

Tazarotene 0.1% Gel versus Tretinoin 0.1% Microsponge in Facial Acne Vulgaris: A Multicenter, Double-Blind, Randomized, Parallel-Group Study

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INTRODUCTION

Topical retinoids are widely used in the treatment of acne vulgaris and their success has spurred the recent development of additional formulations—a microsponge gel formulation for tretinoin, and cream formulations for tazarotene and adapalene.

Previous head-to-head studies have demonstrated that tazarotene 0.1% gel offers greater efficacy than both tretinoin 0.025% gel¹ and adapalene 0.1% gel.² In this study we report the results of a head-to-head study comparing the efficacy and tolerability of tazarotene 0.1% gel and tretinoin 0.1% microsponge.

METHODS

Study design

- Multicenter, double-blind, randomized, parallel-group study.

Inclusion criteria

- Patients at least 12 years of age with mild-to-moderate facial acne vulgaris, defined as:
 - 10-60 papules + pustules
 - 10-200 open + closed comedones
 - ≤ 5 nodulocystic lesions.

Washout periods

- 14 days for topical anti-acne medications.
- 30 days for oral antibiotics and investigational drugs.
- 12 weeks for estrogen/birth control pills if these had been used for less than 12 weeks (however, patients having used these for *more* than 12 weeks prior to study entry were still eligible for enrollment).
- 12 months for oral retinoids.

Treatment regimens

- Patients were randomized to receive up to 12 weeks of treatment with either tazarotene 0.1% gel or tretinoin 0.1% microsponge, applied once daily in the evenings.

Outcome measures

- Patients were evaluated every 4 weeks in terms of:
 - Global response to treatment
 - Open + closed comedo count
 - Papule + pustule count
 - Dryness, burning, pruritus, erythema, and peeling.

RESULTS

Patients

- 169 patients enrolled (74 males, 95 females).
- The patients' mean age was 18 years; 79% were Caucasian and 78% had skin phototype II-IV.
- Patients had a mean comedo count of 50, and a mean papule + pustule count of 24.

Efficacy

- At Week 12, compared with tretinoin microsponge, tazarotene gel resulted in a:
 - Significantly higher incidence of treatment success (67% vs. 49%, $p \leq 0.05$) (Figure 1)
 - Significantly greater reduction in the number of comedones (median of 60% vs. 38%, $p \leq 0.05$) (Figure 2)
 - Greater reduction in the number of papules + pustules (median of 56% vs. 46%, NS) (Figure 3).

Tolerability

- Dryness, burning, pruritus, erythema, and peeling did not exceed "trace" levels in either treatment group throughout the study (Figure 4). There were no significant between-group differences except for a transiently greater level of erythema with tazarotene at Week 4 and this was likely too small to be of clinical relevance.
- The most common adverse effects were irritation (13% and 4% with tazarotene and tretinoin microsponge, respectively), burning (11% vs. 9%), erythema (11% vs. 6%), dryness (7% vs. 6%), peeling (5% vs. 1%), scaling (4% vs. 2%), and pruritus (2% vs. 1%).
- Two patients in each group discontinued due to adverse effects.

Figure 1.
TREATMENT
SUCCESS. Incidence
of patients achieving
treatment success
(at least a 50% global
improvement).

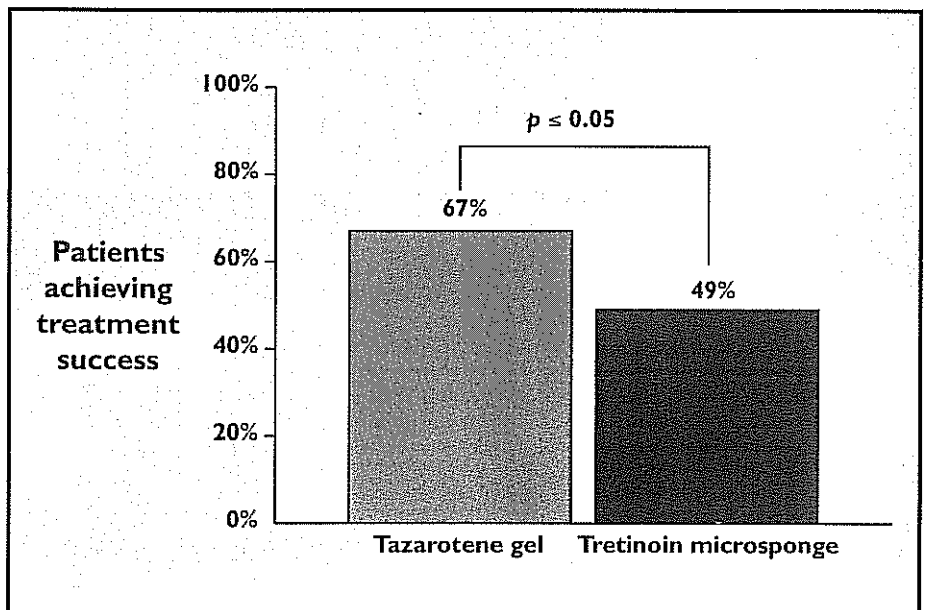


Figure 2.
OPEN + CLOSED
COMEDONES.
 Median percent
 reduction in number
 of open plus closed
 comedones.

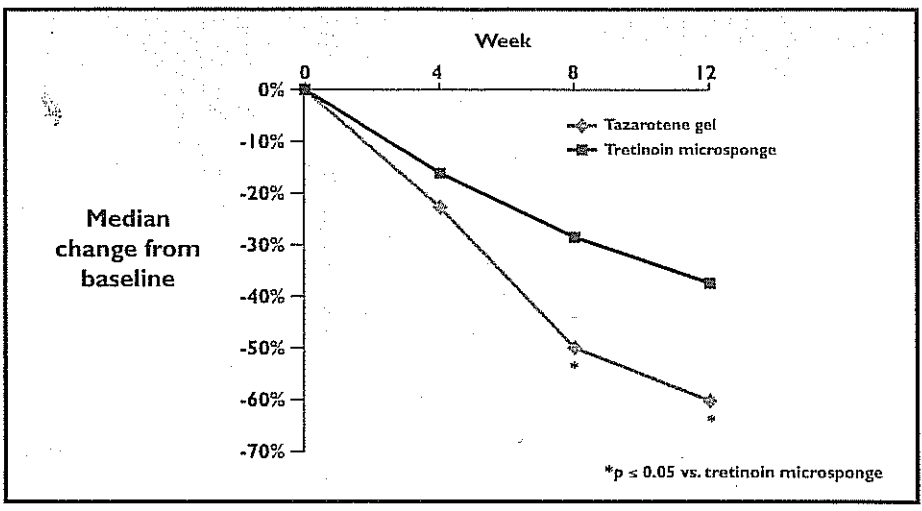


Figure 3.
PAPULES +
PUSTULES. Median
 percent reduction in
 number of papules
 plus pustules.

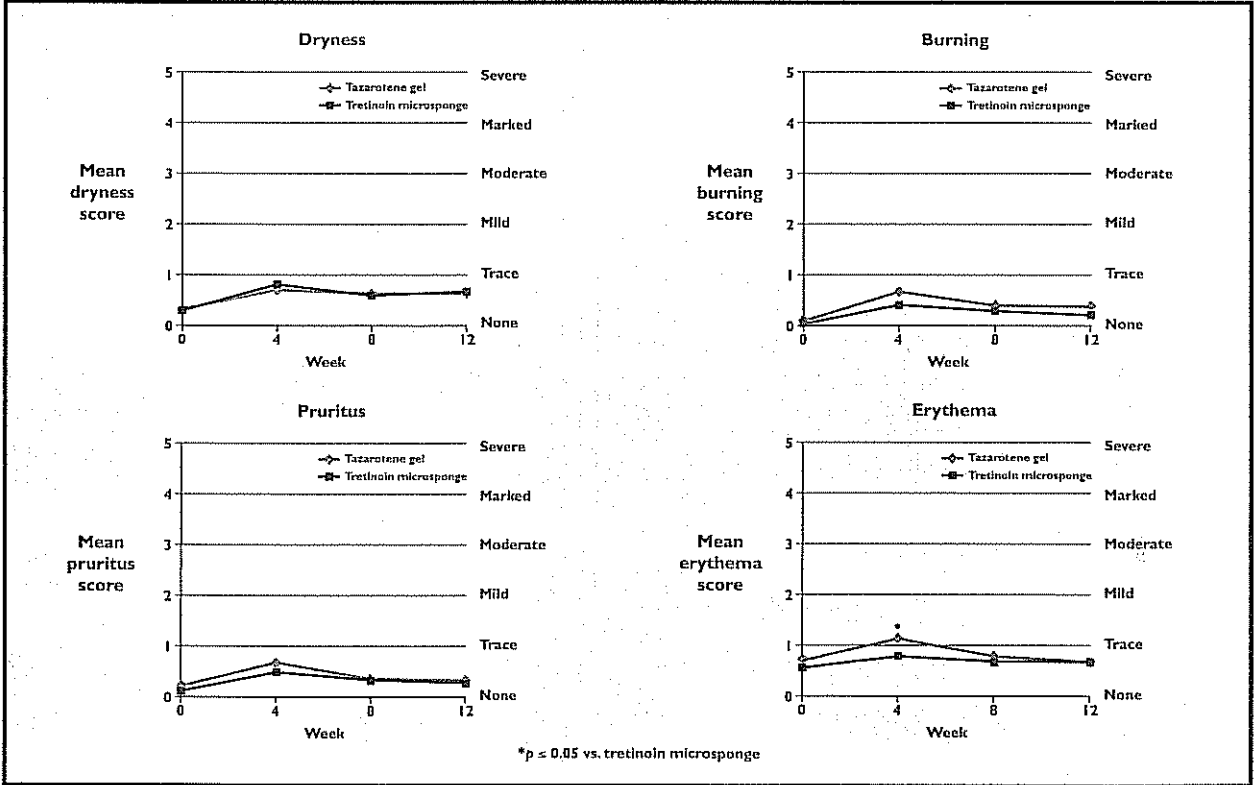
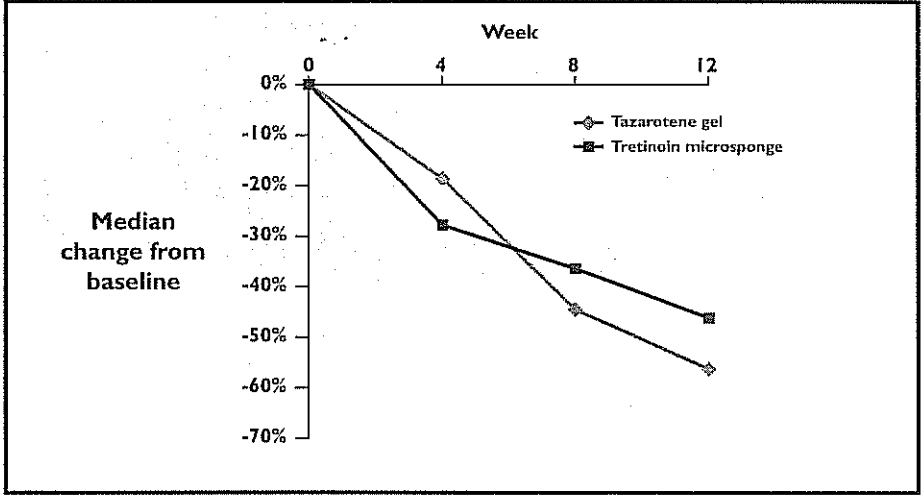
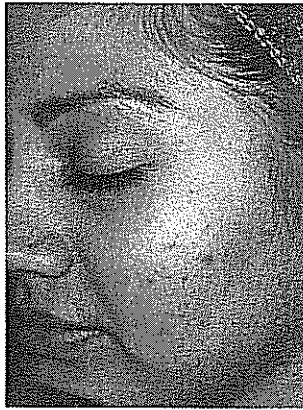
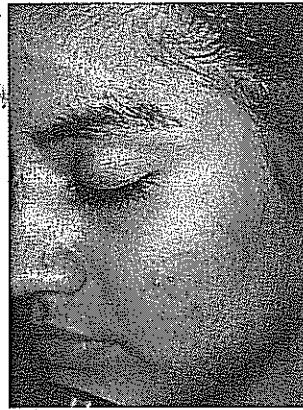


Figure 4. DRYNESS, BURNING, PRURITUS, AND ERYTHEMA. Mean scores with once-daily applications of tazarotene 0.1% gel or tretinoin 0.1% microsphere.

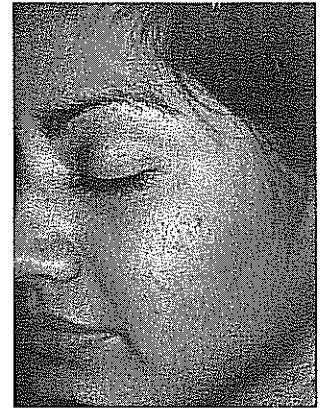
Figure 5.
Patient with
predominantly
comedonal
acne treated
with tazarotene
0.1% gel every
evening.



Baseline



Week 8

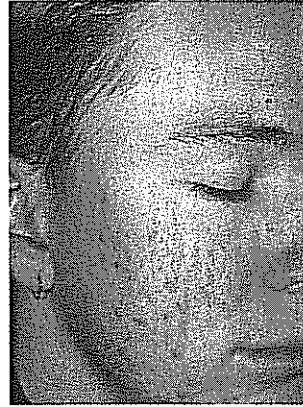


Week 12

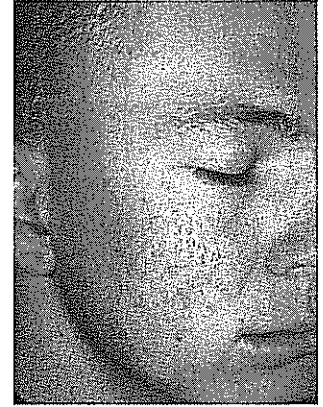
Figure 6.
Patient with
predominantly
inflammatory
acne treated
with tazarotene
0.1% gel every
evening.



Baseline

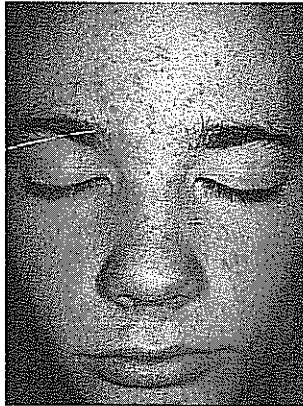


Week 8

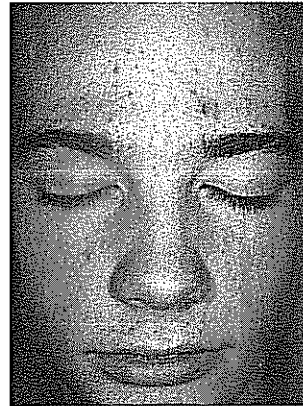


Week 12

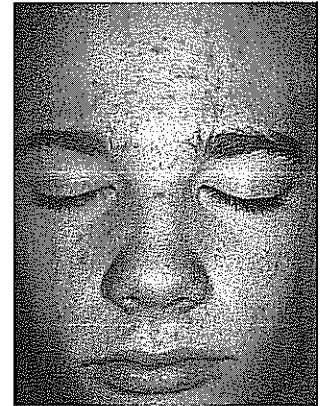
Figure 7.
Patient with
predominantly
comedonal
acne treated
with tretinoin
0.1%
microsponge
every evening.



Baseline



Week 8



Week 12

CONCLUSION

Once-daily tazarotene 0.1% gel offers superior efficacy to once-daily tretinoin 0.1% microsponge.

REFERENCES

1. Webster GF, Berson D, Tanghetti EA, Ling M, Fivenson D. Once-daily tazarotene 0.1% gel versus once-daily tretinoin 0.025% gel in the treatment of facial acne vulgaris. Poster presented at the 58th Annual Meeting of the American Academy of Dermatology, March 10-15, 2000, San Francisco, CA.
2. Shalita A, Webster G, Lowe N, et al. A multicenter, double-blind, randomized comparison of the efficacy and tolerability of treating facial acne vulgaris once daily with tazarotene 0.1% gel or adapalene 0.1% gel. Poster presented at the 59th Annual Meeting of the American Academy of Dermatology, March 2-7, 2001, Washington, DC.

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