

Patient Assessment of Foam Attributes from the Tazarotene Foam, 0.1%, Phase III Trials and Potential Impact on Patient Compliance

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BACKGROUND

Acne vulgaris is a common chronic disease which can affect a patient's physical appearance and psychosocial function and often requires long term use of topical medications.^{1,3} While topical delivery of drugs in the treatment of dermatological conditions is an obvious front-line strategy, patient compliance is a known recurring barrier to treatment success.^{2,3} Lack of adherence to treatment strategy has been linked with both patient dissatisfaction and poor treatment outcomes.² Adherence to treatment is governed by a range of factors including financial and clinical considerations. Recent research also shows that patient vehicle preference is an important, but often overlooked, factor in maintaining compliance.³⁻⁶ A worldwide study found that poor adherence occurs in 40% of patients receiving topical treatment for acne.²

Topical treatments for acne include formulations such as creams, lotions, ointments, gels, solutions and foams. Vehicle choice has an impact not only on drug delivery and potency, but also cosmetic and patient perception attributes.⁴ Studies show that common concerns affecting patient adherence to topical drug regimens in chronic skin conditions are the ability to be used all the time, speed of absorption/disappearance, spreadability, ease of application, messiness, ability to moisturize, and lack of greasiness, stickiness, and scent.^{3,5} After drug efficacy, patient preference should be a primary consideration in choosing topical vehicles.³

Tazarotene foam, 0.1% is the only retinoid in a foam vehicle, and it is well established as a safe, effective, and well tolerated topical treatment for acne vulgaris.⁷⁻⁹ The data presented here highlight the results of patient preference questionnaires, administered at the end of the tazarotene foam Phase III trials, related to evaluation of the foam vehicle as well as other formulations previously used by study subjects for acne treatment.¹⁰

AIMS

- Evaluate patient preference for topical vehicle attributes.
- Examine the link between patient preferences and adherence to treatment strategy.

METHODS

- Two multicenter, randomized, double blind, vehicle controlled, parallel group Phase III studies were carried out, with 1485 patients randomized in a 1:1 ratio into two treatment groups either tazarotene foam, 0.1% (744) or vehicle foam (741).
- Participants were aged 12-45 years with moderate to severe acne vulgaris.
- Study subjects were required to apply foam to the face once daily for 12 weeks and were permitted to apply to the trunk as well.
- Efficacy, safety, and tolerability assessments were carried out at baseline and at weeks 2, 4, 8, and 12.
- At the week 12 (final) visit a patient questionnaire was administered which incorporated questions about formulation attributes, preference for treatment vehicle, and intent to adhere to treatment.
- The questionnaire results presented here have been integrated across the two studies and contain data for both tazarotene foam, 0.1% and vehicle-only cohorts.

Study Population			
Gender	n (%)	Age	n(%)
Male	729 (49)	12-17 years	860 (58)
Female	756 (51)	18-25 years	428 (29)
		26-35 years	143 (10)
		36-45 years	54 (4)

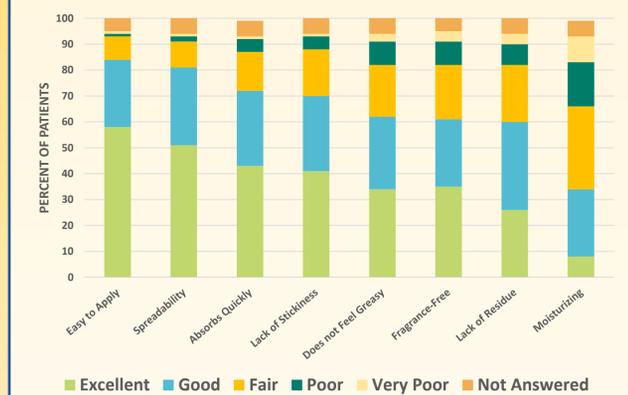
RESULTS

At the conclusion of the Phase III studies, participants were given a questionnaire to complete regarding their personal preferences and experiences with the foam vehicle compared to other formulations they had used. Approximately 94% of study subjects participated in the questionnaire. They were unaware as to whether they were rating vehicle or tazarotene foam. The most pertinent aspects are presented here.

Rate the foam on each of the following qualities: Moisturizing, lack of residue, does not feel greasy, absorbs quickly, easy to apply, fragrance-free, spreadability, lack of stickiness

As can be seen below, the foam vehicle rated very strongly, largely as good or excellent, on all attributes. The exception being moisturizing, which is not surprising given that a number of subjects were rating the active retinoid foam.

Integrated Intent-to-Treat Analysis Set N=1485, n(%)						
	Excellent	Good	Fair	Poor	Very Poor	Not Answered
Easy to Apply	856 (58)	381 (26)	127 (9)	20 (1)	8 (1)	93 (6)
Spreadability	764 (51)	440 (30)	152 (10)	28 (2)	8 (1)	93 (6)
Absorbs Quickly	638 (43)	438 (29)	229 (15)	67 (5)	17 (1)	96 (6)
Lack of Residue	392 (26)	499 (34)	330 (22)	113 (8)	58 (4)	93 (6)
Does not Feel Greasy	505 (34)	411 (28)	291 (20)	133 (9)	51 (3)	94 (6)
Fragrance-Free	515 (35)	384 (26)	312 (21)	128 (9)	53 (4)	93 (6)
Lack of Stickiness	603 (41)	432 (29)	262 (18)	75 (5)	19 (1)	94 (6)
Moisturizing	126 (8)	391 (26)	479 (32)	250 (17)	145 (10)	94 (6)



For all skin medications you have used in the past for acne, rate the following product types in the order you preferred them.

The data show that the foam was rated by far the highest as first preference for treatment vehicle, with 51% of participants rating foam best. This is between 3 to 10 times greater than the number of those rating other formulations best, with the next highest being cream at only 17% of subjects rating it best.

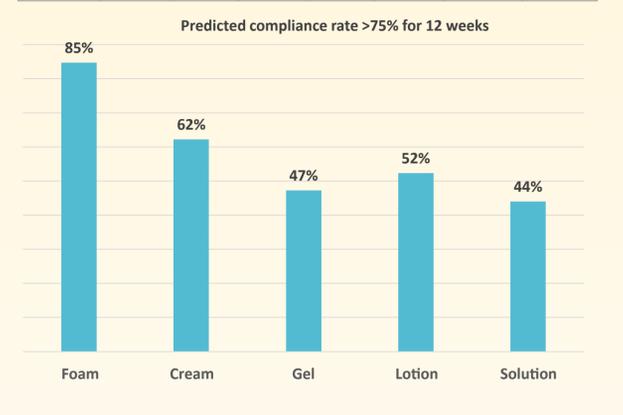
Integrated Intent-to-Treat Analysis Set N=1485, n(%)							
	Liked Best	2nd Best	3rd Best	4th Best	Liked Least	Does Not Apply	Not Answered
Foam	754 (51)	263 (18)	140 (9)	83 (6)	103 (7)	44 (3)	98 (7)
Cream	246 (17)	372 (25)	260 (18)	152 (10)	62 (4)	292 (20)	101 (7)
Gel	136 (9)	201 (14)	170 (11)	135 (9)	150 (10)	594 (40)	99 (7)
Lotion	120 (8)	237 (16)	248 (17)	186 (13)	108 (7)	485 (33)	101 (7)
Solution	75 (5)	155 (10)	165 (11)	189 (13)	176 (12)	622 (42)	103 (7)



If you were asked by your doctor to put medication on your skin once daily for 12 weeks, how likely would you be to follow these instructions based on the product type?

The foam rated most strongly of all formulations, with 85% of participants stating that they would comply between 75-100% of the time over a 12 week treatment course.

Integrated Intent-to-Treat Analysis Set N=1485, n(%)							
	100%	75-99%	50-74%	25-49%	24%	Does Not Apply	Not Answered
Foam	763 (51)	495 (33)	61 (4)	20 (1)	23 (2)	30 (2)	93 (6)
Gel	365 (25)	336 (23)	131 (9)	53 (4)	26 (2)	479 (32)	95 (6)
Cream	481 (32)	443 (30)	138 (9)	48 (3)	30 (2)	250 (17)	95 (6)
Lotion	422 (28)	355 (24)	123 (8)	61 (4)	27 (2)	401 (27)	96 (6)
Solution	338 (23)	315 (21)	132 (9)	57 (4)	36 (2)	512 (34)	95 (6)



CONCLUSIONS

Tazarotene is the only retinoid approved for use in a foam vehicle, and as such, is uniquely situated to offer the benefits of such a formulation to acne sufferers. Whilst its safety and efficacy are well established, the data presented here are the first to examine patient preference for the foam vehicle compared to other formulations and intent to comply with physician instructions. It has been previously well established that topical vehicle impacts not only safety, efficacy, and tolerability, but also patient preference and therefore adherence to treatment protocols.^{3,4} This data clearly shows that the foam formulation rated strongly in a range of properties which other studies have found to be important to patients when choosing a topical vehicle.² In addition, the foam was rated the most favorable formulation by 51% of study participants, with the next highest being cream at 17%. Perhaps most significantly, when participants were asked if they would use the foam product once a day for 12 weeks, 85% said they would comply 75-100% of the time. It is noted that no direct data has been collected on compliance rates amongst users of tazarotene foam, 0.1%. However, the data presented here strongly suggest that the favorable attributes the foam were preferred by participants and, as has been noted in other studies, positive patient preference can lead to increased compliance and therefore better treatment outcomes for acne sufferers.

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Disclosures

1. Ms. Schreiber and Ms. Crane are employees of Mayne Pharma.
2. Dr. Lewis is the Director of Clewy Communications.
3. This analysis and presentation was sponsored by Mayne Pharma and prepared by Clewy Communications.
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