Evaluation of the Anti-Wrinkle Efficacy and Adjuvant Effect of Age Intervention® Dark Circles Eye Defense, Aimed at Reducing the Appearance of Skin Imperfections Caused by Dark Circles and Bags under the Eyes

**Summary Provided by Jan Marini Skin Research, Inc.**

**INTRODUCTION.** Anyone who has dark circles knows how much older it can make you look and feel. Even with a healthy sleeping pattern, one can still appear exhausted with the appearance of under-eye discoloration. While concealer is often used as a means to cover-up the unsightly problem, many women hope to be able to look refreshed without using makeup, let alone resorting to laser and injectables. In recent years, the amount of concerns regarding under-eye circles has grown significantly. Roughly 53 percent of the 13,000 Clinique users surveyed by the company in 2006 cited under-eye circles and puffiness as their number one beauty concern. In response to increasing consumer demand for an effective topical product to address the appearance of dark circles and skin imperfections under the eyes, Jan Marini Skin Research has introduced Age Intervention® Dark Circles Eye Defense. This product contains pure Retinol in Microsponge®, that is already known as an excellent anti-wrinkle ingredient, in combination with a new special blend of ingredients in Microsponge, that has been tested for its efficacy to fight against dark circles.

**SUMMARY.** Under the conditions employed in this study, Age Intervention Dark Circles Eye Defense was effective in addressing the appearance of dark circles. Results of visual/clinical assessment were corroborated instrumentally with significant improvement observed in skin elasticity, smoothness, wrinkleness, wrinkle volume. Subjectively, product performance was perceived well and 90% of participants reported desire to continue usage of the product and positive purchase intent.

**BACKGROUND**

As an area that does not have as many oil glands in comparison to the rest of the skin, the skin around the eyes is more prone to fine lines and dehydration. Dark circles, along with fine lines and wrinkles, under the eyes create what is widely perceived as an old, tired appearance. Dark circles can be caused by a variety of different factors. Among the most common are: 1. Thinning skin on the lower eyelids allowing pigment and vessels to be more visible, 2. Gravity which causes under eyelid skin to move downward, initiating more stretching and thinning; thus, allowing blood vessels and pigment to become more noticeable as well as skin to lose its elasticity and become more saggy, 3. Cumulative sun damage plays a significant role in exacerbating the appearance of dark circles by increasing both skin thinning and melanin content, 4. Inflammation.

**STUDY DESIGN**

**Subjects**

For the study purposes, 20 healthy female subjects were enrolled by a dermatologist.

Inclusion Criteria
- Female healthy subjects
- Age: between 30 and 65 years old.
- Type: Caucasian
- Subjects involved in the test who have wrinkles
- Subjects who have eye bags and eye rings
- Subjects who have not been involved in any other similar study for at least the last two months
- Absence of skin disease
- Negative anamnesis for atopy

**Methods**

All subjects followed the product’s mode of use: (1) Remove the cap of the capsule using either the fingers or a scissor. (2) Press the capsule and apply the product around the eyes, once a day, using the fingers. Evaluation of anti-wrinkle efficacy was conducted after 60 days of product continuative use with intermediate checks after 15, 30, 45 and 60 days.

Subjects were evaluated back on the following parameters:

**Instrumental and clinical evaluations**

**Skin elasticity**

Skin elasticity measurement is based on the suction/elongation method with the subsequent release of the skin inside the opening of the instrument device. The instrument used for measuring is the cutometer (CUTOMETER® MPA 580). In this study the skin elasticity is calculated by the ratio between the residual deformation and the maximum elongation of the skin or Ua/Uf. This ratio is known in literature as R2 and indicates the ability of the skin to return to its original state of recovery after a stressing event. Closer the value is to 1, more elastic the skin is.

**Skin profilometry**

Decrease of wrinkle depth is measured by means of Visioscan VC 98; a camera used for in vivo analysis of skin surface. The parameters valued in the image analysis are:
- SEw: skin micro-wrinkleness
- SESm: skin smoothness
- Wrinkle volume

---

1 Fulvio Marzatico, Ph.D., Michela Quaglini, Ph.D., Angela Michelotti, Ph.D., “Evaluation of the Anti-Wrinkle Efficacy and Adjuvant Effect of Age Intervention® Dark Circles Eye Defense, Aimed at Reducing the Appearance of Skin Imperfections Caused by Dark Circles and Bags under the Eyes” FaroDerm s.r.l.
Digital photography
Images are taken using a KODAK EASY SHARE DX6490 camera. (© Eastman Kodak Company, 2003 – Kodak and EasyShare are trademark of Eastman Kodak Company). The camera was set up to the best quality of image (2304 x 1728 pixel, 4.0 Mp). Red (Δa) and blue (Δb) components of the skin were measured using a software dedicated for image analysis.

Clinical evaluation
Clinical evaluations are taken by the dermatologist according to the clinical scores reported in the tables to the right (Figure 1).

Self Assessment
After 60 days of product use the subjects are asked to express their personal opinion answering to a questionnaire.

RESULTS

Skin Elasticity
The percentage change in the mean ratio between the residual deformation and the maximum elongation of the skin (Ua/Uf) at each experimental time point vs. T0:
- T15 (After 15 days): 3.9%
- T30 (After 30 days): 9.2%
- T45 (After 45 days): 14.3%
- T60 (After 60 days): 15.2%

The use of the product demonstrates a statistically significant (p<0.001) increase in skin elasticity at each experimental time point.

Clinical Analysis of Elasticity
After 15 days, an improvement is evident on 15% of the subjects
After 30 days, an improvement is evident on 75% of the subjects
After 45 days, an improvement is evident on 90% of the subjects
After 60 days, an improvement is evident on 95% of the subjects

The clinical analysis carried out confirms the profilometric instrumental analysis (SESm).

Skin Profilometry

SESm: Skin Smoothness
The percentage change in mean SESm at each experimental time point vs. T0:
- T15 (After 15 days): 9.7%
- T30 (After 30 days): 16.3%
- T45 (After 45 days): 21.8%
- T60 (After 60 days): 23.2%

The use of the product demonstrates a statistically significant (p<0.001) increase in skin smoothness at each experimental time point.

Clinical Analysis of Skin Smoothness
After 15 days, an improvement is evident on 15% of the subjects
After 30 days, an improvement is evident on 70% of the subjects
After 45 days, an improvement is evident on 90% of the subjects
After 60 days, an improvement is evident on 90% of the subjects

The use of the product demonstrates a statistically significant (p<0.001) decrease in skin wrinkleness at each experimental time point.

SEw: Skin Wrinkleness
The percentage change in mean SEw at each experimental time point vs. T0:
- T15 (After 15 days): -3.9%
- T30 (After 30 days): -6.8%
- T45 (After 45 days): -10.6%
- T60 (After 60 days): -12.7%

The use of the product demonstrates a statistically significant (p<0.001) decrease in skin wrinkleness at each experimental time point.

Wrinkle Volume
The percentage change in mean wrinkle volume at each experimental time point vs. T0:
- T15 (After 15 days): -5.9%
- T30 (After 30 days): -17.4%
- T45 (After 45 days): -19.3%
- T60 (After 60 days): -21.0%

The use of the product demonstrates a statistically significant (p<0.001) decrease in wrinkle volume at each experimental time point.

Clinical Analysis of Skin Wrinkles
After 15 days, an improvement is evident on 30% of the subjects
After 30 days, an improvement is evident on 75% of the subjects
After 45 days, an improvement is evident on 90% of the subjects
After 60 days, an improvement is evident on 95% of the subjects
Clinical analysis carried out confirms the profilometric instrumental analysis (SEw and Volume) in the decrease in wrinkle appearance.

**Image Analysis of Digital Photography**

**Red Component of the Eye Rings**

The percentage change in mean measurement of red component at each experimental time point vs. T₀:
- T₁₅ (After 15 days): -6.3%
- T₃₀ (After 30 days): -7.2%
- T₄₅ (After 45 days): -10.7%
- T₆₀ (After 60 days): -12.1%

The use of the product demonstrates a statistically significant (p<0.001) decrease in the red component of the eye ring at each experimental time point.

**Blue Component of the Eye Rings**

The percentage change in mean measurement of blue component at each experimental time point vs. T₀:
- T₁₅ (After 15 days): 3.2%*
- T₃₀ (After 30 days): 4.9%*
- T₄₅ (After 45 days): 9.2%*
- T₆₀ (After 60 days): 10.2%*

The use of the product demonstrates a statistically significant (p<0.001) decrease* in the blue component of the eye ring at each experimental time point.

* Being on a negative axis, the parameter increases. This increase corresponds to a decrease in the intensity of the eye ring blue color.

**Clinical Analysis of Dark Color of the Eye Rings**

After 15 days, an improvement is evident on 40% of the subjects
After 30 days, an improvement is evident on 70% of the subjects
After 45 days, an improvement is evident on 100% of the subjects
After 60 days, an improvement is evident on 100% of the subjects

The clinical analysis carried out confirms the instrumental analysis. The use of the product demonstrates a decrease in the appearance of eye rings at each experimental time point.

**Self Assessment**

The following is a summary of results from the self assessment each subject completed after the study period of 60 days:

Have you experienced skin redness/itching/stinging sensation?
- Yes: 0%
- No: 100%

Have you experienced skin desquamation or dryness side effects?
- Yes: 0%
- No: 100%

Does the product apply easily on the skin?
- Enough: 30%
- A lot: 70%

Is it pleasant?
- Not at all: 0%
- A little: 0%
- Enough: 25%
- A lot: 75%

Do you want to continue using the product?
- Yes: 90%
- No: 10%

Would you recommend this product to a friend?
- Yes: 90%
- No: 10%

Would you buy this product?
- Yes: 90%
- No: 10%

**Photographic Evaluations**

*Figure 2A. Subject at T₀*

*Figure 2B. Subject at T₆₀*

The images show the efficacy of Age Intervention® Dark Circles Eye Defense on the appearance of the eye rings. Figure 2A depicts a subject at baseline (T₀) whereas Figure 2B depicts the subject after 60 days of continuous product use (T₆₀). Notice that the product is effective in improving the color of the eye rings and also the smoothing effect it has on the sub-palpebral area.
The images above report the skin surface at baseline through the study term of 60 days of continuous product use. Notice the skin appears more lifted and the wrinkles attenuated.

### Conclusion

Treatment for 60 days with Age Intervention Dark Circles Eye Defense shows an improvement of the skin trophism as stressed by the improvement of the elasticity and the skin compactness. The skin appears more compact and the wrinkles are attenuated, as demonstrated by both the profilometrical analysis and the clinical evaluation carried out by the dermatologist.

Moreover, the use of the product helps to reduce the dark color of the eye ring. In fact, both the instrumental analysis and the clinical evaluation carried out by the dermatologist highlight an attenuation of the eye ring visibility, that is, of their typical color.

The efficacy of the product on the skin wrinkleness and on the improvement of the eye ring is, also confirmed by the subjects participating in the study in that 90% of the cases judged it from “a little” to “very efficacious”.

### Safety Profile

No adverse reactions were observed in any of the volunteers during the test period.

A separate independent repeated insult (semi-occlusive) patch test conducted in 49 subjects demonstrated that under conditions of the test, the product was not associated with skin irritation or allergic contact dermatitis in human subjects.