

Introduction

- Artificial tears are commonly recommended by eye care professionals in the management of dry eye disease (DED), regardless of disease severity and subtype.¹
- I-DROP[®] MGD is a novel formulation of viscoadaptive hyaluronic acid, phosphorylcholine and glycerin to support integration, stabilization and enhancement of the tear film lipid layer, as well as hydration of the ocular surface.

Purpose

The purpose of this two-part pilot study was to:

- Compare the difference in tear film measures over 2 hours after instilling I-DROP MGD (test) compared with Thealoz Duo (control) – another hyaluronic acid-based lubricant drop.
- Examine the subjective relief of dry eye symptoms with I-DROP MGD over 1 week vs. participants' habitual drops.

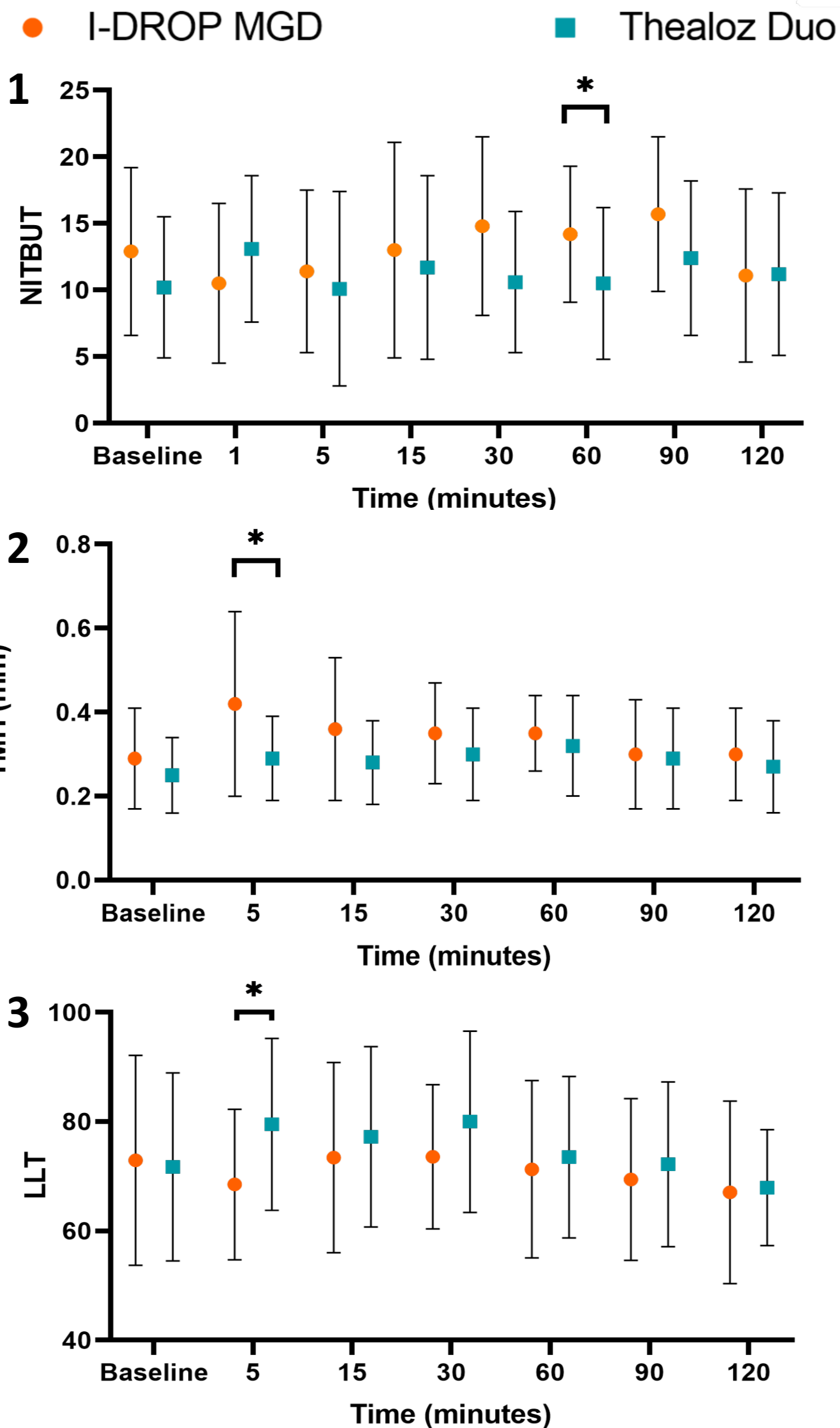
Methods

Ten participants with DED that habitually used artificial tears at least once daily for the past 30 days participated in a two-part study. **Part 1** was a randomized, double-masked study involving contralateral application of test and control drops, followed by a 2-hour observation period of objective non-invasive tear break-up (NITBUT) and tear meniscus height (TMH), assessed using the Keratograph 5M (Oculus, Germany), and lipid layer thickness (LLT), assessed using the TearScience LipiView II (Johnson & Johnson Vision, USA). In **Part 2**, participants were provided with one bottle of I-DROP MGD to use bilaterally at least once daily for 7 days. After 7 days, subjective ratings (0-100 scale, 0=poor

outcome) of comfort, dryness, soothing and quality of vision along with OSDI and SPEED scores were collected and compared with participant's habitual eye drops.

Results

Part 1: Contralateral study, 0-120 minutes



Figures 1-3: NITBUT, TMH and LLT over two hours (mean, SD). *p<0.05

- NITBUT was higher in eyes that received I-DROP MGD from 5 to 90 minutes and was significantly greater than Thealoz Duo at 60-minutes (Fig. 1, 14.2 ± 5.1 vs. 10.5 ± 5.7s, p=0.037).
- TMH was higher in the eyes that received I-DROP MGD from 5 to 120 minutes and was significantly greater than Thealoz Duo at 5 minutes (Fig. 2, 0.42 ± 0.22 vs. 0.29 ± 0.10mm, p=0.005).
- LLT was significantly greater with Thealoz Duo at 5 minutes (Fig. 3, 79.5 ± 15.7 vs. 68.5 ± 13.8nm, p=0.005). LLT in eyes that received I-DROP MGD varied less than eyes that received Thealoz Duo (6.5 vs. 12.1nm).

Part 2: Bilateral, 7-days I-DROP MGD

- Subjective ratings for comfort and soothing were significantly greater with I-DROP MGD compared to habitual drops; no statistically significant differences were found for dryness or quality of vision (Table 1).
- There was a statistically significant and clinically relevant reduction (-12) in OSDI score² after using I-DROP MGD for 7 days compared to habitual drops.
- A similar statistically significant reduction (-4) in SPEED score was also observed.

Table 1: Subjective ratings & questionnaire scores (mean ± SD)

Subjective Rating / Questionnaire	Habitual eye drop	I-DROP MGD	p-value
Comfort	73 ± 14	82 ± 6	0.027
Dryness	68 ± 17	79 ± 6	0.091
Soothing	75 ± 20	86 ± 8	0.010
Quality of vision	81 ± 25	86 ± 10	0.799
OSDI	45 ± 15	33 ± 12	0.017
SPEED	15 ± 3	11 ± 4	0.006

Conclusions

Over 2 hours, I-DROP MGD generally resulted in longer NITBUT and higher TMH compared to Thealoz Duo. When used for 7 days, I-DROP MGD resulted in clinically relevant reductions in dry eye symptoms, measured with OSDI compared to another hyaluronic acid-based lubricant. Improvements (>10%) in subjective ratings for comfort and soothing may be considered clinically relevant.

References

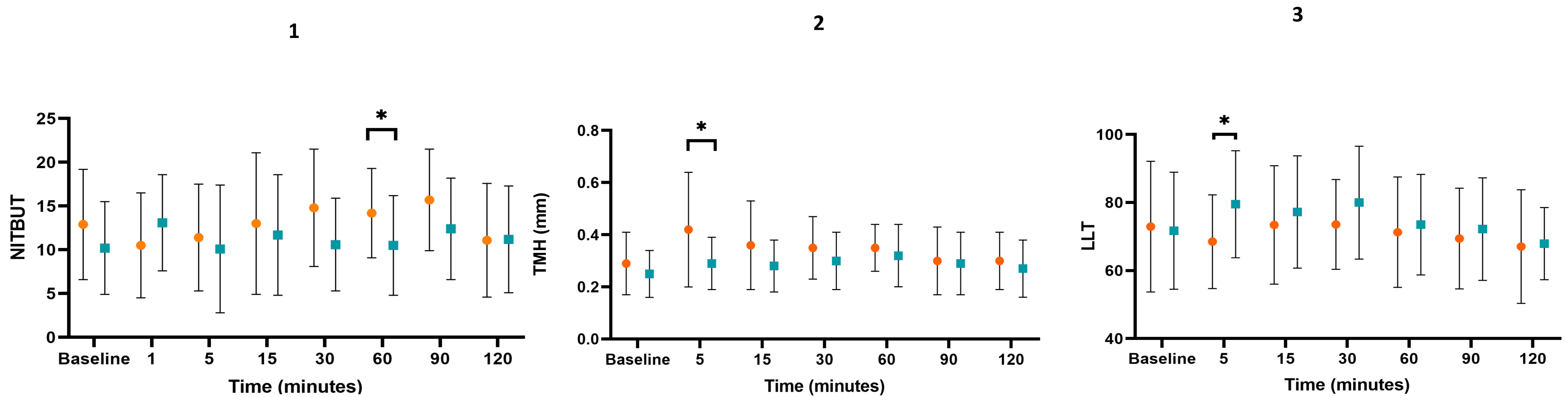
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- Miller KL, Walt JG, Mink DR, et al. Minimal clinically important difference for the ocular surface disease index. *Arch Ophthalmol.* Jan 2010;128(1):94-101



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Results

● I-DROP MGD ■ Thealoz Duo



Figures 1-3: NITBUT, TMH and LLT over two hours (mean, SD).

*p<0.05