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Effectiveness of Virgin Coconut Oil in Treating Dry Eyes

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Background

There are a few dry eye remedies available in the market. Currently, artificial tears and lubricants are still the most common management for dry eyes.

Objective

We proposed a new method in managing dry eyes.

Methods

A pre-soaked contact lens in virgin coconut oil (VCOCL) is being used as a vehicle to deliver virgin coconut oil (VCO) in dry eyes. VCOCL was prepared in sterilised conditions where daily soft hydrogel contact lenses were immersed in raw VCO. The efficacy of VCOCL in delivering the VCO to eyes was assessed by measuring the Tear Break-Up Time (TBUT) values, corneal staining of the anterior eye, Schirmer Test values and the measurement of residual VCO volume in tears at baseline and at 15 minutes after insertion on subjects with dry eyes. Pre- and post-data were used to analyse all the measurable variables.

Results

This study showed a significant difference in the TBUT, corneal staining, and residual VCO volume for both eyes ($p<0.05$). However, there were no changes in the Schirmer Test value ($p>0.05$). VCOCL was proven to improve tear quality in dry eye subjects and was able to maintain its presence in the eye even after 15 minutes.

Conclusion

This study suggests a new method for dry eye management.

Keywords: *Contact Lens, VCO, Therapeutic, Dry Eye, Tearfilm*

INTRODUCTION

Dry eye is often characterised by increased tear film osmolality and inflammation of the ocular surface, leading to symptoms such as discomfort, blurred vision, and unstable tear film, especially in individuals who wear contact lenses.[1,2] Adequate tear volume is crucial for maintaining overall ocular health, which in turn ensures clear vision.[3]

The remedies commonly used are artificial tears and eye lubricants. Some artificial tears containing hyaluronic acid are well known to relieve dry eye symptoms in dry eye treatment.[4] However, tear substitutes are not specifically designed to improve symptoms, but to prevent the build-up of those pre-existing problems. Some of the formulation of those artificial tears may contain preservatives which potentially cause some side effects and induced irritation after prolonged usage.[5] Many types of artificial tears have attempted to enhance their effectiveness by modifying the composition, viscosity, and/or osmolarity of the solution. Although many of these rewetting drops are available over the counter, they are often known to provide only temporary relief from symptoms or may not be effective treatments at all.[5] Additionally, most of these products have not been scientifically tested for their efficacy.[4]

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Ophthalmic drug delivery system is often prescribed in eye drops and ointment through topical ocular administration. Approximately 95% of the drugs contained in the drops are very likely to be lost through tear drainage.[6] Using therapeutic contact lenses as vehicles for drug delivery were introduced and approved in 1970s in United States on cornea related treatments. This has led to the expansion of inventing a variety options of contact lens materials and parameters in the market and lately high DK silicone hydrogel lenses were used.[7] Therapeutic contact lens of high water content can be used to load the drugs, thus providing longer residence time of the drug on cornea, which has effectively overcome the short residence time of drugs in tears that results in a low corneal bioavailability of 1-5%. Hence, therapeutic contact lens wearer can maintain the efficacy of drug loadings to maintain its efficacy, thus increasing its bioavailability.[8] To solve the dry eye problem for evaporative dry eye patient, the stabilisation of tear film can be achieved by increasing lipid layer thickness. If the quantity of the oily layer is unstable, it will cause the watery layer to be dried up rapidly.[9]

A new horizon in discovery of the benefits of VCO has been emphasised in most systemic diseases either in curing or in treating at the same time. One study has been conducted on efficacy of VCO as ocular rewetting agent on rabbit eyes whereby VCO did not cause harmful effects when used on rabbit's eyes which concludes that it is safe to be used on human's eyes.[10] The fatty acid and anti-inflammatory agents on VCO may act as protective layer over the tear film layers to reduce evaporation, which is useful for those with dry eyes problem.[11,12] However, there is no further study on efficacy of VCO as rewetting agent using contact lenses as its vehicle.

In this study, pure VCO was pre-soaked in daily disposable aspherical soft contact lenses for four hours before the insertion on a dry human eye randomly. The main aim of this pilot study was to evaluate the efficacy of contact lens in virgin coconut oil (VCOCL) used to relieve symptoms of dry eyes.

MATERIAL AND METHODS

Subjects

A prospective, non-randomised, double-masked, placebo-controlled, contralateral – eye comparison clinical study was carried out in Universiti Kebangsaan Malaysia. Approval was obtained prior to commencement of the study from the Institutional Ethics Committee (Universiti Kebangsaan Malaysia, UKM1.21.3/244/NN-2019-042). All subjects were volunteers among the students and staff of the Kuala Lumpur Campus. All subjects were screened from having active ocular allergy/infection, significant eye deformities (ectropion, ptosis, use of systemic medication, uncontrolled diabetes, and pregnancy or lactation), having undergone intra-ocular or extra-ocular surgery or having worn contact lenses regularly in the previous six months were excluded. All subjects were also ensured free from topical eye medication. They were asked to fill out a McMonnies questionnaire.[13] The scores ranged from 0 to 45. Fifty subjects were tested using the McMonnies Test and subjects having McMonnies score greater than 14.5 were accepted as dry eye subjects for this study. Forty-four individuals were enrolled in the study after a brief explanation on this clinical trial and a written consent for the participation in the study were filed. Six subjects were terminated as they were classified as having normal eye condition using McMonnies.

Forty-four subjects aged between 19 to 28 years old (22.39 ± 1.06 years); 10 males (23%) and 34 females (77%) were recruited to participate in this clinical trial at Optometry Clinic Kuala Lumpur Campus. The total numbers recruited were sufficient. The sample size for this study was obtained by using G Power 3.1.9.4 software.[14] The effect size was derived from a previous study with a similar background.[12] Comparing two means and their standard deviations; 3.17 ± 0.99 and 4.05 ± 1.08, the effect size was 0.85. This indicates a medium-to-large effect size, suggesting the effectiveness of one treatment compared to the other. Based on a priori power analysis, the minimum required sample size was determined to be 22 subjects per group. Since only one eye per subject is used, the total sample size was doubled to 44 eyes per group. We were able to retain a sample size of 44 eyes for each group.

Preparation and insertion of VCOCL

Forty-four pieces of daily disposable aspherical soft contact lenses were soaked in individual sterilised lens casings in 5ml of VCO for at least four hours before insertion onto the subject's cornea by another operator. Another 44 pieces of similar contact lenses were soaked in normal saline (CCL) for four hours and acted as controls. All these lenses were labelled to indicate the type of lens inserted to the right and the left eye. Two different operators were used in the preparation of the material. The second operator which handled the insertion of lenses into subjects' eyes and parameter measurements was masked.

In this clinical trial, soft daily disposable aspheric hydrogel contact lenses with a power of -1.00 DS, 58% water content, and an oxygen transmissibility (Dk/t) of 36.7 were used. The -1.00 DS lenses were selected as a standard low-power option for all subjects, as some had a Plano prescription. As vision testing was not part of the study, subjects still had to wear their spectacles for clarity, if needed. All apparatus for VCOCL preparation were sterilised and prepared in a standard lab of controlled temperature 21-23 degrees Celsius.

Subjects were fitted with a VCOCL on one eye and a conventional contact lens which acted as control (CCL) on the other, with the allocation done randomly using a simple randomisation calculator. Both the second operator and the subjects were masked throughout the clinical trial. Measurements were taken at baseline and again 15 minutes after the insertion of the VCOCL. All subjects underwent a 15-minute adaptation period to ensure they could comfortably open their eyes following the VCOCL insertion. All 44 subjects were staggered in a fixed schedule. This assessment was not done concurrently for all subjects. The whole assessment process took three weeks to complete. Each subject spent about 45 minutes at the clinic. All subjects were blinded throughout the assessment. When the entire clinical trial ended, the second operator handed over the results and analysis to the first operator for identification of intervention done.

Parameters Measured

Measurements of residual VCO volume in tears after contact lens wear

After 15 minutes of wearing the contact lens, the lenses were removed from both eyes. Tear samples were collected from the lower tear meniscus (the small pool of tears at the edge of the lower eyelid)

using a glass capillary tube. The collected tears were then dropped onto a piece of oil paper and left to dry at room temperature. Once the tears had fully evaporated, a pattern appeared on the oil paper. This pattern represented the remaining VCO in the tears. The size of the stain on the oil paper, which indicated the amount of VCO left, was measured manually in square millimeters (mm^2). The measurement was repeated three times to help standardise measurements, improving the reliability and reproducibility of results.[15]

TBUT (Tear Break-Up Time)

A 2% fluorescein strip was moistened with a drop of saline and placed in the lateral one-third of lower lid in a non-anaesthetised eye and patient was asked to blink only once or twice to avoid pooling of fluorescein, following which the strip was removed. Using the cobalt blue light of the slit lamp (Type; Haag Streit) the time lapses between the last blink and the appearance of the first randomly distributed dark spots in the fluorescein-stained tear film was the tear break-up time. Values of less than 10 seconds were considered abnormal. Three measurements were taken once sightings of dry spots appear, and the average of the three readings was recorded. The room temperature and humidity were kept constant at 23-24 degree Celsius and 50-60%, respectively.

Corneal Staining

Cornea epithelium was observed under cobalt blue light with slit lamp biomicroscope (Type; Haag Streit). The grading of corneal staining was evaluated using the Efron Grading Scale as reference, from 0 to 4, where – 0 = normal; 1 = trace; 2 = mild; 3 = moderate; 4 = severe.[16]

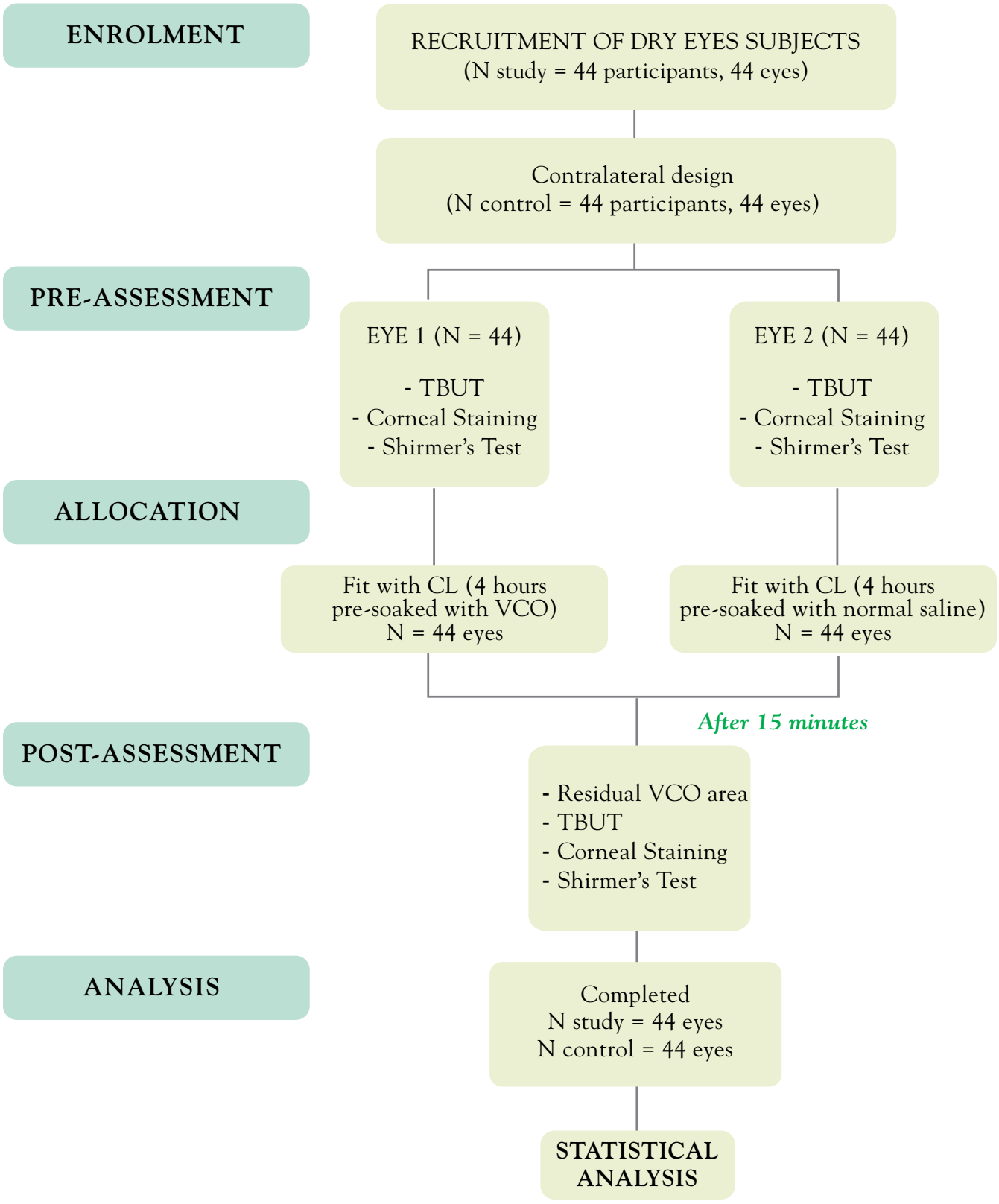
Schirmer's Test (ST)

A standard 35mm Schirmer's strip (Clement Clarke International Limited) was placed over the lateral one-third of lower lid without the instillation of topical anaesthesia. After five minutes, the level of strip wetting (in millimetres) was noted. Reading less than ten millimetres wetting was considered as positive Schirmer's test. An interval of five minutes was kept between two tests. Positive Schirmer's test was considered as Aqueous Tear Deficiency. The amount of wetness on the test paper was immediately measured against a standard scale calibrated in millimetres and recorded in two decimal values.

Statistical Analysis

These analyses were accomplished by using statistical analyses system configured for computer (SPSS 28.0). Shapiro-Wilk test was analysed to evaluate the normality of the data. A p-value of <0.05 was considered significant. However, all the collected data were not normally distributed. Therefore, non-parametric test of Wilcoxon Signed Rank and Mann Whitney U Test were carried out to analyse the data.

Figure I. Flowchart of the participants from screening to study completion.



RESULTS

The results of the TBUT, Schirmer's Test, corneal staining and residual VCO in tears were measured as shown in Table I. Wilcoxon Signed Rank Test were used to compare the value recorded at 0 and 15 minutes for all tests. In addition, Mann Whitney U test was used to compare the differences of every parameter recorded on both eyes after contact lens wear.

Table I: TBUT, Schirmer's Test, corneal staining and residual VCO volume in tears at baseline and 15 minutes after contact lens wear.

Median±IQR	Group	0 min	15 min	%	P value
TBUT (seconds)	VCO CL	3±1	6±2	100	<0.05
	CCL	3±1	4±1	10	
Schirmer's Test (mm)	VCO CL	35±5	35±8	0	0.69
	CCL	35±10	35±13	0	
Corneal Staining (Grade)	VCO CL	1±1	3±1	200	<0.05
	CCL	1±1	1±1	0	
Residual VCO volume in tears after CL wear (mm^2)	VCO CL	NA	12±10	NA	<0.05
	CCL	NA	8±13	NA	

TBUT

The baseline readings for TBUT of both eyes were similar, however, the TBUT values increased in both eyes after 15 minutes of contact lens insertion. As shown in Figure I, the increase in TBUT on VCOCL (3.3 secs) was relatively higher compared to CCL (1.43 secs). Significance difference ($p<0.05$) was observed for TBUT of both eyes.

Schirmer's Test

In this study, Schirmer's test showed no significant difference ($p>0.05$) during pre- (30.66 and 29.11 for VCOCL and CCL, respectively, and post-measurement (29.11 and 27.32 for VCOCL and CCL, respectively). Mann Whitney U test indicated no significant difference, $p>0.05$, between both lenses.

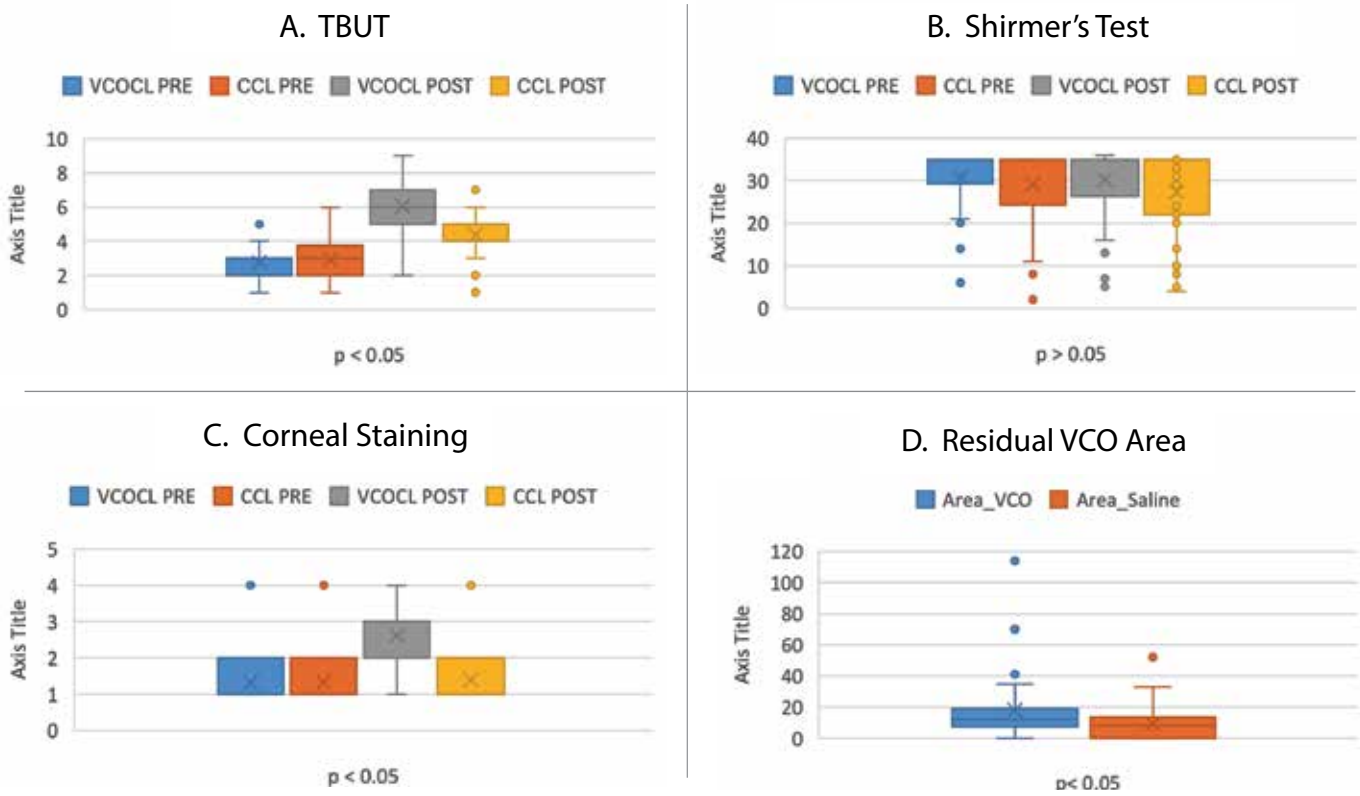
Corneal Staining

Less corneal staining was observed (1.29; $p<0.05$) before and after insertion of VCOCL, whereas no significant difference (0.07; $p>0.05$) was observed for the controlled eye.

Residual VCO area

For the measurement of residual VCO area in tears after 15 minutes of contact lens wear, the area of the VCO pattern on the oil paper of both eyes were compared and significant difference were shown, $p<0.05$. The mean was 10.48 ± 5.05 mm^2 for VCO CL whereas the area min was 5.73 ± 5.05 mm^2 for CCL. Both groups were found to be significant ($p<0.05$).

Figure II: Mean and standard deviation of eyes wearing VCOCL and CCL (A) TBUT, (B) Schirmer's Test, (C) Corneal Staining, and (D) Residual VCO area at 15 minutes compared to the baseline 0 minute.



DISCUSSION

In this study the increment in TBUT was observed due to the medium chain triglycerides (MCTs) that provides the anti-oxidant effects.[13] The VCO behaves differently as compared to animal fatty acid, which is the long chain triglycerides (LCTs) where MCTs is water soluble. This explained the effect of VCO on human tears which promoted improvement in tears quality. The VCO deposited on the CL was then transferred on the cornea surface coated with tears, where the water-soluble properties action took place slowly.

MCTs work by enhancing the lipid layer of the tear film, reducing evaporation, providing anti-inflammatory effects, and stabilising the overall tear film structure. This makes them more effective for long-term relief of dry eye symptoms, especially in cases where tear evaporation is the primary cause of discomfort.[17]

Conventional lipid-based artificial tears often use synthetic oils or longer-chain triglycerides, which may not integrate as effectively into the tear film. These oils might not spread as efficiently or may not form as stable a barrier as MCTs, resulting in less effective tear film stabilisation.

Increment of TBUT value in the control eye was lower compared to the increment in VCOCL eye. The contact lens used in the control eye was immersed in saline instead of VCO. So, this will add moist to the

eye condition but will not prevent it from rapid drying. This condition can be explained further where the insertion of contact lens causes intervention on the tear film. In 2007, silicone hydrogel contact lens was used to treat dry eye patients with chronic graft-versus-host disease. The lenses are known as therapeutic contact lens, it acts as a bandage to stabilise tear film and protect ocular surface from complication such as trichiasis and fibrotic lid change.[18] The indications of using contact lens to serve as drug delivery is well known but it is an uncommon practice as the contact lenses available in the market vary in properties and finding the ideal lens to be used as the vehicle for drugs is still unclear.[19] In this study we used a normal hydrogel lens instead of Silicone Hydrogel as previous research has shown that these lenses absorb deposits better than the Silicone Hydrogels.[20]

As expected, Schirmer's test did not show any effect as this test quantified tears measurement from the combination of reflex and basal tears. Both VCOCL and CCL eyes showed decreased in the results as shown in Figure II. However, the decrease in tear quantity in CCL eye was much more compared to the contralateral eye. The reduction of the results in post contact lens insertion in this parameter was due to the induced reflex tears during the first insertion of Schirmer strip at 0 minute. After 15 minutes wear of contact lens, the eyes were less responsive to foreign body after adaptation, thus results in the decrease in reflex tears. The VCO did not cause changes to tear quantity as MCTs act as internal phase in lipid layers in the tear film to link the drug in ophthalmic emulsion to stabilise the tear film.[17]

The TBUT test is primarily used to evaluate the quality and stability of the tear film, which helps in identifying issues like meibomian gland dysfunction or problems with the lipid layer. On the other hand, Schirmer's Test measures the quantity of tears produced, making it effective in diagnosing conditions that cause tear production deficiencies, such as Sjogren's syndrome. Both tests provide complementary insights into different aspects of tear film function – TBUT for stability and Schirmer's Test for tear volume.

In Figure II, no significant difference in corneal staining was observed in the CCL eye before and after insertion. However, the corneal staining in subjects wearing the VCOCL was more pronounced, likely due to the high viscosity of the VCO.[21] The corneal staining results from the 44 subjects ranged from Grade 0 to Grade 3, indicating none to moderate staining according to the Efron grading scale. This corneal staining is a temporary clinical sign that gradually fades as the VCO is naturally drained from the tear film through the nasolacrimal duct.

In this study, we introduced a new technique to measure residual VCO in tears by using a glass capillary tube to extract tears from the tear prism, representing the amount of VCO in the tear film after lens insertion. This procedure was conducted 15 minutes after contact lens wear. The results revealed a significant difference in the surface area of the VCO pattern on oil paper between the tear samples collected from both eyes. This conventional method proved to be simpler and faster for determining the residual VCO in the tear samples. The findings indicated that VCO remained in the tear layer, and after 15 minutes, the volume of VCO, reflected by the size of the stained area, was significantly greater in the VCOCL eye compared to the CCL eye.

For future studies, a better and more accurate method to measure tear quantity and/or improvisation on tear sample collection can be applied. Since the Schirmer test values remained unchanged, indicating that further research is necessary to understand the full impact of VCO on tear production. Besides that, the duration of the study should be extended to know the period of VCO presence. This study provides a new insight of how the dry eyes subjects can benefit from VCO, and how contact lenses can be used as a vehicle to retain the effect of VCO in the eye.

Dry eye symptoms are a relatively common ophthalmic disease that can manifest in various degrees of severity and can be caused by many factors. While not life threatening, patients may often have to continuously endure discomfort or even pain, which puts a damper in their quality of life. Given the multitude of conditions which Dry Eye Syndrome can originate from, a variety of treatment options is critical to ensure inclusivity and effectiveness.[22]

CONCLUSION

The eye wearing the VCOCL showed a significant increase in TBUT after lens insertion. The greater amount of residual oil in the tears 15 minutes after insertion demonstrated that the contact lens absorbed the VCO and helped retain it in the tear film, thereby reducing tear evaporation and maintaining moisture in the eye. The staining revealed that the new oil layer formed a protective coating over the corneal surface. These findings suggest that VCOCL is safe for use in human dry eyes and offers prolonged effects compared to regular eye drops. Further research could explore its potential as an effective alternative treatment for dry eye symptoms.

CONFLICT OF INTEREST

The authors declare that there is no conflict of interest.

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