Research Article
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Comparing signs and symptoms of dry eye treated with organic versus conventional lubricant eye drops

Abstract

Purpose: This study aimed to investigate and compare changes in symptoms, signs, and clinical tests between two different lubricant eye drop treatments in patients with dry eye secondary to Meibomian gland dysfunction (MGD).

Methods: This prospective clinical study included 20 symptomatic patients with MGD-induced dry eye. Participants who were diagnosed with dry eye were treated with either a certified organic artificial tear (AT) (O group) or a non-organic AT (C group) for 4 weeks and re-evaluated. Both treatments consisted of the same active ingredient, glycerin. The findings from the first and second visit were assessed.

Differences between the effect of each treatment on signs and symptoms were analyzed. Dry eye symptoms, subjective wellness, tear break-up time (TBUT), tear osmolarity, and lid margin assessment were the variables evaluated.

Results: Both treatment groups demonstrated improvements in objective tests, symptoms, and wellness. A larger percentage of patients in the C group reported symptomatic improvement, which was greater than in the O group. The O group exhibited a higher average improvement in wellness as well as greater improvement in TBUT and tear osmolarity than the C group.

Conclusion: Conventional and organic lubricant eye drops both achieved clinical improvements in the signs and symptoms of MGD-induced Evaporative dry eye (EDE). Organic eye drops demonstrated a greater effect on overall wellness, TBUT, and tear osmolarity.

Keywords: dry eye disease, meibomian gland dysfunction, lubricant eye drops, organic

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Dan Friederich
Clinical Optometrist and Dry Eye Specialist, Vision Care Consultants, USA

Correspondence: Dr. Dan Friederich, Vision Care Consultants, 12121 Tesson Ferry Professional Center, St. Louis, MO 63128, Tel 314.843.5700, Fax 314.843.1353, Email danfriederich@gmail.com

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Abbreviations

AT, Artificial tear; DED, Dry eye disease; EDE, Evaporative dry eye; MGD, Meibomian gland dysfunction; NOP, National Organic Program; SANDE, Symptom Assessment in Dry Eye; SD Standard deviations; TBUT, Tear break-up time; TMH, Tear Meniscus Height

Introduction

Dry eye is increasingly affecting people worldwide, and its symptoms negatively influence the quality of life.[1] Dry eye is a multifactorial condition that affects the tears and ocular surface. Its primary symptoms and signs are discomfort, visual disturbance, increased tear film osmolarity, and inflammation.[1,2] Meibomian gland dysfunction (MGD) is the leading cause of dry eye, with literature indicating that up to 86% of patients with dry eye demonstrate signs of MGD.[2] Contradictions are prevalent among diagnostic testing methods, especially in mild or moderate dry eye. Some studies have revealed a lack of correlation between the signs and symptoms of dry eye patients.[3–6] Practitioners find themselves more guided by symptoms than signs when evaluating the depth and extent of treatment options to use, and the most meaningful outcome measure is frequently the patient's subjective improvement.

Studies have revealed an increase in both physical and subjective well-being among people who consume organic food.[7–11] The quantity of organic foods and goods on the market has steadily increased over the past couple of decades, accounting for 6% of total food sold in the United States, and 15% of fruits and vegetables are certified organic.[7] The United States Department of Agriculture, through its National Organic Program (NOP), enables manufacturers to have their products certified as organic. Certified organic products are audited and proven to comply with the NOP, and recertification and on-site inspection are required annually. Organic standards are designed to allow organic and natural substances while prohibiting synthetic substances.

This study aimed to compare the changes in symptoms and signs between the two different lubricant tear treatments, organic (O group) and conventional (C group), in patients with MGD-induced dry eye. We also measured the correlations between dry eye signs and symptoms and patients' levels of happiness and well-being.

Material and methods

Patient recruitment

This prospective cross-sectional study included patients presented to our clinic with dry eye-related symptoms from December 2022 to July 2023, and diagnosed with dry eye secondary to MGD. The study enrolled patients with at least 6 months of symptoms untreated for the past 3 months. Dry eye was defined as the presence of dry eye symptoms with an irregular tear break-up time (TBUT), along with MGD-associated changes in the lid margin and Meibomian gland secretion.

We excluded patients who used contact lenses, had any other ocular disease, were pregnant or nursing, had systemic disease other than high blood pressure or high cholesterol controlled without pharmaceuticals, or had ocular allergies. Each patient provided informed consent.

Clinical evaluation and tests

The same eye care provider performed examinations in the following sequence at each exam:

Dry eye-related symptomatology

Each participant completed a modified "Symptom Assessment in Dry Eye" (SANDE, Figure 1) questionnaire at the first visit. The SANDE visual analog scale was used to assess the frequency and intensity of dry eye symptoms. For SANDE version 1, the patients put one mark on two different lines (frequency and severity) to record the severity of their symptoms. The modified SANDE version 2 was administered during the second visit, where patients compared the frequency and severity of their current level of symptoms with that during their previous visit (Figure 2). A happiness and well-being questionnaire modeled after SANDE 1 and 2 was completed at the first and second visits (Figures 1 & 2).

PLEASE COMPLETE THE FOLLOWING QUESTIONS REGARDING THE FREQUENCY AND SEVERITY OF YOUR DRY EYE SYMPTOMS, AS WELL AS YOUR OVERALL HAPPINESS AND WELLBEING.

1. Frequency of symptoms:
Please place an 'X' on the line to indicate how often, on average, your eyes feel **dry and/or irritated:**

Rarely _____ **All the time**

2. Severity of symptoms:
Please place an 'X' on the line to indicate how severe, on average, you feel your symptoms of dryness and/or irritation are:

Very Mild _____ **Very Severe**

3. Overall happiness:
Please place an 'X' on the line to indicate how happy, on average, you feel:

Very Unhappy _____ **Very Happy**

4. Overall wellbeing:
Please place an 'X' on the line to indicate how healthy/well, on average, you feel:

Very Unhealthy/Unwell _____ **Very Healthy/Well**

Figure 1 SANDE version 1 with additional wellness questions.

PLEASE COMPLETE THE FOLLOWING QUESTIONS REGARDING THE FREQUENCY AND SEVERITY OF YOUR DRY EYE SYMPTOMS, AS WELL AS YOUR OVERALL HAPPINESS AND WELLBEING.

1. Frequency of symptoms:
Please place an 'X' on the line to indicate how often, on average, your eyes feel dry and/or irritated **now** compared to at your last visit approximately 1 month ago:

Rarely _____ **All the time**
Last Visit

2. Severity of symptoms:
Please place an 'X' on the line to indicate how severe, on average, you feel your symptoms of dryness and/or irritation are **now** compared to at your last visit approximately 1 month ago:

Very Mild _____ **Very Severe**
Last Visit

3. Overall happiness:
Please place an 'X' on the line to indicate how happy, on average, you feel **now** compared to at your last visit approximately 1 month ago:

Very Unhappy _____ **Very Happy**
Last Visit

4. Overall wellbeing:
Please place an 'X' on the line to indicate how healthy/well, on average, you feel **now** compared to at your last visit approximately 1 month ago:

Very Unhealthy/Unwell _____ **Very Healthy/Well**
Last Visit

Figure 2 SANDE version 2 with additional wellness questions.

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TBUT

Fluorescein strips (Amcon) wetted with 0.9% sodium chloride (1.0 mL of Vibrant Vue) were touched to the inferior bulbar conjunctiva for TBUT measurements. TBUT was assessed, and the average of three values was recorded. Measurements of less than 10 s were considered abnormal.

Tear Meniscus Height (TMH)

TMH was assessed with the slit lamp 5 min after the instillation of fluorescein for TBUT evaluation. A value of <0.35 mm was considered abnormal.

Tear osmolarity

The TearLab Osmolarity System (TearLab™) for collecting nanoliter volumes of tear fluid directly from the eyelid margin with the system's test card and pen was used to measure tear osmolarity.

Meibomian gland assessment

Blepharitis was classified based on previous reports in the literature. Posterior blepharitis caused by MGD was diagnosed based on Meibomian gland orifice inspissation and thickened secretion after pressure was applied with the index finger for 10 s to the upper and lower lids. MGD severity was measured by observing secretion quality as 0, 1, 2, and 3 indicating clear, cloudy, cloudy particulate, and solid, respectively. Additionally, Meibomian gland expressibility was measured as 0, 1, 2, and 3 indicating no pressure, mild pressure, moderate pressure, and hard pressure, respectively.

Treatment protocol and follow-up

After the first visit, participants received either an organic non-preserved AT (O group) or a conventional non-preserved AT (C group). Each treatment contains an active ingredient, glycerin, and they both used the ophthalmic squeeze dispenser (Aptar™) bottle design. Patients were provided drops and instructed to instill the tears thrice daily. The drops were dispensed in their usual commercial cartons. After 4 weeks, the same provider re-evaluated the patients using the same measurement criterion as the first visit. The participants were queried about their treatment regimen during the second visit to ensure compliance.

Statistical analysis

Differences in SANDE symptom data and clinical signs/tests between the two visits were analyzed. Data were recorded as means and standard deviations (SD as ±). P-values of ≤0.05 were considered statistically significant. Pearson's correlation coefficient was used to estimate correlations between questionnaires and clinical signs/results in the first and second visits. Statskingdom was used to calculate confidence intervals for these coefficients.

Results

This study enrolled 20 participants (14 females and 6 males) with a mean age of 58.8. Each treatment (O and C) was dispensed to 10 patients. The second evaluation after 4.3 (±0.5) weeks was completed by 17 patients. The three participants did not complete their follow-up visit and were therefore excluded. Each of these three patients had been assigned to the conventional drops.

Findings at first visit

The frequency and intensity of symptom scores in the SANDE questionnaire were 59.75 (±22.3) and 51.65 (±29.4), respectively, indicating moderate dry eye symptoms. The Meibomian glands expressibility was either moderate or hard; their secretions were cloudy or cloudy particulate. TBUT indicated tear instability, and all readings were lower than the normal limits. TMH was within normal limits. Tear osmolarity was 302.1 (±26.4). All of the participants were classified as MGD-induced dry eye of mild-to-moderate intensity based on clinical examination and diagnostic tests. Participants' overall happiness was 76.2 (±26.8) and overall wellness was 65.65 (±20.6).

Changes from visit 1 to visit 2

Dry eye-related symptomatology

Both the O and C groups reported more and less intensity and frequency of symptoms via the SANDE version 2 after 1 month of drops (Figures 3 & 4). The majority of both the O and C groups reported an improvement in the intensity and frequency of symptoms, with a larger percentage of C patients reporting greater improvement. One patient from each of the O and C groups reported being less happy and less well. The O group exhibited a higher average improvement (27.6 ± 21.7 and 20 ± 18.1) in happiness and wellness than the C group (25.2 ± 28.3 and 18.8 ± 24.6) (Figures 5 & 6).

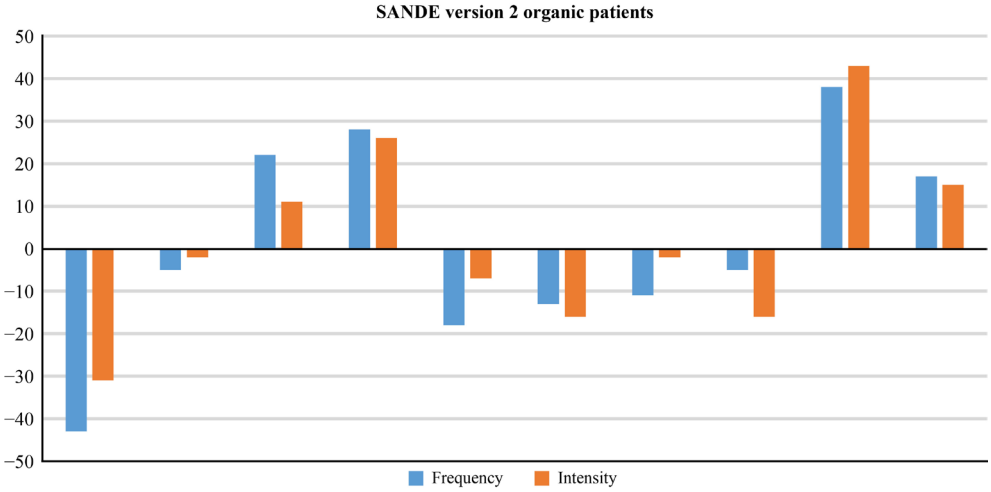

Figure 3 SANDE version 2 results for organic patients.

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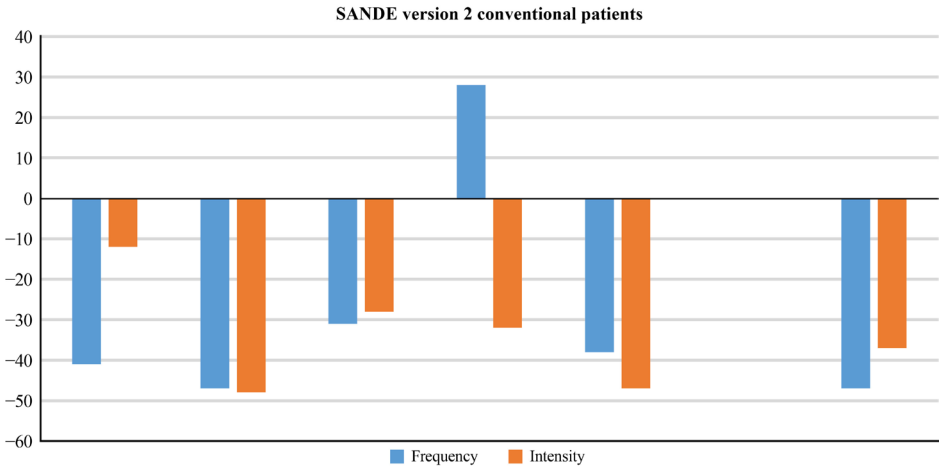

Figure 4 SANDE version 2 results for conventional patient.

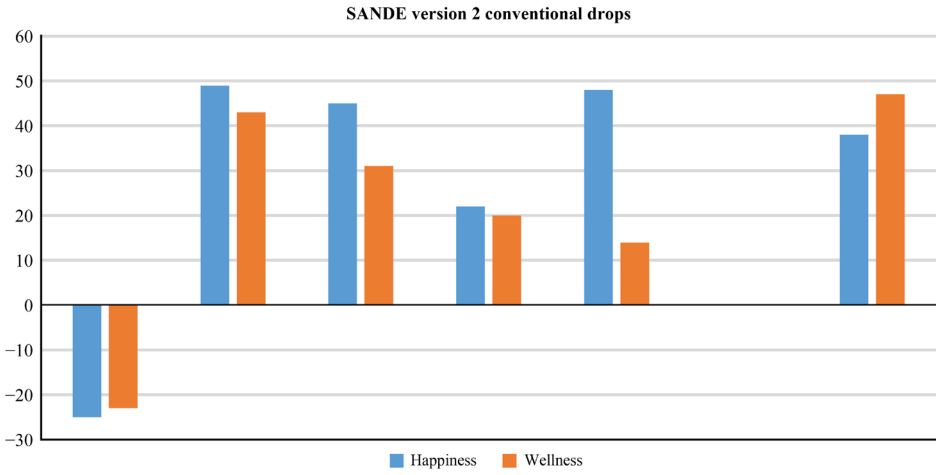

Figure 5 SANDE version 2 results conventional patients.

Clinical signs and diagnostic tests

Osmolarity increased by an average of 2.7 (±21) points in the C group and decreased by an average of 11.45 (±35) points in the O group. TMH was slightly improved in both groups. TBUT improved by an average of 20% in the C group and 100% in the O group. Neither group demonstrated any significant improvement in MGD.

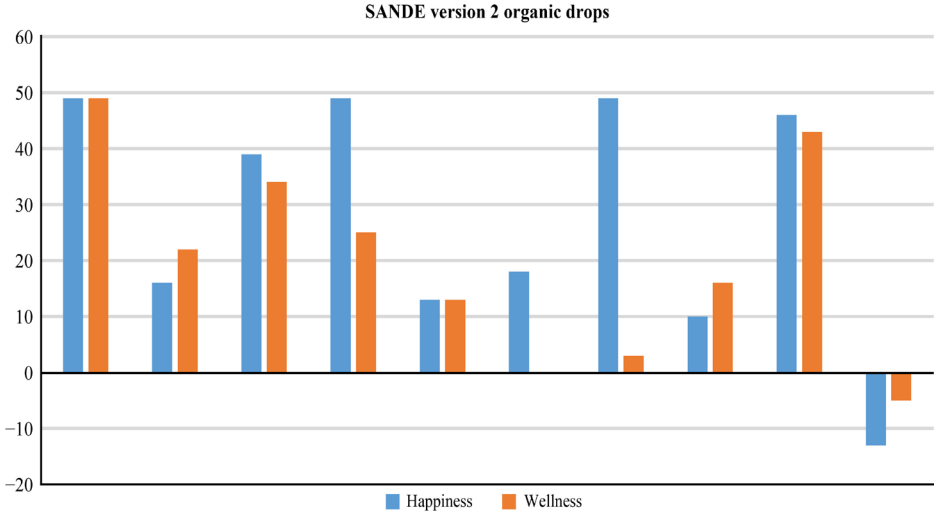

Figure 6 SANDE version 2 results organic patients.

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Correlations between questionnaires and clinical findings

Very little to no consistent correlation was observed between osmolarity, TBUT, TMH, and any of the four SANDE questions, neither for visit 1 and version 1 nor for visit 2 and version 2.

Discussion

The incidence and prevalence of MGD and dry eye have steadily increased, thereby increasing the myriad of treatments targeting them.[12–14] Therapy that directly targets the Meibomian glands, as well as prescribed pharmaceuticals, continue to be introduced by the industry and successfully implemented by practitioners.[15,16] With that being said, over-the-counter lubricant eye drops remain the most used dry eye treatment.[17,18] Their accessible cost and instantaneous relief position them as an ongoing, primary therapy for patients at every dry eye level. We investigated the existence of symptomatic and clinical differences between organic and traditional AT treatment outcomes, with the recent introduction of a certified organic lubricant eye drop. The patients selected for this study represent the most prevalent type of DED, which is MGD-induced EDE.

Previous studies have shown a lack of association between dry eye symptoms, signs, and diagnostic testing—potentially because of dry eye symptoms being difficult to define and highly variable.[19] Various patient questionnaires are used as tools for assessing the dry eye symptom severity.[20–22] We used the SANDE and added two questions based on happiness and wellness. The SANDE is a visual analog questionnaire. All of the participants demonstrated abnormal values for the intensity and frequency of their dry eye symptoms. After approximately 4 weeks of treatment, the large majority of participants showed symptomatic improvement in all of the questionnaire queries. The conventional eye drop users exhibited a greater reduction of their symptoms, while the organic users demonstrated a greater increase in their reported happiness and well-being.

All of the patients had MGD; no improvement was seen in MGD at the second evaluation, indicating the chronic nature of MGD and the inability of ATs alone to alter it. However, the participants' symptoms did improve despite the absence of lid margin enhancement. At the first visit, tear film instability secondary to MGD was reflected by low tear break-up times. The TBUT values improved after treatment, particularly in the organic tear group, but remained abnormally low for both groups. Only the O group demonstrated an improvement in tear film osmolarity and the C group showed a slight increase.

Very small, insignificant correlations were found between symptoms and clinical signs/tests, other than that all were abnormal.

The strength of our study is that it is unique and innovative. It is the first research ever to evaluate organic eye drops in any way. It is also the first study that we know of to evaluate the effect of using eye drops on overall wellness and happiness. The weakness of our study is its small sample size.

Conclusion

In summary, patients with MGD-induced dry eye had symptomatic improvement after a month of lubricant eye drop treatment, in spite of continued tear film instability and lid margin dysfunction. The lack of significant correlation between symptoms and signs, as has been previously reported, indicates the independence of subjective and objective measurements in this complex pathology. Subjective improvements matter more than objective ones in helping a patient with DED. Previous studies on organic food consumption demonstrated increases in subjective well-being. Our study supports this notion, as the organic tears caused higher reported happiness and wellness. A future study could include initially inquiring about current organic food consumption and health-consciousness levels. More studies are warranted to explore the correlations between health-conscious patients with dry eye and their response to more natural treatments.

Acknowledgments

None.

Conflicts of interest

This study was designed and operated by John Friederich, founder of Eyeganics Organic Tears.

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