SKINCEUTICALS

SILYMARIN CF

INTRODUCTION

Acne is a chronic inflammatory disease that is common in adolescents, but blemish-prone skin can persist well into adulthood. Its pathogenesis is characterized by increased sebum production, follicular hyperkeratinization, c. acnes colonization, and inflammation, which manifests as visible cutaneous lesions such as blackheads, whiteheads, papules, and pustules.[1]

Growing research shows a causative link between oil oxidation and the formation of blemishes. Blemish-prone skin is known to have higher levels of oxidative stress and lower levels of antioxidants than healthy skin. Daily environmental factors like UV and pollution generate free radicals that can exacerbate this condition. Oxidative stress, particularly lipid peroxidation, contributes to inflammation, which creates a favorable environment for acne-causing bacteria, which may ultimately lead to breakouts. There is an opportunity for a topical antioxidant treatment to help disrupt this pathogenesis and prevent breakouts. Silymarin is an antioxidant derived from the milk thistle plant that is shown to prevent oil oxidation that can contribute to blemishes, and thus serve as a promising ingredient for blemish-prone skin.[2-4]

Silymarin CF is a powerful triple-antioxidant serum featuring a combination of 0.5% silymarin, 15% L-ascorbic acid, and 0.5% ferulic acid to provide protection against free radicals that cause premature signs of aging and oil oxidation that may contribute to breakouts. This oil-free serum also contains 0.5% salicylic acid to help clear blemishes and prevent new breakouts from forming. Formulated with an optimal combination of glycols and at a low pH in accordance with the Duke parameters, Silymarin CF helps reduce fine lines and wrinkles, minimize pore appearance, and refine skin texture.

SkinCeuticals conducted a series of comprehensive clinical tests to assess the effectiveness of Silymarin CF across parameters of aging, as well as inflammatory and lipid peroxidation markers in blemish prone skin (Table 1).

TABLE 1 - STRATEGIC CLINICAL TESTING OVERVIEW

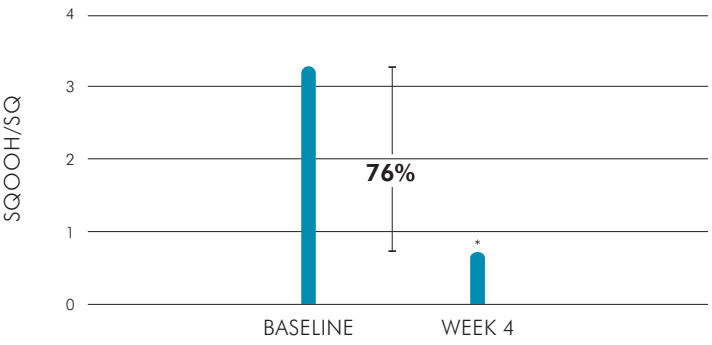
STUDY	N	RECRUITMENT	DURATION	DESCRIPTION
Ex Vivo Lipid Peroxidation	--	--	1 Day	Evaluation of ability to prevent peroxidation of sebum collected from human volunteers upon UV exposure
Clinical study on oily, blemish-prone skin (China)	53	Ages 18–50 Fitzpatrick skin type III–IV	12 Weeks	Consumer self-assessment. Analysis for markers of lipid peroxidation and sebumeter analysis.
Minimum Erythemal Dose (MED) study	12	Ages 18–60 Fitzpatrick skin type II–III	1 Week	Evaluation of protection from UV radiation. Colorimeter analysis of erythema. Biopsy analysis for markers of damage and inflammation.
Clinical study on oily, blemish-prone skin (Brazil)	60	Ages 18–50 Fitzpatrick skin type II–V	12 Weeks	Clinical grading on skin tone, clarity and PIH. Consumer self-assessment. Analysis for markers of lipid peroxidation and sebumeter analysis.
Clinical study on signs of aging	55	Ages 25–50 Fitzpatrick skin type I–V	8 weeks	Clinical grading on signs of aging including wrinkles, fine lines, firmness, radiance, texture, skin tone evenness. Consumer self-assessment.

CLINICAL TESTING

LIPID PEROXIDATION

SkinCeuticals evaluated Silymarin CF for its effectiveness in preventing sebum peroxidation both ex vivo and in blemish-prone skin in vivo. The in-vivo lipid peroxidation evaluation was part of a clinical study in which 53 Asian male and female subjects aged 18–50 with mild-to-moderate blemishes applied the serum once daily. A randomized subset of 35 subjects had sebum sampled from the forehead at baseline and week 4. At week 4, subjects showed a significant reduction in both oiliness and squalene peroxidation compared to baseline (Figure 1).

FIGURE 1 – IN VIVO REDUCTION IN LIPID PEROXIDATION

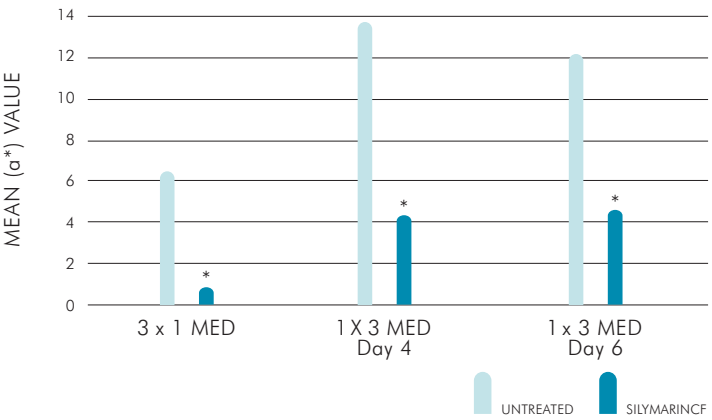


Statistically significant change from baseline ($p \leq 0.05$)

MINIMAL ERYTHEMAL DOSE (MED)

Silymarin CF was evaluated for its ability to protect from markers of cutaneous damage and inflammation when exposed to several dosage concentrations and patterns of UV radiation. Subjects received application of Silymarin CF on the back for four consecutive days followed by UV-irradiation with one exposure of 3 x MED or three consecutive daily exposures of 1 x MED. Measurements of erythema and photographs were taken 24 hours after the final exposure. Silymarin CF provided significant protection from UV induced redness under all conditions tested (Figure 2). Silymarin CF provided especially good protection from consecutive doses of 1 x MED of UV radiation which is likely more representative of realistic daily usage by consumers. Under more extreme exposure conditions of 3 x MED of UV radiation, the formula still provided significant protection from redness.

FIGURE 2 – SILYMARIN IMPACT ON ERYTHEMA INDUCED BY UV RADIATION

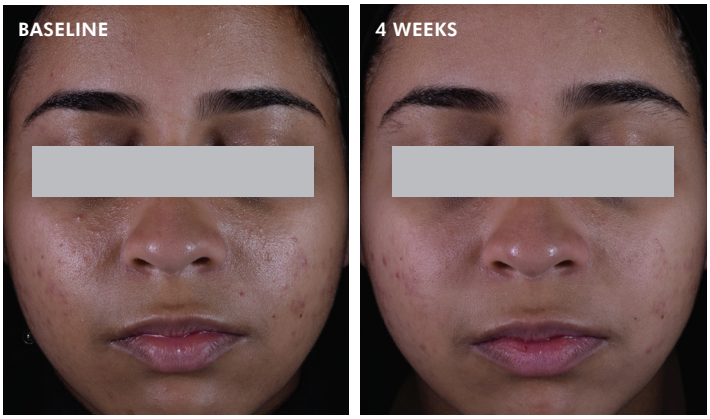


Statistically significant change from baseline ($p \leq 0.05$)

OILY AND BLEMISH-PRONE SKIN

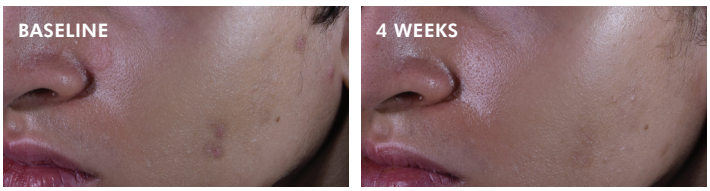
SkinCeuticals evaluated Silymarin CF to assess its effectiveness across multiple parameters in oily, blemish-prone skin. A 12-week, single-center study was conducted on 60 men and women ages 18–50 with oily and blemish-prone skin. Silymarin CF was applied once daily in conjunction with a sunscreen. While the study is ongoing, 4-week results show statistically and clinically significant improvement in skin clarity by 13%, post-inflammatory hyperpigmentation (PIH) by 13%, and overall appearance by 12%. Figures 3 and 4 show visual improvement in subjects across these parameters. In addition, sebumeter testing showed a 16% reduction in oiliness at week 1.

FIGURE 3 – VISIBLE IMPROVEMENT IN OVERALL APPEARANCE



AVERAGE results

FIGURE 4 – VISIBLE IMPROVEMENT IN CLARITY AND PIH

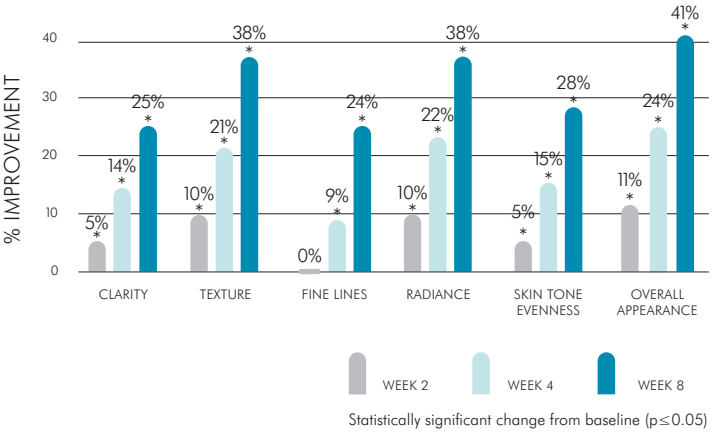


AVERAGE results

AGING

SkinCeuticals evaluated Silymarin CF for its efficacy in reducing signs of premature aging. A double-blinded clinical study was conducted over the course of 8 weeks on 55 subjects between the ages of 25–50 who presented with mild-to-moderate signs of facial photodamage. Subjects applied the serum to the face once daily, followed by a sunscreen, for the duration of the study. Investigator clinical grading, tolerance evaluations, and subject self-assessments were conducted at baseline, and weeks 2, 4, and 8. Clinical images were collected at all time points. Subjects showed statistically significant improvements in fine lines, radiance, clarity, uneven skin tone and skin texture when compared to baseline (Figure 5). After 2 weeks of treatment, subjects showed statistically significant improvement in skin texture and radiance. By week 4, subjects also displayed significant improvement in fine lines, wrinkles, pigmentation, skin tone evenness, and skin clarity. At week 8, significant improvement in skin firmness and laxity were also observed. The overall appearance of facial skin steadily improved throughout the course of the study. Furthermore, Figures 6–8 show visual improvement in the subjects across multiple parameters. Overall, Silymarin CF was well tolerated by subjects through the course of the study.

FIGURE 5 – SIGNIFICANT IMPROVEMENT ACROSS KEY MARKERS OF VISIBLE AGING



Statistically significant change from baseline ($p \leq 0.05$)

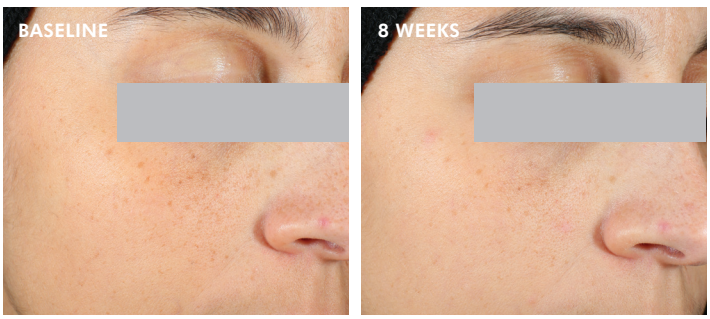
FIGURE 6 – VISIBLE IMPROVEMENT IN SKIN TEXTURE

AVERAGE results

FIGURE 7 – VISIBLE IMPROVEMENT IN TEXTURE AND FINE LINES

AVERAGE results

FIGURE 8 – VISIBLE IMPROVEMENT IN SKIN RADIANCE AND CLARITY



AVERAGE results

CONCLUSION

Silymarin CF is shown to have significant benefit in reducing lipid peroxidation, oiliness, PIH, and improving key markers of skin aging and overall appearance. In addition, clinical testing demonstrated significant improvement in these clinical skin attributes, which could serve as a promising solution for a variety of aging concerns, specifically in oily, blemish-prone skin. Clinical studies are ongoing in blemish-prone skin, however, results are promising thus far and have shown both statistical and clinical significance across multiple parameters.

REFERENCES

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