

A Multicenter, Evaluator-Blinded, Randomized Clinical Study to Evaluate the Efficacy and Tolerance of Two Acne Treatments on Subjects With Mild to Moderate Acne Vulgaris

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Abstract

- Acne vulgaris is a multifactorial skin disease, characterized by proliferation of bacteria, hyperkeratinization, inflammation and excess sebum production, mainly prevalent in adolescents and young adults. Current over-the-counter treatment options include topical therapies such as benzoyl peroxide (BPO) and salicylic acid, but patient adherence to topical treatments can often be challenging. Various types of blue and red light-emitting diodes (LEDs) have been used independently and in combination as an alternative, chemical-free option for the treatment of acne.
- A multicenter, evaluator-blinded clinical study was conducted to evaluate the efficacy and tolerance of a new low-level blue and red light therapy face mask. Subjects were men and women aged 12–35 years with mild to moderate acne vulgaris. Subjects were randomized at baseline to receive either a once-per-day 10-minute treatment with the light emitting face mask, or twice-per-day treatment with topical 2.5% BPO. The primary efficacy endpoint was the percent change from baseline to week 12 in total lesion counts, with investigator global acne (IGA) assessment, self-assessment questionnaires, and skin tolerance also evaluated throughout the course of the 12-week study period.
- This clinical study demonstrated the efficacy and tolerance of a new low-level blue and red light therapy technology and was found to significantly reduce total acne lesion counts over the 12-week study period. Subjects also reported significant improvements in their acne and overall skin appearance, which is critical for continued compliance to a daily treatment regimen.

Objective

- Evaluate the **efficacy and tolerance of a new low-level blue and red light therapy face mask** on subjects with mild to moderate facial acne, in a multicenter, evaluator-blinded, randomized clinical study over the course of 12 weeks of treatment.

Study Design

- Population

- Subjects were males and females aged 12–35 years, presenting with mild to moderate acne based on baseline lesion counts and investigator global acne assessment (IGA) score.
- Subjects with Fitzpatrick skin type I-VI were eligible for enrollment.

- Acne Mask Treatment

- 52 subjects completed the 12-week study using the once-daily treatment with the low-level blue and red light therapy face mask. Subjects washed their face with a mild facial cleanser in the morning and evening and performed the 10-minute treatment session with the mask after cleansing in the evening.

- Evaluations

- Investigator clinical evaluations included acne efficacy (lesion counts and IGA), as well as additional skin benefits.
- Self-assessments for subject-perceived acne and skin benefits were performed, in addition to an acne-related quality of life questionnaire.
- Tolerance was assessed by clinical grading of objective irritation parameters and subject reporting of subjective irritation parameters.

Results

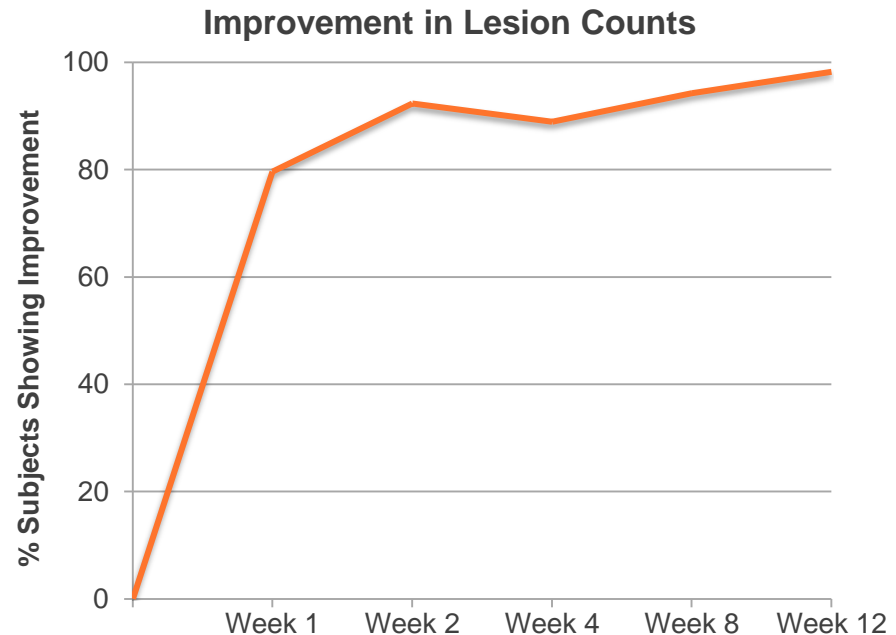
Acne Clinical Efficacy

Total Lesion Count and Investigator Global Assessment (IGA) vs. Baseline

- Subjects using the new low-level blue and red light therapy face mask had significantly fewer total acne lesions (vs. baseline, $p < 0.05$) at all measured time points starting within 1 week, with an average change in total acne lesions of 44% by week 12. After 12 weeks of treatment, **98% of subjects** demonstrated an improvement in total number of lesions.
- The Investigator Global Assessment confirmed improvement in the global acne severity, with improvement starting at week 1 and continuing to increase throughout the 12-week treatment period.

	Total Lesion Counts		Investigator Global Assessment (IGA)	
	% Reduction	% Subjects Improved	% Improvement	% Subjects Improved
Week 1	-18.7	80	7.6	26
Week 2	-28.0	92	12.4	52
Week 4	-34.5	89	18.2	61
Week 8	-39.9	94	26.0	79
Week 12	-44.0	98	30.5	81

All time points are significant vs. baseline at $p < 0.05$

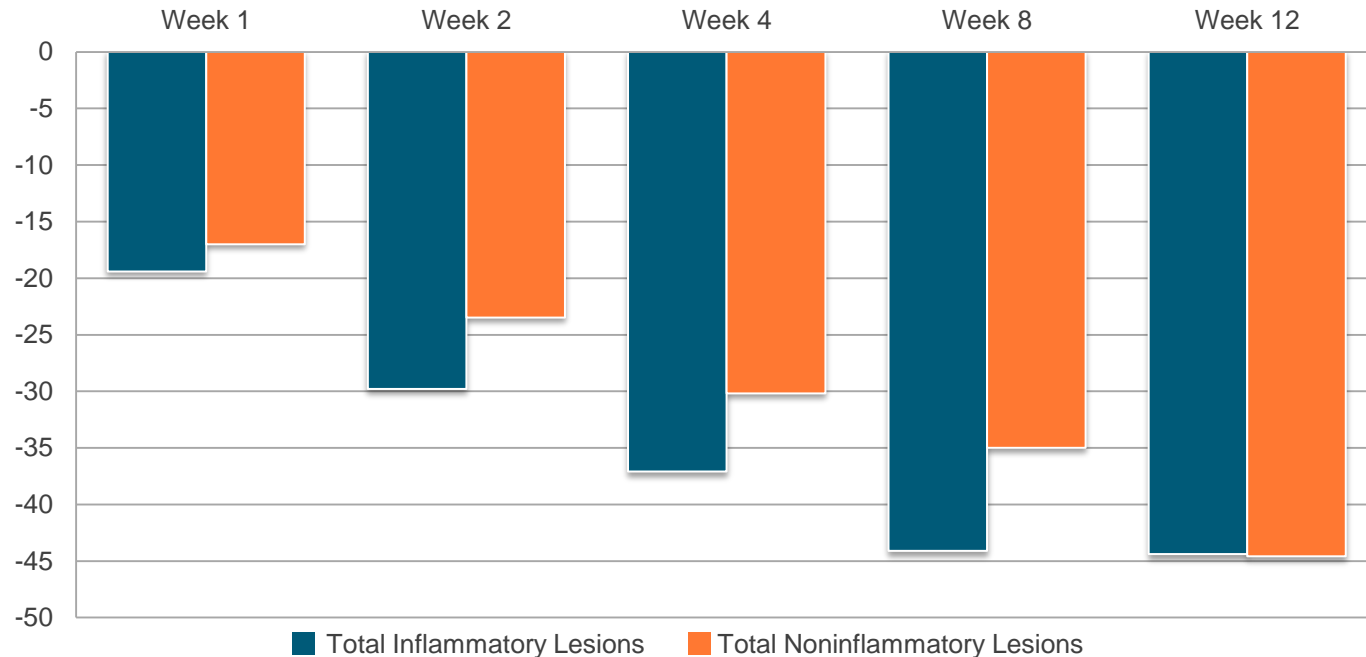


Results

Acne Clinical Efficacy

Inflammatory and Non-Inflammatory Lesion Count Reductions vs. Baseline

- Inflammatory and Noninflammatory Lesion Counts showed significant reductions ($p < 0.05$) vs. baseline starting at week 1, with both types of lesions continuing to resolve over the course of the 12-week study.
- 90% of subjects using the low-level blue and red light therapy face mask demonstrated an improvement in inflammatory lesions, and 92% demonstrated improvements in total non-inflammatory lesions by the end of the study.

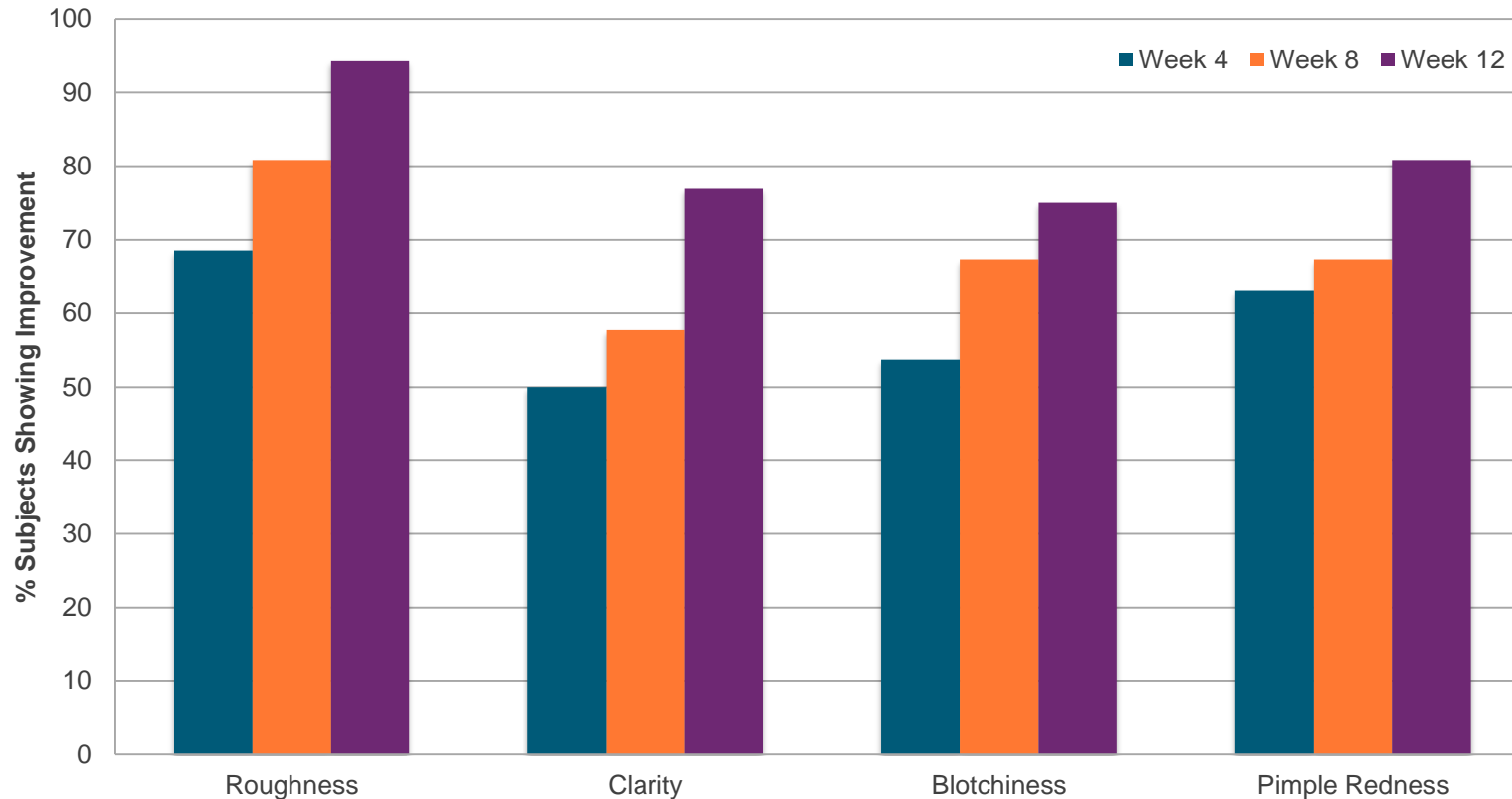


All time points are significant vs. baseline at $p < 0.05$.

Results

Clinical Efficacy - Additional Skin Benefits

- Investigator evaluations demonstrated improvements in skin texture, clarity and skin blotchiness starting at Week 4, with 94% of subjects demonstrating smoother skin after 12 weeks treatment

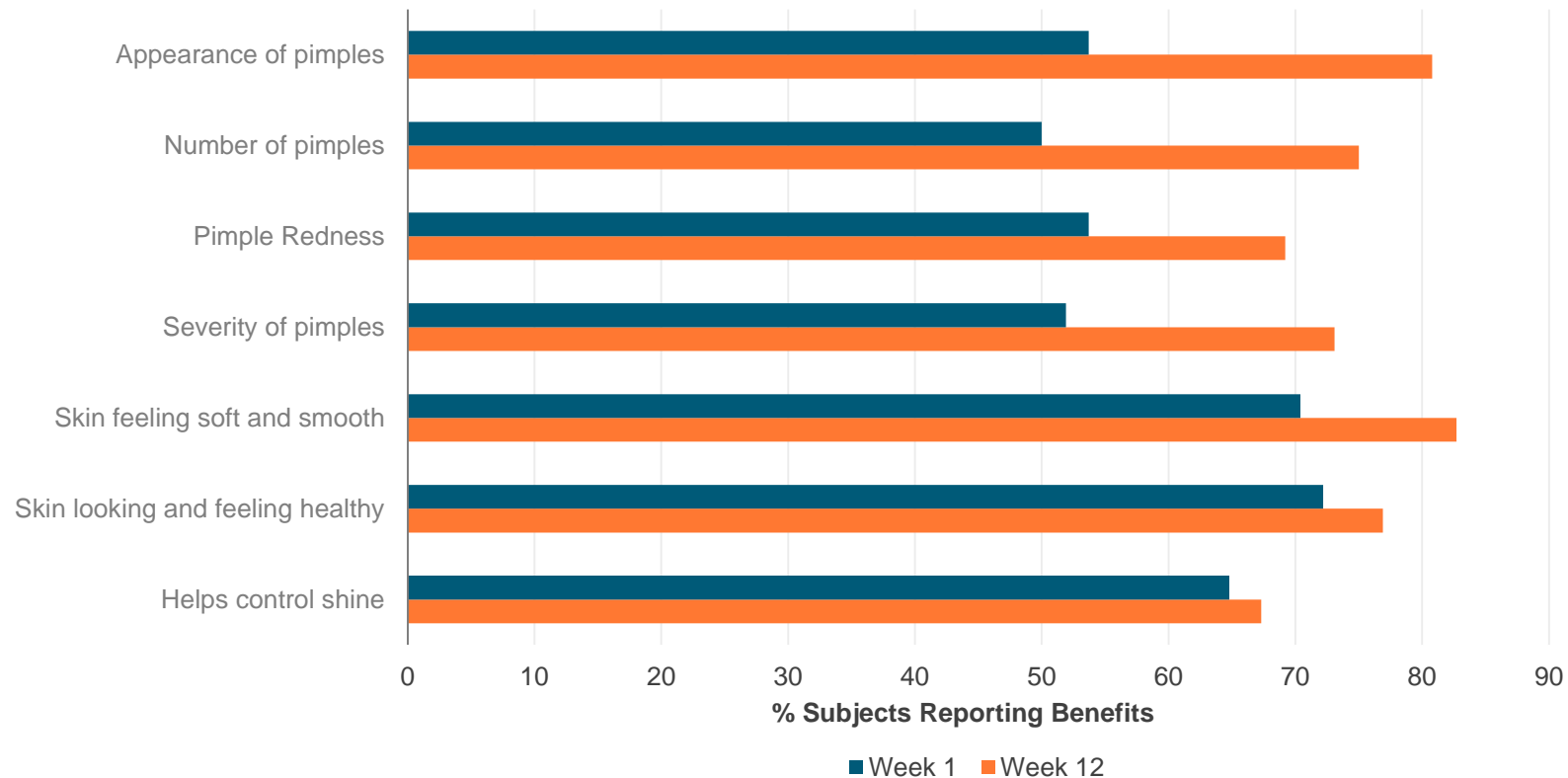


All time points are significant vs. baseline at $p < 0.05$.

Results

Subject Self-Assessments – Acne and Skin Benefits

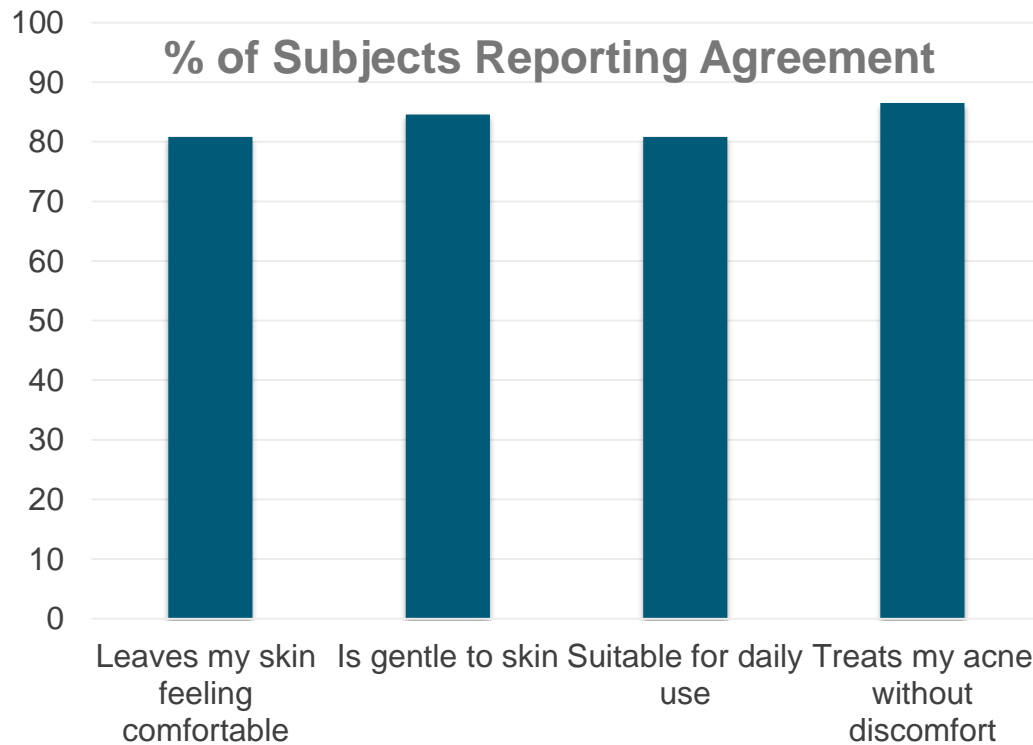
- Subjects observed noticeable and statistically significant ($p < 0.05$) improvements in the severity, redness and number of acne lesions and improvements in their overall skin condition starting within 1 week of treatment, with the degree of improvement increasing through the week 12 time point.
- Subjects agreed that their skin felt soft and smooth, looked and felt healthy and fresh, and they saw reduced shine.



Results

Tolerance and Skin Safety

- Investigator and self-assessments for tolerance confirmed that once per day treatment with the mask is well tolerated.
- After 12 weeks daily use, the percentage of subjects who scored as none-to-mild (0–1) for erythema was 98% and for tightness was 96%, versus 96% and 95%, respectively, at baseline.
- No treatment-related adverse events were reported over the study.

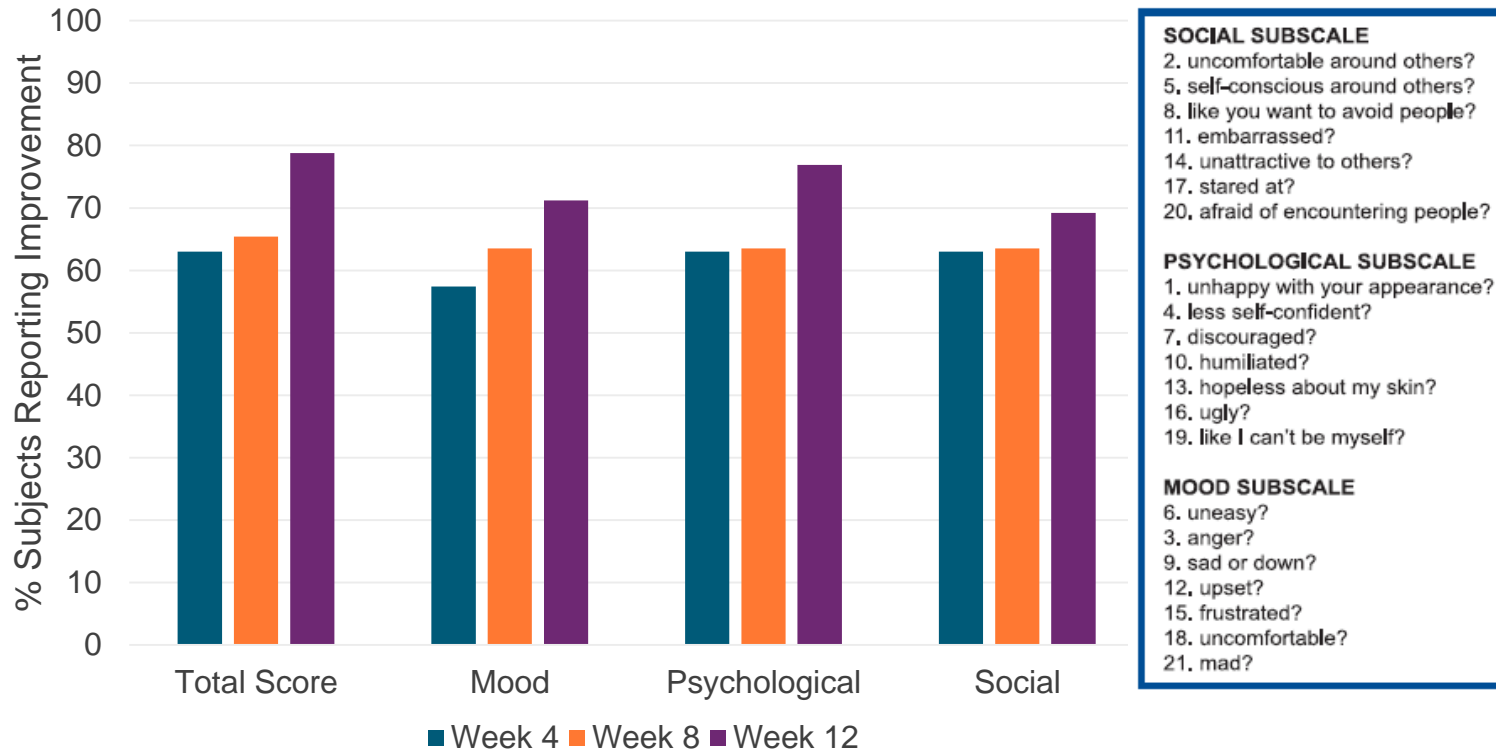


	% Subjects Rated None-to-Mild (Score 0–1)	
	Baseline	Week 12
Erythema	96.4	98.1
Dryness/Scaling	100	100
Edema	100	100
Burning/Stinging	100	96.2
Itching	98.2	96.2
Tightness/Dry Feeling	94.6	96.2

Results

Acne-Related Quality of Life (AQOL)

- Research has confirmed that acne patients report levels of social, psychological, and emotional problems that impact their quality of life, leaving patients feeling embarrassed and lowering their self-esteem.
- Results from the AQOL questionnaire demonstrate that proper care and intervention with the new mask helps improve QOL by helping to alleviate negative emotional impacts and improve self-esteem.



Digital Imaging

Digital imaging demonstrates the visible improvements seen after use of the low-level blue and red light therapy face mask over the course of the 12-week study.

Baseline



Week 12



Conclusions

- Once-daily treatment with the new low-level blue and red light therapy face mask demonstrated significant acne improvement observed by both investigators and subjects.
- There were significant reductions in total acne lesion counts and Investigator Global Assessment versus baseline, with improvement starting as early as week 1 and continuing to progress over time. Nearly 80% of subjects showed fewer breakouts starting at 1 week, and 98% of showed improvement after 12 weeks.
- The 2.5% BPO product demonstrated lesion count reductions aligned with performance expectations for topical OTC treatments, confirming the robustness of this multicenter study.
- Additional significant improvements in skin texture, clarity and blotchiness were observed by the investigators following treatment with the mask, with 94% of subjects showing smoother skin by week 12.
- Subjects also noticed meaningful acne and overall skin benefits, including visible improvement in pimple number, severity and redness, as well as improvement in skin smoothness, comfort and overall healthy-look of skin.
- Use of this UV-free and chemical-free treatment was well-tolerated, with no treatment-related adverse events, and subjects agreeing that it was gentle and good for everyday use.

Acknowledgments

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Conflicts of Interest

- This study was sponsored by Johnson & Johnson Consumer Inc. (Skillman, NJ, USA).
- The authors are employees of Johnson & Johnson Consumer Inc.