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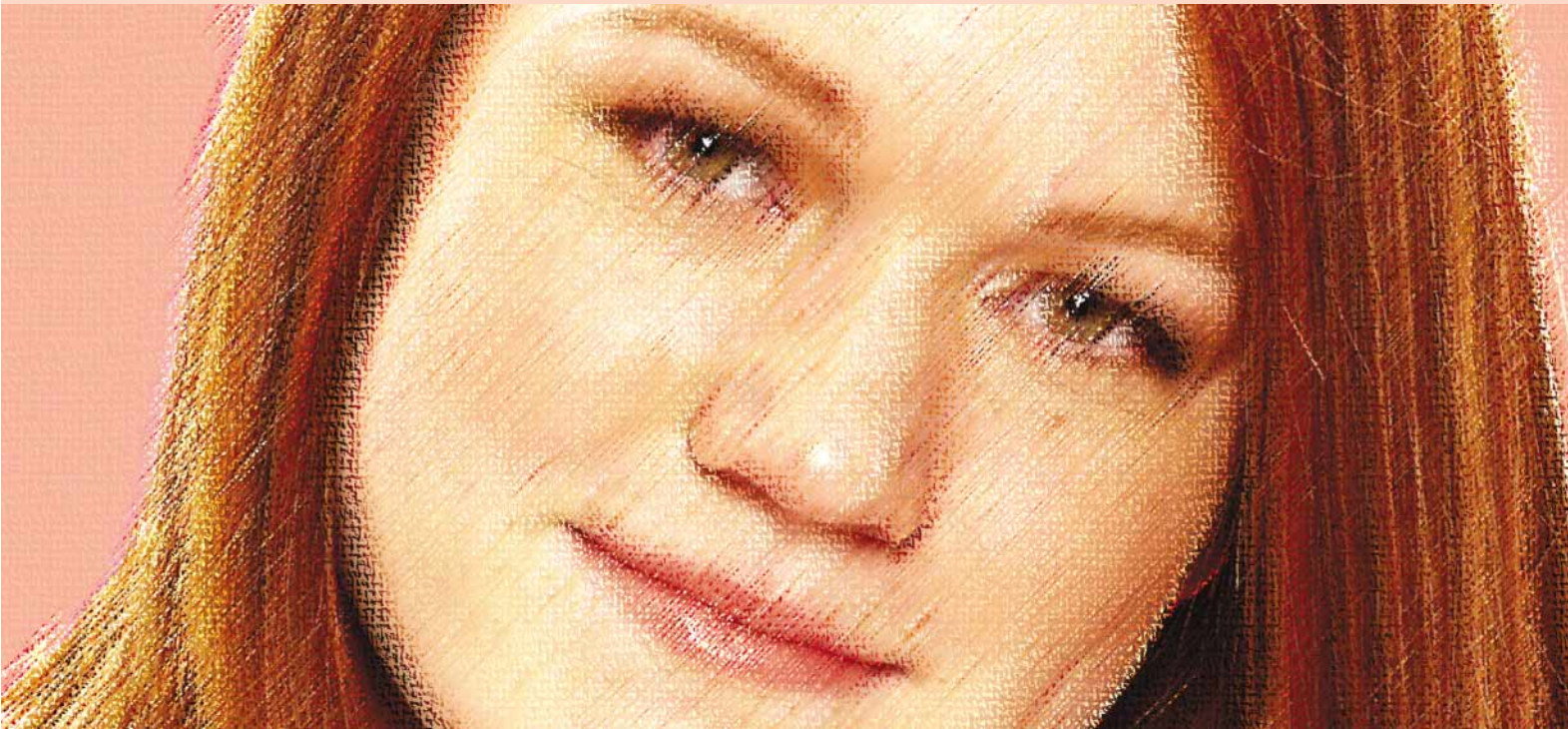
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Hawaii Dermatology Seminar

# ACNE VULGARIS AND ROSACEA: OPTIMIZING THERAPY



**The Importance of  
Vehicle in Acne Therapy**

**Acne Management:  
Treatment Strategies  
and Challenges**

**Cosmetic Management of  
Patients with Acne Vulgaris  
and Acne Rosacea**

**The Resurgence of Benzoyl  
Peroxide in Acne Therapy**

**New Treatment Options  
for Acne Rosacea**

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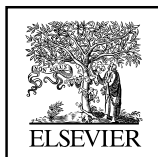
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**INTERNATIONAL  
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## TARGET AUDIENCE

This activity has been designed for healthcare professionals, including dermatologists and pediatricians, who are involved in the treatment of patients with acne vulgaris and acne rosacea.

## FACULTY AND UNAPPROVED USE DISCLOSURES

Faculty/authors must disclose any significant financial interest or relationship with proprietary entities that may have a direct relationship to the subject matter. They must also disclose any discussion of investigational or unlabeled uses of products.

**Dr Berson** has served on advisory boards for Allergan, Inc., Connetics Corporation, Dermik Laboratories, Galderma International, and Medicis Pharmaceuticals Corporation.

**Drs Lupo, Solomon, and Tanghetti** are consultants to Stiefel Laboratories, Inc. **Dr Lupo** also serves as a consultant to Allergan and Dermik.

**Dr Gold** indicates he has no financial relationships to disclose.

**Dr Lupo** discusses the investigational use of a derma-membrane structured product to prevent the disruption of the epidermal moisture barrier in patients with irritated skin, atopic dermatitis, radiation dermatitis, stasis dermatitis, and other common skin problems.

**Dr Solomon** discusses the investigational use of clindamycin 1% and benzoyl peroxide 5% for the treatment of acne rosacea.

# INTRODUCTION

In this supplement, our faculty discusses the clinical evaluation and treatment of patients with acne vulgaris and rosacea. Many patients with these conditions have sensitive skin, and these topics are addressed within that context.

For many years, benzoyl peroxide (BPO) has been a mainstay in the everyday practice of physicians who see patients with acne. Some years ago, BPO products were alcohol-based and were far less tolerated than the newer, water-based formulations. When combined with clindamycin, BPO provides a topical treatment with excellent results. Two products containing clindamycin 1% and BPO 5% are discussed in this supplement. One of these, Duac topical gel, provides these active ingredients in a drug-delivery vehicle containing emollients (4% glycerin, a humectant; and 1% dimethicone, an occlusive agent). The other clindamycin/BPO combination product is BenzaClin topical gel, which contains no emollients.

The treatment of patients with rosacea also requires particular attention to skin sensitivity. Topical medications are available that provide effective treatment. One combination agent, sodium sulfacetamide 10%/sulfur 5% (Rosac Cream), is in a cream vehicle that also contains a moisturizer and sunscreens. Having all three components in one product increases patient compliance (especially with the recommendation for sunscreen use) and reduces the risk of exposure to ingredients that may be irritating.

In addition to these topics, members of our faculty also address the latest information on the role of vehicle in protecting the barrier function of the skin, provide recommendations for cosmetic management of patients with acne vulgaris or rosacea, and provide an overview of light and laser treatment options.

## THE IMPORTANCE OF VEHICLE IN ACNE THERAPY

Emil A. Tanghetti, MD, Chair

Physicians attempting to balance aggressive acne treatment with tolerability stress the importance of restoring hydration of the stratum corneum. Research demonstrating the stratum corneum's pivotal role in drug delivery has sparked renewed interest in this topic.

Many common conditions directly and indirectly affect barrier function. For example, atopic dermatitis, psoriasis, and acne affect barrier function directly through the impact of the inflammatory process on epidermal growth and maturation. Medications used to treat a number of conditions indirectly disrupt barrier function. Topical retinoids—the mainstay of acne treatment—change and disrupt barrier function.<sup>1</sup>

Several signs and symptoms characterize damage to the epidermal barrier. Dryness and peeling occur when the water content of the stratum corneum falls below 10%.<sup>2</sup> This creates a damaged and leaky epidermis that may lead to overabsorption of topical medications and products, causing even more barrier damage.

### Improving Barrier Function

A strategy for improving barrier function consists of rehydrating the stratum corneum. There are two pharmacologic approaches that help promote rehydration. One is to inhibit the loss of moisture by using occlusive moisturizing agents (including hydro-

carbon oils such as petrolatum and mineral oil, and silicones such as dimethicone and cyclomethicone). The other is to attract moisture to the stratum corneum from the lower epidermal and dermal layers by using humectants (such as glycerin and propylene glycol). (The Table

**Table. Categories of Occlusive Moisturizers and Humectants<sup>2</sup>**

**Occlusive Moisturizers: Retard loss of moisture from the stratum corneum**

- Hydrocarbon oils and waxes (petrolatum, mineral oil, squalene, paraffin)
- Vegetable and animal fats (cocoa butter, lanolin)
- Silicone (dimethicone, cyclomethicone)
- Others (fatty acids, fatty alcohol, polyhydric alcohols, wax esters, vegetable waxes, phospholipids, sterols)

**Humectants: Attract moisture to the stratum corneum from the lower epidermal and dermal layers**

- Glycerin
- Sodium lactate
- Urea
- Propylene glycol
- Others (including some vitamins and proteins)

provides a summary of the most common occlusive moisturizers and humectants.)

Recent studies demonstrate that barrier restoration alone often results in substantial improvement in patients with dermatitis. For example, a study comparing betamethasone-17 valerate, hydrocortisone, and petrolatum alone in patients with contact dermatitis revealed that the vehicle was as effective as betamethasone ointment in treating this condition.<sup>3</sup>

Manufacturers who understand the importance of restoring and maintaining barrier function to treat skin diseases currently market a number of medications and skin care products. Major skin care manufacturers have introduced new nonsoap cleansers and improved moisturizers. These products also benefit patients with sensitive skin. (See Dr. Berson's article on page 7.)

### Vehicle Affects Tolerability

Treating acne with products that contain either occlusive or humectant agents alone can be problematic. An occlusive agent retards transepidermal water loss (TEWL) and protects the stratum corneum but does not provide sufficient hydration to the epidermis. Humectants draw water to the stratum corneum but, used alone, they do not prevent the loss of water from the stratum corneum. Thus, the ideal strategy for treating acne patients combines occlusive and humectant agents as drug-delivery vehicles.

Two studies using products with clindamycin 1%/benzoyl peroxide (BPO) 5% gel as the active ingredients investigated whether vehicle had an appreciable effect on the tolerability of otherwise identical acne treatment formulations. One of the gels contained a vehicle with emollients—specifically, 4% glycerin and 1% dimethicone; the other gel contained no emollients.

Fagundes and colleagues<sup>4</sup> conducted a randomized, evaluator-blinded, split-faced comparison trial. Sixty-one patients between 15 and 25 years of age with mild acne participated in this week-long study. Local tolerance was graded by a blinded evaluator and patients at baseline and at the end of one week.

Patients who received the emollient-

based product had significantly less peeling ( $P=0.045$ ), dryness ( $P=0.059$ ), and burning ( $P=0.034$ ). The investigators reported no significant difference in erythema between the groups.

A second study—a crossover design—involved 52 patients (mean age 21 years) with mild to moderate acne.<sup>5</sup> The patients began using one of the clindamycin 1%/BPO 5% gels for 2 weeks following a 2-week washout period, during which they discontinued all current acne medications. On completion of the first 2 weeks of treatment, the patients underwent a 2-week washout period, and then used the second gel for 2 weeks. The investigators determined the degree of peeling (judging this as “worse” or as “the same or improved” compared to baseline) and observed dryness. Patients also evaluated dryness before and during the use of each product.

After 2 weeks, patients who used the moisturizer-containing formulation exhibited significantly better local tolerability ( $P<0.05$ ). Patient-reported dryness also was significantly less with the moisturizer-based formulation versus the formulation without emollients ( $P<0.05$ ).

### Moisturizing Vehicles Helpful During Retinoid Therapy

The benefit of moisturizer-containing vehicles was evident in patients with acne who received a combination of the topical retinoid tazarotene plus clindamycin 1%/BPO 5% in a vehicle containing 4% glycerin and 1% dimethicone. In a 12-week study<sup>6</sup>, 121 patients (mean age 20 years) with mild to severe acne received the retinoid alone or tazarotene plus the clindamycin/BPO/emollient medication.

Eighty-two percent of the retinoid-only group and 87% of the combination-therapy group completed the study. No patients in either group dropped out of the trial because of lack of efficacy or adverse events.

At the end of the study, observation between the two groups revealed differences in the parameters of dryness and peeling. These differences did not reach statistical significance over the entire course of the study. However, the group receiving combination therapy at week 4 exhibited significantly less dryness and peeling ( $P<0.05$ ).

This is important, as the first 4 to 6 weeks of retinoid therapy—the period of retinization—is the time when barrier dysfunction is at its peak. After this period, barrier function usually improves, and dryness and peeling often resolve. Thus, during the time of the worst barrier dysfunction and greatest sensitivity, patients tolerated better a product formulated with a vehicle containing moisturizer. Better tolerability more likely leads to better compliance with a retinoid-containing treatment regimen.

### Summary

Restoring and maintaining barrier function is critical for outcomes in patients with dermatologic diseases. For optimal hydration, a vehicle that is both occlusive and humectant is ideal. The addition of moisturizers such as dimethicone and glycerin to acne treatment products helps maintain barrier function and will provide better outcomes. This is particularly important when topical retinoids are included in the therapeutic regimen. For comedonal acne, combination products containing moisturizers may be effective first-line agents. Finally, clinicians should consider the vehicle prior to prescribing or recommending any products to patients with acne. ■

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# ACNE MANAGEMENT: TREATMENT STRATEGIES AND CHALLENGES

Mary P. Lupo, MD

**A**ny acne strategy must be individualized to the characteristics and needs of the individual patient. Assessing a patient who presents with acne includes an evaluation of the severity of the condition on presentation as well as the previous treatments prescribed by other clinicians, the patient's skin type, and other relevant factors.

Topical retinoids (adapalene, tazarotene, and tretinoin) are indicated as first-line therapy for all forms of acne—both noninflammatory (comedonal) types and inflammatory acne, characterized by papular and pustular lesions. For patients with mild, inflammatory acne, topical antibiotics should be added to the retinoid regimen. To speed results for patients with mild acne, acne surgery and chemical peels may be considered.

For patients with moderate acne of either type, oral antibiotics can be given in addition to topical therapy. Hormonal therapy should be considered for female patients, if the history warrants. In addition, non-ablative laser (for its effect on the sebaceous glands), intense-pulse light with aminolevulinic acid, or blue light are options to enhance the therapeutic response.

When acne is severe, topical retinoids plus an oral sulfa medication (such as trimethoprim/sulfamethoxazole) or retinoids plus high-dose doxycycline or minocycline may bring the patient's condition under control. Other topical and oral combinations may be tried before resorting to isotretinoin, still the gold standard in terms of efficacy in the treatment of severe acne.

## Important Treatment Challenges

Successful management of patients with acne today and in the future depends on how well clinicians and researchers meet at least two impor-

tant challenges: emerging bacterial resistance and patient noncompliance.

The literature in every medical specialty is rife with reports of infections that have become resistant to treatment with antimicrobial agents that once were effective. Bacterial resistance continues to increase and is a growing concern, largely the result of widespread use—and, in some cases, overuse—of broad-spectrum antimicrobials. As a result, clinicians in every specialty have the obligation to consider where the use of oral antibiotic agents can be circumvented.

In the treatment of acne, therefore, it makes sense to use topical antimicrobial agents whenever possible. Topical therapy may be enhanced by the use of combinations of agents rather than monotherapy with one antimicrobial. In addition, and if oral therapy is needed, subantimicrobial doses of doxycycline or minocycline may be considered; because these drugs usually are given for their antiinflammatory properties, antimicrobial doses may not be necessary. Topical retinoids alone should be used for patients on maintenance therapy once an acne flare is under control.

The other main challenge concerning acne treatment is patient noncompliance (Table). Noncompliance primarily is the result of patient dissatisfaction due to treatment-related side effects and the inability of some patients to follow what can be complex, multiproduct regimens. Also, drying of the skin from retinoids is a

common complaint. In addition to possibly contributing to emerging resistance of bacteria to antimicrobial agents, oral antibiotics may cause gastrointestinal complaints, and vaginal yeast infections can be a problem in female patients; topical therapy addresses all of these issues.

Patient compliance also may be enhanced if patients are taught how to properly cleanse the skin. Many believe that aggressive cleansing with harsh scrubs and astringents will somehow improve their condition by removing the sebaceous secretions that are visible on the surface of the skin. Gentle cleansing is required, however, to prevent dryness and irritation and, when retinoid treatment is started, to prevent further disruption of the moisture barrier caused by retinoids.

Clinicians should stress that patients should avoid using hot water, scrub gels or other such products, or rough pads (such as loofah sponges). They should also recommend an emollient cleanser and moisturizer that are gentle as well as noncomedogenic.

## Importance of Lipid Barrier Integrity

A principal cause of skin irritation is loss of the integrity of the skin-lipid barrier, a fact that has long been recognized (Figure).<sup>1,2</sup> Most commonly, inherent dysfunction of the skin-lipid barrier is associated with atopic dermatitis, but inherent dysfunction also may exist in patients with acne. In addition, iatrogenic disruption of the

**Table. Four Ways to Overcome Patient Noncompliance With Acne Therapy**

- Use therapies that add moisture and prevent drying.
- Eliminate oral antibiotics (use topical therapy instead).
- Use combination dermatologic products to eliminate multiple agents.
- Provide better patient education about cleansing.

skin lipid barrier can result from treatments used for a variety of conditions. Two well-known examples are the emulsifiers that are commonly used in patients with atopic dermatitis and topical retinoids that represent the first-line therapy for patients with acne.

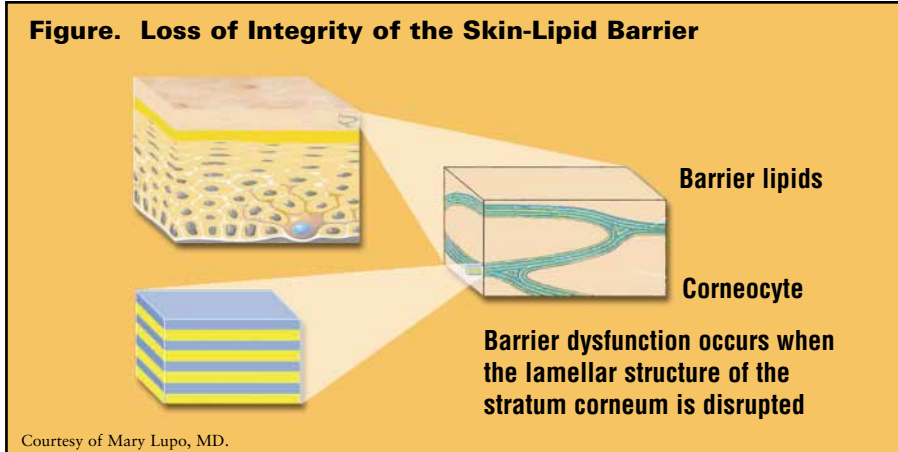
Barrier dysfunction occurs when the lamellar structure of the stratum corneum lipids—that is, the intercellular lipids—is disrupted. Two important consequences of barrier dysfunction are recognized: allergens, irritants, and viruses may penetrate the skin, and transepidermal water loss (TEWL) increases. As a result, patients with acne may experience problems such as irritant dermatitis from topical retinoids or allergic contact dermatitis on exposure to an ingredient in a topical antibiotic. In addition, excess TEWL causes a dehydrating effect, manifesting as itching and flaking.

Along with education regarding the techniques for proper cleansing already discussed, patients with acne vulgaris who begin treatment with topical retinoids require special attention to minimize the risk for irritation during the first several weeks of therapy. They should be instructed to use only emollient cleansers and to avoid using salicylic acid or glycolic acid cleansers once they begin their retinoid regimen.

Another strategy is to use a “mask application” technique for the topical retinoid. With this technique, the retinoid is not left on the skin overnight but instead is applied, left on the skin for 1 to 5 minutes, and then removed with an emollient cleanser. Barrier function in retinoid users also may be preserved by having patients apply the medication on alternate days, or two or three times a week at the beginning of treatment, until the skin adapts to the product.

Some clinicians recommend the concomitant use of occlusive agents—nonphysiologic lipids such as petrolatum, silicones, and paraffins. However, occlusive products, by nature, can be acnegenic.

A therapeutic option under development currently is an engineered mimic of the lamellar structure that is designed to overcome skin lipid barrier dysfunction. The system is described as derma-membrane structure (DMS).



### Derma-Membrane Structure

Most barrier creams contain an emulsifier, making the product with either a water-in-oil or oil-in-water emulsion. In contrast, DMS does not require the use of an emulsifier. DMS mimics the composition of the skin’s phospholipids and the skin’s layered structure that constitutes the physiologic lipid barrier. Therefore, DMS helps promote the preservation of the lamellar structure. An emerging product that uses DMS technology will include an antiinflammatory agent and will be useful for acne patients with irritated skin, as well as for patients with other common skin problems, including atopic dermatitis, radiation dermatitis, and stasis dermatitis.

In one study involving 15 patients with barrier dysfunction due to atopic dermatitis,<sup>3</sup> a DMS-based product was shown to perform as well as hydrocortisone 1% in reducing itching, skin infiltration, excoriation, and lichenification. The DMS-based product was better than the corticosteroid was in reducing skin dryness in the first week of treatment. No side effects were reported in patients using the DMS-based product.

In addition, the DMS-based product reduced pruritus and dryness in a group of 21 patients with uremic pruritus, and, in a group of 20 patients with dry, sensitive skin, the product significantly reduced TEWL, redness, and roughness.<sup>3</sup>

In my practice, a group of 15 randomly selected patients who were sensitive to retinoids were instructed to apply DMS 20 minutes prior to topical retinoid application. These patients experienced reduced

redness, flaking, and burning, allowing them to stay on their retinoid regimen and to increase the frequency of retinoid application to optimal levels.

### Conclusion

Noncompliance due to retinoid intolerance can be addressed by better patient education, particularly regarding skin cleansing, and the use of combination topical antibiotics when antimicrobial therapy is indicated. To prevent contributing to the problem of emerging resistance of microbes, oral antibiotics should be avoided whenever possible, and both systemic and topical antibiotics should be stopped as soon as the patient’s condition improves. In addition, when oral antibiotics are indicated, consider using subantimicrobial dosages of doxycycline whenever possible. A short application time—described above as mask application—may help reduce irritation from retinoid use, particularly during initiation of therapy. In the near future, a DMS system is expected to become available that will protect the skin lipid barrier during therapy with otherwise-irritating agents such as topical retinoids. ■

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# COSMETIC MANAGEMENT OF PATIENTS WITH ACNE VULGARIS AND ACNE ROSACEA

Diane S. Berson, MD

**A**cne vulgaris and acne rosacea are two of the most common and challenging disorders seen by clinicians. While each condition has its own pathophysiology and clinical expression, the affected patient populations share similarities. One such similarity is product intolerance due to sensitive skin (Table).

When treating patients with acne vulgaris or rosacea, it is important to understand the characteristics of sensitive skin and how the manifestations differ in men and women. Physicians must carefully counsel patients on their treatment options as well as their use of over-the-counter products and lifestyle issues.

## Characterizing Sensitive Skin

Symptoms of sensitive skin that may be reported by patients include burning, stinging, itching, and tightness. Signs that may be present on examination include redness, scaling, hives, and acneiform eruptions. Most of the signs occur on the face, likely because skin products are used most often on facial skin.

The postulated causes of sensitive skin in patients with acne vulgaris or rosacea include a diminished barrier function, which allows increased penetration of product ingredients that are potential irritants (see Dr Lupo's article on page 5 for additional discussion of barrier dysfunction). Heightened neurosensory input also is possible, with nerve endings in the skin easily provoked by stimuli. Another proposed mechanism is enhanced immune responsiveness, leading to increased irritation as well as contact dermatitis and contact urticaria.

Sensitive skin also may be self-induced by the simultaneous overuse of over-the-counter products, a form of cosmetic polypharmacy. Among the products that patients misuse are

cleansers, toners, scrubs, moisturizers, exfoliants, and cosmetics. As part of their management plan, patients with acne vulgaris or rosacea must be educated about the choice and proper use of skin care products and cosmetics. They should be counseled about which skin product ingredients to avoid and which are beneficial. Patients who use cosmetics also should be advised on the choices that will adequately camouflage their condition without worsening it.

### Table. Facts About Sensitive Skin

**Increased incidence in patients with dermatologic diseases, including:**

- Acne
- Atopic dermatitis
- Rosacea
- Seborrheic dermatitis
- Urticaria

**May be self-induced by overuse of many products simultaneously, such as:**

- Cleansers
- Cosmetics
- Exfoliants and scrubs
- Moisturizers
- Toners

## Skin Care Regimen

The foundations of the skin care regimen for patients with acne vulgaris or rosacea are: cleansing, treating, moisturizing, and protecting the skin, and, for those who use cosmetics, choices appropriate to their condition.

### Cleansing

Both groups of patients should be cautioned to avoid chemical over-cleansing and extensive scrubbing of the skin. There is a pervasive misconception, particularly among teenagers, that acne is caused by dirty skin, so many patients vigorously scrub their skin many times a day with abrasive pads. They should be counselled that

this increases irritation and makes acne worse.

Other misused products include alcohol-based cleansing products. Gentle cleansing in the morning and at night using mild agents such as synthetic detergents and lipid-free cleansers usually is sufficient. If the patient is involved in a sports activity or exercise, a third cleansing after the activity may be needed. Cleansers with a slightly acidic pH tend to be better tolerated than those that are alkaline. In addition, nonion surfactants leave minimal residue. Also available are medicated cleansers and masks that can unclog pores and improve the skin's appearance.

For some patients with acne vulgaris, toners and astringents can be a useful adjunct to a comprehensive management plan. This is especially true for those who have very oily skin or who live in warm, humid environments. Toners containing 2% salicylic acid or alpha hydroxy acids (AHAs), in particular, can help remove some of the surface oil and unclog pores.

Patients with rosacea should be discouraged from using toners and astringents. These products tend to irritate their skin and decrease their tolerance for topical medications.

### Treatment: Topical Medications

In addition to the wide variety of oral medications available to treat acne vulgaris and rosacea, many topical agents also are available. Thus, therapy can be matched to specific patient needs and skin types.

Antimicrobial agents clindamycin and metronidazole each are available in lotion, cream, gel, powder, and foam formulations. Antiinflammatory agents containing sodium sulfacetamide and sulfur, which have both keratolytic and antimicrobial properties, have made a comeback and are useful for both acne vulgaris and rosacea. These products treat acne

lesions as well as reduce redness and inflammation. One rosacea product is available that contains an emollient and sunscreen—sodium sulfacetamide 10%/sulfur 5%. This type of combination product may help ensure patient compliance with sun protection recommendations and limit overexposure to potentially irritating ingredients from separate moisturizing and sunscreen products.

Benzoyl peroxide (BPO) products also are making a comeback for patients with acne vulgaris (see Dr Solomon's article on page 9). Patients with dry or sensitive skin may achieve better results from water-based BPO products that also contain glycerin and dimethicone. Glycerin acts as a humectant and decreases irritation.

Topical retinoids are the current mainstay of acne treatment and are available in a variety of strengths, formulations, and forms. They also come in a wide variety of vehicles, including emollient vehicles.

Postinflammatory hyperpigmentation, a condition that often is more upsetting to patients than either acne vulgaris or rosacea, can be treated by a variety of products, including hydroquinones, retinoids, azelaic acid, and combinations of these agents.

#### **Treatment: Procedures**

A variety of cosmetic procedures can be used to help manage patients with acne vulgaris or rosacea. These procedures include peels, microdermabrasion, and light therapy.

Chemical peels may be helpful for patients with inflammatory acne as well as for those with oily skin. The lightest of these are the salicylic acid peels. These are quick "lunchtime" procedures with a pleasing cosmetic outcome. The keratolytic effect and slight swelling that results make pores appear smaller and cause the skin to look smoother.

Next in line are glycolic acid peels. These have a role for patients who may have concomitant hyperpigmentation and whose skin quality suggests that this agent may be well tolerated. Trichloroacetic acid peels are helpful for patients with slight acne scarring.

Microdermabrasion has become a popular procedure in the United States and can be a helpful adjunct to other acne treatments. The superficial "vac-

uuming" action of microdermabrasion can result in increased absorption and, perhaps, greater penetration of topical acne agents. Microdermabrasion is becoming more widely available in the form of over-the-counter products.

Nonablative laser therapy is another option for treating superficial acne scars. For more significant scarring, such as ice-pick scars, punch excisions or resurfacing with carbon dioxide laser (for example, Yag laser) is preferred. Boxcar scars can be managed with punch elevation, excision, or grafting; subcision; or resurfacing.

Telangiectasias and redness can be treated effectively with light therapy (see Dr Gold's article on page 11). Intense-pulse light (IPL) procedures can be particularly helpful in patients with fair skin who also have some degree of photodamage. IPL treatment also can help resolve redness, blotchiness, and areas of hyperpigmentation and is useful in eliminating visible capillaries. Electrosurgery and vascular lasers also are effective for treating telangiectasias.

#### **Moisturizing**

Moisturizers are helpful for patients with acne, who often are given medications such as topical retinoids that can cause dryness. At the beginning of a topical regimen, these patients often experience peeling and scaling. Moisturizers can decrease the peeling and irritation and also may increase a patient's compliance with a topical medication regimen.

Patients with acne vulgaris should be guided to moisturizers that are non-comedogenic and have the fewest possible ingredients.

Patients with rosacea, especially those with sensitive skin, may do best with moisturizers that contain the humectant glycerin, which binds water to hydrate the skin; petrolatum, which prevents evaporation of water from the skin's surface; or other antiirritants such as aloe vera or chamomile. Patients with rosacea should avoid products with too many preservatives. Products that contain parabens may be less irritating than those containing sorbic acid. With respect to surfactants, products that contain amphoteric, sulfosuccinates, and betaines are milder than those that contain other surfactant compounds.

Salicylic acid and polyhydroxy acid are preferable to AHAs. Although AHAs have become popular for acne and photodamaged skin, these agents can be irritating for patients with rosacea. Glycolic acid is a small, hydrophilic molecule that penetrates into the dermis and can exacerbate irritation or redness in patients with rosacea. Salicylic acid, on the other hand, is a larger, lipophilic molecule that can enter the sebaceous follicle and will help unclog the pores; in addition, salicylic acid has some anti-inflammatory properties, which can be helpful in mitigating redness in patients with rosacea.

#### **Protecting**

Both groups of patients should use a sunscreen every day. Patients with acne should select noncomedogenic products, and those with oily skin may prefer alcohol-based gels.

Patients with rosacea should use hypoallergenic, chemical-free products. They also will do best with physical blocks such as transparent zinc oxide or titanium dioxide, which are less irritating than some other products.

#### **Cosmetics**

Several cosmetic product lines currently on the market are formulated for acne-prone skin. These products are labeled noncomedogenic and/or nonacnegenic. The latter term indicates that the product will not cause perifollicular irritation and will not contribute to the development of papules and pustules.

Patients with acne vulgaris also should purchase products that are labeled oil-free and that contain a silicone such as dimethicone and cyclomethicone. Loose, transparent powders increase coverage and help absorb excess facial oil. These are preferable to pressed powders that often contain oils. Powder blushes and eye shadows are preferable to liquid products; matte lipsticks are preferable to glosses, which may increase the development of comedones along the vermilion border of the lip.

The most appropriate cosmetic choices for patients with rosacea meet the following criteria: They

*Continued on page 12*



# THE RESURGENCE OF BENZOYL PEROXIDE IN ACNE THERAPY

Barry A. Solomon, MD, JD

**B**enzoyl peroxide (BPO) and BPO-combination products represent a large and growing segment of both the proprietary and the over-the-counter acne therapy markets. There are a number of reasons for the increased interest in BPO formulations. Current water-based BPO formulations are less irritating than the earlier alcohol-based products. In addition, many of these newer formulations contain moisturizers that provide even more protection against irritation, especially for patients with sensitive skin.

BPOs also are lipophilic, enter the pilosebaceous units easily, and have antiinflammatory properties. Recent evidence suggests that BPOs may be helpful in controlling non-inflammatory, comedonal-type acne. In addition, there is growing evidence that BPOs may be bactericidal against both antibiotic-sensitive and antibiotic-resistant *Propionibacterium acnes*. Finally, BPOs combined with topical antibiotics seem to enhance therapeutic efficacy and reduce the risk for the development of bacterial resistance during combination treatment.<sup>1</sup>

## Efficacy of BPO/Antibiotic Combinations

Although BPOs are recognized as effective therapy for many patients with mild acne, a number of studies have demonstrated that BPOs have an additive effect when combined with topical antibiotics and that the combinations are more effective than either class of agent alone.<sup>2</sup>

Lookingbill and colleagues<sup>3</sup> compared a clindamycin 1%/BPO 5% combination in an emollient vehicle with each agent used alone in patients with multiple types of lesions. Subjects were required to have at least 12 non-inflammatory, 12 inflammatory, and 3 nodulocystic lesions. A total of 334 patients completed this 11-week trial.

At the end of the study, a 61% mean

reduction in inflammatory lesions and a 36% mean reduction in noninflammatory lesions were seen in the group of patients (n=95) who used the clindamycin/BPO combination. In the BPO-only group (n=92), mean reductions of 39% and 30% were seen in inflammatory and noninflammatory lesions, respectively. The use of clindamycin alone (n=89) yielded a mean reduction of 35% in inflammatory lesions and 9% in noninflammatory lesions. The mean improvement in inflammatory lesions was significantly better with the combination than with BPO alone or clindamycin alone ( $P<0.02$ ). The mean improvement in noninflammatory lesions was significantly better with the combination and with BPO alone than with clindamycin alone ( $P<0.02$ ). These data suggest that BPO is effective in controlling noninflammatory, comedonal-type acne.

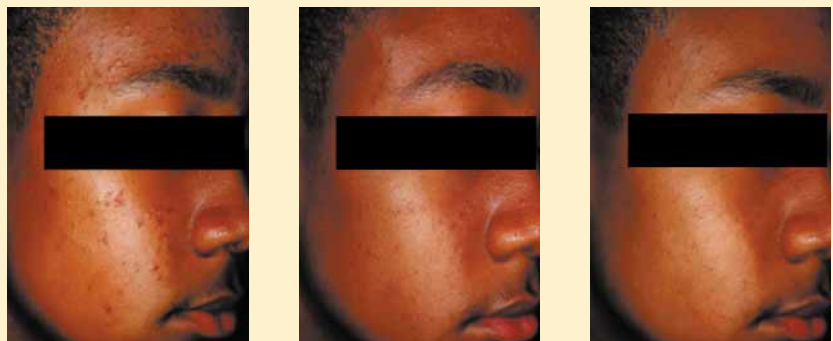
In a similar study, Tschén and colleagues<sup>4</sup> compared clindamycin/BPO in a water-based vehicle with either agent alone. In this randomized, double-blind, parallel-group study,

patients with moderate or moderately severe acne used a combination of clindamycin/BPO, BPO alone, clindamycin alone, or vehicle alone for 10 weeks. The investigators reported that the patients in the group using combination therapy had a significantly greater mean reduction in inflammatory lesions than did those using vehicle at all weeks ( $P<0.02$ ). The differences were statistically significant compared with BPO alone and clindamycin alone at weeks 8 and 10 ( $P<0.03$ ).

## BPO/Clindamycin Tolerability With Retinoids

To determine the impact on efficacy and tolerability when a topical retinoid is added to a clindamycin/BPO combination, Tanghetti and colleagues<sup>5</sup> conducted a multicenter, randomized, double-blind, parallel-group study of 121 patients with stable, moderate to severe facial inflammatory acne vulgaris. The patients had 15 to 60 papules plus pustules (inflammatory lesions), 10 to 100 comedones (noninflammatory lesions), and no more than two nodulocystic lesions  $\leq 5$  mm in diameter.

**Figure. Retinoid Plus Clindamycin/Benzoyl Peroxide**



**Baseline**

**8 Weeks**

**12 Weeks**

This patient used a combination of tazarotene plus clindamycin 1%/benzoyl peroxide 5% in an emollient vehicle. The clearing of lesions seen here occurred, without excessive dryness, over a period of 12 weeks.

Source: Tanghetti et al.<sup>5</sup>

All patients received tazarotene 0.1% cream plus a moisturizer once daily at night for 12 weeks. Patients were randomly assigned to receive an emollient-based formulation of clindamycin 1%/BPO 5% or vehicle alone; these were used each morning. The data completed to date show that tazarotene plus the emollient-based formulation of clindamycin and BPO offers superior efficacy to tazarotene and vehicle alone. Further, tolerability with the two regimens appears to be comparable. Publication of completed data is anticipated once all patients in the study have been evaluated.

### Data Suggest Clindamycin/BPO Improves Comedonal Acne

Most patients have both noninflammatory (comedonal) and inflammatory lesions. In those with milder acne, comedonal lesions predominate. Both clindamycin and BPO have mild comedolytic properties when used alone, but as noted above, the combination of these two agents yields a significantly better response.<sup>2</sup>

The study by Lookingbill and colleagues<sup>3</sup> demonstrated a mean reduction of 36% in noninflammatory lesions in patients (n=95) who used clindamycin/BPO in an emollient vehicle. In contrast, the group who used clindamycin only (n=89) had a mean reduction of 9% in noninflammatory lesions ( $P<0.02$ ). In the patients who used BPO only (n=92), the reduction in noninflammatory lesions was 30% ( $P<0.02$ ).

In a 2002 study, Cunliffe and colleagues<sup>6</sup> compared clindamycin/BPO gel with clindamycin monotherapy applied twice daily. A total of 79 patients with mild to moderate acne were assigned to receive the combination (n=40) or the topical antibiotic alone (n=39). After 16 weeks, the patients who used the combination medication had significantly greater reductions in total lesion counts as well as in numbers of inflammatory lesions and comedones compared with the monotherapy group ( $P\leq 0.046$ ).

### Bacterial Resistance Lower With Combinations

It has been demonstrated that the efficacy of BPO is improved when

used in combination with a topical antibiotic.<sup>3,4</sup> However, it is important to consider antimicrobial resistance of *P. acnes* when using topical antibiotics.

Although resistant strains of *P. acnes* had not been seen with the use of systemic antibiotics, resistance was observed in the 1980s after the introduction of topical antibiotics. Resistant strains of this microorganism have been identified worldwide. Thus, strategies are needed to minimize the continued emergence of resistant strains of *P. acnes*.<sup>7</sup>

Combining topical antibiotics with BPO seems to be helpful in this regard. For example, in the study cited by Cunliffe and colleagues<sup>6</sup> comparing *P. acnes* counts with clindamycin 1% alone and clindamycin 1% combined with BPO 5% in a water-based vehicle, the investigators found that the *P. acnes* counts were significantly lower at weeks 4, 12, and 16 in the group of patients who used the combination product compared to the clindamycin-only group ( $P=0.004$ ). In addition, the counts of resistant *P. acnes* increased over the 16 weeks with the use of clindamycin alone ( $P=0.018$ ).

A recent report by Donald and coworkers<sup>8</sup> indicated that use of a clindamycin 1%/BPO 5% combination in an emollient vehicle resulted in a greater reduction of both erythromycin-resistant and clindamycin-resistant *P. acnes* compared with a solution containing 40 mg/mL of erythromycin and 12 mg/mL of zinc.

In this study 73 patients were randomized to receive the clindamycin/BPO medication and 75 patients received the erythromycin/zinc combination. Reductions in inflammatory and total lesion counts were significantly greater in the clindamycin/BPO group ( $P=0.029$  and  $P=0.017$ , respectively).

### Conclusion

BPO is effective in managing both inflammatory and noninflammatory comedonal-type acne. BPO has antimicrobial activity as well as anti-inflammatory and comedolytic effects. The combination of BPO and a topical antibiotic is more effective than either agent alone. The mechanisms of action of these agents are additive, and the use of BPO with the topical antibiotic

helps protect against the emergence of *P. acnes* resistance. Clindamycin/BPO combination agents have been shown to be effective in treating both inflammatory and noninflammatory lesions.

Topical retinoids currently are the treatment of first choice for mild to moderate inflammatory and noninflammatory acne. However, given the recent evidence demonstrating the efficacy of BPO and BPO-combination products in both inflammatory and noninflammatory acne, it is becoming clear that BPO can be a useful agent in first-line treatment for such patients. ■

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# NEW TREATMENT OPTIONS FOR ACNE ROSACEA

Michael H. Gold, MD

**R**osacea is a common, chronic, relapsing disease of the skin characterized by vascular and acneiform components. It occurs mainly in fair-skinned individuals, especially in those of Celtic ancestry, and although rosacea is seen in both genders, it is much more common in women. The typical age of onset is between 30 and 50 years.

Patients have an inherited tendency to blush and flush, with the cheeks and nasal skin most commonly involved, although symptoms may extend to the chin and forehead areas, and extrafacial areas (the neck, ears, scalp, back, extremities, and abdomen) also may be affected. In addition, it is important to remember that rosacea can cause conjunctivitis (ocular rosacea), and, in patients who are not diagnosed and treated early, rosacea also may be associated with granulomatous changes, lymphedema, and rhinophyma.

The underlying cause of rosacea remains unknown. It is thought that a vascular hyperresponsiveness causes a recurrent dilatation of the blood vessels, resulting in flushing and blushing. A microcirculatory disturbance of the facial angular vein may be involved. In addition, solar elastosis and rosacea frequently coexist. Thus, the disease process itself is likely to be multifactorial, suggesting that combination therapy, including medications and the use of a variety of devices, may be the most effective approach to management for patients with rosacea.

## Systemic and Topical Medications

The standard medications used for rosacea include systemic tetracyclines and derivatives, topical or systemic metronidazole, sulfur derivatives, isotretinoin (an off-label use reserved for the most severe and recalcitrant cases), and azelaic acid.

The tetracycline class of antibiotics has been a mainstay of therapy for

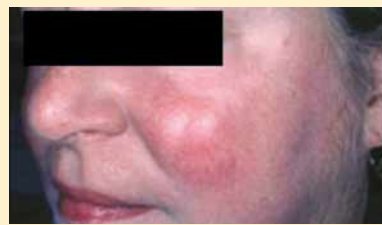
patients with rosacea. The low-dose formulation of doxycycline 20 mg may be effective for rosacea. In addition to the low-dose doxycycline formulation, options for rosacea now also include newer formulations of the sulfur drugs, which are less irritating than their predecessors and, unlike the earlier products, have no unpleasant odor.

At least one product on the market (sodium sulfacetamide 10% and sulfur 5%) is combined with sunscreens. Studies of azelaic acid<sup>1</sup> and the sunscreen combination product,<sup>2</sup> have shown these compounds to be superior to metronidazole topicals in the treatment of rosacea.

**Figure.**  
**Visible Capillaries in Rosacea**



Before



After

This patient with rosacea (top) underwent treatment with intense-pulse light to remove the visible capillaries that are characteristic of this condition (bottom).

Courtesy of Michael H. Gold, MD.

Investigational use of a clindamycin 1%/benzoyl peroxide (BPO)5% combination in a water-based vehicle has shown promise in treating rosacea. Breneman and colleagues<sup>3</sup> recently published a study conducted to determine the efficacy of clindamycin/BPO vs vehicle alone. In

this study, 53 patients were treated once daily for 12 weeks. The investigators reported a significantly greater reduction in papules and pustules with the clindamycin/BPO treatment ( $P<0.006$ ) and significant reductions in global severity on both physician and patient ratings ( $P<0.003$  for both parameters). Tolerance was good, with 15% of patients in the active-treatment group reporting application-site reactions (drying and irritation).

This combination, in a product with a glycerin/dimethicone emollient base, also was studied in a randomized, double-blind, multicenter trial comparing clindamycin/BPO to clindamycin alone, BPO alone or vehicle alone, in a population of 147 patients with moderate papulopustular rosacea<sup>4</sup>. Patients were treated once daily for 9 weeks. Efficacy was evaluated by counting the total inflammatory lesions by grading nonlesional erythema and telangiectasias, and by the investigators' assessments of global severity at baseline and after weeks 3, 6, and 9 of treatment. In addition, patients were asked to assess their own global improvement. Safety was evaluated according to overall tolerance to the study medication at the end of treatment; patients were asked about adverse events, including any problems with dryness, pruritus, stinging, or burning. Results of this study will be published in the future.

## Devices and Procedures

Medical devices play a major role for many clinicians who treat rosacea, having utility in managing erythema and small telangiectatic lesions. For facial telangiectasias, a variety of lasers may be used, but currently in favor are 595-nm long-pulse dye lasers and intense-pulse light (IPL) devices (Figure).

Efficacy of the long-pulse dye laser has been documented in a number of studies. One of these studies, by Jasim

and colleagues,<sup>5</sup> involved 12 patients. At an 8-week follow-up assessment after one treatment, two patients experienced 75% improvement, two had between 50% and 75% improvement, and six had improvements rated between 25% and 50%.

In a study of the long-pulse dye laser by Tan and Tope,<sup>6</sup> after three treatments, flushing reactions decreased from 65% to 22%, burning decreased from 35% to 11%, signs of itching decreased from 28% to 11%, and skin sensitivity decreased from 49% to 18%.

IPL technology has been available since the 1990s and was initially used principally for cosmetic applications such as the treatment of surface leg veins and hair removal. Later, IPL protocols were modified to permit use of these devices in treatment of photodamage to the skin, a procedure known as photorejuvenation. Over the past several years, marked improvements have been made in the IPL devices, which are now widely available.

The advantages of IPL treatments are many, including improvements in erythema and telangiectasias, dyschromia, and photodamage on both the face and other areas of the skin. IPL treatments require little or no recovery time, have a low incidence of serious adverse effects, and have a high level of patient satisfaction.

In a study of a series of IPL treatments in 32 consecutive patients with rosacea, Taub<sup>7</sup> found an 83% decrease in erythema, a 75% decrease in flushing, a 75% improvement in skin texture, and a 64% decrease in acneiform breakouts.

Finally, photodynamic therapy (PDT) with aminolevulinic acid (ALA), currently approved for the treatment of actinic keratosis, is being investigated in the treatment of rosacea. A single treatment with PDT/ALA seems to be effective in reducing rosacea-associated erythema. Other cutaneous conditions also may be improved with PDT/ALA treatment, and these uses are being studied. They include acne vulgaris, sebaceous gland hyperplasia, and hidradenitis suppurativa.

## Conclusion

A variety of effective options now exists to treat patients with acne rosacea. These include devices such as lasers and light sources, PDT, and medications. In addition to the standard medical treatments with which most clinicians are familiar (such as the oral tetracyclines and topical metronidazole), more recent additions to the armamentarium include azelaic acid, sulfacetamide-sulfur with sunscreens, and, currently under study, the combination of clindamycin/BPO. ■

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## Cosmetic Management of Patients With Acne Vulgaris and Acne Rosacea *Continued from page 8*

should be labeled as hypoallergenic, indicating that they are free of the most common allergens; they should be water based and fragrance-free; and they should contain as few ingredients as possible to avoid additives that can worsen rosacea. As a general guide, patients can be told to follow the “rule of 10”—look for products with fewer than 10 ingredients. Specific additives to avoid include antioxidants, vitamins, and chemical sunscreens.

### Lifestyle Factors

Patients in both populations should be counselled about avoiding certain environmental and dietary stimuli that could trigger or worsen their acne vulgaris or rosacea.

Patients with acne should be reminded to avoid traumatizing the acne lesions. Both teenagers and some young adults tend to pick at open and closed comedones in an attempt to eliminate them. They should understand that traumatizing these lesions can cause them to rupture, and this increases the tendency for the development of inflammation, pigmentary changes, and scarring.

Patients with rosacea—particularly those who experience flushing—should avoid temperature extremes, especially heat. Other potential triggers for symptoms include sun exposure, emotional stress, alcoholic beverages (especially wine), and spicy foods. If the patient’s rosacea outbreaks are associated with hormonal fluctuations,

managing those fluctuations also may be helpful.

## Conclusion

The successful management of patients with acne vulgaris or acne rosacea depends largely on the clinician taking a thorough history of over-the-counter products the patient is using, teaching the patient about the most effective skin care regimen appropriate to his or her individual case, and counseling the patient about lifestyle adjustments. Patients who are knowledgeable about the products they use and who have received guidance about which products and ingredients minimize irritation will be more compliant and will achieve better overall results. ■