A NEW INNOVATION FOR THE MANAGEMENT OF HYPERPIGMENTATION

A Roundtable Discussion on Novel Management Strategies for Hyperpigmentation

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**Introduction**

Disorders of hyperpigmentation, including melasma, lentigines, and postinflammatory hyperpigmentation, are extremely common among patients seen in dermatologists’ offices. While various modalities have been available for treating these problems, none of the interventions is ideal. Hydroquinone remains the gold standard as a topical skin-lightening agent, but it can cause skin irritation, contact dermatitis, and exogenous ochronosis, and based on animal studies, there are theoretical concerns about carcinogenicity with hydroquinone. Arbutin has been introduced as another topical agent for skin lightening, but it can be hydrolyzed to hydroquinone by normal skin microflora. Chemical peels, as well as laser and light-based procedures, can also be used to treat hyperpigmentation, but these procedures may be associated with downtime and are accompanied by other risks, including additional hyperpigmentation.

The limitations of existing treatments for hyperpigmentation have fueled research to develop better alternatives. Recently, a distinguished panel of dermatologists convened to discuss their use of Lytera® Skin Brightening Complex ("Lytera" SkinMedica®, An Allergan Company) in the context of clinical trials and clinical practice. The discussion was chaired by Mitchel P. Goldman, MD, San Diego, CA, and the panel participants included Suzanne Bruce, MD, Houston, TX; Valerie D. Callender, MD, Glenn Dale, MD; Annie Chiu, MD, North Redondo Beach, CA; Sabrina Guillen Fabi, MD, San Diego, CA; Mona Foad, MD, Cincinnati, OH; and Wendy E. Roberts, MD, Rancho Mirage, CA.

Dr. Goldman: Dr. Bruce, you were involved in a premarketing clinical trial evaluating the efficacy and safety of Lytera. Please tell us about your findings.

Dr. Bruce: Our study enrolled patients with Fitzpatrick skin types I to IV having moderate-to-severe facial hyperpigmentation who used Lytera twice daily with a standardized skin care regimen for 12 weeks. In preparation for this discussion, I reviewed photographs from participants in the trial, and what struck me was that in addition to the lightening of brown spots, the patients had improvements in skin texture and in the background erythema that is seen in significantly photodamaged skin (Figure 1A and B).

I believe the redness in these patients represents inflammation from sun damage and that it improved because Lytera has ingredients with anti-inflammatory activity, including 4-ethoxybenzaldehyde, glabridin from licorice root extract, and niacinamide.

The changes in skin texture, including reduction in fine lines and pore visibility, were also remarkable. Lytera contains retinol, but the study participants were prohibited from using other topical products that can affect skin texture. And, it is worth noting that Lytera provided these global improvements in skin appearance without causing the irritation that can be seen with hydroquinone and retinoids.

Dr. Goldman: Certainly, other treatments for hyperpigmentation can produce inflammation that can even lead to hyperpigmentation. Dr. Roberts, have you seen similar effects in your patients treated with Lytera?
Dr. Roberts: Absolutely. My experience includes skin of color (SOC) patients with melasma or postinflammatory hyperpigmentation (PIH) secondary to acne that I started on Lytera prior to performing a chemical peel or laser procedure. In looking at their photographs, I was amazed at the amount of pigment and textural improvements they achieved using Lytera alone. I also noticed some improvement in active acne lesions, which perhaps might be the result of the anti-inflammatory ingredients in Lytera.

Dr. Goldman: Dr. Fabi was also involved in conducting premarketing studies with Lytera. What did you notice in terms of erythema?

Dr. Fabi: Some patients developed more erythema than I expected, but that is because they were also using a topical retinol every night along with Lytera twice a day. In clinical practice, I do not see the erythema when I use Lytera alone, and when incorporating a topical retinol into the regimen, I do so slowly to avoid the irritation it can cause.

Focus on Melasma

Dr. Goldman: Melasma is probably the most challenging hyperpigmentary disorder we treat. What has been your experience with Lytera for managing melasma?

Dr. Food: I especially like using Lytera for melasma, and I have been impressed over the past few months that it seems to minimize the severity of recurrences that are inevitable during the summer (Figure 2A and B).

Dr. Bruce: I have made the same observation. We expect melasma to get worse in the summer, but Lytera seems to temper those flares.

Dr. Roberts: I find Lytera a great choice for maintenance in melasma patients, and agree that patients who are using it seem to benefit with reduced severity of recurrent hyperpigmentation.

Dr. Callender: I also like to use Lytera for maintenance in melasma patients, but a prescription-strength 4% hydroquinone is indicated for initial treatment. Then, once the skin is clear or almost clear, I switch to Lytera. Lytera gives patients a necessary hydroquinone holiday, and I am finding it works well to mitigate melasma flares.

Dr. Chiu: I also start with prescription hydroquinone when using a topical agent to treat patients with significant melasma, and I use a compounded product that contains 8% hydroquinone with ascorbic acid and kojic acid. After 2 months, I switch to azelaic acid 15% gel (Finacea®, Bayer HealthCare Pharmaceuticals Inc., Wayne, NJ) with Lytera for maintenance, and I’ve had good success with that approach. However, I have also used Lytera alone to treat melasma with good results (Figure 3A and B).

FIGURE 2A and B: This 38-year-old female with Fitzpatrick skin type III was treated previously for melasma with a Vitalize® peel and 6 weeks later with a 1927-nm nonablative fractional laser procedure. In September, 2012, (A) 3 months after the laser treatment, she started using the Lytera Skin Brightening System, including Lytera twice daily and topical retinol at night (M and W x 2 weeks, M, W, and F x 2 weeks, then nightly). After 8 weeks, her melasma was significantly improved (B). She continued using the Lytera Skin Brightening System, and through the summer of 2013, her melasma is much better than in past summers despite spending a lot of time outdoors watching her four children play sports.

FIGURE 3A and B: (A) This 37-year-old female of Filipino descent presented for the treatment of melasma. (B) She was started on Lytera twice daily and already had significant improvement after 6 weeks.
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Dr. Goldman: I have also used Lytera alone to treat melasma and achieved good results (Figure 4A and B).

However, I think the combination of Lytera with intense pulsed light (IPL) is particularly effective, and the explanation may relate to the ability of each modality to affect both pigment and the vasculature. Interactions between the vasculature and melanocytes is a proposed mechanism in the development of melasma, and histological studies show increased vascularity in the dermis of melasma lesions. Consistent with the latter study, our VISIA® Complexion Analysis images taken of melasma patients show areas of hypervascularity correspond with sites of increased vascularity.

Who else is using Lytera with a procedure to treat melasma?

Dr. Fabi: I agree with you about the beneficial effects of IPL and Lytera on the vascular component in melasma.

I am using Lytera in patients with melasma as an alternative to hydroquinone in those who have been using hydroquinone long term and also as a maintenance regimen after laser or IPL treatment for patients who have refused to use hydroquinone. Returning for a procedure every month is impractical, and by using Lytera, these patients seem to be maintaining their treatment benefit longer. I think it is the first topical product we have that works comparably to hydroquinone and can be used safely long term.

Dr. Goldman: Has anyone used Lytera with a fractional nonablative laser to treat patients with melasma?

Dr. Roberts: My first-line choice for a procedure to treat melasma has evolved over time. I first used chemical peels, then the 1550-nm fractional laser (Fraxel® Dual), but now I favor the 1927-nm fractional thulium laser (Fraxel® Dual) because I think it is even safer, especially in SOC patients. Histological studies also show melasma is accompanied by increased solar elastosis in the dermis in addition to the increased vascularity, and I believe that Lytera plus treatment with a fractional nonablative laser addresses all of these features.

Using the 1927-nm laser with conservative settings, I get up to 50% clearance after a single treatment. Using Lytera, I feel more comfortable being sufficiently aggressive with the laser.

Dr. Food: I love the 1550/1927 fractional nonablative laser for treating hyperpigmentation, and we now pretreat patients with Lytera instead of hydroquinone. For melasma, I use only the 1927-nm wavelength and do 4 passes. I tell patients they may need additional treatments, but I’d rather start conservatively to avoid causing inflammation. I also use TNS Recovery Complex® (SkinMedica®) pretreatment, restart it 1 week after the laser procedure, and restart Lytera 2 weeks post laser.

Dr. Bruce: I have combined Lytera with both the 1550-nm and the 1927-nm fractional nonablative lasers for treating melasma. I have not seen any patients whose melasma worsened after their laser treatment, which is a problem that would occur in an occasional patient before I was using Lytera. Now, I am trying to be even more conservative, and I am using the 1440-nm fractional nonablative laser (Clear+Brilliant®, Solta Medical, Inc.).

Dr. Fabi: I like IPL to treat melasma in patients with Fitzpatrick skin types I to III, but for patients with recalcitrant hyperpigmentation or type IV skin, I use the 1927-nm thulium laser (Figure 5A and B).

FIGURE 4A and B: (A) This 53-year-old Hispanic female with melasma was treated using IPL in August, 2007, and November, 2010, but without much improvement. Subsequently, she had no improvement after fractional nonablative laser treatment (Fraxel® Dual) performed in February, 2011. She was started on Lytera Skin Brightening Complex, and her follow-up photo (B) shows significant improvement of her melasma after 12 weeks.

When using a laser, I generally pretreat patients using the 4-component skin brightening system (Lytera Skin Brightening System, SkinMedica®), but have them stop the retinol and Lytera 1 week before the procedure. I add clobetasol 2 days before the laser in darker skinned patients when using the thulium laser, and add clobetasol for 3 days post treatment in all patients. I restart Lytera at 1 week and add back the topical...
retinol after about 3 weeks. I think this combination approach provides greater pigment clearance than monotherapy with Lytera alone and minimizes the risk of PIH, although there are no studies yet to validate that concept.

**Dr. Goldman:** We published a study in 2002 in which we found hydroquinone pretreatment in patients with Fitzpatrick skin type IV did not prevent PIH after fractional resurfacing with a nonfractional ablative laser. The only possible benefit of pretreatment was that it allowed insight into how much irritation individuals developed with hydroquinone, which could help with decisions on post-operative care. To the best of my knowledge, there has not been a similar study done in patients undergoing fractional resurfacing. What are your thoughts about pretreating darker skin type patients with Lytera to minimize PIH after a fractional laser procedure?

**Dr. Fabi:** Anecdotally, I believe that use of Lytera is mitigating the PIH that can definitely occur after treatment with the 1927-nm laser or other lasers and light devices. Since Lytera contains ingredients with anti-inflammatory activity, it may decrease the postop redness and secondarily the PIH.

**Dr. Roberts:** Dr. Goldman, your 2002 paper changed the landscape in terms of using hydroquinone prior to laser resurfacing. However, I think some controversy remains. I still feel more comfortable using a skin-lightening agent prior to laser to prevent PIH in SOC patients, and before Lytera was available, I was using hydroquinone. However, not all people with SOC are recognized as such, and I published the Roberts Skin Type Classification System that addresses these individuals who phenotypically appear to be Fitzpatrick type II or III, but tend to develop postprocedural irritation individuals developed with hydroquinone, which could help with decisions on post-operative care. To the best of my knowledge, there has not been a similar study done in patients undergoing fractional resurfacing. What are your thoughts about pretreating darker skin type patients with Lytera to minimize PIH after a fractional laser procedure?

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I agree that we have several options that are effective for treating simple discrete lentigines from photodamage. However, when the findings are more complex so that patients also have hazy patchy pigmentation and macular SKs, I find Lytera is a great product for cleaning up the diffuse pigmentation after doing a treatment that specifically targets the lentigines and macular SKs.

Dr. Callender: Photoaging in SOC patients often presents as generalized facial hyperpigmentation, and sun protection with a broad-spectrum, SPF30 or higher sunscreen plus hydroquinone has been the standard treatment. Now, I am using Lytera instead of hydroquinone and am finding that Lytera not only works to lighten the skin but also provides textural improvements to produce better overall cosmetic results.

However, I want to emphasize that differential diagnosis is important in SOC patients who present with diffuse darkening of the face because there are multiple etiologies for this problem and we want to address any underlying cause. Aside from being photoaging-induced, the hyperpigmentation may represent exogenous ochronosis from long-term use of OTC hydroquinone, and in this situation there is a particular benefit for switching to Lytera. Alternatively, diffuse facial hyperpigmentation may be associated with some systemic diseases, including lupus or Addison’s disease, or it may develop with use of certain systemic medications, such as minocycline, chloroquine, or some diuretics, among others.

Dr. Goldman: Has anyone used Lytera with the Vitalize Peel® (SkinMedica®)?

Dr. Callender: The Vitalize peel is now my most commonly used peel, and I do a series of five peels spaced 2 to 4 weeks apart. I use Lytera to both treat hyperpigmentation and to prevent it in these patients, and a nice thing about Lytera is that I don’t feel I have to discontinue it between peels. Patients start using Lytera about 2 weeks before the first peel and are also instructed on daily use of a broad-spectrum SPF 30+ sunscreen.

Dr. Roberts: We had a pre-spring boot camp where patients were started on the Lytera Skin Brightening System plus TNS Essential Serum® (SkinMedica®) and then could choose to receive a series of peels with the Rejuvenize Peel™ (SkinMedica®) or IPL treatments. We had a number of participants, and my aesthetician who was helping with this program told me it was very effective and the patients were very happy with their results. While Lytera seems helpful when treating melasma, as we’ve said before, melasma can be difficult to treat, and I think Lytera works even better for hyperpigmentation problems that are not melasma.

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Peeling Protocols

Dr. Goldman: So, we have discussed using Lytera before and/or after IPL, fractional nonablative laser resurfacing, and chemical peels as well as using Lytera for maintenance after initially treating patients with more aggressive regimens, such as compounded 8% hydroquinone. We’ve also touched on the use of Lytera with and without retinol. Now, let’s talk about other potential uses for Lytera.

We’ve just launched a clinical study to explore whether treating with the 1565-nm fractional nonablative laser might improve the clinical results achieved using Lytera based on the idea that the microzones created with the laser could be a pathway for enhancing penetration of the topical product.

Dr. Fabi: Approaches to facilitate intraepidermal and even superficial dermal delivery of Lytera represent an interesting area of investigation. I have been using the Clear+Brilliant Permea™ laser (Solta Medical, Inc.) immediately before Lytera in some of my patients with recalcitrant pigment,
which takes advantage of the increased Permea™bility of the epidermis and dermis following the nonablative laser resurfacing treatment. Given how gentle Lytera is, patients tolerate the procedure very well, and their results are enhanced from a single laser treatment. I would also like to see more research on Lytera for clearing PIH, which can be very stubborn and even made worse by some of the devices used for its treatment.

Dr. Roberts: I have had good results incorporating Lytera as a therapeutic skin lightener in primary and maintenance peeling regimens for patients with PIH (Figure 7A and B). I am interested in using Lytera for rejuvenating the appearance of skin off the face, especially on the chest.

FIGURE 7A and B: This 32-year-old Latina female presented with postinflammatory hyperpigmentation, superficial scarring, and uneven skin tone secondary to acne (A). She was treated with two salicylic acid peels with a between-peel interval of 4 weeks, chosen based on her scored risk of hyperpigmentation and scarring using the Roberts Skin Type Classification system.16 Lytera Skin Brightening Complex was started 1 week after the first peel and held 2 days prior to the second peel. Her skin appearance is significantly improved at 4 weeks after the second peel (B).

Dr. Callender: I think there is great potential for using Lytera off the face, and especially for restoring a more youthful appearance to the hands. I am also interested in using it to treat hyperpigmented skin in the axillae where women with SOC often develop darkening as a result of irritation from shaving and deodorant use.

In addition, I am substituting Lytera for hydroquinone as a pretreatment when performing laser hair removal for hirsutism in women with SOC, and it has been working well. These patients can develop pseudofolliculitis barbae with secondary PIH, and eliminating the excess pigment in the skin is helpful to maximize absorption of the laser’s energy by its intended target.

Dr. Chiu: I had a patient who was using Lytera for melasma and had dark circles under the eyes. We know there are a multitude of causes for the latter problem, including photodamage, and I find it is a tough area to treat because retinoids and hydroquinone can be especially irritating on the infraorbital skin. She applied Lytera below the eyes and had a true brightening effect. I don’t know if it was depigmentation or brightening through some other mechanism, and unfortunately, this patient did not want any photographs taken. I am interested to see how Lytera would work combined with a very conservative fractional laser procedure to treat these dark circles.

Dr. Foad: I also have patients who feel they benefited with an overall brightening of their complexion after using Lytera, and treating under the eye area would be an interesting topic for a study. I agree that using Lytera off the face is very appealing because certainly we see a lot of problems with hyperpigmentation off the face. In addition, I would like to see research that could provide guidance on how soon we can safely restart Lytera after different procedures because now everyone is using their own empirical approaches.

Dr. Chiu: I am wondering if anyone has experience with Lytera in patients with poikiloderma. That is a tougher problem because it is a mix of hyper- and hypopigmentation along with textural changes and telangiectasias.

Dr. Roberts: I treated poikiloderma in a patient using Lytera combined with three 1550-nm fractional nonablative laser procedures spaced 1 month apart, and she did very well.

Dr. Bruce: The only thing I would add to the ideas already mentioned is that I would love to see some formal studies investigating use of Lytera after fractional laser treatment for melasma.

Patient Acceptance and Adherence

Dr. Goldman: What are your thoughts about tolerability when using Lytera or the Lytera Skin Brightening System?

Dr. Foad: I like to use Lytera plus a topical retinol, because I think the combination is more efficacious than Lytera alone whether I am treating melasma or photodamage (Figure 8A and B). However, in order to limit irritation, I have patients start on the topical retinol Monday and Thursday only. Then, I have them increase the frequency of topical retinol use as they are able to tolerate it.

FIGURE 8A and B: (A) This 41-year-old female with Fitzpatrick skin type I began treatment for her melasma with the Lytera Skin Brightening System in August 2012. She used SPF 30 Daily Physical Defense™ every morning, Lytera twice daily, and a topical retinol at night (M and Th x 2 weeks, M, W, and F x 2 weeks, then nightly). Her melasma was significantly improved after just 6 weeks (B), and the patient was exceedingly happy with her results.
Dr. Roberts: When I am going to use a topical retinol, I sometimes start patients on a milder product to mitigate tolerability issues.

Dr. Bruce: I do the same thing because I prefer that patients follow a routine daily application schedule from the start.

Dr. Goldman: Does anyone have tips on getting patients to accept treatment with Lytera and making sure they adhere to the regimen?

Dr. Fabi: There are pamphlets from the manufacturer that feature before and after photos, but I like to show photos from patients we’ve treated and especially from patients in our study who only used Lytera. A lot of patients are skeptical that a topical agent can work well on its own, especially if they had a disappointing experience with other products previously, and then they are hesitant to buy a new product or a whole system.

Patients also need to understand that they have to use the product according to the instructions, that it takes 3 to 4 months of treatment to achieve significant results, and that they can see improvement sooner if the topical product is used with a laser treatment or some other procedure. I also think it is important that physicians personally reinforce the efficacy of the product, and they can do so by citing published studies in addition to showing pictures from their own patients.

Dr. Bruce: I totally agree about showing a book of before and after photos from your own patients because then the physician can speak with authority about efficacy. I also agree that patients must understand the improvement will be gradual so that they will not be discouraged by a perceived lack of benefit and discontinue treatment prematurely.

Using photography and other imaging to document personal improvement for individual patients can promote their adherence. We do a Visia Complexion Analysis at baseline in all patients and try to get a follow-up. Sometimes, however, the numerical results on the Visia analysis are worse at follow-up than at baseline despite obvious clinical improvement, and then I am reluctant to share the data with patients. Has anyone else had this experience?

Dr. Goldman: I expect we all have and we noticed that issue when we did the initial validation studies for the Visia. It is a matter of having less than exact alignment with the repeat imaging as the numbers can be dramatically different even at the same session if the facial positioning is shifted by even a millimeter. I omit the numbers and show patients the results for the different scales of pigmentation, redness, etc. Another factor to consider is whether there has been a change in software between the two visits, because there have been several upgrades over the years and the numbers will differ depending on what software version was used for the imaging.

Pre- and post-treatment images are essential. However, it can be difficult to get the lighting and positioning perfect with the Visia system or digital photography, and so we use the 3D imaging system (Vectra® M3, Canfield Scientific, Inc.) to try to get the best pictures that we can. Does anyone else have any thoughts on photography?

Dr. Food: We like to zoom in with the Visia in order to capture the textural changes in the skin.

Dr. Goldman: Patients absolutely notice improvements in texture when looking at their before and after pictures, and so photography is helpful not only for documenting changes in hyperpigmentation with use of Lytera but also so that patients can see how much better they look globally.

Dr. Callender: Overall, I’ve seen good patient compliance with Lytera. The formulation feels very elegant on the skin and women like using it.

Dr. Goldman: This has been a very informative discussion, and I think we have all learned a lot from each other’s insights and experience. I hope that readers will also take away useful ideas and, if they are not already using Lytera, be encouraged to incorporate it into their management of patients with hyperpigmentary disorders.