

# ORİJİNAL MAKALE / ORIGINAL ARTICLE

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# Evaluation of the Relationship between the Gel Eyeliner and Ocular Comfort

# Gülşah GEDİK 51

# ABSTRACT

Aim: The aim of this article is to investigate the relationship between ocular comfort and effect of eyeliner containing a microscale colorant, together with the Ocular Surface Disease Index (OSDI) test method. Material and Methods: The formulations were evaluated by determination of sensory, physicochemical parameters, microbial contamination and dermatological patch tests, survey study and calculation of OSDI score. **Results:** The physicochemical and sensorial parameters of the eyeliner formulation were appropriate for the dermal application. No microbial growth was observed. According to the patch test with 15 volunteers, the eyeliner did not show any allergic or irritant properties. All of the 20 participants who participated to the survey found that the permanence performance of the product successful, 35% of the participants think that the product does not leak or contaminate, 85% of respondents said that the product is easily cleaned and 65% of the participants stated that the product is durable in contact with water. The median OSDI score for the cohort was 22,3 (IQ range 10.4–55.6). OSDI scores were found to be 43,9 (IQ range 12.5 -6.4) after eyeliner use. Dry eye disease severity remained moderate. 20% of redness the participants stated that the product caused around the eves. **Conclusion:** This study shows that eveliner use is associated with the effect of the chosen dye and the perception of ocular discomfort. In this study, although the participants stated that it was a 95% blacker product, the formulation containing micro dyes had to be reformulated in a discomfort-reducing wav. Keywords: OSDI; Keratoconjunctivitis sicca; microcapsule; eyeliner

# Jel Eyeliner ile Oküler Konfor İlişkisinin Değerlendirilmesi

# ÖΖ

**Amaç:** Bu makalenin amacı, Oküler Yüzey Hastalık İndeksi (OSDI) test yöntemi ile birlikte mikro ölçekli bir renklendirici içeren eyeliner formülasyonunun oküler konfor ve etkisi arasındaki ilişkiyi araştırmaktır. **Gereç ve Yöntemler:** Formülasyonlar duyusal, fizikokimyasal parametrelerin belirlenmesi, mikrobiyal kontaminasyon ve dermatolojik yama testleri, anket çalışması ve OSDI skorunun hesaplanmasıyla değerlendirildi.

Bulgular: Jel eyeliner formülasyonunun fizikokimyasal ve duyusal parametreleri dermal uygulama için uygundur. Mikrobiyal büyüme gözlenmemiştir. Onbeş gönüllü ile yapılan yama testine göre eyeliner formülasyonu herhangi bir alerjik veya tahriş edici özellik göstermemiştir. Anket çalışmasına katılan 20 katılımcının hepsi ürünün kalıcılık performansını başarılı bulmuştur, katılımcıların %35'i ürünün sızdırmadığını veya kirletmediğini düşünmektedir, katılımcıların %85'i ürünün kolayca temizlendiğini söylemektedir ve katılımcıların %65'i ürünün su ile temasında dayanıklı olduğunu belirtmiştir. Kohort için medyan OSDI skoru 22,3'tür (IQ aralığı 10.4-55.6). Eyeliner kullanımı sonrası OSDI skorları 43,9 (IQ aralığı 12,5 - 6,4) olarak bulunmuştur. Kuru göz hastalığı şiddeti orta düzeydedir. çevresinde Katılımcıların %20'si ürünün kızarıklığa neden olduğunu belirtmistir. göz Sonuç: Bu çalışma, eyeliner kullanımının seçilen boyanın etkisi ve oküler rahatsızlık algısı ile ilişkili olduğunu göstermektedir. Bu çalışmada katılımcılar %95 daha siyah bir ürün olduğunu belirtseler de mikro boya içeren formülasyonun rahatsızlığı azaltacak şekilde yeniden formüle edilmesi gerekmektedir. Anahtar Kelimeler: OSDI; keratoconjunctivitis sicca; mikrokapsül, eyeliner

<sup>1</sup> Trakya University, Faculty of Pharmacy, Deparment of Pharmaceutical Technology, Edirne, Turkey

Sorumlu Yazar / Corresponding Author: Gülşah Gedik, e-mail: gulsahgedik@gmail.com Geliş Tarihi / Received: 25.09.2021, Kabul Tarihi / Accepted: 28.11.2021

## INTRODUCTION

Eye cosmetics are frequently used worldwide among female populations of all age groups and rarely among men (1). Many women report that they use cosmetics to improve self-confidence and express themselves psychosocially (2,3).

According to statistics, for example, 93.91 million women used eyeliner in 2019 in the USA. This figure is expected to rise to 95.26 million in 2024 (4).

Cosmetic products can cause a variety of symptoms including redness, swelling, small vesicles/bubbles, and sweating, tingling, burning, tightness, itching, or pain (5). Preservatives and fragrances added to products are the main causative agents of irritant contact dermatitis (6,7). Also, dermatitis can be seen around the eyelids at the rate of about 4% (8).

There have been a few reported cases where the use of mascara and eyeliner formulations resulted in increased conjunctival pigmentation. There have been similar case studies reporting the accumulation of cosmetic products in the lacrimal system and on the ocular surface (9-11).

Some clinical studies have shown migration of externally applied cosmetic material along the eyelid margin (12), and this is thought to predispose eye cosmetics users to tear film instability and the development of dry eye (13,14).

Dry eye disease is one of the most common diseases (15). Dry eye symptoms significantly and adversely affect quality of life (16). Epidemiological studies have consistently reported a higher prevalence of dry eye in women (17). It is also thought to be an increasing trend for eye cosmetics users to develop dry eye symptoms, due to reduced tear film stability and lipid layer quality (18).

It has been suggested that dry eye patients experience symptoms of dryness and discomfort when using eye cosmetics despite using tears regularly. It has been suggested that dry eye patients using eye cosmetics despite the regular use of tears causes symptoms of dryness and discomfort (19,20). Eye irritation is due to several factors: particles, pigments, preservatives and fragrances in cosmetic products can cause foreign body sensation and toxic and allergic responses (21). Incorrect eyeliner application and make-up residues can cause clogging of the meibomian gland openings and may cause the tear film to deteriorate. This can result in faster tear breakage and evaporation time and exposure of the corneal surface to air. Some make-up materials, such as eyeliner, can also change the viscosity of the meibum, which adversely affects its tear stability (18).

However, many users remove the products when they are uncomfortable with their daily use and do not report side effects (7,14). Ocular surface disease index (OSDI) is a questionnaire consisting of 12 questions compatible with dry eye. This survey is compatible with dry eye identifies symptoms of ocular irritation and enables assessment of their functional relevance (22). Therefore, OSDI should be added to the questionnaire applied to determine user comfort in eye cosmetics such as eyeliner and the results should be evaluated together.

The aim of this article is to investigate the relationship between ocular comfort and effect of eyeliner containing a microscale colorant, together with the OSDI test method.

# MATERIAL AND METHODS

#### Materials

All analytical grade chemicals CAS No and functions were given in Table 1. The mixture was prepared with the ingredients added in the specified proportions. Nanotechnological commercial product CarbonCap<sup>TM</sup>20 was used as colorant.

Table 1. The	complete	formula	of	the	standard	and
microcolourant	eyeliner fo	ormulation	ıs.			

COMPONENTS	CAS NO	FUNCTION
Isododecane Disteardimonium Hectorite Propylene Carbonate	31807-55-3 97280-96-1 1 08-32-7	Solvent Viscosity Controlling
Cyclopentasiloxane	541-02-6	Solvent
Trimethylsiloxysilicate	56275-01-5	Fixing Agent Film Forming Binding
Isopropyl Titanium Trisostearate	61417-49-0	Emollient
Butylene Glycol Cocoate Polymethyl Methacrylate	9011-14-7	Encapsulating Agent Film Forming
Ozokerite	64742-33-2	Binding
Polyethylene Microcrystalline Wax	9002-88-4 63231-60-7	Film Forming Binding
Dimethicone/Vinyl Dimethicone Crosspolymer Silica	243137-53-3 7631-86-9	Viscosity Controlling Bulking
Phenoxyethanol Ethylhexylglycerin	122-99-6 70445-33-9	Preservative
CI 77499/ Iron Oxides- for standard formulation, or CarbonCap™20- for microcolourant formulation	12227-89-3 1333-86-4	Cosmetic Colorant

# **Characterization of formulation**

The standard and microcolourant formulations were evaluated for their sensorial (appearance, odor, color) and physicochemical (pH viscosity density) parameters detected by a digital pH-meter (Mettler Toledo S 220, Switzerland), a pycnometer (Mettler Toledo 30330857, Switzerland), and a viscometer (Brookfield RVDVII, Rheocalc V2.4, cone spindle no: 52, UK). The experiments were repeated three times at 25°C.

## Microbial contamination tests

The microbiological contamination of formulations was evaluated by validated tests methods TS EN ISO 22718, 22717, 21149, 16212, 18416 for cultures of Staphylococcus aureus, Pseudomonas aeruginosa, Escherichia coli, Candida albicans and total yeast and mold.

#### **Dermatological tests**

Dermatological tests were performed in accordance with the Declarion of Helsinki and COLIPA Guidelens for the Assessment of Human Skin Compability. Reading the tests and results registration have been done in accordance with the recommendations of the International Contact Dermatitis Research Group. These tests have been performed at SGS Polska as subcontracted. The report number is TRC004428. Informed consent was obtained from all participants.

## Patch test

Fourteen women and one man, aged 24-56 years were selected for the dermatological tests of the product. All the probands selected for testing met the requriments for inclusion in the study and were informed about: the purpose of the study, how it is carried out and what are the possible side effects. During the tests all the probands were under constant dermatological care.

Standard IQ chambers were used for patch testing. A small amount of product was applied with patch test to voluntary forearm for 48 hours and then removed. Baseline readings were recorded 30 minutes after removal of the product from skin. Additional readings were performed after 72, 96 hours and done according to graphical scale, which was consistent with generally accepted clinical dermatological scale.

#### Survey study

The purpose of this study is to evaluate the performance of eyeliner products with a survey after volunteers have applied for a certain period of time.

Twenty volunteers were selected according to the following criteria: between the ages of 18-60, woman, makes up at least 3-4 times a week, using eyeliner at least once a week. Exclusion criteria for volunteers: people with dermatological or other physical medical conditions. Volunteers can leave the study at any time without stating a reason. Volunteers after use 5 times in 1 week asked to answer questions. The daily evaluation of the product was made 16 hours after the application of the product. The panelists applied eyeliner containing microencapsulated dye to their right eyes and similar formulation eyeliner containing standard dye to their left eye. Evaluation was made by comparing the two formulations.

The survey consisting of 24 questions was prepared and summarized in Table 2. The first 6 questions collected the subject demographics, followed by questions to obtain information about the weekly use of eyeliner and the frequency of applying makeup, the intensity of the makeup applied, and the number of makeup products used in total, and to calculate the Ocular Surface Disease Index (OSDI) score.

**Table 2.** Summary of questions analysed in the cosmetics survey

Questions Number	Questions content
1-6	Collection of demographical data
	(name,age, gender, skin colour,skin
	type, previous history of allergies
	and eye sensitivity
7–10	Use of eye cosmetics, type and
	frequency of cosmetic use
11-15	Questions on use evaluation
16-18	OSDI questionnaire
19–24	Questions on post-use evaluation
	_

### **Statistical Analysis**

Data are presented as median values with interquartile (IQ) ranges. The raw data were performed by using MS Excel Software. The different conditions were compared

using the Student's t-test and two-sided p values  $\leq 0.05$  were considered significant for all statistical tests.

# RESULTS

### **Characterization of formulation**

The physicochemical and sensorial characterization parameters of the formulation are reported in Table 3. The pH of the developed eyeliner ranged between 7.5-8.0. The density found  $1.35 \pm 0.1$  g/mL. The viscosity found  $55 \pm 0.01$  P. The physicochemical and sensorial parameters of the eyeliner formulation were appropriate for the dermal application.

Table	3.	The	e physicocl	physicochemical				sorial
character	rizati	ion	parameters	of	the	eyeli	ner	with
microcol	oura	nt an	d standard fo	rmul	ation	s		

Physicochemical 1	Parameters	Sensorial Parameters				
Eyeliner with Microcolourant	Standard Eyeliner	Eyeliner with Microcolourant	Standard Eyeliner			
Density (g/mL) $1,35 \pm 0.1$	Density (g/mL) 1,28 ± 0.04	Appearance, Pasta	Appearance, Pasta			
pH range 7.5-8.0	pH range 7.5-8.0	Odor, Characteristic	Odor, Characteristic			
Viscosity (P) $55 \pm 0.01$	Viscosity (P) 57±0.05	Color, Black	Color, Black			

## Microbial contamination tests

All results about microbiological contamination studies were given in Table 4. No microbial growth was observed. Both of eyeliner formulations suitable for clinical evaluations.

**Table 4.** The microbiological results

Test Microorganisms	Microbiological Parameters					
Total Bacteria	< 100 CFU/mL					
Yeast and Mould	None					
Escherichia coli	None					
Staphylococcus aureus	None					
Pseudomonas aeruginosa	None					
Candida albicans	None					

# Patch test

As stated in Table 5, none of the 15 people, who were exposing the patch testing have shown positive reactions during the test reading. Testing the eyeliner with microcolorant does not exhibit any allergic or irritating properties.

#### Survey study

The survey was completed by 20 respondents. The median age was 30.45 (IQ range 18–57) years old, median makeup frequency was 5-6 (IQ range 3–7), median products number which used during the makeup was 6 median the number of products used makeup was (IQ range 4–10), median eyeliner usage frequency was 4.7 (IQ range 2–7), median Fitzpatrik Scale skin color was 3 (IQ range 1–4), median makeup intensity (IQ range mild-intense) was medium. The results are presented in Tables 6 and 7. 100% of the participants found sufficient of the black density and black color of the product.

While 95% of the participants found positive of the convenience of applying the product. 100 % of the participants found successful of the drying time performance of the product. While 75% of the participants gave a positive opinion about the brush structure of the product.

100% of the participants has found successful of the permanence performance of the product. 95% of the participants has found successful of the permanence performance of the product for 16 hours. 35% of the participants think that the product does not leak or contaminate. 85% of the participants say that the product can be cleaned easily. 65% of the participants stated that the product is durable in contact with water. 95% of the participants think the product is more black than other product.

The median OSDI score for the cohort was 22,3 (IQ range 10.4-55.6). OSDI scores were found to be 43,9 (IQ range 12.5 -6.,4) after eyeliner use. The results are presented in Table 8. Dry eye disease severity remained moderate. 20% of the participants stated that the product caused redness around the eyes. One of the users was excluded from the study because of the product causes redness around the eyes.

**Table 5**. The patch test results

			Test Results						
No.	Sex	Age	48 h	72 h	96 h	One week			
1	Female	33	(-)	(-)	(-)	(-)			
2	Female	47	(-)	(-)	(-)	(-)			
3	Female	27	(-)	(-)	(-)	(-)			
4	Female	26	(-)	(-)	(-)	(-)			
5	Female	24	(-)	(-)	(-)	(-)			
6	Female	24	(-)	(-)	(-)	(-)			
7	Female	24	(-)	(-)	(-)	(-)			
8	Female	33	(-)	(-)	(-)	(-)			
9	Female	24	(-)	(-)	(-)	(-)			
10	Female	30	(-)	(-)	(-)	(-)			
11	Female	29	(-)	(-)	(-)	(-)			
12	Female	54	(-)	(-)	(-)	(-)			
13	Female	56	(-)	(-)	(-)	(-)			
14	Female	27	(-)	(-)	(-)	(-)			
15	Male	27	(-)	(-)	(-)	(-)			

#### DISCUSSION

The OSDI questionnaire is a valid and reliable tool with good sensitivity for assessing dry eye severity. This

finding may also reflect the fact that OSDI is based on dry eye symptoms rather than irritation. We consider the OSDI scale is to be a suitable measure of ocular comfort for this study. In this survey, participants had an average OSDI score that is greater than 15, which is the recommended limit for diagnosing symptomatic dry eye using the OSDI questionnaire (22).

Nanotechnology is widely preferred in modern generation cosmetics to increase efficiency such as color, transparency, solubility, texture, and durability (23).

The dye used in this formulation is a microcapsule consisting of butylene glycol cocoate and polymethyl methacrylate, which is more resistant to flow and smearing, but still migrated and caused redness. Once eyeliners are in the tear film, pH and tear osmolarity may change and discomfort and redness may ocur (14). Surfactants, preservatives, dyes and emulsifiers may cause irritation to the ocular surface (21).

Particles like pigments suspended in eye products may cause foreign body sensations when in contact with the ocular surface. Certainly, in the formulation of ophthalmic pharmaceutical preparations, it has been recommended that particle sizes are no larger than 10  $\mu$ m to minimise eye irritation (24). The microcapsule dye we use in our work CarbonCap<sup>TM</sup>20' s average particle size of 20-30  $\mu$ m. This particle size may have caused the rash (25).

This product should be reformulated to be less migratory to the eyes. The formulation, which contain less sensitising ingredients and particle size, further reducing the potential for irritation, which may be ideal for sensitive eyeliner users (14).

The hypothesis that product placement closer to the lid margin may contaminate the tear film resulting in tear film changes and subsequent discomfort (14). We do not have any data on whether the rash is caused by this application. When preparing such efficacy tests, a standard should be set for eye application. A study showed that both lipid eye drops and liposomal sprays appear to exacerbate the migration of cosmetic products across the eyelid margin. Although significant increases in lipid layer thickness were observed and, lipid formulations's clinical efficacy in improving tear film stability appeared (18).

#### CONCLUSION

This study shows that eyeliner use is associated with the effect of the chosen dye and the perception of ocular discomfort. All of the participants found the black density, drying time and permanence performance of the product as successful. Most of the participants reported that the product is easy to apply and clean and is blacker than the standard dyed product. In this study, although the participants stated that it was a 95% blacker product, the formulation containing micro dyes had to be reformulated in a discomfort-reducing way. Better tolerated formulations can be achieved by adding oilbased or liposome-produced ingredients and dyes and reducing their size. In addition, the OSDI test to the efficacy questionnaires for eye cosmetics will make the evaluations more meaningful.

#### GEDİK

No.	Age	Makeup Frequency (per week repetition number)	The Number of Products Used Makeup	Eyeliner Usage Frequency (number of repetitions per week)	Skin Color (Fitzpatrik Scale)	Skin Type	Makeup Intensity	Previous history of allergies and eye sensitivity
1	29	6-7	7	2	3	Combination	Medium	None
2	30	6-7	5	2	3	Normal	Medium	None
3	29	6-7	5	2	2	Normal	Medium	None
4	24	3-4	3	2	3	Sensitive	Mild	None
5	28	3-4	5	4	3	Normal	Mild	None
6	29	6-7	7	7	3	Dry	Medium	None
7	26	5-6	8	7	1	Combination	Medium	None
8	31	5-6	8	7	4	Sensitive	Medium	None
9	25	3-4	8	2	3	Normal	Mild	None
10	30	3-4	7	2	3	Combination	Medium	None
11	25	5-6	5	7	3	Normal	Mild	None
12	26	5-6	4	7	2	Sensitive	Mild	None
13	29	5-6	9	7	3	Combination	Medium	None
14	36	6-7	10	7	4	Normal	Intense	None
15	57	3-4	4	2	3	Dry	Medium	None
16	24	5-6	5	4	3	Combination	Medium	None
17	29	3-4	6	2	2	Oily	Medium	None
18	33	3-4	8	7	3	Normal	Mild	None
19	31	6-7	4	7	2	Combination	Medium	None
20	18	3-4	6	7	3	Oilv	Medium	None

# Table 6. The survey results of demographical data

# Table 7. The survey results of use and post-use evaluation

Eva	Evaluation of During Use		2 (%)	3 (%)	4 (%)	5 (%)	6 (%)	7 (%)	Mean*	S.D.**
1	Do you think the product is sufficient intense black?	-	-	-	15	25	35	25	5.7	1.0
2	Evaluate the application comfort of the product.	-	-	5	5	35	45	10	5.5	0.9
3	Was the black color of the product enough for you?	-	-	-	-	30	30	40	6.1	0.9
4	Evaluate the brush structure of the product.	5	15	5	25	30	15	5	4.3	1.6
5	Evaluate the drying time after product application.	-	-	-	10	20	20	50	6.1	1.1
Eva	luation of After Use	1 (%)	2 (%)	3 (%)	4 (%)	5 (%)	6 (%)	7 (%)	7 (%) Mean *	
6	Do you think the product is blacker than the other product?	-	-	5	25	30	10	30	5.4	1.3
7	Do you think the product is permanent?	-	-	-	15	20	30	35	5.9	1.1
8	Do you think the product last for 16 hours?	-	-	-	10	20	35	30	5.9	1.0
9	Does the product leak or smear? ***	5	20	-	10	45	5	10	4.3	1.7
10	Does the product come out immediately in contact with water? ***	10	20	15	20	5	10	15	3.8	2.0
						-			+	1

The meanings of the numbers in the table above are as follows: 1 - 3 / Unsuccessful, 4 - 7 / Successful For the negative questions: (9,10) 1 - 4 / Successful, 4 - 7 / Unsuccessful

\*: Mean

\*\*: Standard deviation

\*\*\*: One of the users was excluded from the study and left the questions unanswered, as the product causes redness around the eyes.

#### GEDİK

		4 (%)	3(%)	2(%)	1(%)	0 (%)	Mean*	S.D.**
Have week?	you experienced any of the following changes during the last (pre/post)							
l	Sensitivity to light	-	15	50	30	5	1.75	1.1
2	Grit sensation	5	20	35	30	10	1.80	1.7
;	Eye pain		5	5	25	65	0.50	1.3
ļ	Blurry vision	-	-	5	40	55	0.50	1.0
;	Bad vision	-	-	5	35	60	0.45	1.2
	bu had eye problems that have limited or prevented you from any of the following actions during the last week? (pre/post)	4 (%)	3(%)	2(%)	1(%)	0 (%)	Mean*	S.D.**
Ď	Read	-	5	5	40	50	0.75	1,0
,	Driving at night	-	-	5	45	50	0.55	1,1
;	Work with a computer or bank machine (ATM)	-	25	45	10	20	1.75	1,3
)	Watch TV	5	20	20	10	45	1.30	1.4
	ou felt discomfort in your eyes in any of the following ns during the last week? (pre/post)	4(%)	3(%)	2(%)	1(%)	0 (%)	Mean*	S.D.**
0	Wind	5	5	10	65	15	1.2	1.9
1	In dry areas	5	30	45	15	5	2.15	1.8

#### Table 8. The survey results of OSDI questionnaire (pre/post)

\*Values to determine dry eye disease severity calculated using the OSDI© formula:

OSDI<sup>©</sup> = (sum of scores) x 25

(# of questions answered)

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