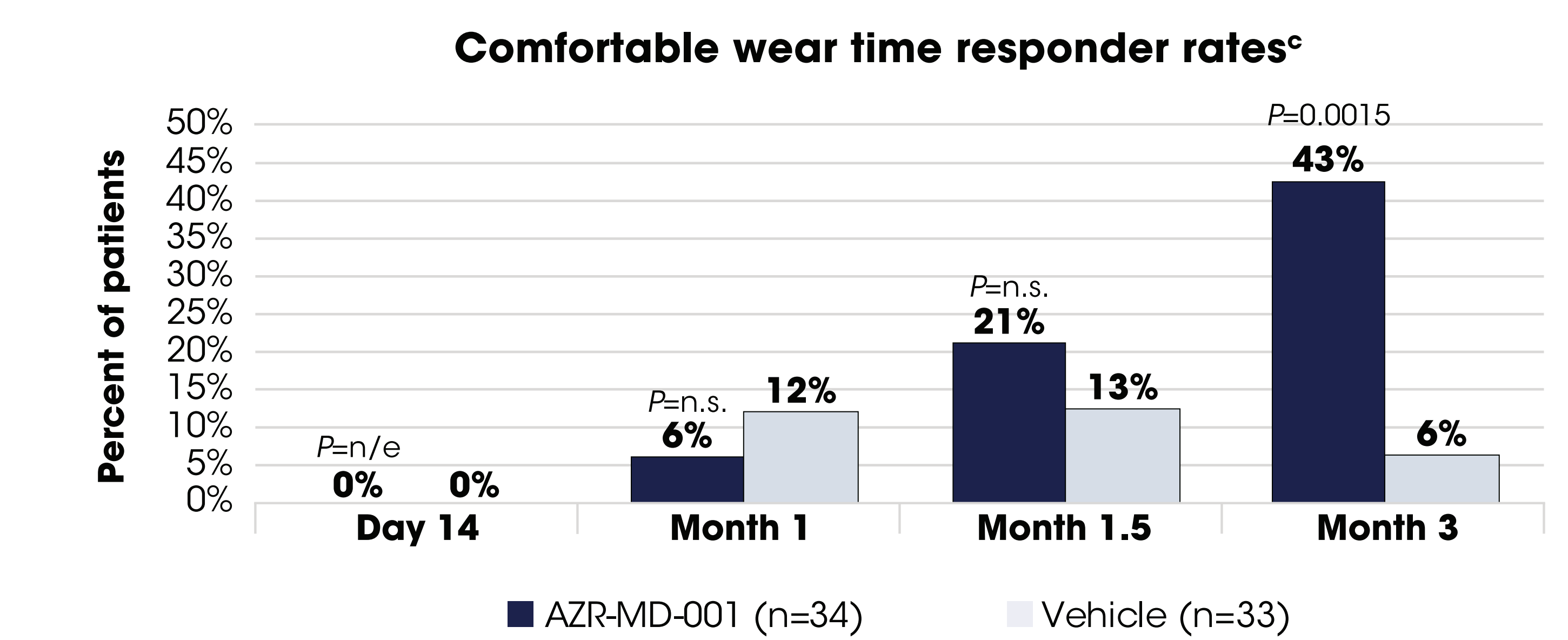
<sup>a</sup>MGYSL responders: Patients with a ≥5-gland increase from baseline in the study eye. ITT, intent-to-treat population (all randomized patients); MGYSL, Meibomian Glands Yielding Liquid Secretion; n.s., not significant (P>0.05) relative to vehicle.

**FIGURE 2. MEIBUM QUALITY IMPROVEMENTS OVER TIME (ITT)**



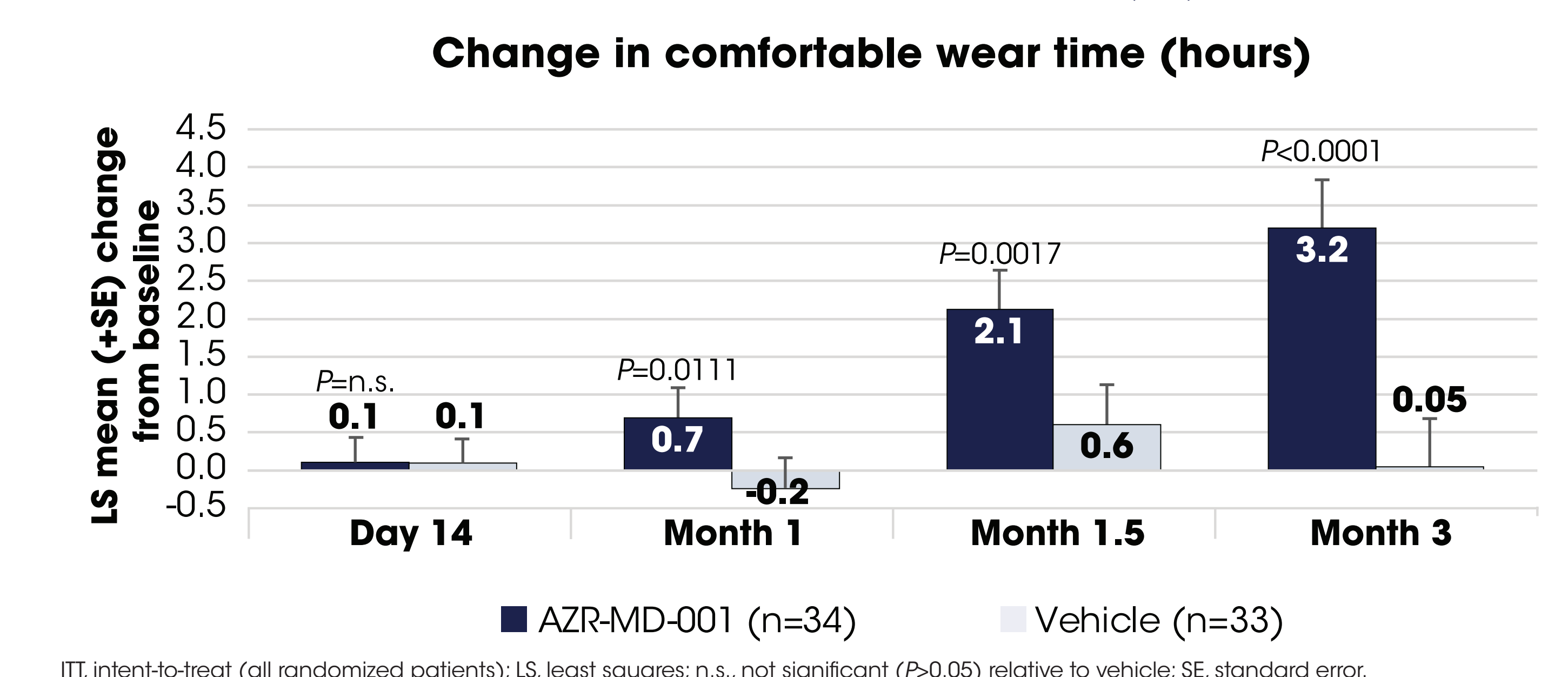
<sup>b</sup>MGS responder: Patients with an MGS score >12. ITT, intent-to-treat population (all randomized patients); LS, least squares; MGS, meibomian gland secretion.

**FIGURE 3. PERCENT OF PARTICIPANTS ABLE TO COMFORTABLY WEAR THEIR CONTACTS AS DESIRED (ITT)**



<sup>c</sup>Comfortable wear time responder: participants who reported the ability to comfortably wear contact lenses for as long as desired. ITT, intent-to-treat population (all randomized patients); n/e, not estimable; n.s., not significant (P>0.05) relative to vehicle.

**FIGURE 4. IMPROVEMENTS TO CONTACT LENS WEAR TIME (ITT)**



ITT, intent-to-treat (all randomized patients); LS, least squares; n.s., not significant (P>0.05) relative to vehicle; SE, standard error.

## CONCLUSIONS

AZR-MD-001 treatment was associated with a statistically significant percentage of participants experiencing a clinically meaningful increase in number of functional meibomian glands and normal meibum secretion quality, resulting in more patients who could wear their contact lenses comfortably for as long as they desired compared to vehicle.

## METHODS

- Study design:** Phase 2, multicenter, parallel-group, double-masked, vehicle-controlled, randomized trial (NCT05548491)
- Eligible patients:** Adults (≥18 years) with evidence of MGD (based on a 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 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 Gland Yielding Liquid Secretion (MGYSL), (2) CLDEQ-8 total score, and (3) CLDEQ-8 fluctuating vision items
- Responder rates:** All thresholds were prespecified and based on literature cutoffs.
  - Analyzed using a Cochran-Mantel-Haenszel test, controlling for duration of disease category and baseline MGS score category.
  - Missing data were imputed via multiple imputations using Markov Chain Monte Carlo approach.
  - All P-values are descriptive due to the hierarchical approach.

### MGYSL



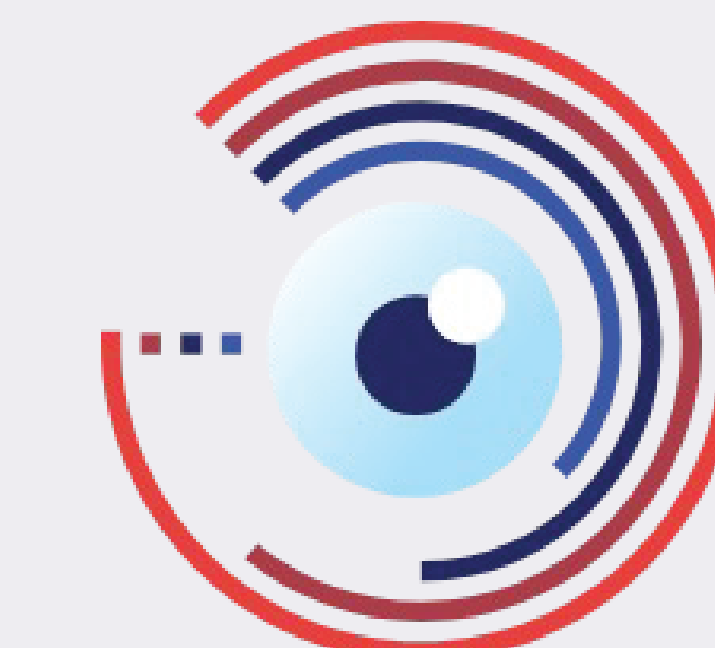
The number of glands (out of 15) on the lower lid observed to secrete liquid<sup>a</sup>

### MGS



Meibum quality of 15 glands on the lower lid (MGS >12 is normal)<sup>4,6</sup>

### Comfortable wear time



Commonly used to assess the effects of changing lenses, lens routines, or rewetting solutions

## Contact

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## References

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## Disclosures

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