A 12 Week Study Evaluating the Efficacy of a Novel Standardized Nutraceutical to Improve Acne and Skin Health

Isabelle Raymond, PhD, Emily Hu, MS, Nicole Townsend, BA, Ryan McLendon, MS, Adina Hazan, PhD

Nutraceutical Wellness, Inc. New York, NY

INTRODUCTION

Although acne is generally viewed as the result of a localized immune response at the pilosebaceous unit, it is a condition with multifactorial etiology. While conventional treatments have focused primarily on the four major pathogenic factors, nutraceuticals offer an alternative or complementary approach to address more systemic, intertwined mechanisms involved in acne pathogenesis. These include stress, diet and metabolism, skin and gut microbiome, hormonal fluctuations, oxidative stress, and immune function. Therapies which target these underlying mechanisms have gone largely unexplored as ways to address acne. Here, we present the results of a novel nutraceutical addressing these root causes in patients with non-cystic acne.

METHODS

Inclusion Criteria:

- Healthy women and men
- Age range 18-50
- All Fitzpatrick Skin Types
- **Mild to moderate** acne with Investigator's Global Assessment (IGA) severity score of 2-3 with at least:
  - >3 inflammatory lesions
  - >5 non-inflammatory lesions
- **Severe acne** with IGA severity score of 4 with at least:
  - >5 inflammatory
  - >5 non-inflammatory lesions

Exclusion Criteria:

- Cystic acne
- Pregnant or breastfeeding
- **Current use of any oral or topical medications for acne**
- Isotretinoin <6 months
- Current use of prescription testosterone therapy
- Having started, stopped or changed dose of HRT, birth control <3 months prior to start
- Health condition(s) or pre-existing/ dormant dermatological disease on test area/face
- Known reactivity and allergies to test materials
- Current use of immunosuppressive, medications/biologics, or corticosteroids

Clinic visits: at Baseline, Week 4, 8 and 12.

Wash Out Phase

- Oral and/or topical prescription wash out was 14 days
- Systemic medication (antibiotics, steroids) wash out was 30 days
- OTC retinol containing products and any other OTC acne products wash out was 14 days

Subjects instructed to take 4 capsules per day of the nutraceutical for 12 weeks

Study Assessments

- FDA Investigator's Global Assessment (IGA) of Acne Severity
- Inflammatory and non-inflammatory lesion counts
- Clinical grading (0-9 scale) of skin texture, skin smoothness, hyperpigmentation, redness, and acne marks (PIH/PIE)
- Bioinstrumentation: Tewameter, Sebumeter, and Corneometer
- Self-Assessment Questionnaire

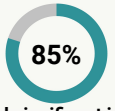
Statistical Analyses

- Statistical analyses included Paired *t* Tests, Wilcoxon-signed Rank Tests and Binomial (sign) Tests.

RESULTS

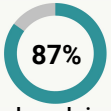
51 subjects entered with 39 subjects completing the study (mean age = 31.5 ± 7.7 years, range = 19-48).
Subject demographics were female (67%), White/Caucasian (41%, 6:10 M:F ratio), Black (41%, 5:11 M:F ratio), and Asian (13%, 1:3 M:F ratio).
All Fitzpatrick Skin Types were represented.
Reasons for discontinuation were lost to follow-up/withdrawal (N=7), non-compliance (N=1), and adverse events (N=4). AEs deemed probably related to the product included headache, pain, malaise and nausea. AEs were not serious and all resolved.

IGA scores for acne severity

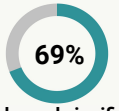


85% showed significant improvements in **IGA scores** for acne severity at Week 12 compared to BL (p<0.001)

Lesion Count



87% showed significant improvements in **non-inflammatory lesion count** by Week 12 compared to BL. (P<0.001)



69% showed significant improvements in **inflammatory lesion count** by Week 12 compared to BL. (P<0.001)

Table 1. Clinical Grading of Skin Parameters

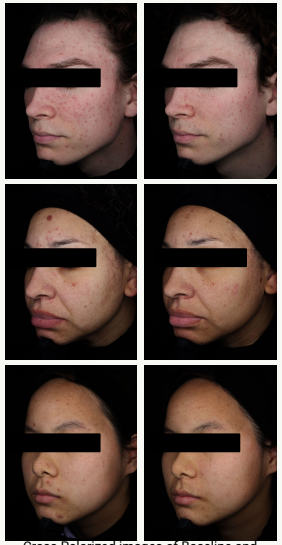
Parameter	% Subjects Improved at 12 weeks	p-value
Skin Texture (Visual)	85%	p<0.001
Skin Smoothness (Tactile)	85%	p<0.001
Hyperpigmentation	67%	p<0.001
Redness (Visual)	80%	p<0.001
Acne Marks (PIH/PIE)	80%	p<0.001

Table 1 Percent of subjects improved at Week 12 compared to baseline in clinically graded skin quality parameters. Overall, there was a progressive improvement of most parameters throughout the duration of the study. p-value indicates 12 week values analyzed compared to BL.

Table 2. Bioinstrumentation

Measurement	Baseline	Week 12	% Subjects Improved	p-value
Sebumeter	158.1	121.6	72%	p=0.002
Corneometer	35.0	42.7	74%	p=0.002
Tewameter	17.3	26.9	41%	NS

Table 2 Indicated measurements showing decrease in sebum (sebumeter) and increased hydration (corneometer). No significant change detected in transepidermal water loss (TEWL). Measurements taken at baseline, week 4, week 8 and week 12. p-value indicates 12 week value compared to BL.



Cross Polarized images of Baseline and week 12 timepoints in 3 subjects

Table 3. Self-Assessment Questionnaire

Select Acne Attributes	Week 4	Week 8	Week 12
My skin is clearer.	61%	82% ***	87% ***
I have less breakouts.	61%	82% ***	77% **
My skin is less oily.	74% **	74% **	74% **
My acne has improved	71% *	87% ***	87% ***

Table 3 Self-assessment questionnaire results showing percent of favorable responses for weeks 4, 8, and 12. Significance determined by comparing proportion of favorable responses to unfavorable responses for each statement. *p<0.05, **p<0.01, ***p<0.001.

CONCLUSION

The paucity of scientific evidence and lack of clinical data on the efficacy of CAM, including nutraceuticals, have limited their recommendation for use in acne. This proof-of-concept study showed improvements in acne and skin parameters. Although more studies are needed, these results offer insight into the potential benefits of nutraceuticals addressing underlying mechanisms that up to now, have gone largely unexplored. Addressing root causes that contribute to a generalized inflammatory response leading to the development of acne may prove to be an important step in expanding our toolbox in providing more options for patients and improving skin health.

Conflicts of interest/Disclosure: All authors are employed by Nutraceutical Wellness Inc.