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ORIGINAL RESEARCH

Real-World Experience with Lifitegrast Ophthalmic Solution in Patients with Dry Eye Disease: A Provider Survey in the USA and Canada

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ABSTRACT

Introduction: Lifitegrast ophthalmic solution 5% is indicated to treat signs and symptoms of dry eye disease (DED). This study assessed eye-care professionals' (ECPs) real-world experiences with lifitegrast in DED.

Methods: A total of 12 ECPs (6 ophthalmologists and 6 optometrists) with experience prescribing lifitegrast completed a cross-sectional survey on practice characteristics, lifitegrast utilization, satisfaction, and adverse events (AEs). ECPs rated satisfaction with lifitegrast overall and for specific clinical outcomes versus other prescription eye drops on a 1 (very dissatisfied) to 10 (very satisfied) Likert scale.

Results: ECPs reported a mean of 1288 (range, 35–6000) patients with DED treated annually, with 20.9% receiving lifitegrast. Overall, 66.7% of ECPs reported near/complete symptom resolution in patients after 1–3 months of lifitegrast treatment. Mean (range) satisfaction ratings for onset/effectiveness were 6.8 (3–9)/6.6 (3–9). Satisfaction with

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reduction of DED signs was generally high: increased tear film breakup time, 5.8 (3–9); reduced conjunctival/corneal staining, 6.9 (3–9); increased Schirmer test score, 6.0 (3–9); increased tear meniscus height, 6.0 (3–9); and reduced Ocular Surface Disease Index severity, 7.0 (3–10). Symptom reduction satisfaction ratings were: itching, 5.3 (1–9); dryness, 6.9 (3–9); burning/stinging, 6.3 (1–9); redness, 6.2 (4–9); pain, 6.3 (3–9); light sensitivity, 6.5 (3–9); and blurred/poor vision, 6.8 (4–9). Overall satisfaction (ECPs/patients) was rated 7.1 (3–10)/6.8 (2–9). Predominant uses of lifitegrast included contact lens-induced DED (91.7%) and DED before/after refractive or cataract surgery (83.3% each). AEs reported were consistent with the known AE profile of lifitegrast and included burning/stinging, blurred vision, and dysgeusia.

***Conclusions*:** This real-world survey showed that ECPs use lifitegrast to treat one fifth of their patients with DED and reported moderate-to-high personal and patient satisfaction with lifitegrast treatment.

Keywords: Cross-sectional survey; Drug utilization; Dry eye syndromes; Lymphocyte function-associated antigen-1; Physician satisfaction; Signs and symptoms

Key Summary Points

Why carry out this study?

In the rapidly evolving dry eye disease (DED) landscape, a better understanding of real-world lifitegrast use by eyecare professionals (ECPs; ophthalmologists and optometrists) is needed.

The purpose of this study was to assess ECPs' real-world experiences with lifitegrast in patients with DED, including the rationale for prescribing, clinical outcomes, and provider/patient satisfaction.

What was learned from this study?

ECPs indicated that 20.9% of their patients with DED are treated with lifitegrast each year and typically initiate lifitegrast treatment early in the course of therapy (i.e., within the first 3 months after DED diagnosis).

ECPs expressed moderate-to-high levels of satisfaction with lifitegrast overall, as well as for its effectiveness for treating the signs and symptoms of DED.

These real-world survey data provide important insights into the utilization and effectiveness of lifitegrast in routine clinical practice.

INTRODUCTION

Dry eye disease (DED) is a common disorder of the ocular surface characterized by a loss of homeostasis of the tear film, which leads to ocular signs (e.g., decreased tear fluid, tear film instability, and ocular surface damage) and symptoms (e.g., dryness, burning, pain, light sensitivity, and blurred vision) [1, 2]. This condition is broadly classified as aqueous-deficient or evaporative dry eye, although these subtypes frequently overlap and coexist [1]. DED is associated with a wide range of intrinsic and extrinsic risk factors [2, 3]. Common iatrogenic causes include contact lens use and ophthalmic surgeries [4]. An increasingly common extrinsic risk factor is digital eye strain due to prolonged

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use of digital devices and a shift to technology-based employment [5]. The symptoms of DED, in particular fluctuating vision and ocular discomfort, can adversely affect patients' quality of life (QOL) and activities of daily living [6, 7]. Patients with DED report limitations related to mobility, self-care, usual activities, and work productivity, as well as elevated levels of anxiety and depression.

Although the etiology of DED is multifactorial, tear film instability and hyperosmolarity, ocular surface inflammation and damage, and abnormalities in neurosensory processing are believed to play central roles [1]. In DED, tear film hyperosmolarity damages the ocular surface directly, as well as indirectly, by triggering a cascade of inflammatory events [3]. The release of inflammatory mediators and proteases from epithelial cells, along with tear hyperosmolarity, results in loss of epithelial and goblet cells as well as damage to the epithelial glycocalyx [3]. Recruitment of activated T cells to the ocular surface and their subsequent release of inflammatory cytokines cause further disruption of the epithelial corneal barrier and additional loss of conjunctival goblet cells [3]. The damaging cascade of ocular surface inflammation and cell loss contributes to tear film instability and breakup, which worsen tear hyperosmolarity and perpetuates the vicious circle of DED [3].

Initial management of DED involves managing causative factors (e.g., adverse environments, prolonged visual efforts) as well as patient education, eyelid hygiene, and use of warm compresses and over-the-counter ocular lubricants [8]. If these steps are inadequate, several options are recommended, such as tear-conservation interventions, physical heating and expression of Meibomian glands, overnight treatments (e.g., ointment or moisture chamber devices), and the use of prescription medications [8]. Prescription medications used to manage DED include nasal sprays, topical formulations of corticosteroids, secretagogues, nonglucocorticoid immunomodulatory drugs (e.g., cyclosporine), tear evaporation inhibitor (perfluorohexyloctane), the antiinflammatory agent lifitegrast, and blood-derived products [8].

Lifitegrast ophthalmic solution 5% (Xiidra®; Bausch & Lomb Americas Inc.; Bridgewater, NJ, USA) is a lymphocyte function–associated antigen-1 (LFA-1) antagonist indicated to treat the signs and symptoms of DED [9]. Randomized, placebo-controlled trials have demonstrated that twice-daily lifitegrast is safe and efficacious for treating the signs and symptoms of DED [10–14]. Significant improvement with lifitegrast versus placebo was observed in the symptom of eye dryness as early as day 14 [14] and in corneal fluorescein staining at day 84 [11]. Previous studies have evaluated real-world treatment patterns (through June 2021) and effectiveness (through February 2020) of lifitegrast outside of the clinical trial setting [15–18]. Amidst the rapidly evolving DED treatment landscape [19, 20], an updated understanding of lifitegrast utilization and effectiveness in the real-world setting is needed. The purpose of this study was to assess eyecare professionals' (ECPs) real-world experiences with the use of lifitegrast in patients with DED.

METHODS

Study Design and Participants

This study used a retrospective cross-sectional design. Data were collected via a survey and interviews with 12 ECPs who had experience prescribing lifitegrast. The primary objectives of the study were to document lifitegrast prescribing patterns/utilization and to explore the "real-world" experience with lifitegrast among currently available treatments for DED, including the rationale for prescribing, clinical outcomes, and provider/patient satisfaction. A secondary objective was to conduct a convenience sample of patient cases to characterize the utilization of lifitegrast. The study protocol was determined to be institutional review board (IRB)–exempt by WCG IRB (Princeton, NJ, USA). The study was exempt from IRB approval under 45 CFR § 46.104(d)(2) because the research only includes interactions involving survey procedures; and there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

A steering committee of 12 ECPs (ophthalmologists [MDs] and optometrists [ODs]) with experience prescribing lifitegrast was recruited to participate in the study. All ECPs on the steering committee had sufficient lifitegrast utilization within their practice to allow detailed feedback on a variety of patient subtypes diagnosed with DED. The steering committee provided expert feedback on the project content and survey development. These 12 ECPs completed a lifitegrast utilization survey (included in the Supplementary Appendix) that included methods and questions adapted from peer-reviewed publications [16, 17]. The survey instrument was developed to collect data on ECP practice characteristics, patient characteristics, utilization of lifitegrast and other therapeutic options, clinical outcomes, provider/patient satisfaction, and adverse events. ECPs rank-ordered their responses regarding the most important signs and symptoms for assessing lifitegrast treatment effectiveness, primary reasons for prescribing lifitegrast, and most common reasons for dissatisfaction and/or discontinuation with lifitegrast compared with other prescription medications (if more than one answer was selected). Overall provider and patient satisfaction and provider satisfaction across various aspects of lifitegrast treatment were rated on a Likert scale of 1 (very dissatisfied) to 10 (very satisfied).

All data are descriptive in nature and presented as number (%) for categorical variables and mean (range) for continuous variables.

RESULTS

Provider and Practice Characteristics

In total, 12 geographically diverse ECPs (6 MDs, 6 ODs) who had clinical experience with prescribing lifitegrast for DED were recruited to participate in this study. ECPs treated a mean (range) of 1287.8 (35–6000) patients with DED annually, with a mean of 373 patients newly diagnosed and 40.3% referred by other providers (Table 1). The majority of ECPs were based in the USA (83.3%) and worked in private practice (58.3%); half worked in small practice settings of 2–10 ophthalmologists/optometrists. ECPs indicated that most patients with DED in their practice were 36–60 years of age (40.4%) or 61 years of age or older (47.1%), and the majority (76.9%) were female. Overall, ECPs reported that approximately half (52.5%) of their patients with DED had discontinued a prescription treatment or that treatment had failed.

Lifitegrast Treatment Patterns

ECPs ranked their primary reasons for prescribing lifitegrast (Fig. 1). Top reasons included long-term relief of symptoms, improvement in signs, insurance coverage (i.e., the lifitegrast prescription was covered), and immediate relief of symptoms. Among patients with DED, an average of 20.9% per year were treated with lifitegrast (MDs, 24.2%; ODs, 17.0%). Overall, ECPs reported that DED severity, on average, was mild in 24.1%, moderate in 50.5%, and severe in 19.1% of patients to whom lifitegrast was prescribed. When ECPs were asked how they would best describe their typical prescribing pattern with lifitegrast, the top ranked responses were (1) after DED diagnosis and in combination with other prescription therapies and (2) as the first DED prescription therapy following treatment with artificial tears. The most commonly reported typical time gap between a DED diagnosis and a lifitegrast prescription was 1–3 months ($n=5$, 41.7% of ECPs), followed by less than 1 month ($n=3$, 25.0%) and 4–6 months ($n=2$, 16.7%).

According to ECPs, 34.2% of patients self-reported that their DED symptoms nearly or completely resolved after their first prescription of lifitegrast. Most ECPs (66.7%; among MDs, 50.0% and ODs, 83.3%) reported that it takes 1–3 months for their patients to report near or complete resolution of the symptoms of DED after their first lifitegrast prescription (Fig. 2). The most common reasons for dissatisfaction and/or discontinuation with lifitegrast, compared with other prescription medications for DED, were tolerability issues (e.g., instillation site reaction, instillation site irritation, or blurred vision), insurance coverage issues, and insufficient immediate relief of symptoms.

Table 1 Eyecare provider and practice characteristics

Characteristic	MD ($n = 6$)	OD ($n = 6$)	All ($n = 12$)
Country			
USA	5 (83.3)	5 (83.3)	10 (83.3)
Canada	1 (16.7)	1 (16.7)	2 (16.7)
Clinical practice setting, n (%)			
Academic	3 (50.0)	2 (33.3)	5 (41.7)
Private practice	3 (50.0)	4 (66.7)	7 (58.3)
Size of practice, n (%)			
Solo	1 (16.7)	0	1 (8.3)
Small (2–10 MDs/ODs)	1 (16.7)	5 (83.3)	6 (50.0)
Medium (11–50 MDs/ODs)	2 (33.3)	1 (16.7)	3 (25.0)
Large (≥ 51 MDs/ODs)	2 (33.3)	0	2 (16.7)
Years in practice, n (%)			
≤ 10	0	0	0
11–20	2 (33.3)	2 (33.3)	4 (33.3)
> 20	4 (66.7)	4 (66.7)	8 (66.7)
Patients with DED treated per year, mean ± SD (range)	1741.7 ± 2114.3 (500–6000)	834.0 ± 715.8 (35–2000)	1287.8 ± 1577.8 (35–6000)
Newly diagnosed patients per year, mean ± SD (range)	458.3 ± 363.9 (100–1000)	288.0 ± 374.4 (0–1000)	373.2 ± 363.1 (0–1000)
Percent of patients with DED referred by other providers per year, mean ± SD (range)	45.0 ± 32.1 (10–90)	35.7 ± 32.4 (4–70)	40.3 ± 31.1 (4–90)
Percentage age breakdown of patients with DED in practice, mean ± SD (range)			
18–35 years	10.8 ± 4.9 (5–20)	15.0 ± 10.0 (5–30)	12.9 ± 7.8 (5–30)
36–60 years	35.0 ± 12.6 (15–50)	45.8 ± 12.0 (30–60)	40.4 ± 13.0 (15–60)
≥ 61 years	54.2 ± 15.0 (30–75)	40.0 ± 10.5 (35–55)	47.1 ± 14.4 (30–75)
Percentage sex breakdown of patients with DED in practice, mean ± SD (range)			
Female	76.3 ± 11.8 (65–98)	77.5 ± 12.1 (65–95)	76.9 ± 11.4 (65–98)
Male	23.7 ± 11.8 (2–35)	22.5 ± 12.1 (5–35)	23.1 ± 11.4 (2–35)
Percentage of causes/types of DED in practice, mean ± SD (range)			

Table 1 continued

Characteristic	MD ($n=6$)	OD ($n=6$)	All ($n=12$)
Evaporative deficiency only	15.0 ± 13.4 (0–30)	27.0 ± 32.3 (5–90)	21.0 ± 24.4 (0–90)
Aqueous deficiency only	8.3 ± 2.6 (5–10)	6.8 ± 3.8 (1–10)	7.6 ± 3.2 (1–10)
Both evaporative and aqueous deficiency	76.7 ± 15.4 (60–95)	66.2 ± 30.3 (9–90)	71.4 ± 23.6 (9–95)
Percentage of patients who have discontinued and/or had failure of a prescription DED treatment, mean ± SD (range)	56.7 ± 22.5 (20–80)	48.3 ± 29.8 (15–95)	52.5 ± 25.5 (15–95)

DED dry eye disease, *MD* Medical Doctor, *OD* Doctor of Optometry

Satisfaction

ECPs indicated generally moderate-to-high levels (a score of 6–8 on the 10-point Likert scale) of satisfaction with lifitegrast effectiveness attributes for clinical outcomes compared with other prescription eye drops for DED, with the highest levels of satisfaction reported for the onset of action of lifitegrast (mean, 6.8) and the effectiveness of lifitegrast after onset (mean, 6.6; Fig. 3a). ECPs were moderately to highly satisfied with the ease of administration of lifitegrast (mean, 6.9; range, 5–10) and with drop comfort after treatment administration (mean, 6.2; range, 4–9) compared with other prescription eye drops for DED.

Based on ECP responses, the most important signs to use for assessing lifitegrast effectiveness (in order from most to least important) were reduction in corneal/conjunctival fluorescein dye staining (cell loss), increase in tear film breakup time (TBUT), increase in tear meniscus height, and increase in Schirmer test score. Provider satisfaction ratings were moderate to high for improvement of these DED signs with lifitegrast treatment compared with other prescription eye drops for DED (Fig. 3b). ECPs identified (in order from most to least important) eye dryness, burning/stinging, pain, blurred/poor vision, light sensitivity, redness, and itching as the most important symptoms to consider when assessing lifitegrast effectiveness. ECPs indicated moderate-to-high satisfaction with lifitegrast compared with other prescription eye drops for DED for reducing all of these symptoms and reducing symptom severity, as assessed by the Ocular Surface Disease Index (OSDI) [21, 22] (Fig. 3c). Overall provider satisfaction and provider-reported patient satisfaction ratings were also moderate to high with lifitegrast treatment (Fig. 4). Satisfaction ratings with the effectiveness of lifitegrast for treating signs of DED, symptoms of DED, and with lifitegrast overall are shown by provider type in Supplementary Figs. S1, S2, and S3, respectively.

Additional Clinical Considerations

Nearly all ECPs (91.7%) reported treating contact lens-related DED with lifitegrast (Fig. 5). On average, 31.5% of patients with DED treated by ECPs had a history of contact lens use. Supplementary Fig. S4 shows lifitegrast usage by provider type. All ECPs rated the effectiveness of lifitegrast with patients wearing contact lenses as "somewhat" or "very" effective. Other predominant uses of lifitegrast included DED prior to or after refractive surgery or cataract surgery (83.3% of providers for each; Fig. 5).

When asked whether their patients reported any QOL improvements following treatment with lifitegrast, ECPs indicated benefits primarily with respect to activities of daily living (e.g., driving and reading), ocular well-being, and general well-being (Fig. 6).

Adverse Events

Overall, seven ECPs (58.3%) reported that at least one patient experienced an adverse event (AE) during lifitegrast treatment. All AEs (burning/

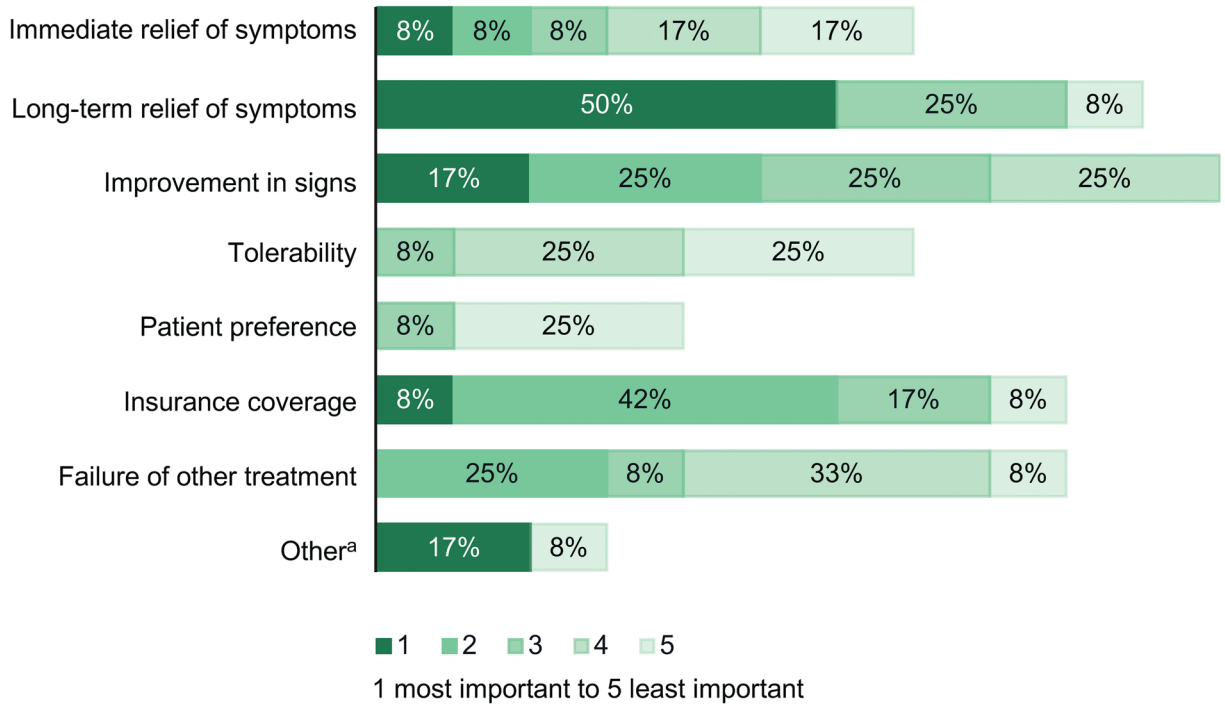

Fig. 1 Primary reasons for prescribing lifitegrast. In response to the question, "What are your primary reasons for writing lifitegrast prescriptions?" ECPs were instructed to rank-order their top five responses (from 1 = most important to 5 = less important). A few participants provided and ranked more than five responses. [a]Written responses to "other" included "prevent progression," "indicated for both signs and symptoms," and "Xiidra is uniquely beneficial in the context of allergic conjunctivitis"; *ECP* eyecare professional

stinging [reported by six ECPs], blurred vision [five ECPs], dysgeusia [three ECPs], and discharge [one ECP]) were considered related to treatment, and all were mild or moderate in severity. Two ECPs (both MDs) reported that patients experienced ongoing treatment-related AEs with moderate intensity (blurry vision with drop instillation, stinging, discharge, and dysgeusia).

DISCUSSION

This real-world survey of ECPs from the USA and Canada provides important insights regarding the utilization and effectiveness of lifitegrast in routine clinical practice, which represents a broader population of patients with DED than those eligible for clinical trials. Lifitegrast is typically prescribed within 3 months of DED diagnosis, which suggests that most ECPs are using lifitegrast early in treatment, with or without other therapies. Accordingly, ECPs indicated that they most typically prescribe lifitegrast after DED diagnosis and in combination with other prescription therapies or as the first DED prescription therapy following treatment with artificial tears. Approximately half of patients who were prescribed lifitegrast at the time of the survey had moderate DED. These observations are largely aligned with current treatment guidelines (American Academy of Ophthalmology Preferred Practice Pattern), which recommend considering prescription drugs such as lifitegrast when initial management (patient education; environmental and dietary modification; identification and modification or discontinuation of contributing medications; eyelid hygiene; and use of warm compresses and over-the-counter ocular lubricants) is inadequate [8]. These guidelines recommend consideration of lifitegrast for treatment of patients with moderate or severe DED because they are most likely to require steps

beyond initial management and are the patients seeking care for dry eye symptoms at an ophthalmologist or optometrist practice.

The use of lifitegrast in patients with moderate (50.5%) or severe (19.1%) DED may relate also to its mechanism of action (MOA) targeting ocular surface inflammation, as patients with moderate-to-severe DED are more likely to have greater levels of inflammation. The proinflammatory ocular environment associated with DED contributes to ocular inflammation and symptoms such as conjunctival hyperemia (redness) [23]. Conjunctival hyperemia, hyperosmolarity, and levels of MMP-9 and inflammatory cytokines are useful markers of the extent of ocular surface inflammation in DED [23].

The intracellular adhesion molecule-1 (ICAM-1) is instrumental in homing of activated T cells to the ocular surface, where they release inflammatory cytokines that help drive the "vicious circle" of DED [3, 24]. ICAM-1 may be overexpressed in the corneal and conjunctival epithelium of patients with DED and predisposes ocular tissues to immune-mediated inflammation [25–27]. Lifitegrast binds to LFA-1, a cell surface protein found on leucocytes, and prevents binding of LFA-1 to its ligand, ICAM-1 [9]. Although the precise mechanism of action (MOA) is unknown, lifitegrast has been shown to inhibit T cell adhesion to ICAM-1; to reduce the activation, migration, and proliferation of lymphocytes; and to inhibit the secretion of inflammatory cytokines from activated lymphocytes [9, 28, 29]. By reducing overall inflammatory responses, lifitegrast may improve the signs and symptoms of DED and disrupt the vicious circle of disease. This MOA may also make lifitegrast effective for treating patients with DED in the setting of an underlying systemic inflammatory disease, such as Sjögren disease, although studies are needed to examine whether such patients are more likely to respond to lifitegrast [30].

The ability of lifitegrast to improve signs and symptoms of DED and to provide long-term relief of symptoms were among the top reasons why ECPs prescribed lifitegrast. This is consistent with the results across phase 3 studies in which

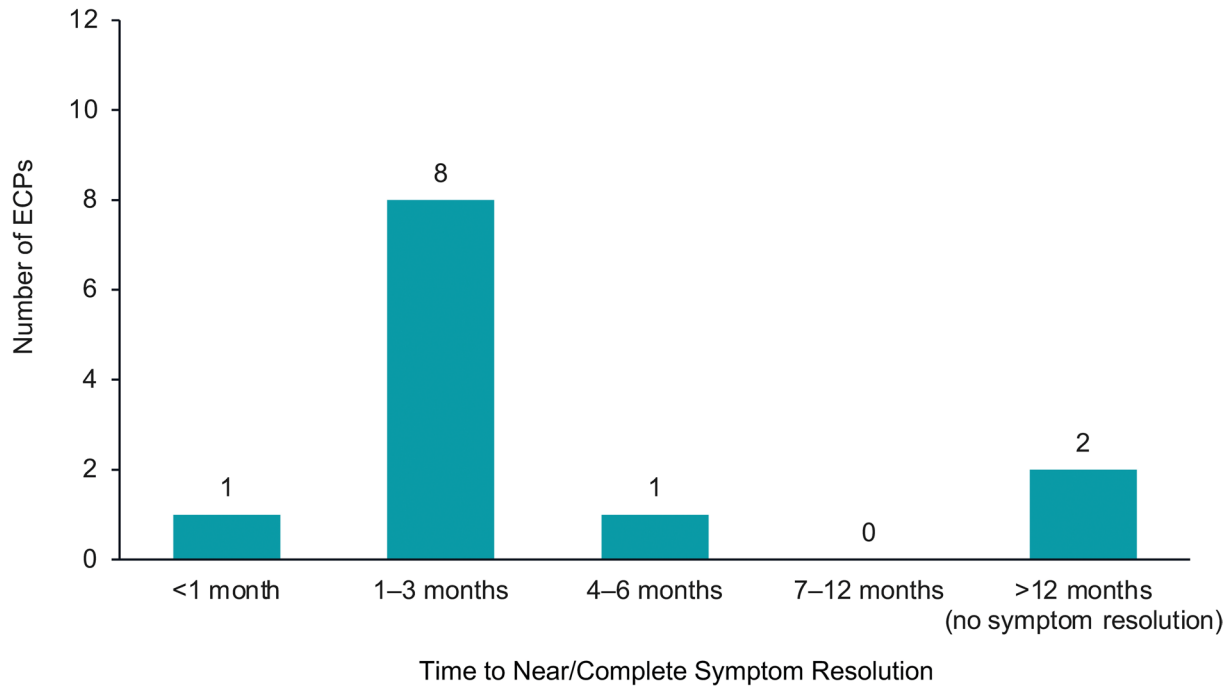

Fig. 2 Time to near/complete DED symptom resolution with lifitegrast treatment. In response to the question, "How long does it take for your patients to report nearly or complete resolution of the symptoms of DED after their first lifitegrast prescription?" *DED* dry eye disease, *ECP* eyecare professional

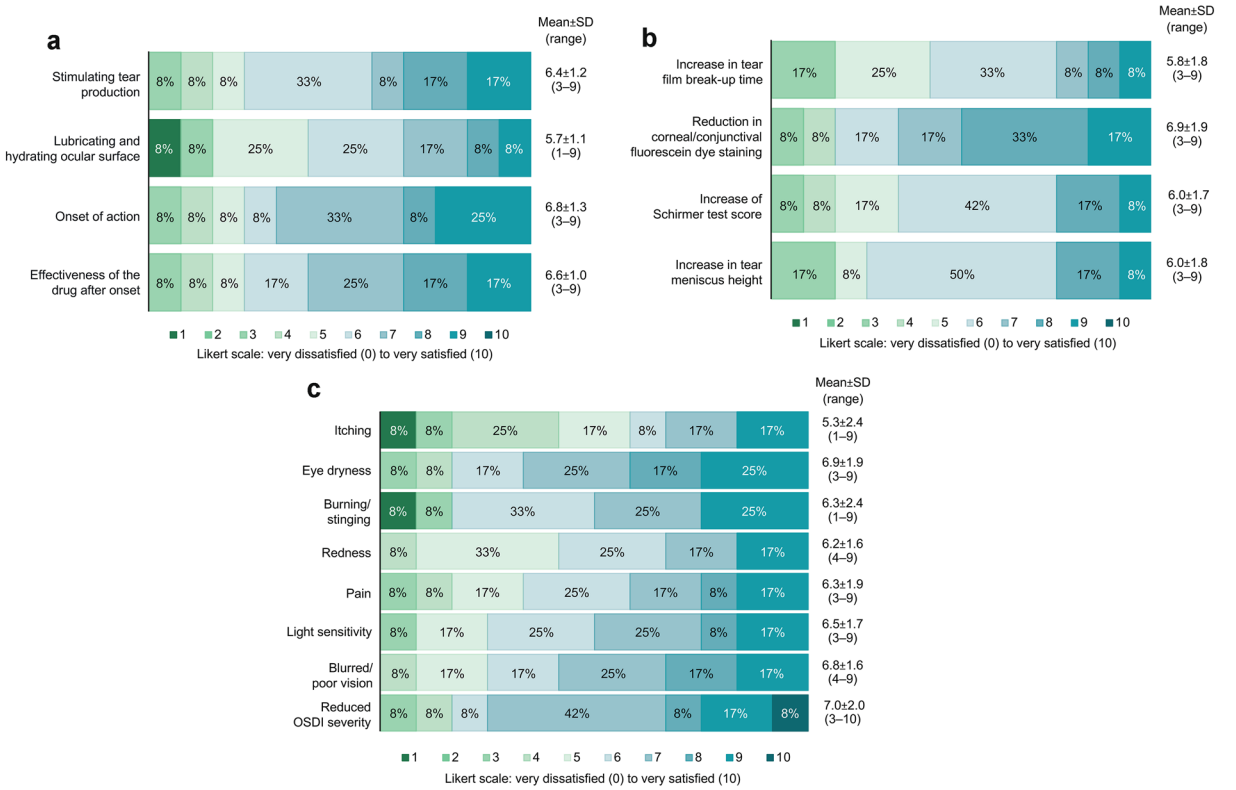

Fig. 3 Eyecare provider satisfaction **a** with the effectiveness attributes of lifitegrast in response to the question, "Compared to other prescription eye drops for DED, how satisfied are you with the lifitegrast effectiveness attributes below?"; **b** with lifitegrast at improving the signs of DED in response to the question, "Compared to other prescription eye drops for DED, how satisfied are you with lifitegrast at improving the signs below?"; and **c** with lifitegrast at improving the symptoms of DED in response to the question, "Compared to other prescription eye drops for DED, how satisfied are you with lifitegrast at improving the symptoms below?" ECPs were instructed to circle on the Likert scale from very dissatisfied (1) to very satisfied (10); *DED* dry eye disease, *ECP* eyecare professional, *OSDI* Ocular Surface Disease Index

lifitegrast demonstrated significant improvements compared with placebo in corneal staining and eye dryness [11, 12, 14]. According to most ECPs, patients typically report near or complete resolution of DED symptoms within 3 months after their first lifitegrast prescription, although time to follow-up visits and perceptions of effectiveness may be confounding variables. Nonetheless, early improvement is consistent with observations in the clinical trial program, during which patients reported symptom improvement as early as 2 weeks after starting lifitegrast and full effects within 3 months [14, 31, 32].

Overall, ECPs reported moderate-to-high personal and patient satisfaction with lifitegrast for the treatment of DED. In particular, ECPs expressed moderate-to-high satisfaction with the onset of action of lifitegrast and the effectiveness of lifitegrast after onset. Levels of ECP satisfaction with the attributes of lifitegrast were similar to those reported in a survey conducted between October 2018 and January 2019 of 21 US ECPs [16], although the current survey reported higher levels of satisfaction with the onset of action of lifitegrast than the earlier survey. The signs of DED that ECPs in the current survey identified as most important for assessing the effectiveness of lifitegrast were reductions in corneal/conjunctival fluorescein dye staining, reduced OSDI scores, and increased

Fig. 4 Overall provider satisfaction and provider-reported patient satisfaction with lifitegrast treatment. In response to the question, "Considering all aspects of your experience with lifitegrast, how would you rate:" ECPs were instructed to circle on the Likert scale from very dissatisfied (1) to very satisfied (10); *ECP* eyecare professional

TBUT, whereas the most important symptoms were eye dryness, burning/stinging, and pain. The signs and symptoms that ECPs consider most important may be related to the severity of DED. In addition, tests considered as producing the most important results for effectiveness assessments may reflect individual practice patterns. There is an unmet need to consider the most appropriate assessments for each therapy on the basis of MOA. Notably, however, the signs and symptoms that ECPs considered the most important for assessing the effectiveness of lifitegrast were among those for which they reported the greatest levels of satisfaction with lifitegrast.

Survey results showed that lifitegrast is used frequently in contact lens wearers and in patients undergoing various ocular surgeries, although the survey did not differentiate whether these conditions were causes and/or comorbidities of DED. Ocular discomfort is the most common reason for discontinuation of contact lens use among established contact lenses wearers [33]. In addition, ophthalmic surgical procedures, such as refractive/cataract surgery, may affect the ocular surface and cause dry eye, which is a key reason for dissatisfaction following laser-assisted in situ keratomileusis (LASIK) surgery [34]. Clinical data on the effectiveness and safety of lifitegrast in contact lens users and patients with a recent history of LASIK or similar ocular surgery are limited because of the exclusion of such patients from the 12-week phase 2 and 3 trials of lifitegrast [10–12, 14] and the inclusion of only nine contact lens users (five in the lifitegrast group and four in the placebo group) in the 1-year phase 3 study [13]. Lifitegrast demonstrated promise for the treatment of contact lens discomfort in two small ($n=21$ and $n=40$), single-center, open-label studies [35, 36], but larger studies are warranted. In addition, a report from the Tear Film & Ocular Surface Society suggested that ocular surface inflammatory modulators such as lifitegrast and cyclosporine may improve signs and symptoms of DED following intraocular refractive surgery, although the cited studies did not evaluate lifitegrast [34]. The reported utilization of lifitegrast in contact lens wearers and patients with DED associated with ocular surgeries in this study suggests that ECPs are comfortable with the effectiveness and safety of lifitegrast in these patient populations. Although this survey did not differentiate presurgical versus postsurgical use of lifitegrast in patients with cataracts, DED is a pre-existing condition in patients with cataracts and is diagnosed at the time of cataract evaluation and treated to optimize surgery outcomes [37, 38]. In a multicenter, open-label study ($n=100$), lifitegrast significantly improved preoperative corneal power measurement accuracy in patients with DED scheduled for cataract surgery [39].

Considering the negative impact of DED on QOL [6, 7], the ability of treatments such as lifitegrast to reduce activity limitations caused by symptoms (e.g., blurred vision) and to improve overall QOL is of interest. ECPs in the current survey indicated that their patients treated with lifitegrast most frequently report QOL benefits with respect to activities of daily living (e.g., driving and reading), general well-being, and ocular well-being. These findings are consistent with results of a survey in which patients reported high satisfaction with lifitegrast owing to improvements in vision, better ability to engage in social activities, and reduced dependence on others [40]. Another publication reported improvements in DED-related QOL on the basis of a chart review of patients after initiating lifitegrast treatment [17]. However, in

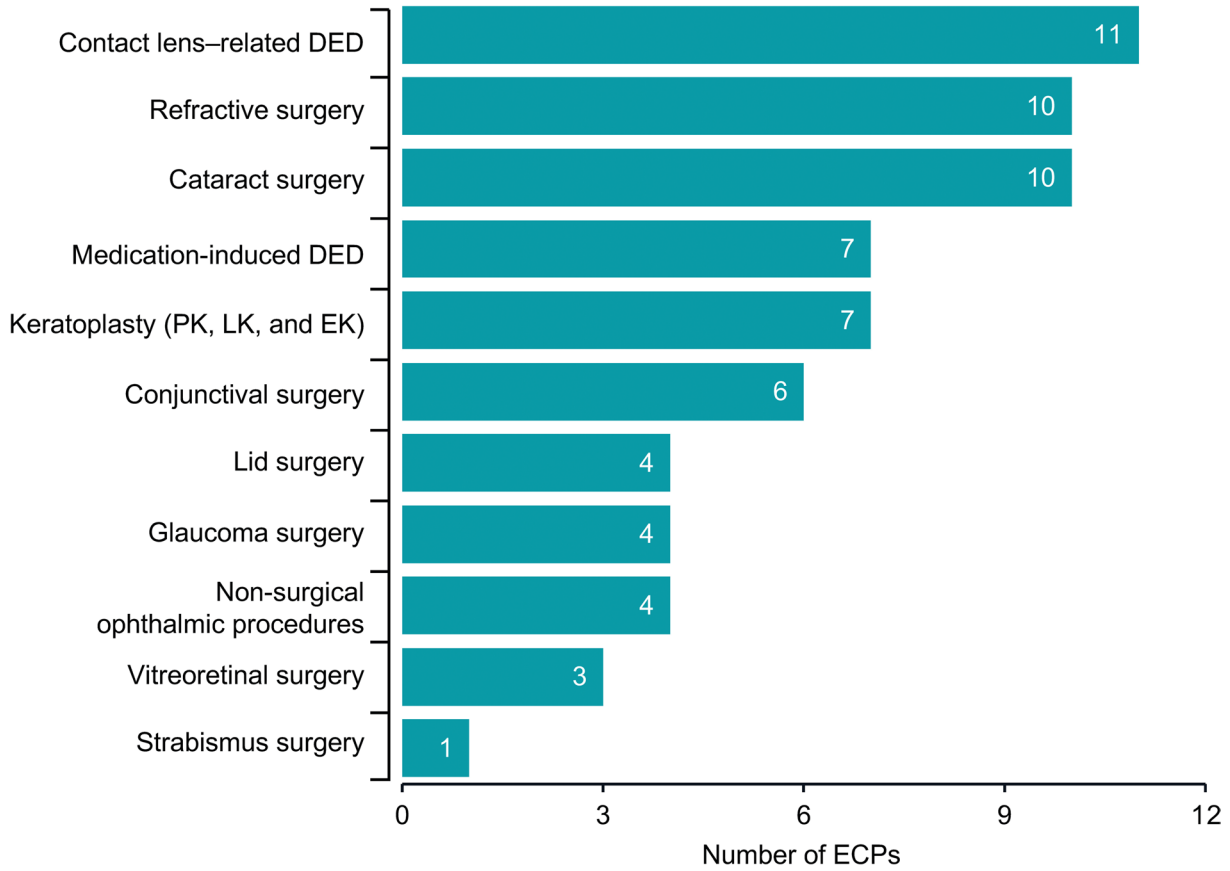

Fig. 5 Lifitegrast real-world usage pattern for DED associated with acute or chronic iatrogenic interventions. ECPs were instructed to choose all options that applied; *DED* dry eye disease, *ECP* eyecare professional, *EK* endothelial keratoplasty, *LK* lamellar keratoplasty, *PK* penetrating keratoplasty

a physician survey, only 33% of respondents considered lifitegrast to be very effective or extremely effective at improving patients' QOL [16]. Prospective studies are needed to systematically assess the impact of lifitegrast treatment on QOL in patients with DED.

Treatment-related AEs reported by ECPs in this survey were mild or moderate in severity and were consistent with the known side effect profile of lifitegrast [9]. ECPs identified tolerability issues as the most common reason for dissatisfaction and/or discontinuation of lifitegrast, which suggests a need for strategies to prevent or manage side effects.

Ophthalmologists and optometrists generally were aligned on their treatment practices when using lifitegrast, although ophthalmologists tended to express higher satisfaction than optometrists with the effectiveness of lifitegrast for treating the signs and symptoms of DED, and with lifitegrast overall, as compared with other prescription eye drops for DED.

This study was limited by potential biases (e.g., participant selection and recall bias), retrospective nature of the data collection, lack of a control group, and lack of objective outcomes. In addition, ECPs were asked to rate their patients' overall satisfaction with lifitegrast, and those results may differ from patient-reported satisfaction. The small number of respondents (six MDs and six ODs) and the inclusion of only two respondents from Canada further limits generalizability of the findings. The specific data we collected also did not allow us to compare the characteristics of patients with DED who were treated with lifitegrast versus characteristics

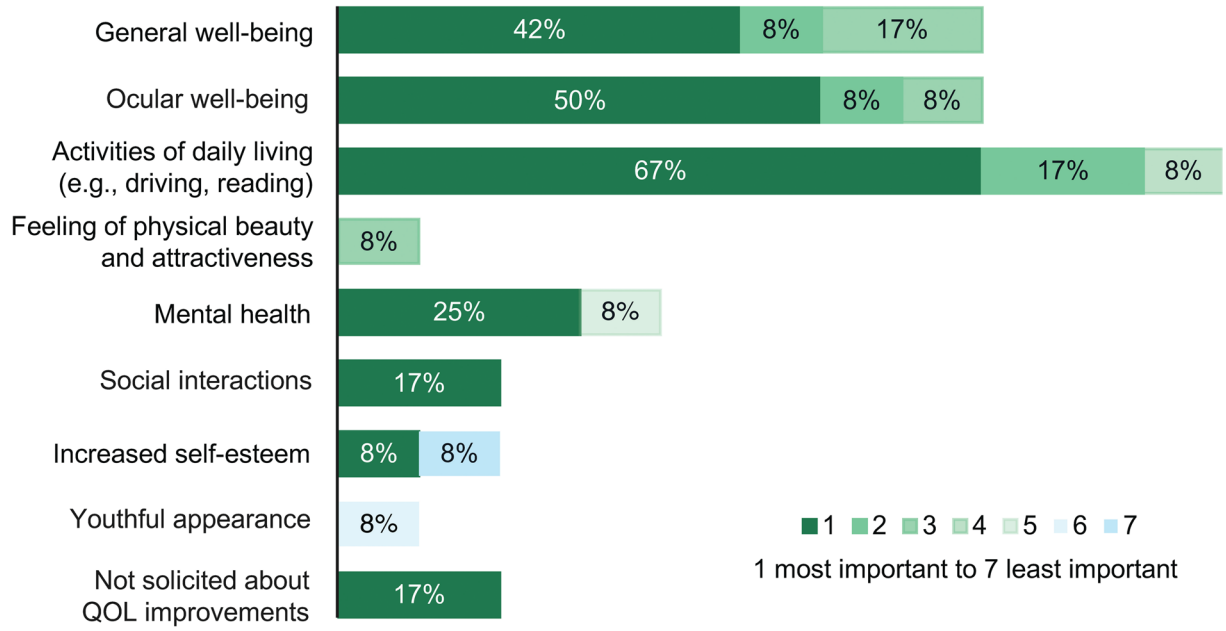

Fig. 6 Patient-reported improvements in quality of life. In response to the question, "Did your patients report any quality-of-life improvements following treatment with lifitegrast?" ECPs were instructed to choose all options that applied and rank-order them if more than one answer was checked; 1 indicated the most important; *QOL* quality of life

of all patients with DED, independent of lifitegrast treatment, or patients with DED who were not prescribed lifitegrast. Further, while the survey captured ECPs' responses regarding severity, treatment relatedness, and resolution of any AEs experienced by patients treated with lifitegrast, information on how the ongoing AEs were resolved was not captured. Analysis of quantitative data from medical charts/electronic medical records (EMRs), to be reported separately, will provide additional insight regarding the real-world utilization and effectiveness of lifitegrast.

CONCLUSIONS

This real-world survey showed that ECPs use lifitegrast to treat approximately one fifth of their patients with DED. ECPs reported that lifitegrast is typically used early in treatment, either alone or in combination with other prescription therapies for DED, and provides rapid symptom resolution, usually within 3 months of initiating treatment. Overall, ECPs indicated moderate-to-high personal and patient satisfaction with lifitegrast for the treatment of DED. ECPs reported that lifitegrast is used frequently in the management of DED in contact lens wearers and in patients undergoing various ocular surgeries. Adverse effects observed by ECPs in their practices were mild or moderate in severity and were consistent with the known tolerability profile of lifitegrast.

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Declarations

Conflicts of Interest. Cecelia Koetting reports serving as a speaker, consultant, research, and/or advisory for Allergan/AbbVie, Alcon, Azura, Bausch + Lomb, Blinkjoy, Bruder, Dompe, Harrow, Myze, Orasis, PRN, Tarsus, Topcon Healthcare, Trukera Medical, and Viatris. Justin Schweitzer reports serving as a consultant or speaker for Alcon, Allergan/AbbVie, Bausch + Lomb, Bruder, Dompé, Glaukos, Iveric Bio, LKC Technologies, MediPrint Ophthalmics, Ocuphire Pharma, Reichert Technologies, ScienceBased Health, Sight Sciences, Sun Pharmaceutical Industries, Tarsus Pharmaceuticals, Théa, Topcon Healthcare, Trukera Medical, Visus Therapeutics, and Zeiss; and serving as Chief Medical Editor for *Modern Optometry*. Kelly K. Nichols reports receiving research funding from Aramis Biosciences, Kowa, ScienceBased Health, Sylentis, and TearScience; and serving as a consultant to and receiving honoraria from Allergan/AbbVie, Alcon, Aldeyra Therapeutics, Azura Ophthalmics, Bausch + Lomb, Bruder, Cavalry Biosciences, Dompé, HanAll Biopharma, Harrow, Novaliq, Novartis, Oyster Point Pharma (now Viatris), Sight Sciences, Sydnexis, Tarsus, TearSolutions, Théa, Topcon Healthcare, and Trukera Medical. Marguerite McDonald reports serving as a consultant to AbbVie, Alcon, Bausch + Lomb, Brill, Johnson & Johnson, Nordic Pharma, Ocuphire Pharma, Sun Pharma, Tarsus, and Trukera. Christopher E. Starr reports serving as a consultant to Alcon, Aldeyra Therapeutics, Allergan/AbbVie, Allgenesis, Amgen, Azura, Bausch + Lomb, BlephEx, Bruder Healthcare, CSI Dry Eye, Dompé, Èssiri, Eye Care International (ECI), Glaukos, Johnson & Johnson Vision, Kala Pharmaceuticals, Lumenis Be, Novaliq, Novartis, Nuvissa, Oculis, Oyster Point Pharma (now Viatris), Quidel, Sight Sciences, Sofia Biologics, Sun Pharmaceutical Industries, Tarsus, Thea Pharma, Trukera Medical, and Verséa Health; and having stock options in CSI Dry Eye, Sofia Biologics, and Nuvissa. Clara C. Chan reports serving on advisory boards, speakers bureaus, or as a consultant

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Ethical Approval. This study was determined IRB-exempt by WCG IRB (Princeton, NJ, USA; IRB tracking ID 202425583). The study was exempt from IRB approval under 45 CFR § 46.104(d)(2) because the research only includes interactions involving survey procedures; and there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

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