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. 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.

Inclusion criteria
• Mild to moderate facial acne vulgaris

Exclusion criteria
• Pregnancy, planning a pregnancy, or breastfeeding

Eczematous facial skin

Key inclusion criteria
• Predominantly:
  – Caucasian (74% Caucasian, 11% Hispanic, 7% African American, 5% Asian, 3% other)
  – Female (78%)

Key exclusion criteria
• Eczematous facial skin
• Pregnancy, planning a pregnancy, or breastfeeding

Treatment regimen
• A 3-step acne system containing a novel solubilized 5% benzoyl peroxide (BPO) gel (Eminence Acne System; OMP, Inc.) was prescribed for use twice daily for 10 weeks. This system contains BPO gel (5%), salicylic acid gel (2%), and toner with salicylic acid (2%).

RESULTS
Patients
• 214 patients enrolled
• Mean age of 25 years
• Prevalence:
  – Female (78%)
  – Caucasian (74% Caucasian, 11% Hispanic, 7% African American, 5% Asian, 3% other)
  – Fitzpatrick type II or III (81% II, 15% III, 4% II or VI)

Among those patients who considered 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 70-73% of patients
  – Twice daily by 19-22% 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:

– 58% of patients at week 2
– 71% 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 35% considering the system to be “as effective”).
– 77% considered the acne system was more effective than over-the-counter medications they had tried previously.

Effect of acne system withdrawn from BPO/clindamycin treatment
Among 23 patients who switched away from using BPO/clindamycin combination product to use the 3-step acne system (Figure 3) who showed at least moderate overall improvement (over and above any improvement already attained with the BPO/clindamycin product) (Figure 4) in:

– 91% of patients for the cleanser
– 95% of patients for the toner
– 61% of patients for the solubilized BPO gel.

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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, M.D. on behalf of the FAST (First Acne System Trial) Group
Center for Dermatology and Laser Surgery, Sacramento, CA

PATIENT SATISFACTION
• Overall, the proportion of patients who were satisfied or very satisfied with the acne system (Figure 4) was:
  – 71% at week 2
  – 73% at week 10.

• Immediately after applying the acne system at week 10, 65% of patients agreed or completely agreed that their skin was refreshed and that like the acne system was working.

• 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 incidences of adverse effects reported by patients were:
  – 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 BPO/clindamycin combination product to use the acne system instead, 77% showed at least moderate overall improvement (over and above any improvement already attained with the BPO/clindamycin product) in:

– 61% of patients at week 2
– 71% 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.

REFERENCES
2. Supported by OMP, Inc.

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

ACNE SYSTEM (%) Patients (%)

<table>
<thead>
<tr>
<th>Expression</th>
<th>Week 2 (%)</th>
<th>Week 10 (%)</th>
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<tbody>
<tr>
<td>Overall improvement</td>
<td>71</td>
<td>73</td>
</tr>
<tr>
<td>Moderate improvement</td>
<td>61</td>
<td>67</td>
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<td>24</td>
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<tr>
<td>Unchanged</td>
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<td>0</td>
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<tr>
<td>Worsened</td>
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<td>5</td>
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Figure 4. Proportion of patients who were satisfied or very satisfied with the 3-step acne system.