Abstract

Introduction - Salicylic acid (SA) and benzoyl peroxide (BPO) have been mainstays of acne vulgaris therapy for decades. Salicylic acid has a strong comedolytic effect that is produced by reducing cellular adhesion and facilitates keratinocyte sloughing. Benzoyl peroxide exerts rapid anti-inflammatory activity preventing any resistance making benzoyl peroxide an effective long term therapy for acne vulgaris.

Tocopherol is an antioxidant and may reduce oxidative stress in the skin, thereby reducing inflammation.

Methods & Materials - We conducted an eight-week open label trial in a private practice setting to determine the efficacy of a combination therapeutic regimen involving these three compounds. Subjects with mild to moderate facial acne vulgaris applied either 1% salicylic acid with 4% benzoyl peroxide or 2% salicylic acid with 8% benzoyl peroxide morning and evening, respectively. These were in a novel pad delivery system. Additionally 5% tocopherol supplied in a unique silicone capsule was applied in the morning post salicylic absorption. Seven (7) subjects were evaluated at baseline and at weeks 2, 6 and 8. Efficacy endpoints included reduction in nominal and percent lesion counts and Global Physician Evaluation Score. Local tolerability and safety were also assessed.

Results - Results indicate that combination salicylic acid, benzoyl peroxide and 5% tocopherol is an effective acne vulgaris therapy showing a reduction of non-inflammatory lesions (41%), inflammatory lesions (60%), and the Global Physician’s Evaluation score (47%). Although, there was an increase in the number of macules, representing cleared inflammatory lesions, these were mildly erythemic. No treatment-related serious adverse effects were reported.

Conclusion - In this open community-based efficacy trial, combination therapy with salicylic acid 1% pads, benzoyl peroxide 4% pads and topical tocopherol 5% capsules was effective in the treatment of acne vulgaris with a favorable side effect and tolerability profile.

Clinical Summary

AVERAGE GLOBAL EVALUATION

PERCENT OF FACIAL LESION REDUCTION COMPARED TO BASELINE

Week 6

Non-inflammatory Lesions 41% Reduction

Inflammatory Lesions 60% Reduction

Subjects’ Comments

1 - “Acne is much improved. Redness and size has gone down drastically. Very pleased, aside from peeling.”

2 - “My face is clearing more and more. Less all over acne than before. Still having trouble with constant peeling.”

3 - “I switched to the 4% and 1% system and it helped the dryness a lot. Overall, very satisfied.”

4 - “The Vitamin E helped keep the dryness down and felt nice like a moisturizer.”

5 - “It was very easy to use. Not very time consuming at all.”

6 - “I love it, this really works for me.”

7 - “It was very easy to use. Not very time consuming at all.”

8 - “The treatments seemed to have evened out, overall my complexion is better with occasional breakouts.”

9 - “My skin feels so much better. I haven’t seen any whiteheads. The vitamin E oil feels good on my skin. I love it.”

10 - “I love the pads, I really see a difference. I have tried a lot of things, but I think that this works.”

11 - “I see less whiteheads and less breakouts. I would recommend it to anyone, it has really worked for me.”

12 - “Because I spend less time putting a lot of things on my face while trying to get myself and children ready in the morning and it works.”

13 - “The vitamin E left my skin feeling smooth, but not oily. I love it!”

14 - “My skin feels so much better, I haven’t seen any whiteheads. The vitamin E oil feels good on my skin. I love it.”