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Efficacy, Tolerance, and Safety of a Novel Botanical Anti-Inflammatory Moisturizer in Rosacea: Results From a Double-Blinded, Randomized Controlled Trial

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ABSTRACT

Background: Rosacea is characterized by facial erythema that can be resistant to improvement.

Aims: This research evaluated the efficacy and tolerability of a topical anti-inflammatory moisturizer containing oat and aloe as compared to 0.75% metronidazole cream over 12 weeks.

Methods: This double-blinded, randomized, controlled trial enrolled 60 adults with mild-to-severe rosacea, randomized to either the study anti-inflammatory moisturizer or 0.75% metronidazole cream daily for 12 weeks. Participants were evaluated at baseline and Weeks 4, 8, and 12. Efficacy was measured by investigator global assessment (IGA) of erythema and inflammatory lesion counts. Tolerability was assessed by the investigator and subjects.

Results: Both study products demonstrated similar IGA scores at Week 4. By Week 8, the study oat and aloe anti-inflammatory moisturizer demonstrated significantly greater reduction in both erythema IGA (50% vs. 22%, $p = 0.001$) and lesion counts (74% vs. 6%, $p = 0.015$). At the conclusion of the 12-week study, the anti-inflammatory moisturizer produced a reduction in IGA erythema of 54% vs. 23% ($p < 0.001$) and a reduction in inflammatory lesion counts of 74% vs. 17% ($p = 0.044$). No tolerability issues were noted.

Conclusions: The oat and aloe anti-inflammatory moisturizer was superior and outperformed 0.75% metronidazole cream in both erythema and lesion reduction in rosacea subjects after 8 and 12 weeks of treatment.

1 | Introduction

The management of facial erythema in rosacea remains a challenge. The recently revised rosacea classification system considers erythema as a primary diagnostic phenotype [1]. As many as 80% of people with rosacea find their facial redness difficult to control, even with a combination of prescription medication and lifestyle changes [2]. There is an unmet need for a rosacea moisturizer that can be used long-term to assist in facial erythema reduction [3, 4].

Newer higher purity anti-inflammatory botanical extracts are currently available that might be of value as topical agents in rosacea, as they have the potential to provide inflammation reduction in a biologically active manner. The aim of the current study was to evaluate the efficacy, tolerability, and safety of a topical oat kernel oil (*avena sativa*) and aloe (aloe barbadaensis) cream vs. 0.75% metronidazole cream in adults with mild to severe facial rosacea. The entire spectrum of rosacea severity was enrolled to better understand the true anti-inflammatory capabilities of the study products.

2 | Methods

This single-center, double-blind, randomized, comparator-controlled clinical trial was designed to assess the efficacy, tolerability, and safety of the oat and aloe anti-inflammatory moisturizer (Crescel, Miami Beach, FL) as compared to 0.75% metronidazole cream (MetroCream, Galderma, Lausanne, Switzerland). To be sure that the moisturizing capability of both study arms was balanced, a bland moisturizer was added to the 0.75% metronidazole cream arm (CeraVe Lotion, L'Oréal, New York City, NY). This allowed isolation of the anti-inflammatory impact of both the oat and aloe ingredients and the metronidazole, which was the study focus.

60 subjects 18+ years of age with Fitzpatrick skin types I-III and mild, moderate, or severe rosacea were enrolled. This sample size of 30 subjects per arm was based on a prior pilot rosacea study using the investigational formulation, in which statistical significance ($p < 0.05$) was demonstrated. Qualified subjects were not using any topical or oral treatment for rosacea and had not done so for the past 90 days, isolating the ability of the study products to induce erythema reduction. Further, subjects were asked to use only their assigned treatment products for the duration of the study, with no other treatments or moisturizers to the face. Subjects could continue using the ancillary skin care products (e.g., skin cleansers, sunscreen) and colored cosmetics that they had been using for at least 30 days without difficulty. Individuals were excluded from participating if they had any concomitant facial dermatological disorder that, in the study investigator's opinion, could interfere with an accurate evaluation of the participant's skin characteristics. Other exclusion criteria included not agreeing to refrain from direct sun exposure during the study; having a previous reaction to any of the ingredients in the study products; and being currently pregnant, breastfeeding, or planning to become pregnant.

A computer-generated randomization schedule assigned 30 subjects to each study arm, balancing the two arms for rosacea severity. The study oat and aloe moisturizer or 0.75% metronidazole 0.75% cream plus moisturizer were applied to the entire face twice daily for 12 weeks. Both the dermatologist-investigator and the subjects were fully blinded. The study administrator was not blinded, to enable accurate distribution of the assigned study product at each weekly evaluation visit. This was not witnessed by other patients or by the dermatologist-investigator. The study administrator also determined compliance from subjects' diary entries and from product weights.

Weekly investigator global assessments (IGA) for facial erythema utilized a 5-point ordinal whole-point grading scale typically used in rosacea drug studies with the following erythema ordinals: 0 = none, 1 = minimal, 2 = mild, 3 = moderate, 4 = severe. If inflammatory lesions were present, the investigator also performed facial inflammatory papule and pustule counts. The investigator assessed tolerability in terms of dryness, desquamation, erythema, edema, and irritation using the 5-point ordinal scale detailed above. Subjects used the same 5-point ordinal scale to assess tolerability in terms of dryness, peeling, tingling, stinging, itching, and burning. Digital images were taken with a Visia CR4.3 imaging system (Canfield Scientific, Parsippany, NJ) of the right, left, and central face at each visit.

This study was reviewed and approved by the Allendale Institutional Review Board (AIRB). All participants signed an informed consent form prior to any study procedures.

2.1 | Investigational Novel Botanical Anti-Inflammatory Moisturizer

Four synchronized novel proprietary technologies integrate a spectrum of anti-inflammatory, antioxidant, and moisturizing compounds extracted from *aloe barbadensis* and oat kernel oil, historically used to treat skin conditions. Aloe compounds constitute more than 10% of the proprietary formula, and oat kernel oil compounds constitute more than 5%. *Technology 1* creates a breathable polymer system integrating the hydrophilic, biologically active complex of the extracted compounds. *Technology 2* is designed to optimize the polymer system's activity. *Technology 3* creates a metabolically active hydrophilic/hydrophobic polypeptide complex. *Technology 4* enables the optimal synergistic synthesis of the plant compounds. The topical delivery is enhanced through a microemulsion. The typical microemulsion is composed of water, oil, and a surfactant to create thermodynamically stable nanoparticles, and created by solubilizing the oil phase into the water phase to create nanospheres able to penetrate the stratum corneum [5–8]. A critical aspect of this botanical anti-inflammatory is that these four unique technologies themselves integrate dynamically to expand this microemulsion, including very fine hydrophilic and hydrophobic droplets that engage in continuous surface-to-surface interactions. This novel microemulsion further enhances product activity. The silicones cyclopentasiloxane and cyclohexasiloxane, globally recognized as safe, are added to create product spreadability. Phenoxyethanol, a highly protective preservative that is globally recognized as safe, is also included.

2.2 | Statistical Analysis

The nonparametric ordinal data were analyzed using Wilcoxon signed-rank tests for paired comparisons between the intervention groups at each time point. Change was considered significant at the alpha level of 0.05.

3 | Results

60/60 successfully completed the study. Baseline characteristics are shown in Table 1. Participants were 87% female and 95% Caucasian, consistent with the population afflicted with rosacea.

Mean IGA erythema ratings decreased significantly from baseline at each follow-up visit ($p < 0.001$) in both groups. Facial inflammatory lesion counts decreased significantly at all time points ($p < 0.05$) with the study product, but not with the 0.75% metronidazole 0.75% cream and moisturizer. The two test arms performed similarly at Week 4 (Figures 1 and 2). By Week 8, there was significantly greater reduction in IGA erythema (50% vs. 22%; $p = 0.001$) and lesion count (74% vs. 6%, $p = 0.015$) with the oat and aloe moisturizer vs. the 0.75% metronidazole cream and moisturizer. The oat and aloe moisturizer produced

TABLE 1 | Study population baseline characteristics.

	Total sample ($N=60$)	Investigational product ($n=30$)	Metro 0.75% cream ($n=30$)
Age	53.0 years (mean)	51.1 years (mean)	53.9 years (mean)
Gender, % (*n*)			
Male	13% (8)	13% (4)	13% (4)
Female	87% (52)	87% (26)	87% (26)
Race/Ethnicity, % (*n*)			
White	95% (57)	94% (28)	97% (29)
Hispanic	5% (3)	6% (2)	3% (1)
Africa-American	0% (0)	0% (0)	0% (0)
Asian	0% (0)	0% (0)	0% (0)
Fitzpatrick Skin Type, % (*n*)			
I	42% (25)	47% (14)	37% (11)
II	53% (32)	47% (14)	60% (18)
III	3% (2)	3% (1)	3% (1)
IV	2% (1)	3% (1)	0% (0)
V	0% (0)	0% (0)	0% (0)
VI	0% (0)	0% (0)	0% (0)

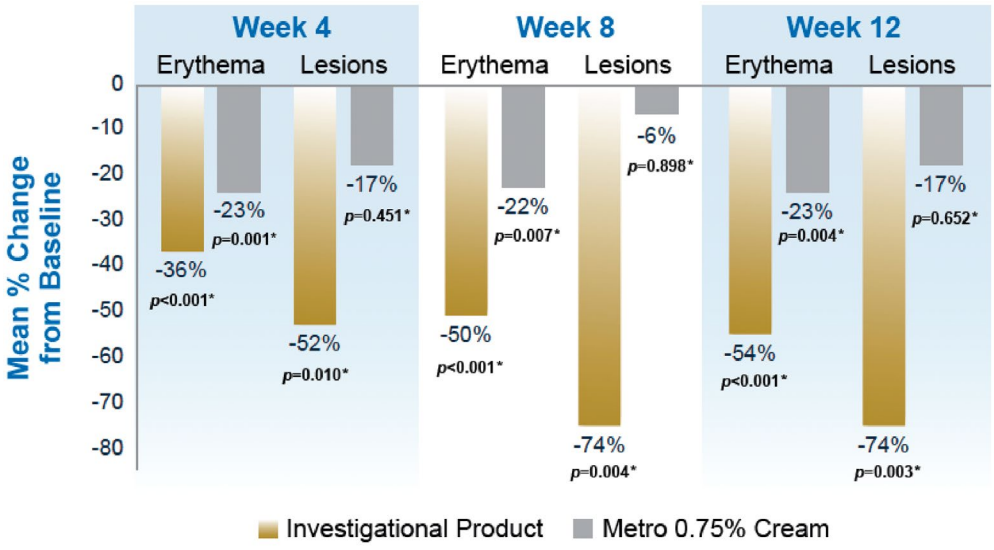

FIGURE 1 | Intragroup mean % change in investigator-assessed erythema and lesions over 12 Weeks. *$p \leq 0.05$ is significant.

additional IGA facial erythema reduction at Week 12 (54% vs. 23%, $p < 0.001$) with a stable lesion count (74% vs. 17%, $p = 0.044$). Representative before and after redness reduction images with the use of the oat and aloe moisturizer are presented in Figure 3. No tolerability issues were identified in either study arm.

4 | Discussion

The biobotanical concept is developing in dermatology due to the availability of purer, higher concentration plant materials from suppliers. "Bio" refers to the biologic activity that can be conferred by plant-derived active ingredients. "Botanical" refers to the plant source of the active ingredients. In order to achieve biologic effect, many biobotanical formulations must use concentrations higher than 5%, which was the case in the oat kernel oil and aloe test formulation. Both of these ingredients have established anti-inflammatory profiles functioning by quenching reactive oxygen species (ROS) in a microemulsion [9].

Aloe vera, a mucilage gel prepared from fresh *aloe vera* leaves, contains enzymes, polysaccharides, fat-soluble vitamins, minerals, and flavonoids [9]. It contains the anti-inflammatory ingredients choline salicylate, bradyknase, and aloe emodin

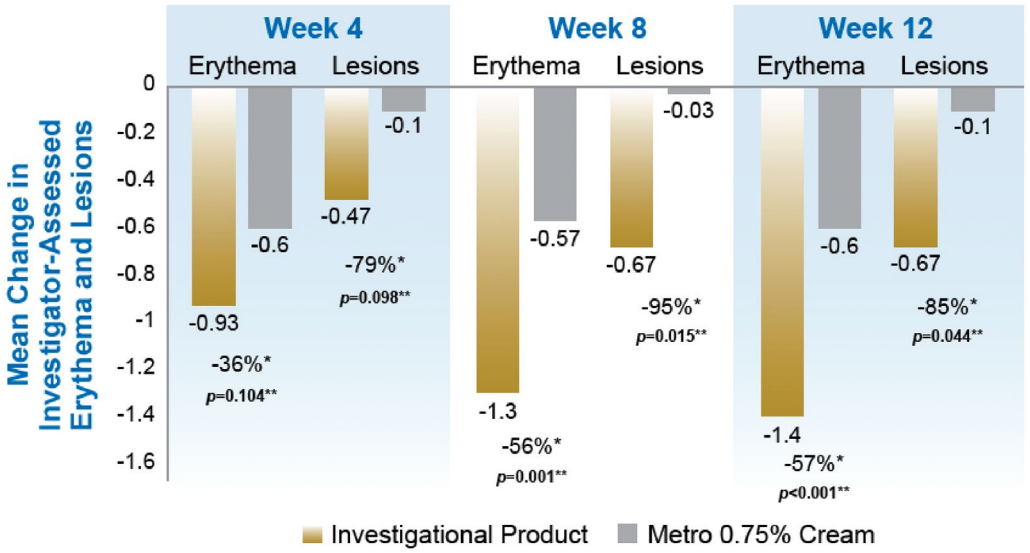

FIGURE 2 | Intergroup mean change in investigator-assessed erythema and lesions over 12 weeks. *% change = (mean control score—mean investigational score)/mean investigational score. **$p \leq 0.05$ is significant. Investigator assessment used a 5-point scale from 0 = none to 4 = severe. A higher negative score indicates greater symptom reduction.

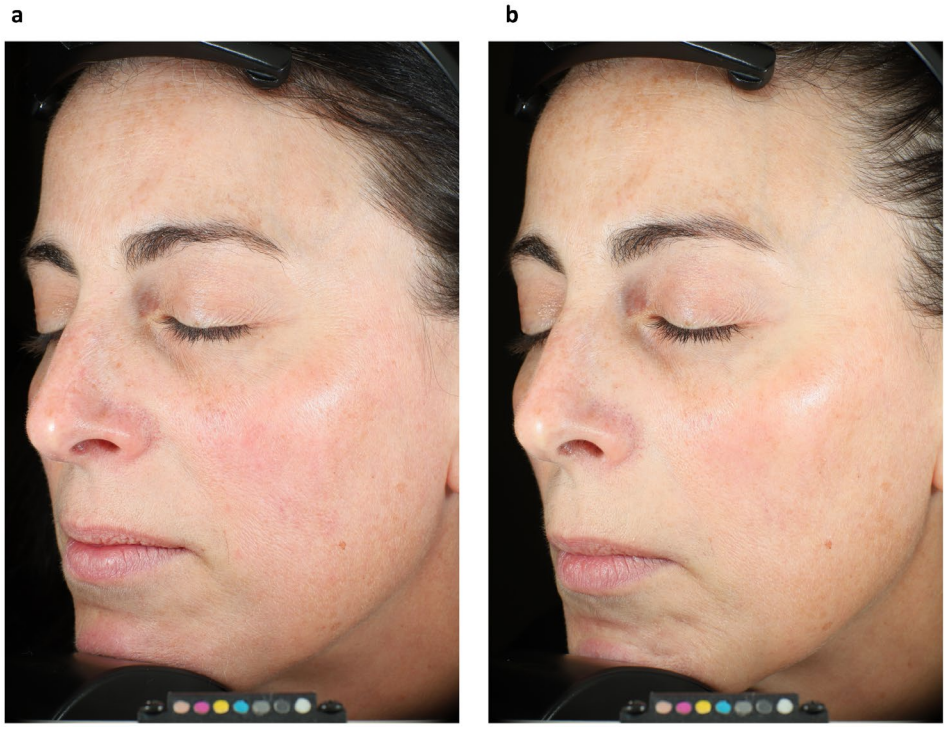

FIGURE 3 | Baseline (a) and 12-week follow-up (b) of a study subject randomized to the investigational product.

summarized in Table 2. Oat, a member of the grass family, produces active ingredients in the plant fruit, stem, leaves, and seeds. The dried fruit (*avena sativa*) is used therapeutically, most often in colloidal form (a finely ground powder of oats evenly dispersed and suspended in a liquid), for skin care. It is listed in the U.S. Food and Drug Administration's skin protectant monograph. It contains unsaturated fatty acids and avenanthramides summarized in Table 2.

The oat and *aloe vera* moisturizer was compared to 0.75% metronidazole cream since this is the lowest insurance tier easiest to obtain widely used topical for rosacea treatment. It too functions as an anti-inflammatory. 0.75% metronidazole cream has been validated for acute and maintenance therapy for rosacea and thus was felt to be a good comparator [14]. The 0.75% metronidazole cream was combined with a moisturizer so as not to bias the study. Nevertheless, the facial erythema reduction was rated as superior by the blinded dermatologist investigator. The value of appropriate skin care for rosacea sufferers has been well established [15]. As a matter of fact, moisturizers are felt to be an integral part of rosacea treatment [16]. This may be due to the barrier defects inherent in the skin of rosacea patients [17].

TABLE 2 | Constituents of the investigational product for rosacea.

Aloe Vera
Choline salicylate: inhibits cyclooxygenase, part of the arachidonic acid pathway, which is the precursor of prostaglandins [10].
Bradykinase: inhibits bradykinin contributing to vasodilation seen in rosacea [10].
Aloe emodin: suppresses nitrous oxide and the proinflammatory cytokines interleukin-6 and interleukin-1β [11, 12].
Oat kernel oil
Unsaturated fatty acids: prevent lipid peroxidation [13].
Avenanthramides: polyphenols inhibiting NF-kB signaling and decreasing the production of proinflammatory cytokines, such as IL-8 [10, 13].

The moisturizing vehicle of the nanoemulsion study product combined with the anti-inflammatory biobotanical effect of the oat and *aloe vera* actives may have accounted for the excellent results observed across a wide range of rosacea severity.

The limitations of this study include the fact that the subjects were only followed for 12 weeks. A 12-week study period was selected because this is commonly the time frame used in rosacea drug studies, but longer studies will be needed to look at the durability of the topical benefit observed with this novel botanical anti-inflammatory cream. Another limitation of this study was that while the subjects demonstrated facial erythema improvement, this did not result in rosacea clearing in most patients. Supplemental rosacea therapy will likely need to be considered on a case-by-case basis.

5 | Conclusion

A novel oat and aloe botanical anti-inflammatory moisturizer demonstrated significant facial erythema and lesion reduction in rosacea sufferers following 12 weeks of twice daily application in mild to severe rosacea. It was superior to 0.75% metronidazole cream.

Author Contributions

Z.D.D.: conceptualization, methodology, study design, study recruitment, study administration, subject evaluation, data collection, analysis, drafting and editing.

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Ethics Statement

The study was reviewed and approved by the Allendale Institutional Review Board. All participants signed an informed consent form prior to performing any study procedures. The author confirms that the ethical policies of the journal, as noted on the journal's author guidelines page, have been adhered to.

Consent

This study was reviewed and approved by the Allendale Institutional Review Board. All participants signed an informed consent form prior to performing any study procedures. Anonymity and confidentiality were maintained throughout the study, including data collection and analysis. All participants signed informed consent forms before starting the study and also for imaging to be published. They were informed of the nature, benefits, and potential risks of their participation in the study.

Conflicts of Interest

Z.D.D. received grant funding from Crescel to conduct the research.

Data Availability Statement

The data that support the findings of this study are available on request from the corresponding author. The data are not publicly available due to privacy or ethical restrictions.

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