

Novel Over-the-Counter Hydrogen Peroxide Based Acne Kit in Treating Acne: Randomized, Controlled Multi-Center Trial of Hydrogen Peroxide-based Acne System versus Benzoyl Peroxide-based Acne System in the Treatment of Mild to Moderate Acne Vulgaris

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BACKGROUND

Since acne stems from multifactorial causes (overproduction of sebum due to hormonal influences, irregular shedding of keratinocytes with hyperkeratinization of epidermis and obstruction of pores, and overgrowth of bacteria and inflammation), effective consumer products should attempt to address all contributing factors. Historically, the most popular topical anti-acne ingredient has been benzoyl peroxide; however, drawbacks include irritant potential and unwanted bleaching. Hydrogen peroxide, which has been documented to speed wound healing, decrease bacterial colonization and promote wound healing, has also shown recent promise in reduction of inflammatory acne and possesses an excellent tolerability profile.

PURPOSE

The purpose of this study is to compare the safety and effectiveness of a hydrogen peroxide-based acne regimen (Aknekit®, BMG Pharma) to a benzoyl peroxide based regimen (Proactiv®, Gunthly Renker).

METHODS

Study Design: Randomized control trial, with 1:1 assignment, at multiple three university-based dermatology practices .

Subject Selection: 14-40 year old women and men in good general health who had mild to moderate facial acne in the opinion of the enrolling investigators.

Study Procedures: Subjects were randomized, and both they and the raters were blinded as to assignment. Participants received treatment with either the hydrogen peroxide based regimen or the benzoyl peroxide based regimen.

Each acne kit was composed of three products. Active ingredients for the fragrance-free Aknekit® products were as follows: Purifying Cleanser (Salicylic acid, glycolic acid and urea peroxide), Day Treatment (Hydrogen Peroxide, Hyaluronic Acid), Night Treatment (Ratania extract, Glycolic Acid, Kojic Acid). Active ingredients for the Proactiv® products include: Renewing Cleanser (Benzoyl Peroxide 2.5%), Revitalizing Toner (glycolic acid, hamamelis virginiana [witch hazel]), Repairing Lotion (benzoyl peroxide). Both cleansers were used twice daily. In the Aknekit® arm, the Day Treatment was used in the morning and the Night Treatment in the evening. In the Proactiv® arm, the toner and lotion were both applied twice daily.

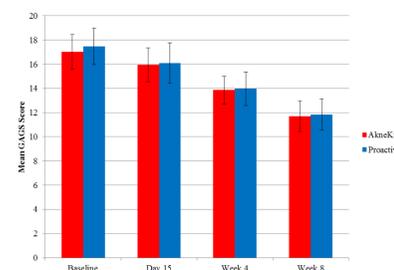
The Global Acne Grading System was used to gauge aggregate severity based on local scores from regions of the face. Overall scores were then computed. GAGS score range designations were: Mild (1-18), Moderate (19-30), and Severe (31-38). Other assessed scales by the physician and patient evaluated efficacy (1- no efficacy to 4 –excellent efficacy) and cosmetic acceptability by the patient (1- very poor to 4- excellent)

Follow-up visits were at 4 weeks and 8 weeks. At each visit, adverse events and changes in medications were recorded. Digital photographs were obtained at one center. At week 8, the subject completed a self-satisfaction questionnaire and investigators were also queried regarding safety and cosmetic benefit.

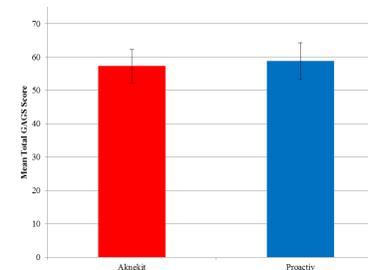
RESULTS

- 120 subjects were consented and enrolled, 102 completed all study procedures and were analyzed.
- Subject ages 14 years an older (range: 14 -40) males and females.
- No severe adverse events reported.

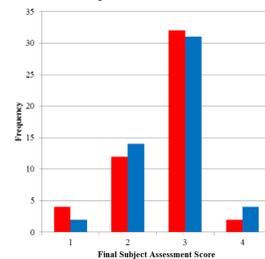
Mean GAGS Scores Over Time



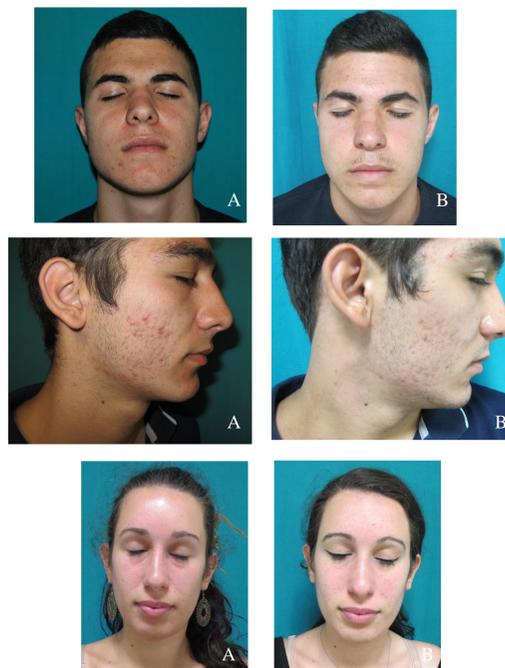
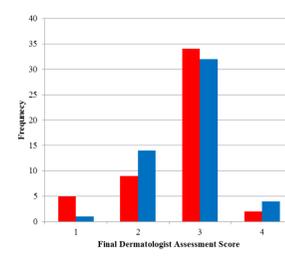
Overall Mean GAGS Scores



Final Subject Assessment Scores



Final Doctor Assessment Scores



Figs. 1-3 Acne at Baseline (A) and after Aknekit at 8 weeks (B) Improvement in inflammatory acne lesions is seen.

RESULTS

- Both treatment regimens were associated with improvement of GAGS score at 8weeks compared to baseline (p<0.0001).
- GAGS scores did not differ significantly between the 2 acne regimens over the same time period (p=0.7765)
- No adverse events were reported by subjects or investigators in either treatment arm.
- Both subjects and investigators found both acne regimens to be effective and cosmetically pleasing. No difference across treatment arms (subjects p=0.6994; investigators p=0.6565).

DISCUSSION

The Hydrogen Peroxide based acne regimen (Aknekit®) demonstrated comparable efficacy, safety and cosmetic acceptability to benzoyl peroxide based regimen (Proactiv®) in the treatment of mild to moderate acne vulgaris.

This study extends the findings of earlier research on hydrogen peroxide based products in the treatment of acne. Milani et al found that Hydrogen Peroxide 1% cream had a better tolerability profile and as equally effective to 4% benzoyl peroxide gel for both inflammatory and non-inflammatory acne lesions. Similar improvement in inflammatory acne was documented by Muizzuddin and colleagues. Hydrogen peroxide in combination (adapalene) has also been shown effective in mild to moderate acne.

Topical hydrogen peroxide's antimicrobial properties and positive effects on fibroblast proliferation and activity of have been well documented in the wound healing literature.

To our knowledge, ours is the first study to examine efficacy of hydrogen peroxide when used in combination with synergistic agents: humectant (hyaluronic acid), botanical agent (Ratania extract with known antibacterial and astringent properties), and active acids (Glycolic and Kojic acids with known exfoliative and lightening attributes) in the treatment of acne.

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