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CLINICAL TRIAL REPORT

Systane iLux Thermal Pulsation System in the Treatment of Meibomian Gland Dysfunction: A Post-Hoc Analysis of a 12-Month, Randomized, Multicenter Study

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Purpose: This study aimed to demonstrate the effectiveness of Systane iLux, a thermal pulsation device, in patients with MGD, over 12 months post-single treatment.

Methods: This is a post-hoc analysis of a previous prospective, assessor-masked, parallel-group, multicenter study (NCT03956225) that compared the effectiveness and safety of iLux with LipiFlow in subjects with MGD. The original study included subjects with meibomian gland score (MGS) ≤12 in lower eyelids, Impact of Dry Eye on Everyday Life-Symptom Bother (IDEEL-SB) module score >16, and non-invasive tear break-up time (NITBUT) <10 seconds. Subjects were randomized (1:1) to receive a single bilateral treatment of iLux or LipiFlow. In this post-hoc analysis, mean changes in MGS, NITBUT (first break-up; seconds), IDEEL-SB module score, and corneal staining, from baseline to 12 months were analyzed post-single treatment with iLux.

Results: Data from 119 patients (n=238 eyes) treated with iLux were analyzed. The mean±SD age of the subjects was 58.4±13.4 years, with majority being female (79.0%). MGS (mean±SD) for both eyes improved significantly from baseline to 12 months (OD [baseline: 6.9±3.69; month 12: 22.8±11.31; change: 15.9±11.57, p<0.0001]; OS [baseline: 6.4±3.66; month 12: 23.0±11.33; change: 16.7±11.40, p<0.0001]). Similarly, significant improvements were observed in NITBUT (OD [baseline: 5.2±1.97; month 12: 7.0±3.68; change: 1.9±3.69, p<0.0001]; OS [baseline: 5.6±1.96; month 12: 7.9±4.58; change: 2.3±4.59, p<0.0001]) and IDEEL-SB score (p<0.0001). Corneal staining reduced significantly from baseline to 12 months (OD [baseline: 2.1±2.96; month 12: 0.7±1.56; change: −1.4±2.65, p<0.0001]; OS [baseline: 2.1±2.94; month 12: 0.7±1.44; change: −1.4±2.75, p<0.0001]). Improvements in MGS, NITBUT, IDEEL-SB module score, and corneal staining were seen as early as week 2, and at months 1, 3, 6, and 9 (all p<0.001).

Conclusion: A single treatment with iLux significantly improved clinical parameters of MGS, NITBUT, and corneal staining, and patient-reported symptom assessment with IDEEL-SB in patients with MGD over 12 months.

Keywords: corneal staining, meibomian gland dysfunction, meibomian gland score, tear break-up time

Introduction

Meibomian gland dysfunction (MGD), which contributes to evaporative dry eye, is the leading cause of dry eye disease.[1] The prevalence estimates of MGD range from 3.5% to 69.3% and this wide variation is attributed to differences in geographic region, age distribution, and specific clinical signs used to define MGD.[2] MGD is a chronic abnormality of meibomian glands and generally characterized by obstruction of terminal ducts and/or changes in glandular secretions

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(qualitative/quantitative).[3] Epithelial hyperkeratinization and increased meibum viscosity lead to duct obstruction, cystic dilation, acinar cell atrophy, and gland dropout.[4–6] As a result, tear film alteration, eye irritation, inflammation, and ocular surface disease may occur.[3] MGD symptoms can have a substantial impact on patients' quality of life.[7]

Treatments for MGD include: (1) eyelid hygiene (including warming/massage/expression), which is the mainstay therapy; (2) medical treatment such as antibiotics, non-steroidal and steroidal anti-inflammatory agents, hormone therapy, and treatment of *Demodex* infestation; (3) surgical options/procedures, such as intraductal meibomian gland probing, thermal pulsation devices, intense pulsed light therapy, and intranasal tear neurostimulation; and (4) supplements including topical lipids and oral essential fatty acid supplementation.[7–10]

The melting point of normal meibum ranges from 10°C to 40°C; however, this is increased in MGD and may lead to impaired spreading of meibum and increased evaporation of the tear film.[11,12] Thus, the treatment of MGD generally focuses on application of external heat and pressure, which helps in melting meibum and increasing secretion.[13] Although self-treatments such as warm compress and eyelid massage are the first steps in MGD treatment, patient compliance is generally low and some patients may not achieve long-lasting improvement in symptoms.[13] In such cases, in-office eyelid heating therapy, such as thermal pulsation systems, are a good alternative.[13] These devices apply heat at appropriate temperature and compress the meibomian glands simultaneously, to facilitate the release of contents into the tear film.[14] Thermal pulsation therapies, such as LipiFlow and Systane iLux, have been reported to be highly efficient, with the effects lasting for up to 12 months.[15–17]

The Systane iLux MGD treatment system (Alcon, Fort Worth, TX, USA) is a handheld, thermal pulsation device.[18] Two recent studies have compared Systane iLux and LipiFlow treatments in patients with MGD.[17,18] Both devices were reported to significantly improve MGD signs and symptoms, over 4 weeks of treatment.[18] Further, Systane iLux was reported to be non-inferior to LipiFlow in improving MGD scores, over 12 months.[17] Although previous studies have evaluated Systane iLux,[17–19] comprehensive monadic data describing trends in outcomes associated with Systane iLux treatment over the long-term have not been reported so far. Here, we report post-hoc analysis of a previous randomized controlled trial (NCT03956225) to demonstrate the effectiveness of Systane iLux in patients with MGD over 12 months post single treatment.

Materials and Methods

Study Design

This is a post-hoc analysis (not pre-planned) of a prospective, randomized, assessor-masked, parallel-group, multicenter, 12-month, post-approval study that evaluated the effectiveness of Systane iLux and LipiFlow in patients with MGD (NCT03956225). The study details have been published in detail previously.[17] In the current post-hoc analysis, we report data on the Systane iLux treatment group from baseline to 12 months.

Study Population

Subjects aged ≥18 years, of any gender or race, with signs and symptoms of evaporative dry eye in both eyes were included. At the screening visit, subjects were required to have meibomian gland score (MGS) ≤12[20] in lower eyelids, Impact of Dry Eye on Everyday Life-Symptom Bother (IDEEL-SB) module score >16, and non-invasive tear break-up time (NITBUT) <10 seconds.

Subjects with a history of intraocular/oculo-plastic surgery within the 6 months prior to screening, LipiFlow or Systane iLux treatment (in either eye) in the last 12 months, punctal plugs or punctal occlusion, meibomian gland loss >50% at screening (as indicated by meibography), uncontrolled active systemic diseases that cause dry eye, or those not on a stable dose of any dry eye or MGD medication were excluded.

Treatment

Eligible subjects from 15 sites were randomized (1:1) to receive a single bilateral treatment with either Systane iLux (TearFilm Innovations, Inc., Alcon, Fort Worth, TX, USA) or LipiFlow (Johnson & Johnson Vision, Jacksonville, FL, USA). Subjects attended a total of eight study visits: screening/baseline; treatment; and follow-up visits at 2 weeks, 1

month, 3 months, 6 months, 9 months, and 12 months. Both eyes were treated on the same day. Makeup was removed and anesthetic eye drops were instilled in both eyes before treatment with Systane iLux. The treatment time ranged from 8 to 12 minutes. Both upper and lower lids were treated: upper lid, central-nasal area; lower lid, central-nasal region; lower lid, central-temporal region.

Systane iLux MGD Treatment System

The Systane iLux MGD treatment system is a thermal pulsation, hand-held, battery-powered instrument with a disposable tip. It consists of LEDs that heat the meibum glands from 38°C to 42°C. Temperature sensors in the instrument turn off the LEDs automatically if the inner eyelid exceeds 44°C or outer eyelid exceeds 45°C. The instrument allows viewing of gland orifices and customization of pressure during heating and compression phases.[13,18]

Outcomes and Measures

In this post-hoc analysis, effectiveness of Systane iLux treatment was measured as mean changes in MGS, NITBUT, IDEEL-SB module score, and corneal staining from baseline to the 12-month follow-up visit (post single treatment with Systane iLux).

MGS was assessed using a Meibomian Gland Evaluator (Johnson & Johnson Vision), while viewing the lower eyelid margin through a slit-lamp biomicroscope. In each eye, a total of 15 glands of the lower lid were evaluated from the nasal, central, and temporal regions. The glands were graded on a scale of 0 to 3 based on the quality of the expressed meibomian fluid (0=no secretion, 1=inspissated, 2=cloudy, 3=clear liquid), with a maximum MGS score of 45 in each eye.[16,21] NITBUT was evaluated using the OCULUS Keratograph® 5M. It was performed three times using infrared illumination. The Keratograph 5 M projects a ring pattern from a placido disc onto the tear film surface and detects a disruption automatically. NITBUT first break-up time (the first disruption in the projected placido rings) was recorded in seconds separately for each eye. The IDEEL-SB module comprises 20 questions that measure general dry eye symptoms (over the past two weeks) in patients; scores range from 0 to 100, with higher scores indicating greater bother. Corneal staining was evaluated in five corneal regions (superior, inferior, central, temporal, and nasal), using sodium fluorescein-impregnated strips. The National Eye Institute (NEI) grading scale was used; the grades ranged from 0 to 3 (0=normal, 1=mild, 2=moderate, 3=severe), with a maximum score of 15 in each eye.[22]

Post-Hoc Statistical Analyses

Descriptive statistics, such as means and standard deviations for continuous variables, and numbers and percentages for categorical variables, were reported for all study measures. The 95% confidence intervals (CIs) and p-values were calculated from analysis of covariance (ANCOVA), with the baseline measurement considered as a covariate for each outcome analyzed. Adjustment for multiplicity was not performed.

Results

Socio-Demographic and Clinical Characteristics

Data from 119 subjects (238 eyes) were evaluated. The mean±SD age of the subjects was 58.4±13.4 years (Table 1). The majority of subjects were female (79.0%), white (86.6%), and non-Hispanic/Latino (95.8%). At baseline, the mean±SD total MGS (combined scores from both eyes) was 6.6±3.68, total NITBUT (combined values from both eyes) was 5.4 ±1.97 seconds, and IDEEL-SB module score was 55.8±15.93. The corneal staining score was approximately 2.1±2.9 in both eyes (Table 1).

Change in MGS from Baseline to 12 Months Post-Treatment

The MGS (mean±SD) for both left (OS) and right (OD) eyes improved significantly from baseline to 12 months (OD [baseline: 6.9±3.69; month 12: 22.8±11.31; change from baseline: 15.9±11.57, p<0.0001]; OS [baseline: 6.4±3.66; month 12: 23.0±11.33; change from baseline: 16.7±11.40, p<0.0001]) (Table 2). Furthermore, for both eyes, significant

Table 1 Baseline Socio-Demographic and Clinical Characteristics of the Study Subjects

Socio-Demographic Characteristics	iLux (N=119)
Age, mean±SD	58.4±13.4
Age group, n (%)	
8–64 years	78 (65.5)
≥65 years	41 (34.5)
Sex, n (%)	
Male	25 (21.0)
Female	94 (79.0)
Race, n (%)	
White	103 (86.6)
Black or African American	6 (5.0)
American Indian or Alaska Native	0 (0.0)
Asian	8 (6.7)
Native Hawaiian or Other Pacific Islander	1 (0.8)
Other	0 (0.0)
Multi-racial	1 (0.8)
Ethnicity, n (%)	
Hispanic or Latino	5 (4.2)
Not Hispanic or Latino	114 (95.8)

Abbreviations: OD, right eye; OS, left eye; SD, standard deviation.

Table 2 Meibomian Gland Scores at Baseline and Post-Treatment Follow-Up Visits

Visits		OD	OS	Total
Baseline	n	119	119	238
	Mean±SD	6.9±3.69	6.4±3.66	6.6±3.68
Week 2	n	118	118	236
	Mean±SD	19.5±9.99	19.5±9.18	19.5±9.57
	Change from baseline (mean±SD; 95% CI)	12.7±9.98; 10.9 to 14.4	13.2±9.73; 11.5 to 14.49	12.9±9.84; 11.7 to 14.1
	p-value	<0.0001	<0.0001	<0.0001
Month 1	n	119	119	238
	Mean±SD	20.6±9.60	21.2±9.92	20.9±9.75
	Change from baseline (mean±SD; 95% CI)	13.7±10.06; 11.9 to 15.4	14.8±10.85; 13.0 to 16.6	14.3±10.46; 13.0 to 15.5
	p-value	<0.0001	<0.0001	<0.0001
Month 3	n	118	118	236
	Mean±SD	23.1±10.0	23.1±9.96	23.1±9.96
	Change from baseline (mean±SD; 95% CI)	16.2±10.82; 14.4 to 18.0	16.8±10.40; 14.9 to 18.6	16.5±10.59; 15.2 to 17.8
	p-value	<0.0001	<0.0001	<0.0001

(*Continued*)

Table 2 (Continued).

Visits		OD	OS	Total
Month 6	n	93	93	186
	Mean±SD	24.3±10.09	24.4±9.93	24.3±9.99
	Change from baseline (mean±SD; 95% CI)	17.5±10.74; 15.4 to 19.6	18.2±10.04; 16.2 to 20.2	17.8±10.37; 16.4 to 19.3
	p-value	<0.0001	<0.0001	<0.0001
Month 9	N	98	98	196
	Mean±SD	22.1±10.72	22.6±10.66	22.4±10.66
	Change from baseline (mean±SD; 95% CI)	15.4±10.94; 13.2 to 17.5	16.2±10.46; 14.1 to 18.3	15.8±10.68; 14.3 to 17.3
	p-value	<0.0001	<0.0001	<0.0001
Month 12	n	113	113	226
	Mean±SD	22.8±11.31	23.0±11.33	22.9±11.29
	Change from baseline (mean±SD; 95% CI)	15.9±11.57; 13.8 to 18.0	16.7±11.40; 14.6 to 18.8	16.3±11.47; 14.8 to 17.8
	p-value	<0.0001	<0.0001	<0.0001

Abbreviations: CI, confidence interval; MGS, meibomian gland score; OD, right eye; OS, left eye; SD, standard deviation.

improvement in MGS from baseline was observed as early as week 2, as well as at month 1, month 3, month 6, and month 9 (all p<0.0001).

A similar trend was observed for the total MGS; the score improved significantly from baseline to 12 months (p<0.0001), and at all other visits post-treatment (week 2, month 1, month 3, month 6, and month 9; all p<0.0001) (Table 2).

Change in NITBUT from Baseline to 12 Months Post-Treatment

NITBUT (first break-up time; mean±SD; seconds) for both eyes improved significantly from baseline to 12 months (OD [baseline: 5.2±1.97; month 12: 7.0±3.68; change from baseline: 1.9±3.69, p<0.0001]; OS [baseline: 5.6±1.96; month 12: 7.9 ±4.58; change from baseline: 2.3±4.59, p<0.0001]) (Table 3). Furthermore, for both eyes, significant improvement in NITBUT from baseline was observed as early as week 2, as well as at month 1, month 3, month 6, and month 9 (all p<0.001).

Similarly, the total NITBUT improved significantly from baseline to 12 months (p<0.0001); the improvement was also observed at all other visits post-treatment (week 2, month 1, month 3, month 6, and month 9; all p<0.0001) (Table 3).

Table 3 Non-Invasive Tear Break-Up Time (First Break-Up Time) at Baseline and Post-Treatment Follow-Up Visits

Visits		OD	OS	Total
Baseline	n	119	119	238
	Mean±SD	5.2±1.97	5.6±1.96	5.4±1.97
Post-treatment	n	119	119	238
	Mean±SD	6.1±3.00	6.7±3.48	6.4±3.26
	Change from baseline (mean±SD; 95% CI)	0.9±2.85; 0.4 to 1.4	1.1±3.39; 0.5 to 1.7	1.0±3.13; 0.6 to 1.4
	p-value	0.0006	0.0004	<0.0001

(*Continued*)

Table 3 (Continued).

Visits		OD	OS	Total
Week 2	n	117	118	235
	Mean±SD	6.2±3.12	7.2±4.23	6.7±3.74
	Change from baseline (mean±SD; 95% CI)	1.1±3.29; 0.5 to 1.6	1.6±4.16; 0.9 to 2.4	1.3±3.75; 0.9 to 1.8
	p-value	0.0003	<0.0001	<0.0001
Month 1	n	118	119	237
	Mean±SD	6.2±2.71	7.3±3.87	6.8±3.38
	Change from baseline (mean±SD; 95% CI)	1.1±2.87; 0.6 to 1.5	1.7±4.06; 1.0 to 2.4	1.4±3.52; 1.0 to 1.8
	p-value	<0.0001	<0.0001	<0.0001
Month 3	n	118	117	235
	Mean±SD	6.2±3.13	7.4±3.88	6.8±3.57
	Change from baseline (mean±SD; 95% CI)	1.1±3.19; 0.5 to 1.6	1.9±4.13; 1.2 to 2.6	1.5±3.70; 1.0 to 1.9
	p-value	0.0002	<0.0001	<0.0001
Month 6	n	93	93	186
	Mean±SD	7.1±4.18	7.5±3.94	7.3±4.06
	Change from baseline (mean±SD; 95% CI)	1.9±4.15; 1.1 to 2.8	1.8±4.16; 1.0 to 2.6	1.9±4.14; 1.3 to 2.5
	p-value	<0.0001	<0.0001	<0.0001
Month 9	n	98	98	196
	Mean±SD	7.3±4.62	8.5±5.01	7.9±4.84
	Change from baseline (mean±SD; 95% CI)	2.2±4.31; 1.3 to 3.1	2.9±4.85; 1.9 to 3.8	2.5±4.59; 1.9 to 3.2
	p-value	<0.0001	<0.0001	<0.0001
Month 12	n	113	113	226
	Mean±SD	7.0±3.68	7.9±4.58	7.5±4.17
	Change from baseline (mean±SD; 95% CI)	1.9±3.69; 1.2 to 2.5	2.3±4.59; 1.5 to 3.2	2.1±4.16; 1.6 to 2.6
	p-value	<0.0001	<0.0001	<0.0001

Note: NITBUT data are shown in seconds.
Abbreviations: CI, confidence interval; NITBUT, non-invasive tear break-up time; OD, right eye; OS, left eye; SD, standard deviation.

Change in IDEEL-SB from Baseline to 12 Months Post-Treatment

The total IDEEL-SB score (mean±SD) improved significantly from baseline to 12 months (baseline: 55.8±15.93; month 12: 34.3±16.65; change from baseline: −21.1±16.46; p<0.0001). Significant improvement in total IDEEL-SB score from baseline was also observed at all other visits post-treatment (week 2, month 1, month 3, month 6, and month 9; all p<0.0001) (Table 4).

Change in Corneal Staining from Baseline to 12 Months Post-Treatment

Corneal staining scores (mean±SD) for both eyes reduced significantly from baseline to 12 months (OD [baseline: 2.1±2.96; month 12: 0.7±1.56; change from baseline: −1.4±2.65, p<0.0001]; OS [baseline: 2.1±2.94; month 12: 0.7±1.44; change from baseline: −1.4±2.75, p<0.0001]) (Table 5). Furthermore, for both eyes, a significant reduction in corneal staining scores from baseline was observed as early as week 2, as well as at month 1, month 3, month 6, and month 9 (all p<0.0001).

Table 4 Impact of Dry Eye on Everyday Life-Symptom Bother at Baseline and Post-Treatment Follow-Up Visits

Visits	n	IDEEL-SB Score (Mean±SD)	Change from Baseline (Mean±SD; 95% CI)	p-value
Baseline	119	55.8±15.93	NA	NA
Week 2	118	39.7±15.09	−16.2±13.98; −18.4 to −14.0	<0.0001
Month 1	118	36.3±16.05	−19.5±14.32; −21.8 to −17.1	<0.0001
Month 3	118	36.1±17.38	−19.5±14.20; −21.9 to −17.0	<0.0001
Month 6	93	33.9±17.68	−22.2±16.63; −25.3 to −19.1	<0.0001
Month 9	98	35.3±17.07	−20.4±16.60; −23.4 to −17.4	<0.0001
Month 12	113	34.3±16.65	−21.1±16.46; −23.8 to −18.4	<0.0001

Abbreviations: CI, confidence interval; IDEEL-SB, Impact of Dry Eye on Everyday Life-Symptom Bother; NA, not applicable; SD, standard deviation.

Discussion

Thermal pulsation systems, such as Systane iLux, have been shown to substantially improve signs and symptoms of MGD up to 4 weeks after treatment.[18,19] Systane iLux has been reported to be non-inferior to LipiFlow in treating MGD,

Table 5 Corneal Staining Scores at Baseline and Post-Treatment Follow-Up Visits

Visits		OD	OS
Baseline	n	118	118
	Mean±SD	2.1±2.96	2.1±2.94
Post-treatment	n	119	118
	Mean±SD	2.2±2.63	2.4±2.65
	Change from baseline (mean±SD; 95% CI)	0.2±2.55; −0.2 to 0.6	0.2±2.96; −0.2 to 0.7
	p-value	0.4151	0.2809
Week 2	n	118	118
	Mean±SD	1.2±1.88	1.3±1.92
	Change from baseline (mean±SD; 95% CI)	−0.9±2.17; −1.2 to −0.7	−0.8±2.12; −1.1 to −0.6
	p-value	<0.0001	<0.0001
Month 1	n	119	119
	Mean±SD	1.0±1.73	1.3±1.87
	Change from baseline (mean±SD; 95% CI)	−1.1±2.23; −1.3 to −0.8	−0.8±2.23; −1.1 to −0.6
	p-value	<0.0001	<0.0001
Month 3	n	118	118
	Mean±SD	0.8±1.63	1.0±1.53
	Change from baseline (mean±SD; 95% CI)	−1.3±2.52; −1.5 to −1.0	−1.2±2.55; −1.4 to −0.9
	p-value	<0.0001	<0.0001

(*Continued*)

Table 5 (Continued).

Visits		OD	OS
Month 6	n	93	93
	Mean±SD	0.7±1.76	0.7±1.33
	Change from baseline (mean±SD; 95% CI)	−1.1±2.29; −1.4 to −0.8	−1.2±2.34; −1.5 to −1.0
	p-value	<0.0001	<0.0001
Month 9	n	98	98
	Mean±SD	0.6±1.42	0.7±1.27
	Change from baseline (mean±SD; 95% CI)	−1.0±1.94; −1.2 to −0.8	−1.0±2.15; −1.2 to −0.8
	p-value	<0.0001	<0.0001
Month 12	n	113	113
	Mean±SD	0.7±1.56	0.7±1.44
	Change from baseline (mean±SD; 95% CI)	−1.4±2.65; −1.7 to −1.1	−1.4±2.75; −1.6 to −1.1
	p-value	<0.0001	<0.0001

Abbreviations: CI, confidence interval; OD, right eye; OS, left eye; SD, standard deviation.

post single treatment, in a 12-month randomized controlled trial.[17] The current post-hoc analysis of the previous randomized trial[17] was conducted to provide comprehensive monadic data on long-term Systane iLux effectiveness. Our results demonstrated that a single treatment with Systane iLux significantly improved outcomes in patients with MGD, over 12 months of follow-up. Specifically, improvements were noted in the clinical parameters of MGS, NITBUT, and corneal staining, along with patient-reported symptom assessment with the IDEEL-SB.

Significant improvements in MGS and NITBUT from baseline were seen in both eyes as early as 2 weeks and the effects were sustained for 12 months. These results are similar to previous studies that reported improvement in MGS and tear break-up time over 4 weeks.[18,19] The improvement of approximately 16 points in MGS in the current analysis (at 12 months) was similar to the improvement observed in the Tauber et al study (17 points, at 4 weeks) and the Schanzlin et al study (14 points, at 4 weeks).[18,19] Further, the improvement of approximately 2 seconds in NITBUT in the current analysis (at 12 months) was similar to the tear break-up time (TBUT) improvement observed in the Tauber et al study (3 seconds, at 4 weeks) but lower than the Schanzlin et al study (4.5 seconds, at 4 weeks); however, the comparisons may be limited due to the differences in NITBUT versus invasive TBUT.[18,19] Our study findings demonstrate that the trends in outcomes associated with Systane iLux extend beyond 4 weeks and are sustained over 12 months.

For the patient-reported outcome measure of symptoms with the IDEEL-SB questionnaire, a difference of 12 points is considered to be clinically significant.[23] The current analysis revealed a substantial decrease in IDEEL-SB scores from baseline to week 2 and up to month 12, ranging from 16- to 22-point reduction; these results indicate a clinically meaningful reduction. The improvement in subjective symptom scores in our study is similar to previous studies that reported improvement in Ocular Surface Disease Index (OSDI) and Standard Patient Evaluation of Eye Dryness (SPEED) scores.[18,19] Further, in our analysis, corneal staining reduced significantly from baseline to 12 months in both eyes, similar to previous studies,[18,19] indicating improvements in ocular surface with a single treatment of Systane iLux.

In the current analysis, the effectiveness of Systane iLux was observed early, even at 2 weeks after treatment; this suggests potential benefits of Systane iLux in patients requiring quick relief, such as those with severe dry eye disease or those planning cataract or refractive surgeries.[19] MGD treatments that stabilize the tear film rapidly and improve ocular surface health may help with providing accurate keratometry measurements and pre-surgical planning.[19,24]

MGD signs and symptoms improvement observed in this study indicate that subjects with MGD may have gland obstruction and/or altered meibum composition that prevents meibum secretion into the tear film. Systane iLux facilitates melting of meibum and improves secretion onto the ocular surface by applying heat and pressure simultaneously to the eyelids.[18] Thus, Systane iLux treatment may be more convenient and time-efficient than eyelid heating devices that require a separate step of manual meibomian gland expression.[19]

In summary, the results of the post-hoc analysis demonstrate that a single treatment with Systane iLux is effective in improving signs and symptoms of MGD over 12 months.

The current analysis had a few limitations. As this was only an assessor-masked study, there could have been a potential bias in unmasked results on the IDEEL-SB questionnaire. The subjective symptom scores (IDEEL-SB) may have been influenced by the better eye and/or worse eye. However, this influence might have been minimal since the objective assessments of MGS, NITBUT, and corneal staining were similar for both left and right eyes. Further, since the subjects were not stratified based on baseline symptom severity, effects of Systane iLux across varying disease severity was not assessed. At-home therapies, such as warm compresses and artificial tears, were not monitored, which may have impacted the results. Further, since this post-hoc analysis evaluated the effectiveness of only Systane iLux over 12 months, any control group comparison was not made.

Conclusion

This post-hoc analysis demonstrated that Systane iLux is effective in improving signs and symptoms of MGD over 12 months after a single treatment. Improvement in MGS, NITBUT, corneal staining scores, and IDEEL scores were observed as early as 2 weeks and sustained over 12 months.

Data Sharing Statement

Due to varying rights of individuals and contractual rights of parties involved, Alcon does not make a practice of sharing datasets.

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Author Contributions

All authors made a significant contribution to the work reported, whether that is in the conception, study design, execution, acquisition of data, analysis and interpretation, or in all these areas; took part in drafting, revising or critically reviewing the article; gave final approval of the version to be published; have agreed on the journal to which the article has been submitted; and agree to be accountable for all aspects of the work.

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Disclosure

GW is a consultant for Alcon, Aerie, Allergan, Bausch, BioTissue, CooperVision, Johnson & Johnson, OcuSoft, Optovue, Orasis, and Tarsus Medical. CH is an educational consultant for Valley Contax and reports grants from Alcon during the conduct of the study. SM and BF are consultants for Alcon. JT and JM were paid as clinical investigators with a research grant from Alcon. DK was paid as a researcher for Alcon and reports payment for research from Specialty Eyecare Group and Johnson & Johnson. KB reports compensation as an investigator for this study by Alcon. JD, BG, and DL have no financial interests to disclose. SK has received speaking, consulting and research fees from AbbVie, Alcon, Bausch and Lomb, Essilor, Johnson & Johnson, Kala, Sun, Osmotica, Tear Care, and Vision

Source. SK is also an investigator in a study for Alcon on thermal pulsation for meibomian gland disease. SS and TNY are employees of Alcon. The authors report no other conflicts of interest in this work.

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