

Comparison between SYSTANE iLux and LipiFlow in the Treatment of Meibomian Gland Dysfunction (MGD): A 12-Month, Multicenter Study

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Background



- Meibomian gland dysfunction (MGD) is one of the most common and underdiagnosed ocular conditions in ophthalmic practice with an estimated prevalence of 3.5% to almost 70%^{1,2}
- MGD, a leading cause of evaporative dry eye (EDE) disease, is commonly characterized by obstruction or atrophy of the meibomian gland, which leads to altered meibum^{1,3}
- Clearing meibomian gland obstruction may alleviate the chronic pathologic progression of MGD^{2,3}
- Treatment of MGD often involves the application of heat to the eyelids to melt the abnormal meibum and facilitate its re-entry into the tear film²
- Eyelid Thermal Pulsation devices apply heat at an appropriate temperature closer to the meibomian glands and simultaneously compressing the glands to evacuate their contents^{2,4}
- The SYSTANE iLux System is a novel thermal pulsation device that effectively treats MGD.² Compression and heat can be applied through directly visualizing any cloudy or inspissated meibum in each region of the eyelid depending on the level of obstruction²

EDE, evaporative dry eye; MGD, meibomian gland dysfunction.

1. Schaumberg DK, Nichols JJ, Papas EB, et al. The international workshop on meibomian gland dysfunction: report of the subcommittee on epidemiology of, and associated risk factors for MGD. *Invest Ophthalmol Vis Sci.* 2011;52(4):1994-2005.
2. Tauber J, Owen J, Bloomenstein M, Hovanesian J, Bullimore MA. Comparison of the iLUX and the LipiFlow for the treatment of meibomian gland dysfunction and symptoms: a randomized clinical trial. *Clin Ophthalmol.* 2020;14:405-418.
3. Geerling G, Baudouin C, Aragona P, et al. Emerging strategies for the diagnosis and treatment of meibomian gland dysfunction: Proceedings of the OCEAN group meeting. *Ocular Surf.* 2017;15(2):179-92
4. Blackie CA, Coleman CA, Holland EJ. The sustained effect (12 months) of a single-dose vectored thermal pulsation procedure for meibomian gland dysfunction and evaporative dry eye. *Clin Ophthalmol.* 2016;10:1385-1396.

Objective



To demonstrate noninferiority of SYSTANE iLux compared with LipiFlow in change from baseline in Meibomian Gland Score (MGS) at 12 months post single treatment in MGD subjects with EDE disease

Methods (1/5)



Prospective, randomized, assessor-masked, parallel-group, multicenter, 12-month, follow-up study



Study period (June 2019 to October 2020)

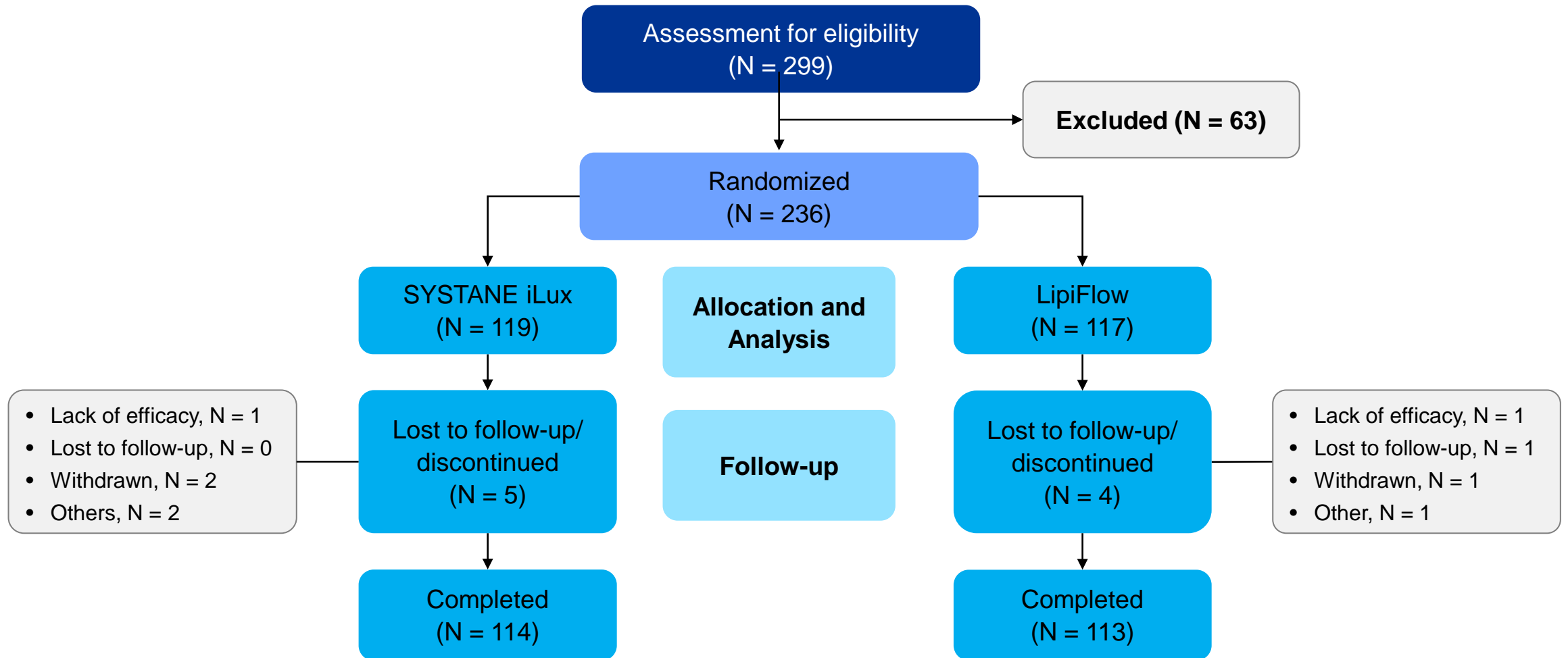


Total subjects, N = 299 (enrolled from 15 different sites in USA)



Subjects attended 8 visits (baseline, treatment, and follow-up at week 2, 1, 3, 6, 9, and 12 months)

Methods (2/5)





Inclusion criteria

- Subjects aged ≥ 18 years with signs and symptoms of EDE
- Impact of dry eye on everyday life—Symptom bother module score > 16
- Noninvasive tear break-up time < 10 seconds
- MGS ≤ 12 in lower eyelids
- Subjects agreed to not start any MGD/EDE treatment or systemic medications known to cause dry eye
- Subject agreed to avoid wear of contact lenses



Exclusion criteria

- Meibomian gland loss $> 50\%$
- History of refractive or vitreoretinal surgery
- History of other intraocular or oculoplastic surgery
- Subjects with punctal plugs or punctal occlusion
- Subjects not on a stable dose of any dry eye or MGD medications (if using)
- Subjects with uncontrolled active systemic diseases that cause dry eye



Endpoint



Change from baseline in MGS at 12 months

Meibomian Gland Functionality Assessment

- Fifteen glands of the lower eyelid (3 zones—nasal, temporal, and central) were evaluated on each eye
- Each gland was graded from 0 to 3 with a maximum MGS of 45 in each eye

Grade	Secretion quality
0	No secretion
1	Inspissated
2	Cloudy
3	Clear liquid



Statistical analysis



- Mixed effects repeated measures model to test noninferiority for the change in MGS from baseline
- One-sided 95% lower confidence limit (LCL) of least squares mean (LSM) difference > -5 indicates noninferiority

Results (1/2)



Baseline Characteristics of the Study Subjects

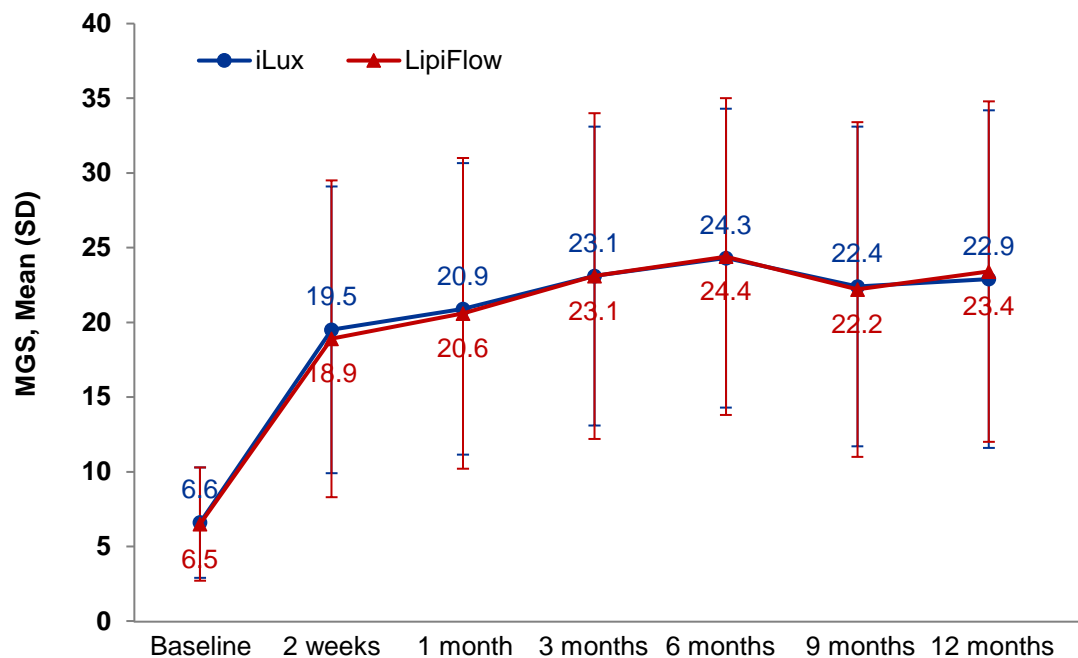
	SYSTANE iLux (N = 119)	LipiFlow (N = 117)	Overall (N = 236)
Age (years), mean (SD)	58.4 (13.4)	56.2 (14.1)	57.3 (13.8)
Age group (years), n (%)			
18-64	78 (65.5)	80 (68.4)	158 (66.9)
≥65	41 (34.5)	37 (31.6)	78 (33.1)
Sex, n (%)			
Male	25 (21.0)	31 (26.5)	56 (23.7)
Female	94 (79.0)	86 (73.5)	180 (76.3)
Race, n (%)			
White	103 (86.6)	108 (92.3)	211 (89.4)
Black or African American	6 (5.0)	4 (3.4)	10 (4.2)
American Indian or Alaska Native	0 (0.0)	0 (0.0)	0 (0.0)
Asian	8 (6.7)	5 (4.3)	13 (5.5)
Native Hawaiian or other Pacific Islander	1 (0.8)	0 (0.0)	1 (0.4)
Other	0 (0.0)	0 (0.0)	0 (0.0)
Multiracial	1 (0.8)	0 (0.0)	1 (0.4)
Ethnicity, n (%)			
Hispanic or Latino	5 (4.2)	2 (1.7)	7 (3.0)
Not Hispanic or Latino	114 (95.8)	115 (98.3)	229 (97.0)

N, number of subjects in each treatment group; n, number of subjects with non-missing response in specified category (percentages calculated as $[n/N] \times 100$); SD, standard deviation.

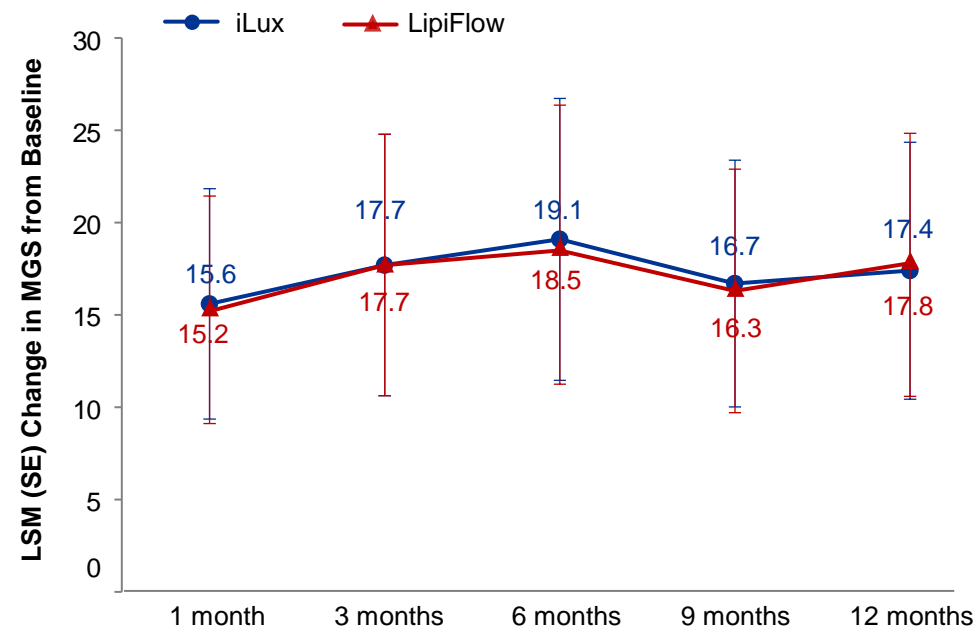
Results (2/2)



Mean MGS Over Time



LSM Change From Baseline in MGS Over Time



Noninferiority of SYSTANE iLux compared with LipiFlow in MGS was demonstrated at all follow-up visits

Conclusions and Summary



The SYSTANE iLux System is noninferior to the LipiFlow Thermal Pulsation System in demonstrating change in MGS up to 12 months following a single treatment



Both treatments offer statistically similar efficacy in the treatment of MGD