# EVALUATION OF A NOVEL ACNE TREATMENT SYSTEM (CLENZIderm MD™) DESIGNED TO ENHANCE THE EFFICACY OF BENZOYL PEROXIDE TREATMENT: AN INVESTIGATOR-BLIND, RANDOMIZED STUDY

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## INTRODUCTION

A novel system for treating facial acne vulgaris has recently become available exclusively through physician offices. Designed to enhance the bioavailability and penetration of benzoyl peroxide (BPO)—and ultimately, the efficacy of treatment—this 3-part system involves applying a novel solubilized 5% BPO gel (Serum Gel) after cleansing and toning with 2% salicylic acid-based products (Daily Care Foaming Cleanser and Pore Therapy, respectively).

The results of previous studies have demonstrated that the Serum Gel alone appears to be able to penetrate the skin and follicles more readily than a generic BPO formulation.[1] Possibly as a result of this, the Serum Gel has also been shown to achieve greater intrafollicular and skin surface bactericidal activity against *P. acnes* than both a prescription generic BPO formulation and a prescription BPO/antibiotic combination product.[1]

Using the Serum Gel as part of the 3-part acne treatment system (i.e. in conjunction with the salicylic acid-based cleanser and toner) is designed to enhance its efficacy still further as salicylic acid is believed to weaken the intercellular cement between horny cells, thereby promoting the disorganization and exfoliation of comedones.[2] In a 2-week randomized split-face study in which the Serum Gel was used in conjunction with the toner (without the cleanser), the reduction in non-inflammatory lesion count at week 2 was greater with the novel BPO formulation than with a prescription BPO/antibiotic product (34% vs. 21%).[1] Furthermore, the reduction in inflammatory lesion count at week 2 was comparable with both products (52% vs. 50%). Achieving a comparable reduction in inflammatory lesion count in the absence of the antibiotic could confer significant safety advantages by avoiding the potential for adverse effects, such as pseudomembranous colitis, that have been associated with the antibiotic.[3]

A clinical evaluation of the complete 3-part acne treatment system (including the cleanser as well as the Serum Gel and toner) has recently been completed and is reported here.

## METHODS

### *Study design*

- Investigator-blind, randomized study

### *Key inclusion criteria*

- Mild to moderate facial acne:
  - 17-40 inflammatory lesions
  - 10-100 non-inflammatory lesions
  - No more than 2 nodules
- Physician Global Assessment rating of mild or moderate (see Table 1 for scale)
- Willing to avoid sunbathing and tanning booths during the study
- Willing to refrain from using other medications, moisturizers/sunscreens, fragrances, aftershaves, and makeup on the face during the study (except mascara, eyeshadow, and lipstick, and products provided by the sponsor)

### *Key exclusion criteria*

- Facial cosmetic procedures in the preceding 6 months
- Sunburn, papulopustular rosacea, and other skin diseases (except acne) that could interfere with study evaluations
- Known sensitivity to benzoyl peroxide, salicylic acid, sunscreens, or any ingredients in the study acne treatment system
- Patients whose daily activities involve prolonged exposure to sunlight
- Beard or sideburns if they would interfere with study evaluations
- Pregnancy or lactation

### *Washout periods*

- 1 week for medicated facial cleansers
- 2 weeks for topical alpha hydroxy acids and anti-acne medications except topical retinoids and antibiotics
- 4 weeks for topical retinoids, topical and systemic antibiotics, and topical and systemic steroids
- 3 months for estrogens/birth control pills for acne treatment (unless already used for at least 3 months preceding study entry)
- 1 year for systemic retinoids

### *Treatment regimen*

- Patients were randomly assigned to receive one of three regimens using the novel acne treatment system for 21 days. All patients applied the cleanser and toner twice daily plus:
  - A = one pump of the Serum Gel once daily
  - B = two pumps of the Serum Gel once daily
  - C = one pump (or two if needed to cover the face sufficiently) of the Serum Gel once daily for days 1-7, increasing to twice daily for days 8-21 if tolerated.
- Patients visited the study site daily for 21 days at which time:
  - The patient used the cleanser to wash their face, then rinsed their skin thoroughly and patted it dry.
  - After allowing the skin to dry completely, the study technician applied the toner. This was not rinsed off but allowed to air dry on the skin.
  - The technician then applied the Serum Gel, instructing the patient to keep it on their skin for at least 8 hours.
- For products requiring twice-daily applications, the patients performed the first application themselves at home and the other application was performed at the study site at least 8 hours later.
- Patients were instructed not to wash the medication off their face for at least 8 hours after application and to avoid the use of soap or any non-study cleanser throughout the study.
- Patients were supplied with a non-comedogenic moisturizer which had a sun protection factor of 15 for use as needed (and which was only to be applied after the Serum Gel had dried).

### *Outcome measures*

- Inflammatory acne lesion count (papules + pustules)
- Non-inflammatory acne lesion count (open + closed comedos)
- Physician Global Assessment (Table 1)
- Investigator rating of erythema and dryness (Table 1)
- Patient rating of itching and stinging/burning (Table 1)

**TABLE 1** Scales used for outcome measures.

| Score | Physician Global Assessment | Erythema | Dryness | Itching | Stinging/burning |
|---|---|---|---|---|---|
| 0 | **Clear** Normal, clear skin with no evidence of acne vulgaris | **None** No erythema present (may be minor discoloration) | **None** No dryness | **None** No itching | **None** No stinging/ burning |
| 1 | **Almost Clear** Skin almost clear: rare non-inflammatory lesions present, with rare non-inflamed papules (papules must be resolving and may be hyperpigmented, though not pink) | **Mild** Light pink, noticeable | **Mild** Slight but definite roughness | **Mild** Occasional, slight itching | **Mild** Light warm, tingling sensation, not really bothersome |
| 2 | **Mild** Some non-inflammatory lesions present, with few inflammatory lesions (papules/pustules only; no nodulocystic lesions) | **Moderate** Pink-red, easily noticeable | **Moderate** Moderate roughness | **Moderate** Constant or intermittent itching that is somewhat bothersome | **Moderate** Definite warmth, tingling/stinging sensation that is somewhat bothersome |
| 3 | **Moderate** Non-inflammatory lesions predominate, with multiple inflammatory lesions evident: several to many comedones and papules/ pustules, may or may not be one small nodulocystic lesion | **Severe** Deep or bright red, may be warm to the touch | **Severe** Marked roughness | **Severe** Bothersome itching which is disturbing normal activity | **Severe** Hot tingling/ stinging sensation which is disturbing normal activity |
| 4 | **Severe** Inflammatory lesions are more apparent: many comedones and papules/pustules, may or may not be a few nodulocystic lesions | | | | |
| 5 | **Very Severe** Highly inflammatory lesions predominate: variable number of comedones, many papules/ pustules and/or nodulocystic lesions | | | | |

## RESULTS

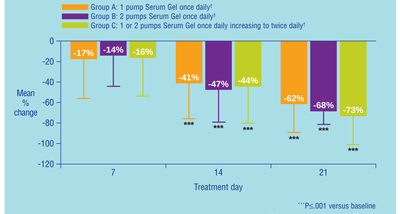
### *Patients*

- Among 42 patients enrolled:
  - 41 (98%) completed
  - 1 discontinued due to a travel commitment.
- Overall, 51% of patients were female and 49% were male.
- At baseline, patients had a:
  - Mean age of 19 years (range, 12-41 years)
  - Mean of 23 facial inflammatory lesions
  - Mean of 36 facial non-inflammatory lesions.
- All group C patients tolerated twice-daily applications of Serum Gel from days 8-21:
  - 54% needed 1 pump of Serum Gel per application to cover their face sufficiently
  - 46% needed 2 pumps of Serum Gel per application to cover their face sufficiently.

### *Efficacy*

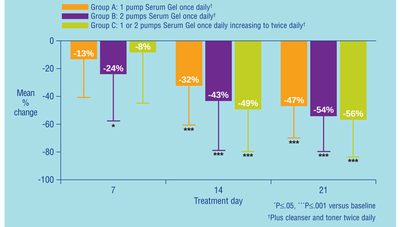
- All regimens showed significant (P≤.001) reductions in inflammatory and non-inflammatory lesion counts within only 2 weeks of treatment (Figures 1 and 2). There were no significant between-group differences.
- At days 14 and 21, respectively, the inflammatory lesion count was significantly (P≤.001) reduced by a mean of:
  - 41% and 62% in group A
  - 47% and 68% in group B
  - 44% and 73% in group C.
- At days 14 and 21, the non-inflammatory lesion count was significantly (P≤.001) reduced by a mean of:
  - 32% and 47% in group A
  - 43% and 54% in group B
  - 49% and 56% in group C.

**FIGURE 1** Reduction in inflammatory lesion count (mean + standard deviation).




***P≤.001 versus baseline
†Plus cleanser and toner twice daily

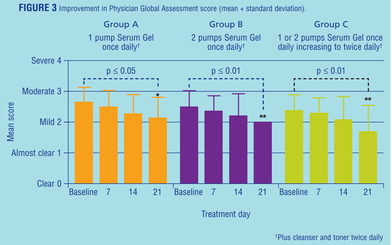
**FIGURE 2** Reduction in non-inflammatory lesion count (mean + standard deviation).




*P≤.05, ***P≤.001 versus baseline
†Plus cleanser and toner twice daily

- At day 21, the mean Physician Global Assessment score was significantly (P≤.05) improved relative to baseline in all groups (Figure 3):
  - From 2.6 to 2.1 in group A
  - From 2.5 to 2.0 in group B
  - From 2.4 to 1.7 in group C.

**FIGURE 3** Improvement in Physician Global Assessment score (mean + standard deviation).

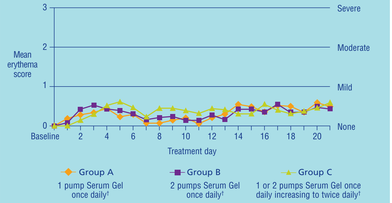



†Plus cleanser and toner twice daily

### *Tolerability*

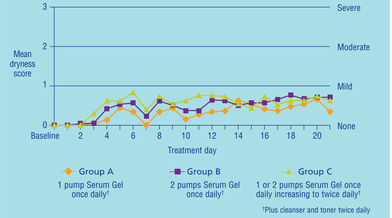
- All treatment regimens were well tolerated with mean levels of erythema, dryness, itching, and stinging/burning less than mild throughout the study (Figures 4-7).
- The severity of dryness, itching, and stinging/burning may be related to dose (mean values in Group B were generally slightly higher than mean values in Group A).
- Stinging/burning was transient.
- No treatment-related adverse events were reported.

**FIGURE 4** Mean erythema score.



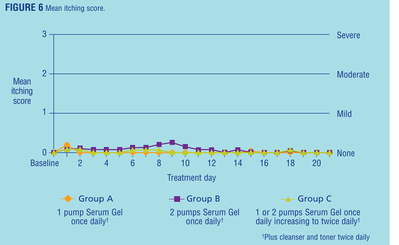

†Plus cleanser and toner twice daily

**FIGURE 5** Mean dryness score.



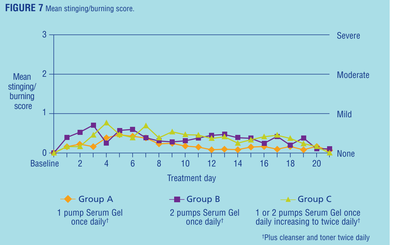

†Plus cleanser and toner twice daily

**FIGURE 6** Mean itching score.




†Plus cleanser and toner twice daily

**FIGURE 7** Mean stinging/burning score.




†Plus cleanser and toner twice daily

## CONCLUSIONS

The novel 3-part acne treatment system is a highly effective and well tolerated approach to treating acne vulgaris, achieving significant reductions in lesion counts in only 2 weeks.

Physicians have the flexibility to titrate between once-daily and twice-daily applications of the Serum Gel according to the sensitivity of an individual's skin. In many patients, applying one pump of the Serum Gel once daily may offer the optimal balance between efficacy and tolerability.

## REFERENCES

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## DISCLOSURES

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