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ORIGINAL RESEARCH

Effects of Lotilaner Ophthalmic Solution, 0.25% on *Demodex* Blepharitis Patients with Meibomian Gland Disease

Preeya K Gupta[1], Ian Benjamin Gaddie[2], Mitchell C Shultz[3], Patrick Vollmer[4], Steven Marc Silverstein[5], Bridgitte Shen Lee[6], Leslie O'Dell[7], Kavita Dhamdhere[7], Elizabeth Yeu[7,8]

[1]Triangle Eye Consultants, Raleigh, NC, USA; [2]Gaddie Eye Centers, Louisville, KY, USA; [3]Shultz Chang Vision, Los Angeles, CA, USA; [4]Vita Eye Clinic, Shelby, NC, USA; [5]Silverstein Eye Centers, Kansas City, MO, USA; [6]Vision Optique, Houston, TX, USA; [7]Tarsus Pharmaceuticals, Inc., Irvine, CA, USA; [8]Virginia Eye Consultants, Norfolk, VA, USA

Correspondence: Preeya K Gupta, Triangle Eye Consultants, 9650 Brier Creek Parkway, Suite 103, Raleigh, NC, 27617, USA, Tel +1 919-391-7224, Email preeyakgupta@gmail.com

Purpose: To evaluate the safety and efficacy of lotilaner ophthalmic solution, 0.25% compared with vehicle in *Demodex* blepharitis patients with meibomian gland disease.

Patients and Methods: This was a pooled analysis of two prospective, randomized, double-masked studies of *Demodex* blepharitis patients with meibomian gland disease, Ersa (N=39), and Rhea (N=40). The two studies had the same design, eligibility criteria, and sample size, except Ersa studied lotilaner ophthalmic solution, 0.25% while Rhea studied the associated vehicle. Study outcomes were collarette grading, meibomian gland secretion score (MGSS), number of glands yielding any liquid secretions (MGYLS), number of glands yielding clear liquid secretions (MGYCLS), patient-reported outcomes, and adverse events (AEs).

Results: On Days 43 and 85, there was a statistically significantly higher proportion of patients in the lotilaner group versus the vehicle group with collarette reduction to grade 0 (0–2 collarettes/lid) (44.7% vs 0.0% and 65.8% vs 0.0%) and grade 0 or 1 (0–10 collarettes/lid) (81.6% vs 8.8% and 100% vs 0.0%) (all $p<0.001$). Mean MGSS, MGYLS, and MGYCLS in the lotilaner group were statistically significantly higher than in the vehicle group. The proportion of lotilaner patients achieving improvement to ≥ 3 glands with clear meibum (grade 3) was significantly higher than the vehicle group on Day 43 (44.7% vs 17.6%, $p<0.05$) and Day 85 (78.9% vs 18.2%, $p<0.001$). At Days 43 and 85, fluctuating vision, itching, burning, and redness were significantly better in the lotilaner group than in the vehicle group. No serious treatment-related AEs were reported.

Conclusion: In patients with *Demodex* blepharitis and meibomian gland disease, lotilaner ophthalmic solution, 0.25% demonstrated statistically significant improvements in collarette reduction, meibomian gland function, and patient-reported outcomes at 6 and 12 weeks compared to baseline. Following lotilaner treatment, these parameters were also significantly better than vehicle at 6 and 12 weeks, with a similar safety profile.

Keywords: *Demodex* blepharitis with meibomian gland disease, *Demodex* blepharitis and meibomian gland disease, meibomian gland function, meibomian glands yielding liquid secretions, collarette reduction, lotilaner, ocular surface disease

Introduction

Meibomian gland disease is a common eye condition characterized by a chronic, diffuse abnormality of the meibomian glands, terminal-duct obstruction, and/or qualitative/quantitative variations in glandular secretion.[1] Meibomian gland disease is the leading cause of the most common form of ocular surface disease, evaporative dry eye. Currently, up to 40 million people in the United States (US) suffer from dry eye disease, and the overall economic burden is estimated to approach $4 billion.[2–4]

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Luo et al found that symptomatic meibomian gland disease was more prevalent in patients with *Demodex* blepharitis (90%) than in dry eye patients without *Demodex* (64%), and the patients with *Demodex* also demonstrated a higher degree of meibomian gland loss (58%) compared to dry eye patients without *Demodex* blepharitis (2.2%).[5] Conversely, *Demodex* infestation has been reported in 57% to 89% of meibomian gland disease cases compared to 34% to 44% of non-meibomian gland disease controls.[6–9] Bhandari et al reported that *Demodex* infestation of the lashes was nearly twice as high in patients with meibomian gland disease than in non-meibomian gland disease controls.[6]

Demodex mites can pathologically infest the meibomian glands and have been implicated in causing or exacerbating meibomian gland disease.[7,10] *Demodex* infestation has been correlated with changes in meibomian gland structure and meibum quality,[7,11] with ≥96% of individuals with moderate to severe *Demodex* blepharitis demonstrating structural and/or functional meibomian gland disease.[11] Changes in meibum secretion or lipid composition in meibomian gland disease may, in turn, provide a more favorable environment for *Demodex* mites to proliferate, triggering a cyclical worsening of both conditions.

Several thermal pulsation systems, including LipiFlow, iLux, and TearCare, have been approved by the US Food and Drug Administration (FDA) for use in patients with meibomian gland disease.[12–14] In addition, microblepharoexfoliation, intense pulsed light (IPL), radio frequency, and low-level light therapy have also been utilized in the management of meibomian gland disease.[15–17] Although these treatments have been documented to yield significant improvements in meibomian gland function and patients' ocular irritation, they do not treat *Demodex* blepharitis or address mite infestation in the meibomian glands. Historically, *Demodex* blepharitis has been addressed with lid hygiene regimens, over-the-counter options such as tea tree oil (TTO) or manuka honey, and off-label use of antiparasitics like ivermectin and metronidazole, with varying levels of efficacy, safety, and tolerability.[18–25] Among these, some forms of TTO have been shown to be harmful to the meibomian glands in vitro.[26]

Recently, lotilaner ophthalmic solution, 0.25% (Tarsus Pharmaceuticals, Irvine, CA), a gamma-aminobutyric acid (GABA)-gated chloride channel inhibitor selective for mites, was approved by the FDA for the treatment of *Demodex* blepharitis following an extensive clinical trial program in humans that demonstrated high levels of safety and efficacy.[27–32] The purpose of the present study was to ascertain whether treatment with lotilaner ophthalmic solution, 0.25%, an approved treatment for *Demodex* blepharitis, could also influence meibomian gland disease outcomes in patients with both conditions.

Materials and Methods

The present study was a post-hoc pooled analysis of two prospective, randomized, double-masked studies that evaluated lotilaner ophthalmic solution, 0.25% (Ersa, NCT05454956) or vehicle (Rhea, NCT06054217) in *Demodex* blepharitis patients with meibomian gland disease. Ersa recruited 39 *Demodex* blepharitis patients across five US clinical sites from August 2022 to May 2023, and Rhea recruited 40 *Demodex* blepharitis patients across two US clinical sites from August 2023 to March 2024. Both studies were conducted under institutional review board (IRB)-approved protocols (Advarra IRB) that adhered to the tenets of the Declaration of Helsinki. All enrolled patients provided written informed consent using the IRB-approved informed consent form. Although the two studies were performed at different time points, with lotilaner (Ersa) or vehicle (Rhea) as noted above, they otherwise had the same study design, eligibility criteria, and sample size.

For each of the studies, patients needed to meet all of the following criteria (in at least one eye to be enrolled): >10 upper lid lashes with collarettes (Grade 2 or higher), ≥1.0 mites/lash on epilated lashes from the upper/lower eyelids combined, meibomian gland secretion score (MGSS) of 12–32 (out of 45), ≥Grade 1 erythema of the lower eyelid, tear breakup time (TBUT) <10 seconds, and ≥33% total gland area of the lower eyelid with intact partial to full meibomian glands (per meibography). Additional inclusion criteria were a visual analog scale (VAS) score >40 for at least one patient-reported outcome (eg, fluctuating vision, itching, burning, or redness) within the week prior to Day 1 and corrected distance visual acuity (CDVA) better than or equal to 0.7 logMAR on the Early Treatment of Diabetic Retinopathy Study (ETDRS) scale in each eye at Day 1.

Patients were excluded from either study if they had used any artificial tear product within 24 hours of Day 1; systemic antihistamines within 30 days of Day 1; cyclosporine or lifitegrast within 60 days of Day 1; any topical prostaglandin analog within 6 months of Day 1; isotretinoin within 2 years of Day 1; or other prescription drugs,

systemic drugs, drug delivery implants, or ocular topical antibacterial, antiparasitic or anti-inflammatory corticosteroid treatments within 14 days of Day 1 or anticipated using any of these treatments during the study. Patients could not have used any treatment(s) for blepharitis within 14 days of Day 1 or lid hygiene measures (eg, lid scrubs, warm compresses, or lid massage) within 7 days of Day 1, or be unwilling to forego the use of these treatments for the duration of the study. The use of lid heating therapies, IPL, meibomian gland probing or therapeutic meibomian gland expression in either eye within 6 months of Day 1 or during the study was prohibited, as were the use of contact lenses, artificial eyelashes, eyelash extensions or other cosmetic eyelash or eyelid procedures (eg, eyeliner tattooing, eyelash tinting, eyelash curling perm, etc.) within 7 days of Day 1 or for the duration of the study.

Patients were excluded from participating in either study if they had conditions or prior procedures that, in the opinion of the investigator, could affect study outcomes including a history of corneal transplant, a recent history of ocular surgery, eyelid abnormalities, ocular surface abnormality or disorder, punctal plugs, corneal disease, active ocular infection or inflammation other than blepharitis and meibomian gland disease, or systemic disease or medications known to cause dry eye. Patients with known hypersensitivity to lotilaner or any of the formulation components and those who were pregnant or lactating were also excluded.

In the Ersa study, eligible patients were randomly assigned in a 1:1 ratio to receive twice daily (BID, n = 21) or three times daily (TID, n = 18) dosing of lotilaner ophthalmic solution, 0.25% for 12 weeks, followed by a 30-day untreated safety follow-up period. In the Rhea study, 12 patients were dosed with vehicle BID for 12 weeks, 11 patients TID for 12 weeks, and 17 patients were dosed TID for six weeks and then BID for six weeks.

The study parameters were collarette grading; meibum quality; MGSS; number of meibomian glands yielding any liquid secretions (MGYLS); number of glands yielding clear liquid secretions (MGYCLS); patient-reported outcomes; and adverse events (AEs) assessments. Collarettes were graded from 0 to 4 (Grade 0= 0 to 2 lashes with collarettes per eyelid; Grade 1= 3 to 10 lashes with collarettes per eyelid; Grade 2= >10 to <1/3 of the lashes with collarettes per eyelid; Grade 3= ≥1/3 to <2/3 of the lashes with collarettes per eyelid; and Grade 4= ≥2/3 of the lashes with collarettes per eyelid). Meibum quality was graded from 0 to 3, with a higher grade meaning better meibum quality (0=no secretion, 1=inspissated/toothpaste, 2=cloudy, 3=clear). MGSS was calculated by summing the meibum quality scores for each of the 15 glands of the lower eyelid (5 consecutive glands in each of the temporal, central, and nasal regions) to determine the overall MGSS (range: 0–45). The number of MGYLS (cloudy or clear liquid with a grade of 2 or 3) and the number of MGYCLS (grade 3) for all 15 glands were evaluated on the lower eyelid, with a range of 0 to 15. Patient-reported outcomes, including fluctuating vision, itching, burning, and redness, were rated on a VAS score from 0 (no discomfort) to 100 (maximal discomfort).

To assess if the two studies were homogeneous enough to be poolable, propensity scores were calculated through a logistic regression with the following baseline and disease burden characteristics as covariates: age, collarette grade, eyelid margin erythema grade, MGSS, MGYLS, MGYCLS, patient-reported fluctuating vision, patient-reported itching, patient-reported redness, and patient-reported burning. The demographic and baseline covariates were balanced between the lotilaner ophthalmic solution, 0.25% (Ersa) and vehicle (Rhea) groups (Table 1) and the two studies were determined to be poolable.

Table 1 Demographic and Baseline Characteristics

	Lotilaner Ophthalmic Solution, 0.25% (N = 39)	**Vehicle (N = 40)**	**p-value**
Age, years (Mean ± SD)	63.7 ± 14.7	63.4 ± 12.1	0.92
Sex, n (%)			
Female	23 (59)	23 (58)	1.00
Male	16 (41)	17 (43)	

(*Continued*)

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Table 1 (Continued).

	Lotilaner Ophthalmic Solution, 0.25% (N = 39)	Vehicle (N = 40)	p-value
Race, n (%)			
White	33 (84.6)	34 (85.0)	1.00
African American/Black	3 (7.7)	3 (7.5)	
Asian	3 (7.7)	3 (7.5)	
Collarette Grade (Mean ± SD)	2.9 ± 0.8	2.7 ± 0.8	0.22
MGSS (Mean ± SD)	21.9 ± 5.1	22.0 ± 4.8	0.93
Number of Expressible* Glands (Mean ± SD)	7.1 ± 4.0	7.4 ± 3.3	0.72
Number of Glands Yielding Clear Liquid Secretion (Grade 3) (Mean ± SD)	0.8 ± 1.1	0.7 ± 1.1	0.69

Note: *glands with grade 2 or 3.
Abbreviation: SD, standard deviation; MGSS, meibomian gland secretion score.

The Intent-to-Treat (ITT) population included all randomized subjects. The safety population included all subjects who received any amount of study drug. The analysis eye was defined as the eye that met all inclusion criteria. If both eyes met all inclusion criteria, then the eye with the lowest MGSS at Day 1 was chosen as the analysis eye.

Continuous variables were analyzed as mean and standard deviation (SD) and were compared between the lotilaner ophthalmic solution, 0.25% and vehicle groups using the 2-sample *t*-test. Categorical variables were presented as frequencies and percentages and were analyzed using the chi-square test. Meibomian gland disease function and patient-reported outcomes were compared between baseline and follow-up visits (Day 43 and Day 85) within the lotilaner ophthalmic solution, 0.25% and vehicle groups using a paired *t*-test. P <0.05 was considered statistically significant.

Results

There were no statistically significant differences in baseline characteristics by dosing frequency arm (BID/TID) in either study. Outcomes were also comparable whether dosed BID or TID. Therefore, this manuscript presents the findings for the pooled data of all lotilaner-treated patients together (N = 39) and all vehicle-treated patients together (N = 40), regardless of dosing frequency in either group.

Table 1 shows the demographics and baseline characteristics of patients in the lotilaner treatment and vehicle groups. No statistically significant differences were observed between the lotilaner treatment and vehicle study groups at baseline.

Collarette Reduction

On Day 43 and Day 85, the lotilaner treatment group showed a statistically significantly higher proportion of patients with collarette reduction to grade 0 (0–2 collarettes/lid) (Figure 1A) and grade 0 or 1 (0–10 collarettes/lid) (Figure 1B) compared to the vehicle group (p <0.001).

Meibomian Gland Function

On Days 43 and 85, the lotilaner treatment group demonstrated statistically significantly higher mean MGSS compared to baseline. The between-group comparison showed statistically significantly better mean MGSS in the lotilaner treatment group than in the vehicle group (Figure 2).

The mean MGYLS (grade 2 or 3) in the lotilaner group was statistically significantly higher on post-treatment Days 43 and 85 than at baseline. The between-group comparison showed a statistically significantly higher mean MGYLS in the lotilaner group compared to the vehicle group (Figure 3).

The lotilaner treatment group achieved a statistically significantly higher mean MGYCLS (grade 3) than the vehicle group on Day 43 (p <0.01) and Day 85 (p <0.001) (Figure 4). Correspondingly, the proportion of patients achieving

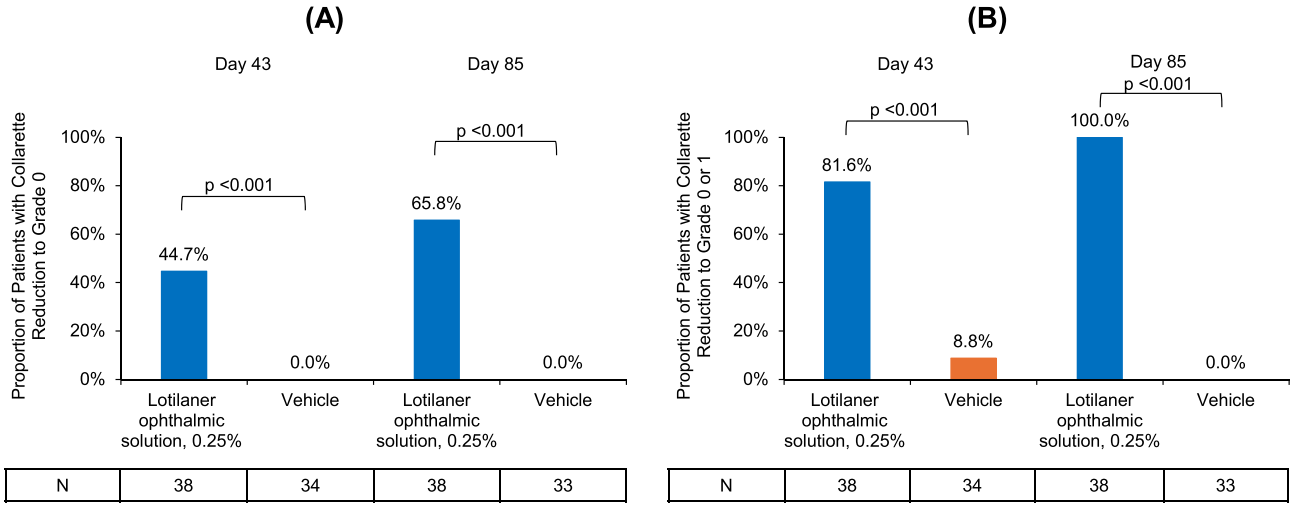
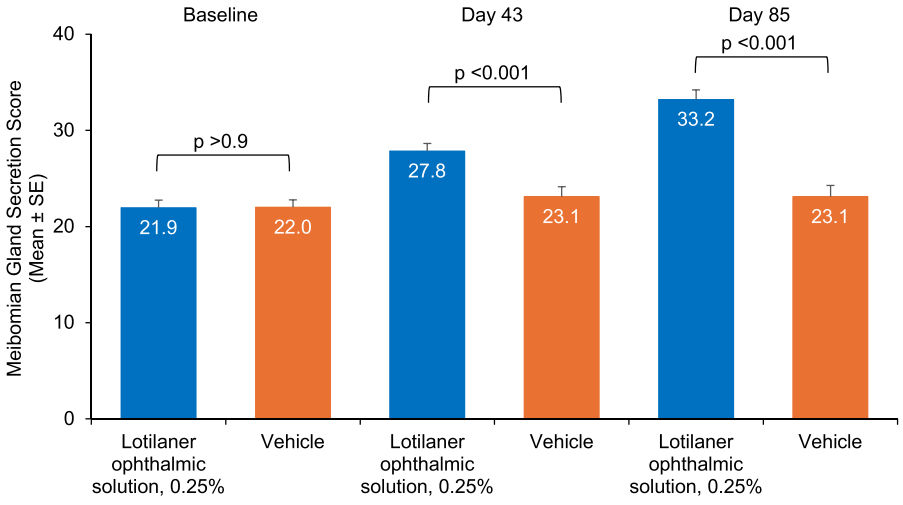


Figure 1 Proportion of patients showing collarette reduction to (**A**) grade 0 and (**B**) grade 0 or 1 in the lotilaner treatment group versus the vehicle group.



N	39	40	38	34	38	33
p-value (Change from baseline)			<0.001	0.074	<0.001	0.095
Mean change from baseline			+5.7	+1.8	+11.1	+1.6

Figure 2 Mean meibomian gland secretion score (MGSS) at baseline, Day 43 and Day 85 in the lotilaner treatment group versus the vehicle group.

improvement to at least 3 glands (at least 20% of the examined 15 glands) with clear meibum (grade 3) was significantly higher in the lotilaner group than in the vehicle group on Days 43 and 85 (Figure 5).

Patient-Reported Outcomes

The mean VAS score in the lotilaner group was statistically significantly lower (better) on Days 43 and 85 from baseline for all patient-reported outcomes (fluctuating vision, itching, burning, and redness). The lotilaner group also showed lower VAS scores when compared to the vehicle group on Days 43 and 85 for all patient-reported outcomes (Figure 6A–D).

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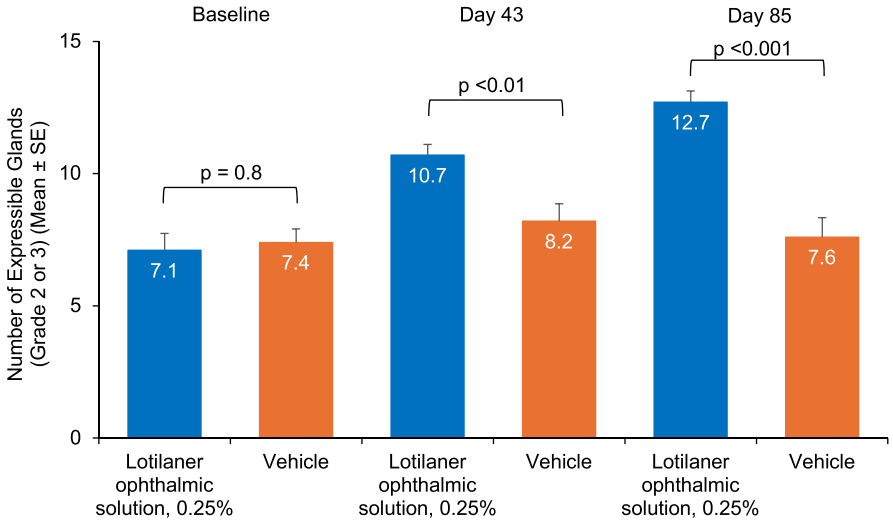
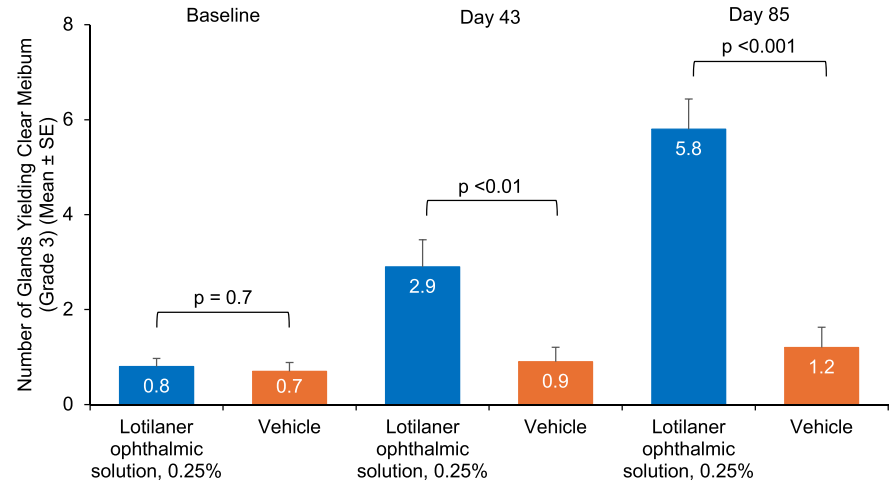


N	39	40	38	34	38	33
p-value (Change from baseline)			<0.001	0.048	<0.001	0.310
Mean change from baseline			+3.3	+1.4	+5.4	+0.7

Figure 3 Mean number of meibomian glands yielding any liquid secretions (MGYLS) (grade 2 or 3) at baseline, Day 43 and Day 85 in the lotilaner treatment group versus the vehicle group.



N	39	40	38	34	38	33
p-value (Change from baseline)			0.001	0.078	<0.001	0.013
Mean change from baseline			+2.1	+0.3	+5.1	+0.7

Figure 4 Mean number of meibomian glands yielding clear liquid secretions (MGYCLS) (grade 3) at baseline, Day 43 and Day 85 in the lotilaner treatment group versus the vehicle group.

Safety and Tolerability

Two patients (5.1%) in the lotilaner group and 7 patients (17.5%) in the vehicle group reported treatment-related ocular adverse events (AEs) (Table 2). No serious treatment-related AEs were observed. No AEs led to discontinuation from treatment or discontinuation from the study in the lotilaner group.

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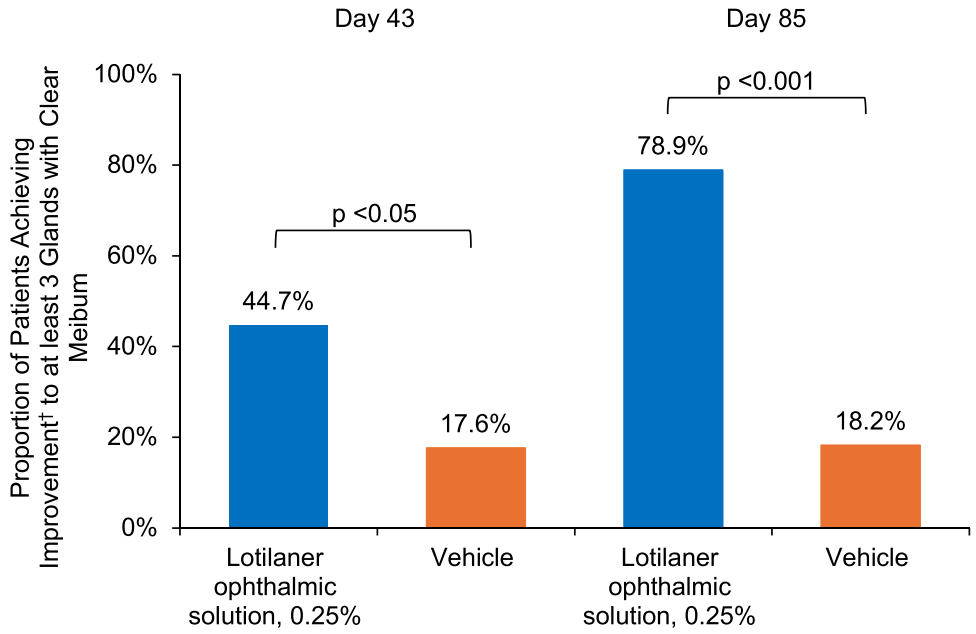
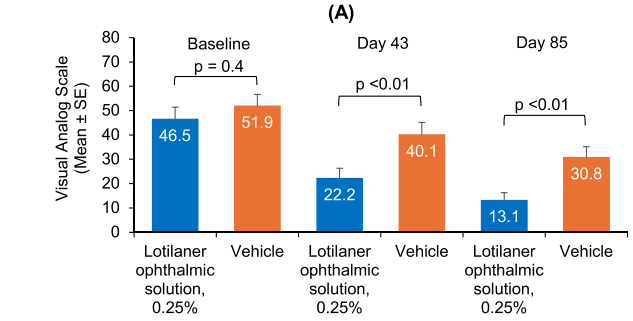
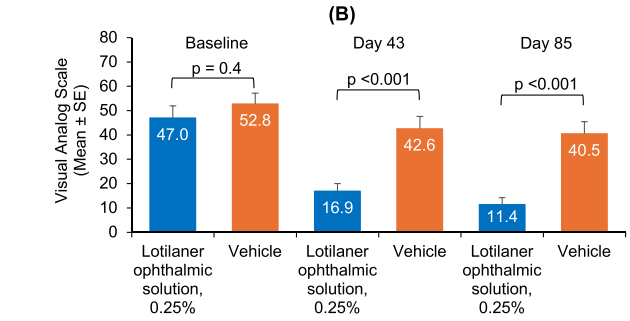


N	38	34	38	33

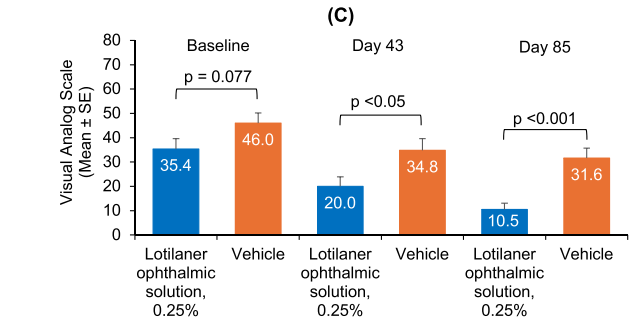
Figure 5 Proportion of patients achieving improvement to at least 3 glands with clear meibum at Day 43 and Day 85 in the lotilaner treatment group versus the vehicle group.
Note: †denotes improvement from baseline.



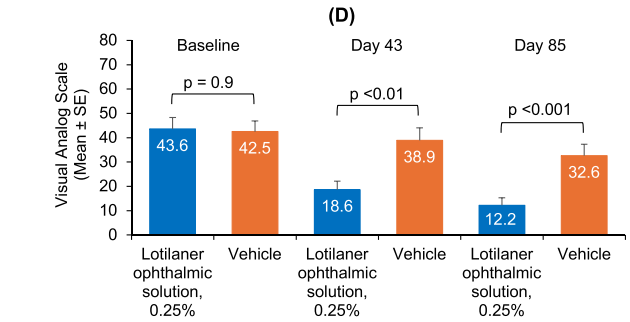
N	39	40	38	34	38	33
p-value (Change from baseline)			<0.001	0.010	<0.001	<0.001
Mean change from baseline			-22.9	-13.4	-32.0	-23.3



N	39	40	38	34	38	33
p-value (Change from baseline)			<0.001	0.191	<0.001	0.133
Mean change from baseline			-29.8	-6.2	-35.2	-8.6



N	39	40	38	34	38	33
p-value (Change from baseline)			0.005	0.074	<0.001	0.030
Mean change from baseline			-15.0	-9.4	-24.6	-12.1



N	39	40	38	34	38	33
p-value (Change from baseline)			<0.001	0.466	<0.001	0.032
Mean change from baseline			-24.7	-3.7	-31.1	-10.6

Figure 6 Patient-reported outcomes based on Visual Analog Scale (VAS score ranging from 0 to 100) at baseline, Day 43 and Day 85 in the lotilaner treatment group versus the vehicle group, (**A**) Fluctuating vision, (**B**) Itching, (**C**) Burning, and (**D**) Redness.

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Table 2 Treatment-Related Ocular Adverse Events in the Lotilaner and the Vehicle Groups

	Lotilaner Ophthalmic Solution, 0.25% (N = 39)	Vehicle (N = 40)
Patients with ≥1 AEs*, n (%)	2 (5.1)	7 (17.5)
Conjunctival irritation	0	1 (2.5)
Conjunctivitis	1 (2.6)	0
Dry eye	0	1 (2.5)
Eye irritation	0	1 (2.5)
Instillation site irritation	0	1 (2.5)
Noninfective conjunctivitis	0	1 (2.5)
Ocular discomfort	1 (2.6)	0
Ocular hyperemia	0	1 (2.5)
Punctate keratitis	0	2 (5.0)
Visual acuity reduced	0	1 (2.5)

Note: *Patients may have reported >1 AE.
Abbreviation: AE, Adverse event.

Discussion

Several previous studies have documented that *Demodex* mites play a pathogenic role in the development of meibomian gland disease.[7,10,33–36] Compared to *Demodex*-negative meibomian gland disease patients, *Demodex*-positive meibomian gland disease patients are reported to have significantly worse meibum quality, meibomian gland expression, plugging of meibomian gland orifices, lid margin abnormality, and meibomian gland dropout.[35] Such literature-reported findings suggest that it is important to pay attention to the diagnosis and treatment of *Demodex* infestation in meibomian gland disease.

Lotilaner ophthalmic solution, 0.25% is the first FDA-approved drug to target *Demodex* mites, the root cause of *Demodex* blepharitis.[37] In previous lotilaner clinical trials, a 6-week BID treatment regimen was followed, yielding significant reductions in collarettes and mite eradication.[27,30–32] In the present study, the treatment period was extended to 12 weeks with the dosing frequency of BID or TID. This extension of the treatment regimen was based on the hypothesis that concomitant lid margin diseases could prove more resistant to treatment and require a longer duration of therapy. Additionally, there may be multiple pathogenic mechanisms by which *Demodex* infestation influences meibomian gland disease, including inflammatory, bacterial, and mechanical effects.[7,33,38–40]

In the present study, we observed good improvement up to 6 weeks, and continued improvement in MGSS (the meibomian gland secretion score), MGYLS (the number of glands yielding any liquid secretions), MGYCLS (the number of meibomian glands yielding clear liquid secretions), and patient-reported VAS outcomes at 12 weeks. There were no statistically significant differences based on dosing frequency in either the lotilaner or vehicle arm, suggesting that more frequent dosing does not have much impact.

The quality and quantity of meibomian gland secretions are critical for ocular surface health. In the lotilaner-treated group, significant improvements from baseline were observed in the total MGSS and the number of glands yielding any liquid (MGYLS). Also, the statistically significant difference between groups on Day 43 and Day 85 points to the efficacy of lotilaner treatment in *Demodex* blepharitis patients with meibomian gland disease. Of note, compared to baseline, the lotilaner group exhibited a 50.7% improvement from baseline in MGYLS on Day 43 and 78.9% on Day 85. Correspondingly, in the lotilaner group, the percentage of patients achieving improvement to ≥3 glands (20% of the examined 15 glands) with clear meibum (MGYCLS) was 44.7% (17/38) on Day 43 and 78.9% (30/38) on Day 85.

Restoration of meibomian gland function may lead to a reduction in the symptoms of meibomian gland disease, and thus improved patient-reported outcomes. On Days 43 and 85, the lotilaner group demonstrated a statistically significant decrease from baseline in the mean VAS score for fluctuating vision, itching, burning, and redness. Additionally, the mean VAS scores for all four of these measures were significantly lower in the lotilaner group compared to the vehicle group at both time points post-treatment, which is clinically meaningful.[41] Fluctuating vision, a hallmark symptom of meibomian gland disease, is

known to interfere with quality of life, work performance, productivity, and other daily activities.[1,42,43] Moreover, in patients with ocular surface disease and fluctuating vision, preoperative measurements can often be erroneous and may negatively impact patient satisfaction post-cataract surgery.[44] Itch has been identified not only as highly characteristic of *Demodex* blepharitis, but also one of its most bothersome symptoms for patients.[45–49] Ocular redness, which can occur in various lid margin and ocular surface diseases, is also highly bothersome and has a number of psychosocial impacts because it is noticeable to others.[48] The improvements observed in the patient-reported outcomes in the present study support the efficacy of lotilaner treatment in patients with *Demodex* blepharitis and meibomian gland disease.

Lotilaner ophthalmic solution, 0.25% and its vehicle have been shown to be well-tolerated eye drops.[27–32] Regular use of any comfortable eye drop might be expected to relieve ocular irritation in meibomian gland disease. By comparing lotilaner-treated patients to vehicle-treated patients, the present study can help to distinguish between the effects of lotilaner ophthalmic solution, 0.25% and its vehicle.

Demodex blepharitis patients with meibomian gland disease represent an important sub-population for further study. A recent paper showed that nearly all patients (96% to 99%) with moderate to severe *Demodex* blepharitis (collarette grades 2 to 4) were found to have either reduced meibum quality or meibomian gland atrophy suggestive of meibomian gland disease.[11] Since Trattler et al previously reported the prevalence of *Demodex* blepharitis among meibomian gland disease patients to be 57.3%, it is recommended that patients with meibomian gland disease be evaluated for *Demodex* and vice versa.[9]

Although the sample size in this study was relatively small, this limitation is mitigated by highly statistically significant results. The patients included in the study all had *Demodex* blepharitis and meibomian gland disease that could be characterized as mild to moderate, an important stage for the treatment of meibomian gland disease prior to gland atrophy. Future studies in *Demodex* blepharitis patients with more severe meibomian gland disease and/or other ocular surface diseases could be beneficial, as could studies with longer follow-up. Additionally, there may be potential bias due to unobserved confounders. The results of the present study indicate that treatment with lotilaner ophthalmic solution, 0.25% is beneficial for *Demodex* blepharitis patients with concomitant meibomian gland disease.

Conclusion

To conclude, for patients presenting with *Demodex* blepharitis with meibomian gland disease, lotilaner ophthalmic solution, 0.25% demonstrated statistically significant improvements in measures of meibum quality, meibomian gland function, and patient-reported outcomes at 6 weeks and 12 weeks compared to baseline. Following lotilaner treatment, these parameters were also significantly improved when compared with vehicle. The drug was well tolerated with a similar safety profile as the vehicle group.

Abbreviations

MGSS, meibomian gland secretion score; MGYLS, number of glands yielding any liquid secretions; MGYCLS, number of glands yielding clear liquid secretions; FDA, Food and Drug Administration; IPL, intense pulsed light; TTO, tea tree oil; GABA, gamma-aminobutyric acid; TBUT, tear breakup time; VAS, visual analog scale; CDVA, corrected distance visual acuity; ETDRS, Early Treatment of Diabetic Retinopathy Study; BID, twice daily; TID, three times daily; AEs, adverse events; ITT, Intent-to-Treat; SD, standard deviation.

Data Sharing Statement

The data that support the findings of this study are available from the corresponding author (Preeya K. Gupta) upon reasonable request.

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Disclosure

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