

Real World Patient Perceptions of the use of Tazarotene 0.1% Foam in the Treatment of Acne Vulgaris

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INTRODUCTION

Acne vulgaris (AV) is the most common inflammatory skin disorder seen in outpatient dermatology clinics in the United States. Both adolescents and adults of all races and genders are frequently affected. In addition to the impact of AV on physical appearance, there are several adverse psychosocial consequences that impair quality of life. Continued patient compliance with topical therapies is a recognized barrier to optimal treatment of chronic disorders such as AV.¹ Patient satisfaction with a topical vehicle formulation strongly influences adherence with treatment.²⁻⁴ Tazarotene 0.1% foam is the only retinoid approved for use in a foam vehicle and is well established as an effective, safe, and well tolerated topical treatment for AV.⁵⁻⁷ Data from the Phase III studies evaluating tazarotene 0.1% foam for AV supported positive patient experiences with both therapeutic outcomes and formulation characteristics.⁸ These overall positive patient experiences from clinical trial patients in a controlled setting prompted a subsequent analysis using a series of surveys administered to current users of tazarotene 0.1% foam to gather perspectives on its use in “real world” clinical practice. Patients with AV on the face and/or trunk who were being treated with tazarotene 0.1% foam were asked to rate their experiences of using the product over the course of 12 weeks.

METHODS

- Around 3000 survey kits were distributed across the USA to capture data from diverse geographical areas and climates
- Two waves of the survey were administered in order to capture use in the winter months as well as non-winter months
- Surveys were administered at baseline, weeks 2, 4, 8 and 12
- Feedback was gathered on overall patient satisfaction with use of the product, perceived therapeutic impact on AV, and topical vehicle preference
- After registering at baseline patients completed surveys within 3 days of the 2, 4, 8, and 12 week dates to ensure feedback was gathered at the specific time points
- Patient responses were gathered and tabulated by a third party vendor to ensure consistency of reporting and objectivity of analysis
- A total of 372 patients participated in the surveys through week 12 with a broad range of diversity across gender, age, and race (not all responded to every question; n values = number of respondents to each question in results graphs)

Total Respondents Through Week 12 n=372		n(%)
Gender	Male	118 (31.7)
	Female	252 (67.7)
	Other	2 (0.6)
Age	12-20	107 (29)
	21-30	121 (33)
	31+	143 (38)
Race	Caucasian	252 (68)
	African American	36 (10)
	Hispanic or Latino	46 (12)
	Other	37 (10)

DISCUSSION

It is well known that topical vehicle formulation can significantly alter drug delivery and therefore impact safety, efficacy and tolerability.³ In recent years aqueous-based foam formulations have become a preferred vehicle in treating skin disease as their favorable tolerability and cosmetic elegance have led to positive patient preference, increasing the likelihood that adherence to treatment regimens including these foam vehicles will also improve. However, early foam formulations were positioned for use in diseases that affected large body surface areas, leading to a general belief amongst clinicians that the foams were only suitable for large areas, such as the trunk, due to their spreadability.³ In addition, the strength of tazarotene as a topical retinoid, the dryness and irritation commonly associated with early formulations, and lack of familiarity with proper application techniques has also led clinicians to avoid use of tazarotene 0.1% foam on the face and during the dry winter months, regardless of its novel foam formulation and the efficacy shown in Phase III trials. The results of specific questions from the surveys that address these historical perceptions of topical tazarotene and foam formulations were tabulated and can be seen in the graphs to the right.

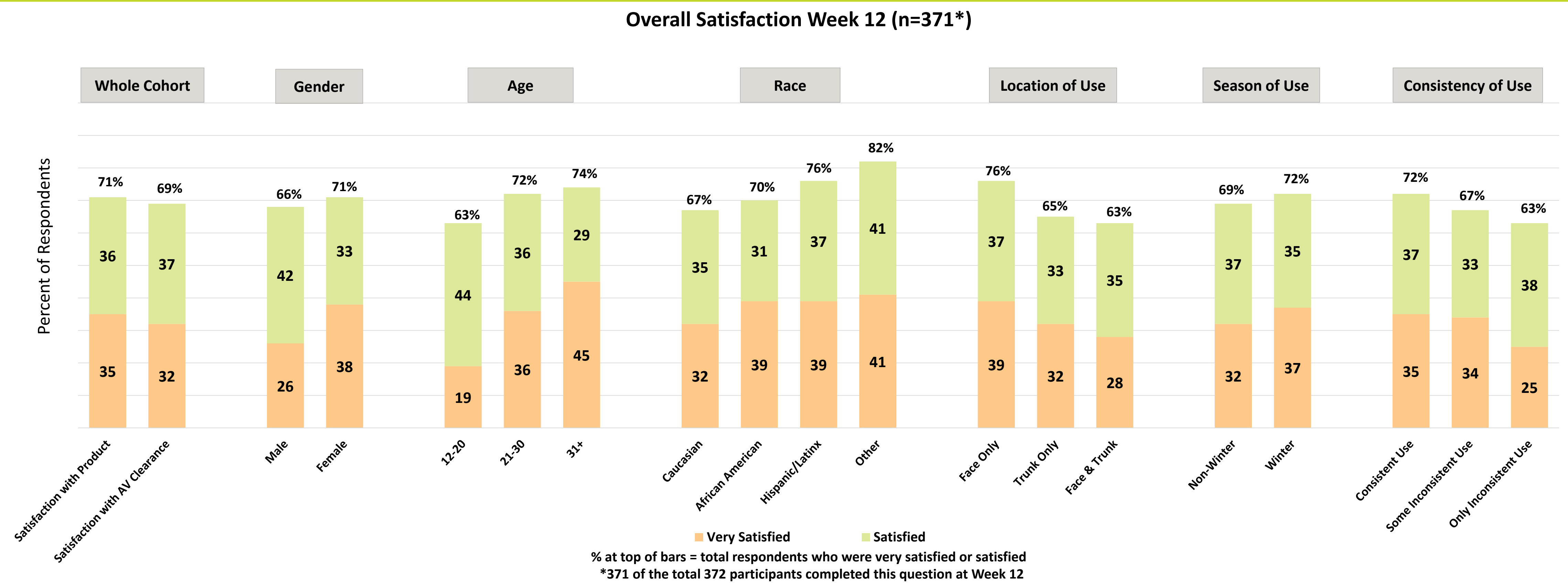
CONCLUSION

The data presented here, captured from patients who had completed 12 weeks of treatment using the novel foam formulation of tazarotene 0.1% foam, represent a significant sample size with diversity across gender, race, and age. These results contradict many prior assertions regarding topical tazarotene products. Patient satisfaction levels increased over the treatment period and after 12 weeks of treatment were consistently high across gender, age and race, regardless of the time of year the treatment was used or the area of the body being treated, and were higher with consistent use vs. inconsistent use. Overall, these real-world responses support the results of patient questionnaires from the Phase III studies, with tazarotene 0.1% foam being rated by a strong majority of patients as an effective, tolerable, and easy-to-use treatment option for AV of the face and body.

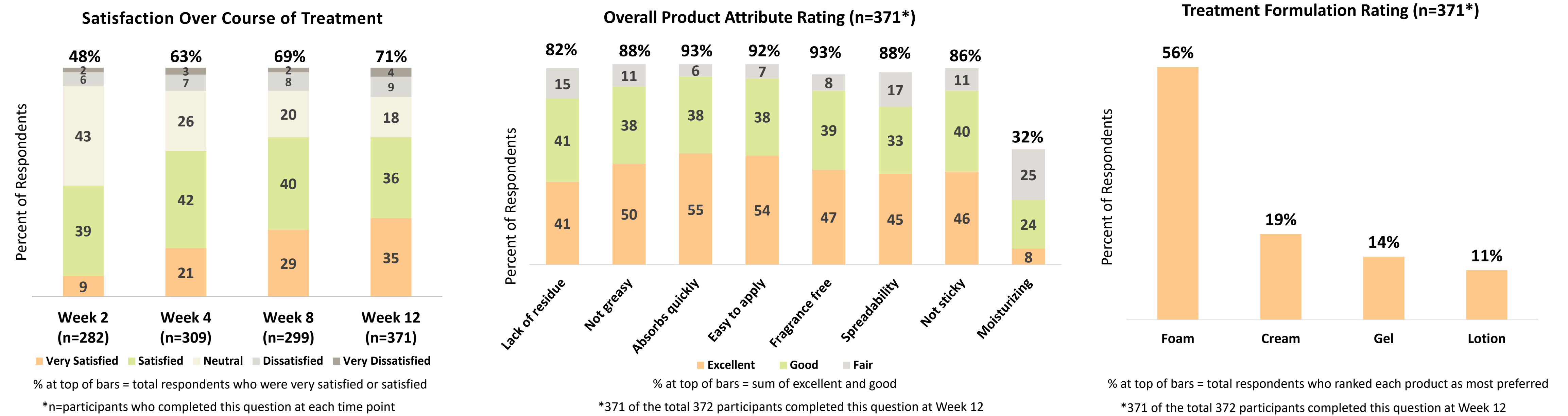
REFERENCES

1. Dréno B, Thiboutot D, Gollnick H, Finlay AV, Layton A, Leyden JJ, Leutenegger E, Perez M; Global Alliance to Improve Outcomes in Acne. Large-scale worldwide observational study of adherence with acne therapy. *Int J Dermatol*. 2010 Apr;49(4):448-56.
2. Kirck LH. Importance of vehicles in acne therapy. *J Drugs Dermatol*. 2011 Jun;10(6):s17-23.
3. Del Rosso JQ, Kirck LH, Zeichner J, Stein Gold L. The Clinical Relevance and Therapeutic Benefit of Established Active Ingredients Incorporated into Advanced Foam Vehicles: Vehicle Characteristics Can Influence and Improve Patient Outcomes. *J Drugs Dermatol*. 2019 Feb 1;18(2):s100-s107.
4. Eastman WJ, Malahias S, Delconte J, DiBenedetti D. Assessing attributes of topical vehicles for the treatment of acne, atopic dermatitis, and plaque psoriasis. *Cutis*. 2014 Jul;94(1):46-53.
5. Smith JA, Narahari S2, Hill D, Feldman SR. Tazarotene foam, 0.1%, for the treatment of acne. *Expert Opin Drug Saf*. 2016 Jan;15(1):99-103.
6. Feldman SR, Werner CP, Alió Saenz AB. The efficacy and tolerability of tazarotene foam, 0.1%, in the treatment of acne vulgaris in 2 multicenter, randomized, vehicle-controlled, double-blind studies. *J Drugs Dermatol*. 2013 Apr;12(4):438-46.
7. Epstein EL, Stein Gold L. Safety and efficacy of tazarotene foam for the treatment of acne vulgaris. *Clin Cosmet Investig Dermatol*. 2013 May 14;6:123-5.
8. Data on file, Mayne Pharma.

RESULTS



In the 12 week survey, participants were asked “Overall how satisfied are you with tazarotene 0.1% Foam?”. Satisfaction rates increased from Week 4 to Week 12 and of the 371 patients who responded to this question at Week 12, 71% stated they were either very satisfied or satisfied with tazarotene 0.1% foam and 69% were satisfied with the clearance of acne achieved during the survey period. While satisfaction was favorable overall the highest levels were reported by the following subsets: female patients, those who used the product on their face only, those who used the product in winter, and those who used the product most consistently. Satisfaction increased slightly with age, however the difference between the 3 sub-groups of age was quite low. The same can be seen across the various races who participated in the surveys. While non-white responders reported slightly higher levels of satisfaction, the differences between the sub-groups are also low. While common perception is that foams are suited better to large treatment areas and topical retinoids are poorly tolerated on the face, 77% of participants in these surveys were using tazarotene 0.1% foam on the face and the data showed higher satisfaction levels in those using the product on the face only vs. those using it on the trunk only or face and trunk. When satisfaction was rated based on season of use, tazarotene 0.1% foam again showed results that contradict traditional views that topical retinoids are not well tolerated in the dry winter months. In these satisfaction was very similar regardless of season of use, with participants using the product during the winter months actually rating satisfaction slightly higher. Participants who reported using the product daily or every other day on every survey were defined as ‘Consistent Use’ (n=215). Those who marked an option other than daily or every other day use on any survey were defined as ‘Some Inconsistent Use’ (n=156). A subset of the latter group were those who never reported daily or every other day use, defined as ‘Only Inconsistent Use’ (n=61). Patients in the ‘Consistent Use’ group reported slightly greater satisfaction rates, which aligns with expectations that consistent use or adherence to treatment regimen should result in increased satisfaction with treatment outcomes.



Patients were asked to rate their satisfaction with tazarotene 0.1% foam on all surveys. Patient satisfaction with the product increased over the course of 12 weeks and dissatisfaction remained very low throughout. At week 12, 71% of respondents indicated they were very satisfied or satisfied with tazarotene 0.1% foam and 67% indicating that they were likely or very likely to continue use of the product while only 6% stated they were unlikely to continue.⁸

Participants were asked to rate a number of qualities of tazarotene 0.1% foam at all time points during the surveys. The product rated very strongly, largely as excellent or good, in all attributes with the exception of moisturizing. However, given that topical retinoids have been historically considered to be drying, a total of 32% of respondents ranking “moisturizing” as excellent or good speaks favorably to the novel tazarotene 0.1% foam vehicle.

Participants were asked to rank topical vehicles on a scale of 1 to 5, with 1 being the most preferred formulation and 5 being the least preferred. Foam vehicle formulations received the highest ranking by far, with 56% of respondents rating it as “most preferred”. This is between 2-5 times greater than the other vehicles, with the next highest being cream at only 19% of subjects rating it “most preferred”.

Participants were permitted to share self taken photos of their progress throughout the patient experience program



- 24 year old Caucasian male using tazarotene 0.1% foam as monotherapy consistently every other day to treat AV on his face, chest, and back
- He was using a moisturizer, but provided no details as to the type or order of application
- He had tried other “topicals” in the past as well as oral antibiotics
- He has visible clearance over the 4 weeks he submitted photos and was “satisfied” at Week 8
- 20 year old Caucasian female using tazarotene 0.1% foam inconsistently “a couple of times a week” at Week 4 and every other day at Week 8 in conjunction with oral minocycline to treat AV on her face
- She has visible clearance over the 4 weeks she submitted photos and was “unsatisfied” at Week 4 during the inconsistent use period, but “neutral at Week 8 when she was using more consistently

DISCLOSURE

1. JDR Dermatology Research/Thomas Dermatology, Las Vegas, NV; Touro University, Henderson, NV; 2. Skin Wellness Dermatology, Birmingham, AL; University of Alabama Birmingham, AL; 3. Clewy Communications, Raleigh, NC. 4. Mayne Pharma, Greenville, NC. These surveys and analysis were sponsored by Mayne Pharma.