

# Comparing a Novel Solubilized Benzoyl Peroxide Gel With Benzoyl Peroxide/Clindamycin: Final Data From a Multicenter, Investigator-Blind, Randomized Study

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## ABSTRACT

**Introduction:** A solubilized 5% BPO gel has been developed to enhance the bioavailability, follicular penetration, and efficacy of BPO.

**Methods:** Sixty-five patients with moderate facial acne vulgaris were randomly assigned to apply solubilized 5% BPO gel to one facial side and 5% BPO/1% clindamycin to the contralateral side, twice daily for four or 12 weeks.

**Results:** The solubilized BPO gel resulted in significantly greater reductions in non-inflammatory lesion count than BPO/clindamycin at weeks 1, 2, 3, 4 and 12 and comparable reductions in inflammatory lesion count at all time points. Mean values for patient satisfaction with acne improvement were comparable and mean levels of erythema, dryness, peeling, stinging/burning and itching were consistently less than mild.

**Conclusion:** Compared with BPO/clindamycin, the solubilized BPO gel offers significantly greater reductions in non-inflammatory lesion count and comparable reductions in inflammatory lesion count in the absence of an antibiotic.

## INTRODUCTION

Benzoyl peroxide (BPO) has been used successfully in the treatment of both comedonal and inflammatory acne for over 30 years.<sup>1-3</sup> It is useful not only for first-line therapy but also for maintenance therapy because, unlike antibiotics, long-term use is not associated with a risk of bacterial resistance. However, solubility and stability issues have challenged formulators<sup>3-5</sup> because BPO is only sparingly soluble in water and efforts to formulate BPO in different solvents have been hindered by stability problems. Because of its poor solubility in water, BPO molecules tend to cluster together to form crystals of BPO. This not only reduces bioavailability (as many of the BPO molecules become trapped and unavailable in the interior of the clusters) but can also hinder intrafollicular penetration, and therefore the intrafollicular efficacy, of BPO (because the clusters may be larger than the follicular opening).<sup>6</sup> If these solubility and stability problems could be overcome, it may be possible to enhance the efficacy of BPO.

Using patented Soluzyl™ technology to solubilize BPO, a 5% solubilized BPO gel and 5% solubilized BPO lotion have recently been developed. These aim to enhance the bioavailability and

intrafollicular penetration of BPO and, as a consequence, enhance anti-acne efficacy.

The authors sought to compare the efficacy and tolerability of the solubilized 5% BPO gel with those of a leading 5% BPO/1% clindamycin prescription product in a multicenter investigator-blind study. Interim four-week data from this study showed that the solubilized 5% BPO gel resulted in a significantly greater reduction in the non-inflammatory lesion count than the BPO/clindamycin product at week 1, and a significantly greater reduction in the inflammatory lesion count at week 4.<sup>7</sup> Additional patients have subsequently been enrolled into the study and the period of treatment has been extended to 12 weeks. Overall results from both parts of the study are reported here.

## METHODS

### Patients

Patients were eligible to enroll in this multicenter, investigator-blind, randomized, split-face study if they had moderate facial acne vulgaris (25-100 non-inflammatory lesions, 25-100 inflammatory lesions, and up to two nodulocystic lesions) and were between 11 and 45 years of age. Study participants were

also required to be willing to avoid excessive exposure to the sun, the use of tanning booths, and facial use of non-study acne medications, moisturizers, sunscreens, fragrances, aftershaves and make-up (however, oil-free non-comedogenic make-up, mascara, eye shadow, and lipstick were allowed).

Exclusion criteria included: allergy to benzoyl peroxide, clindamycin, lincomycin, salicylic acid, sunscreens or other ingredients in the study products; having undergone a facial cosmetic procedure in the preceding six months; papulopustular rosacea and other skin diseases on the face (other than acne) that could interfere with study evaluations; facial sunburn at the baseline visit; males with a beard or sideburn that could interfere with study evaluations; uncontrolled systemic disease or infection with human immunodeficiency virus; history of regional enteritis, ulcerative colitis, or antibiotic-associated colitis; concurrent facial use of other medicated products; and participation in an investigational study in the preceding 30 days.

The following washout periods were required: one week for medicated facial cleansers; two weeks for topical alpha-hydroxy acids, anti-acne medications, topical retinoids, topical and systemic antibiotics, and topical and systemic steroids; three months for estrogens/birth control pills (unless use had been stable for at least three months); and six months for systemic retinoids.

### Treatment Regimen

Patients were instructed to apply solubilized 5% BPO gel to one side of their face and a 5% BPO/1% clindamycin gel\* to the contralateral side of their face, twice daily for four or 12 weeks. Allocation of treatments to a facial side was determined by random assignment.

\*The formulation packaged in a pump.

Before applying either product, patients were required to wash their face using a gentle cleanser (provided). They were instructed to wet their face with warm water, dispense a dime-sized amount of cleanser into the palm of their hand, create a lather, and gently massage it over their entire face for at least 20 seconds. After rinsing the skin thoroughly and patting dry, patients were asked to wait 10 minutes to allow the skin to dry completely before applying their study medication. They were also instructed to avoid applying the test products around the lips and eyes. The use of a non-comedogenic moisturizer with sunscreen (of at least SPF 15) was allowed as needed during the study.

The study protocol (NOA010A) was approved by the relevant institutional review boards and the study was performed in accordance with the Declaration of Helsinki. All patients signed informed consent documents.

### Outcome Measures

Investigators evaluated the non-inflammatory lesion count (open comedones plus closed comedones), inflammatory lesion count (papules plus pustules plus nodules), and levels of erythema, dryness, peeling, stinging/burning and itching (Table 1).

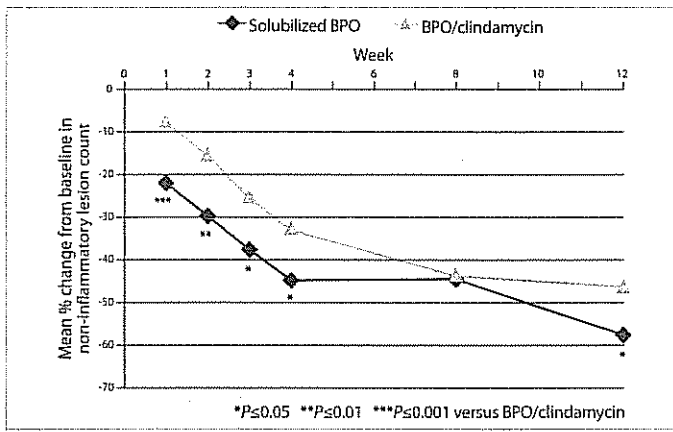
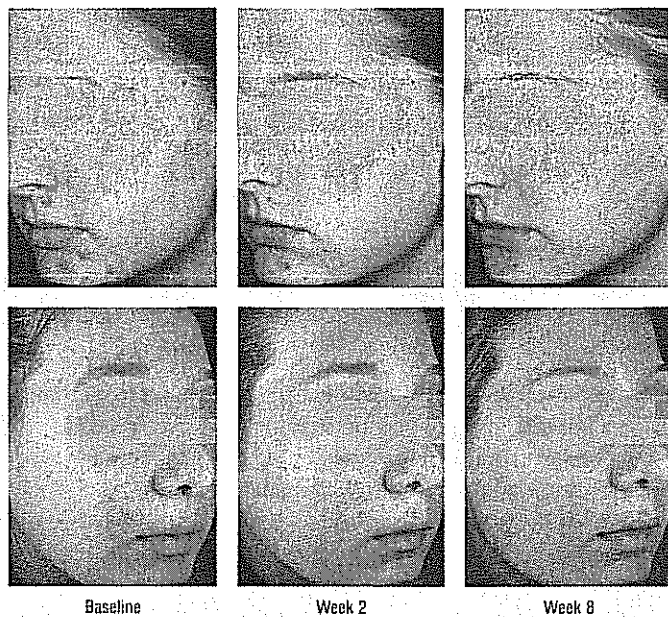
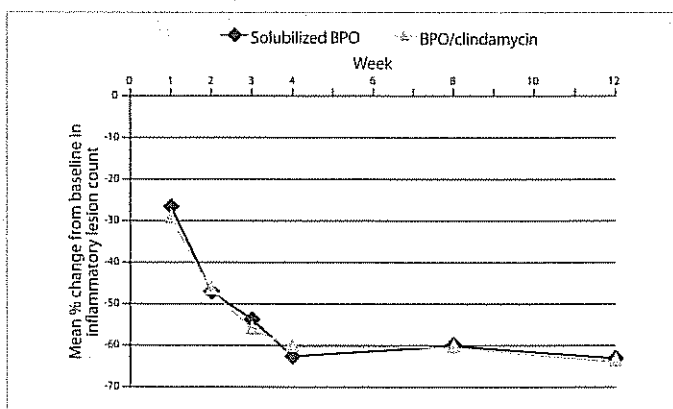
Patients evaluated their satisfaction with the improvement in their acne on a scale of very satisfied, satisfied, somewhat satisfied, indifferent or dissatisfied. All evaluations were performed at weeks 1, 2, 3, 4, 8 and 12.

### Statistical Analyses

The sample size was determined empirically and not by using a power analysis. Between-treatment differences were compared using a paired T test or Wilcoxon signed rank test for lesion count reductions, and using a Wilcoxon signed rank test for patient satisfaction, erythema, dryness, peeling, stinging/burning and itching. A *P* value of  $\leq 0.05$  was considered statistically significant.

TABLE 1.

Scales Used To Evaluate Tolerability Parameters					
Scale	Erythema	Dryness	Peeling	Stinging/burning	Itching
0	None—no erythema present (may be minor discoloration)	None—no dryness present	None—no peeling present	None—no stinging/burning	None—no itching
1	Mild—light pink, noticeable	Mild—slight but definite roughness	Mild—slight peeling	Mild—light warm, tingling sensation, not really bothersome	Mild—occasional, slight itching
2	Moderate—pink-red, easily noticeable	Moderate—moderate roughness	Moderate—definitely noticeable peeling	Moderate—definite warmth, tingling/stinging sensation that is somewhat bothersome	Moderate—constant or intermittent itching that is somewhat bothersome
3	Severe—deep or bright red, may be warm to the touch	Severe—marked roughness	Severe—extensive peeling	Severe—hot tingling/stinging sensation which is disturbing normal activity	Severe—bothersome itching which is disturbing normal activity

**FIGURE 1.** Mean percent reduction in non-inflammatory lesion count.**FIGURE 2.** Clinical improvement attained with the solubilized 5% BPO gel.**FIGURE 3.** Mean percent reduction in inflammatory lesion count.**RESULTS****Patients**

A total of 65 patients enrolled—23 to receive four weeks of treatment (of whom, 100% completed) and 42 to receive 12 weeks of treatment (of whom, 37 (88%) completed). Premature discontinuations from the study were due to non-compliance (two), burning sensation and erythema (one), voluntary withdrawal (one), and loss to follow-up (one).

The patients had a mean age of 19 years and 54% were female. They were predominantly Caucasian (71% Caucasian, 14% Black, 6% Caucasian Hispanic/Latino, 3% Asian, 6% other) and of Fitzpatrick skin type III (13% I, 25% II, 39% III, 8% IV, 5% V, 10% VI).

**Efficacy**

The solubilized BPO gel resulted in a significantly greater reduction in non-inflammatory lesion count than did BPO/clindamycin at weeks 1 and 2 ( $P \leq 0.01$ , Figure 1). It also resulted in significantly greater reductions at weeks 3, 4 and 12 ( $P \leq 0.05$ ). The early reduction in non-inflammatory lesion count with the solubilized BPO gel can be seen in Figure 2. At week 12, the non-inflammatory lesion count was reduced by a mean of 57% with the solubilized BPO gel and 46% with BPO/clindamycin ( $P \leq 0.05$ ) (Figure 1).

A subgroup of pediatric patients (45 patients, aged 12–17 years) also showed significantly greater reductions in non-inflammatory lesion count with the solubilized BPO gel in the early weeks of treatment (weeks 1, 2 and 3), as well as at week 12, relative to BPO/clindamycin ( $P \leq 0.05$ ). At week 12, the non-inflammatory lesion count was reduced by a mean of 55% with the solubilized BPO gel and 41% with BPO/clindamycin ( $P \leq 0.05$ ).

In the whole study population, both regimens showed comparable reductions in inflammatory lesion count at all time points (Figure 3). At week 12, the inflammatory lesion count was reduced by a mean of 63% with the solubilized BPO gel and 64% with BPO/clindamycin (NS) (Figure 3). In the subgroup of pediatric patients, the equivalent reductions in inflammatory lesion count were 64% and 70%, respectively (NS).

**Patient Satisfaction**

Patient satisfaction with the improvement in their acne was comparable with both regimens at all time points (Figure 4).

**Tolerability**

Mean levels of erythema, dryness, peeling, stinging/burning, and itching were consistently less than mild with both regimens throughout the study although they were, transiently, significantly higher with the solubilized BPO relative to BPO/clindamycin in the first three of four weeks of treatment (Figures 5–9). Box plots of the data are consistent with a relatively

greater increase in skin sensitivity with the solubilized BPO relative to BPO/clindamycin during the first three of four weeks of treatment while the patients acclimated to the products. During the first four weeks of treatment with the solubilized 5% BPO, the 75th percentile values for erythema, dryness, peeling, and itching were no different to, or no more than one point higher than, those with BPO/clindamycin (Figures 5, 6, 7, and 9). And, for stinging/burning, the equivalent values were no different to, or no more than 1 or 2 points higher than, those with BPO/clindamycin (Figure 8). After week 4, the tolerability of the solubilized BPO gel improved with continued treatment and was comparable with BPO/clindamycin through week 12.

One patient discontinued prematurely due to adverse events (burning sensation on the side of the face treated with BPO/clindamycin, and erythema on both sides of the face). In addition, another patient discontinued applying the solubilized 5% BPO gel to one side of the face (due to a burning sensation on the temple) but continued applying BPO/clindamycin to the other side of the face. Tolerability in the pediatric subgroup was similar to that in the whole study population.

## DISCUSSION

The results of this trial demonstrate that the solubilized 5% BPO gel can not only achieve significantly greater reductions in non-inflammatory lesion count than a combination 5% BPO/clindamycin product—but can also achieve these results as early as week 1. Furthermore, the solubilized 5% BPO gel regimen—which is an antibiotic-free regimen—achieves comparable reductions in the inflammatory lesion count compared with the BPO/antibiotic product. The solubilized BPO gel therefore offers the ability to treat acne lesions not only more effectively and more rapidly than BPO/clindamycin but also without any exposure to antibiotics. Furthermore, the solubilized BPO gel treatment was associated with comparable ratings for patients' satisfaction with the improvement in their acne.

The solubilized BPO gel may achieve relatively greater efficacy as a result of greater BPO bioavailability and greater intrafollicular BPO penetration. The solubilized BPO gel has previously been shown to result in greater intrafollicular bactericidal activity than a 5% BPO/antibiotic combination product. In a split-face randomized study, the solubilized 5% BPO gel resulted in a greater reduction in colony forming units of *P. acnes* than the 5% BPO/antibiotic product (2.5 versus 1.7 log<sub>10</sub> reduction, respectively, at eight hours post-treatment).<sup>6</sup> The solubilized 5% BPO gel has also shown greater bactericidal activity on the skin surface than has the 5% BPO/antibiotic product. In another split-face randomized study, the solubilized BPO gel resulted in a greater reduction in colony forming units of *P. acnes* on the surface of the cheek than the BPO/antibiotic product (2.8 versus 2.4 log<sub>10</sub> reduction, respectively, after 16 days of once-daily treatment).<sup>6</sup>

The solubilized 5% BPO gel is available both as a stand-alone product<sup>9</sup> (as used in this study) and also as part of a three-step acne system for normal to oily skin<sup>9</sup> (where it is used in conjunction with a proprietary cleanser and toner, each of which contains 2% salicylic acid). Some patients prefer such systems and their use may improve patient compliance.<sup>10</sup>

Results from a clinical study with the three-step acne system for normal-to-oily skin are consistent with the results presented

FIGURE 4. Patient satisfaction with the improvement in acne.

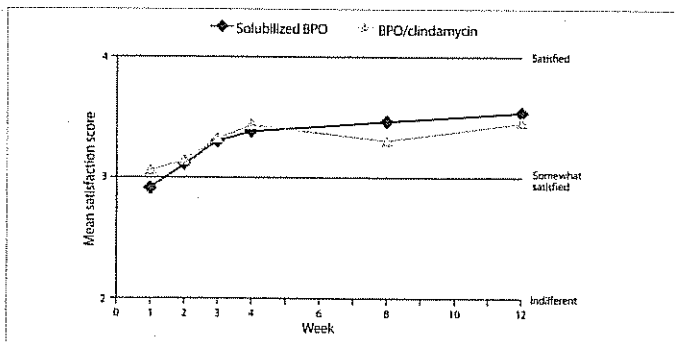


FIGURE 5. Erythema.

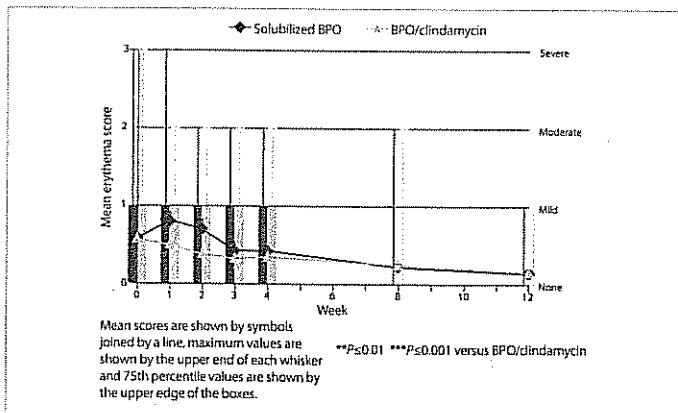


FIGURE 6. Dryness.

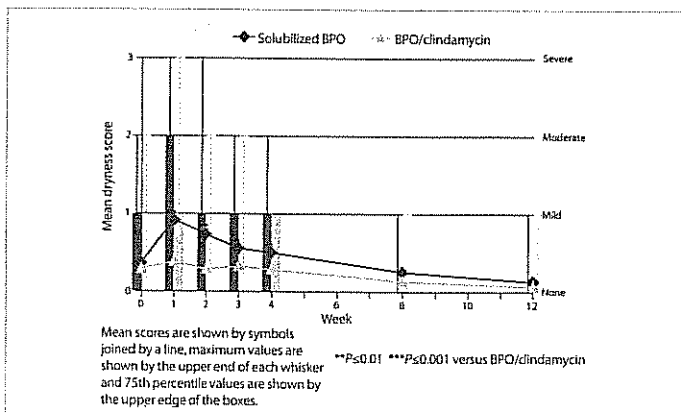
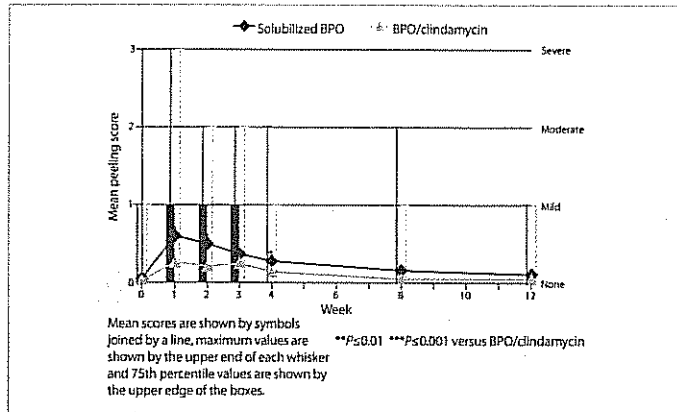


FIGURE 7. Peeling.



here—it has been shown that the three-step acne system can be at least as effective in reducing the non-inflammatory lesion count as BPO/clindamycin,\* particularly in the early weeks of therapy.<sup>11</sup> The acne system may therefore enhance the speed at which these lesions are reduced.<sup>11</sup> The acne system also demonstrated comparable efficacy against inflammatory lesions and comparable tolerability.

In the study reported here, both regimens were generally well tolerated. Although the mean levels of erythema, dryness, peeling, stinging/burning and itching were, transiently, significantly higher with the solubilized BPO gel than with BPO/clindamycin in the first three or four weeks of treatment, mean levels were consistently less than mild and the differences were likely not clinically significant in the majority of patients—as evidenced by the fact that there was no significant between-treatment difference at any time point in the mean scores for patient satisfaction with the improvement in their acne.

Although reductions in lesion counts cannot be compared across different trials, it is noteworthy that the reductions in non-inflammatory lesion count with the solubilized 5% BPO gel appear to be similar to those reported with the more potent topical retinoids. In the current trial, the solubilized 5% BPO gel was associated with a mean 57% reduction in non-inflammatory lesion count at week 12. In the literature, topical retinoids have been associated with mean or median reductions of 32%–71% (33%–52% with tretinoin 0.025% gel,<sup>12–14</sup> 32%–49% with tretinoin 0.1% microsphere,<sup>15,16</sup> 35%–58% with adapalene 0.1% gel,<sup>12,13,17–19</sup> 40%–52% with adapalene 0.3% gel,<sup>18,19</sup> 34%–36% with adapalene 0.1% cream,<sup>20,21</sup> 45% with tazarotene 0.05% gel,<sup>22</sup> 43%–71% with tazarotene 0.1% gel,<sup>14,16,17,22,23</sup> and 41%–68% with tazarotene 0.1% cream).<sup>20,24</sup> It is difficult to determine the equivalent data at earlier time points from the published literature because earlier values are often evident only in graphs or are not included at all.

The authors' findings reinforce the importance of BPO in the treatment of comedonal acne. The relative efficacy of the solu-

\* The formulation packaged in a pump.

FIGURE 8. Stinging/burning.

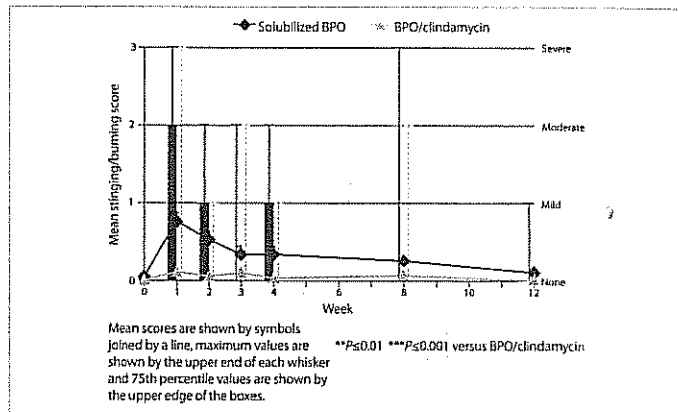
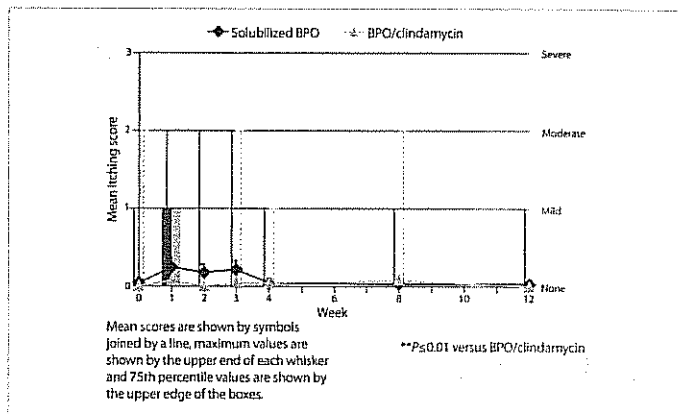


FIGURE 9. Itching.



bilized 5% BPO gel vis-à-vis topical retinoids can only be fully evaluated in a direct comparative trial but, in the meantime, the data do suggest that the solubilized 5% BPO gel offers similar levels of efficacy against non-inflammatory lesions. Undoubtedly it would be useful to perform comparative studies to further understand the relative advantages of each of these classes of medication.

## CONCLUSION

In this study, twice-daily monotherapy with the solubilized 5% BPO gel resulted in significantly greater reductions in non-inflammatory lesion count compared with twice-daily therapy with a 5% BPO/clindamycin combination product. Levels of patient satisfaction, and reductions in inflammatory lesion count, were comparable with both treatments. The significantly greater reduction in non-inflammatory lesion count with the solubilized BPO gel is likely attributable to enhanced follicular penetration of BPO. It is also possible that the unique solvent technology used in the BPO formulation could play a role.

The solubilized BPO gel has two advantages of considerable clinical importance. First, significantly greater reductions in non-inflammatory lesion count may be evident after only one week

of treatment (and speed of improvement is very important to patients). Second, the clinical advantages of the solubilized 5% BPO gel in achieving a comparable reduction in inflammatory lesion count and a significantly greater reduction in non-inflammatory lesion count are achieved in the absence of an antibiotic.

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### DISCLOSURES

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Dr. Green has been a speaker, investigator, or consultant to Allergan, OMP, Sanofi-Aventis, and Stiefel. For non-acne products he has also been a consultant to Amgen, Abbott, Bioform, and Centocor, and an investigator for Amgen and Bioform.

Dr. Thiboutot has been an investigator, consultant, or advisory board member for Allergan, Arcutis, Dow Pharmaceutical Sciences, Dusa, Galderma, Intendis, OMP, and Stiefel. She has also received honoraria or grant support.

Dr. Tanghetti is a consultant to Allergan, Stiefel, and OMP, Inc.

Dr. Wilson has no conflicts of interest to disclose.

Dr. Dhawan has no conflicts of interest to disclose.

Dr. Parr was an employee of, and holds stock options in, OMP, Inc. and was the medical monitor overseeing the conduct of this study. Her role as a participating author was to ensure the integrity of the data and the accuracy of the information reported.

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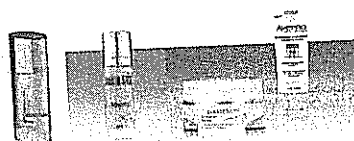


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