

Evaluation of Safety and Efficacy of Under Eye Cream: A Clinical Study

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ABSTRACTS

Herbal Under Eye Cream of The Himalaya Drug Company, Bangalore, was evaluated for its efficacy and safety in decreasing under eye wrinkles and puffiness in 22 patients. The results indicated that this Under Eye Cream significantly reduces wrinkles, laxity and dark circles in the under eye region. It also indicated refreshing, cleansing and soothing effect. This product was well tolerated by all these subjects and there were no adverse effect which could be attributed to the application of Under Eye Cream. This clinical trial indicates, safety and efficacy of herbal Under Eye Cream.

INTRODUCTION

People strive hard for years to maintain youthful appearance. Youthful appearance is characterized by non-wrinkled skin and the skin that is hydrated and silky, firmed and toned, radiant, smooth and without any pigmentation. Wrinkles are the main problems leading to under eye puffiness and disfigurement. Facial wrinkling is one of the most striking signs of skin ageing¹. Ageing and photo exposure are the main causative factors for wrinkling. In addition to, over exposure to sun, changes in fat content and skin collagen, and dehydration may contribute to the process of wrinkling. As the skin ages, water retaining properties are compromised and dry skin is actually a hallmark of excessive water loss. This loss can be corrected by use of moisturization process. In addition to these, once the skin ages, the production of ground substances called glycosaminoglycans (GAGs) are also in decline. These GAGs are essential because it surrounds collagen, elastic tissue and cells of the skin. These substances bind water molecules and assist in hydrating skin proteins. The GAG is also known to relax the muscles which

are associated with wrinkling. The puffiness under the eye is usually the result of fat accumulating on the lower lids leading to tired and aged appearance. These adipose tissues get hypertrophied due to severe load of triglycerides in connecting tissues. Free radicals, glycosylation and inflammatory pigmentation lead to darkening of the eye lids and initiation of dark circles. Aesthetic medicine is largely concerned with the correction of perceived physical imperfection and outward signs of aging in the face.² A number of agents have been used to correct the under eye problem and a number of herbs are claimed to have beneficial effects to make the skin hydrated and glowing.³⁻⁵ These indigenous remedies are developed with an intention of efficacy with minimum or no side effects. The medicinal plants are important therapeutic aids for alleviating various ailments of humankind. In the recent past there has been a tremendous increase in the use of plant-based health products in developing as well as developed countries resulting in an exponential growth of herbal products globally. Herbal medicines have a strong traditional or conceptual base and the potential to be useful as drugs in terms of safety and effectiveness leads for treating different diseases. India, with its mega-biodiversity and knowledge-rich ancient traditional systems of medicine viz. Ayurveda, Siddha, Unani, Amchi and local health traditions, provides a strong base for the utilization of a large number of plants in general healthcare and alleviation of common ailments of the people.

Under Eye Cream has been developed with a special intention of correcting the under eye problem with adequate safety and efficacy. This formulation contains *Winter begonia*, *Cipadessa baccifera* and *Wheat germ oil*. The ingredients of this formulation are claimed to have beneficial effects in skin functions. The present study was carried out to evaluate the safety and efficacy of Under Eye Cream in the management of dark circles, wrinkles and under eye puffiness.

MATERIAL AND METHODS

This study was carried out at the Department of Dermatology, Apollo Hospitals, Chennai. Patients who had fulfilled the inclusion criteria (Table 1) were enrolled in this study after obtaining their informed consent. The protocol of the study was approved by local ethics committee.

The patients who were pregnant and those who had previous history of allergic reaction to any medication were excluded from the study. In all 22 patients (Table 2) completed the study and most of the patients were females. The history of under eye dark circles and wrinkles were ranging from 6 month to 5 years.

These patients were asked to apply the Under Eye Cream (Batch No. FD/UE/36) twice a day for a period of 1 month. They underwent clinical evaluation on entry and at fortnightly interval. During this evaluation the anti-wrinkling effect, anti laxity effect, soothing effect and dark circles were evaluated by an evaluating grade using 0-4 grading scale (0- no response, 1 – fair, 2- good, 3 – very good, and 4 – excellent). Data collected was

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Table 1: Inclusion criteria	
Sl. No.	Parameters
1	Wrinkles
2	Laxity of the skin
3	Dark circles
4	Under eye pigmentation
5	Skin irritation

evaluated statistically by using GraphPad Prism Software Volume 4.01. Adverse effects reported by the subjects were recorded in a data sheet.

RESULTS

Twenty two patients completed the study and there were no dropouts. Evaluation of effect of Under Eye Cream on clinical parameters in the management of dark circles and wrinkles indicate (Table 3) that Under Eye Cream has statistically significant effect in giving rise to anti-wrinkling effect, soothing effect and in eradicating dark circles. It also produced antilaxity effect and skin tightening effect, though the results were not significant. Out of 22 subjects, 15 had good improvement (68.1%), 6 had fair response whereas 1 person out of 22 had very poor response (4.5%). None of the patients exhibited any adverse reaction like erythema, edema, pruritus and urticaria. The Under Eye Cream did not produce any effect on lid margins, eye lashes, and sclera, conjunctiva, pupil and eye lenses. It did not produce any rise in intraocular pressure. These results indicate significant beneficial effects of Under Eye Cream in subjects with dark circles and wrinkles under the eyes without any adverse effect.

DISCUSSION AND CONCLUSION

Aging leads to the impaired tension and elasticity of the facial skin which undergoes sclerotization, becomes slack, develops numerous wrinkles and deep folds.⁶ The problem of under eye puffiness, pigmentation and wrinkles is a very common problem in clinical practice, this leads to tired and aged appearance. This problem appears to be due to increase in collagenase activity probably due to ultraviolet rays stimulation from sunlight. The puffiness of the eye is usually caused by edema. It may also be accentuated by chemicals or environmental pollutions. This is

Table 2: Demographic Data	
Number	22
M : F	3 : 19
Mean age (in years)	34.6 ± 9.8
Duration of dark circles and wrinkling (range in years)	0.5 to 5

Table 3: Effect of Under Eye Cream on clinical evaluation of various parameters				
No.	Parameters	Clinical evaluation		
		Initial	Visit II	Visit III
1.	Anti-wrinkle effect	0.00 ± 0.00	1.55 ± 0.60 <i>p</i> <0.001	1.73 ± 0.63 <i>p</i> <0.001
2.	Anti-laxity effect	0.00 ± 0.00	0.45 ± 0.60	0.59 ± 0.91
3.	Skin tightening effect	0.00 ± 0.00	0.41 ± 0.59	0.50 ± 0.86
4.	Refreshing effect	0.00 ± 0.00	0.82 ± 0.85 <i>p</i> <0.05	1.00 ± 1.11 <i>p</i> <0.05
5.	Cleansing effect	0.00 ± 0.00	1.36 ± 0.58 <i>p</i> <0.001	1.50 ± 0.67 <i>p</i> <0.001
6.	Soothing effect	0.00 ± 0.00	1.23 ± 0.75 <i>p</i> <0.001	1.41 ± 0.73 <i>p</i> <0.001
7.	Dark circles improvement	0.00 ± 0.00	1.64 ± 0.49 <i>p</i> <0.001	1.86 ± 0.56 <i>p</i> <0.001
8.	Removal of lines	0.00 ± 0.00	1.05 ± 0.72 <i>p</i> <0.001	1.09 ± 0.87 <i>p</i> <0.001
Note: Significance as compared to initial values				

accentuated by poor blood circulation, free radical formation which has been blamed to be causative agent. The photo ageing by UV rays involves competing reactions, chain cleavage and cross linking specially due to long term exposure. These factors may increase collagen and elastic formation. The inflammatory stimuli will increase the synthesis and alpha melanocyte stimulating hormone leading to possibility of increased deposition of dark pigment such as melanin. The Under Eye Cream of The Himalaya Drug Company, Bangalore, has plant ingredients like *Winter begonia*, *Cipadessa baccifera* and *Wheat germ oil* and they have dermatological beneficial effects. *Winter begonia*, botanically known as *Bergenia ciliata*, has small pink flowers which emerge in spring and has beneficial medicinal effects. It has cytoprotective, antibacterial and anti-inflammatory effect.⁷⁻⁹ *Wheat germ* supplementation has anti-oxidant efficacy and decreases oxidative stress.¹⁰⁻¹² Present evaluation indicates clinically beneficial effect of Under Eye Cream and its safety as far as its anti-wrinkle effect is

concerned. It is possible that the beneficial effects seen with Under Eye Cream may be a sum total effect of these ingredients. This study also indicates safety of Under Eye Cream and it does not have any adverse effect on the eye structure.

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