AD treatment advances on psoriasis research

Continued research and development in psoriasis has led to a translational revolution — the lessons from which can now be observed in other common inflammatory diseases, such as atopic dermatitis, alopecia areata, vitiligo, hidradenitis suppurativa, acne, and rosacea. According to one expert, the journey has been arduous but, due to the years-long work on psoriasis, the future is bright for patients with inflammatory skin diseases.

Atopic dermatitis and psoriasis are characterized by immune-mediated inflammation and abnormal keratinocyte differentiation and, although their T-cell infiltration characterizes both diseases, T-cell polarization differs. Because of their similarities however, the therapeutics for atopic dermatitis, in particular, have benefited from continued psoriasis research.

“It took decades for us to get from relatively primitive treatments of psoriasis to the very advanced perfected treatments that we currently have available, and we can clear almost everybody with these therapies. The advent of the biologics around the turn of the century has changed the treatment and management of inflammatory skin diseases forever,” says Mark Lebwohl M.D., FAAD, Sol and Clara Kest professor and chairman of the department of dermatology at Mount Sinai School of Medicine, New York, New York.

Genetic test could rule out melanoma diagnosis

An existing non-invasive gene expression test could effectively rule out a diagnosis of melanoma in a suspicious lesion, eliminating or reducing the need for a surgical biopsy.

In an analysis published in Dermatology Online Journal, researchers examined whether results from the commercially available Pigmented Lesion Assay (PLA) test remained accurate after 12 months. The findings confirmed the test’s critically important high negative predictive value, potentially altering how dermatologists could choose to approach future lesion diagnosis in clinic.

Future of skincare

Investigators examine vehicle for adding PRP to personalized topicals

Many physicians are already using platelet-rich plasma (PRP) in practice to enhance results from skin rejuvenating and hair replacement procedures. Now new scientific developments suggest that doctor’s also could be using enriched platelet cells derived from the patient’s whole blood to make a personalized skincare product, according to dermatologist Zoe Diana Draenlos, M.D., who practices in High Point, N.C., and founded Dermatology Consulting Services, a company that works with firms to develop formulations and conduct product testing.

Dr. Draenlos says the approach is so cutting edge that her lab is testing a base serum that has been developed to maintain the viability of platelet cells.
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Provide practical analysis of recent studies, regulatory updates, techniques, devices & business solutions; and facilitate discussion to optimize practice and improve patient care.

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While its cause remains mysterious and treatment has shown only slow progress, there is enough to hope ...”

A basic primer on vitiligo

by DR. RONALD G. WHEELAND, MD

Dr. Wheeland is a private practitioner in Tucson, Ariz.

Having been born and raised in Arizona, I benefitted from being exposed to multiple ethnicities, religions, cultures and languages starting when I was just a kid. Many of my friends were Hispanic but we were all like a big, happy family. Differences in skin color were just not relevant. My best friend was Jorge (Spanish for “George”), and we played every day at the school playground, nearby parks or at each other’s homes where Jorge’s mother introduced me to my first homemade green chile and bean burrito. It was love at first bite.

Jorge’s mom had a very noticeable discoloration on her face that I couldn’t ignore, but it didn’t seem to bother her — at least to my five-year-old eyes, and Jorge had no knowledge or even awareness of his mother’s condition.

“Oh, no,” he told me, “she’s always looked like this,” which ended the discussion so we could get back to the more important task of kickball.

Of course, as I got older, I learned that Jorge’s mom had vitiligo, which is a relatively common disease of unknown cause that affects 3 million people of all skin types per year in the United States. As this month’s issue on disorders of pigmentation, I thought I would use this opportunity to update my knowledge on vitiligo which would perhaps serve as an introduction to this month’s issue.

Since I have only treated a small number of patients with vitiligo and that was a while ago, I had a lot to learn. Here are some of the things that I learned:

The blotchiness of vitiligo is due to the death of melanocytes. The disease proceeds unpredictably as far as extent and rate of progression are concerned. It can last a life time or persist for just a few years. It can begin at any age, but often before 20 years of age. It may be familial or may develop following some stressful event or even a severe sunburn. It may also represent an autoimmune disease.

Vitiligo usually first develops on sun-exposed areas, like the face, lips, hands and arms. It may also affect the retina. It may appear in a segmental distribution, remain localized or become generalized. There is no known cure.

It should be obvious that the loss of pigmentation can be life altering and may cause significant psychological problems like depression, depending on the extent or areas of involvement. With the loss of pigmentation due to melanocyte death or cessation of function, patients may be susceptible to sun burns and iritis may also develop.

Treatment may be successful if application of steroid creams is started early. Similarly, application of calcineurin inhibitor ointments ( tacrolimus or pimecrolimus) may provide some improvement. Cautious use of UVB or careful application of phototherapy using topical or oral psoralen coupled with UVA or light from an excimer laser two to three times a week for six months has proven helpful in some cases. However, only rarely does the normal skin color return to normal. Tattooing can be performed on small areas of involvement, but the color around the tattooed site is difficult to match and seasonal fluctuation in color due to sun exposure can be expected. For small areas of involvement, transplantation of melanocytes contained in suction blisters from areas of uninvolved skin that can be hidden by clothing may be useful, but irregularity in the skin color may persist.

The greatest number of published articles dealing with the treatment of vitiligo have focused on producing irreversible depigmentation using a variety of chemicals. However, this approach is usually not recommended unless the involvement is greater than 50-60%.

The most common medicines used for this purpose are monobenzyl ether of hydroquinone (MBEH) or monoethyl ether of hydroquinone (MMEH). Topical application of 88% phe- nol to small areas only has been reported to provide some degree of depigmentation, but potential harm to internal organs is possible if larger areas are treated. There are some reports of a drug used for the treatment of chronic myeloid leukemia (imatinib) having an unexpected complication of depigmentation suggesting that more research is needed to determine its potential usefulness in treating vitiligo.

Use of protein kinase inhibitors, prosta- glandin E-2, tofacitin Ib, EGFR inhibitors and afamelanotide injected under stable lesions to induce repigmentation all provide hope that a successful treatment for vitiligo may be developed in the near future.

There are also some uncontrolled reports of herbs like gingko biloba, protea madiensis and myrica ruba being useful in treating vitiligo, but further research is required before they can be recommended.

Lastly, there is hope that the development of immunotherapy for treating melanoma may prove useful for treating vitiligo as well.

My conclusion from updating my knowledge of vitiligo is that while its cause remains mysterious and treatment has shown only slow progress, there is enough to hope that people like my childhood friend’s mother won’t have to live with this disfiguring disease forever.
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A couple of months ago I came across Ronald Wheeland’s commentary in *Dermatology Times* (DT) and saw that I was mentioned. Reflecting back as DT celebrates its 40th anniversary, Dr. Wheeland spoke of my annual visits to Arizona — in my capacity as managing editor and later editor-in-chief — to meet with his colleague and fellow medical editor Norman Levine. “Dean was an avid fan of the Cleveland Indians and would occasionally fly to their spring training in Tucson Arizona, meeting Norm Levine for a game or two and dinner,” Dr. Wheeland wrote.

Uh-oh, I’ve been found out, I thought. It took nearly 40 years, but they finally figured out that I just happened to schedule my visits to coincide with baseball’s attempt to wake us from our winter slumber.

Kidding aside, I think they knew then what I was up to. And truth be told, these visits proved to be invaluable in setting the tone for meaningful collaboration. In his commentary, Dr. Wheeland added: “It is that kind of relationship the physician editors have always had with the DT staff.” It warmed my heart to read those words, and to think that the tone we set many years ago carries on today.

When you think about it, so much has changed in the field of dermatology over the past 40 years, yet the one constant over time is the need for clinicians to keep up with the latest developments and understand how those developments impact their practice. When I became involved with DT, I understood the goal was to provide practical, actionable information. But I was a little worried about delivering on that goal — until I met and started working with Drs. Wheeland and Levine, along with Dr. Lawrence Schachner, who were DT’s first medical editors. Their firm grasp of the specialty, as well as their willingness to explore and communicate how key developments impacted the typical office-based dermatologist, formed the basis of how we developed content. They were leaders in the field, but they were also busy practitioners who understood what readers needed.

What’s more, I always felt I could ask them the so-called dumb questions, which they patiently answered. I use this approach in my medical writing to this day. I imagine a young, inquisitive clinician having a hallway conversation with an expert. What questions would she have? How could she come away from the discussion with something she could put to work right away in practice to improve patient care? It forms the foundation for education that not only informs, but is actionable and meaningful.

As I reflect on my time with DT back in the 1980s, so much of the day-to-day is fuzzy to me, a natural occurrence as time marches on. But one thing remains crystal clear: my interactions with the medical editors. I remember the dinners where we planned strategy. I remember attending meetings with them, such as the AAD annual session. So much happens at those meetings, you hardly know where to focus. The medical editors helped me do that. I remember conducting Q&A sessions during these meetings. We’d bring dermatology’s key thought leaders to a hotel suite and our medical editors would ask great questions, elicit meaningful responses, and always convey that important “tell me what it means to my practice” advice.

In a way, DT was ahead of the times. Just the other day I was asked by a client, a medical publisher, to complete a required planning document for a medical education activity. I needed to identify knowledge, competence, and performance gaps, and explain how the activity would impact practice. I like to think that, back in the day, we at DT did these things without a second thought — without having to fill out a form to make sure we were on target. We just did it. And every now and then we’d also take in a ballgame.

**Bringing it home**

by **DEAN CELIA**

Dean Celia is a medical writer and CME product development specialist. He was a member of the *Dermatology Times* editorial staff between 1985 and 1994.
“This practice, despite being a major part of some dermatology practices, now, is fraught with liability issues.”

What are my liabilities with telemedicine?

by DAVID J. GOLDBERG, M.D., J.D.

Dr. TM, a practicing dermatologist in Florida, has spent the last several years looking for new revenue sources. He has a very active interactive website and is also active on a variety of social media sites. Because of this, he receives hundreds of questions from potential patients all over the country.

Before he began to charge for email consults, he received a photo four years ago from an individual in Oregon with a classic blue nevus. He told the patient the lesion was nothing to worry about. It turned out he was wrong. The patient had a rare malignant blue nevus and died from metastatic malignant melanoma 18 months later. Ultimately the deceased patient’s estate sued for negligence, wrongful death and practicing telemedicine without a license in Oregon.

Dr. TM is beyond distraught and seeks legal advice. Should he be worried?

The term “telemedicine” covers any use of electronic communication technology to convey medical information. It can be as basic as seeking a consultation or as advanced as robotic surgery. Teleradiologists and telepathologists use electronic communication to send radiographs and specimen images for diagnostic or consultation purposes. Teledermatology can be practiced in a consultation or as advanced as robotic surgery. Telemedicine has expanded the scope of telemedicine. The patient can bring the telemedicine consultant into a court in his state. A state may also require venue for the telemedicine service in a state different from where the patient lives. Most jurisdictions will permit a resident to bring a lawsuit where the patient received care or where the defendant physician’s office is located. Telemedicine obviously expands the scope of venue exposure. The plaintiff can bring the telemedicine consultant into a court in his state. A state may also require venue. For example, Montana and North Carolina both require that any medical malpractice claims by their residents that are based on telemedicine must be brought within their state. A physician who practices in a state with a short Statute of Limitations should not assume that time limit will apply if he is sued for telemedicine. Different states also take different approaches to the Standard of Care. Some use a national standard and some use a local one. The consulting telemedicine physician should therefore become acquainted with the standards used in the states they extend their practice to.

So you must determine if your state permits you to act as a telemedicine practitioner. (ii) Are you engaging in the unlicensed practice of medicine in other states? There is no national consensus on what states demand from physicians located outside their borders and are practicing telemedicine within any one state. Some states demand full licensure, some offer restricted licenses for telemedicine, and some offer licensing by endorsement under reciprocity agreements with neighboring states. Despite the wide range of options, there is a common thread to keep in mind: If there is a regular, ongoing practice of telemedicine in the state (as opposed to an occasional consultation), the state will want some degree of licensure. A physician who lacks such licensure can be subject to prosecution for the unlicensed practice of medicine.

1. LICENSURE (i) Are you exceeding the license granted by your own state? If so, you can be subject to disciplinary action in your own state if you use your license inappropriately as a predicate to practice telemedicine.

So you must determine if your state permits you to act as a telemedicine practitioner. (ii) Are you engaging in the unlicensed practice of medicine in other states? There is no national consensus on what states demand from physicians located outside their borders and are practicing telemedicine within any one state. Some states demand full licensure, some offer restricted licenses for telemedicine, and some offer licensing by endorsement under reciprocity agreements with neighboring states. Despite the wide range of options, there is a common thread to keep in mind: If there is a regular, ongoing practice of telemedicine in the state (as opposed to an occasional consultation), the state will want some degree of licensure. A physician who lacks such licensure can be subject to prosecution for the unlicensed practice of medicine.

2. INSURANCE COVERAGE (i) Most malpractice policies specifically exclude coverage for unlicensed activities. Some states require insurers to cover work that extends beyond state borders and some do not. Know where your state stands and obtain coverage in any state with patients affected by your consulting if you do not have that protection. (ii) Does your carrier cover you for telemedicine practice? Telemedicine consulting may not be covered by your malpractice insurer and you may need to obtain surplus lines coverage.

3. NEGLIGENCE LIABILITY (i) Can a medical malpractice action be brought in the setting of telemedicine? Yes. (ii) Where can the action be brought? The issue of “forum shopping” comes into play if the doctor provided the telemedicine service in a state different from where the patient lives. Most jurisdictions will permit a resident to bring a lawsuit where the patient received care or where the defendant physician’s office is located. Telemedicine obviously expands the scope of venue exposure. The plaintiff can bring the telemedicine consultant into a court in his state. A state may also require venue. For example, Montana and North Carolina both require that any medical malpractice claims by their residents that are based on telemedicine must be brought within their state. A physician who practices in a state with a short Statute of Limitations should not assume that time limit will apply if he is sued for telemedicine. Different states also take different approaches to the Standard of Care. Some use a national standard and some use a local one. The consulting telemedicine physician should therefore become acquainted with the standards used in the states they extend their practice to.

In the end, Dr. TM is right to be concerned. The fact that he did not charge the now deceased patient will be no defense. Dermatologists need not fear adding teledermatology to their practices. They do need to understand the unique legal issues that may arise in the practice of teledermatology.
Q Can the currently fashionable eyelid glitter cause problems with contact lenses?

Glitter is everywhere, including in eye shadow. The glitter can be applied as part of the eye shadow color or as a glitter liquid that can be applied to the eyelid with a sponge and allowed to dry. Glitter can be made from mica, ground pigments/metals, and bismuth oxychloride. Many of the new glitter formulations are made by blending very small particles with different light reflective properties to create unique optical characteristics. The glitter can be irritating to the eye if placed under the contact lens. For this reason, it is best to apply the contact lens prior to applying eyelid glitter or any eye cosmetics, for that matter.

Q Is permanent eyeliner safe?

Permanent eyeliner is safe, but there are potential problems. Permanent eyeliner is a tattoo placed along the upper and/or lower eyelashes. The tattoo can be of any color, but is usually matched to the eyelash hair color. The pigment is placed deeply in the skin in a line or small dots to mimic the appearance of eyelashes. Fading does occur over time, but the pigment is permanent. One problem is migration of the pigment over time as it is phagocytized by macrophages and moved toward the lymph nodes. This results in blurring of the eyeliner and the need for additional tattooing. A second problem is the change in the shape and appearance of the eyes with aging that cannot be compensated for by the permanent eyeliner.

Patients with alopecia or other causes of eyelash loss may find permanent eyeliner valuable. The tattoo may also be helpful for patients with a tremor or other hand/eye coordination difficulties who may not be able to apply a steady line of eyeliner. Patients who undertake permanent eyeliner must be sure that they will always enjoy the appearance of the permanent cosmetic.

Q What is eyebrow microblading, and how is it done?

Eyebrow microblading has become very popular to darken, thicken and replace the appearance of missing eyebrow hairs. It is call microblading because a hand tool with attached needles in a curvilinear grouping is used to superficially penetrate the skin of the eyebrows. The cuts are made individually by hand and designed to artistically mimic the thin, crisp lines of natural hair. Pigment matching the natural eyebrows is inserted in the cuts to create a superficial tattoo lasting one to three years.

It takes about two hours to perform a complete procedure. First, a wax marker is used to outline where the eyebrow will be microbladed. The extent of the microblading and the shape of the final eyebrow must be predetermined. This requires an artistic operator eye and a good consumer visual image of the final eyebrow shape.

Second, the eyebrow skin is numbed with topical and/or injectable anesthesia. Third, the micro-cuts are made, and the selected pigment is inserted. It takes five to 10 days for the skin to superficially heal, but the skin must be protected for 30 days from swimming, rubbing, manipulating, or direct shower water. These precautions prevent the pigment from being removed. However, not all the microbladed pigment remains in the skin and touch-ups are frequently performed 30 to 90 days after the procedure.

Microblading is different than eyebrow tattooing, where more pigment is placed deeper into the skin. The deeper tattoo pigment has greater longevity and more permanence, although fading occurs with all tattoo pigment over time. Microblading should be considered a superficial permanent tattoo. The pigment fades with time, but will never completely disappear.

Permanent eyeliner is safe, but there are potential problems.
"We hope to reveal the story behind the story..."

Continuing the journey

by STEVE XU, M.D., FAAD, AND WILLIAM JU, M.D., FAAD

Dr. Xu is an instructor in dermatology at Northwestern University Feinberg School of Medicine, medical director, Center for Bio-Integrated Electronics, Simpson Querrey Institute for Bioactuator Technology, Northwestern University, and co-founder, Advancing Innovation in Dermatology Accelerator Fund. Dr. Ju is co-founder of Advancing Innovation in Dermatology, Inc. and co-founder of the Advancing Innovation in Dermatology Accelerator Fund.

It’s hard to imagine that this column is now on its first anniversary. We hope that you as a reader have found the information inspiring and actionable help in your own innovation journey. Over the past year, we have covered a range of topics. Defining great problems is essential in successful innovation. For dermatologists to have a leg up in this regard, we discussed the importance of building a “people pipeline” of innovators, how their medical school and residency years start thinking about problems worth solving and begin training on how to approach solving them via the creation of new products and services.

We argued that physician organizations such as the American Academy of Dermatology and Society of Investigative Dermatology are interested in and have the ability to be powerful drivers of innovation for their members. This expanded into articles that highlighted innovations in dermatology related to digital health and pharmaceuticals. We provided educational content centered on intellectual property, technology transfer and working with industry. Finally, we highlighted key takeaways from innovation conferences and dermatology-focused hackathons.

As we embark on a second year for this column, we want to make the content even more useful, actionable and inspiring for readers. Over the past few months we have received a lot of wonderful feedback. Using that, we thought carefully about how to structure this year’s column of Innovation Matters.

Innovation is driven by exceptional individuals—particularly in the earliest stages, and it is often best told through real-world examples. Thus, upcoming columns will include more stories from innovators. This will include those who have successfully taken ideas to products. But, we will also include individuals early in the formation of a successful venture or idea. Our hope is that innovators sharing their stories will provide you with both inspiration and insights. We hope to reveal the story behind the story, with each identifying a meaningful lesson relevant to the innovation journey. This could be something important related to ideation, invention, asset creation, licensing, fundraising or product design. We hope that these real-world lessons will be impactful and memorable.

Finally, our topics will broaden to include more areas of innovation, including, for example, novel clinical delivery systems and creative physician-wellness initiatives. We want to highlight a broader scope of innovation that extends beyond new drugs and devices. We hope you the reader will be able to look forward to the columns as much as we look forward to writing them.

References:

A year of innovation

1. A critical first step in defining great problems.
2. The need for entrepreneurship education in medical school & residency training.
3. Medical societies can support innovation.
6. How to use patents to maximize value for your venture.
7. What you should know about technology transfer.
8. Opportunities for collaboration with industry.
9. Innovation dispatches from the AAD.
10. The case for hackathons in dermatology.
Psychophysiological disorders are true dermatologic diseases that are exacerbated by emotional stressors. It is not to say that because someone is stressed emotionally or physically that they will develop a disease, but that a stressor that disrupts the homeostatic balance of the patient can exacerbate a chronic condition.

Atopic dermatitis, acne, rosacea, herpes simplex, psoriasis and hyperhidrosis are all examples of conditions that patients report worsen when they are under stress. When a patient presents with a flare, it is not uncommon that, when prompted, the patient will report some stressor in their everyday life.

The hypothalamic-pituitary-adrenal (HPA) axis and the sympathetic nervous system are among the two major neural pathways that are activated by stressors. There is a multitude of chemical signals released in response to stress. For this article, I am going to give a basic version of these complex pathways to illustrate the take home point that the mind impacts the body.

The hypothalamus is triggered by neurosensory signals to release corticotropin-releasing hormone (CRH) and vasopressin. CRH then goes on to activate the HPA axis, which leads to the release of adrenocorticotropic hormone (ACTH), which then induces the adrenal cortex to secrete glucocorticoids along with catecholamines.

CRH also releases norepinephrine and epinephrine from the adrenal medulla. All of these mediators have dramatic effects on the immune system. New literature and novel treatments with off-label use of naltrexone, address the role of psychological stress and increased CNS levels of opioid neuropeptides, which not only cause pruritus but aggravate certain dermatological conditions with both psychosomatic and immunological components, such as psoriasis, chronic idiopathic urticaria and atopic dermatitis. (See Figure 1.)

Another piece to this complex puzzle is the role of neuropeptides, such as calcitonin gene-related peptide (CGRP), vasoactive intestinal peptide (VIP) and substance P. These mediators are released from nerve terminals present in the cutaneous sensory nerves. The complex interplay between these mediators on the immune system, specifically the activation of mast cells and T-lymphocytes, exacerbate many inflammatory skin conditions.

Patients like this are easy to recognize because they are often in your office for a flare. Not all patients with a flare will have a history of stress, but why not ask?

Asking about a patient’s life fosters a better patient-doctor relationship and can help the dermatologist understand why they are having an increase in severity or frequency of flares. For a psychophysiological disorder, I believe that motivational interviewing techniques are useful in these situations. I often openly recommend the patient see a psychiatrist if they are going through major life changes, such as a death in the family, terminal illness, loss of a job or a divorce.

The most important role for the dermatologist is to recognize the role of stress in their disease, validate the patient’s feelings and remove the stigma around psychotherapy and asking for help during hardship.

I do not believe the dermatologist has a major role outside of the skin disease, unless, of course, they feel comfortable doing so. As dermatologists, we do have a major role in empowering our patients to pursue any and all avenues for managing their disease, especially if they would benefit from psychotherapy.

In this subset of patients, I believe they have insight into the role of their stress on their skin condition and are motivated to seek help outside of their dermatologist. Assuming the dermatologist has a patient with no contraindications and the physician is comfortable prescribing medications, hydroxyzine 25 mg - 50 mg helps with itch and low level anxiety. Doxepin starting at 10 mg is another option in addition to standard of care. However, doxepin is indicated for depression and insomnia and the dermatologist should be comfortable prescribing it for these indications.

In this article, I decided to discuss the role of stress in dermatologic conditions, such as psoriasis, chronic idiopathic urticaria and atopic dermatitis, because the mind impacts the body in their everyday life. This article is not meant to be a comprehensive review on stress and the skin, but to simply provide the dermatologist with some ideas on how to address stress in their patients. Not all patients will benefit, but why not ask?

For this article, I am going to give a basic version of these complex pathways to illustrate the take home point that the mind impacts the body.

References
he 24th World Congress of Dermatology is an international conference hosted by the International League of Dermatological Societies and takes place in a unique location every four years. The first large-scale international gathering for dermatology began in 1889 in Paris, France. Since then, it has been held 23 times under the auspices of the International League of Dermatological Societies (ILDS), which is made up of 180 global dermatological societies. In the past it has been hosted in Vancouver, Seoul, Sydney, Buenos Aires, Berlin, Tokyo, Mexico City, Washington, Padua-Venice, Stockholm, London, Copenhagen, New York and London.

This year, the meeting was hosted in Milan June 10-15, 2019. The Italian Society of Dermatology (SIdE-MaST) served as a co-host to bring Italian hospitality and a warm welcome to one of the world’s largest dermatology congresses to celebrate skin health around the world.

Milan was an excellent choice given its rich heritage, which dates back to when it served as the capital of the Roman Empire. It is known for its gorgeous buildings from the Renaissance and gothic eras, as well as its preservation of Leonardo da Vinci’s “Last Supper” and the iconic Vitruvian man. Today it serves as a dynamic, industrial city and is an internationally recognized capital for fashion design, arts and sciences.

The highlight of my experience was getting to visit Milan’s Historical Dermatological Clinic (Clinica Dermatologica), where the 4th Abraham Buschke Lecture, “Dermatology at the Circus,” was held in the amphitheater and given by Carlo Gelmetti, M.D., Ph.D., of the department of pediatric dermatology at Ospedale Maggiore Policlinico, University of Milan, Milano, Italy.

There were many historical moulages around the lecture hall and clinic, many of which were hundreds of years old and have been very well preserved behind glass vitrines. I learned that, before photos, lifelike moulages were one of the few ways medical students and residents could visually learn and understand the characteristics of rare dermatological diseases such as leprosy, connective tissue diseases and cutaneous tuberculosis.

The lecture discussed circuses and its performers with a dermatologic twist. For example, many circus performers suffer from dermatologic ailments, genetic disorders and congenital anomalies such as congenital hypertrichosis lanuginosa.

“Bearded ladies” who participated in the circus sideshows of the 19th and 20th centuries often had hirsutism as a result of a hormonal imbalance or a genetic predisposition to hypertrichosis.

“Human alligators” or “crocodile boys” had different variants of ichthyosis, a group of cutaneous disorders that often begins at or shortly after birth and causes extremely dry, thick and scaly skin that resembles fish scales.

For decades, it was thought that Joseph Merrick, known as the “Elephant man,” had suffered from neurofibromatosis type 1; however, geneticists Tibbles and Cohen demonstrated in 1986 that he actually had Proteus syndrome, a much rarer condition.

The “tree man” suffered from epidermolyssia verruciformis, an extremely rare condition in which warts caused by the human papillomavirus continue to grow on one’s extremities and is associated with a high risk of skin cancer.

Piebaldism afflicted these characters known as “leopard boy” or “leopard girl,” which is characterized by the absence of melanocytes in certain areas of the skin and hair.

Ehlers-Danlos syndrome tends to affect people who are exceptionally flexible, such as circus performers, gymnasts, dancers and contortionists, as these patients have highly elastic joints, flexible extremities and stretchy, rubbery skin.

Lastly, an interesting fact related to hair was that, in some circuses, individuals hang by their hair. Hair hanging is a trick in which someone is suspended by their hair and swung around in the air, often while performing other tricks. Although we may think of the hair as being weak and easily snapped, it has an incredibly strong tensile strength, with a relative weight limit of 100 grams per strand. With about 150,000 follicles on the average person’s scalp, the combined strength of a head of hair is incredible; thus, it actually is possible for a head of human hair to support the person’s entire weight. As you might expect, haircare and maintenance is of utmost importance when it comes to hanging by the hair for dozens or even hundreds of shows a year.

As a whole, the World Congress of Dermatology focused on major breakthroughs and advances, ranging from clinical practice to research, technology and innovation. The event brought together thousands of international dermatologists to share their professional experiences, knowledge and skills for the goals of improving patient care. In addition, the ILDS is involved in many global projects and humanitarian work for the International Foundation of Dermatology.

At the conclusion of the event, Singapore was selected as the host city for the 2023 World Congress of Dermatology.

The World Congress of Dermatology was one of my favorite dermatology conferences, and I look forward to many more to come.
Promising acne treatments

**1. TOPICAL ANTIANDROGENS**

While they’re still in clinical trials for acne treatment, topical antiandrogens could be an option for controlling sebogenesis in patients with especially moderate-to-severe refractory acne, according to the authors.

Researchers studying clascoterone 17α-propionate (clascoterone), a topical androgen antagonist being investigated as an acne treatment in a phase 3 clinical trial, write that studies have shown that clascoterone is a potent and well-tolerated antiandrogen, according to a paper published May 2019 in the *Journal of Drugs in Dermatology.*

“The study described herein elucidates for the first time the mechanism of action of clascoterone. Clascoterone was found to bind the androgen receptor (AR) with high affinity in vitro, inhibit AR-regulated transcription in a reporter cell line, and antagonist androgen-regulated lipid and inflammatory cytokine production in a dose-dependent manner in human primary sebocytes,” according to the authors of the paper in *Dermatologic Therapy.*

**2. INSULIN-LIKE GROWTH FACTOR-1 INHIBITORS**

A component of green tea, epigallocatechin-3-gallate (EGCG), has been shown to decrease comedone size by reducing the size of sebaceous glands and number of sebocytes, according to the paper in *Dermatologic Therapy.*

“…patients who have inflammatory and noninflammatory acne lesions, treated with EGCG solution showed a 79% to 95% reduction in lesions in eight weeks,” according to the authors.

**3. PEROXISOME PROLIFERATOR-ACTIVATED RECEPTOR MODULATORS**

By downregulating interleukin- (IL-)6 and leukotriene B4, the oral 5-lipoxygenase inhibitor zileuton (Zyflo, Cornerstone Therapeutics) reduces inflammatory acne lesions. Zileuton also temporarily inhibits synthesis of sebaceous lipids, according to *Dermatologic Therapy.*

“New anti-inflammatory compounds, such as the 5-lipoxygenase inhibitor zileuton, may replace systemic antibiotics in the future, especially under the scope of antibiotic resistance prevention,” according to authors of the paper in the *British Journal of Dermatology.*

**4. ORAL AND TOPICAL DAPSONE**

Dapsone gel (Aczone, Almirall) is approved by the U.S. Food and Drug Administration to treat acne vulgaris. The sulfone oral dapsone has antibacterial and anti-inflammatory effects, according to *Dermatologic Therapy.*

Dr. Dursun’s go-to treatment for refractory acne is oral isotretinoin. However, based on positive results in the literature on oral dapsone’s use in refractory acne treatment, he now recommends oral dapsone for some acne vulgaris patients.

“Oral dapsone … can be a good alternative with anti-inflammatory effect for inflammatory acne lesions,” Dr. Dursun says.

**5. PROBIOTICS AND PREBIOTICS**

Researchers cited several studies that looked at the effects of probiotics on acne in a paper published this year in the *Journal of Clinical Medicine.* Among those, a study by Kang et al., published in 2009 found eight weeks of topical enterococcus faecalis treatment resulted in a 50% reduction in inflammatory acne count compared with placebo.

In another study published in 2012, Muizuddin et al. found a 5% extract of lactobacillus plantarum reduced acne severity. Collectively, these and other findings suggest that the microbiota plays an important role in acne pathogenesis.

“Novel systemic and topical interventions that influence the microbiota (i.e., probiotics, prebiotics), custom tailored to each patient according to their unique microbial ‘fingerprint,’ are worthy of intense research,” according to authors of the paper in the *Journal of Clinical Medicine.*

Finally, dietary factors in skin disease are hard to ignore, even though there isn’t consensus on the role of diet in acne vulgaris etiopathogenesis, according to Dr. Dursun.

“That’s why probiotics and prebiotics are very popular terms in the advances recently,” he says.

**Quick Takes**

**Improved therapeutic options are becoming available.**

**Topical antiandrogens could be an option for controlling sebogenesis.**

Zileuton downregulates IL-6 and leukotriene B4 and temporarily inhibits synthesis of sebaceous lipids.

**Topical enterococcus faecalis treatment resulted in a 50% reduction in inflammatory acne count compared with placebo in one study.**

**References**


Poor sleep is a common problem for many patients, affecting approximately one out of three individuals, according to the Centers for Disease Control (CDC). Chronic sleep dysfunction is associated with decreased concentration and impaired performance and is also associated with the following comorbid conditions: cardiovascular disease, hypertension, obesity, type 2 diabetes mellitus, and depression.

Chronic sleep dysfunction is divided into insufficient quantity of sleep and poor quality of sleep. Insufficient quantity is easy to assess and is defined as less than seven hours of sleep per day. On the other hand, assessing sleep quality is far more complex and difficult to assess as sleep quality is measured by sleep latency, continuity, depth, and post-sleep restoration. Assessing sleep quality requires objective evaluation using polysomnography and other specialized methods.

Poor sleep is especially prevalent in patients with psoriasis with almost 90% of psoriasis patients reporting issues sleeping. Sleep dysfunction among psoriasis patients is particularly concerning because psoriasis is independently associated with many of the same comorbid conditions as sleep dysfunction compounding their impact. One study showed that psoriasis patients with sleep disorders had an increased incidence of ischemic heart disease and strokes.

In order to investigate chronic sleep dysfunction prevalence in psoriasis, Dr. Smith and colleagues from the Department of Dermatology, University of California, San Francisco, used the Citizen Pscientist (CP), an online patient portal developed by the National Psoriasis Foundation (NPF). The CP is an online forum that allows patients with psoriasis to connect with one another. When joining CP, psoriatic patients fill out a survey that includes demographic details, symptoms and treatment histories, and quality of life topics such as the impact of their condition on diet, exercise, and of course sleep.

The CP survey was completed by 3,118 patients. The CP Survey contained 79 questions of which 15 questions were analyzed. Psoriatic patient sleep characteristics were derived from survey questions about hours of sleep per day on average and trouble sleeping. ‘Low sleep quality’ was defined as patients that report sleeping less than seven hours per day on average. ‘Sleep difficulty’ was defined as participants that answered “yes” to the question “Do you have trouble sleeping?”

Results showed that ‘sleep difficulty’ was associated with psoriatic arthritis (OR 2.15, 95% CI [1.79–2.58]), female gender (2.03 [1.67–2.46]), obese body mass index (BMI ≥ 30) (1.25 [1.00–1.56]), sleep apnea (1.41 [1.07–1.86]), psoriasis severity of moderate (1.59 [1.30–1.94]) or severe (2.40 [1.87–3.08]), and smoking (1.60 [1.26–2.02]).

With regards to ‘low sleep quantity’ results showed an association with obesity (1.62 [1.29–2.03]), sleep apnea (1.30 [1.01–1.68]), psoriasis severity of moderate (1.41 [1.16–1.72]) or severe (1.40 [1.11–1.76]), and smoking (1.62 [1.31–2.00]). Surprisingly ‘sleep difficulty’ and ‘low sleep quantity’ were not associated with age, alcohol consumption, or timing of worst itch.

This was a large study that shows that psoriasis is associated with sleep dysfunction, and that increased psoriatic activity may enhance sleep dysfunction. The study was limited by the CP instrument and patient reported unconfirmed data. It reinforces the need to better understand the role of sleep in psoriasis and vice versa to improve the quality of life of psoriatic patients and to prevent the associated comorbid conditions associated with psoriasis and sleep dysfunction.

References
... patients who have skin psoriasis or atopic dermatitis in visible areas, such as the face and neck, may experience cosmetic concerns.

Alexander Egeberg, M.D., PhD, Herlev and Gentofte Hospital, Hellerup, Denmark

Study underscores patients’ desire for clearance

INGRID TORJESEN | Staff Correspondent

Complete or almost complete skin clearance is more important for patients with atopic dermatitis than for patients with psoriasis, suggests research recently published in *Journal of the American Academy of Dermatology*.

Findings from the Danish study also indicated that both patient groups find almost complete clearance more important than complete skin clearance. Greater disease severity, itch, skin pain and site of the condition increased this importance.

“Surprisingly, itch was more strongly associated with importance of skin clearance in psoriasis patients compared to atopic dermatitis patients,” notes study investigator Alexander Egeberg, M.D., PhD, Department of Dermatology and Allergy, Herlev and Gentofte Hospital, Kildégårdsvej, Hellerup, Denmark. “Although speculative, pruritus is experienced in nearly all atopic dermatitis patients whereas this is seen in greater variation among psoriasis patients, possibly explaining the difference in pruritus impact between these diseases.”

In psoriasis, affected palms, soles or genitals were associated with greater patient-perceived importance of skin clearance, whereas in atopic dermatitis involvement of the scalp, palms, soles, genitals or nails were not. And for atopic dermatitis patients, the desire for clearance was greatest when lesions were situated on the face and neck.

“Our results indicate that patients who have skin psoriasis or atopic dermatitis in visible areas, such as the face and neck, may experience cosmetic concerns,” adds Dr. Egeberg.

The study, which occurred between May and July 2018, examined 3,842 adult patients with atopic dermatitis and 4,016 with psoriasis. Individuals were asked how important it was for complete or almost complete skin clearance. Our study fills not only this research gap, but further identified specific factors that may affect the patients subjective need greater skin clearance,” Dr. Egeberg says.

While little was previously known about the importance patients attach to obtaining clearance in atopic dermatitis, or what strengthen this desire, a greater understanding of these factors could prove useful for dermatologists who suggest systemic agents to this patient population.

Novel systemic therapies, including biologics, have dramatically improved outcomes in psoriasis and now increasingly in atopic dermatitis, but only a small proportion of patients are currently on systemic therapy. This could be due to patient concerns over adverse effects or cost, as well as contraindications for certain individuals.

In this study only 7% of patients with severe atopic dermatitis and 27% of those with severe psoriasis were taking any systemic therapy, and the most frequently used was methotrexate. Those taking systemic therapy expressed a higher wish for almost complete or complete skin clearance.

“This could be an indicator that these patients may be more affected by their disease, but also that they may be more motivated to obtain skin clearance since they are willing to take systemic medications (including biologics) and accept the risk of potentially serious side effects,” Dr. Egeberg says.

Also, as advertising directly to patients is not allowed in Denmark, he adds, “It is possible that their knowledge about novel treatment options are lower than in the U.S., which may affect patients subjective need for skin clearance.”

Ultimately, Dr. Egeberg concludes, the study’s findings, “emphasize the considerable undertreatment among patients with psoriasis and atopic dermatitis, and the apparent disconnect between the use of systemic treatments and patients need for complete or almost complete skin clearance.”

References

Newer therapies promising, require stronger data

LISETTE HILTON | Staff Correspondent

Quick Takes
Lasers and light therapies are popular advances, allowing dermatologists to target the appearance of telangiectasias and provide a quick aesthetically pleasing option for patients.

Topicals appear to relieve symptoms, but require more head-to-head studies.

One small study indicates intradermal botulinum toxin injections reduced erythema and rejuvenated skin on the facial cheeks of rosacea patients.

Topicals, intradermal botulinum toxin-A, and laser and light therapies are among today’s newer rosacea treatment options. But many of these lack the data needed to prove they’re effective and safe for the indication, researchers report in a therapeutic hotline paper published July 11, 2019 in Dermatologic Therapy.

Effectively managing rosacea, which presents as erythema, papules, pustules, telangiectasias, fibrosis and phyma, is important for not only a patient’s quality of life but also to avoid complications of blepharitis or conjunctivitis, according to the paper.

Dermatologists often use topicals and systemic agents to treat and manage chronic papulopustular rosacea and periocular dermatitis.

Among today’s newer options:

LASER AND LIGHT THERAPIES
Laser and light devices target vascular manifestations of rosacea. For example, to treat erythematotelangiectatic rosacea, providers might use a pulsed dye laser or intense pulse light, according to Dermatology Therapy.

We prefer alaser treatment option at our center, says author of the Dermatology Therapy paper Professor Recip Dursun, M.D., of the department of dermatology and venereal diseases at Necmettin Erbakan University, in Konya, Turkey.

“We have the Quadrastar PRO Yellow 577 nm laser device for the treatment of vascular lesions and capillary abnormalities. The erythematotelangiectatic rosacea and papulopustular rosacea patients who suffer from flushing, redness and appearance of telangiectasias usually leave satisfied [with the treatment],” he says.

Lasers and light therapies are popular advances in rosacea treatment around the world, according to Dr. Dursun. They allow dermatologists to offer an aesthetically pleasing and quick option for patients, he says.

TOPICAL IVERMECTIN 1% CREAM
Approved by the U.S. Food and Drug Administration (FDA) in 2014 for the treatment of rosacea, topical ivermectin 1% cream targets Demodex folliculorum and Demodex brevis, according to the paper.

Researchers reported in 2014 in the Journal of Drugs in Dermatology that ivermectin 1% cream effectively and safely treats inflammatory lesions of papulopustular rosacea.

Researchers report in an update in rosacea management published June 2019 in the Journal of Clinical and Aesthetic Dermatology on a meta-analysis of 19 clinical trials that show ivermectin 1% cream once daily seems more effective than and at least as tolerable and safe as other available topical agents used to treat papulopustular rosacea. However, there are no true head-to-head comparative studies except for studies comparing ivermectin 1% cream to metronidazole 0.75% cream, according to the Journal of Clinical and Aesthetic Dermatology.

TOPICALS BRIMONIDINE AND OXYMETAZOLINE
The FDA approved brimonidine 0.33% gel to treat rosacea in 2013. It relieves rosacea symptoms by targeting vasomotor dysregulation in rosacea pathogenesis, according to the paper in Dermatologic Therapy.

Published guidelines recommend use of topical brimonidine, along with topical ivermectin, for the treatment of papulopustular rosacea with diffuse persistent facial erythema of at least moderate severity. Topical brimonidine also is recommended in combination with the potassium iontophoretic device to address diffuse persistent facial erythema associated with rosacea, according to authors of the update in the Journal of Clinical and Aesthetic Dermatology.

Oxymetazoline is a topical α-1 agonist. It was approved by the FDA to treat persistent facial erythema in adult rosacea. Dermatologists should consider using oxymetazoline 1% cream to manage persistent, nontransient, facial erythema associated with adult rosacea. The cream has also been shown to reduce persistent facial erythema when used concurrently with agents that reduce papulopustular lesions and perilesional erythema in papulopustular rosacea patients, according to the Journal of Clinical and Aesthetic Dermatology.

INTRADERMAL BOTULINUM TOXIN-A
“Neurogenic vascular dysfunction can be a crucial pathogenic event in rosacea,” according to the authors of the paper in Dermatologic Therapy. Botulinum toxin-A blocks presynaptic acetylcholine release and acetylcholine is thought to be effective for vasodilation on the skin, they write.

Intradermal botulinum toxin injections significantly reduced erythema and rejuvenated skin on the facial cheeks of rosacea patients, according to a small study published earlier this year in Dermatologic Surgery.

While promising, more research is needed to confirm the efficacy and safety of these newer therapies for rosacea treatment, including intradermal botulinum toxin-A, authors of the Dermatologic Therapy paper conclude.

Disclosures
Dr. Dursun reports no relevant conflicts.

References
Genetics may play role in keloid formation

ILYA PETROU, M.D. | Staff Correspondent

The formation of keloids may be due to a genetically based switch normalization failure in the remodeling stage of wound healing, says Greg Goodman, M.D., associate professor of dermatology, Monash University, Clayton, Victoria, Australia, who recently spoke on the topic at the World Congress of Dermatology in Milan.

According to Dr. Goodman, the wound healing process is a continuum that progresses from scarless fetal wound healing to adult wound healing to keloidal wound healing. Adult wound healing is scarred but still considered normal, whereas keloidal wound healing is characterized as uncontrolled persisting proliferation of scar tissue.

The three overlapping phases of wound healing are an inflammatory phase, a proliferative phase, and a remodeling phase; and it is the abnormal perpetuation of the proliferative phase due to the switch normalization failure into the remodeling phase that results in keloid formation in predisposed individuals.

“Why this physiologic turn-off switch does not occur in the keloid patient population remains an unknown,” he notes. “However, there is some evidence that the formation of keloids is genetically based, which could be the focus and direction for potential future therapeutic interventions that could help prevent keloid formation.”

Keloids are benign growths of dense fibrous tissue that develop from an abnormal response to a cutaneous injury. Keloids are a challenge to treat and manage because they’re often symptomatic and can have a significant psychosocial impact in affected patients.

There are a number of key parameters that can contribute to keloid formation in a patient, including the age of the individual, the size and tension of the area, the depth of the lesion and the family history of the patient.

“In normal wound healing, there is an expected turn-off of the collagen production, chronic inflammation, and generation of growth factors and cytokines. However, this turn-off or switch normalization in the final stage of wound healing does not happen in keloid prone patients,” Dr. Goodman says.

The central mechanism behind the inability to turn off the switch appears to be a failure of apoptotic control, which is inherited. Also, keloids are 5% to 15% more common in dark-skinned populations, hinting toward the role of melanocytes in its pathogenesis.
“...there is some evidence that the formation of keloids is genetically based, which could be the focus...for potential future therapeutic interventions...”

Greg Goodman, M.D., Monash University, Clayton, Victoria, Australia

Unfortunately, there are no current therapeutic interventions that can interfere with the genetics to help prevent keloid formation; however, this avenue may be the focus of future research efforts to help in the treatment, management and prevention of keloids.

Another of the key factors in the development of keloids is tension between the cells and their extracellular matrix, but, according to Dr. Goodman, that tension also works very well in the treatment and prevention of keloids. A certain stiffness between the cells (i.e., fibers, ground substance) and the extracellular matrix (i.e., fibroblasts, myofibroblasts) and the push back on that appears to play a very central yet still somewhat ambiguous role in the wound healing process.

“Tension on a wound can work both ways. If you have a tense wound, it is going to cause a keloid and if you apply pressure on a keloid the lesion may decrease in size,” he explains.

“Clinicians should be mindful of the rules of keloid production when selecting patients for a procedure, and, whenever possible, deep dermal wounding needs to be avoided, or treated aggressively early,” Dr. Goodman advises.

Disclosures
Dr. Goodman reports no relevant disclosures.

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Mark Lebwohl, M.D., FAAD, Mount Sinai School of Medicine, New York
Cheek swab IDs genes linked to non-melanoma risk

WHITNEY J. PALMER | Staff Correspondent

A recent study indicates that a quick swab of the inside of a patient’s cheek could help dermatologists identify whether an individual is at risk for non-melanoma skin cancer before the disease even presents.

In an article published recently in the *Journal of Drugs in Dermatology*, investigators tested whether a 20-stroke buccal swab could accurately identify patients in the general population who had particular genetic markers for non-melanoma skin cancer. According to the results, the test pinpointed four single nucleotide polymorphisms (SNPs) that could potentially predict future disease onset, says study author Lauren Moy, M.D., a dermatologist with Loyola University Medical Center.

This test introduces a new, potentially more definitive way, for dermatologists to identify genetic components present in individual patients that might be at risk for developing non-melanoma skin cancer. It’s an evolving tool that could be highly useful in the future, she says. Therefore, it could facilitate proactive treatment in these patients.

A lot of clinicians just classically look at the skin type and sun exposure history, but now science and consumers are evolving and getting smarter,” Dr. Moy says.

The purpose of the study was to determine if results similar to those of the test’s manufacturing company could be achieved in a real-world situation.

Dr. Moy and her colleagues reviewed the test results of 38 individuals — 19 with a history of non-melanoma skin cancer and their 19 age-matched spouses who had no skin cancer history. All participants lived in Southern California and were an average of 45.5 years old. By choosing married couples, the team maximized the likelihood that all individuals had roughly the same level of exposure to the sun, as well as contact with other environmental factors, Dr. Moy says. This made the results as generalizable to the overall population as possible, she adds.

The analysis searched for the presence of seven SNPs that were previously identified to be associated with non-melanoma (and melanoma) skin cancer: TDG/GLIT2D2, XRCC1, MCM1, TP53, PIGU, Chromosome 1, and PAD16.

The researchers used a polymerase chain reaction method to genotype the SNPs. While no data was strong enough to be considered statistically significant, the results did show a direction of trend, she says. Based on the evaluations, four SNPs — Chromosome 1, PAD16, PIGU, and TDG — showed a positive trend toward a non-melanoma skin cancer association. The probability values were 0.64 for Chromosome 1, 0.40 for PAD16, 0.19 for PIGU, and 0.72 for TDG — all with an expected association between genotype and outcome. The other SNPs showed no discernible effect on outcomes.

Additional testing with a larger population is needed to further define the impact of these SNPs, Dr. Moy says. Confirming the role these markers play in potential diagnosis could directly affect patient care. While it is possible that life-long sun exposure plays a bigger role in prompting skin cancer than a patient’s genetic make-up, studies conducted with more participants could help create a more detailed genetic profile of individuals who are at a greater risk of developing skin cancer.

“We’re at the start of really understanding the genetic contribution that affects DNA damage,” she says. “And, a test like the buccal swab can point us in the right direction to focus on the people who have more DNA damage who might need more chemo-preventive measures.”

This test could help dermatologists target patients who could benefit from early treatment with DNA repair enzymes or oral nicotinamide, she says. Pinpointing at-risk patients and initiating therapy with various treatment regimens or medications before significant disease presents could help dermatologists to eliminate or limit the impact of melanoma.

This type of test also presents benefits to patients, Dr. Moy says, because it is simple to complete. In addition, patients do not need to be in any certain level of good health for the test to be successfully administered.

“The buccal swab is a great method for people to do this at home,” she says. “It’s very attractive because you don’t have to do a skin biopsy or test tissue — you just open your mouth. It’s something that everyone can be comfortable with.”

Quick Takes

Researchers examined tests for presence of any of seven SNPs previously identified as being associated with non-melanoma skin cancer.

Four genetic markers showed a positive trend toward a non-melanoma skin cancer association.

If additional studies can confirm the role these markers play in potential diagnosis, it could directly affect patient care.

Reference


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**GENETIC TESTING**

38.46 Non-melanoma

Study finds strong correlation between HPV and non-melanoma skin cancers; immunotherapy agents show promise.

39 Squamous Cell Carcinoma

Study indicates immunotherapeutic agent for AK may have long-term prevention effect.

45 Basal Cell Carcinoma

One-day fractionated photodynamic therapy offered complete response at 30 days.
The presence of HPV was strongly correlated with non-melanoma skin cancers in a recent study published in the European Journal of Clinical Microbiology & Infectious Diseases.

“The public service announcement opportunity here is to remind us all that UVR [ultraviolet radiation], as well as immunosuppression, lead to skin cancer, and that chronically sun-exposed skin is more likely to have HPV,” said Sumaira Aasi, MD, a professor of dermatology and the director of Mohs and Dermatologic Surgery at Stanford Medicine, in Stanford, CA, in an exclusive interview with Cancer Network.

Baez et al found that 75% of tested non-melanoma skin cancer biopsies exhibited at least one of three viruses: HPV, Merkel cell polyomavirus, and Epstein-Barr virus. Only 38% of non-cancerous skin biopsies, however, were positive for these viruses ($P = .02$).

Importantly, HPV detection was common in non-melanoma skin cancers (43%; $n = 83$), but was nearly absent in non-cancerous biopsies (6.7%; $n = 16$; $P = .007$). Furthermore, Merkel cell polyomavirus was correlated with sites of increased exposure to ultraviolet radiation ($P = .10$), whereas Epstein-Barr virus was significantly linked to immunocompromise ($P = .032$).

Ultimately, HPV was strongly associated with non-melanoma skin cancer, while Epstein-Barr virus and Merkel cell polyomavirus were associated with other risk factors. Thus, the authors suggest that oncocogenic viruses may play a role in non-melanoma skin cancers.

Aasi noted that other studies have found correlations between viruses and non-melanoma skin cancer, but this one is unique. “There have been multiple studies that have shown a correlation between viruses and non-melanoma skin cancer, particularly HPV, SCC [squamous cell carcinoma], and BCC [basal cell carcinoma],” she said.

“This is the first study that shows an association between Merkel cell polyomavirus with non-melanoma skin cancer. However, correlation still has not proven causation, and I do not think this data will change how we currently treat patients. We need further data to determine a causative role of viruses in non-melanoma skin cancer, and then we can move toward determining whether treating the virus would decrease incidence of skin cancer in patients,” Aasi said.

The investigators suggest that, once confirmed, the results of the study may help with non-melanoma skin cancer treatment and prevention. Because an HPV vaccine is available for the prevention of cervical cancer, this vaccine could possibly decrease non-melanoma skin cancer development in at-risk populations. Moreover, intratumoral treatment with the HPV vaccine could serve as an alternative to surgery, which is standard treatment, according to the authors.

The authors also reported the first association between Merkel cell polyomavirus detection and non-melanoma skin cancer in sun-exposed areas. This finding could support the co-carcinogen hypothesis. Alternatively, this higher incidence of Merkel cell polyomavirus in the elderly could be due to immune senescence, wherein increased levels of viral shedding from skin tissue is likely expected.

Aasi raised concerns about the design of the current study. “[There were] significantly fewer normal skin biopsies vs those with non-melanoma skin cancer—it would have been helpful to have equal numbers represented. Also, normal skin in those patients with non-melanoma skin cancer did not appear to have been tested. Do those patients have virus in the normal skin?” she questioned.

Finally, she noted, “Almost all the HPV found in skin biopsies were from UVR sites. No discussion about the presence or impact of HPV in skin cancers that develop in sun-protected sites [was presented].”
A brief course of treatment with calcipotriol plus 5-fluorouracil (5-FU) applied to the face and scalp is associated with induction of T cell immunity and tissue-resident memory (Trm) cell formation against actinic keratoses, according to a recent study published in *JCI Insight*. This combination also reduces the risk of squamous cell carcinoma (SCC) manifestation within three years of treatment, the researchers found.

“This study solidifies the combination of calcipotriol and 5-fluorouracil as a great option,” says dermatologist Jerry D. Brewer, M.D., M.S., a professor of dermatology at the Mayo Clinic in Rochester, Minn.

Rosenberg et al found that calcipotriol with 5-FU–induced Trm cell formation in the skin at the level of the face and scalp was associated with significantly higher erythema scores vs control ($P < .01$).

More patients in the test cohort were SCC-free over ≥ 1,500 days of follow-up ($P = .0765$), with significantly fewer developing SCC on the treated face and scalp within three years (2 of 30 [7%] vs 11 of 40 [28%] in the control group [hazard ratio, 0.215; 95% CI, 0.048–0.972]; $P = .032$). Thus, significantly more epidermal Trm cells persisted in the calcipotriol with 5-FU–treated face and scalp skin vs control ($P = .0028$). No significant difference in basal cell carcinoma (BCC) incidence was observed between the treatment groups.

A four-day course of topical calcipotriol plus 5-FU combination was compared with Vaseline plus 5-FU (control) in the current blinded prospective cohort study involving participants in a randomized double-blind clinical trial focusing on treatment of actinic keratoses. Frequencies of SCC and BCC were determined at one, two, and three years after the trial ended. Furthermore, tissues were evaluated for calcipotriol plus 5-FU–induced T cell skin immunity.

Previous research has shown that a four-week course of topical 5-FU monotherapy for actinic keratosis field treatment decreases SCC risk on the face and ears at one year post-treatment; this effect, however, was gone at two years. The results of the current study suggest that calcipotriol plus 5-FU treatment is effective in thwarting SCC development on the face and scalp within three years after treatment.

This chemopreventive effect is linked to the induction of a long-lasting T cell immunity in the skin. Thus, the researchers suggest that their findings hold broad implications by establishing a novel concept: that an immunotherapeutic agent that is effective in eliminating precancerous lesions can possibly offer long-term cancer prevention.

Lack of protection vs BCC manifestation on the face and scalp after treatment with calcipotriol plus 5-FU could be secondary to the immune-based mechanism of this combination therapy. The four-day course of calcipotriol plus 5-FU immunotherapy targets actinic keratoses, which carry a mutational burden and an antigenic composition akin to SCC. Lack of protection vs BCC, a distinct cancer from SCC, makes sense in light of the likely antigen-specific Trm cell response induced by calcipotriol plus 5-FU.

“Field treatment in patients with significant actinic damage can be so impactful and potentially improve the quality of life of patients with a high skin cancer tumor burden,” Dr. Brewer says. “This study solidifies the combination of calcipotriol and 5-fluorouracil as a great option.”

**AK immunotherapy may prevent SCC**

NAVEED SALEH, M.D., M.S. | *Cancer Network*

**Quick Takes**

Combination immunotherapy for AK reduced risk of developing SCC within three years of treatment.

Previous research has shown that a four-week course of topical 5-FU monotherapy for AK decreased SCC risk at one year.

Immunotherapeutic agent effective in eliminating precancerous lesions may also offer long-term cancer prevention.
One-day fractionated PDT effective for BCC treatment

NAVEED SALEH, M.D., M.S. | Cancer Network

Fractionated photodynamic therapy offers good aesthetic results and complete response in patients with basal cell carcinoma when assessed at 30 days after treatment, according to the results of a study published in Photodiagnosis and Photodynamic Therapy.

The total dose of light is delivered in steps with fractionated photodynamic therapy, and the intervention lasts one day (administered over two three-hour sessions). In Europe, photodynamic therapy is typically given in two doses, a week apart, which exposes the patient to added pain and discomfort compared with a one-time intervention.

Meenal Kheterpal, M.D., a dermatologist at Duke Health, likened the additional day of treatment to experiencing a painful injury twice in a week. “If you tore your ACL, would you go in and have it torn again the next week?” she asks. “Probably not. Pain and discomfort are big issues. The fact that they can do it all in one day…might be a viable treatment.”

Dr. Kheterpal suggests an alternative to fractionated photodynamic therapy: a topical immunotherapy cream called imiquimod. “Would you choose PDT where you have to come in and have this painful experience?” asks Dr. Kheterpal. “Or, would you rather use a cream at home once daily for six weeks and theoretically get a more effective response? Aldara [imiquimod] is more effective and cheaper, based on five-year, longitudinal, prospective data when compared to photodynamic therapy and may be more convenient for many.”

Dr. Kheterpal recognizes that fractionated photodynamic therapy may still be the best option in patients who would not adhere to daily doses of imiquimod. Notably, although not as painful as fractionated photodynamic therapy, which she compared to the pain of a “severe” sunburn, imiquimod still hurts and causes symptoms akin to poison ivy rash, she says.

“PDT is a very nice treatment,” concludes Dr. Kheterpal. “There is data to support that PDT also has some cosmetic benefit to it, and patients should know that. Our job as physicians is to help our patients understand the risks and benefits of treatment, such that they can choose the right option for their condition.”

“Re-applying MAL may allow it to penetrate deeper and improve efficacy,” she says. She notes, however, that the price of an additional applicator, which can be high, may be tricky to get covered by insurers.

Dr. Kheterpal suggests an alternative to fractionated photodynamic therapy: a topical immunotherapy cream called imiquimod. “Would you choose PDT where you have to come in and have this painful experience?” asks Dr. Kheterpal. “Or, would you rather use a cream at home once daily for six weeks and theoretically get a more effective response? Aldara [imiquimod] is more effective and cheaper, based on five-year, longitudinal, prospective data when compared to photodynamic therapy and may be more convenient for many.”

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Meenal Kheterpal, M.D., Duke Health, Raleigh, N.C.
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Basal Cell Carcinoma 45

Review touts benefits of immunotherapy

NAVEED SALEH, M.D., M.S. | Cancer Network

"We now have a new class of therapy, which has robust evidence in terms of overall response, disease control, and outcomes in a fair number of patients."

Meenal Kheterpal, M.D., Duke Health, Raleigh, N.C.

A recent review published in *Drugs in Context* focused on the use of immunotherapy to treat non-melanoma skin cancers.

Meenal Kheterpal, M.D., a dermatologist at Duke Health, in Raleigh, N.C., notes that although the paper is a brief review, it offers several valuable insights.

"The article is well-timed. It mentions that we now have a new class of therapy [immunotherapy], which has robust evidence in terms of overall response, disease control, and outcomes in a fair number of patients," she says. "The article could bring attention to immunotherapy as a potential treatment option for medical, radiation, and surgical oncologists, who are at the forefront of deciding the fate of these patients."

The authors predict that advanced cutaneous squamous cell cancer (CSCC) will soon be treated with checkpoint control. Recent studies have supported the use of cemiplimab and pembrolizumab as treatments for patients with locally advanced and metastatic disease.

"We now have data to support the use of these therapies," says Dr. Kheterpal. "What it would take for these drugs to become first-line treatment for locally advanced and metastatic squamous and basal cell carcinoma? I don’t know if immunotherapy could ever be first-line for CSCC. There are medical reasons for that."

Dr. Kheterpal explains that a large proportion of people with advanced non-melanoma cancers are solid organ-transplant recipients, as well as those who harbor advanced metastatic disease and have no other options.

"Dr. Kheterpal stresses that the benefit of immunotherapy in skin cancers is variable, with certain cancers being much more vulnerable to its effects.

"Immunotherapy is now first-line treatment for Merkel cell carcinoma, one of the most aggressive skin cancers, which is extremely rare. The article talks about Merkel cell carcinoma, but it doesn’t mention that pembrolizumab was recently approved as first-line treatment for recurrent locally advanced and metastatic MCC," she says.

"In some cases—like Merkel cell carcinoma and melanoma—immunotherapy is far more promising and the path far more clear. However, in cutaneous squamous cell cancer—due to other comorbidities—the use is somewhat challenging. Potentially, alternative scheduling, such as lower dosing or intralesional routes of drug administration, can help sort that out," she says.

In addition to discussing immunotherapy, the authors of the review reported that although the incidence and prevalence of cutaneous squamous cell cancer and basal cell carcinoma have increased from 3% in 1960 to 8% now, the frequencies of these cancers are not formally documented.

Dr. Kheterpal foresees consequences due to underreporting, including lack of drug development for these cancers. Without adequate numbers, it is hard for drug companies to gauge consumer need.

"Almost all cancers are reportable," she says. "You can quantify and look at every cancer. We don't know the true incidence of basal and squamous cell cancers. It's very hard to quantify. There is no SEER database reporting requirement for non melanoma skin cancers in the United States."
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And, based on the outcomes, says study author Daniel Siegel, M.D., a dermatology professor at SUNY Downstate Medical Center, the test could benefit patients, as well as providers.

“For melanoma, there is no other purely diagnostic assay for doctors to use,” he says. “We have good prognostic assays, but this is the only diagnostic test that is both sensitive and specific, that isn’t disruptive or harmful to the patient.”

To determine PLA’s long-term validity, Dr. Siegel and his team followed up on previous research that determined whether 1,575 lesions contained genes associated with melanoma, particularly Preferentially Expressed Antigen in Melanoma (PRAME) and Long Intergenic Non-Coding RNA 518 (LINC00518). In the current analysis, they re-examined the 734 previously PLA-evaluated lesions that tested negative for any melanoma gene expression. Follow-ups to identify any status changes occurred at three-month, six-month, and 12-month intervals. Throughout the year, only 13 lesions (1.8 percent) were referred for surgical biopsy. Six were biopsied at patient request, and seven were biopsied to provide information on changing lesions.

ONE TESTED POSITIVE FOR MELANOMA.

These results on test performance are clinically important, he says, because they underscore the importance, he says, because they underscore the importance of a non-invasive diagnostic method that is far easier to administer than a surgical biopsy. Dermatologists or primary care providers could use the PLA test to gather cells in under two minutes by pressing adhesive patches over the suspicious lesion four times. Those patches are, then, packaged and sent off for analysis. Results are available within 72 hours.

Overall, the test prevents fewer opportunities for a missed or incorrect diagnosis, he says.

“Melanoma, under the microscope, can range from being obvious enough for a first-year medical student with minimal training to recognize it to being something a 25-year veteran dermatopathologist will scratch his or her head trying to figure out,” Dr. Siegel says. “But, with the PLA test, if a patient doesn’t have the genes, there’s a good chance he or she doesn’t have melanoma.”

The adhesive patch test is potentially a superior diagnostic method, he says, because traditional lesion biopsies examine only a small portion of a single slice of the suspicious area, much like examining one corner of a single slice of bread. Instead of getting a random view, PLA pulls cells from across the top of a lesion, in essence giving providers a detailed look at the entire spot. The test might also save money by helping doctors determine whether biopsies give a false negative or if the patient might be spared unnecessary surgery.

Ultimately, Dr. Siegel says, these study results support using the PLA test as a method to quickly and non-invasively determine whether a suspicious lesion requires additional intervention. It’s also a strategy that could minimize discomfort and fear for the patient while avoiding any unnecessary permanent scarring.

“If you don’t have to cut, you don’t leave a mark or a scar,” he says. “If there’s something concerning in a cosmetically sensitive area, and you can simply take a strip of cells from the surface to conduct an assay, then you can potentially reassure the patient that a lesion might be benign without leaving him or her with a mark to be remembered for the rest of their lives.”

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Statistics released this year by the American Society of Plastic Surgeons (ASPS) reveal high demand for body shaping options, with a spike in noninvasive fat reduction procedures in 2018.

Nonsurgical fat reduction device choices are taking the market by storm, with technologies that target fat via cryolipolysis, laser lipolysis or radiofrequency. To get a pulse on the current state of the noninvasive fat reduction market, we asked providers what they’re using and why.

**CRYOLIPOLYSIS ON TOP**

Nonsurgical fat reduction treatments, like CoolSculpting (Allergan), are taking center stage, while Kybella (deoxycholic acid, Allergan) takes a back seat, according to Omaha-Neb.-dermatologist and cosmetic surgeon Joel Schlessinger, M.D.

“While Kybella hasn’t turned out to be the blockbuster that many thought it would be, CoolSculpting has filled the void dramatically. With new treatment heads and protocols, CoolSculpting has significantly improved,” Dr. Schlessinger says. He is president of Skin Specialists PC in Omaha, Neb., and CEO of LovelySkin.com.

The most notable change, according to Dr. Schlessinger, has been the benefits of using CoolSculpting’s CoolMini on the chin area.

“I think that’s the gateway procedure for fat reduction for most of my patients. They come in for the chin and submental area and during the conversation express interest in other areas,” Dr. Schlessinger says.

And the updated CoolSculpting treatment protocol has boosted patient satisfaction.

Experts report on device benefits, patient selection

**LISETTE HILTON | Staff Correspondent**

**WE ASKED OUR ONLINE READERS**

**HOW MANY NONSURGICAL FAT REDUCTION DEVICES THEY HAVE IN THEIR PRACTICE?**

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Vanquish ME is our preferred device in patients who are heavier (BMI of greater than 30) or who have insufficient fat for CoolSculpting to suction up into the applicator.”

Richard Moore, M.D., St. Louis, Mo.

Fat reduction outcomes with the device are comparable to that of other 1064 nm body contouring technologies, at 11% to 13%, according to Dr. Kilmer.

Radiofrequency (RF), devices also have a place in noninvasive fat reduction.

“TruSculpt is a different technology that uses heat to trigger fat apoptosis and lipolysis, but it also cools skin at the same time, so it protects the skin. It’s very comfortable. And you can apply up to six of these applicators in any way that you want to six of these applicators in any way that you want to six of these applicators in any way that you want to six of these applicators in any way that you want to six of these applicators in any way that you want to,” Dr. Kilmer says.

New York City dermatologist Sapna Palep, M.D., says she recommends truSculpt as one of the best options in noninvasive fat reduction technology because it improves skin laxity through the heating of the skin. TruSculpt is best for a weight stabilized patient with stubborn areas resistant to diet and exercise, she says.

Richard Moore, M.D., an aesthetic physician who practices in St. Louis, Mo., says his practice offers three non-invasive devices for fat destruction: CoolSculpting, and RF devices Vanquish Me (BTL) and BodyFX (InMode).

“Vanquish ME is our preferred device in patients who are heavier (BMI of greater than 30) or who have insufficient fat for CoolSculpting to suction up into the applicator,” Dr. Moore says.

“Our preference for the overweight or obese individual is based on the need for diffuse fat destruction. These patients may be more prone to having deformities on the edge of the applicators when CoolSculpting is used. With the Vanquish ME large treatment panel size, there is virtually no risk of deformities making this our treatment of choice. Vanquish ME is also our treatment of choice for patients who are not good candidates for CoolSculpting on the outer thighs, and it has the added benefit of treatment of the inner and outer thighs at the same time.”

For patients whose arms have insufficient fat for the CoolSculpting applicator, Dr. Moore’s treatment of choice is BodyFX.

“This is a good treatment for small focal areas of fat that may not be treated with CoolSculpting,” Dr. Moore says.

MUSCLE-STIMULATING TECHNOLOGY

TRENDING

Emsculpt (BTL) has been a game-changer in this arena, not so much for fat reduction but for muscle stimulation, according to Dr. Kilmer.

“You get a butt lift and flattening of the abdomen, with improvement in the look of the muscle. It has some fat reduction by MRI and CT, but I think the novelty here is, once you get rid of some of that fat, you have improvement in the muscular structure underneath, so that becomes more visible giving more of a six-pack or buttock lift look,” Dr. Kilmer says.

Dr. Kilmer says Emsculpt’s ability to increase fitness hasn’t been shown in studies yet, but she believes it does and says she plans to do a study on that soon. Dr. Kilmer says her personal experience with Emsculpt treatment to the abdomen is that her abdomen feels tighter, she stands up straighter and can exercise more easily.

“For me, personally, it has been really helpful for yoga positions, including holding a plank position. After doing Emsculpt, I can do them much longer,” Dr. Kilmer says.

BTL announced in July 2019 that Emsculpt, which uses High Intensity Focused Electro-Magnetic (HIFEM), now is cleared by the FDA to treat the arms and calves using new small contour applicators.

CoolSculpting’s new CoolTone (Allergan) device is similar to Emsculpt in that it tones muscle on the abdomen, according to Dr. Kilmer.

“I am particularly excited to see how CoolTone integrates with and enhances the CoolSculpting...”
As with any technology, there are clearly limitations and benefits, and it is incredibly important to pick the right candidate for the right procedures. Without this, all is lost.”

Joel Schlessinger, M.D., Skin Specialists PC, Omaha, Neb.

Body contouring requires proper patient selection from page 51

experience. This could be a huge benefit for our patients and increase the flow of patients who could be candidates for fat and laxity treatments,” according to Dr. Schlessinger.

Seattle-based facial plastic surgeon Wayne F. Larrabee, Jr., M.D., M.S.H., says that most patients looking for body contour enhancement, especially in the abdomen, desire body toning as well as fat removal.

“We have evaluated the science behind CoolTone and decided it would be complementary to our practice and benefit many of our CoolSculpting patients,” Dr. Larrabee says. “I believe that the magnetic muscle stimulation (MMS) of CoolTone is 50% greater than competitors. Although there isn’t good public data to evaluate this, I have spoken to many enthusiastic about the potential of CoolTone,” Dr. Larrabee says.

And not to be overlooked is the new muscle sculpting platform from Cutera — TruSculpt Flex. This muscle sculpting technology uses Multi-Directional Stimulation (MDS) and is cleared by the FDA for the strengthening, toning, and firming of the abdomen, buttocks and thighs.

SYNERGISTIC FAT REDUCTION

Dr. Kilmer says she will, in some cases, use CoolTone or Emsculpt in conjunction with CoolSculpting to combine fat reduction with muscle tightening.

New York dermatologist Dendy Engleman, M.D., says her favorite noninvasive fat reduction device is Emsculpt, which she typically uses as a standalone treatment, but she will combine it with another device in some patients.

“While all body types can benefit from Emsculpt, very high BMI patients are not ideal candidates,” Dr. Engleman says. “Despite significant strengthening of their muscles due to treatment, this improvement may stay hidden beneath the patient’s excessive fat deposits. For these patients, I use BTL Vanquish ME first before Emsculpt to reduce the circumference of the entire abdominal area or inner and outer thighs.”

Los Angeles facial cosmetic surgeon Alexander Rivkin, M.D., says he believes that the field of noninvasive fat reduction or noninvasive body contouring is still in an early stage, where each technology cannot yet achieve the reliable, dramatic results that patients are demanding. A single device has not yet proven to be effective enough to dominate the field, Dr. Rivkin says.

“The two most promising modalities are cryolipolysis (CoolSculpting) and transcutaneous magnetic muscle stimulation (CoolTone). My favorite way to achieve fat reduction is to use a combination of these two devices in a synergistic amplification of effect,” Dr. Rivkin says. “CoolSculpting and CoolTone in combination reduce fat in different ways that seem to be synergistic with one another. I think that this will bring patients the best results.”

Boca Raton dermatologist Jeffrey S. Fromowitz, M.D., says he packages two treatments: CoolSculpting and truSculpt, which some call “fire and ice.”

“This allows us to combine the best of both worlds with fat reduction from [CoolSculpting], then we fine tune the treatments with RF truSculpt. The addition of the RF also adds tissue tightening in areas where we have reduced fat pockets,” Dr. Fromowitz says.

San Antonio, Texas, plastic surgeon Thomas T. Jeneby, M.D., says his number one noninvasive fat reduction technology is CoolSculpting, but he, too, uses a fire and ice approach in some patients with CoolSculpting and Vanquish ME.

“The Vanquish is a no-touch fat melting system that hovers over the body and spins water molecules causing them to heat up and eventually rupture the fat cells by vibration,” Dr. Jeneby says. “So while CoolSculpting uses cold; Vanquish uses heat. We use both back to back…. This gives synergistic fat reduction to people who do not want surgery.”

In the end, different technologies offer different benefits, according to Beverly Hills plastic surgeon Payman Daniepour, M.D., who says that, in his practice, if fat reduction is the sole objective his favorite device is CoolSculpting.

“It has been clearly proven that cryolipolysis works and can be used in multiple areas of the body, even the hard-to-treat areas,” Dr. Daniepour says. “Radio-frequency can be effectively used for circumferential reduction and skin tightening but the fat reduction is not as pronounced. Lastly, Emsculpt… is revolutionary [on] its own because it’s the first machine to effectively build muscle and lose fat.”

The bottom line: Proper patient selection is key when recommending noninvasive fat reduction or body sculpting technologies, according to Dr. Schlessinger.

“As with any technology, there are clearly limitations and benefits, and it is incredibly important to pick the right candidate for the right procedures. Without this, all is lost,” Dr. Schlessinger says.

“For example, about 50% of people that come in for CoolSculpting consultations… simply aren’t candidates. Some, however, are candidates for tumescent liposuction or SmartLipo [Cynosure] that we perform in the office, and when they’re good candidates for that we explain the opportunities and options. For those who are not candidates for either one, we’re just as clear and politely explain the fact that they aren’t a candidate for anything at this time. Many of these are better candidates for bariatric surgery and abdominoplasty,” he says.

Disclosures

Dr. Engleman, Jeneby, Engleman, Larrabee and Rivkin report no relevant disclosures. Dr. Schlessinger has performed clinical trials for Liposculpt, Ultrasound and Kybella. Dr. Fromowitz is a speaker for Cutera. Dr. Kilmer has received research support from and has been a medical advisory board member with Cutera (stock options), CyteLLA (stock options), Alcon, Allergan, Dermison, Pulset Biosciences, Lumenis, Lutronic, Merz, Solta, Sienterra, Solta/Vallek (advocatory board only) and Synergy Candescent. She has received research support in the past year from Galderma, BTL, 23/skincare and Allergan.

She has stock in Avava and HintMD.
Perspectives on Otezla® (apremilast): A systemic treatment option for moderate to severe plaque psoriasis

INDICATIONS
Otezla® (apremilast) 30 mg tablets are indicated for the treatment of patients with moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy. Otezla is also indicated for the treatment of adult patients with active psoriatic arthritis.

PSORIASIS CAN BE A DEBILITATING DISEASE, AND PLAQUES IN VISIBLE AREAS POSE AN ADDITIONAL BURDEN

There is a high prevalence of psoriasis in areas that are very visible and burdensome to patients. Approximately 80% and 55% of psoriasis patients have scalp involvement and nail psoriasis, respectively.1,2 Unfortunately, these highly visible areas can be the most intractable.2

Another impactful and common symptom for patients with psoriasis is pruritus, with 60-90% of patients experiencing itch.3 According to the FDA Patient-Focused Drug Development Initiative, a high proportion of individuals rate itch as one of the most important factors impacting the severity of their disease, describing it as an “intense subcutaneous itch” that results in torn skin, pulled-out hair, and scratch holes.4,5

“When certain localized areas such as the hands, face, and scalp are involved the emotional impact on the patient may be of sufficient magnitude to warrant systemic therapy.” — National Psoriasis Foundation, 20166

Topical therapies are considered standard first-line treatment for psoriasis in patients with these challenging manifestations.7,8 However, topical treatment of these areas can be time-consuming and messy, which can lead to low rates of adherence and overall treatment dissatisfaction.2,7,9 Additionally, psoriasis on the scalp and nails may be less accessible or practical to treat with topicals.7

The availability of a systemic treatment option with an acceptable risk-benefit profile in moderate to severe plaque psoriasis is important for patients who may also have visible and debilitating manifestations of psoriasis.

OTEZLA IS AN ORAL, NON-BIOLOGIC, SYSTEMIC TREATMENT

Otezla is the only FDA-approved oral option in over 15 years indicated for patients with moderate to severe plaque psoriasis.9,10 Otezla works differently from other systemic medications through intracellular mechanisms early in the inflammatory cascade.11,12,13 Otezla is an oral, non-biologic phosphodiesterase-4 (PDE4) inhibitor.14,15

The specific mechanism by which Otezla exerts its therapeutic action is not well defined.16 Based on preclinical evidence, Otezla has anti-inflammatory properties and is thought to indirectly modulate production of both pro- and anti-inflammatory mediators through its effect on elevating cyclic adenosine monophosphate (cAMP) concentrations and signaling (Figure 1).17,15

“Plaques on the scalp and nails are a huge burden for my patients and are very challenging to treat with topical therapy only. Otezla is an oral option that has data in patients with these challenging manifestations of plaque psoriasis.” — Linda Stein Gold, MD; Bloomfield, MI*

OTEZLA HAS DEMONSTRATED EFFICACY IN PATIENTS WITH MODERATE TO SEVERE PLAQUE PSORIASIS

Otezla was evaluated in a multicenter, double-blind, placebo-controlled trial, known as ESTEEM® 1. Patients with moderate to severe plaque psoriasis (N=844) were randomized 2:1 to Otezla 30 mg twice daily (BID) or placebo for 16 weeks after a 5-day titration.9,16 At Week 16, all patients originally assigned to placebo were transitioned to receive Otezla 30 mg BID. Patients originally randomized to Otezla who achieved ≥75% reduction in the Psoriasis Area and Severity Index score (PASI-75) at Week 32 were re-randomized 1:1 to either placebo or Otezla. Patients re-randomized to placebo who lost their PASI-75 response were re-treated with Otezla no later than Week 52. Patients originally randomized to placebo and switched to Otezla at Week 16 who achieved ≥PASI-75 at Week 32 continued on Otezla. For patients originally randomized to Otezla or placebo who did not achieve a PASI-75 by Week 32, concomitant topicals and/or UVB therapy could have been added based on the discretion of the investigator.16 Select inclusion criteria were: age ≥18 years, body surface area (BSA) involvement ≥10%, static Physician Global Assessment (sPGA) ≥3, PASI score ≥12, and candidates for phototherapy or systemic therapy. The primary endpoint was the proportion of patients achieving PASI-75 at Week 16. Patients entering the long-term extension phase could be treated through 5 years.16

The 156-week datasets from ESTEEM 1 represent post-hoc analysis of pooled data, from all patients who entered the open-label long-term extension phase at Week 52.18

“Plaques on the scalp and nails are a huge burden for my patients and are very challenging to treat with topical therapy only. Otezla is an oral option that has data in patients with these challenging manifestations of plaque psoriasis.” — Linda Stein Gold, MD; Bloomfield, MI*

* Serves as a consultant to Celgene.

IMPORTANT SAFETY INFORMATION

Contraindications
Otezla® (apremilast) is contraindicated in patients with a known hypersensitivity to apremilast or to any of the excipients in the formulation.

Warnings and Precautions
Diarrhea, Nausea, and Vomiting: Cases of severe diarrhea, nausea, and vomiting have been reported with the use of Otezla. Most events occurred within the first few weeks of treatment. In some cases patients were hospitalized. Patients 65 years of age or older and patients taking medications that can lead to volume depletion or hypotension may be at a higher risk of complications from severe diarrhea, nausea, or vomiting. Monitor patients who are more susceptible to complications of diarrhea or vomiting; advise patients to contact their healthcare provider. Consider Otezla dose reduction or suspension if patients develop severe diarrhea, nausea, or vomiting.

Depression: Treatment with Otezla is associated with an increase in depression. During clinical trials 1.3% (12/920) of patients reported depression, compared to 0.4% (2/506) on placebo. Suicidal behavior was observed in 0.1% (1/1308) of patients on Otezla, compared to 0.2% (1/506) on placebo. Carefully weigh the risks and benefits of treatment with Otezla for patients with a history of depression and/or suicidal thoughts/behavior, or in patients who develop such symptoms while on Otezla. Patients, caregivers, and families should be advised of the need to be alert for the emergence or worsening of depression, suicidal thoughts or other mood changes, and they should contact their healthcare provider if such changes occur.

Please see Important Safety Information presented throughout and Brief Summary of Full Prescribing Information on last page.
Patients with scalp involvement (Scalp Physician Global Assessment [SPGA] ≥3) saw a change in SGPA score after treatment with Otezla in ESTEEM 1.16,18 At Week 16, 51% of patients taking Otezla 30 mg BID achieved a SGPA score of 0 (clear) or 1 (minimal) compared with 19% of patients taking placebo (Figure 2).16 At Week 156, 61% of patients on Otezla achieved clear or minimal scalp involvement (Figure 2).16

Pruritus, as measured using a 100-mm visual analog scale (VAS), was improved over 16 weeks in ESTEEM 1.18 At Week 16, patients treated with Otezla saw a 33.8 mm change from baseline pruritus VAS score (a secondary endpoint) compared with a 7.7 mm change in patients on placebo.18 At Week 156, patients on Otezla achieved a mean change in pruritus VAS score of 37.2 mm (Figure 4).18

At Week 16, patients taking Otezla in ESTEEM 1 achieved an improvement in Dermatology Life Quality Index (DLQI) score (a secondary endpoint) compared with patients taking placebo: Otezla, 7; Placebo, 2.1,18,19 At Week 156, patients on Otezla achieved a mean change in DLQI score of 7.6.18

Weight Decrease: Body weight loss of 5-10% occurred in 12% (96/874) of patients treated with Otezla and in 5% (19/382) of patients treated with placebo. Monitor body weight regularly; evaluate unexplained or clinically significant weight loss, and consider discontinuation of Otezla.

Please see Important Safety Information presented throughout and Brief Summary of Full Prescribing Information on last page.
SAFETY PROFILE OF OTEZLA® (APEMILAST)

In psoriasis clinical studies, the most common adverse reactions that occurred within the 2 groups of patients were diarrhea, nausea, upper respiratory tract infection, tension headache, and headache (Table 1). The majority of patients who reported nausea or diarrhea did so within the first 2 weeks of therapy. The events tended to resolve over time with continued dosing. Postmarketing reports of severe diarrhea, nausea, and vomiting have been associated with the use of Otezla. In some cases patients were hospitalized. Monitor patients who are more susceptible to complications of diarrhea or vomiting.

Table 1: Adverse Reactions Reported in ≥1% of Patients With Psoriasis on Otezla and With Greater Frequency Than in Patients on Placebo for Up to Week 16

<table>
<thead>
<tr>
<th>Adverse Reactions</th>
<th>Placebo (N=506) n (%)</th>
<th>Otezla 30 mg BID (N=920) n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diarrhea</td>
<td>32 (6)</td>
<td>30 (6)</td>
</tr>
<tr>
<td>Nausea</td>
<td>35 (7)</td>
<td>155 (17)</td>
</tr>
<tr>
<td>Upper respiratory tract infection</td>
<td>31 (6)</td>
<td>84 (9)</td>
</tr>
<tr>
<td>Tension headache</td>
<td>21 (4)</td>
<td>75 (8)</td>
</tr>
<tr>
<td>Headache</td>
<td>19 (4)</td>
<td>55 (6)</td>
</tr>
<tr>
<td>Abdominal pain*</td>
<td>11 (2)</td>
<td>39 (4)</td>
</tr>
<tr>
<td>Vomiting</td>
<td>8 (2)</td>
<td>35 (4)</td>
</tr>
<tr>
<td>Fatigue</td>
<td>9 (2)</td>
<td>29 (3)</td>
</tr>
<tr>
<td>Dyspepsia</td>
<td>6 (1)</td>
<td>29 (3)</td>
</tr>
<tr>
<td>Decreased appetite</td>
<td>5 (1)</td>
<td>26 (3)</td>
</tr>
<tr>
<td>Insomnia</td>
<td>4 (1)</td>
<td>21 (2)</td>
</tr>
<tr>
<td>Back pain</td>
<td>4 (1)</td>
<td>20 (2)</td>
</tr>
<tr>
<td>Migraine</td>
<td>5 (1)</td>
<td>19 (2)</td>
</tr>
<tr>
<td>Frequent bowel movements</td>
<td>1 (0)</td>
<td>17 (2)</td>
</tr>
<tr>
<td>Depression</td>
<td>2 (0)</td>
<td>12 (1)</td>
</tr>
<tr>
<td>Bronchitis</td>
<td>2 (0)</td>
<td>12 (1)</td>
</tr>
<tr>
<td>Tooth abscess</td>
<td>0 (0)</td>
<td>10 (1)</td>
</tr>
<tr>
<td>Folliculitis</td>
<td>0 (0)</td>
<td>9 (1)</td>
</tr>
<tr>
<td>Sinus headache</td>
<td>0 (0)</td>
<td>9 (1)</td>
</tr>
</tbody>
</table>

“The safety of Otezla was assessed in 1426 subjects in 3 randomized, double-blind, placebo-controlled trials (including ESTEEM 1 and ESTEEM 2); 2 patients treated with Otezla experienced serious adverse reaction of abdominal pain.

“With over 3 years of data demonstrating the safety profile of Otezla, I feel confident prescribing it to my appropriate patients, especially for patients who could benefit from a systemic therapy.”

— Robert Casquejo, PA; Scottsdale, AZ

IMPORTANT SAFETY INFORMATION

Drug Interactions: Apremilast exposure was decreased when Otezla was co-administered with rifampin, a strong CYP450 enzyme inducer; loss of Otezla efficacy may occur. Concomitant use of Otezla with CYP450 enzyme inducers (e.g., rifampin, phenobarbital, carbamazepine, phenytoin) is not recommended.

Adverse Reactions

Adverse reactions reported in >5% of patients were (Otezla%, placebo%): diarrhea (17, 6), nausea (17, 7), upper respiratory tract infection (9, 6), tension headache (8, 4), and headache (6, 4).

Use in Specific Populations

Pregnancy: Otezla has not been studied in pregnant women. Advise pregnant women of the potential risk of fetal loss. Consider pregnancy planning and prevention for females of reproductive potential. There is a pregnancy exposure registry that monitors pregnancy outcomes in women exposed to Otezla during pregnancy. Information about the registry can be obtained by calling 1-877-311-8972 or visiting https://mothertobaby.org/ongoing-study/otezla/.

Lactation: There are no data on the presence of apremilast or its metabolites in human milk, the effects of apremilast on the breastfed infant, or the effects of the drug on milk production. The developmental and health benefits of breastfeeding should be considered along with the mother’s clinical need for Otezla and any potential adverse effects on the breastfed child from Otezla or from the underlying maternal condition.

Renal Impairment: Otezla dosage should be reduced in patients with severe renal impairment (creatinine clearance less than 30 mL/min); for details, see Dosage and Administration, Section 2, in the Full Prescribing Information.

Please see Important Safety Information presented throughout and Brief Summary of Full Prescribing Information on last page.

REFERENCES:


THE OTEZLA PRESCRIBING INFORMATION HAS NO REQUIREMENT FOR ROUTINE LAB MONITORING

Overall, the proportion of patients who discontinued treatment because of any adverse reaction was 6.1% for Otezla-treated patients and 4.1% for placebo patients. The common adverse reactions that led to discontinuation for patients taking Otezla were nausea (1.6%), diarrhea (1.0%), and headache (0.8%).

“Following topical therapy, Otezla is the first systemic option I consider for my appropriate patients with moderate to severe psoriasis in challenging treatment areas who need a different therapy. I like that Otezla is an oral option and has no requirement for them to undergo routine laboratory monitoring.”

— M. Shane Chapman, MD, MBA; Lebanon, NH

* Serves as a consultant to Celgene.

THE LONG-TERM SAFETY PROFILE OF OTEZLA THROUGH 3 YEARS WAS GENERALLY SIMILAR TO THAT OBSERVED WITH OTEZLA THROUGH 16 WEEKS, WITH THE EXCEPTION OF NASOPHARYNGITIS

WHEN MIGHT SYSTEMIC TREATMENT, LIKE OTEZLA, BE APPROPRIATE?

Patients with moderate to severe plaque psoriasis who:

• Have been on topicals previously and are not adequately controlled
• Find it challenging to adhere to the complex administration of topicals
• Have psoriasis in areas with a high emotional impact (eg, scalp, face, hand, nail)

Otezla may be a good option for patients with moderate to severe plaque psoriasis who prefer an oral option with no requirement for laboratory monitoring. Otezla is also indicated for adult patients with active psoriatic arthritis.

* © 2019 Celgene Corporation 8/19 US-OTZ-19-0418
OTEZLA® (apremilast) tablets, for oral use

The following is a Brief Summary of the Prescribing Information; see Full Prescribing Information for complete product information.

4 CONTRAINDICATIONS

OTEZLA is contraindicated in patients with a known hypersensitivity to apremilast or to any of the excipients in the formulation. See Adverse Reactions [6.1].

5 WARNINGS AND PRECAUTIONS

5.1 Diarrhea, Nausea, and Vomiting: There have been postmarketing reports of severe diarrhea, nausea, and vomiting associated with the use of OTEZLA. Most events occurred within the first few weeks of treatment. In some cases patients were hospitalized. Patients 65 years of age or older and patients taking medications that can lead to volume depletion or hypotension may be at a higher risk of complications from severe diarrhea, nausea, or vomiting. Monitor patients who are more susceptible to complications of diarrhea or vomiting. Patients who reduced dosage or discontinued OTEZLA generally improved quickly. Consider OTEZLA dose reduction or suspension if patients develop severe diarrhea, nausea, or vomiting.

5.2 Depression: Treatment with OTEZLA is associated with an increase in adverse reactions of depression. Before using OTEZLA in patients with a history of depression and/or suicidal thoughts or behavior, prescribers should carefully weigh the risks and benefits of treatment with OTEZLA in such patients. Patients, their caregivers, and families should be advised of the need to be alert for the emergence or worsening of depression, suicidal thoughts or other mood changes, and if such changes occur to contact their healthcare provider. Prescribers should carefully evaluate the risks and benefits of continuing treatment with OTEZLA if such events occur.

Psoriatic Arthritis: During the 0 to 16 week placebo-controlled period of the 3 controlled clinical trials, 1.0% (10/998) of subjects treated with OTEZLA reported depression or depressed mood compared to 0.6% (6/989) treated with placebo. During the clinical trials, 0.3% (1/4144) of subjects treated with OTEZLA discontinued treatment due to depression or depressed mood compared with none in placebo-treated subjects (0.0%). Depression was reported as serious in 0.2% (2/1414) of subjects exposed to OTEZLA, compared to none in placebo-treated subjects (0.0%)."
Tephrosia purpurea extract benefits skin homeostasis, a balance disrupted by endogenous stress, including emotions, and external forces, such as UV radiation and pollution. Clinically, using the extract topically can improve skin appearance—specifically the appearance of dark under-eye circles, according to research published earlier this year in the *Journal of Cosmetic Dermatology*.

The study’s authors had shown in previous work that the *T. purpurea* extract helps stimulate well-being hormones while reducing cortisol release. The extract represents a component of “well-aging,” a term and way of life embraced by today’s mature women, who reject the concept of anti-aging, according to the paper.

*T. purpurea* is a common wasteland weed known for its therapeutic benefits. Researchers reported in 2010 in *Pharmacognosy Research* that *T. purpurea* often is grown as a green manure in paddy fields in India and in tobacco and rubber plantation in other countries.

“It grows ubiquitously in all soils, sandy, rocky and loamy. In India and South Africa, it is used as a fodder before flowering, but in Australia it is reported to cause livestock poisoning. In northern India, dry plants are collected for fuel. All parts of the plant have tonic and laxative properties. The dried plant is deobstruent, diuretic and useful in treating bronchitis, bilious febrile attacks and obstructions of the liver, spleen and kidneys. It is also recommended as a blood purifier, in the treatment of boils and pimples and is considered a cordial treatment,” the authors write.

Among the calls to action of the Royal Society for Public Health’s report “The Age Old Question” is to stop use of the term antiaging in the cosmetic and beauty industries. Mature women are likely to embrace a lifestyle promoting wellbeing and health, better described as “well-aging” or “healthy-aging,” according to the *Journal of Cosmetic Dermatology* paper.

To study the extract’s impact on well-aging, researchers used normal human epidermal keratinocytes from forehead skin to analyze *T. purpurea*’s effects in a cortisol release study, a gene expression study and for assays for heme oxygenase-1 (HMOX-1)—which has anti-inflammatory, antioxidative and antiapoptotic properties—and H-quinone oxidoreductase (NQO-1), which has antioxidant activity.

They found the 1% extract significantly reduced cortisol release by 70%, induced beta-endorphin production at 0.0125% and 0.0625% by 220% (P < 0.01) and 197.5% (P < 0.05), respectively, and increased dopamine release by 21%. The extract upregulated genes involved in antioxidant response and skin renewal. And the researchers confirmed induction of HMOX and NQO-1 expression.

The authors also studied 21 healthy women who lived in polluted areas, who applied a cream with *T. purpurea* 2% twice daily. They write that since pollution leads to premature aging and darkened skin especially under the eyes, they looked for the active topically’s impact on skin clarity, skin redness and quantifying skin color. They found that at 14 and 28 days, extract-treated dark eye circles were lighter, as evidenced by reduced skin redness.

“A state of well-being, represented in our study by the secretion of beta-endorphin and dopamine, demonstrated the beneficial impact on this balance and suggests a healthier aging for mature women,” the authors write.

**Quick TAKES**

- *T. purpurea* is known for its therapeutic benefits.
- The extract was shown to reduce cortisol.
- *T. purpurea* may offer a component for “well-aging.”

**References**

Skincare advice specific to each generation

JOHN JESITUS | Staff Correspondent

To meet the skin’s changing needs over various life stages, experts at the Generational Dermatology Symposium held earlier this year suggest being proactive about barrier problems and moisturization is key to maintaining skin health.

As a baseline, Ellen C. Gendler, M.D., says that one should use the same type of sunscreen from childhood to old age. She is a clinical associate professor of dermatology at New York University Langone Medical Center.

“Not all sunscreens are created equal,” she says. “And starting early with a real UV A-blocking sunscreen is very important.” She advises against typical American-made chemical sunscreens containing avobenzone, octocrylene, oxybenzone and octinoxate in favor of ingredients from Europe (see Table).

Zinc oxide can block a large percentage of UVA, adds Dr. Gendler, but it requires a trade-off between efficacy and elegance.

MILLENNIAL MUSTS

“All millennials should use some form of retinoid,” she says, “even a mild one. Retin-A (tretinoin, Ortho Dermatologics) is the only thing that’s ever been shown to help prevent the progression of wrinkles and the formation of precancerous keratoses and, possibly, skin cancer. So, when possible, starting prescription-strength Retin-A young is very helpful.” If that’s too irritating, or a woman of childbearing age doesn’t want to go on and off it, Dr. Gendler recommends over-the-counter retinoids such as retinol.

Also for 20-somethings, she suggests creams containing DNA repair enzymes, which can reverse the DNA damage that occurs immediately upon sun exposure. However, identifying these ingredients can be tough, Dr. Gendler says, because manufacturers often combine extracts of plankton or algae with other ingredients and give the resulting formulation a proprietary name. Photosomes (Barnet), for example, are light-activated DNA repair enzymes for daytime use. DNA repair enzymes for nighttime use include UV-specific endonucleases and 8-oxoguanine glycosylase (OGG1), says Dr. Gendler.

European sunscreens sometimes contain DNA repair enzymes, she adds. Examples include Eryfotona Actinica 50 (Isdin), which is also available stateside.

THE 30S

According to Dr. Gendler, “The 30s is the right time to start an eye cream.” To target sagging skin and wrinkling, these products should also contain DNA repair enzymes — particularly those that support elastin, says Dr. Gendler. Additional eye cream ingredients aim to lighten under-eye pigmentation.

“Whether or not they actually do is another issue. But getting

Quick Takes

Epidermal barrier function changes at different life stages.

Retinoids and DNA enzymes are musts for younger generations.

Convincing patients to follow skincare advice can be challenging.

<table>
<thead>
<tr>
<th>TABLE</th>
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<td>SELECTED INTERNATIONAL UVA BLOCKERS</td>
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<table>
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<tr>
<th>TRADE NAME</th>
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<tr>
<td>Mexoryl XL</td>
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<td>Tinosorb S</td>
<td>Methoxyphenyl Triazine (bemotrizinol)</td>
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<tr>
<td>Tinosorb M</td>
<td>Methylene bis-benzotriazolyl tetramethylbutyl-phenol (biscotrizole)</td>
<td>BASF</td>
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</table>
Making the Once Impossible, Possible: Innovation in Antibiotic Delivery

The delivery of antibiotics for dermatological conditions represents a unique challenge. Topical antibiotics are generally preferred to oral therapies because they have less systemic absorption. Despite the widespread use of topical antibiotics in dermatology, systemic antibiotics continue to play a significant role in practice, in part, because some antibiotics remain unavailable in topical formulations. Among the most commonly prescribed antibiotics by dermatologists are the tetracycline class, of which doxycycline and minocycline, to date, have proven difficult to formulate topically. Some of the challenges in the development of a topical formulation of tetracyclines include solubility, maintaining stability, and efficiently delivering the active ingredient into the skin. Overcoming the hurdles associated with creating effective topical formulations of tetracyclines has continued to be a challenge since the original development of topical antibiotics more than 50 years ago.13

Foamix is an entrepreneurial, technology-savvy specialty pharmaceutical company that is developing proprietary, innovative, and differentiated delivery systems intended to help solve some of today’s most difficult therapeutic challenges in dermatology and beyond. By challenging the status quo, Foamix is reimagining what’s possible for conditions with high unmet needs. Created with the formulation of topical tetracyclines in mind, the proprietary Molecule Stabilizing Technology (MST™) platform is the foundation that allows the company to rethink and reengineer topical delivery. MST™ enabled the creation of the first investigational topical antibiotic approach that is formulated without surfactants, using instead natural oils that work with the natural moisturizing oils of human skin. By leveraging foam, a prominent topical delivery system that can be engineered, refined, and elevated, Foamix is taking advantage of an innovative and easy-to-apply investigational alternative to creams and ointments. Potential significant advantages of the foam formulation are that it spreads easily on large skin areas, does not leave an oily film after application, and does not impart a greasy feeling upon, and after, application.45

Through the unique MST™ approach, formulations are in development that may allow for effective topical delivery of tetracyclines. Although some tetracyclines like doxycycline and minocycline are stable in their solid state, they degrade extensively in the presence of water and are sensitive to oxidation, thus preventing their formulation into aqueous compositions. The formulation of these tetracyclines as a suspension in hydrophobic composition was identified as a possible solution to mitigate the risk for degradation. Different carriers were evaluated for solubility and stability; a correlation was found between higher solubility (polar/hydrophilic solvents) and degradation, suggesting a hydrophobic carrier would be favorable. With this in mind, MST™ was designed as a way to formulate a suspension containing these molecules, utilizing an essentially nonaqueous formulation to mitigate degradation risk by reducing the interaction between the active ingredient and the rest of the composition.

Beyond tetracyclines, leveraging MST™ holds promise in the development of additional topical products that deliver proven therapeutic agents. With expertise in topical medicine innovation as its springboard, Foamix is working to develop and commercialize solutions that meet unmet needs in the dermatological market.


Sponsored by Foamix Pharmaceuticals Inc.
The product base serum was introduced to dermatologists and skincare professionals at The Aesthetic Show in Las Vegas in July. Dr. Draelos, whose team oversaw the clinical study, says Aesthetics Biomedical is one company focused on the science of PRP and facial rejuvenation.

“There’s much research going on involving PRP. The reason it’s so popular is that platelet-rich plasma contains key growth factors which reside in the platelet granules,” she says. PRP can be harvested from the blood and the enriched platelets returned to the individual through various mechanisms. It can be injected, used topically or now, as directed and provided by a physician, used in combination with the base to be applied topically at home, according to Dr. Draelos.

TO prepare the topical PRP, the dermatologist draws 50 mL of blood from a patient in the office, adding an anticoagulant into the blood to avoid clotting. The doctor centrifuges the blood to extract both PRP and platelet poor plasma (PPP). Using the centrifuge that produced the study results is important to ensure a reliable, reproducible yield of platelets in the PRP, Dr. Draelos says.

Dermatologists processing the blood will get about 9 mL of PRP, as well as about 20 mL of PPP from the original 50 mL of blood, she says.

“Many people are putting that platelet-rich plasma into a syringe and injecting it into the scalp when they do hair transplants to increase the viability of the hair transplants,” Dr. Draelos says. “Or in the case of topical PRP, the physician can take that platelet-rich plasma, put it into a uniquely developed cosmetic serum to be used at home by the patient twice per day. The company reports that their topical product includes a preservative system and ingredients that maintain the platelet and its function for upwards of 90 days.”

Topical PRP could be offered by physicians in combination with a variety of aesthetic devices and surgical procedures, where PRP is already being produced for patient use, according to Dr. Draelos.

“This is the new direction in personalized cosmetics, where you use your body products and are making your own, theoretically, more functional, customized cosmetics,” she says.

Topical PRP requires refrigeration according to Dr. Draelos, and mini-refrigerators are provided for the patients to store their topical PRP product in at home. The base serum alone does not require refrigeration.

There’s abundant ongoing research to validate early findings and fine-tune the use of PRP in moisturizers and other skincare products, she says.

“There’s still much work that needs to be done,” Dr. Draelos says. “But this is the future of skincare products. Platelet-rich plasma is a very easy way to harvest cells because you can do it by drawing blood, and the physician uses the PRP without any manipulation. You don’t have to cut up tissue. You can centrifuge and obtain these enriched platelets in 15 to 30 minutes.”

The vehicle used is important because there are many things that are present in traditional moisturizers that could kill viable cells, including certain preservatives, Dr. Draelos says.

Dermatologists could be at the forefront in the delivery of these customized skincare products because they would prepare these products at the point-of-care. And preparation requires a trained professional to draw and prepare the PRP, according to Dr. Draelos.

We asked: Do you perform PRP-enhanced treatment in your practice?
You responded:

33% Yes, and in my experience it enhances recovery, results.

28% Yes, but I’m not 100% convinced that it’s truly efficacious.

28% No, but I’m interested in doing so.

11% No, and I have no plans to.
Four themes emerged from face-to-face and telephone interviews with six melasma patients: Self-esteem suffered. Patients felt melasma robbed them of freedom. They were frustrated with costly and ineffective melasma treatments. And their quality-of-life improved after successful treatment with an oral tranexamic acid and a triple combination cream.

Researchers published results of their pilot study in the International Journal of Women’s Dermatology in March 2018. The authors interviewed women with moderate-to-severe melasma who had gone to the University of Texas Southwestern Pigmentary Disorders Clinic, in Dallas, for follow up. The same provider treated all six patients with a similar regimen of oral tranexamic acid 325 mg twice daily and triple combination cream with 6% hydroquinone, 0.0125% tretinoin and 0.1% dexamethasone once daily, along with sunscreen. Two of the women had severe melasma; four had a history of moderate melasma.

Interviewees asked each participant 13 open-ended questions about the effect melasma had on their self-esteem, including:

“How noticeable do you think your melasma is to others?”

“Does your melasma have an impact on your sense of self-worth/self-esteem?”

“Has your self-esteem improved after being treated for your melasma?”

The researchers focused on self-esteem because while many studies have assessed melasma patients’ quality of life, using the melasma-specific MelasQoL questionnaire among others, few have studied focus groups of patients to help determine self-esteem and psychological stressors associated with having melasma, according to the authors. Research to date suggests that melasma’s effect on quality of life is multifactorial — not due only to severity. And treatment might impact quality of life in these patients.

NEGATIVE SELF-ESTEEM

All the women in this study reported melasma had a significant negative impact on both quality of life and self-esteem.

Among those with melasma, many indicated that increased self-consciousness was associated with decreased self-confidence and self-esteem. Several said they were frustrated that melasma occurred on their faces versus other less obvious places on their bodies. Some admitted being obsessed about their melasma.

One patient said during the interviews, “You are less than a person or not as good as the next person in line [because of melasma]. You aren’t as whole or complete.”

Another patient who described having to interact with high society said, “I always felt self-conscious about it; in that group of people, where everyone was so pretty and so well dressed, here I was with [dark stains] on my face.”

All the women mentioned that melasma had in some way affected their freedom, with many wanting to avoid social situations because of the skin condition. Some avoided outdoor activities, fearing the melasma would get worse. Several of the women interviewed were frustrated with ineffective treatments that dermatologists and other providers had prescribed. Many said they didn’t trust and felt betrayed by providers who prescribed ineffective melasma treatments.

A POSITIVE OUTLOOK

Patients surveyed had unsuccessfully tried other treatments for their melasma, including 4% hydroquinone cream, tretinoin cream, intense pulsed light or a combination of these for three months or more prior to their first visit for this study.

“Many of the patients expressed improvement in their [quality of life] after successful treatment of their melasma with oral tranexamic acid and triple combination cream that was prescribed in our clinic,” the researchers write. “Patients also expressed that they were more willing to be in social situations, participate in outdoor activities and had a more positive outlook on life and had increased self-confidence after treatment.”

Dermatologists and others who treat melasma patients should strive to improve not only pigmentary changes but also patients’ quality-of-life and self-esteem, according to the study.

A limitation of this small pilot study is that while it offers interesting information, that information isn’t necessarily generalizable.

References

into the habit of using a lightweight eye cream is a wise introduction to the world of skincare.”

For women in their 30s who are through having children, she recommended Premarin (Pfizer) cream under the eyes. “Topical estrogens have been shown to keep skin thick.”4,5

THE 40S

In the 40s, patients may exhibit pigmen
tary changes that require bleaching agents. “These can range from something powerful like hydroquinone to things that are less powerful like kojic acid, topical tranexamic acid or arbutase,” Dr. Gendler says.

The 40s are also the decade when women typically start noticing neck laxity. It is unknown whether neck creams really do much, she says, “But applying a gentle retinoid to the neck will certainly help you maintain the integrity of your skin there.”

Additionally, Dr. Gendler suggests maintenance treatments in the 40s. “It doesn’t have to be anything deep. But chemical peels are helpful. Clear + Brilliant, which is a gentle form of a Fraxel laser (both by Solta Medical), can be very helpful.”

THE 50S AND BEYOND

In the 50s and 60s, she advises using hand creams to reduce sun damage that becomes evident as skin starts to thin. She particularly likes Restorsea Repairing Hand Treatment (Resto
sea, LLC), which is derived from a salmon skin. “It has been shown to keep skin thick.”1-3

SKINCARE EDUCATION & ADVICE

Key moisturizers used in sophisticated cleansers and body washes include humectants, such as glycerin, which draw water outward to the SC. Occlusives such as petrolatum and mineral oil prevent evaporation through the SC. These ingredients can compensate for the lipids removed during the cleansing process, says Dr. Alexis.

Andrew F. Alexis, M.D., adds, “The barrier function of our epidermis changes with different stages of life, from infancy to the opposite extreme of age.” He is professor and chair, Department of Dermatology, Mount Sinai St. Luke’s and Mount Sinai West in New York.

As people reach their 70s, he says, the stratum corneum (SC) begins to lose lipids and acid-

ity. These changes reduce the desquamation rate of keratinocytes, leading to scaling and dryness. Moisturizing cleansers and appropriate moisturizers can help to mitigate these changes, he says.

“Cleansing is a delicate balance between removing what we don’t want and leaving behind what we do want.” While it’s important to remove pathogens and debris from the skin’s surface, he explains, soaps remove natural lipids and oils, resulting in dryness.

Traditional soaps are made of long-chain fatty acid alkali salts with a high pH. These salts disrupt the skin barrier by stripping many of its natural lipids and increasing skin-surface pH, which causes further barrier disruption. To better preserve natural pH, says Dr. Alexis, synthetic detergents now used in moisturizing body washes and soaps contain milder surfactants that are less disruptive to the skin barrier.

The traditional, commonly used surfactant sodium lauryl ether sulfate (SLES) is more likely to dry out lipids and alkalize the skin than are newer, milder surfactants such as sodium cocoyl isethionate (SCI) and glycinate, Dr. Alexis says.

SKINCARE ADVICE

Key moisturizers used in sophisticated cleansers and body washes include humectants, such as glycerin, which draw water outward to the SC. Occlusives such as petrolatum and mineral oil prevent evaporation through the SC. These ingredients can compensate for the lipids removed during the cleansing process, says Dr. Alexis.

“Then after the shower, what you moisturize with is important,” according to Dr. Alexis. These products should also include occlusives and humectants, he says, and people should apply them immediately after bathing or showering, while skin is still moist, to trap water before it evaporates.

Aside from normal skin, adds Dr. Alexis, studies show that daily moisturization can be an important adjunct in managing atopic dermatitis. In one study, median time to relapse among patients who used daily moisturizer was 180 days, versus 30 days for those who did not.4

Convincing patients to heed sound skincare advice can prove challenging. “There’s sometimes resistance when patients are loyal to specific brands or home remedies and skincare practices that they’ve been told in their communities are helpful,” says Dr. Alexis.

A classic example involves bar soap, which leaves dry, tight skin that patients may associate with cleanliness. “To shift from that to a body wash that leaves the skin with some sheen and smoothness because of its moisturizing properties takes some getting used to,” he says. Another example is black soap, a “natural” product made from the ash of African plants such as plantain skins and palm tree leaves. Dr. Alexis says black soap is popular among West Africans and, increasingly, African-Americans. While it can provide antimicrobial effects, he says, it can also leave skin very dry.

Another traditional practice involves using coconut oil as a moisturizer. However, according to Dr. Alexis, single-ingredient moisturizers likely won’t work as well as those formulated with humectants and occlusive ingredients.

The education process often involves having patients try free moisturizer samples in the office. “When it comes to cleansers, giving samples for them to try at home goes a long way. Then they see the effect for themselves,” Dr. Alexis says.

Disclosures

Dr. Alexis is a consultant and an advisory board member for Shiseido, L’Oreal and Beiersdorf. Dr. Gendler reports no relevant financial interests.

References


Dr. Alexis

Dr. Gendler

Ellen C. Gendler, M.D., New York University Langone Medical Center, New York
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Understanding melasma risk and how best to prevent and treat the skin condition has many dermatologists scratching their heads. While management and treatment hurdles remain, there is a growing arsenal of melasma remedies at dermatologists’ disposals.

For now, there is no way to prevent melasma outright, but it can be treated and controlled, according to dermatologist Daniel P. Friedmann, M.D., Westlake Dermatology and Cosmetic Surgery, Austin, Texas.

**THE MAKING OF MELASMA**

Patients at most risk for melasma are female — especially those who are pregnant, on oral contraceptives or hormone supplementation, according to Dr. Friedmann.

“This is because a high estrogen environment is essential to trigger melasma. While estrogen may be the spark the ignites this chronic condition, ultraviolet radiation (potentially in combination with visible light and infrared radiation) is the fuel that keeps the fire going,” Dr. Friedmann says.

It’s difficult to predict who will develop melasma, according to Calabasas, Calif., dermatologist Anna Guanche, M.D.

“It usually starts in your late 20s or early 30s and then progresses. Although all skin types may develop it, types III through IV can have the most difficult time camouflaging the robust pigment that develops,” Dr. Guanche says.

Some studies suggest other potential causes or associations, including thyroid disease and genetic influences, according to Lisa Guidry Pruett, M.D., a dermatologist with U.S. Dermatology Partners, Carrollton, Texas.

**PREVENTION AND TREATMENTS TIPS**

The most important thing to do to prevent melasma is to minimize skin stress, according to Dr. Pruett.

“This means cover up and seek shade, wear tinted sunscreen that will protect against UV radiation, but also infrared and [high-energy visible (HEV) radiation,] and apply antioxidants to the skin. There is also good science behind ingesting *polypodium leucotomos* orally,” Dr. Pruett says.

Dr. Pruett’s first-line treatment includes a tinted sunscreen like EltaMD UV Elements (EltaMD), an antioxidant like [SkinBetter Science’s Alto Defense Serum] and a prescription topical cream that includes hydroquinone and kojic acid. She recommends patients ingest *polypodium leucotomos* orally twice daily to improve melasma.

“For patients that want to take it a step further, I’ll recommend a series of SkinPen microneedling [Bellus Medical] treatments with topical tranexamic acid or Dermalfusions [Envy Medical] along with the topical regimen,” Dr. Pruett says.

According to Dr. Friedmann, treating melasma rests on two factors: sun protection and avoidance and arrest of the skin’s pigment production pathways.

“Sunscreen, reapplied every two to three hours, is the simplest and often most cost-effective option,” Dr. Friedmann says. The problem is patients typically apply sunscreen, then makeup and do not reapply during the day, which provides only a small, brief fraction of sun protection, according to Dr. Friedmann.

Dr. Friedmann recommends Colorescience’s Sunforgettable brush-on sunscreen, which he says helps women wearing makeup to maintain sun protection throughout the day. For women who don’t wear makeup, Dr. Friedmann recommends SkinMedica’s Total Defense and Repair sunscreen, which provides simultaneous protection against both ultraviolet and infrared radiation.

Dr. Guanche recommends sun protection with an SPF greater than 40 daily and 60 when outdoors.

“I have found that a cosmetic primer can augment the effects of the sunscreen by making it stay put. Dermablend makes a sticky jelly primer that I love to recommend. Also, I recommend [brighteners such as] glycolic and azelaic acid for daytime, and hydroquinone with isotretinoin and kojic acid at night time,” Dr. Guanche says. “Of course, avoidance of...”
Dr. Guanche also recommends what she calls “micro peel pads” by ZO. These have glycolic in them to provide daily exfoliation.

“This should be done only in conjunction with strict sunscreen use. Otherwise there is a risk of worsening the condition,” Dr. Guanche says.

Dermatologist Rita Linkner, M.D., of Spring Street Dermatology in New York City, says dermatologists should ideally recommend a sunscreen with an infrared blocker like Alastin’s Hydratint, which blocks infrared heat energy. New research suggests infrared heat energy is associated with skin discoloration and aging, she says.

Dr. Friedmann says that by preventing new pigment from forming, existing pigment will gradually improve.

“The gold standard [for this] is hydroquinone cream. At low concentrations, it is exceptionally safe and associated with only mild irritation. While the addition of tretinoin or a mild acid may improve the effect, it often leads to a significant increase in irritation and decrease in patient compliance with use of the product,” Dr. Friedmann says. “I often recommend twice-a-day use of hydroquinone 4% cream and SkinMedica’s Lytera 2.0, the latter leading to arrest of other pigment production pathways in the skin not affected by the former.”

Dr. Friedmann has melasma patients on this treatment regimen for at least six weeks.

Anya Stassiy, RPA-C, who practices medical and aesthetic dermatology at Klirom Dermatology in Brooklyn, N.Y., says she recommends that melasma patients start taking Helioceare supplements and apply EltaMD sunblock.

“Altreno [Ortho Dermatologics] is my new favorite retinol, that is not irritating and doesn’t disintegrate in the sun, so it can be used during the day,” Stassiy says.

**TREATING RESIDUAL OR STUBBORN MELASMA**

Dr. Friedmann will often treat residual pigment using different options, including microneedling, peels or laser resurfacing.

“The best analogy that I have for patients is that treating melasma with any of these is like playing a game. The longer to see results. Fairer skin patients are a little more likely to get results using these treatments. Drs. Linkner and Dr. Pruett and Ms. Stassiy report no relevant disclosures.

Dr. Friedmann reports no relevant disclosures.

**WHAT IS THE GOLD STANDARD TREATMENT FOR MELASMA?**

Dr. Batra: In my hands, it’s a combination of a cell turnover agent, a retinoid, with hydroquinone.

Hydroquinone is still the gold standard across the board. It inhibits the enzyme tyrosinase, which allows the skin to lay down pigment. But I find the gold standard to be combining hydroquinone with a cell turnover agent — whether or not it’s a triple cream that’s compounded or one that patients alternate or layer. I think those two agents have to be on board for it to be a gold standard melasma treatment.

**ARE THERE ANY LIMITATIONS TO TREATMENT STRATEGIES?**

Dr. Batra: There is no permanent cure for melasma. I think it results from a combination of hormones, genetic predisposition, ultraviolet exposure, and it tends to be chronic. The limitation is while we often improve melasma, we have to educate our patients that this is something that tends to recur and needs ongoing maintenance and ongoing sun protection. Just because it fades doesn’t mean that it’s not going to come back.

**WHAT DO YOU TELL PATIENTS?**

Dr. Batra: I think it’s important that patients understand this is a long-term strategy. It takes time to see results and those results need to be maintained. When I counsel patients before we embark any sort of treatment plan, I will say that this requires ongoing maintenance. It’s not something that you’re going to do one procedure and it’s done. I tell the patient: You, on your own, have a huge responsibility to maintain these results by using strict sun protection and an ongoing fading cream, day to day.

**WHAT ARE YOUR KEY TAKEAWAY MESSAGES TO COLLEAGUES?**

Dr. Batra: Using a combination of approaches — topicals, orals and in-office procedures — often yields the best improvement. But melasma is a condition that doesn’t have a cure, so it requires patience and an ongoing relationship with the patient, in which patients understand that they need to maintain and continue at-home efforts to see the best results.

Dr. Batra reports no relevant disclosures.
The Overall Landscape for the Treatment of Melasma

Dermatology Times: What makes melasma so difficult to treat?

Dr. Desai: While for many years, we have talked about melasma, primarily from the aesthetic standpoint—what makes the condition so challenging to treat is that it is also a chronic skin disease. From that perspective, we have to approach melasma in the same manner as psoriasis or atopic dermatitis. It is important to emphasize the chronic nature of melasma in that first patient consult and to set appropriate patient expectations. While our community of board-certified dermatologists are there to help patients manage their condition and improve their symptoms both medically and cosmetically, patients need to understand that this is not a curable disease.

Melasma has a high relapse and recurrence rate because the pigmentation triggered by increased melanin production is always lurking in the background.

Dermatology Times: Do you have a lot of melasma patients coming in to see you with the expectation that this is a permanently curable condition?

Dr. Desai: Absolutely. In fact, I would say that the majority of patients I see think that I am going to be able to give them a quick fix to resolve their issues. While there are things we can do rather quickly in some cases to improve patients’ melasma-related symptoms, we can’t make the disease go away overnight. It takes time.

Dermatology Times: What are the most common approaches to the treatment of melasma?

Dr. Desai: In my practice, we take a multidisciplinary approach. Successful treatment often requires combination therapy, and while it’s important to recognize that topical therapy remains the gold standard as first-line treatment of melasma, one prescription alone is often not enough for these patients.

I like to start with topical therapy, which usually includes a triple combination that includes hydroquinone, a retinoid and a steroid. In addition to topical therapy, it’s important to reinforce the importance of proper sunscreen application and photoprotection. Even though sunscreen is not prescription therapy, it’s important that patients understand that it is something they need to apply multiple times each day, especially during prolonged sun exposure.

I also talk to my new melasma patients about topical antioxidants. Specifically, I like to suggest vitamin C, often combined with vitamin E. Topical antioxidants are great to let patients know that they have options besides prescription therapy.

I will typically have melasma patients initiate that therapeutic combination for anywhere from six to 12 weeks before seeing them for an initial follow-up visit. I do tell them before they leave the initial consultation that we may discontinue the hydroquinone at the initial follow-up visit to give their skin a break. Depending upon the level of improvement at this visit, we may move on to second-line topical agents or introduce physical modalities such as chemical peels.

Dermatology Times: Why is hydroquinone typically considered the anchor drug for the treatment of melasma? Why is it thought to work in these patients?

Dr. Desai: Hydroquinone is still the gold standard in topical skin lightening. The reason is because it remains the most potent tyrosinase inhibitor available. There are other agents that can target tyrosinase enzyme activity, but we haven’t found anything better than hydroquinone in terms of the topical lightening.

The problem with hydroquinone is that it is not meant for long-term use, which can be challenging for melasma patients to understand. There are potential side effects when hydroquinone is used for extended periods of time such as irritation, possible risk of ochronosis, initial worsening of pigmentation, peeling, and dryness. Those things are all important to discuss with patients, and we need to make sure that they understand hydroquinone is given during, what I like to call, the “induction phase” of skin lightening.

I equate our use of hydroquinone in patients with melasma to an overactive car engine that’s going too fast. You’re trying to slow that engine down and get it back into a normal speed with aggressive measures — that’s what we use the hydroquinone for — but then you need to maintain that normal, steady speed with other, longer-term approaches so that there aren’t major safety issues.

Dermatology Times: What is your preferred second-line topical agent for the treatment of melasma?

Dr. Desai: I use oral tranexamic acid for many of my patients with recalcitrant melasma who don’t respond to initial treatment and chemical peels. While it’s an off-label use, oral tranexamic acid therapy has been studied in melasma quite extensively in recent years, particularly in Asia.

While it’s been typically dosed in clinical studies between 250–500 mg twice daily, only a 650 mg dose of tranexamic acid is available in the United States. Consequently, I’ll have my patients split the medication in half, taking 325 mg in the morning and 325 mg at night.

Further reading @ INSIGHTS, next page

Seemal R. Desai, MD, FAAD, is president and medical director at Innovative Dermatology in Plano, TX, and clinical assistant professor of dermatology at the University of Texas Southwestern. His clinical interests include the treatment of vitiligo and other disorders of pigmentation, psoriasis, acne, atopic dermatitis, aesthetic safety in skin of color, and phototherapy. Dr. Desai is also the immediate past president of the Skin of Color Society and past president of the Texas Dermatological Society. He serves on the American Academy of Dermatology’s Board of Directors as well as the U.S. Food and Drug Administration Pharmacy Compounding Advisory Committee.

Please see INSIGHTS, next page
There are side effects associated with tranexamic acid, so it’s vital to take a detailed medical history of any patient in whom you are considering its use to ensure that they don’t have any history of deep vein thrombosis, pulmonary emboli, or hypercoagulability, that they aren’t planning on getting pregnant or nursing, that they aren’t taking oral contraceptives, and that they’re not a smoker. You want to make sure you document the medical record very thoroughly and review all of the potential side effects of tranexamic acid thoroughly.

However, if you do have a young, healthy patient with melasma, tranexamic acid can be a good option. We’ve seen some really impressive results with its use.

**Dermatology Times: How much of a concern is adherence to topical therapy regimens in melasma, knowing that patients are often having to apply one, two, or potentially three topical therapies at a time?**

**Dr. Desai:** Adherence certainly can be an issue. What I try to explain to my melasma patients is that the main driver of their condition is the fact that their body is making more melanin because the tyrosinase enzyme activity in their cells is being overactive. However, at other levels in that melanogenesis pathway, there are multiple different areas where melanin is either packaged, transferred, or modified, and it’s on those therapeutic targets that we need more data.

For example, we are starting to learn more about the transfer of melanosome from the melanocyte to the keratinocyte, the peroxidase enzymes, and the oxidation of melanin production. That’s where combination therapy comes in handy so we can target multiple levels of the disease.

For example, if a patient comes in with recalcitrant melasma, I will usually start them on triple combination topical treatment, antioxidants, and sunscreen. Follow up is in eight to 12 weeks. If they are not improving, we’ll talk about either continuing their current regimen and adding a second-line topical agent, such as azelaic acid, and moving on to tranexamic acid or trying a chemical peel.

**Dermatology Times: How commonly will you try a chemical peel in a patient with melasma? How would you characterize the success you have seen with its use?**

**Dr. Desai:** I have seen a great deal of success with chemical peels. In my opinion, chemical peels are somewhat of a lost art in dermatology. We are luckily talking about it more now. What I find really helpful about chemical peels is that you can tailor their use to a patient’s specific skin type and condition.

For example, there are often melasma patients who have concomitant acne, and salicylic acid peels are great for those patients because they help with oil reduction and unclogging pores, while also being beneficial for their melasma-related symptoms.

We are starting to see more studies using a combination of peeling agents. I will often combine lactic acid with pyruvic and glycolic acid into its own peel suspension. We’ve seen nice results with that combination.

In the literature, the data supporting glycolic acid is likely better than salicylic acid for patients with melasma, but I will still use salicylic acid in some cases, especially if I have an overly oily patient with blackheads, pustules, open comedones, and significant acne.

Mandelic acid is another chemical peel that I like to use, although it’s use for melasma is off-label. It comes typically in a variety of concentrations. Personally, I prefer 40% mandelic acid in my patients with melasma.

The important thing about the use of chemical peels in patients with melasma is that they need to be done every few weeks for at least four to five sessions before you’ll see noticeable improvement. One peel alone is rarely going to lead to a major improvement. The other thing you want to tell patients is that they need to stop using any topical retinoid or retinol-containing product at least one week before each chemical peel.

**Dermatology Times: What about laser surgery? Is that ever indicated for the treatment of melasma?**

**Dr. Desai:** Laser surgery for the treatment of melasma is somewhat controversial. In my practice, it’s the option of last resort. Some of my colleagues may disagree, but I don’t even bring up laser as an option until we’ve exhausted all of the other options we’ve discussed earlier.

When I opt for laser treatment, I use low fluence settings — typically 1.5–2 joules — and fairly small spot sizes. I’ll have patients come in for treatment every three to four weeks. That said, laser is rarely used in my personal practice for the treatment of melasma and, again, usually as a last option. That certainly may change with newer devices and, of course, more clinical study data.

The problem with laser treatment in melasma is that, in a lot of our patients with darker skin types, you run the risk of post-inflammato-ry hypopigmentation as well as relapse. There have been several studies showing that laser does work for the treatment of melasma, and especially now that we’re moving more into the use of picosecond lasers, there is increasing interest in their use. Once more data becomes available, I think we’ll have a better idea of the best settings for the use of laser in patients with melasma.

**Dermatology Times: Once the initial treatment of melasma is successful, regardless of the therapeutic approach that was taken, what steps do you recommend to your patients that may help them avoid a recurrence of the condition?**

**Dr. Desai:** This is something that is really important to discuss with melasma patients because the relapse rate is so high. One of the most important things I tell patients is that they need to do their best to avoid excessive sun exposure. Patients need to apply a broad-spectrum sunscreen with a minimum SPF of 30 or higher and reapply frequently. I also tell patients to wear a hat, seek shaded areas, and avoid very sunny or hot parts of the day.

I also talk to patients about the use of oral contraceptives and hormonal therapies and give them somewhat of a precautionary warning that these can exacerbate their melasma and possibly cause a relapse.

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Newer and emerging modalities are addressing the need for better therapeutic options for vitiligo, but there remains a broader need for dermatologists to understand the existing, useful therapies for this disfiguring, but undertreated autoimmune condition.

“Vitiligo affects an estimated 1% to 2% of the population, which is similar to the prevalence of psoriasis, and yet it historically has received relatively little attention. Consequently, it seems that too often, dermatologists in practice advise patients with vitiligo that they have a challenging condition for which there are no treatments,” says Victor Huang, M.D., assistant professor of dermatology, UC Davis Medical Center, Sacramento, Calif.

“Good treatment is available that can stabilize vitiligo and repigment the skin for many patients. Dermatologists should also be aware that targeted treatments for vitiligo are being developed based on understanding the cellular and molecular aspects of disease pathophysiology. These investigations hold exciting promise for providing interventions that can achieve repigmentation even in patients who did not respond to conventional approaches.”

Dr. Huang and Andrea Tovar, M.D., private practice, Uniq Dermatology, Monterey, Mexico, discussed medical and surgical treatments for vitiligo at the 2019 American Academy of Dermatology (AAD) Summer Meeting.

STANDARDS OF CARE

Phototherapy offers an effective treatment for vitiligo that can be used alone but is also a valuable adjunct to medical and surgical therapies.

“Phototherapy is a pillar of treatment for vitiligo that actually dates back to ancient Egyptian times as medical papyri describe combining ingestion of psoralen-containing botani-
MKTP results in 70% to 90% successful repigmentation. A response can be seen as early as six weeks, but repigmentation can continue over the course of a year, and so I usually do not consider repeating MKTP for at least one year.”

Andrea Tovar, M.D., Uniq Dermatology, Monterrey, Mexico

is being planned. Dr. Huang said this approach is particularly exciting because it targets the skin resident T cells that are thought to be responsible for the disease and the return of skin lesions after discontinuing conventional treatments.

“Lesional T cells in animal models of vitiligo and affected patients have been shown to display a resident memory phenotype. IL-15 promotes persistence of these T cells, and treatment with an antibody that targets IL-15 signaling has been shown to cause durable repigmentation in mice with established vitiligo and deplete the resident memory T cells from the skin,” Dr. Huang explained.

SURGICAL OPTIONS
Surgical interventions involving tissue or cellular graft approaches offer an option for treating vitiligo patients with stable disease.

“Establishing disease stability is critical before offering surgical treatment for vitiligo to limit the likelihood for autoimmune destruction of the transplanted melanocytes,” Dr. Tovar says.

Patients are considered candidates for surgical intervention if they have not developed any new or expanding lesions within the past year. Confetti-like lesions, trichrome vitiligo, and Koebnerization are other indicators of unstable disease.

“To determine disease stability, it is useful to obtain photographic documentation in patients with vitiligo considering that a recent study showed that patient recall has poor reliability,” Dr. Tovar says.

“A minipunch test graft can be done if there is any doubt about disease stability. If after eight weeks, there is a halo of repigmentation that extends at least 1 mm beyond the original mini-punch graft, patients can be considered candidates for surgical intervention.”

Conventionally, surgical therapy for vitiligo has involved tissue grafting techniques. Punch grafts and suction blister grafts are used most often in the United States. Split-thickness skin grafts offer another approach that is more commonly used abroad.

The choice between the tissue grafting techniques can depend on the area of vitiligo and physician surgical skills.

Punch grafting in which punch biopsies of 1 to 1.5 mm are taken from a donor site and transferred to the prepared recipient site is a technically simple technique that results in about 50% to 65% repigmentation after three months. Suction blister grafting can cover a larger area than punch grafting because the blisters used as donor tissue are larger (0.8 to 1 cm). It also affords better cosmesis at the donor site, and has been reported to result in 52% to 87% successful repigmentation.

Suction blister grafting is more technically complex and time-intensive than punch grafting because it involves separating the blister at the dermoepidermal junction to obtain the tissue for transplantation. However, a novel automated system designed for epidermal harvesting (Cellutome) can be a good option for dermatologists because it has a high graft viability, causes low patient discomfort, and is an easily operated device. Dr. Tovar says.

Melanocyte keratinocyte transplantation (MKTP), also known as non-cultured epidermal suspension (NCES), is a surgical technique that allows grafting larger vitiligo areas with less donor tissue. However, it is offered at a limited number of centers.

Dr. Tovar is the only dermatologist performing MKTP in Latin America. Dr. Huang says that UC Davis is building the infrastructure for MKTP and expects it will be introduced later in 2019. As of August 2019, it was currently only available in the United States at UT Southwestern Medical Center, Dallas, the University of Massachusetts, Worcester, Mass., and Henry Ford Hospital, Detroit.

The main benefit of MKTP is that it provides a very high recipient to donor ratio that enables treatment of much larger areas of vitiligo with less donor tissue, Dr. Tovar says.

“The recipient to donor ratio is just 1:1 with the tissue grafting techniques, whereas it is 1:5 or 1:10 with MKTP,” she explains.

In MKTP, donor tissue is obtained with either a split-thickness graft or suction blisters. The latter technique results in faster healing of the donor site with a more aesthetic scar and avoids the need for specialized personnel to separate the dermis from the epidermis in order to obtain the cellular suspension.

The suction blisters are incubated for a short time in a solution that enables separation of the epidermis. The blisters are placed into a test tube for centrifugation that creates a cellular pellet containing the melanocytes and keratinocytes. Next, the cellular suspension is transferred to the recipient site that has been prepared using either a carbon dioxide laser, dermabrasion, or erbium:YAG laser to the point of creating pinpoint bleeding.

“MKTP results in 70% to 90% successful repigmentation. A response can be seen as early as six weeks, but repigmentation can continue over the course of a year, and so I usually do not consider repeating MKTP for at least one year,” Dr. Tovar says.

“With all surgical procedures, additional treatment with NB-UVB phototherapy or excimer laser will result in better repigmentation.”

Disclosures
Dr. Tovar and Huang report no relevant conflicts.

Woods lamps photos showing a patient before and after treatment with topical 2% tofacitinib ointment. The patient achieved 100% repigmentation three months after initiation of therapy. Photos: Victor Huang, M.D.
New understanding yields new treatment possibilities

WHITNEY J. PALMER | Staff Correspondent

Historically, melasma has been a difficult-to-treat condition, confounded by hard-to-avoid sun exposure and characterized by flare rebounds. Recent research, though, is shedding light on how the hyperpigmentation occurs, cueing dermatologists into potential new treatment avenues.

Having a better understanding of what might cause the condition and being able to recognize it can help providers give patients the highest level of care possible, meeting their physical and mental needs.

“We know melasma is a therapeutically challenging condition because when you cease to treat it — or even during treatment — there can almost be a universal relapse with the current tools we have in our toolbox,” says Pearl Grimes, M.D., director of the Vitiligo and Pigmentation Institute of Southern California. “Ideally, we’d love to find something we can use to clear up the patient and get them in a sustained state of remission, but we’re not there yet.”

Still, she says, new data surrounding melasma is launching dermatology in the right direction.

THE PATHOGENESIS OF MELASMA

Sunlight is known to be a major player in melasma with ultraviolet light being a significant trigger, she says. But, new data also points to a role for visible light. By activating the exon 3 pathway on melanocytes, visible light triggers the dopachrome complex responsible for the sustained hyperpigmentation of melasma.

But, there’s more at play than sunlight exposure, says Seemal Desai, M.D., president of the Skin of Color Society.

“There is a good amount of data now that talks about melasma as almost an inflammatory skin condition,” Dr. Desai says, who is also the president and medical director for Innovative Dermatology in Plano, Texas. “It’s one of those things where we also want to mention to patients who have melasma that there is a vascular component to the disease.”

This increased vascularity causes blood vessel dilation. Different from what is usually associated with rosacea, he says, this vascularity appears to be mediated by mast cells. They degranulate chemokines, such as histamines and other proteins. Over time, that degranulation causes damage to the epidermal-dermal basement membrane junction, the area of tissues connecting the epidermal and dermal skin layers.

Other blood vessel markers, such as vascular endothelial growth factor, are found in higher levels in melasma-affected skin versus unaffected skin, Grimes says.

“When you look at these changes that have been identified, it suggests melasma probably represents a phenotype of photodamage,” she says. “It creates a paradigm shift in how we treat it.”

In addition to sunlight and vascular involvement, recent research also points to pollution as being a potential factor in melasma development, says Arianne Kourosh, M.D., MPH, a pigmentary disorder specialist at Massachusetts General Hospital.

“In urban settings, pollution could also damage the skin and give rise to hyperpigmentation,” she says. “This is important because it’s an external factor that might give rise to melasma or worsen it.”

Research published in the *Journal of Drugs in Dermatology* revealed airborne particulate matter and polycyclic aromatic hydrocarbons can enter the skin and create quinones that produce reactive oxygen species that lead to skin pigmentation. The results also highlight increased rates of melasma among patients with skin types III-VI in areas with documented high pollution levels, including India and South East Asia.

“THERE IS A GOOD AMOUNT OF DATA NOW THAT TALKS ABOUT MELASMA AS ALMOST AN INFLAMMATORY SKIN CONDITION.”

Seemal Desai, M.D., president, Skin of Color Society
RECOGNIZING MELASMA

Overall, dermatologists can recognize and diagnose melasma by one clinical feature — symmetry.

“Melasma tends to be a predominantly symmetrical hypermelanosis. It affects both sides of the face,” Dr. Desai says. “And, if it’s going to be extrafacial, such as on the forearms, it’s important to note that symmetry before making a diagnosis.”

Mostly, melasma appears only on certain parts of the face. It is generally centrally located, covering areas laterally across the cheeks and in front of the ear. Overall, he says, it is respectful of facial bony contours, rarely impacting any spots above the cheek bone or in the periorbital area.

These characteristics can help dermatologists avoid a misdiagnosis. For example, while patients with acanthosis nigricans experience lateral hyperpigmentation, it is concentrated in the hollows of the cheeks. And, hyperpigmentation found on the lateral parts of the temple or the forehead is most frequently associated with either drug-induced hyperpigmentation or lichens planus pigmentosus.

THE PSYCHOSOCIAL IMPACT

Alongside addressing the physical nature of melasma, it’s also vital for dermatologists to hone in on how the hyperpigmentation affects a patient’s mental state. For many patients, these skin changes can be distressing, pushing them to wear heavy make-up or avoid going out in public, Dr. Desai says.

“This isn’t the way we should encourage our patients to deal with hyperpigmentation,” he says. “We want them to feel comfortable in their own skin, and sometimes that requires counseling.”

Dr. Grimes agrees. But, although she readily brings in a counselor to talk with patients who struggle with melasma’s emotional and psychosocial impact, she says her first strategy to help patients develop a healthy perspective about their condition is education. Explaining the chronic nature of the condition, as well as the potential treatment options, is critical to helping them both learn how to manage the condition and feel more comfortable with it.

“Whereas, we should never be cavalier and tell patients, ‘It’s just melasma, you’ll be fine,’” she says. “You need to have empathy and compassion for the patient while doing your best to offer them effective treatment.”

For some patients, though, the psychosocial angst associated with melasma doesn’t come from within. Providers should also be aware melasma can present a cultural component, says Dr. Kourosh.

“Dermatologists need to be culturally sensitive. In certain cultures, there is significant pressure on patients to have light skin,” she says. “For that reason, having hyperpigmentation can be additionally distressing. That’s why it’s important from the outset to establish healthy goals for treatment — specifically the goal is to have a healthy, even skin tone, not to have light skin.”

Regardless of the reasons behind why a patient experiences distress when learning they have melasma, Dr. Grimes says, dermatologists shouldn’t be timid when utilizing the resources necessary to deliver the highest level of care while helping patients process their diagnosis.

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Treatment toolkit expands

Physicians have more solutions for managing melasma

WHITNEY J. PALMER | Staff Correspondent

As a hyperpigmentation condition known for relapses, melasma is a chronic condition that requires dermatologists to effectively manage patient expectations while trying to treat the skin. “As providers, we want to underpromise and over-deliver,” says Emil Tanghetti, M.D., founder of the Center for Dermatology and Laser Surgery in Sacramento, Calif. “Melasma is a very challenging disease to treat because there are many factors that impact it.” Consequently, dermatologists need a hefty arsenal of treatment options to provide patients with the highest level of care possible. Fortunately, he says, the toolkit is expanding. While many long-standing therapeutic recommendations are still part of standard treatment, the industry is expanding the methods and products it uses to combat the day-to-day impacts.

LONG-STANDING THERAPIES

**Sunscreen:** For decades, sun protection has been the first therapeutic option prescribed to patients upon a melasma diagnosis, says Pearl Grimes, M.D., director of the Vitiligo and Pigmentation Institute of Southern California. Historically, most attention has been given to protecting patients from UV light, but recent research indicates visible light, particularly low-spectrum blue light, also exacerbates hyperpigmentation.

Consequently, dermatologists should encourage patients to choose sunscreen and cosmetics that contain iron oxide, such as those from Dermablend, she says, because it can effectively block out both UV and visible light. “I have patients mix it with their regular make-up or sunscreen to be able to give them some additional protection against visible light,” she says.

**Hydroquinone:** Hydroquinone has been a standard topical monotherapy for melasma for nearly 60 years. For many patients, it can still be the most efficacious treatment option because it interferes with the melanin production, leading to lighter skin. It’s available with a prescription as a 4-percent concentration topical, and it’s most often used with patients who have moderate-to-severe disease.

NEWER THERAPEUTIC OPTIONS

‘To maximize treatment options for melasma, the industry is

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**Quick Takes**

Sunscreen with iron oxide can block UV, visible light that affects hyperpigmentation.

Hydroquinone is most effective, but new agents show promise for patients that need to stop using the topical.

Peels and laser treatment can be effective when used correctly, but use should be limited to winter.

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“This is just the beginning of . . . new and better products to therapeutically treat this challenging condition.”

Pearl Grimes, M.D., Vitiligo and Pigmentation Institute of Southern California, Los Angeles.
exploring new nonhydroquinone options that are equally effective.

“It’s been a great paradigm shift for me, knowing that now, in addition to having new agents that are as effective as primary agents in patients, I can also use them when I need to get patients off hydroquinone,” Dr. Grimes says. “It’s a way to work to keep the patients in remission.”

Dr. Seemal Desai, M.D., president of the Skin of Color Society. It’s available both topically and orally and can be considered in patients where hydroquinone or other combination topical therapies have failed. Products containing tranexamic acid can also be used for maintenance after patients achieve sufficient clearing via hydroquinone, though they can experience a melasma flare when they come off tranexamic acid products.

Use it cautiously, however, and avoid it with patients with a history of skin disorders, as tranexamic acid can also be used for maintenance after patients achieve sufficient clearing via hydroquinone, though they can experience a melasma flare when they come off tranexamic acid products.

“There’s a concern, but, as dermatologists, we use it in lower concentrations than what’s used to control hemorrhage,” Dr. Grimes says. “It absolutely works, but get a thorough patient history if you’re going to use it.”

The standard dose is between 250-500 mg twice daily, but only a 650 mg pill is available in the United States. Desai recommends patients split the pill between morning and night. Topicals treatments are available in 2 percent and 3 percent concentrations.

Dr. Seemal Desai

Cysteamine: This nonhydroquinone topical cosmeceutical is made from the amino acid precursor cysteine. The 5-percent cream, which produces a sulfuric odor, contains cysteamine hydrochloride that can inhibit melanin synthesis. Although additional research is needed to determine how it works, Dr. Desai says, “it’s proven to be an effective option for melasma treatment. Patients apply it like a mask that must be washed off.

Heliocare: This oral antioxidant offers an extra layer of protection against free radicals in sunlight, infrared light, and visible light that can damage the skin. It is not a replacement for sunscreen, however, and should be used in conjunction with sunscreen that offers UV protection, Dr. Grimes says.

RESURFACING PROCEDURES

Overall, resurfacing procedures, such as peels and lasers, are not recommended as first-line defenses against melasma. And, in many cases, they will be more effective during certain times of the year when patients can exert more control over their levels of sun exposure, Dr. Tanghetti says.

“Most devices used for resurfacing are probably better used in the winter because it’s too easy for patients to be stimulated by the sun during the summer,” he says.

But, peels and laser treatments can be effective when employed properly.

Peels: While peels should never be used as a primary or monotherapy, Dr. Grimes says, they can be used in conjunction with an appropriate topical regimen that fits a patient’s specific needs. In most cases, they are a safer option than laser treatments because melasma-affected skin is very fragile and easily irritated. Peels are a less aggressive treatment that are less likely to launch patients into post-inflammatory hyperpigmentation that can be even more difficult to treat.

Lasers: Do not use lasers as a primary or secondary treatment option. But, for patients with recalcitrant disease, Dr. Desai says, a low-frequency Q-switch laser can be effective, and new research has also shown that narrow pulse width picosecond lasers can reduce the appearance of melasma.

COMBINATION THERAPIES

Microneedling/Tranexamic Acid: Studies are underway to determine whether combining microneedling and tranexamic acid topicals can be a more effective in combatting melasma. The small channels created by microneedling can potentially allow the tranexamic acid to penetrate deeper into the skin.

Overall, whether the treatment is oral, topical or device-related, the industry is actively creating therapeutic options to help patients control the skin condition.

“We are working on getting better agents to treat melasma. This is just the beginning of, hopefully, a tsunami of new and better products to therapeutically treat this challenging condition,” Dr. Grimes says. “It’s coming. I think the train has left the station, and it’s moving fast.”
Do CME, certifications improve patient safety?

STEPHANIE STEPHENS | Staff Correspondent

Physician education and initial certification improves outcomes.

Physician knowledge and ability to recognize gaps that affect outcomes declines over time.

CME and MOC show mixed results in affecting outcomes and patient safety, with “a big maybe” as to whether they improve patient safety.

More research and changes are needed as noted by the Vision Initiative.

Quick TAKES

T o err is human,” says Abel Torres, M.D., J.D., M.B.A., professor and chairman of the department of dermatology, University of Florida, Gainesville, Fla., and past president of the American Academy of Dermatology, reminding an audience at the 24th World Congress of Dermatology in Milan of a 1999 Institute of Medicine report.

Assessing patient safety is in the eye of the beholder, he says. Patients interpret safety as how they can prevent being harmed; the government, regulators and insurers look at how to prevent cost of that harm; and physicians consider how to improve outcomes of care for patients to prevent harm.

Since most data looks at outcomes, Dr. Torres says he uses outcomes as a proxy for discussing safety, and he raises logical questions about the impact of continuing medical education (CME) programs and certification programs on the improvement of patient safety.

BOARD CERTIFICATION

Multiple studies have shown that voluntary board certification is associated with higher quality care in numerous specialties. Dr. Torres cites a meta-analysis prior to July 1999 with 16 findings showing a positive association between board certification and quality of patient care, and two surgery studies also linking initial board certification with better outcomes.

However, Father Time takes its toll on everyone. One review of 62 studies showed that physician knowledge, skills and compliance with evidence-based care and outcomes tends to decline as a function of time. Also critical, multiple studies have shown that physicians often can’t accurately identify this decline and accurately address it. This correlates with other studies showing that the incidence of adverse licensure actions increases as a function of time and the harm leads to malpractice claims.

MOC AND CME CONUNDRUMS

Dr. Torres explores the conundrums in the context of four parts of the United States maintenance of certification (MOC) format that address the following:

#1 COMMUNICATION

Research underscores the relationship between communication skills and physician patient outcomes. However, research on improving physician interpersonal and communication skills also has yielded mixed results, casting doubt on how well this problem can be fixed or measured.

#2 CONCERNS ABOUT CME ACTIVITIES

Past studies showed a small-to-moderate association between CME formats and improvement in patient health outcomes. The Institute of Medicine (IOM) reported in 2010 that “there are major flaws in the way continuing education…is conducted, financed, regulated, and evaluated.” Furthermore, externally-guided self-assessment is important given what’s known about inaccurate physician self-assessment. Yet there is substantial and more recent positive data celebrating CME effectiveness, including a Cochrane review that revealed a positive cor-

“Assessing patient safety is in the eye of the beholder.”

Abel Torres, M.D., J.D., M.B.A., University of Florida, Gainesville, Fla.
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7 tips to get the most from your posts

STEPHANIE STEPHENS | Staff Correspondent

Quick TAKES
Plan ahead and create a mix of media: articles, pictures, videos, etc.

Post consistently.

Be human.

What used to be “the wild, wild west” of social media has evolved to a more familiar landscape, but it requires a savvy approach in order to make the most of this tool, says Doris Day, M.D., of New York, who presented on the topic at the recent Music City SCALE meeting in Nashville, Tenn. Dr. Day, who describes herself as a dermatologist, artist, journalist and world traveler, has embraced social media with a vibrant presence on Facebook, Twitter, Instagram and YouTube.

As you ponder “What is appropriate for a medical doctor to post on social media?” you might also ask yourself these two questions, she says:

- How much of your story is about you, the person?
- How much is about your professionalism?

If you’re already active on social media, you may be driven by “likes” and the level of interaction between you and your followers. It’s true that more engagement usually yields more followers. And if you’re not active, but think you want to be, you, too, can consider Dr. Day’s advice to make the most of being social.

#1 BE CONSISTENT
- Post regularly, daily or weekly, and ideally at the same time. People will know when to look for you.

#2 DON’T OVERDO
- You needn’t spend hours constructing and editing videos. You’re already busy enough. Just ensure that your content is authentic and keep up with technology as best you can.

Dr. Day uses the Canva program for graphics. “It definitely can be challenging at first, but stick with it, and it gets easier,” she says.

#3 THINK, THEN POST
- Think ahead about what you want your post to say and how it should look. Go for an interesting mix of content. If you choose engaging content, add a picture or graphic to go with it — you can locate plenty for free.

#4 RELATE AND BE YOU
- Dr. Day wants patients to get to know her as a human being who’s relatable. She also shares when something nice happens in the office, or someone wins an award, or she sees a beautiful flower or scene that marries perfectly with an inspirational quote, ideally relating to dermatology. She might share a special family moment.

“If I think this is interesting, I’m hoping my followers will too,” she says. “Content should be a reflection of who you are.”

#5 SHARE THE NEWS
- Yes, she posts about the latest science and trends in dermatology, for that’s her expertise and patients want to see more. When they are links to articles, they usually run on her Facebook or Twitter pages or as part of the Linktree on her Instagram pages. Linktree is a free tool for optimizing your Instagram traffic. This summer, for example, she’s posted about ticks and mosquitoes — research and safety tips. Post articles in which you’re quoted, and those that you think readers will like from other news sources, she says.

#6 STAY THE COURSE
- Don’t get too graphic, for the average person isn’t a physician. “Remember, too that representatives from RUC (RVS Update Committee) and others you might not expect look at your content,” she says. “When you post a procedure, you may be ‘giving away the magic,’ and you can alienate a potential patient, or you may be giving the wrong impression about how complicated, or not, a procedure may be.

Content should be a reflection of who you are.” Doris Day, M.D., New York
relation in patient outcomes and an AHRQ review showing that CME impacts knowledge retention, professional skills, practice behaviors and patient outcomes.12

#3 COGNITIVE EXPERTISE
A substantial body of research supports the validity of initial certification examinations and the impact on patient outcomes. Yet, the data to support the value of recertification exams is weak at best, with most studies having focused on initial certification testing.

#4 PRACTICE IMPROVEMENT ACTIVITIES
Randomized comparative trials found practice improvement modules can help facilitate improvements in care. But a primary limitation of these activities is the time, effort and cost required relative to the improvement.

VERDICT FOR CME AND MOC
Data on whether MOC helps is weak, and most shows mild-to-moderate improvement, at best, in terms of patient outcomes. Just as important, a number of more recent studies could not show that MOC participation was associated with a difference in quality of care or patient outcomes. Recently a large study looking at national Medicare claims complications for eight elective procedures showed that board-certified surgeons were less likely to be outliers, but completion of MOC was not associated with differences in complication rates.13 Dr. Torres says this speaks to both CME and MOC because MOC actually incorporates CME.

A NEW ‘VISION’ FOR MOC
On Feb. 12, 2019 the 27-member Continuing Board Certification: Vision for the Future Commission, representing the American Board of Medical Specialties (ABMS)—among many other constituents and including a survey of 34,000 physicians—recommended that the term “maintenance of certification” be abandoned in favor of a new term, but still invoked the importance of lifelong learning.14

According to Dr. Torres, key takeaway points from the report were:

- There are gaps in research evidence that conclusively demonstrate that MOC results in better patient outcomes, so do more research.
- Better data sharing between the ABMS with societies, CME and licensing bodies can better help identify gaps and reduce burdens.
- Practice improvement activities are onerous or difficult to implement for some diplomats.
- Highs stakes exams should be revisited. Overall, Dr. Torres offers these insights on the current landscape:

  - The modern world of the internet and the rapid pace of new information demand a new paradigm.
  - Research shows physician deficits are critical factors in medical errors and poor quality healthcare, and a recent study by the American Board of Internal Medicine suggests that declining knowledge is more reflective of a failure to acquire new knowledge. Thus, once a basic minimum fund of knowledge is established by initial certification, this may, in fact, be sufficient for a physician to access new knowledge.
  - In light of the mixed results regarding CME and MOC, it may be best to not concentrate on a physician’s ability to “cram” more knowledge that will quickly be outdated.
  - Instead, measure a physician’s skills at rapidly accessing and utilizing new knowledge and using modern tools such as computers, cell phones, tablets and the internet.

Consider research on how this type of approach improves patient outcomes and safety.4

References
Antibiotics play a significant role in the treatment of multiple dermatologic conditions, with a long history of proven efficacy and a well-known safety profile. However, there are also important downsides to their use and, particularly, their overuse. Antibiotic resistance has become a worldwide problem, and many published guidelines urge caution when prescribing antibiotics for an extended period of time.

In this conversation, two experts discuss the rationale behind antibiotic stewardship among practicing dermatologists and detail their approaches when utilizing these medications in clinical practice.

James Del Rosso, DO: One of the things that I’ve observed is there are different camps when we talk to our colleagues in dermatology regarding antibiotic resistance. There are those who are aware of it and try to treat their patients responsibly to the best of their ability, and then there are those who say, “I just don’t see it,” or “I don’t believe that it makes a difference in my patients at these small doses.”

Dr. Baldwin, what is your observation regarding your colleagues’ opinion of antibiotic resistance?

Hilary E. Baldwin, MD: I equate the dermatology community’s response to antibiotic resistance to the overall population’s response to global warming. You have people who recognize that it exists and are doing the best that they possibly can to combat it. Then you have the folks who are nonbelievers and say that they need more data. They aren’t buying into the whole concept of antibiotic resistance.

At this point, I’m not sure what more data they need. I don’t know how one “sees” antibiotic resistance, at least not visually. It’s not as if the bacteria have a scarlet R on their chest. It’s a real challenge for us to find a way to bring our community together so that every dermatologist has a healthy respect for the phenomenon of antibiotic resistance and is able to recognize the problem on a daily basis within their clinical practice.

Dr. Del Rosso: I see opinions changing, albeit slowly. Obviously, antibiotics are important. In some circumstances, they can be lifesaving. They don’t pack quite that big a punch in dermatology, but we use them a lot to treat infections and inflammatory diseases such as acne and rosacea.

Dr. Baldwin: I think that the people who were on the fence four to five years ago about the impact of antibiotic resistance in dermatology have switched over to being believers, but I’m still worried about that group that doesn’t “see resistance.” I’ve had a hard time making headway with them.

Dr. Del Rosso: When I use an antibiotic in my patients with acne, it’s typically one of the tetracycline derivatives such as doxycycline or minocycline. What I find important is to discuss your exit plan as soon as you write the initial antibiotic prescription with patients. That involves setting a timeline for the drug’s use and planning for its removal.

Is that something that you prioritize as well?

Dr. Baldwin: I agree that the development of an early antibiotic exit strategy is vital. We have to make sure that our patients recognize that although the antibiotics may serve as the heavy lifters initially to get their symptoms under control, we can’t use them chronically to manage their condition.

What I tell my patients is that we are going to use an antibiotic for a maximum of two to three months, so they better get used to using topical agents as well from the very start. While there are times I will extend the use of the antibiotic beyond that three-month period, the whole point of that initial conversation is so that patients recognize the importance of topical agents as our long-lasting maintenance therapy.

What I always find interesting when I’m talking to a patient who has been prescribed an oral antibiotic as well as two topicals is that they’ll tell me, “I just took the pills because the topicals weren’t working.” I ask them why they came to the conclusion that it was the antibiotic that was helpful and not the topicals, and they don’t usually have a good answer.

Dr. Del Rosso: A significant proportion of our use of antibiotics in dermatology comes when we are treating acne and rosacea. I know a lot of us use oral antibiotics to kickstart therapy, but how do you decide when the antibiotics aren’t working well enough and it’s time to shift to something else, such as oral isotretinoin?

Dr. Baldwin: I consider myself to be an early transitioner away from antibiotics. If I’m convinced the patient is adherent to their regimen of the oral antibiotic and topical medications and they aren’t improving, I’ll often switch to oral isotretinoin after the first or second follow-up visit. In women, hormonal therapy is also an option. I don’t find it useful to continue trying with an oral antibiotic for too long if it is clear that it is destined to fail.

Please see ANTIBIOTIC, next page
Dr. Del Rosso: There was a paper in 2016 from New York University that reviewed patient records to look at the duration of systemic antibiotic use in patients with inflammatory/nodulocystic acne who eventually required isotretinoin. Some patients were treated by different clinicians for their acne over time. The study authors found that a significant percentage of these patients — 66.2% — had been treated with an oral antibiotic for at least six months and 33.6% of patients for longer than one year. A lot of patients were treated with antibiotics multiple times and at multiple centers during the period of the records review. That study really hammered home how frequently some of our patients are exposed to oral antibiotics.

Dr. Baldwin: The study authors also pointed out how foolhardy we are when a patient comes to us who, for example, used doxycycline in the past that didn’t work particularly well. Yet we’ll try it again thinking that, because we wrote the prescription, it will magically work better the second time around instead of jumping right to oral isotretinoin. Logically, that makes no sense.

Dr. Del Rosso: When we’re treating acne, antibiotics have a known effect in impacting the bacterium that we now call *Cutibacterium acnes*. But in rosacea patients, we aren’t using antibiotics to treat any specific bacterium. Instead, their impact is limited to anti-inflammatory mechanisms. Consequently, will you use antibiotics differently in rosacea versus acne patients?

Dr. Baldwin: Absolutely. I almost never use full-dose antibiotics in my rosacea patients. For years, I would use doxycycline, but since the introduction of topical ivermectin, we now have a choice of agents that are equally efficacious. I use doxycycline and ivermectin both independently and in combination, but I will very rarely prescribe a full antibiotic dose of doxycycline.

Dr. Baldwin: For years, both you and I have been harping on the importance of using benzoyl peroxide and never using an antibiotic as monotherapy in acne patients. I think it’s starting to catch on. One of the problems with benzoyl peroxide is that patients complain about the way in which it bleaches fabric, and a lot of clinicians are loathe to prescribe it because they get so much pushback from their patients. I think we need to learn not to give in so easily because benzoyl peroxide works well in acne patients and can prevent or reverse the development of resistant bacteria.

Dr. Del Rosso: That’s a great perspective with which to end our discussion. I hope we’ve been able to offer insight for the dermatology community today that will force clinicians to think about their current and prospective future use of antibiotics in their acne and rosacea patients.

References
“There is no technology or marketing in the world that will fix a practice with broken people and broken processes.”

Adam DeGraide, CEO, Crystal Clear Digital Marketing, Orlando, Fla.

A bullet-proof marketing strategy

LISETTE HILTON | Staff Correspondent

Marketing campaigns might vary by practice but successful marketing always comes down to addressing three key issues, according to Adam DeGraide, CEO of Orlando, Fla.-Based Crystal Clear Digital Marketing.

- Finding a higher quality and quantity of patients.
- How to sell or serve patients.
- And most importantly how to keep patients.

A practice marketing strategy that focuses on DeGraide’s “find, serve, keep” strategy can’t fail, he tells Dermatology Times. That’s because in order to find, serve and keep patients, practices have to focus on the fundamental strength of excellent customer service.

THE PHONE CALL

DeGraide says the most important part of any bullet-proof strategy has nothing to do with social media, email or search engine optimization (SEO). Rather it comes down to how well the people in the practice answer the phone.

“You’d be amazed at the difference from one practice to the next — even from one staff member to another,” he says.

DeGraide says Crystal Clear Digital Marketing has captured thousands of dermatology and other practice phone calls in recent years. While some staff members might answer the call introducing themselves and asking callers how they can help, others answer with an unwelcoming, generic “doctors’ office” response.

Having a bullet-proof marketing strategy starts with finding, serving and keeping people when they call, says DeGraide.

“We’ve listened to the calls and realized that the average time it takes a person at the phone from a dermatology practice to say, ‘And who do I have the pleasure of speaking with today?’ is 2 minutes, 34 seconds,” DeGraide says.

Instead, the majority of calls result in a flurry of quick questions, like date of birth, but staff tend not to establish a rapport with the caller, which is vital to marketing success.

SIMPLE BULLET-PROOF STRATEGIES

DeGraide recommends these simple bullet-proof strategies:

- “You need to have a website that is well built and mobile responsive. Highlight the features and procedures at the dermatology practice that you want to grow and want people to be aware that you offer. It’s really not rocket science. You have to have phone numbers, social media links, forms. And it has to be maintained on a weekly if not monthly basis. It has to stay fresh,” he says.

THE ULTIMATE TEST:
Have you listened to how your staff handle incoming phone calls lately?

3 Things You Can Do

1. Implement a software that captures every inbound phone call and forms in real time.
2. Actually listen to those phone calls. “We highly recommend that dermatologists hide their weapons and drink an adult beverage before they start doing that,” DeGraide jokes.
3. Sit with your team on a regular basis and train and practice together. Pull up the software, listen to the leads, listen to the phone calls together and role play to improve customer service.
Once medical training ends and the time comes to negotiate a job offer, you may realize that you haven’t been prepared for this part.

“People can be scared to negotiate, especially their first offer, because they think it’s going to cost them the job,” says Ron Lebow, senior counsel at the health practice firm of Greenspoon Marder, LLP, in New York. If you’re surprised and suffer a major setback with the first contract, you may hire a lawyer to breathe life into the boiler-plate document the next time.

This usually happens to most newly-employed physicians, Lebow says.

“The practice lawyer drafts a lengthy legal document that’s hard to understand. The practice owner thinks, ‘I’m hiring this doctor and here are his salary and benefits.’ It’s very unilateral, in favor of the employer, who also may not totally understand that document.”

However, the interaction should be a two-way street.

Don’t forget that, as a new hire, you have leverage — often because the hiring physician has motivation for a better lifestyle. Maybe the hiring physician has too many patients and wants more time with them, plus there’s a desire to make a profit while paying you, says Lebow.

FINE TUNE THE DETAILS

“Be sure the contract has language or provisions for how things might change, for pay increases and a time when partnership will happen,” he says.

Many contracts contain termination clauses stipulating that an employee may be terminated at any time, with 30 days’ notice.

“Don’t get hung up on these terms, but pay attention to future prospects, which includes finding out what and when you get paid now,” Lebow says.

Pay is typically determined one of three ways, he says. It’s

What to know before you sign

Expert insights into negotiating employment contracts

STEPHANIE STEPHENS | Staff Correspondent

Quick TAKES

Pay attention to the details and include language for pay increases and partnerships.

Make sure you understand the terms of your bonus plan and what happens if you leave.

If you need clarification, get a contract lawyer, accountant or consultant to help you.
Next, be active on social media platforms that reach the people you want to reach. It makes sense, according to DeGraide, that dermatology practices wanting to attract cosmetic and even medical patients should consider being on Instagram, Facebook, Twitter, Pinterest and LinkedIn.

Being active on social media means having an SEO strategy, which requires that dermatologists write lots and lots of content to educate people about everything from skin cancer screening and preventive maintenance, to acne treatments and elective aesthetic procedures.

Finally, DeGraide suggests practices run their marketing through customer relationship management (CRM) software. CRM software — which is different than practice management software or the electronic medical record (EMR) — helps practices build and promote to a database of people that aren’t yet patients. It allows dermatologists to manage and automate those processes in a practice, he says. Crystal Clear Digital Marketing has developed CRM software specifically to serve the needs of their clients.

“Your have to actually make sure you have people and processes in place to convert the phone calls and forms into patients who come in for consultations and provide a five-star consultation, so they become patients. And provide five-star service and care, so they get the results that you talked about. And then they leave the practice and become what we call a raving fan of the practice,” he says.

WHERE DOCTORS GO WRONG

The biggest hurdle many dermatologists have for building a bulletproof marketing strategy is themselves, according to DeGraide.

“Typically, the dermatologist will abdicate, not delegate, the responsibility of marketing to somebody that might not have any real vested interest in the process,” he says. “I’m not suggesting you can’t delegate the responsibility, but you still have to monitor it. You still have to be involved in it and care about it.” Dermatologists, he says, should avoid “the check box mentality.”

“The doctor who owns the dermatology practice will say: Do I have a website? Check. Do I have an SEO company? Check. Am I doing social media posts on a regular basis? Check. Do I send out emails to my existing and prospective patients? Check. Am I using technology to help me? Check,” DeGraide says. “But there’s typically a check box that’s not filled out and that’s: When was the last time I sat and listened and trained my staff on how I want my practice to be represented on the phone when we reach out to these people?”

The bulletproof bottom line: Dermatologists have to care about and oversee practice marketing, according to DeGraide.

“There is no technology or marketing in the world that will fix a practice with broken people and broken processes,” he says.

Contracts: What to know before you sign

either by your base plus percentage, pure percentage, or by the greater of both and a guaranteed minimum amount.

“The reason is the practice is not sure how busy you’re going to be,” Lebow says. “They bring you in, promote you, and hope you ramp up the business.”

BONUS PLANS

An employer may do a percentage bonus based on a number anywhere from two to two-and-a-half times the employees’ base salary.

“You get a piece of all income above the threshold, which needs to be reasonable,” Lebow says.

Percentages usually start at 40 and then rise to 45 and 50, he says. So if base is $200,000, the offer might be 40% of every dollar above $400,000 — two times the salary. Your bonus begins at $401,000. Maybe the percentage is 45 if the doctor reaches $750,000, and 50% above $1.2 million.

“If you leave, be sure your agreed-to threshold is prorated,” he says.

Bonuses can be annual, paid 30 to 90 days after year-end, but being paid quarterly or monthly yields more income, Lebow says.

“An employer may want you to reach an annual threshold, then advance you money every quarter, based upon the prorated threshold,” he says.

Beware of not getting credit for accounts receivable that are collected after you leave.

“If the bonus is based upon the percentage of your revenues, most employers won’t pay even though you billed for it before you left,” he says. “You could leave tens of thousands behind.”

COVENANT RESTRICTIONS

Don’t let your contract restrictively stipulate that you can’t work within 20 miles of your former employer company’s offices if you leave—they could have five locations.

“Understand the circumstances by which you can get out, because it’s expensive to litigate,” he says.

Maybe you can complete a 120-day probationary period to test the waters.

“Request that covenants not apply to other non-competing, part-time gigs,” Lebow says.

PICTURE THE PERFECT PARTNERSHIP

“An increasing number of dermatologists ask about partnership terms but they don’t really understand what that means,” says founder Kimberly Campbell of Dermatology Authority, who collaborates with Lebow. “Practice owners may initially say they’ll offer this; they don’t. And the new physician is left dangling. Get a date in writing for partnership discussions,” she suggests.

“Just get an answer, and if you don’t care, ask anyway,” Lebow adds. “That says you’re in it for the long haul and invested, even if you want to go on your own.”

“Also,” Campbell adds, “Ask what happens if the practice is sold to a hospital, multi-specialty group or private equity company.”

If “contract speak” feels daunting, and you’re short on time, you do have help, Lebow says. Ask for it from not only lawyers, but also from recruiters and accountants.

"Be sure the contract has language or provisions for how things might change, for pay increases and a time when partnership will happen.”

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It’s every physician’s worst nightmare: Receive payment for services rendered, but then a payer identifies an aberrant pattern in claims data, audits the records, decides it has overpaid the practice, and recoups those funds. That money you already allocated for overhead, staff salaries, bonuses, or new medical equipment? Gone. With one post-payment audit, you now owe thousands of dollars or more. The good news is, physicians can take steps to focus on accurate billing and avoid costly recoupments. This article explores five billing vulnerabilities and provides tips to maintain compliance.

E/M CODING: FOUR TIPS TO SELECT THE CORRECT LEVEL

Payers don’t usually deny evaluation and management (E/M) codes on the front end, says Toni Elhoms, CCS, CPC, a provider coding and education consultant in Denver. It isn’t until they look at the totality of the data retrospectively—long after physicians are paid—that financial penalties ensue, she adds. “Payers are like the IRS,” says Elhoms. “You don’t want them on your back because recoupments are insidious. They come out of nowhere.”

Consider the difference in reimbursement for established patient office visits levels 2 versus 3 (i.e., CPT codes 99212 and 99213)—approximately $29. Let’s say 10 to 20 times per week over a year, a physician bills 99213 when their documentation only supports 99212. They’ll be paid initially, but likely have a $15,000-$30,000 recoupment on their hands if a payer uncovers the error during a post-payment audit.

Here are four tips to help physicians avoid denials due to incorrect E/M levels:

**Tip #1—**
ENSURE THE E/M CODE SUPPORTS THE SPECIFIC PATIENT ENCOUNTER.
Not every patient with asthma, for example, will justify reporting CPT code 99213, says Elhoms. Some cases may be exacerbated and/or require medication management and referrals to specialists while others may be relatively straightforward and controlled.

**Tip #2—**
REFER TO THE E/M GUIDELINES
Assigning an E/M code is not a subjective process. Instead, physicians should...
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Coding tips to avoid denials

Refer to the 1995 or ‘97 E/M guidelines that include specific requirements for time-based billing as well as billing based on the three key components: history, exam, and medical decision-making, says Elhoms. She says the most common mistake physicians make when applying these guidelines is under-documenting E/M level 4 and 5 visits for new patients. More specifically, they omit one or more systems in the requisite general multi-system exam or they omit a complete past family and social history.

**Tip #3—**
**USE COPY AND PASTE FUNCTIONALITY WITH CAUTION.**

Copy and paste can save time, but it can also cause serious compliance problems, says Elhoms. That’s because when physicians automatically bring historical information from a previous encounter forward into their current note, they may inadvertently inflate the E/M level. Best practice is to validate any information copied forward to ensure it’s accurate and relevant to the current encounter—or turn off the functionality altogether, she adds.

**Tip #4—**
**WATCH OUT FOR PRE-POPULATED EHR TEMPLATES.**

Pre-populated templates not only lead to upcoding (e.g., if certain body systems are always indicated as having been reviewed even when they’re not relevant to the current encounter), they can also lead to contradictions that raise red flags with payers, says Elhoms. For example, a physician diagnoses a patient with strep throat. If the template defaults to a normal exam for ear, nose, and throat, this could open the door for a post-payment audit. Physicians should ensure their documentation is aligned with the patient’s diagnosis even if it means manually unchecking certain boxes in the template.

When physicians report prolonged services (i.e., CPT codes 99354 [first hour of the prolonged service] and 99355 [each additional 30 minutes]), they signal to payers that more time was necessary, says Patel. More specifically, documentation should include the following:

**TOTAL DURATION OF THE FACE-TO-FACE VISIT**

1. **START AND END TIMES OF THE FACE-TO-FACE PROLONGED SERVICE**
2. **SPECIFICALLY WHAT WAS DISCUSSED WITH THE PATIENT DURING THE ADDITIONAL TIME**
3. **PATEL PROVIDES THESE THREE ADDITIONAL TIPS FOR REPORTING PROLONGED SERVICES CORRECTLY:**
   - Always report a prolonged service code with an E/M code. Prolonged services cannot be billed alone because they are ‘add-on’ codes.

**INCIDENT-TO BILLING: KNOW THE REQUIREMENTS TO ENSURE COMPLIANCE**

Incident-to billing enables non-physician providers to bill services under a supervising physician’s National Provider Identifier (NPI) rather than their own NPI so the practice can collect 100 percent of the Medicare physician fee schedule amount, rather than 85 percent. However, incident-to billing has several requirements that, if unmet, can cause costly recoupments during post-payment audits, says Jamie Claypool, CPC, CPMA, practice management consultant at J. Claypool Associates Inc. in Spicewood, Texas.
WHEN APPENDED TO A CPT CODE, MODIFIERS PROVIDE ADDITIONAL INFORMATION ABOUT HOW Payers SHOULD REIMBURSE CERTAIN SERVICES. CONSIDER THE FOLLOWING:

Three tips to avoid recoupments

1. Know how much time is typically associated with each E/M level as well as the amount of time a physician must spend counseling and/or coordinating care to bill solely based on time rather than the three key components (i.e., history, exam, and medical decision-making).

2. Document the total time spent face-to-face with the patient as well as the total time spent counseling and/or coordinating care.

3. Explain what the counseling and/or coordination of care entailed (e.g., answering questions regarding the treatment plan or extensively discussed treatment options).

Note that counseling and coordination of care does not include administrative tasks such as documenting in the EHR, dictating, refilling prescriptions, completing workers’ compensation applications, communicating with other professionals, or reviewing records and tests before or after the face-to-face visit.

MODIFIERS -25, -26, AND -59: EXPERT ADVICE TO MITIGATE RISK

Physicians need to ensure they send the right message to payers so that message doesn’t come back to haunt them in the form of recoupment, says Joette Dericks, healthcare compliance and revenue integrity consultant in Baltimore. “Many commercial payers have also tightened their reimbursement edits to deny modifiers,” she says. It’s important to check with each payer to determine whether it has published guidance before establishing a policy within the practice for reporting modifiers, she adds.

-25 claims upfront,” she says. It’s important to check with each payer to determine whether it has published any guidance before establishing a policy within the practice for reporting modifiers, she adds. "Many commercial payers have also tightened their reimbursement edits to deny modifier -25 claims upfront," she says. It’s important to check with each payer to determine whether it has published any guidance before establishing a policy within the practice for reporting modifiers, she adds.

-26, the physician may perform a workup to determine whether the patient suffered a concussion during the fall. The physician could report a separate E/M service with modifier -25 for the workup if they document why they felt the patient was at risk for a concussion and what the workup entailed. The same is true for an annual wellness visit and separately signifi cant and separately identifiable. Other services may be separately billable, depending on the circumstances.

Modifier -25

Apply this modifier to the E/M code—not the code for the procedure. Document why the additional E/M service was necessary and why it went above and beyond what’s typically required for the procedure. For example, a patient talks and suffers a laceration that requires stitches. If deemed necessary, the physician may perform a workup to determine whether the patient suffered a concussion during the fall. The physician could report a separate E/M service with modifier -25 for the workup if they document why they felt the patient was at risk for a concussion and what the workup entailed. The same is true for an annual wellness visit and separately significant and separately identifiable. Other services may be separately billable, depending on the circumstances.

Modifier -26

Apply this modifier to a global procedure code (i.e., one that includes the interpretation and test itself) when a more specifi c code is unavailable. For example, apply modifier -26 to CPT code 71045 (single-view chest x-ray) when the physician performs the interpretation only. If the physician owns the equipment and performs the test, modifier -26 isn’t necessary, and reporting it can actually result in an underpayment.

Know when a more specifi c code is available. Consider this scenario: A physician performs the interpretation and report of a routine electrocardiogram (EKG), but doesn’t perform the tracing. In this case, report CPT code 93010 (interpretation and report only) — not CPT 93000 (EKG with tracing, interpretation, and report) with modifier -26.

Ensure compliance when using an outsource coding vendor. Dericks says she provided consulting services to an internal medicine practice that owed several thousand dollars back to the payer because its coding vendor failed to apply modifier -26. The vendor wrongly assumed the physician performed various radiology procedures in addition to the interpretation, resulting in a signifi cant overpayment.

Modifier -59

Only apply this modifier when appropriate to non-E/M codes with a Correct Coding Modifier Indicator of 1’ (modifier allowed). To view modifier indicators for each code, visit https://www.cms.gov/Medicare/Coding/NationalCorrectCodInitEd/NCCI-Coding... Most practice management systems also include this information.

Think of this modifier as a ‘last resort.’ If another modifier is more appropriate, use that modifier instead. Consider these other options fi rst: -RT (right), -LT (left), or -50 (bilaterial procedure). Payers may also accept modifi ers -XE (separate encounter), -XS (separate organ or structure), -XU (unusual non-overlapping service), or -XP (separate practitioner).

Know the criteria. Medicare recently published Medlearn Matters article SE1418 that includes clinical scenarios and guidelines for proper use of modifier -59.
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REGIMEN REDUCES REDNESS IN ROSACEA PATIENTS

Use of Colorscience’s products ALL CALM CLINICAL REDNESS CORRECTOR SPF 50 and SUN-FORGETTABLE BRUSH-ON SHIELD SPF 50 could reduce facial erythema and decrease side effects from light therapy in patients with rosacea, according to a company announcement.

An 18-week study investigated the efficacy and tolerability of these products in individuals with rosacea. Patients used the skin care regimen daily for 12 weeks and, at week 12, received a single intense pulsed light (IPL) treatment followed by an application of the same products. Researchers found that use of the products with a single IPL significantly improved overall facial redness in patients with rosacea. Both products were well tolerated, aside from mild burning that occurred immediately after the IPL treatment.

FOR MORE INFORMATION: colorsience.com

GILLETTE RAZOR EFFECTIVE FOR MEN WITH SENSITIVE SKIN

The GILLETTE SKINGUARD razor may provide a more comfortable shave for men with sensitive skin, according to research presented at the 24th World Congress of Dermatology.

A 28-day study showed significant improvements across all measured irritation endpoints, including redness, dryness, burning, itching, stinging, tightness and tingling. Another study examined how the razor performed in men with pseudofolliculitis barbae, or razor bumps. After 12 weeks of daily shaving with the razor, researchers found that the incidence of razor bumps decreased by more than 60%. Participants also reported emotional and social benefits, such as feeling more attractive and confident.

FOR MORE INFORMATION: gillette.com

FDA CLEARED LASER FOR HAIR REMOVAL

The FDA recently approved the EPILAZE HAIR REMOVAL SYSTEM from Rohrer Aesthetics for permanent hair reduction and removal. The system includes 755nm, 810nm, and 1064nm wavelengths, and can be used on all skin types as well as tanned skin.

The lasers feature a “standard” mode and a “smooth flow technology” mode, which dissipates up to 10 pulses of energy per second allowing providers to treat larger areas in less than 20 minutes.

FOR MORE INFORMATION: rohreraesthetics.com

OVER-THE-COUNTER WASH EFFECTIVE FOR AD PATIENTS

Cln Skin Care’s sodium hypochlorite wash, CLN BODYWASH is a daily body cleanser designed to soothe skin prone to eczema, rash, redness, irritation, folliculitis and infection. The product helps reduce the appearance of skin redness, dryness and flakiness when used for 2 minutes per day when washing and can be used in addition to prescribed atopic dermatitis therapies, according to Cln Skin Care.

Data collected from 50 patients ages 6 months to 17 years with moderate-to-severe atopic dermatitis with S. aureus colonization from a 6-week, prospective, open label study showed improvements for all outcome measures, including improvements in Eczema Area Severity Index (46%) and itching (39%). Participants also indicated preferences for the body wash over bleach bath.

FOR MORE INFORMATION: ClnWash.com

LA ROCHE-POSAY ANNOUNCES NEW ACNE TREATMENT

La Roche-Posay recently announced the launch of EFFACLAR ADAPALENE GEL 0.1% ACNE TREATMENT, an over-the-counter acne treatment formulated with adapalene.

This once-daily product is safe for patients 12 years of age and older, and is designed to offer prescription-strength treatment to reduce blackheads, whiteheads and other blemishes, according to La Roche-Posay. The gel formula is non-greasy, oil-free, non-comedogenic and fragrance free.

FOR MORE INFORMATION: laroche-posay.com

FOR MORE INFORMATION: colorsience.com
TREATMENT GOALS  “We need to stabilize the patient. We need to achieve re-pigmentation, and we need to be able to maintain results,” says dermatologist Pearl E. Grimes, M.D., who directs the Vitiligo and Pigmentation Institute of Southern California and is a clinical professor of Dermatology at UCLA.

Stabilization

STEROIDS  “My most common approach for stabilization is either oral or intramuscular steroids. I tend to use more intramuscular steroids in patients with rapidly progressive disease because the steroids are in the system longer. I like Kenalog [triamcinolone acetonide injectable suspension, USP]. I only have to give it two or three times. Sometimes just one injection will stabilize,” Dr. Grimes says.

CORTICOSTEROID  A more popular stabilization treatment is oral mini-pulse therapy, with two doses of dexamethasone 4 mg twice a week for up to three months. That, in combination with phototherapy and other modalities, is also effective in stabilizing, according to Dr. Grimes.

PHOTOTHERAPY  Studies suggest that narrowband UVB phototherapy also is good for stabilizing patients, and, in some cases, Dr. Grimes uses narrowband UVB for stabilization in combination with antioxidants.

ANTIOXIDANTS  “I check vitamin D levels. In addition to vitamin D being an immunomodulatory agent, it’s also a great antioxidant. Use alpha lipoic acid, vitamin C and a multivitamin that contains antioxidants. I’m a believer in antioxidants for vitiligo and think they help with stabilization,” she says.

Re-pigmentation & maintenance

Dr. Grimes bases her approach to re-pigmentation on disease severity.

TOPICAL THERAPY  If a patient has limited involvement, with less than 5% vitiligo, Dr. Grimes treats with topicals. Her go-to topical agents are mid-to-high-potency topical corticosteroids and tacrolimus.

“I use different topical corticosteroids depending on what the patient has. I like mometasone. I like clobetasol, if I need it. I love the calcineurin inhibitors. My favorite is tacrolimus,” she says. “We published the first studies on the calcineurin inhibitors for vitiligo.”

In some cases, Dr. Grimes will use topicals as monotherapy; often, she’ll “mix and match.” “The beauty of the calcineurin inhibitors is they don’t cause atrophy or thinning, and you can keep the patients on them for an extended period of time; whereas, with the topical steroids, there’s always the concern for acne, atrophy and steroid-related side effects,” Dr. Grimes says.

LIGHT-BASED THERAPY  Dermatologists also can use targeted phototherapy, the excimer laser or other targeted light sources in patients who have limited involvement.

There are some newer targeted narrowband UVB light sources that have come onto the market that are even available for at-home use.

COMBINED THERAPIES  For patients with more generalized involvement, or more than 5% vitiligo, Dr. Grimes is likely to recommend full-body narrowband UVB in combination with topicals. Although the topicals don’t need to be as strong when combined with light therapy, Dr. Grimes suggests a mid-potency topical steroid.

“I still may use a calcineurin inhibitor for localized areas. I typically don’t use calcineurin inhibitors for widespread vitiligo,” she says. “We do narrowband two to three times a week in combination with topicals and oral antioxidants.”

Of course, sunscreen is a must. Dr. Grimes continues to recommend antioxidants and sometimes topical tacrolimus to maintain the achieved re-pigmentation. It can be applied once or twice weekly, she says.

PATIENT SATISFACTION TIPS

Prepare patients that treatment might take six months to a year.

“There is evidence-based medicine but then there’s the art of medicine — showing that patient that you have empathy, compassion and understand the impact vitiligo has on quality of life; that you have an understanding of the disease; and that you really do want to make a difference. I think that goes a long way,” Dr. Grimes says.

IN THE PIPELINE

“The new kids on the block are the JAK inhibitors. We’re running several trials now with JAK inhibitors and are presenting 52-week data on topical ruxolitinib. It works amazingly well on the face,” Dr. Grimes says.

Disclosures:
Dr. Grimes recently received research support from Goldman, Alkergen/SkinMedica, Pictor & Gimbble, Climax, Menz, Valeant, L’Oreal, Johnson & Johnson, Suneva, Laser/Photon, Kig Technologies, Incyte, Pfizer, Thync, and Dermacce. She is a consultant/advisory board member for Intraderm Technologies and Dermacce.
not identified an association with topical tretinoin and major birth defects or miscarriage. The available studies have methodologic limitations, including small sample size and in some cases, lack of physical exam by an expert in birth defects. There are published case reports of infants exposed to topical tretinoin during the first trimester that describe major birth defects similar to those seen in infants exposed to oral retinoids; however, no pattern of malformations has been identified and no causal association has been established in these cases. The significance of these spontaneous reports in terms of risk to the fetus is not known.

Animal Data
Tretinoin in a 0.05% gel formulation was topically administered to pregnant rats during organogenesis at doses of 0.1, 0.3 and 1 g/kg/day (0.05, 0.15, 0.5 mg tretinoin/kg/day). Possible tretinoin malformations (craniofacial abnormalities [hydrocephaly], asymmetrical thyroids, variations in ossification, and increased supernumerary ribs) were observed at maternal doses of 0.5 mg tretinoin/kg/day (approximately 2 times the MRHD based on BSA comparison and assuming 100% absorption). These findings were not observed in control animals. Other maternal and reproductive parameters in tretinoin-treated animals were not different from control. For purposes of comparison of the animal exposure to human exposure, the MRHD is defined as 4 g of ALTRENO applied daily to a 60-kg person.

Animal data from other tretinoin embryofetal development studies have generated equivocal results. There is evidence for malformations (shortened or kinked tail) after topical administration of tretinoin to pregnant Wistar rats during organogenesis at doses greater than 1 mg/kg/day (approximately 5 times the MRHD based on BSA comparison and assuming 100% absorption). Anomalies (humerus: short 13%, bent 6%, os parietal incompletely ossified 14%) have also been reported when 10 mg/kg/day (approximately 50 times the MRHD based on BSA comparison and assuming 100% absorption) was topically applied to pregnant rats during organogenesis. Supernumerary ribs have been a consistent finding in rat fetuses when pregnant rats were treated topically or orally with retinoids.

Oral administration of tretinoin during organogenesis has been shown to induce malformations in rats, mice, rabbits, hamsters, and nonhuman primates. Fetal malformations were observed when tretinoin was orally administered to pregnant Wistar rats during organogenesis at doses greater than 1 mg/kg/day (approximately 5 times the MRHD based on BSA comparison). In the cynomolgus monkey, fetal malformations were reported when an oral dose of 10 mg/kg/day was administered to pregnant monkeys during organogenesis (approximately 100 times the MRHD based on BSA comparison). No fetal malformations were observed at an oral dose of 5 mg/kg/day (approximately 50 times the MRHD based on BSA comparison). Increased skeletal variations were observed at all doses in this study and dose-related increases in embryo lethality and abortion were reported in this study. Similar results have also been reported in pigtail macaques.

Oral tretinoin has been shown to be fetotoxic in rats when administered at doses 10 times the MRHD based on BSA comparison. Topical tretinoin has been shown to be fetotoxic in rabbits when administered at doses 4 times the MRHD based on BSA comparison.

Lactation

Risk Summary
There are no data on the presence of tretinoin or its metabolites in human milk, the effects on the breastfed infant, or the effects on milk production. It is not known whether topical administration of tretinoin could result in sufficient systemic absorption to produce detectable concentrations in human milk. The developmental and health benefits of breastfeeding should be considered along with the mother’s clinical need for ALTRENO and any potential adverse effects on the breastfed child from ALTRENO.

Pediatric Use
Safety and effectiveness of ALTRENO for the topical treatment of acne vulgaris have been established in pediatric patients age 9 years to less than 17 years based on evidence from two multicenter, randomized, double-blind, parallel-group, vehicle-controlled, 12-week trials and an open-label pharmacokinetic study. A total of 318 pediatric subjects aged 9 to less than 17 years received ALTRENO in the clinical studies [see Clinical Pharmacology and Clinical Studies in full Prescribing Information].

The safety and effectiveness of ALTRENO in pediatric patients below the age of 9 years have not been established.

Geriatric Use
Clinical trials of ALTRENO did not include any subjects age 65 years and older to determine whether they respond differently from younger subjects.

NONCLINICAL TOXICOLOGY
Carcinogenesis, Mutagenesis, Impairment of Fertility
A 2-year dermal mouse carcinogenicity study was conducted with topical administration of 0.005%, 0.025% and 0.05% of a tretinoin gel formulation. Although no drug-related tumors were observed in surviving animals, the irritating nature of the drug product precluded daily dosing, confounding data interpretation and reducing the biological significance of these results.

Studies in hairless albino mice with a different formulation suggest that concurrent exposure to tretinoin may enhance the tumorigenic potential of carcinogenic doses of UVB and UVA light from a solar simulator. This effect was confirmed in a later study in pigmented mice, and dark pigmentation did not overcome the enhancement of photocarcinogenesis by 0.05% tretinoin. Although the significance of these studies to humans is not clear, patients should minimize exposure to sunlight or artificial ultraviolet irradiation sources.

The genotoxic potential of tretinoin was evaluated in an in vitro bacterial reversion test, an in vitro chromosomal aberration assay in human lymphocytes and an in vivo rat micronucleus assay. All tests were negative.

In dermal fertility studies of another tretinoin formulation in rats, slight (not statistically significant) decreases in sperm count and motility were seen at 0.5 mg/kg/day (approximately 2 times the MRHD based on BSA comparison and assuming 100% absorption), and slight (not statistically significant) increases in the number and percent of nonviable embryos in females treated with 0.25 mg/kg/day and above (approximately the MRHD based on BSA comparison and assuming 100% absorption) were observed.

PATIENT COUNSELING INFORMATION
Advising the patient to read the FDA-approved patient labeling (Patient Information).
HELP YOUR PATIENT PUT HER BEST SELFIE FORWARD

Experience ALTRENO™ lotion
the first and only acne treatment that provides the proven efficacy of tretinoin in a hydrating lotion.12

See tolerability and efficacy results at ALTRENO.com.

INDICATION
ALTRENO™ (tretinoin) lotion, 0.05% is indicated for the topical treatment of acne vulgaris in patients 9 years of age and older.

IMPORTANT SAFETY INFORMATION
ALTRENO is for topical use only. Not for ophthalmic, oral, or intravaginal use.

Skin Irritation: Patients using ALTRENO may experience application site dryness, pain, erythema, irritation, and exfoliation. Depending upon the severity of these adverse reactions, instruct patients to use a moisturizer, reduce the frequency of the application of ALTRENO, or discontinue use. Avoid application of ALTRENO to eczematous or sunburned skin.

Ultraviolet Light and Environmental Exposure: Minimize unprotected exposure to ultraviolet light, including sunlight and sunlamps. Warn patients with frequent sun exposure and those with inherent sensitivity to sunlight to exercise caution. Use sunscreen and protective clothing over treated areas when exposure cannot be avoided.

Fish Allergies: ALTRENO contains soluble fish proteins. Use with caution in patients with known sensitivity or allergy to fish. Advise patients to contact their healthcare provider if they develop pruritus or urticaria.

Adverse Reactions: The most common adverse reactions in clinical trials were application site dryness (4%), pain (3%), erythema (2%), irritation (1%) and exfoliation (1%).

Nursing Women: It is not known whether topical administration of tretinoin could result in sufficient systemic absorption to produce detectable concentrations in human milk. The developmental health benefits of breastfeeding should be considered along with the mother’s clinical need for ALTRENO and any potential adverse effects on the breastfed child from ALTRENO.

To report SUSPECTED ADVERSE REACTIONS, contact Customer Service at 1-800-321-4576 or the FDA at 1-800-FDA-1088 or fda.gov/medwatch.

Please see Brief Summary of Prescribing Information on following pages.


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