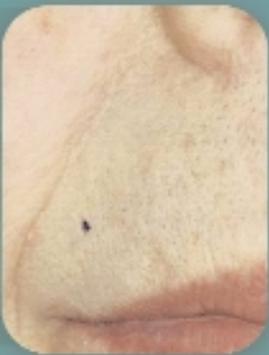


Supplement to the May 2005

**skin**  
& AGING

# Successfully Treating Excessive Facial Hair

Leading dermatologists discuss how they've integrated VANIQA (eflornithine HCl) Cream, 13.9% into clinical practice.



Supported by an unrestricted grant from SkinMedica, Inc. and Shire Pharmaceuticals Group Plc.

## Introduction

**E**xcessive facial hair is a distressing problem for many women. In fact, more than 41 million women of all ages and races in the United States are afflicted with this problem. More than half of these women must use some form of hair removal at least once a week to combat their excessive hair. In addition, 45% of women indicate that their excessive facial hair has a “serious effect” on their self-esteem.

With the advent of VANIQA (eflornithine HCl) Cream 13.9%, dermatologists are helping patients achieve slower hair regrowth rates. Eflornithine is indicated for the reduction of unwanted facial hair in women, and it works by blocking an enzyme necessary for hair growth. This treatment is the only FDA-approved prescription product for the treatment of unwanted facial hair in women. Both clinical and non-clinical studies have demonstrated efficacy in retarding the rate of hair growth with eflornithine.

### Meeting of the Minds

In late February in New Orleans, an international panel of experts met to discuss their experiences using eflornithine for successfully treating unwanted facial hair in women.

We hope that you will benefit from learning about how these practitioners discuss the issue of unwanted hair with patients, how they combine treatment with eflornithine with other hair-removal techniques, and how they optimize treatment outcomes.

Mark Lebwohl, M.D., and  
Ulrike Blume-Peytavi, M.D.  
Moderators

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## MODERATORS



**Mark Lebwohl, M.D.**, is Professor and Chairman of the Department of Dermatology at Mount Sinai School of Medicine in New York, NY. He is the author of the leading book on dermatologic therapy, *Treatment of Skin Disease*.



**Ulrike Blume-Peytavi, M.D.**, is a Professor of Dermatology and is Director of the Clinical Research Center for Hair and Skin Physiology in the Department of Dermatology and Allergy at the Charite Campus Mitte in Berlin, Germany.

## PANELISTS



**Valerie Callender, M.D.**, is Clinical Assistant Professor of Dermatology at Howard University College of Medicine in Washington, D.C. She's also Medical Director of the Callender Skin and Laser Center in Mitchellville, MD.



**Richard E. Fitzpatrick, M.D.**, is an Associate Clinical Professor at the University of California, San Diego. He is the recipient of the 2005 Ellet Drake Award for his contributions to innovative laser procedures and excellence in teaching. He's also in private practice at the La Jolla Cosmetic Surgery Centre in La Jolla, CA.



**Marta Rendon, M.D.**, is Clinical Associate Professor in the Department of Dermatology at the University of Miami School of Medicine. She is also a Fellow of the American Academy of Dermatology and a board member and founding member of the American Society of Cosmetic Dermatology and Aesthetic Surgery. In addition, Dr. Rendon is in private practice at the Dermatology and Aesthetic Center in Boca Raton, FL.



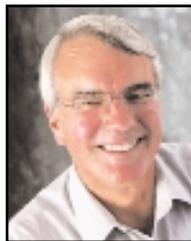
**Janet Roberts, M.D.**, is Clinical Professor of Dermatology at the Oregon Health Sciences University in Portland, OR, and she specializes in the diagnosis and medical treatment of hair disorders. She's currently Secretary-Treasurer of the North American Hair Research Society. In addition, she's Director of the Northwest Dermatology and Research Center in Portland.



**Francesco Mazzarella, M.D.**, is in private practice in Bari, Italy.



**Elia Roo, M.D.**, is Director of the Unit of Aesthetic Dermatology at Hospital Sur Alorcon in Madrid.



**Ron Trancik, Ph.D.**, is Vice President of Research and Development for SkinMedica.

## How Eflornithine Works

### The mechanism of action of this treatment.

**Dr. Mark Lebwohl:** The purpose of this roundtable is to provide guidance on how to integrate VANIQA (eflornithine HCl) Cream 13.9% into clinical practice. I think it makes sense to first discuss the mechanism of action of eflornithine.

This cream is not a hair remover, and it's not a depilatory. Eflornithine doesn't terminate the hair follicles; it reduces the rate of hair growth.

#### So, how does it work?

**Dr. Ron Trancik:** Researchers have conducted animal and basic biochemical studies that show that eflornithine inhibits the enzyme affinity for ornithine decarboxylase (ODC), an enzyme that generates polyamines, which are considered to be the building blocks of the matrix cells in the hair follicle. With eflornithine blocking this enzyme, it inhibits the synthesis of these polyamines and reduces the rate of hair growth.

#### Eflornithine can get to the target ODC enzyme in two ways:

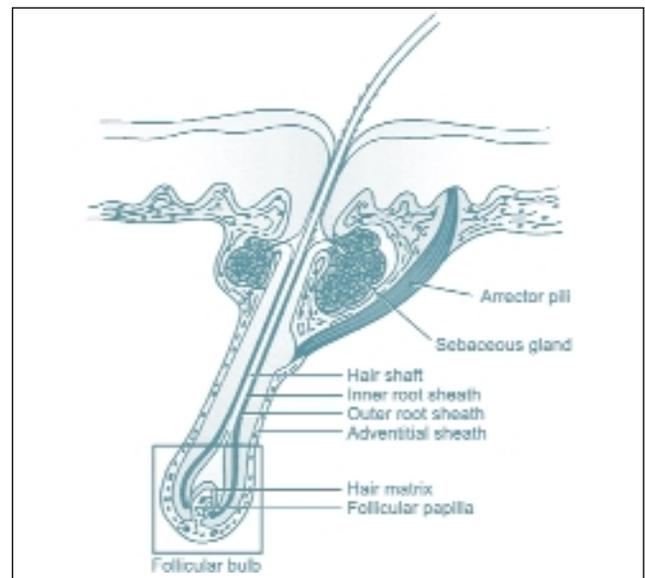
1. trans-follicular penetration — down the hair shaft
2. transdermal penetration through the skin and then into the hair shaft.

**Dr. Janet Roberts:** Does eflornithine affect the inhibition of the growth of hair that is not hormonally induced?

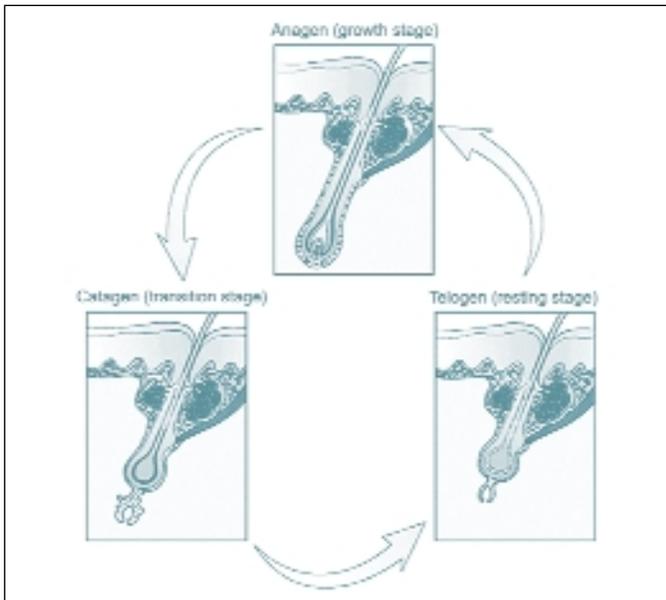
**Dr. Valerie Callender:** I'd say that clinically it does have an effect because I've used it in other areas besides the face.

**Dr. Roberts:** Of course, most of the hair on the body is hormonally energy-sensitive, but it seems as though eflornithine is effective in diminishing the appearance of vellus hair.

**Dr. Trancik:** We know a lot about scalp hair and how drugs such as finasteride (Propecia) and minoxidil (Rogaine) influence hair cycle dynamics (such as the on-off switches between the anagen and telogen phases), but we don't know a lot about what happens with this drug and its relationship to the dynamics of facial hair.



The pilosebaceous unit includes the hair follicle and the sebaceous gland. *Illustration courtesy of SkinMedica.*



An illustrative look at the three phases of hair growth: anagen, catagen and telogen. *Illustration courtesy of SkinMedica.*

**Dr. Ulrike Blume-Peytavi:** We do know that a patient's facial hair has a low percentage of anagen hair (much lower than scalp hair), but it would be interesting to get a view of exactly what's happening at the follicular level. It would also be interesting to know what happens to the follicles when a patient stops using this treatment. Does the hair immediately regrow in the same phase or does it have to initiate a new phase? That's important for communicating the problem of anagen and full-phase relationship.

**Dr. Trancik:** I don't know whether eflornithine works by shortening the anagen phase and thereby producing hair of lesser quality, or whether it just simply slows the rate of growth and doesn't do anything to the duration of the anagen phase.

**Dr. Lebwohl:** You can't cause hair loss using eflornithine, and it would suggest that the mechanism is simply slowing down hair growth. Just to get to the point of the mechanism in lasers, as we get to the clinical studies, there is an article by Dr. Rox Anderson indicating that laser is effective in all stages of the hair.

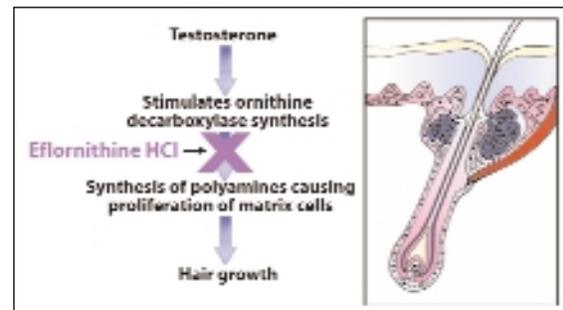
**Dr. Richard Fitzpatrick:** Actually, in all of Dr. Anderson's articles, he mentions that the laser sensitivity affects all stages of the hair follicle. In one article, he mentions that in humans there is the same sensitivity of the laser, independent of the stage of the hair (anagen, catagen or telo-

gen). So for the laser people, it's a misconception that eflornithine would negatively affect the laser treatment.

**Dr. Trancik:** I've heard laser doctors say that it doesn't matter whether the hair is in the anagen or telogen phase. If you have a pigmented hair shaft in the follicle, then lasers are going to cause some destruction.

**Dr. Fitzpatrick:** Some of the confusion is related to the fact that Dr. Anderson conducted two studies: one in rats that showed that the hair removal is dependent on the phase because the pigmentation changes with the phase. But he also conducted a study on humans that showed that hair removal isn't dependent on phase.

**Eflornithine cream is not a hair remover, and it's not a depilatory. Eflornithine doesn't terminate the hair follicles; it reduces the rate of hair growth.**



Eflornithine HCl inhibits ornithine decarboxylase, an enzyme key to the synthesis of polyamines. When polyamines, which help proliferate matrix cells, are inhibited, hair growth slows.

And if you think about it, it makes sense because there are pigment cells surrounding the follicle. So even if the hair isn't present, there is still a target. However, if the hair is present, then it really doesn't matter what phase the growth cycle is in. Even without the hair, you still have melanocytes that can be targeted. The question is: What part of the whole unit has to be destroyed? I'm not sure if that has been answered in any sense regarding the permanent reduction of hair growth. ■

## Reviewing Study Data

### Results from two pivotal studies and a look at studies combining eflornithine and laser hair removal.

**Dr. Ron Trancik:** Two pivotal trials were conducted totaling 594 women. The first trial was conducted at 10 U.S. centers, and the second trial was also primarily in the United States, but one of the centers was in Spain. Patients were randomized two to one, active versus placebo. Patients continued their existing hair removal methods, and the study medication (eflornithine) or placebo was applied for 24 weeks with follow-up visits at weeks 2, 4 and 8. Then, this regimen went to 4-week intervals, 12, 16, etc. Then, after the 24-week treatment phase came an 8-week follow-up for new treatment phase.

The efficacy endpoints were simple and straightforward. First, we used physician global assessment, which employs a four-point categorical scale as the primary endpoint. The second endpoint was a patient self-assessment using a 100-point visual analog scale. Of course, safety parameters were monitored throughout the course of the study as well.

At follow-up visits, the four-point categorical scale was used to measure terminal hairs, not vellus hairs, and then the 0 to 100 visual analog scale was utilized by patients.

According to the results of the study based on the physicians' global assessment, a rating of either clear or almost clear, coupled with marked improvement was necessary for the primary endpoint. That gave an eflornithine response rate of 32% versus 8% for vehicle. Statistically significant improvement was seen as early as week 8 when we combined

the clear/almost clear group with the markedly improved group responders.

#### A Look at Laser Studies

**Dr. Trancik:** Drs. Stacy Smith and Daniel Piacquadio conducted a pilot laser study designed to ascertain whether there is an additive or synergistic effect between the combination of using eflornithine with lasers versus laser alone. There were two investigational sites (one in San Diego and one in La Jolla) where 54 female patients were enrolled. Patients were asked to apply active versus vehicle to their upper lips in a split-face manner. Participants were



Patient shaved 48 hours prior to each photo. At left is before treatment with eflornithine. On the right is the patient after 24 weeks of treatment with eflornithine. Photos courtesy of SkinMedica.

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## Understanding the Adjunctive Nature of Eflornithine

**Dr. Mark Lebwohl:** Many physicians don't understand the adjunctive nature of the treatment. How would you help them understand this? The leading view is that treating patients with eflornithine competes with other methods of hair removal they're using. But this couldn't be farther from the truth. Adding eflornithine in conjunction with another form of hair removal results in the patient ending up happier. More patients actually go through with the procedure because it works better.

**Dr. Janet Roberts:** Certainly, getting education to physicians is critical. It's a matter of really getting this issue front and center in bringing out some of these points that we've been talking about.

**Dr. Marta Rendon:** I think first and foremost, we have to create an awareness among dermatologists about the issue of unwanted facial hair or hirsutism or hypertrichosis because these are all problems that aren't on the radar screen. Physicians aren't necessarily out there evaluating patients to see if they have increased hair. So first, creating awareness of the issue of unwanted hair is the most important thing.

**Dr. Roberts:** Creating awareness among patients and consumers is a second aspect of this, too. But as far as the adjunctive use of eflornithine with laser hair removal, I think a lot of misconceptions exist among the laser hair removal population of physicians. I think first and foremost that misconceptions about how eflornithine should be used should initially be addressed directly to that group of people.

I really want to expand on the point that it's really important to get the physicians on board first. Get them educated and aware first, or they won't understand how to use eflornithine to its full potential. We want to make sure the nurses, the medical assistants and the ancillary staff are educated, too, because they're usually the first contact with the physician's practice, and their viewpoints can help better educate patients as well.

instructed to apply the agent on the face b.i.d. for 34 weeks, and then they were asked to come in at week 2 and week 10 to receive a laser treatment to the upper lip and chin. This study used two different types of lasers, and the patients essentially were divided equally between the two laser treatment facilities. Patients were then followed up with at week 16, 22, 28 and 34, and photographs were taken at the beginning and at the end of the study. A physicians' global assessment was conducted, along with a patient self-assessment.

When patients graded their upper lips, the response with eflornithine plus laser was considerably better than the results patients achieved with the vehicle plus laser. Patients who treated their chins for the facial hair attained the same favorable results when they underwent treatment with eflornithine plus laser. For a photograph of the upper lip results, see page 12.

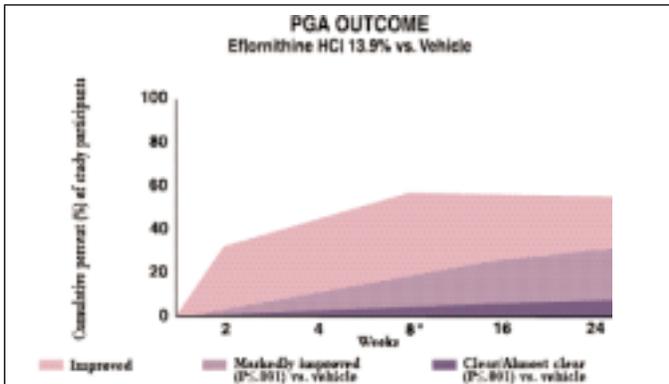
Drs. Lui and Shapiro conducted a second study at one center in Vancouver. The design was similar to the one used by Drs. Smith and Piacquadio. Again, patients were asked to apply either the active agent or placebo on half of either their faces, chins or lips, in a randomized, blind-ed fashion. A physicians' global assessment was used, sim-

ilar to the one used in the Phase III clinical trials that supported U.S. approval of VANIQA (eflornithine HCl) Cream 13.9%. Based on the physicians' global assessment, the group that underwent laser plus placebo had about a 68% response and the group of patients who had laser plus eflornithine had better results with a 96% response.

In the Vancouver study, the physicians also performed hair counts, which the physicians in Drs. Smith and Piacquadio's study didn't do. From these pilot studies, it appears that there is an enhanced effect in the use of the

**Results of a patient self-assessment completed in the pivotal studies showed that women had improved quality of life following use of eflornithine.**

## Highlights from Phase III Pivotal Studies

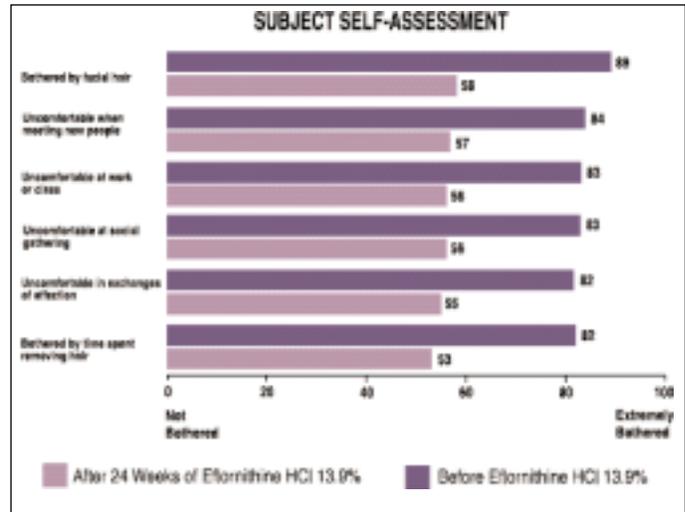


\*Significant results were seen in as soon as 8 weeks.

PGA Outcome	Eflornithine HCl 13.9% (n=373)	Vehicle (n=201)
Clear/almost clear	5%	0%
Marked improvement	27%	8%
Improved	26%	26%
No improvement/worse or missing	42%	66%

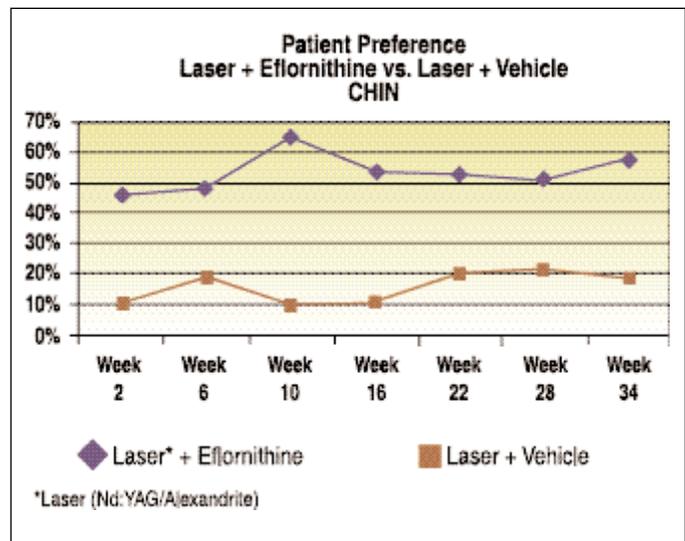
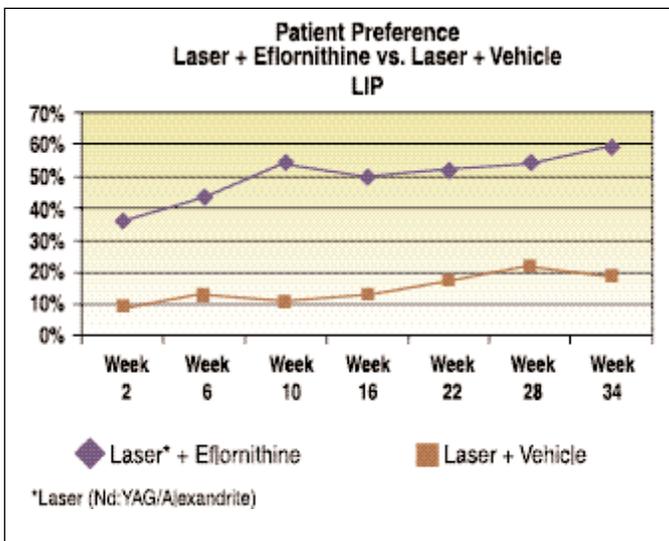
Pooled results of the two Phase III studies

The physician's global assessment outcome data above are based on results from two Phase III multi-center, double-blind, randomized, vehicle-controlled pivotal clinical trials. The studies included 594 women with excessive facial hair. These data were highlighted in a poster that was presented at the 2005 winter AAD meeting. The poster was authored by Stacy Smith, M.D., Michael Gold, M.D., and Daniel Piacquadio, M.D.



The data above are based on results from two Phase III multi-center, double-blind, randomized, vehicle-controlled pivotal clinical trials. The self-assessment was completed by 338 of the women, and they reported more positive results after undergoing treatment with eflornithine. Answers from six quality-of-life questions are represented above. Overall, patients reported a significantly reduced level of distress associated with excessive facial hair. In addition, participants who used eflornithine reported improved quality of life. These data were highlighted in a poster that was presented at the 2005 winter AAD meeting. The poster was authored by Stacy Smith, M.D., Michael Gold, M.D., and Daniel Piacquadio, M.D.

## Highlights from a Pilot Study using Eflornithine and Laser Hair Removal



The above two graphs indicate patient levels of satisfaction with outcomes from combination therapy for the lip and chin areas. In the study, 54 women with excessive facial hair underwent treatment with either a combination of laser and eflornithine or they received treatment with laser and a vehicle. These data were highlighted in a poster that was presented at the 2005 winter AAD meeting. The poster was authored by Stacy Smith, M.D., Michael Gold, M.D., and Daniel Piacquadio, M.D.



Examples of pseudofolliculitis barbae.  
Photos courtesy of Heather Woolery-Lloyd, M.D.  
(above) and Jeff Parks, M.D. (below).

## Treating Pseudofolliculitis Barbae

**Dr. Valerie Callender:** I use eflornithine on some men who are coming in complaining of pseudofolliculitis. Typically, I would say that it takes about 3 to 4 months to slow the rate of re-growth to the point where at least the patient doesn't need to shave every day, and shaving less often is one of the treatments for pseudofolliculitis. The follicular papules and pustules actually diminish in time.

This is an off-label use in the United States but we do use it, not to slow down hair completely, but just to give the skin a rest over several days so it can heal and repair itself.

I'd also like to emphasize that PFB doesn't occur solely in men. Pseudofolliculitis barbae can occur in women as well, as the result of hirsutism.

I think the combination therapy (laser plus eflornithine) is the treatment of choice for pseudofolliculitis barbae, in particular for women. When you think about pseudofolliculitis barbae in men, which is what the literature concentrates on, we know the purists want men to stop shaving and start this renewal method and the hairs will come out of the skin and that is the cure. But that's not a treatment method for women who suffer from pseudofolliculitis barbae, and so I've found that the combination therapy in 4 weeks will make anywhere from 40% to 70% difference in their appearance.

We've already discussed the association between pseudofolliculitis barbae and post-inflammatory hyperpigmentation. And I think in our experience eflornithine works the same in all skin types.

combination of eflornithine with laser hair removal. In addition, it's evident that you can treat both terminal and vellus hairs with this combination. Overall, this treatment approach was well-tolerated and patients preferred the combination therapy.

Generally, we all know that eflornithine is not a hair remover, it is not a depilatory, and it does not terminate the hair follicles. It reduces the rate of hair growth. It is clear that in the Phase III studies that patients felt less bothered by their unwanted facial hair, and that was seen as early as 8 weeks in that study. And as we know, continued use is necessary, and the longer eflornithine is used, the better the results. Also, as the label indicates, if no improvement is seen after 6 months, eflornithine should be discontinued.

**Dr. Mark Lebwohl:** Do we see a difference as patients return after using eflornithine with any method of hair removal? Do they need less and less hair removal over time? For example, if they're using any method of hair

removal at, say, once a week when they start and then once every 2 weeks after using eflornithine for 2 months and then once a month after 6 months of using eflornithine — are we seeing that happen in clinical practice?

**Dr. Valerie Callender:** We've not done a formal analysis, but when we see patients after they've been using eflornithine for 3 months and ask them about its impact on their hair removal, they say initially it was daily, then the second month it was two to three times a week, then eventually it was once a week. And in looking at them over the years when they come into the office, their hair re-growth becomes less and less, and they don't see hair at all.

**Dr. Janet Roberts:** Do you have any idea why it seems to work better with longer duration?

**Dr. Ulrike Blume-Peytavi:** It could be that the upper lip has much shorter growth phases. Naturally, the hair in this body region moves into the telogen phase about



Panelists address the myth regarding whether eflornithine is linked to acne.

*Photo courtesy of David B. Vasily, M.D.*

## Does Eflornithine Cause Acne?

**Dr. Ulrike Blume-Peytavi:** Does eflornithine cause acne in patients? Have you seen this in your practices? If so, how do you manage it? What do you tell your patients?

**Dr. Valerie Callender:** I haven't seen any increase in acne in these patients.

**Dr. Blume-Peytavi:** There was also a question regarding some of the methods of hair removal that patients used and whether it might have contributed to their acne. Were these first-time shavers?

**Dr. Mark Lebwohl:** That's a good point. Also because patients were examined 2 days after shaving, this timeframe might have optimized the chance of seeing pustules.

**Dr. Blume-Peytavi:** All these women who have increased hair loss, increased seborrhea and increased hair growth often have a tendency toward acneic skin. So, in fact, that's a question too.

**Dr. Fitzpatrick:** That's a potential explanation because the percentage of people who had acne is close to the percentage of women who had acne with these other conditions. So the fact may be that we just chose patients who have a tendency toward acne.

**Dr. Ron Trancik:** It could be a reflection of when the drug was applied relative to hair removal (for example, shaving). Also, it might be that the patient is presenting with a folliculitis as opposed to acne.

every 6 to 9 months. Perhaps these hairs do not visibly grow during the anagen phase.

**Dr. Callender:** When I started initially using eflornithine in an 8-week response rate, I wasn't seeing it in my patient population, which mainly has curly and dark pigmented hair. And so it took anywhere from 12 to 16

weeks for me to see a response. And I say this because with a transdermal delivery, the delivery time shouldn't really vary. I'm wondering whether eflornithine takes a bit longer to reach the hair follicle in patients who have curly hair follicles. I don't know for sure, but this is something that might be interesting to explore further. ■

It is clear that in Phase III studies, patients felt less bothered by their unwanted facial hair, and that was seen as early as 8 weeks.



Patient before treatment with eflornithine (left). After 24 weeks of treatment with eflornithine (right). *Photos courtesy of SkinMedica.*



# Maximizing Treatment with Eflornithine and Laser Hair Removal

These experts share their insights for what works best.

**Dr. Richard Fitzpatrick:** I have heard colleagues question whether you can use eflornithine in conjunction with laser hair removal, and I think it would be worthwhile to hear the consensus from people here. My view is that you can start the two processes simultaneously, or if the patient is already using eflornithine, then it's fine to go ahead and start laser hair removal. But I don't see any need to withhold eflornithine during the period of laser hair removal.

**Dr. Mark Lebwohl:** Does anyone do it differently? We start it at the same time, or if they're already on eflornithine, simply continue the applications during the laser hair removal period.

**Dr. Valerie Callender:** I think you should emphasize the fact that eflornithine needs to be used throughout the laser treatments — not stopped like the retinoids, where you discontinue a week before. You can start eflornithine at the same time as laser therapy, and patients can use it all the way up until they have treatment.

The only time I have patients discontinue is when they give a history of irritation or “sensitive” skin, and they might not start the eflornithine immediately after the treatment. I'll have them wait a day to let the skin calm down from the treatment and then begin on eflornithine b.i.d.

**Dr. Ulrike Blume-Peytavi:** I have a tendency to stop 2 or 3 days before doing the next laser session. I do

this based on the idea that perhaps the hair could be hit in the newly starting anagen phase.

**Dr. Fitzpatrick:** In the studies, they continue right through laser treatment. I don't know of any data that support stopping eflornithine for any period during the laser hair removal.

I have heard colleagues question whether you can use eflornithine in conjunction with laser hair removal. My view is that you can start the two processes simultaneously. I don't see any need to withhold eflornithine during the period of laser hair removal.

**Dr. Lebwohl:** Do each of you have your own protocols you use?

**Dr. Fitzpatrick:** We try to tailor the treatment to the individual person. It seems as though some people can withstand longer treatment with the laser depending on the density, and the duration of treatment is a little



Figures 1A and 1B. This split-face study depicts treatment with VANIQO (eflornithine HCl) Cream 13.9% in combination with laser (at left) and laser plus a vehicle (at right). Photos courtesy of SkinMedica.

more easy. Also, toward the end of the therapy, you can space out treatments at longer intervals. And then, of course after that maintenance is infrequent.

**Dr. Janet Roberts:** I would say that I typically space treatments from 4 to 6 weeks.

**Dr. Blume-Peytavi:** Yes, and I think initially that's probably pretty standard.

**Dr. Lebwohl:** I'd agree that 4 to 6 weeks is the usual amount of time — less frequently if there's a lesser amount of hair.

## Would you say you treat a Fitzpatrick Skin Type I and a Fitzpatrick Skin Type VI differently?

**Dr. Marta Rendon:** I treat them the same. I'm just more careful with the laser because they'll have a higher incidence of post-inflammatory hyperpigmentation — especially patients who are Hispanic or African-American, so you'll be more careful in preventing side effects of post-inflammatory hyperpigmentation.

**Dr. Callender:** You have to adjust your laser parameters based on the presentation. For instance, if I have a patient who's a Fitzpatrick Skin Type IV, but she has post-inflammatory hyperpigmentation, which in reality creates an area

of skin that is really almost a Fitzpatrick Skin Type VI, then I have to adjust my laser parameters, extend the duration and lower the energy. So I think it's individualized, but frequency usually doesn't make a difference, just for the laser parameters in that area.

**Dr. Fitzpatrick:** For a patient with a Fitzpatrick Skin Type II who has a tan and now is a Fitzpatrick Skin Type III or IV, all you have to do as far as the laser parameters are concerned is to just be more careful about that pigment that's there. Use a longer pulse width, a lower energy and be more aggressive with cooling. I don't know why this has become such an issue with laser hair removal.

You're not going to have a problem unless you deliver too much energy to the surface of the skin, and that's easy to avoid. My point is that we're treating patients who have darker pigment than that, so when you take a fair-skinned person who has slightly darker skin, all you must do is treat them as if they had darker skin.

**Dr. Blume-Peytavi:** I agree with you, but I think the problem arose because a lot of people determined a phototype while starting laser treatment but didn't adjust the changing of phototypes with the varying seasons. Or perhaps technicians or assistants who are doing the laser hair removal weren't experienced enough to adjust to different skin types, and then it's quite clear why complications surfaced. So I think this is an important recommendation on what we should do to avoid complications. ■



# How Do You Raise the Issue of Unwanted Hair?

## Panelists describe their techniques.

**Dr. Mark Lebwohl:** Do any of you broach the subject of unwanted facial hair with patients? If so, how and under what circumstances?

**Here's my two cents:** Dermatologists are busy. Some of us — many of us — see upward of 50 patients each day. If patients come in for a problem unrelated to unwanted facial hair, we usually don't take the time to ask them about it. I will say that under two circumstances I believe that this is an important conversation to have. First, it's important for the patient who is coming in for either hair loss or acne. Of course, that's because we don't want to miss polycystic ovarian syndrome (PCOS). Second, there are many reasons why it is important for the patient's overall health to establish a diagnosis and begin treatment.

So in those two circumstances, I would raise the issue. I would say that on the average, if someone comes to me for a mole on his foot, I probably would not raise the issue of whether they are experiencing unwanted hair — unless it was an obvious problem the patient was having.

**Dr. Janet Roberts:** I also find that when I am doing a full-body skin exam, I have the opportunity to ask a patient about various other concerns. If I see that the patient has excessive facial hair at that point, then I ask if the patient does something to remove it. I follow up right afterward with another question: "Does this facial hair bother you?" If the answer is "yes," then I explain to the patient that there are ways that I can help.

Very often, I'll get a positive response from a patient such as, "Yes, this really does bother me," and we will talk about methods of removal including laser and eflornithine.

**Dr. Richard Fitzpatrick:** I generally don't bring up this issue unless there's a hormonal factor that I'm trying to understand. This is because 95% of my practice is cosmetic, so usually I ask the patient what bothers them — what they want to have done. I find that if I speak about what I think might bother the patient based on my own assumptions that this doesn't go over too well.

I can think back to some patients who have had obvious facial hair, and in that situation, I think I probably would ask them if they had problems.

**I don't automatically approach patients who have facial hair and assume that they want to discuss solutions for removing the excess hair. Instead, I provide patient education brochures to open the door to discussion.**

**Dr. Francesco Mazzarella:** When patients ask me what can be done for this problem, because I use laser, I suggest that the best results can be obtained by laser treatment. So I give the laser treatment to my patients and suggest that they apply eflornithine 3 days after the laser treatment and to continue the application. (The time between two laser treatments is 5 weeks.)

**Dr. Valerie Callender:** It is so obvious in my patients, who consist mainly of women and men of color, you can see the evidence of their facial hair removal more readily. You can see the post-inflammatory hyperpigmentation, you can see follicular papules and the pustules, so I really don't have to count on the patient to give me this information. As soon as I look at them, I can see that they are having problems with unwanted facial hair.

And I'm not saying that all patients of color have pseudofolliculitis barbae and post-inflammatory hyperpigmentation. But for those who do present with these problems, 75% of them are also complaining of unwanted facial hair. This problem is easily picked up.

**Dr. Ulrike Blume-Peytavi:** I don't bring up the issue of unwanted hair directly with patients if they come in with another problem. We have many patients who are Turkish or Mediterranean, and these patients on the whole tend to be more accepting of facial hair because it runs in their family, so I don't automatically approach patients who have facial hair.

What we do is provide patient brochures in our center for patients to review while they wait. So when they come to our center for another problem, they'll see brochures on treating unwanted hair and this can help initiate the conversation and take away from some of the fear they might have about discussing this problem.

Has anyone else implemented any procedures or materials in your office to facilitate a discussion with patients?

**Dr. Callender:** We have brochures available in our office, and also videos have been successful in the cosmetic side of my practice. We have a T.V. in the patient waiting room that plays various programs, including one on eflornithine. Patients find it educational, and if, for example, they're coming in for a facial or microdermabrasion, and they see this video, they ask questions about facial hair removal as well as eflornithine. ■



## Combination Approaches

**Dr. Mark Lebwohl:** What percentage of your patients would you say use eflornithine with laser hair removal versus other methods of hair removal?

**Dr. Marta Rendon:** My physician assistants perform the hair removal, and we try to make sure that everyone who is getting laser hair removal gets a prescription for eflornithine. So I would say almost 90% of my patients are using eflornithine in conjunction with laser hair removal.

**Dr. Valerie Callender:** I would say about 75% of patients use eflornithine alone, and 25% of those patients fall into the cosmetic side and undergo treatment with both eflornithine and laser hair removal. Probably the majority of our patients are using eflornithine alone with other methods of hair removal other than laser, such as a depilatory or tweezing, in our practice. Of the laser patients, all of them use eflornithine.

**Dr. Lebwohl:** I think that in the general population, although using the laser for hair removal is a growing procedure, the vast amount of hair removal is done by shaving or depilatories, waxing, and/or electrolysis. How do you think eflornithine works in patients who have used it with shaving or depilatories or waxing?

**Dr. Janet Roberts:** I have used it in patients who have opted for other hair removal methods, and I believe that eflornithine works in conjunction with these other methods. I have patients who have used eflornithine with waxing and depilatories, and the time intervals in which they needed to repeat these hair removal techniques was lengthened when they also used eflornithine.



### Optimizing Treatment Outcomes

Panelists describe their tips for setting realistic patient expectations and attaining the best results.

**Dr. Mark Lebwohl:** Is there anything we need to do to prepare patients to use eflornithine long-term? Does anyone have anything to add other than that you have to simply inform patients that you can stop using eflornithine, but if you do, the hair comes back within a matter of weeks? (So, it's a long-term treatment.)

What instructions do you give patients who are about to start treatment? What's important for them to know for greatest success with treatment? For example, in what timeframe will patients see initial results? Will they see continued improvement over time?

We have to make it clear that it's not a method of hair removal.

**Dr. Ron Trancik:** I think it's important to set the proper expectations on the part of the patient, and I think one of the early problems with eflornithine in the United States was that neither patients nor physicians understood the drug or the time necessary for it to take effect.

One of my colleagues who practices in Nebraska uses a lot of eflornithine, primarily because of women who have vellus hairs who come in and ask if he can do anything for them. He tells them that eflornithine is like Rogaine in reverse — that you

have to continue using it, and it may take 6 months before they actually see a significant clinical difference. He says that when we manage patient expectations, patients tend to be more satisfied, especially if they have the misconception that eflornithine is going to remove their facial hair. And I think those kinds of comments have to be made to patients so that they know what to really expect, so that reality will meet their expectations.

**Dr. Marta Rendon:** I agree. I have several patients and when I approach them, I tell them there's always

**I think one of the early problems with eflornithine in the United States was that neither patients nor physicians understood the drug or the time necessary for it to take effect.**

When we manage patient expectations, patients tend to be more satisfied, especially if they have the misconception that eflornithine is going to remove their facial hair.



A patient's chin at baseline (left). At right is the patient after using VANIQO for 24 weeks in conjunction with a hair-removal method. Photos courtesy of SkinMedica.

active phase and maintenance phase as far as response to treatment and what you do. And they'll always know that the active phase has a label and has a 14-week process. And then when it gets to the maintenance phase, we see those patients back and they tell you that they're not shaving daily, they're not shaving monthly, they're not doing this, then you can decrease it to q.d. We don't have any studies that show that q.d. is just as effective during the maintenance phase, but in clinical practice, we see that this works.

**Dr. Lebwahl:** In my experience, patients who are half-hearted about going into treatment from the start and who aren't going to use it every day or who aren't going to use it twice a day because they're concerned about the cost, usually haven't filled the prescription when they come or if they filled it, they underuse it and aren't happy with it.

The patients who approach treatment enthusiastically from the start are usually quite satisfied.

**Dr. Elia Roo:** What do you do for those patients who are non-respondent?

**Dr. Ulrike Blume-Peytavi:** If they aren't responding, they can undergo the laser treatment or they can opt for other approaches. You should be frank and not try to treat everybody with the drug. Treat only those for whom eflornithine will prove beneficial.

**Dr. Janet Roberts:** I would like to make a point of clarification. Dr. Blume-Peytavi was talking about a tube of eflornithine lasting 2 months. I was under the impression it lasted 1 month with b.i.d. application.

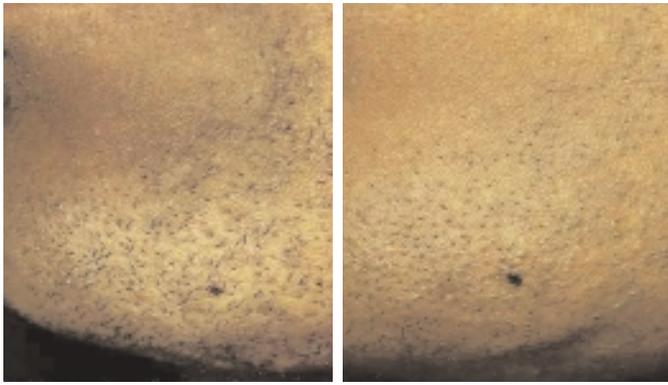
**Dr. Rendon:** I think it depends on the size range. (For example, if you're applying eflornithine to the lip and chin versus just the chin.)

**Dr. Valerie Callender:** I tell patients to use a little amount, and if they'll be using it just on the lips, then sometimes they can use that tube for 3 months. If they're applying it to the lip and chin, the tube may last for about 2 months.

**Dr. Lebwahl:** As we've all said, we need to be sure to tell patients that eflornithine is not a method of hair removal but should be used with other hair removal methods, and that it simply slows down hair re-growth.

## Optimizing Success with Laser

**Dr. Callender:** When looking at the patients who undergo laser hair removal in conjunction with eflornithine, they would tell you as soon as they started the first treatment that they might have had to remove that hair once or twice in 4 weeks. And when we look at them again after the second laser treatment, they'll say, "Well, I have not had to remove the hair at all."



Patient at baseline (left) and after 24 weeks of therapy with eflornithine (right). A significant decrease in visibility of terminal hairs was realized. Photos courtesy of SkinMedica.

Patients who go away on vacation and come back with tan skin can't necessarily undergo laser hair removal [because of increased risk of post-inflammatory hyperpigmentation]. But patients who are on eflornithine can enjoy longer intervals between treatments.

**Dr. Richard Fitzpatrick:** I've found that patients are more willing to undergo laser hair removal when I tell them that with the addition of eflornithine, they may need fewer laser treatments.

In my experience, the primary objections patients have regarding laser hair removal is the number of treatments and the fact that there is maintenance required. So when people worry about eflornithine interfering with their laser hair removal practice, they're thinking about it in the wrong way.

When I present laser hair removal to patients, the primary objection is the number of treatments. So if I'm able to say to patients that with this cream, instead of the needing three or maybe four maintenance treatments a year they going to need three, that's far more appealing to the patients. And maybe instead of six treatments, patients may need only four to reach a steady state.

Those things tend to attract patients to the treatment. And then we have a far happier group of patients who will actually continue to make follow-up visits to complete therapy.

**Dr. Elia Roo:** And also, too, if you can lessen the number of laser treatments, you lessen risk. Patients who go away on vacation and come back with tan skin can't always have a treatment. But those who are on eflornithine can enjoy longer intervals of treatments. ■

## Selecting The Best Patients

**Dr. Mark Lebwohl:** Are there patients who have unwanted facial hair for whom you wouldn't initiate eflornithine? The one barrier that I have found is with cost. Patients simply don't want to spend the money.

**Dr. Valerie Callender:** I would say probably the only reason not to give the patient who has unwanted facial hair eflornithine is if she's pregnant. And I've found that cost hasn't been a problem in my patients. If they want it, they find a way to pay for it.

**Dr. Francesco Mazzarella:** I think that in Italy, the problem of cost is a serious problem.

**Dr. Ulrike Blume-Peytavi:** I hesitate to prescribe eflornithine when a patient is too doubtful or afraid of every side effect. So I never try to convince a hesitant patient to use it. It's better not to include such patients.



### Take-Home Pearls

Panelists share their tips for success with eflornithine.

**Dr. Marta Rendon:** I think that physicians should focus on creating awareness of the problem of excessive facial hair among their patients, and that physicians should be educated about eflornithine's efficacy.

**Dr. Valerie Callender:** I also think it's important to emphasize that eflornithine has an effect in all hair types — not only in terminal hairs.

**Dr. Elia Roo:** For dermatologists who work with lasers, it's important to know that they can achieve better results for hair removal with eflornithine. Also, an important take-home message is that they can treat patients whom they usually can't treat with laser alone because eflornithine is effective in all colors of hair — black, white or blond.

**Dr. Richard Fitzpatrick:** I think setting proper expectations is probably going to be a key factor in success, both from the patient's and the physician's standpoint. And a lot of that will have to do with both the time required for eflornithine to work as well as the fact that there's a need to continue with hair-removal procedures — not to drop them and use eflornithine as the only treatment.

**Dr. Janet Roberts:** I certainly concur with what everyone else has said. I think we talked about education, physician awareness, raising awareness in physicians and patients. And, of course, managing expectations is an important issue.

**Dr. Ulrike Blume-Peytavi:** I would suggest that we need to find better ways for identifying the groups of patients who are responders and those who are non-responders.

**Dr. Lebwohl:** It's important that we convince physicians that eflornithine will improve their results and that they will have better patient satisfaction. Many physicians don't understand the adjunctive nature of eflornithine.

The leading view is that treating patients with eflornithine competes with other methods of hair removal that a physician is using, but this couldn't be farther from the truth. Adding eflornithine in conjunction with another form of hair removal results in the patient ending up happier. And when patients end up highly satisfied, that will only bode well for the dermatology practice.

## SUMMARY HIGHLIGHTS

### Reviewing Clinical Study Results

**Dr. Ron Trancik:** Two pivotal trials were conducted totaling 594 women. The study medication (eflornithine or placebo) was applied for 24 weeks with follow-up visits at weeks 2, 4, 8, 12, 16, etc. There was statistically significant improvement as early as week 8 when we combined the clear/almost clear group with the markedly improved group responders.

Also, in a pilot laser study where 54 women were enrolled, patients were asked to apply active vs. vehicle to their upper lips in a split-face manner. Participants were instructed to apply the agent on the face b.i.d. for 34 weeks, and then they were asked to come in at week 2 and week 10 to receive a laser treatment to the upper lip and chin. Patients were followed up with at weeks 16, 22, 28, and 34 . . . . When patients graded their upper lips, the response with eflornithine plus laser was considerably better than the results patients achieved with the vehicle plus laser. Patients who treated their chins for facial hair attained the same favorable results when they underwent treatment with eflornithine plus laser.

### Managing Patient Expectations

**Dr. Trancik:** I think it's important to set the proper expectations on the part of the patient, and I think one of the early problems with eflornithine in the United States was that neither patients nor physicians understood the drug or the time necessary for it to take effect. One of my colleagues . . . tells patients that eflornithine is like Rogaine in reverse — that you have to continue using it, and it may take 6 months before they actually see a significant clinical difference.

**Dr. Lebwohl:** As we've all said, we need to be sure to tell patients that eflornithine is not a method of hair removal but should be used with other hair removal methods, and that it simply slows down hair re-growth.

### Maximizing Treatment with Eflornithine and Laser Hair Removal

**Dr. Richard Fitzpatrick:** I've found that patients are more willing to undergo laser hair removal when I tell them that with the addition of eflornithine they may need fewer laser treatments.

**Dr. Callender:** I think you should emphasize the fact that eflornithine needs to be used throughout the laser treatments — not stopped like the retinoids, where you discontinue a week before. You can start eflornithine the same time as laser therapy, and patients can use it all the way up until they have treatment.

**Dr. Fitzpatrick:** For a patient with a Fitzpatrick Skin Type II who has a tan and is a Fitzpatrick Skin Type II or IV, all you have to do as far as the laser parameters is just be more careful about that pigment that's there. Use a longer pulse width, a lower energy, and be more aggressive with cooling.

You're not going to have a problem unless you deliver too much energy to the surface of the skin, and that's easy to avoid. My point is that we're treating patients who have darker pigment than that, so when you take a fair-skinned person who has slightly darker skin, all you must do is treat them as if they had darker skin.

### How Do You Talk About Unwanted Hair with Patients?

**Dr. Blume-Peytavi:** I don't bring up the issue of unwanted hair directly with my patients if they come in with another problem. What we do is provide patient brochures in our center.

The leading view is that eflornithine competes with other methods of hair removal a physician is using, but that couldn't be farther from the truth.

### A Look at the Long Term

**Dr. Callender:** . . . in looking [at patients] over the years [who have been using eflornithine], their hair re-growth becomes less and less, and they don't see hair at all. So you do see frequency change with time. ■



83 General Warren Blvd.  
Suite 100  
Malvern, PA 19355