

EVOLUTION OF BENZOYL PEROXIDE: MICROENCAPSULATED 5% CREAM TO IMPROVE TOLERABILITY IN PAPULOPUSTULAR ROSACEA

Hilary Baldwin, MD¹; Boni Elewski, MD²; Ofra Levy-Hacham, MD³; Firas Hougier, MD⁴; Paul Yamauchi, MD, PhD⁵; Kate Hamil, PharmD⁶; JP York, PhD⁶; Julie Harper, MD⁷

1. Acne Treatment and Research Center, Brooklyn, NY and Robert Wood Johnson Medical Center, New Brunswick, NJ
2. The University of Alabama at Birmingham, AL
3. Sol-Gel Technologies Ltd, Ness Ziona, Israel
4. Southeast Dermatology Specialists, LLC, Douglasville, GA
5. David Geffen School of Medicine at University of California, Los Angeles, CA
6. Galderma Laboratories, LP, Fort Worth, TX
7. The Dermatology and Skin Care Center of Birmingham, AL

Introduction: Benzoyl peroxide (BPO) has a marked ability to clear rosacea lesions; however, use of traditional BPO formulations is limited by cutaneous irritation. In addition, BPO may cause irritant contact dermatitis, and, rarely, allergic contact dermatitis. Due to these factors, BPO has not been commonly considered a first-line therapy for rosacea.

Objectives: BPO was recently formulated in a microencapsulated cream (E-BPO Cream 5%) with the drug trapped in silicone microcapsules which extend drug delivery time and potentially reduce the potential for irritation.

Materials and Method: The Sol-Gel process has been developed and applied in a novel BPO formulation (E-BPO). Amorphous silica forms interconnections among colloidal particles until a rigid gel network is formed with pores of submicron dimensions. Silica shells control the release rate of BPO onto the skin, allowing a therapeutic effect while minimizing side effects and optimizing tolerability. E-BPO has been formulated as a topical monotherapy for rosacea and in combination with tretinoin for acne vulgaris.

Results: In two phase 3 studies in patients with papulopustular rosacea (n=733), once-daily E-BPO 5% cream had a rapid onset of action (week 2) and was significantly superior to vehicle. The mean tolerability parameters of both E-BPO and vehicle stayed below 1 on a scale of 0-3 and were not statistically different. In a separate 40-week extension study, >95% of patients reported tolerability scores of "mild" or "none" while 67.2% achieved an IGA score of 0/1 (clear/almost clear).

Conclusions: E-BPO effectively reduced inflammatory rosacea lesions with good tolerability and safety.