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ORIGINAL ARTICLE

Open-Label assessment of the efficacy and tolerability of a skin care regimen for treating subjects with visible and physical symptoms of sensitive skin

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Abstract

Background: Sensitive skin is a common concern with 60%–70% of women and 50%–60% of men reporting skin sensitivity and redness. Facial redness is associated with a higher incidence of embarrassment, social anxiety, and diminished quality of life. While there is no cure for sensitive skin, it can be controlled.

Aims: The objective of this 12-week, open-label clinical trial was to assess the efficacy and tolerability of a topical facial regimen for treating subjects with facial redness and sensitive skin.

Patients/Methods: Enrolled subjects were healthy male and female individuals, 25–60 years old with Fitzpatrick skin types I–VI who were seeking treatment for moderate or severe facial redness. Subjects were provided with products which were applied each morning and evening. The investigator assessed change in subject appearance using Overall Redness and Global Improvement Scales and subjects rated changes in appearance and tolerability with self-assessment scales.

Results: The mean Overall Redness Scale Score improved by 34% and 25% at Weeks 8 and 12, respectively. There was Mild or Moderate improvement in Global Improvement Scale scores beginning at Week 2 with over 50% achieving Marked improvement by Week 12. All subjects Agreed or Strongly Agreed that their facial redness was less noticeable, their skin appeared less inflamed, overall skin appearance improved, and skin looked and felt healthier at Week 12. The regimen was well-tolerated.

Conclusions: This study demonstrated a treatment regimen designed to neutralize skin redness and calm inflamed skin was well-tolerated and improved the symptoms of sensitive skin.

KEYWORDS
clinical trial, efficacy, sensitive skin, tolerability, topical facial regimen

1 | INTRODUCTION

Sensitive skin is a common concern affecting 60%–70% of women and 50%–60% of men.[1] An expert panel has defined sensitive skin as "a syndrome defined by the occurrence of unpleasant sensations (stinging, burning, pain, pruritus, and tingling sensations) in response to stimuli that normally should not provoke such sensations. These unpleasant sensations cannot be explained by lesions attributable to any skin disease. The skin can appear normal or be accompanied by erythema. Sensitive skin can affect all body locations, especially the face."[2]

Changes in epidermal barrier function and neurosensory dysfunction are strongly associated with sensitive skin.[1] Signs of sensitive skin can be visible such as redness and also sensory including

itching, burning stinging, tightness, and dryness.[3] Numerous triggers are known to exacerbate sensitive skin including hot beverages, sunlight, alcohol, spicy foods, caffeine, air pollution, tobacco smoking, and psychological stress.[4–6] The psychosocial effects of rosacea, which is understood to be a contributing factor to sensitive skin, are well-known. Affected individuals have higher a incidence of embarrassment, social anxiety, depression, and overall diminished quality of life.[7,8]

There may not be a cure for sensitive skin, but it can be controlled. As the signs and symptoms of skin reddening can be variable in type and severity and be remitting or persistent, a variety of treatments may be recommended. A systematic literature review comprising 106 studies included 13 631 subjects with moderate to severely reddened skin (rosacea).[9] This review reported high-quality evidence supporting the efficacy of topical azelaic acid, topical ivermectin, oral brimonidine, doxycycline, and isotretinoin for rosacea; moderate-quality evidence for topical metronidazole and oral tetracycline; and low-quality evidence for low-dose minocycline, laser, and intense pulsed light therapy.[9] Approximately half of the studies reviewed reported subjective assessments, only 11 assessed changes to quality of life, and almost all studies reported treatment-related adverse events.

A proprietary non-steroidal topical complex, BioSolace®, has been developed to improve the skin barrier function, reduce inflammatory effects, and provide relief of physical symptoms of sensitive skin. The BioSolace® Complex is incorporated into two formulations. All Calm® Multi Correction Serum and All Calm® Clinical Redness Corrector SPF 50 (Colorescience, Inc., Carlsbad, CA, USA). These two products along with a mineral powder sunscreen, Sunforgettable® Total Protection Brush-on Shield SPF 50 (Colorescience, Inc.) comprise the skincare regimen. The objective of this 12-week, open-label clinical trial was to assess the efficacy and tolerability of this topical facial product regimen for treating subjects with moderate or severe facial redness and sensitive skin.

2 | METHODS

2.1 | Subjects

The study enrolled generally healthy male and female subjects, 25–60 years old with Fitzpatrick skin types I–VI who were seeking treatment for moderate or severe redness on forehead, cheeks, nose, perioral area, or chin. Men with no beards and who shave regularly were allowed to participate. The study was open to subjects of any race or ethnicity. Each subject expressed their willingness to follow all study restrictions. These included restricted travel to areas with significantly increased sun exposure; starting or increasing current outdoor activity; and avoiding cosmetic procedures, such as

TABLE 1 Test product ingredients

All Calm® Serum
Water/aqua, glycerin, C13-15 alkane, dimethyl isosorbide, niacinamide, triethylhexanoin, caprylic/capric triglyceride, sorbitan stearate, polyglyceryl-2 diisostearate, disodium lauriminodipropionate tocopheryl phosphate, polyacrylate crosspolymer-6, bisabolol, sorbityl laurate, cetyl palmitate, *Tremella fuciformis sporocarp* (mushroom) extract, magnesium carboxymethyl beta-glucan, polysorbate 80, betaine, citric acid, *Crithmum maritimum* extract, t-butyl alcohol, hydrogenated lecithin, *Magnolia officinalis* bark extract, tocopherol, *Zingiber officinale* (ginger) root extract, glycolic acid, palmitoyl tetrapeptide-10, sodium benzoate, potassium sorbate, phenoxyethanol, benzoic acid, dehydroacetic acid, chloroacetic acid
All Calm® Clinical Redness Perfector® SPF 50
Active ingredients: titanium dioxide 11.6%, zinc oxide 8.6%. Inactive ingredients: cyclopentasiloxane, caprylic/capric triglyceride, dimethicone crosspolymer, water/aqua/eau, niacinamide, dimethicone/vinyl dimethicone crosspolymer, disteardimonium hectorite, propylene carbonate, disodium lauriminodipropionate tocopheryl phosphates, *Crithmum maritimum* extract, *Magnolia officinalis* bark extract, *Zingiber officinale* (ginger) root extract, magnesium carboxymethyl beta-glucan, *Jojoba* esters, bisabolol, silica, polyhydroxystearic acid, dimethiconol, alumina, glyceryl behenate/eicosadioate, phenoxyethanol, triethoxycaprylylsilane, ethylhexylglycerin, tocopherol, dehydroacetic acid, benzoic acid, glycolic acid, chloroacetic acid, chromium oxide greens (CI 77288), iron oxides (CI 77491, CI 77492, CI 77499)
Sunforgettable® Total Protection Brush-on Shield SPF 50
Active ingredients: Titanium dioxide 22.5%, zinc oxide 22.5%. Inactive ingredients: mica, dimethicone/vinyl dimethicone crosspolymer, dimethiconol/propylsilsesquioxane/silicate crosspolymer, *Lycopodium clavatum* extract, sodium hyaluronate, *Imperata cylindrica* root extract, glycerin, water, *Caesalpinia spinosa* fruit pod extract, *Vitis vinifera* (grape) seed extract, *Camellia sinensis* leaf extract, *Quercus robur* (oak) wood extract, *Helianthus annuus* (sunflower) sprout extract, maltodextrin, methicone, triethoxycaprylylsilane, laureth-4, sodium benzoate, potassium sorbate, chromium oxide greens (CI 77288), iron oxides (CI77491, CI 77492, CI 77499).
All products from Colorescience, Inc., Carlsbad, CA.
0
1
2
3
4

facial neurotoxin injection or dermal fillers, facial tattoos, and lash extensions.

Reasons for exclusion from study participation included hypersensitivity to any test product ingredients; active (flaring) skin diseases, such as atopic dermatitis, eczema or papulopustular rosacea; facial plastic surgery or ablative laser resurfacing during the preceding year; non-ablative laser resurfacing, neurotoxins, or dermal fillers during the preceding 3 months; superficial resurfacing treatment, such as chemical peel, microdermabrasion, microneedling, neurotoxin, or dermal fillers during the preceding 6 weeks; pregnancy, planned pregnancy, or nursing.

TABLE 2 Tolerability assessment scale

Erythema	
0	None/No erythema of the treatment area
1	Mild. Slight, but definite redness of the treatment area
2	Moderate. Definite redness of the treatment area
3	Severe. Marked redness of the treatment area
Edema	
0	None. No edema/swelling of the treatment area
1	Mild. Slight, but definite edema of the treatment area
2	Moderate. Definite edema of the treatment area
3	Severe. Marked edema of the treatment area
Dryness/Dehydration	
0	None. No dryness of the treatment area
1	Mild. Slight, but definite dryness of the treatment area
2	Moderate. Definite dryness of the treatment area
3	Severe. Marked dryness of the treatment area
Scaling	
0	None. No scaling of the treatment area
1	Mild. Barely perceptible, fine scales in limited areas of the treatment area
2	Moderate. Fine scaling generalized to all areas of the treatment area
3	Severe scaling and peeling of skin over all areas of the treatment area
Burning	
0	None. No burning of the treatment area
1	Mild. Slight burning sensation of the treatment area; not really bothersome
2	Moderate. Definite warm, burning of the treatment area that is somewhat bothersome
3	Severe. Hot burning sensation of the treatment area that causes definite discomfort, may interrupt daily activities and/or sleep
Stinging	
0	None. No stinging of the treatment area
1	Mild. Slight stinging sensation of the treatment area; not really bothersome
2	Moderate. Definite stinging of the treatment area that is somewhat bothersome
3	Severe. Marked stinging sensation of the treatment area that causes definite discomfort and may interrupt daily activities and/or sleep

2.2 | Test materials

Subjects were stratified to treatment Groups A and B and received treatment with one of two regimens using three products: Test Product A (All Calm® Multi Correction Serum), Test Product B (All Calm® Clinical Redness Corrector SPF 50), and Test Product C (Sunforgettable® Total Protection™ Brush-on Shield SPF 50). All products are from Colorescience, Inc. The product ingredients are shown in Table 1.

2.3 | Procedures

The study was started in July and final visits in performed in October. Subjects were to limit their travel to hot/sunny places which might significantly increase their sun exposure and not to increase their normal outdoor activity.

2.3.1 | Group A

These subjects had not received any professional treatment for their facial redness, such as chemical peels, IPL, lasers, dermaplaning, or microneedling. They were not using medical grade or prescription skincare products known to affect facial redness, such as topical vitamin A including retinol or retinoic acid, hydroquinone, resorcinol, alpha- or beta-hydroxy acids >10%, niacinamide >2%, sulfur and/or oral or topical tranexamic acid. Subjects were not currently receiving

TABLE 3 Subject self-assessment questionnaire

Regarding your current skin concerns, please rate how bothersome each using of the following factors are using this scale: 0, Not bothersome at all; 1, Slightly bothersome; 2, Bothersome; 3, Very bothersome; and 4, Extremely bothersome
• Facial redness • Appearance of facial Blood Vessels • Facial flushing • Inflamed skin • Visible excess oil • Uneven skin tone • Rough texture • Dullness • Dryness/dehydration • Other (open text)
Please select the statements that apply to you regarding the impact your facial redness has on your life
• I am embarrassed by my facial redness • I feel anxious because of my facial redness • I am not confident to go out in public

oral or topical brimonidine, oxymetazoline, metronidazole, ivermectin, isotretinoin, or oral antibiotics.

Group A subjects were provided with skincare products to be used as follows: Each morning, subjects wash their face with a generic cleanser* provided by the study sponsor or their own current cleanser if approved by study personnel. Immediately afterward, subjects applied 2–3 pumps of Test Product A followed by a generic moisturizer,† if needed, provided by the study sponsor or their own current moisturizer if approved by study personnel. One pump of Test Product B was then applied to the entire face. Test Product C was applied at least three times throughout the day. Each evening, subjects washed their faces using the generic cleanser to remove makeup and daily debris, applied 2–3 pumps of Test Product A, followed by the generic moisturizer, if needed.

2.3.2 | Group B

These subjects were currently receiving treatment for facial redness using professional or prescription topical products to treat facial redness for ≥3 months. These products included, but were not limited to topical vitamin A, including retinol or retinoic acid, hydroquinone, resorcinol, alpha- and beta-hydroxy acids >10%, niacinamide >2%, sulfur, and/or oral or topical tranexamic acid. Subjects were permitted the use of oral or topical brimonidine, oxymetazoline, metronidazole, ivermectin, isotretinoin, or oral antibiotics during the study.

Group B subjects were provided with skincare products to be used as follows: Each morning, subjects washed their faces using their current facial cleanser. Immediately afterward, they applied their prescription/professional products for treating facial redness, with the addition of 2–3 pumps Test Product A, followed by a generic moisturizer lotion,[b] as needed, and one pump of Test Product B. Test Product C was applied at least three times throughout the day. Each evening, subjects washed their faces using their current facial cleanser to remove makeup and daily debris. Immediately afterward, they applied their prescription/professional products for treating facial redness with the addition of 2–3 pumps of Test Product A and the generic moisturizer, if needed.

2.4 | Assessments

Subjects washed their faces at least 30 min prior to each scheduled clinic visit. Subjects were asked to refrain from any activities that would increase body temperature or induce sweating, such as drinking hot beverages, smoking, eating hot or spicy food, exercising or sun exposure at least 1 h prior to each study visit in this study. Subjects acclimated to ambient temperature and humidity conditions for at least 15 min prior to assessment procedures. Clinical assessments were performed at Visit 1 (Baseline), Visit 2 (Week 2), Visit 3 (Week 4), Visit 4 (Week 8), and Visit 5 (Week 12).

At each visit, the investigator assessed facial redness on a 5-point Overall Redness Scale. The Overall Redness Score included ratings of 0 (no erythema, papules, pustules, and no or mild telangiectasias), 1 (mild erythema, papules, pustules, and/or mild telangiectasia), 2 (moderate erythema, papules, pustules, and/or mild telangiectasia), 3 (marked erythema, papules, pustules and or mild telangiectasia), and 4 (severe erythema, papules, pustules and/or mild telangiectasia numerous papules or pustules, confluent inflamed lesions, moderate or severe erythema, moderate or severe telangiectasia).

Local cutaneous irritation or discomfort was assessed on a 4-point Tolerability Assessment Scale. Objective irritation was clinically graded by investigator Objective irritation was clinically graded by the investigator as erythema, edema, dryness, or scaling and subjective irritation was assessed by each subject as burning or stinging (Table 2).

Three digital images were obtained of each subject face with left, center, and right views under: Standard 1 (visible/bright]), Standard 2 (visible), and Standard 3 (raking light), cross-polarized red channel lighting conditions (VISIA® Imaging System. Canfield Scientific, Inc.; Parsippany, NY, USA). Subjects were provided with headbands to keep hair away from the face, and a black matte cloth was draped over clothing. Subjects were instructed to adopt neutral, non-smiling expressions with their eyes gently closed and chin softly positioned over a chin rest.

The investigator used a 5-point Global Improvement Scale to assess overall change in subject appearance: 0 (Worse), 1, No Improvement, 2 (Mild; 25% Overall Improvement), 3 (Moderate; 50%

TABLE 4 Change in overall redness scale scores

	All($N = 17$)	Significance	Group ($n = 12$)	Significance	Group B($n = 5$)	Significance
Baseline	2.59 (0.80)	---	2.42 (0.79)	---	3.00 (0.71)	----
Week 2	2.29 (0.69)	*NS*	2.33 (0.65)	*NS*	2.20 (0.84)	*NS*
Week 4	2.24 (0.83)	*NS*	2.17 (0.83)	*NS*	2.40 (0.89)	*NS*
Week 8	1.59 (0.62)	$p < 0.001$	1.58 (0.67)	$p = 0.03$	1.60 (0.55)	$p = 0.017$
Week 12	1.73 (1.16)	$p < 0.001$	1.91 (1.04)	*NS*	1.25 (1.50)	$p = 0.003$
% Change, Week 8	−34.31 (26.8)	$p = 0.002$	−31.25 (26.1)	$p = 0.002$	−41.67 (30.0)	$p = 0.04$
% Change, Week 12	−25.56 (53.0)	*NS*	−13.64 (51.0)	NS	−58.33 (50.0)	*NS*

Note: Data represent mean (SD), *p*-values represent comparison to mean baseline scores.
Abbreviations: *NS*, not significant.

TABLE 5 Subject tolerability assessments

	Week 2	Week 4	Week 8	Week 12
Overall, *n* (%)				
Burning				
None	7 (41.2)	12 (70.6)	13 (76.5)	14 (93.3)
Mild	7 (41.2)	4 (23.5)	3 (17.6)	1 (6.67)
Moderate	3 (17.6)	1 (5.9)	1 (5.9)	0
Stinging				
None	12 (70.6)	15 (88.2)	16 (94.1)	15 (100)
Mild	3 (17.6)	2 (11.8)	1 (5.9)	0
Moderate	2 (11.8)	0	0	0
Group A, *n* (%)				
Burning				
None	4 (33.3)	8 (66.7)	9 (75.0)	10 (90.9)
Mild	5 (41.7)	3 (25.0)	2 (16.7)	1 (9.1)
Moderate	3 (25.0)	1 (8.3)	1 (8.3)	0
Stinging				
None	8 (66.7)	10 (83.3)	11 (91.7)	11 (100)
Mild	2 (16.7)	2 (16.7)	1 (8.3)	0
Moderate	2 (16.7)	0	0	0
Group B, *n* (%)				
Burning				
None	3 (60.0)	4 (80.0)	4 (80.0)	4 (100)
Mild	2 (40.0)	1 (20.0)	1 (20.0)	0
Moderate	0	0	0	0
Stinging				
None	4 (80.0)	5 (100)	5 (100)	4 (100)
Mild	1 (20.0)	0	0	0
Moderate	0	0	0	0

Overall Improvement), or 4 (Marked; 75% Overall Improvement). Each subject was clinically graded on the global face for fine lines, wrinkles, smoothness (tactile), facial redness, texture, hydration, appearance of facial blood vessels, appearance of oily skin, and skin firmness/laxity. Subjects completed a self-assessment questionnaire electronically using online survey software at Baseline and each subsequent clinic visit (Table 3). The investigator completed a similar questionnaire at the end of each subject's visit.

2.5 | Statistical analysis

Statistical analyses were performed using R v 3.6.3 for Windows (https://cran.r-project.org). Counts and percentages were used to summarize the distribution of categorical variables, and the mean (SD) was used to summarize the distribution of continuous variables. Paired *t*-tests were used to compare the continuous scores between different time points within the same group. In the case of non-normal data, Wilcoxon signed-rank test was used for the analysis. Radar charts were used to summarize the change score (% from the baseline) at Weeks 4 and 8 at different time points, and bar plots were used to summarize the responses to respondents' questionnaires. Error plots were used to summarize the redness score. Linear mixed modeling was used to assess whether the change in redness was statistically significant. Time, group, and interaction between both terms were included in the model. Post hoc pairwise comparisons were used to compare the average scores within the same group. Hypothesis testing was performed at 5% level of significance.

TABLE 6 Change in global improvement scale scores

	All ($N = 17$)	Group A ($n = 12$)	Group B ($n = 5$)
Week 2			
No change	2 (11.8)	2 (16.7)	0
Mild	10 (58.8)	7 (58.3)	3 (60.0)
Moderate	5 (29.4)	3 (25.0)	2 (40.0)
Week 4			
Mild	13 (76.5)	10 (83.3)	3 (60.0)
Moderate	3 (17.6)	2 (16.7)	1 (20.0)
Marked	1 (5.9)	0)	1 (20.0)
Week 8			
Mild	1 (5.9)	1 (8.3)	0
Moderate	10 (58.8)	7 (58.3)	3 (60.0)
Marked	6 (35.3)	4 (33.3)	2 (40.0)
Week 12[a]			
Mild	4 (26.7)	3 (27.3)	1 (25.0)
Moderate	3 (20.0)	3 (27.3)	0
Marked	8 (53.3)	5 (45.5)	3 (75.0)

[a]One subject missing from Group A and Group B.

3 | RESULTS

3.1 | Demographics and baseline characteristics

Group A initially included four male and 19 female subjects and Group B included two male and nine female subjects; however, 16 subjects did not complete the study due to noncompliance ($n = 1$), pregnancy ($n = 1$), COVID-19 ($n = 2$), adverse events ($n = 3$), or were lost to follow-up ($n = 9$). The adverse events were mild and resolved with topical treatment. The study was completed by 12 subjects in Group A and five subjects in Group B.

3.2 | Overall redness scale scores

Across groups, the mean Overall Redness Scale Score improved by 34% and 25% at Weeks 8 and 12, respectively (Table 4). The reduction was higher with Group B, with a 42% and 58% improvement

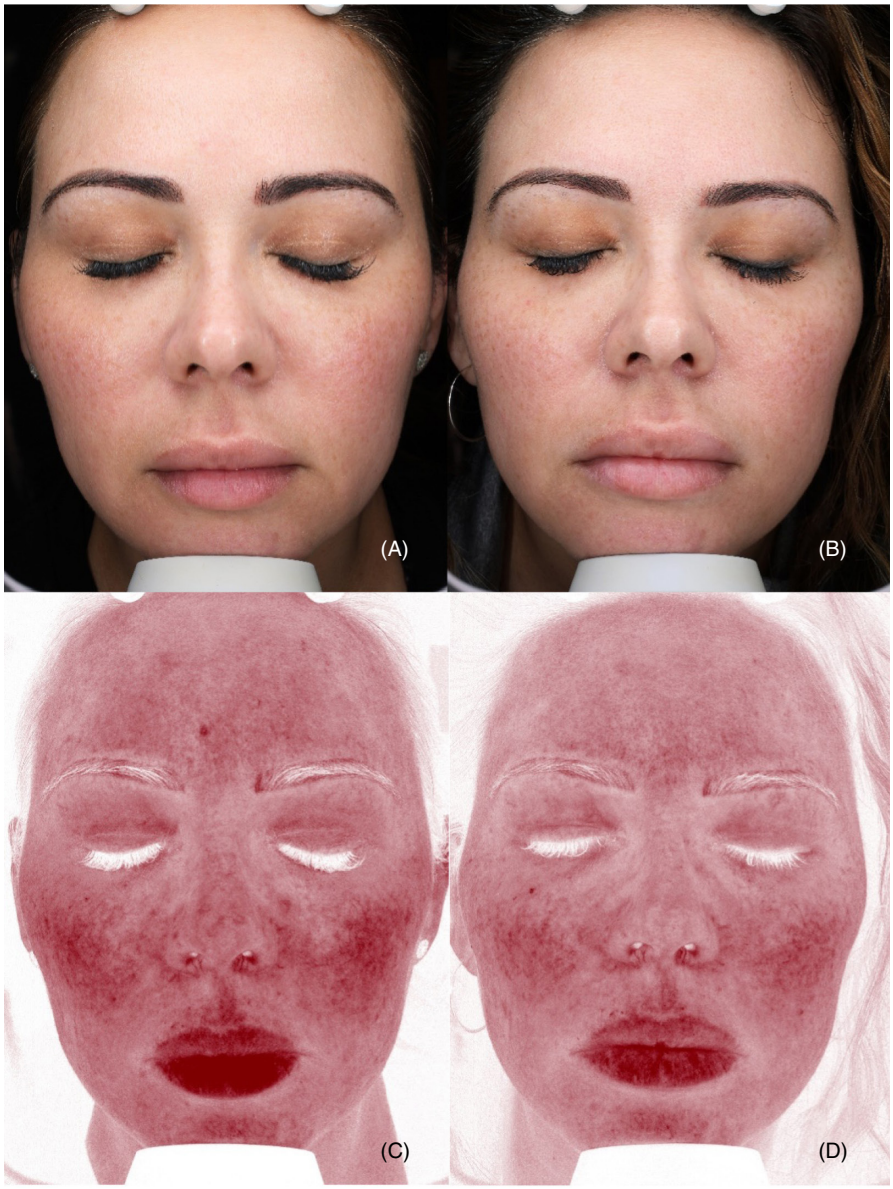

FIGURE 1 (A–D) 40-year-old female, Group A. Baseline standard digital images at baseline (A) and after 12 weeks of treatment (B). Red channel imaging at baseline (C) and after 12 weeks of treatment (D)

observed at Weeks 8 and 12 versus 31% and 14% improvement in Group A.

3.3 | Tolerability assessments

Across groups, the proportion of subjects reporting no discomfort increased during the study, reporting no burning (93.3%) or stinging (100.0%) at Week 12 ($p < 0.001$; Table 5). Tolerability was slightly better for Group B which reported neither burning nor stinging at Week 12.

3.4 | Global improvement scale

Overall, there was Mild or Moderate improvement in Global Improvement Scale beginning at Week 2 with over 50% achieving Marked improvement by Week 12 (Table 6). Representative pre- and post-treatment standard and red channel digital images are shown in Figures 1–5A–D.

3.5 | Subjects self-assessment questionnaire

All subjects (100%) were bothered to some extent by their facial redness, inflamed skin (82%) and facial flushing (76%) upon enrollment. At baseline, 76.5% of subjects were embarrassed by their facial redness, 17.6% were not confident to go out in public, and 11.8% were anxious about their facial redness. After 12 weeks of treatment, all subjects (100%) were no longer embarrassed or anxious about their facial redness and were confident to go out in public.

At Week 12, all subjects (100%) Agreed or Strongly Agreed that their facial redness was less noticeable, their skin appeared less

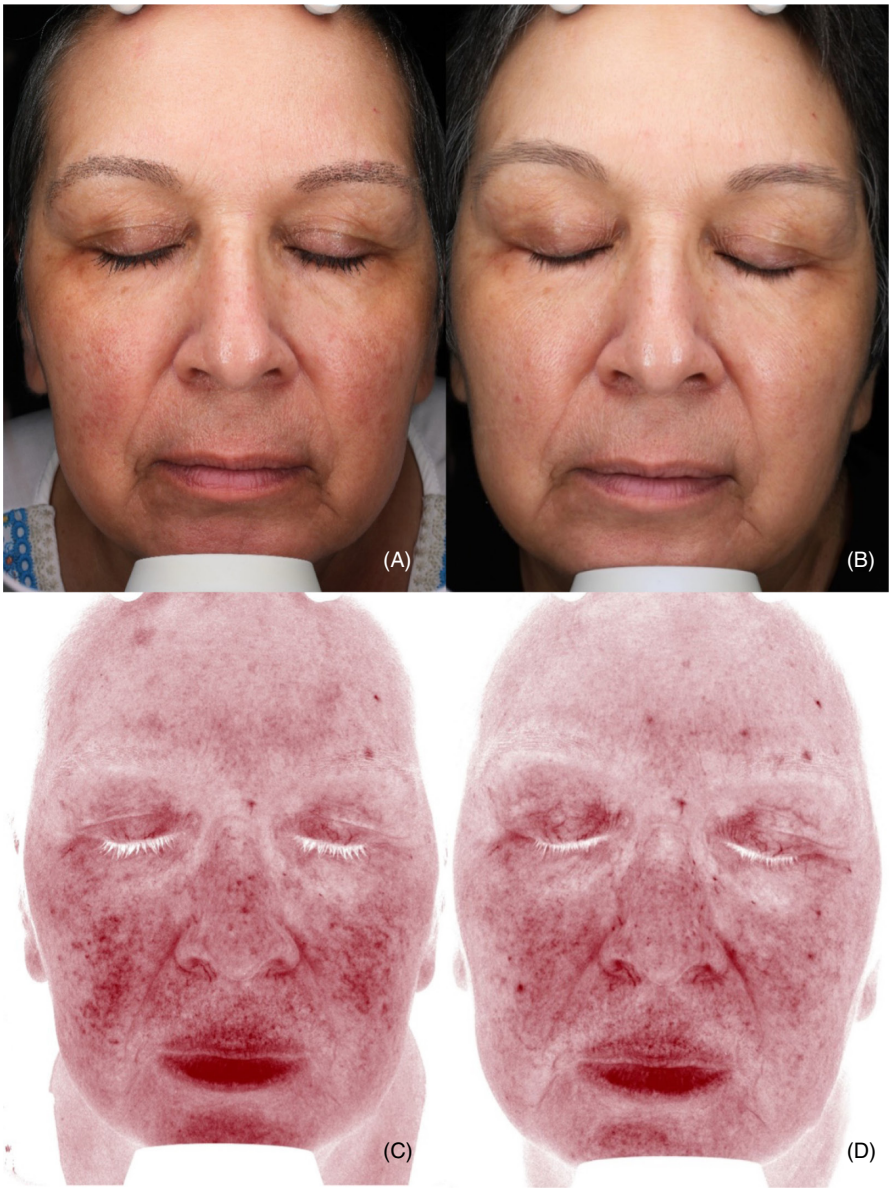

FIGURE 2 (A–D) 57-year-old female, Group A. Baseline standard digital images at baseline (A) and after 12 weeks of treatment (B). Red channel imaging at baseline (C) and after 12 weeks of treatment (D)

inflamed, overall skin appearance improved, and skin looked and felt healthier; 93% Agreed or Strongly Agreed their facial redness was improved; 93% Agreed their skin tone looked more even, skin texture smoother/softer/less rough, skin looked younger, skin looked brighter and more luminous, and the serum alone cooled their skin upon application; 87% Agreed there was a reduction in the appearance of facial blood vessels; 73% Agreed their skin felt more hydrated/less dry and the serum alone calmed their skin upon application; and 53% Agreed there was reduced appearance of excess surface oil.

At least 50% of the respondents had an improvement at Week 2 across nine appearance domains (Table 7). The only domains which were not improved by Week 2 were dryness, surface oil, younger skin, and appearance of facial blood vessels. By Week 8, all the domains improved by approximately 75%, while dryness, facial appearance of blood vessels, and younger skin look improved by at least 50%. At Week 12, there was some improvement across all domains in nearly 100% of subjects.

All subjects (100%) reported they will continue using the treatment regimen and would recommend it to others. Four subjects in Group B believed the addition of the treatment regimen made incremental improvement to their current, advanced skincare regimen.

3.6 | Investigator questionnaire

The investigator Agreed or Strongly Agreed that the treatment regimen improved the appearance of facial blood vessel in 12% of Subjects at Week 4, increasing to 47% at Week 8 and 93% at Week 12. Most subjects (71%) had lower excess surface oil by Week 8 than at Weeks 2 and 4. The investigator also Agreed or Strongly Agreed that 65% of subjects had less dry skin by Week 8 compared

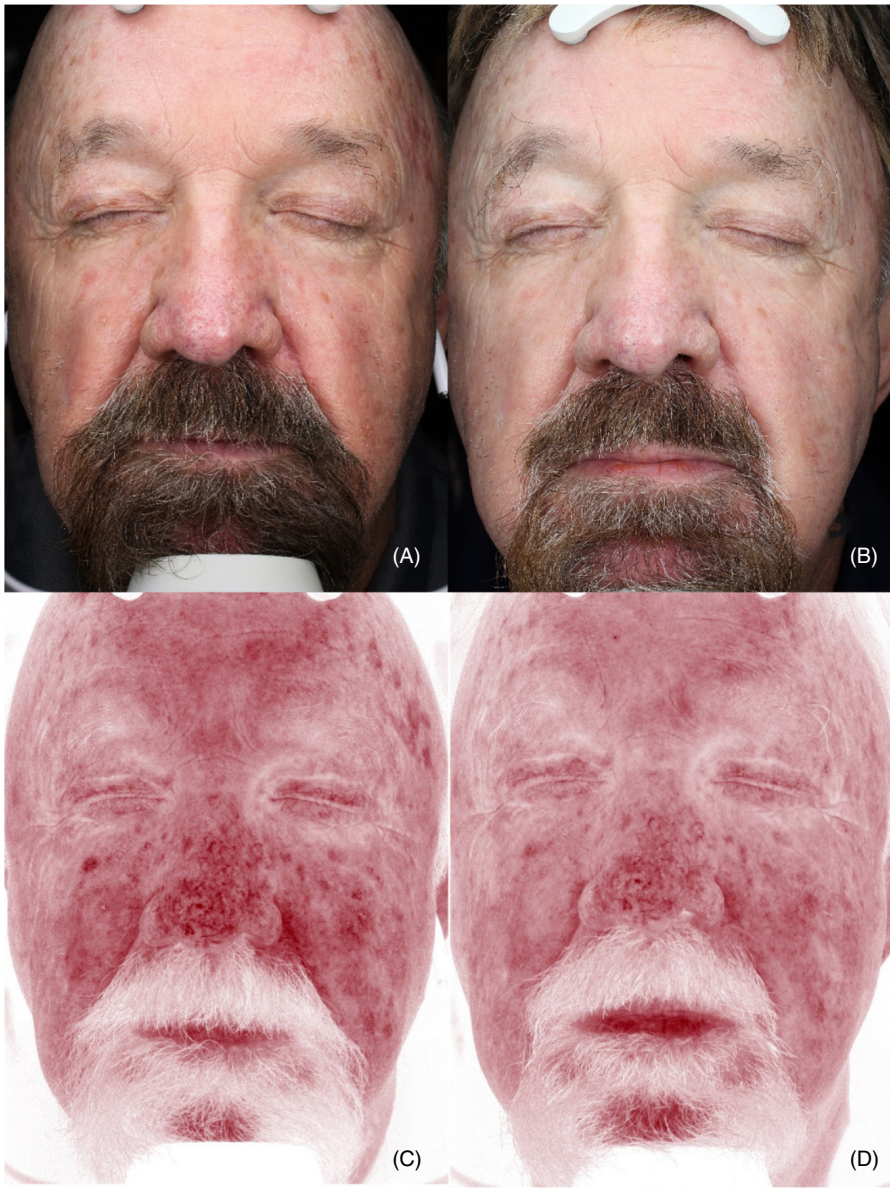

FIGURE 3 (A–D) 60-year-old male, Group A. Baseline standard digital images at baseline (A) and after 12 weeks of treatment (B). Red channel imaging at baseline (C) and after 12 weeks of treatment (D)

to Week 2 (35%) and Week 4 (41%). By Week 8, the skin looked younger in 60% of subjects compared to Week 2 (29%) and Week 4 (40%). The change in investigator questionnaire responses is shown in Table 8.

4 | DISCUSSION

The objective of this study was to assess the efficacy and tolerability of a topical facial product regimen for treating subjects visible and physical symptoms of sensitive skin. Based on the results shown here, this regimen is both effective and well-tolerated. The subjects in this trial demonstrated substantial subjective and objective improvements in facial skin redness after 12 weeks. Additional improvements might be achieved with continued use.

This treatment regimen provides immediate benefits for facial redness. The All Calm® Clinical Redness Perfector SPF 50 is a virtually anhydrous, topical skin care product that uses iron oxides to color correct and immediately neutralize the appearance of skin redness. This product and Sunforgettable® Total Protection Brush-on Shield each provide SPF 50 skin protection against ultraviolet light using non-chemical, all-mineral, sunscreen ingredients to prevent triggering sensitive skin reactions. The All Calm® Multi-Correction Serum and All Calm® Clinical Redness Corrector SPF 50 are both formulated with the proprietary BioSolace® ingredient complex to calm and soothe vulnerable and sensitive skin and diminish the appearance of redness over time and encourage skin resiliency with continued use.

Importantly, although most subjects were bothered and embarrassed by their facial redness and facial flushing at baseline, the

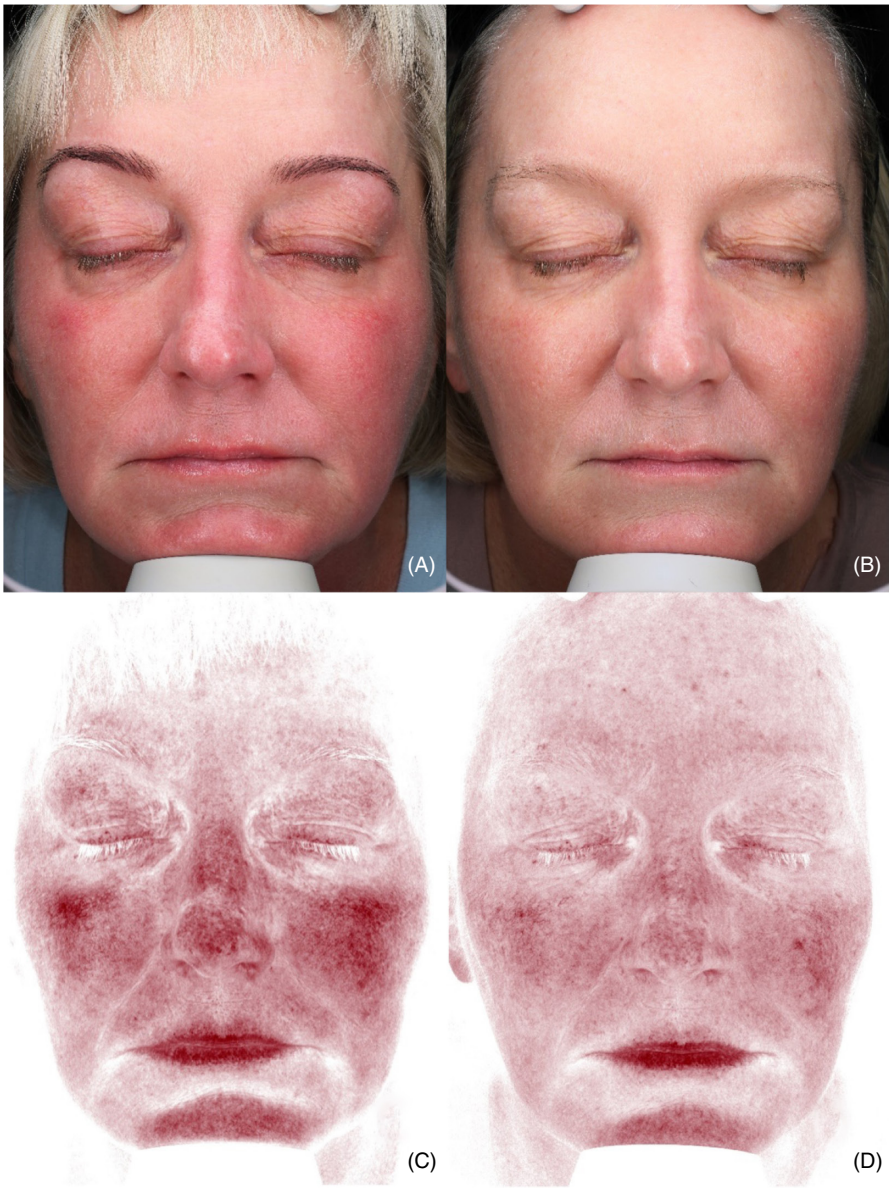

FIGURE 4 (A–D) 58-year-old female, Group B. Baseline standard digital images at baseline (A) and after 12 weeks of treatment (B). Red channel imaging at baseline (C) and after 12 weeks of treatment (D)

improvements in facial redness they achieved after 12 weeks enabled them to confidently be in public without embarrassment or anxiety.

High product satisfaction was indicated by all subjects reporting they will continue using the treatment regimen and will recommend it to others. Product tolerability improved over time with continued use and clinical improvements. Although the number of subjects was small, this treatment regimen was also well-tolerated by subjects using a prescription skincare routine for their facial redness and most believed it provided incremental improvement to their current treatment. Other advantages of this treatment regimen include being a home-based therapy avoiding the high cost of energy-based treatments and potential adverse effects of systemic medications.

Limitations to this study were the open-label design, the small number of subjects, especially in Group B, and lack of a placebo group. Future studies may be conducted that will assess the effects of this treatment regimen over a longer period on a larger population.

5 | CONCLUSION

The results of this 12-week study indicated a treatment regimen designed to neutralize skin redness, calm inflamed skin, and provide sunscreen protection was well-tolerated and improved the visible and physical symptoms of sensitive skin. Importantly, this treatment enabled subjects to confidently be out in public without embarrassment or anxiety.

AUTHOR CONTRIBUTIONS

The author made substantial contributions to conception, design, and acquisition of data and analysis and interpretation of data; was involved in revising and critically reviewing the manuscript

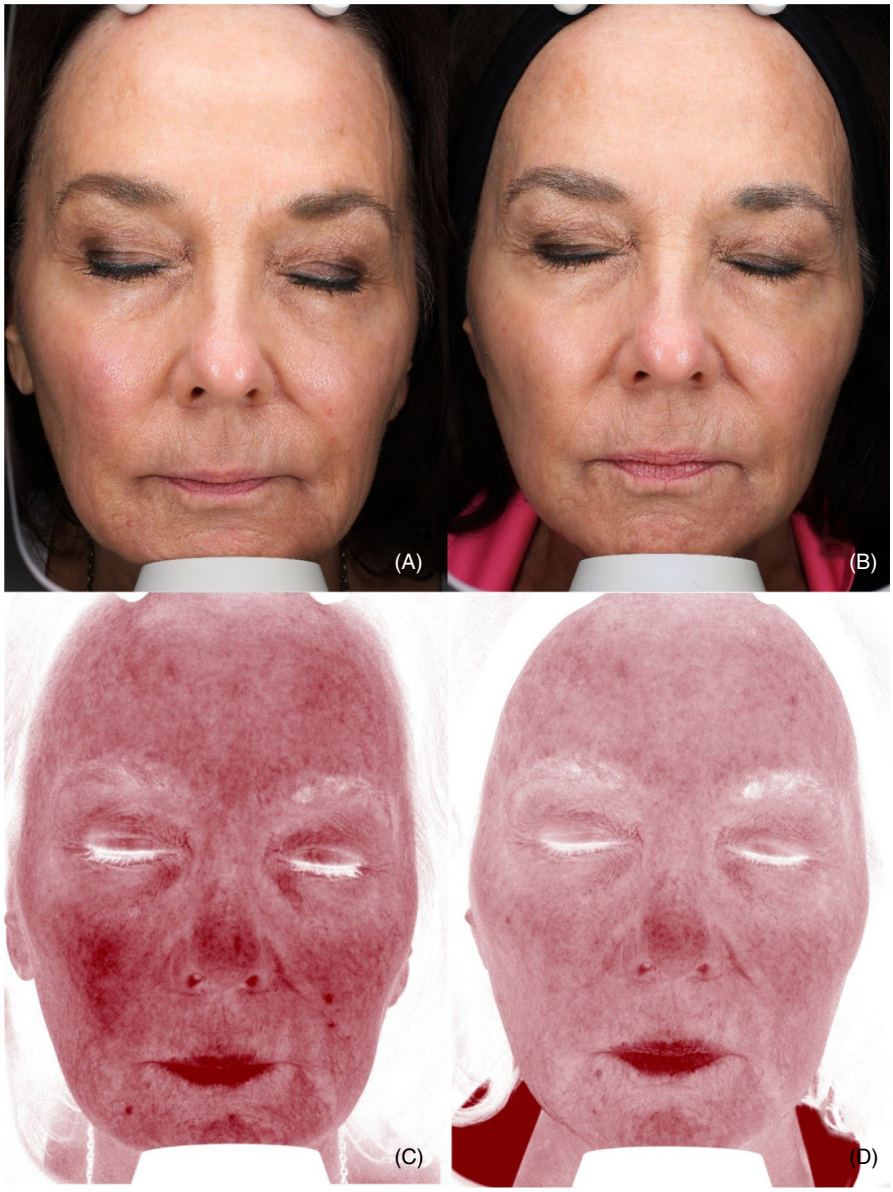

FIGURE 5 (A–D) 60 -year-old female, Group B. Baseline standard digital images at baseline (A) and after 12 weeks of treatment (B). Red channel imaging at baseline (C) and after 12 weeks of treatment (D)

TABLE 7 Change in global improvement scale scores

Parameter	Week 2 ($N = 17$)	Week 4 ($N = 17$)	Week 8 ($N = 17$)	Week 12 ($N = 15$)	Significance
Improve facial redness	3.59 (0.80)	3.82 (0.53)	4.00 (0.00)	4.00 (0.00)	*NS*
Facial redness less noticeable	3.65 (0.70)	3.76 (0.56)	4.00 (0.00)	4.00 (0.00)	$p < 0.001$
Reduces appearance of blood vessels	3.06 (0.66)	3.00 (0.50)	3.35 (0.70)	3.93 (0.26)	$p < 0.001$
Skin less inflamed	3.76 (0.56)	3.53 (0.72)	4.00 (0.00)	4.00 (0.00)	$p < 0.001$
Skin looks brighter	3.35 (0.70)	3.71 (0.59)	4.00 (0.00)	4.00 (0.00)	$p < 0.001$
Skin tone more even	3.53 (0.80)	3.65 (0.79)	4.00 (0.00)	3.87 (0.52)	*NS*
Skin looks healthier	3.76 (0.44)	3.71 (0.59)	4.00 (0.00)	3.93 (0.26)	*NS*
Skin looks younger	3.06 (0.75)	3.12 (0.86)	3.47 (0.72)	3.87 (0.52)	$p = 0.004$
Skin appearance improved	3.41 (0.80)	3.82 (0.39)	4.00 (0.00)	4.00 (0.00)	$p = 0.007$
Skin less dry	3.00 (0.87)	3.29 (0.69)	3.47 (0.80)	3.73 (0.70)	$p = 0.03$
Skin texture smoother	3.53 (0.80)	3.59 (0.71)	3.88 (0.33)	3.87 (0.52)	*NS*
Less excess surface oil	2.94 (0.83)	3.06 (0.75)	3.65 (0.61)	3.73 (0.70)	$p = 0.002$
Reduction in facial flushing	3.35 (0.79)	3.00 (0.87)	3.76 (0.56)	4.00 (0.00)	$p < 0.001$

Abbreviations: *NS*, not significant.

TABLE 8 Change in percent investigator questionnaire responses

	Week 2			Week 4			Week 8			Week 12		
	Disagree	Neutral	Agree	Disagree	Neutral	Agree	Disagree	Neutral	Agree	Disagree	Neutral	Agree
Skin tone more even	18	12	71	18	0	82	0	0	100	7	0	93
Skin texture smoother	18	12	71	12	18	71	0	12	88	7	0	93
Skin looks younger	24	47	29	29	29	41	12	29	59	7	0	93
Skin looks healthier	0	24	76	6	18	76	0	0	100	0	7	93
Skin looks brighter	12	41	47	6	18	76	0	0	100	0	0	100
Skin less inflamed	6	12	82	12	24	65	0	0	100	0	0	100
Skin less dry	35	29	35	12	47	41	18	18	65	13	0	87
Skin appearance improved	18	24	59	0	18	82	0	0	100	0	0	100
Reduced facial flushing	18	29	53	35	29	35	6	12	82	0	0	100
Reduced facial blood vessel appearance	18	59	24	12	76	12	12	41	47	0	7	93
Less excess surface oil	35	35	29	24	47	29	6	24	71	13	0	87
Improved facial redness	18	6	76	6	6	88	0	0	100	0	0	100
Facial redness less noticeable	12	12	76	6	12	82	0	0	100	0	0	100

for important intellectual content; gave final approval of the version to be published; and agreed to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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CONFLICT OF INTEREST

The author reports nothing to disclose.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the sponsor upon reasonable request.

ETHICS STATEMENT

The protocol and related materials used in this study were approved by a commercial IRB (WCG IRB; Puyallup, WA, USA). Each subject provided written informed consent prior to participating in any study-related activities. This study conformed to federal regulations for performing human clinical studies (Code of Federal Regulations Title 21, April 1 2020).[10]

ENDNOTES

* A generic cleanser does not contain any active ingredients for improving facial redness including, but not limited, to alpha- and beta-hydroxy acids >10%, niacinamide >2% or sulfur.

† A generic moisturizer contains only emollients, humectant and hydrators. It does not contain any cosmetic ingredients that diminish the appearance of facial redness and does not contain physical or chemical SPF active ingredients.

REFERENCES

1. Farage MA. The prevalence of sensitive skin. *Front Med (Lausanne)*. 2019;6:98.
2. Misery L, Ständer S, Szepietowski JC, et al. Definition of sensitive skin: an expert position paper from the special interest group on sensitive skin of the international forum for the study of itch. *Acta Derm Venereol*. 2017;97:4-6.
3. Rainer BM, Kang S, Chien AL. Rosacea: epidemiology, pathogenesis, and treatment. *Dermatoendocrinol*. 2017;9:e1361574.
4. Alia E, Feng H. Rosacea pathogenesis, common triggers, and dietary role: the cause, the trigger, and the positive effects of different foods. *Clin Dermatol*. 2022;40(2):122-127.
5. Morgado-Carrasco D, Granger C, Trullas C, Piquero-Casals J. Impact of ultraviolet radiation and exposome on rosacea: key role of photoprotection in optimizing treatment. *J Cosmet Dermatol*. 2021;20:3415-3421.
6. Alinia H, Tuchayi SM, Patel NU, et al. Rosacea triggers: alcohol and smoking. *Dermatol Clin*. 2018;36:123-126.
7. Moustafa F, Lewallen RS, Feldman SR. The psychological impact of rosacea and the influence of current management options. *J Am Acad Dermatol*. 2014;71:973-980.

8. Dai R, Lin B, Zhang X, Lou Y, Xu S. Depression and anxiety in rosacea patients: a systematic review and meta-analysis. *Dermatol Ther (Heidelb)*. 2021;11:2089-2105.
9. van Zuuren EJ, Fedorowicz Z, Carter B, van der Linden MM, Charland L. Interventions for rosacea. *Cochrane Database Syst Rev*. 2015;2015:CD003262.
10. United States Food and Drug Administration. Code of Federal Regulations Title 21, April 1, 2020. Updated November 02, 2021. https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?fr=50.25

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