

# CLINICAL EVALUATION OF A 3-STEP ACNE SYSTEM CONTAINING A NOVEL SOLUBILIZED BENZOYL PEROXIDE FORMULATION FOR THE TREATMENT OF MILD TO MODERATE FACIAL ACNE VULGARIS

Emil Tanghetti, MD,<sup>1</sup> on behalf of the FAST (First Acne System Trial) Group

<sup>1</sup>Center for Dermatology and Laser Surgery, Sacramento, CA

A, pg 1  
B, pg 1  
C, pg 1  
D, pg 1

## INTRODUCTION

A 3-step acne system containing a novel solubilized 5% benzoyl peroxide (BPO) gel formulation has recently become available for the treatment of acne in patients with normal to oily skin.<sup>1</sup> BPO is poorly soluble and, in other formulations, much of it exists as macrocrystals which may be too large to enter the follicles. This new formulation contains solubilized BPO which offers the potential to aid follicular penetration of BPO and improve clinical efficacy. We sought to evaluate the efficacy and patient satisfaction associated with use of the 3-step acne system in a large patient population.

## METHODS

### Study design

- Multicenter, open-label observation study

### Key inclusion criteria

- Mild to moderate facial acne vulgaris

### Key exclusion criteria

- Eczematous facial skin
- Use of dermatologic or cosmetic products with a strong drying effect
- Pregnancy, planning a pregnancy, or breastfeeding

### Treatment regimen

- Patients were instructed to:
  - First, cleanse and tone their face using the proprietary salicylic acid-based products in the acne system (up to twice daily)
  - Second, apply the solubilized 5% BPO gel (once daily for week 1, increasing to twice daily thereafter if desired) for 10 weeks.
- Each investigator was allowed to enroll up to 5 patients.

### Outcome measures

- Investigator assessment of overall improvement (rated as cleared, marked improvement, moderate improvement, mild improvement, no change, or worse)
- Patient assessment of:
  - Effectiveness of acne system compared with prescription or over-the-counter medications used previously (rated as more effective, as effective, less effective, or not applicable)
  - Satisfaction with acne system (rated as very satisfied, satisfied, indifferent, dissatisfied, or very dissatisfied)
  - Skin feeling refreshed and acne system feeling like it is working (rated as agree completely, agree, somewhat agree, or disagree)
  - The acceptability of the feel and scent of the acne system (rated as excellent, good, fair, or poor).

## RESULTS

### Patients

- 214 patients enrolled
- Mean age of 25 years
- Predominantly:
  - Female (78%)
  - Caucasian (74% Caucasian, 11% Hispanic, 7% African American, 5% Asian, 3% other)
  - Fitzpatrick type II or III (9% I, 39% II, 30% III, 15% IV, 5% V, 2% VI)
- Among these patients, 59% considered that the overall acceptability and tolerability of their pre-study acne treatment had been poor or fair.
- At weeks 2 and 10, the acne system was used:
  - Once daily by 70-72% of patients
  - Twice daily by 18-19% of patients
  - Not at all by 9-12% of patients.

### Efficacy

- Investigator ratings indicated that use of the 3-step acne system resulted in at least a moderate overall improvement (over and above any improvement already attained with the regimen being used immediately before study entry) (Figure 1) in:
  - 55% of patients at week 2
  - 81% of patients at week 10.
- Furthermore, patient evaluations at week 10 (Figure 2) revealed that:
  - 52% considered the acne system was more effective than prescription medications they had tried previously (with an additional 30% considering the system to be “as effective”)
  - 77% considered the acne system was more effective than over-the-counter medications they had tried previously.

### Efficacy in subgroup switched from BPO/clindamycin treatment

- Among 23 patients who switched away from using a BPO/clindamycin combination product when they entered the study, use of the 3-step acne system resulted in at least a moderate overall improvement (over and above any improvement already attained with the BPO/clindamycin product) (Figure 3) in:
  - 61% of patients at week 2
  - 77% of patients at week 10.
- In this subgroup of switched patients, evaluations at week 10 revealed that:
  - 41% considered the acne system was more effective than prescription medications they had tried previously (with an additional 46% considering the system to be “as effective”)
  - 74% considered the acne system was more effective than over-the-counter medications they had tried previously.

### Patient satisfaction

- Overall, the proportion of patients who were satisfied or very satisfied with the acne system (Figure 4) was:
  - 71% at week 2
  - 79% at week 10.

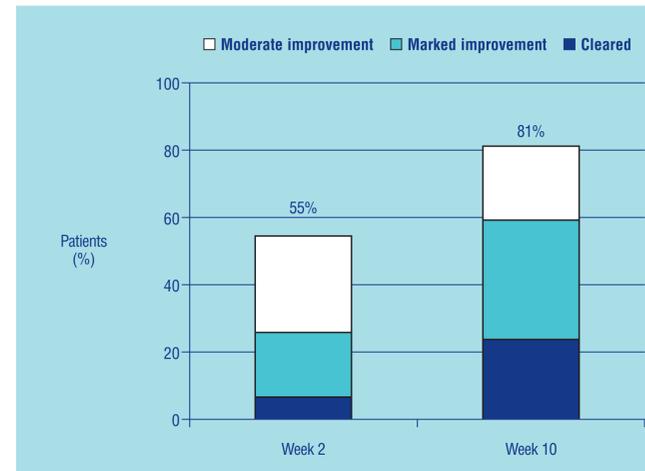


Figure 1. Proportion of patients with at least moderate overall improvement after using the 3-step acne system.

- Immediately after applying the acne system at week 10, 80% of patients agreed or completely agreed that their skin was refreshed and felt like the acne system was working.

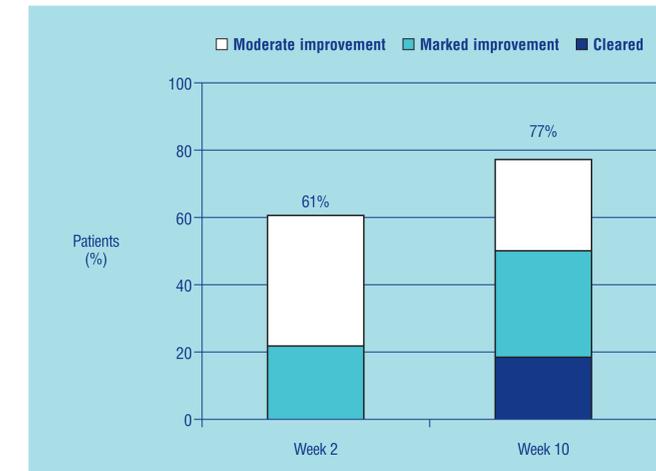


Figure 3. Proportion of patients switching away from a BPO/clindamycin combination product to use the 3-step acne system instead who showed at least moderate overall improvement (over and above any improvement already attained with BPO/clindamycin).

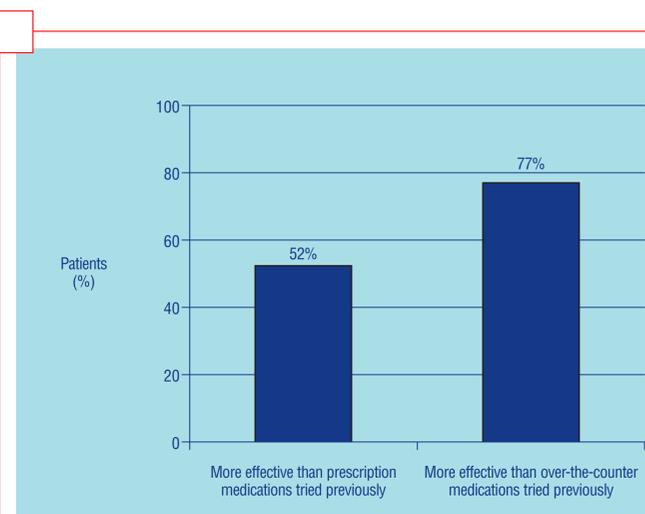


Figure 2. Proportion of patients reporting that the 3-step acne system was more effective than other medications they had tried previously.

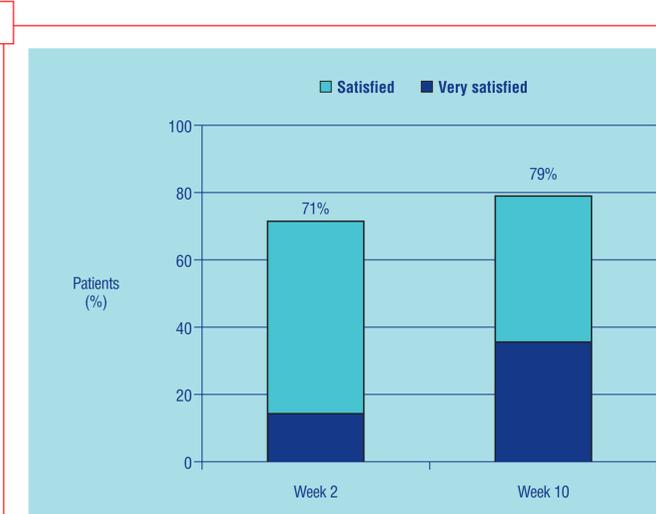


Figure 4. Proportion of patients who were satisfied or very satisfied with the 3-step acne system.

- The acceptability of the feel and scent of the acne system at week 10 was reported to be good or excellent by:
  - 95% of patients for the cleanser
  - 91% of patients for the toner
  - 61% of patients for the solubilized BPO gel.

### Tolerability

- Mean levels of peeling, erythema, dryness, and burning increased between baseline and week 2 (to between trace and mild levels) and then declined (to no more than trace levels) between weeks 2 and 10.
- The incidence of adverse effects reported by patients was:
  - 6% at week 2
  - 5% at week 10.

### CONCLUSIONS

In this multicenter observation study, the 3-step acne system offered good efficacy and high levels of patient satisfaction. The majority of patients considered the acne system more effective than prescription and over-the-counter acne medications they had tried previously.

Among the subgroup of patients who switched away from a BPO/clindamycin combination product to use the acne system instead, 77% showed at least a moderate overall improvement over and above any improvement that had already been attained with BPO/clindamycin.

### REFERENCES

1. CLENZIderm M.D. – Product Detail. Available at: <http://www.obagi.com/article/forpatients/obagiclenzidermm/Products/products.html>. Accessed November 12, 2007.

### DISCLOSURES

Supported by OMP, Inc.

Presented at the 66th Annual Meeting of the American Academy of Dermatology, February 1-5, 2008, San Antonio, TX.