QUALITY OF LIFE IS SIGNIFICANTLY IMPROVED USING A BENZOYL PEROXIDE 5%/CLINDAMYCIN 1% COMBINATION GEL VERSUS ADAPALENE 0.1% IN THE TREATMENT OF MILD TO MODERATE ACNE

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INTRODUCTION
Results of a previous single-blind, multi-center study demonstrated that in 120 subjects with mild to moderate acne, a fixed-dose combination benzoyl peroxide 5%/clindamycin 1% gel (BPO/C) produced an earlier onset of action, was more effective against inflammatory and total lesions, and was better tolerated than adapalene 0.1% (AP) gel.1 This comparative study was undertaken to further compare the profiles of these two products, specifically quality of life. The effects on quality of life were assessed using the Skindex-29 questionnaire, which evaluates a subject’s quality of life in 3 domains: emotional, functional, and symptomatic.2 The instrument has shown good psychometric qualities (eg, internal consistency, reproducibility, construction and content validity, feasibility, and sensitivity to change).3

METHODS
Study Design
- 12-week, multi-center, randomized, investigator-blind, comparative, parallel group study
Key Inclusion Criteria
- Male and female, 12 to 35 years of age
- Subjects with mild to moderate facial acne consisting of at least 25 inflammatory and/or non-inflammatory, but no more than 30 nodular cystic lesions and an acne grade between 2.0 and 7.0
Treatments
- Subjects were randomized in a 1:1 ratio to receive either BPO/C or AP for 12 weeks.
- Treatments were applied to facial acne once daily in the evening.
Assessments
- Efficacy, tolerance, and safety were assessed at Baseline and at Weeks 1, 2, 4, 8, and 12.
Primary
- Global Skindex-29 quality of life score after 2 weeks of treatment
Key Secondary
- Global Skindex-29 quality of life scores at weeks 1 and 12
- Inflammatory, non-inflamatory, and total lesion counts.
- Tolerability (erythema, dryness, and pruritus) assessed by Investigator and Patient
- Safety
- Additional tolerability events were monitored during the study and at a 5-day minimum follow-up period

RESULTS
In total, 168 subjects were enrolled. The demographics and baseline characteristics were similar between the groups. The primary efficacy endpoint was assessed in 107 of the 168 subjects.

PRIMARY ENDPOINT
Quality of Life
- After 2 weeks of treatment, subjects in the BPO/C group had a small, but significantly better improvement in quality of life compared to those in the AP group (P<0.001) (Figure 1). Improvement from baseline (as demonstrated by a reduction in mean global scores) was -4.9 and -1.2 for the BPO/C and AP groups, respectively. Overall, the difference between the 2 groups (mean global score) was -3.7 and -0.6 for the BPO/C and AP groups, respectively. The difference between the 2 treatment groups was -3.0 (95% CI 2.42 to 3.68). These quality of life improvements are likely the result of the superior efficacy and tolerability profile observed with BPO/C.

SECONDARY ENDPOINTS
Lesion Counts
- BPO/C demonstrated a rapid improvement in number of acne lesions, with a significantly greater percent reduction in both total lesions and non-inflammatory lesions at every time point (P<0.001) (Figure 2).
- A significant difference in favor of BPO/C (P<0.001) in the percent change from baseline in non-inflammatory lesion count was observed at weeks 8 and 12.
Tolerability
- BPO/C was significantly better tolerated than AP from week 2 onwards with respect to all investigator-rated (erythema, dryness, and pruritus) and patient-rated (burning, itching) adverse events (P<0.001) (Figure 3).
- A significantly greater percent reduction in investigator-rated adverse events (P<0.001) was observed for BPO/C compared to AP at weeks 8 and 12.
Safety
- The majority of AEs were reported by those in the AP treatment group (41 of 60 total). The most common AEs in both groups are listed in Table 1.

CONCLUSIONS
A significantly better quality of life was achieved with BPO/C compared with AP. These quality of life improvements are likely the result of the superior efficacy and tolerability profile observed with BPO/C.

References


2 Skindex-29 questionnaire, which evaluates a subject’s quality of life in 3 domains: emotional, functional, and symptomatic. The instrument has shown good psychometric qualities (eg, internal consistency, reproducibility, construction and content validity, feasibility, and sensitivity to change).


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