

Use of the Jan Marini Skin Care Management System™ in Addressing the Appearance of Facial Skin Concerns: Efficacy Evaluation

Study Conducted and Summary Provided by Jan Marini Skin Research, Inc.

ABSTRACT. The Jan Marini Skin Care Management System (SCMS) is a 5-step physician and skin care professionally dispensed home care skin rejuvenation program. This paper presents the efficacy results of the SCMS in addressing the appearance of common skin concerns in 32 subjects, with a primary focus on the appearance of acne (Category I), pigmentation (Category II), rosacea (Category III), and overall skin rejuvenation (Category IV).

SUMMARY. 100% of subjects showed visible photographic response. Study responses were defined as moderate, strong, or dramatic, with an excellent safety profile. 75% to 86% of the subjects in all categories assessed experienced a dramatic response under the SCMS. Side effects were noted in only two of the subjects and were transient in nature.

Detailed descriptions of the study methodology, as well as study responses, are presented.

STUDY DESIGN

Subjects

This study included 32 female subjects, age range from 23 to 62 years old (median 46).

Of the 32 total subjects, 19 (59.375%) were categorized as Caucasian, 1 (3.125%) was African-American, 4 (12.5%) were Hispanic, 4 (12.5%) were Asian, and 4 (12.5%) were Other (i.e. Palestinian, Lebanese, Persian).

Based on baseline evaluation, subjects were assigned into one or more of the following skin type categories:

CATEGORY I: ACNE

Acne lesions including papules, pustules, nodules and cysts

CATEGORY II: PIGMENTATION

The appearance of melasma, skin discoloration and non-uniformity of skin pigment

CATEGORY III: ROSACEA

The appearance of skin characteristics associated with rosacea such as redness and flushing, telangiectasia, secondary rosacea lesions and coarse texture

CATEGORY IV: OVERALL SKIN REJUVENATION

The appearance of skin per the following sub-categories:

- Fine lines/Wrinkles and Photodamage
- Texture/Smoothness
- Elasticity/Firmness

Methods

At baseline evaluation, subjects provided informed consent and their personal history was recorded. Jan Marini Skin Research (JMSR) conducted a thorough skin care consultation with each subject to determine the appropriate SCMS to best suit their concerns. Subjects were instructed to use the SCMS as directed morning and evening for the duration of the study. For this study, SCMS used by all subjects included at least four out of the five basic SCMS steps (i.e. Cleanse, Rejuvenate,

Resurface, Hydrate, Protect). Of the 32 subjects, 5 (16%) were on a 4-step SCMS and 27 (84%) were on a complete 5-step SCMS.

Follow-up visits with each subject at the JMSR corporate clinical facility were conducted every 2 to 4 weeks and subsequently adjusted to every 2 weeks. Photos of baseline and subsequent follow-ups were taken using the Canfield Imaging System and Mirror Software Program (zoom set between 19-23 and photos magnified at 50% to 100% in relevant areas).

Subjects were followed from a range of 8 to 128 weeks, with a median study period of 44 weeks. Success was based on the improvement from baseline, and was visually assessed as moderate, strong, or dramatic at the close of each subject's study period. Participant satisfaction evaluations were also conducted at the close of each subject's study period.

RESULTS

Category I: Acne

16 subjects were placed in this category as they exhibited a range of persistent inflammatory acne from mild papules and pustules to nodules and severe cysts. All Category I subjects used Age Intervention® Transitions as part of their SCMS. Subjects showed visible improvement from baseline in 2 to 8 weeks with the median being 2 weeks. Within this group, 12 (75%) had a Dramatic response, 1 (6%) had a Strong response, and 3 (19%) had a Moderate response (Figure 1).

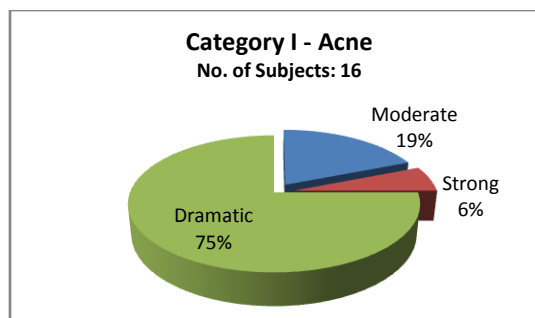


Figure 1.

According to participant satisfaction evaluations, 100% of subjects reported that they had fewer acne lesions up to and including total clearing and believed they saw an improved appearance of skin texture and overall skin refinement. Overall, 94% of the subjects experienced increased confidence and self-esteem as 88% believed that improvements continued to be progressively more noticeable to themselves and to others.

Category II: Pigmentation

13 subjects were placed in this category as they exhibited obvious discoloration. All Category II subjects used Age Intervention Enlighten as part of the SCMS. Subjects showed visible improvement from baseline in 2 to 8 weeks with the median being 4 weeks. Within this group, 11 (85%) had a Dramatic response in lessening the appearance of discoloration, 1 (7.5%) had a Strong response, and 1 (7.5%) had a Moderate response (Figure 2).

Enlighten demonstrated a superior safety profile over other leading products on the market that address the appearance of discoloration. All 13 subjects on Enlighten showed no signs of inflammation, itching, or peeling of the skin – side effects often associated with ingredients commonly found in other prescription/non-prescription products, such as hydroquinone.

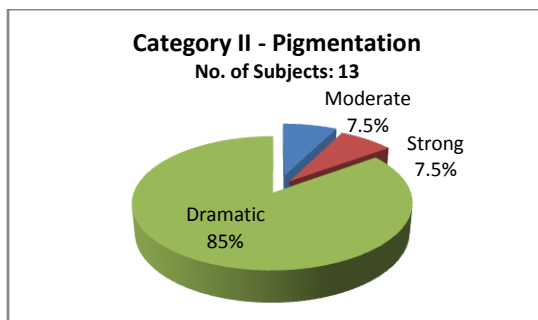


Figure 2.

According to participant satisfaction evaluations, 100% of subjects believed they saw visible improvement of skin tone and uniformity. Overall, subjects reported an increase in self confidence as 92% of the subjects lessened or discontinued the application of camouflage or “cover up” facial products. 85% of subjects noted improvements were significantly visible to others.

Category III: Rosacea

7 subjects were in this category as they showed symptoms such as persistent erythema, telangiectasia, and/or papules and pustules. All subjects showed visible improvement from baseline in 2 weeks. Within this group, 6 (86%) had a Dramatic response and 1 (14%) had a Strong response (Figure 3).

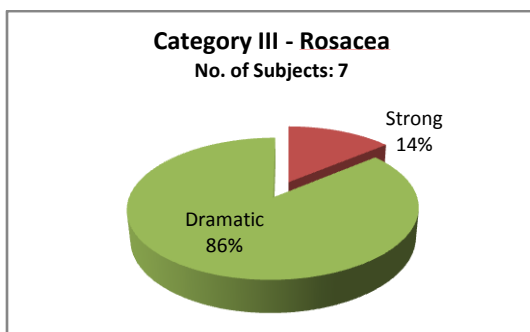


Figure 3.

According to participant satisfaction evaluations, 100% of subjects believed they saw visible improvement in the appearance of their rosacea symptoms and that their rosacea was significantly more manageable and predictable. All subjects reported fewer or no episodes of intense redness or blushing and improved skin refinement and texture leading to either a significant decrease in the usage of cover up makeup or a complete discontinuation in the use of cover up skin products, resulting in their increased confidence and self-esteem. 86% of subjects noted that the appearance of their rosacea was mostly or completely resolved, and that the responses were visible to others.

Category IV: Overall Skin Rejuvenation

21 subjects were placed in the category as they exhibited either textural issues including fine lines, wrinkles, large pores, rough appearance, crepiness and skin laxity. Subjects showed visible improvement from baseline in 2 to 4 weeks with the median being 2 weeks. Within this group, 18 (86%) had a Dramatic response in the improvement of overall skin rejuvenation, 2 (9.5%) had a Strong response, and 1 (4.5%) had a Moderate response (Figure 4).

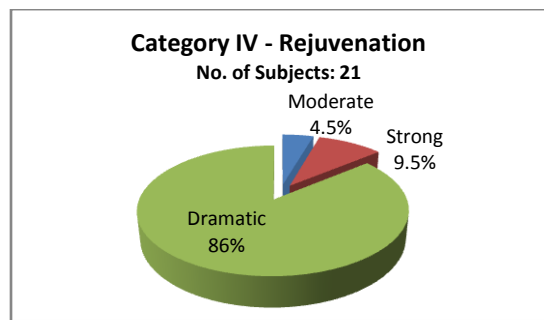


Figure 4.

Subjects in the Overall Skin Rejuvenation category were further evaluated and noticed improvements in the following subcategories:

- Fine lines/Wrinkle and Photodamage
- Texture and Smoothness
- Elasticity and Firmness

Fine lines/Wrinkles and Photodamage:

Subjects had visible improvement in lines and wrinkles in 2 to 6 weeks with a median of 2 weeks. 17 Subjects (81%) had a Dramatic response in the improvement of the appearance of lines/wrinkles, while 3 (14%) had a Strong response and 1 (5%) had a Moderate response (Figure 5).

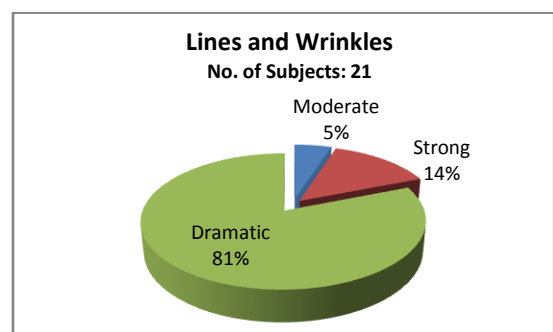


Figure 5.

Texture and Smoothness:

Subjects had visible improvement in texture and smoothness in 2 to 4 weeks with a median of 2 weeks. 19 subjects (90%) had a Dramatic response in improvement of the appearance of skin texture and smoothness while 2 (10%) had a Strong response (Figure 6).

Elasticity and Firmness:

Subjects had visible improvement in elasticity and firmness in 2 to 8 weeks with a median of 2 weeks. 18 subjects (86%) had a Dramatic response, 2 (9.5%) had a Strong response, and 1 (4.5%) had a Moderate response (Figure 7).

According to participant satisfaction evaluations, 100% of subjects reported seeing skin improvement, 71% of which believed that the improvement was dramatic. 95% of the subjects felt more attractive, youthful and confident while 90% of the subjects noted that these improvements were visible to others.

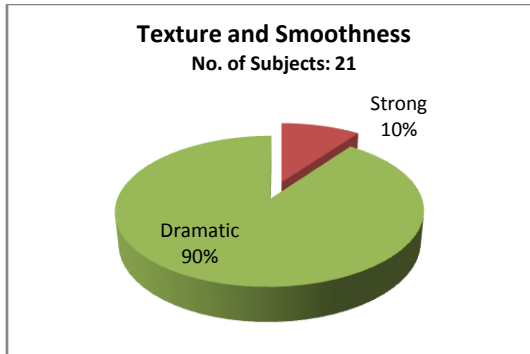


Figure 6.

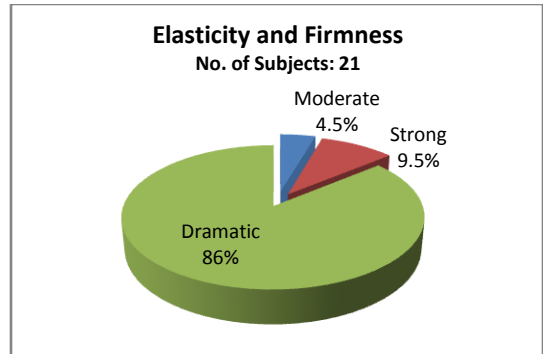


Figure 7.

PHOTOGRAPHIC EVALUATIONS

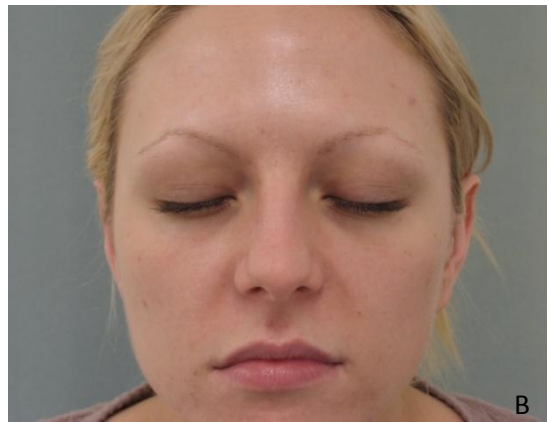
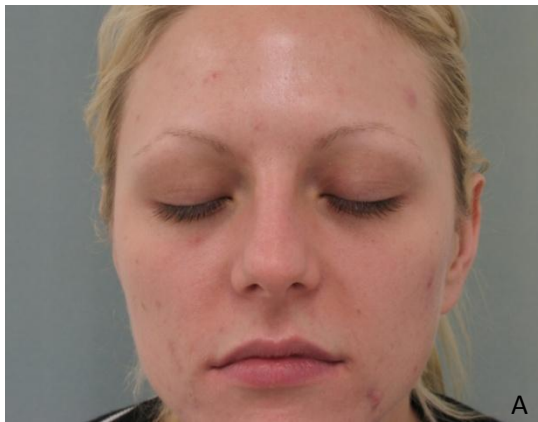


Figure 8. Figure 8A depicts a subject within Category I at baseline. Figure 8B illustrates a dramatic response at week 16. This sample demonstrates the strong efficacy of the SCMS in addressing the appearance of acne within a short study period.



Figure 9. Figure 9A depicts a subject within Category II at baseline. Figure 9B illustrates a dramatic response at week 65. This sample demonstrates the continued increase in efficacy of the SCMS in addressing the appearance of pigmentation within an extended study period.



Figure 10. Figure 10A depicts a subject within Category III and Category IV at baseline. Figure 10B illustrates a dramatic response at week 8. This sample demonstrates the strong efficacy of the SCMS in addressing the appearance of rosacea and overall skin rejuvenation (e.g. softening in the appearance of wrinkles in the under eye area) within a short study period.

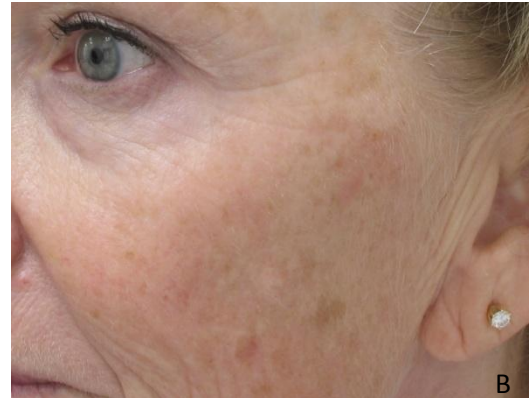


Figure 11. Figure 11A depicts a subject within Category II and Category IV at baseline. Figure 11B illustrates a dramatic response at week 104. This sample demonstrates the continued increase in efficacy of the SCMS in addressing the appearance of pigmentation and overall skin rejuvenation (e.g. softening in the appearance of crow's feet and wrinkles in the under eye area) within an extended study period.

CONCLUSION

The Skin Care Management System was shown to be effective in providing moderate to dramatic improvements to a range of common skin concerns, with a primary focus on the appearance of acne, pigmentation, rosacea, and overall skin rejuvenation. The SCMS provided visible photographic improvements amongst 100% of the subjects. Subjects within each skin category experienced an overwhelmingly dramatic response in their photographic evaluations, ranging from 75% to 86%. The SCMS proved to be effective in addressing the appearance of textural issues including fine lines/wrinkles and photodamage, skin texture and smoothness, & elasticity and firmness.

Of the 32 subjects, 2 (6%) experienced contraindications (i.e. transient dryness and flaking) which were easily resolved and did not require their release from the study. In the first instance, a longer acclimation period was necessary with the Resurfacing step. In the second instance, the addition of a more emollient Hydrator alleviated any mild dryness.

Within the participant satisfaction evaluations, 100% of the subjects in each skin category reported seeing improvements to their skin. An average 87% of the subjects in each skin category noted that the improvements were visible to immediate family and peers.

In addition, participant satisfaction evaluations showed that 100% of the subjects in this study reported satisfaction with the ease of application and that they would continue to use and purchase the SCMS. 100% of the subjects under Categories II to IV reported satisfaction with the ease of acclimation, while 94% of subjects under Category I reported satisfaction when posed with the same inquiry.