THE PSORIASIS ISSUE

Paths toward better outcomes

INGRID TORJESEN | Staff Correspondent

Psoriasis affects more than 8 million Americans and has been associated with a number of comorbidities. Aside from the quality-of-life impact, the disease has an economic impact, as well. Experts say there is a need to capture the true direct and indirect costs to improve outcomes for patients with psoriasis and psoriatic arthritis.

Of the 2%-3% of patients with psoriasis, 10%-30% develop psoriatic arthritis. And, while almost one in four psoriasis patients have moderate to severe disease, many and nearly all psoriatic patients experience the psoriatic arthritis.

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Psoriasis affects more than 8 million Americans and has been associated with a number of comorbidities. Aside from the quality-of-life impact, the disease has an economic impact, as well. Experts say there is a need to capture the true direct and indirect costs to improve outcomes for patients with psoriasis and psoriatic arthritis.

Of the 2%-3% of patients with psoriasis, 10%-30% develop psoriatic arthritis. And, while almost one in four psoriasis patients have moderate-to-severe disease, women and younger patients experience the greatest negative impact on their quality of life.

Nearly 60% of people with psoriasis and 40% of people with psoriatic arthritis report their disease has a large effect on their everyday lives.

Psoriasis is also associated with numerous comorbidities, including metabolic syndrome, diabetes, hypertension, obesity, hypercholesterolemia, joint disease (psoriatic arthritis), depression and anxiety, liver and kidney disease, and malignancy, especially cutaneous T-cell lymphoma.

"It really is in the true sense of the word a systemic disease," says Burden.

**TABLE OF THE MONTH**

**40 YEARS OF PSORIASIS THERAPEUTICS**

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    - Combined modalities may improve skin cancer diagnosis and management.

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    - Practice culture impacts patient safety.

**Genetic insights improve tumor classification**

**ILYA PETROU, M.D. | Staff Correspondent**

**ACCURATELY DIAGNOSING** some melanocytic neoplasms is challenging because they may fall into a grey area histologically, one expert says. These can create disagreement even between the most experienced dermatopathologists.

While some view classifying a melanocytic tumor as intermediate or borderline as indecisiveness, recent progress in molecular genetics has demonstrated that there really is an intermediate or borderline category of melanocytic tumor, corresponding to difficult-to-classify melanocytic lesions, says Iwei Yeh, M.D., Ph.D., associate professor of dermatology, department of dermatology, University of San Francisco School of Medicine, San Francisco, Calif., who recently spoke at the World Congress of Dermatology in Milan.

The recognition of intermediate and borderline tumors helps clinicians and dermatopathologists more precisely classify tumors leading to more appropriate treatment and management choices for this patient population.

"Not being able to classify every tumor as clearly benign or malignant does not reflect an inability of dermatopathologists to agree on the right classification, because we now know that there really is a..."
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Do we have to say goodbye?

by NORMAN LEVINE, M.D.

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

Recently, I had occasion to talk with an individual who recruits senior dermatology residents for practices throughout the United States. He is familiar with my practice and indicated that if I were ever to attempt to add an associate who would ultimately buy the assets of the practice when I retire, it would be extremely difficult — if not impossible — to find someone who would be interested in the opportunity.

The simple reason is that the salaries that these newly minted dermatologists command would be too high to support the addition of a medically oriented person, which would be necessary in a practice like mine. Incidentally, the starting salary would be for more money than I have ever earned in my professional career.

After absorbing this troubling fact of life, I began to contemplate the implications for dermatology as a specialty. There is clearly a market-driven value placed on dermatologists and I strongly suspect that the procedural and aesthetic practices are so profitable and the demand for services is so great in many parts of the country that the increased compensation for all new dermatologists has skyrocketed because of this.

There is ample evidence of this trend in many practices with which I am familiar. Nurse practitioners and physician assistants are performing many of the tasks that fully trained dermatologists have historically performed. These physician extenders funnel patients who request aesthetic services to the dermatologists who can make a significant amount of money in this cash-only business. The more dermatologists who are at the end of this pipeline, the greater the income for the practice.

I know that many individuals will vigorously dispute this notion and might feel insulted that the services they perform are viewed as for-profit only. I do not mean to insinuate this at all. I have come to believe that many patients want to maximize their appearance and aesthetic dermatologists can be very helpful in this endeavor and can please their patients in a major way. My point is that these activities have the unintended consequence of financially squeezing out the medical portion of our specialty.

I can state with 100% assurance, however, that many patients prefer that their dermatologic problems be managed in a medically oriented practice that does not sell products in the office or offer aesthetic services. Medical dermatologists can maintain an “old-fashioned” office environment where it appears less like a business and more like a group of genuinely caring people interested in improving the lives of their patients. I think we are all aware of the different “vibes” of the various practices in our communities. If you do not already know, your patients will tell which practices are run like an assembly line, which try to sell products to all of the customers, and which take the time to address the legitimate needs without aggressively finding lesions to treat.

In short, medically oriented dermatologists are a vital part of overall quality medical care, and it would be sad if they disappeared altogether. Although the momentum is against this form of healthcare delivery, there are alternative strategies (albeit impractical ones) which might be worth considering. Here are a few suggestions:

- Change the reimbursement system that currently rewards procedures over “intellectual” care (my personal favorite idea, for selfish reasons). Payments could also be based, in part, on the time spent with a patient rather than what procedure is performed during the visit.
- Is treating three actinic keratoses with cryotherapy over 30 seconds really more valuable than a 15-minute discussion of the merits and pitfalls of using topical fluorouracil?
- Add more residency slots in university training programs, preferably at institutions which emphasize the medical aspects of the discipline. Increased numbers of graduates will possibly tilt the balance away from too many practices chasing too few potential associates.
- Develop additional fellowships in medical dermatology. A few high quality programs already exist and appear to be successful in training future leaders in medical dermatology.
- Consider changing the rules regarding individuals not being allowed to take more than one Medicare-sponsored residency. In the past, well-trained internists clamored to be accepted into dermatology residency programs. With that internal medicine background and interest, our specialty was greatly enriched by their knowledge and past experience, and many became some of our best medically-oriented dermatologists. This all changed when Medicare chose to balk at supporting more than one residency per person. This could be changed with persuasive arguments made by the leaders in dermatology.

Many who read this editorial will be of the opinion that change is inevitable and those who fail to accommodate new realities will have to step aside for others.

I disagree that the evolution from a great system of healthcare delivery to one where medical care may suffer is a certainty, if only we work to preserve the best of what we have to offer.
Noah had great compassion for the underserved, accepted all patients who came to him looking for help...”

In memoriam: Noah Simeon Scheinfeld, M.D., J.D.

by LISETTE HILTON | Staff Correspondent

One of the specialty’s own, New York City dermatologist Noah Simeon Scheinfeld, M.D., J.D., died unexpectedly in his sleep June 3, 2019. He was 55, according to a New York Times obituary published two days later. Dr. Scheinfeld was a scholar who loved ideas and knowledge, according to the obituary. He graduated with his medical degree from Yale University and completed a dermatology residency at Albert Einstein College of Medicine. But before he pursued medicine, he pursued law, earning a law degree from Harvard Law School.

An assistant clinical professor of dermatology at Weill Cornell Medical College, Dr. Scheinfeld was an editor for Journal Drugs & Dermatology, SKInmed, Cutis, Skin Aging, Dermatology Online Journal and the American Journal of Clinical Dermatology.

One of Dr. Scheinfeld’s colleagues, Perry Robins, M.D., professor emeritus of dermatology, New York University Medical Center, and editor-in-chief of the Journal of Drugs in Dermatology, wrote in an email to Dermatology Times: “[Dr. Scheinfeld] was a wonderful person who helped a lot of patients, and he was always very active in educating other doctors.”

A prolific writer, Dr. Scheinfeld was published extensively in peer-reviewed journals. A PubMed search brings up more than 200 such articles.

He was editor or co-editor of medical textbooks, including Atopic Dermatitis and Eczematous Disorders. And he spoke regularly at dermatology conferences.

Not only was he intelligent, but the husband and father of two was compassionate and willing to invest his time for the good of others.

“Noah had great compassion for the underserved, accepted all patients who came to him looking for help…,” according to the New York Times. “He was a recognized leader in the treatment of hidradenitis suppurativa (HS), and had HS patients from all over the world visit his office in midtown…. He proudly served as the vice president of the Hidradenitis Suppurativa Foundation. Noah was also an active member of the Noah Worcester Dermatological Society, the Dermatologic Society of Greater New York and the Manhattan-Metropolitan Dermatology Society.”

On June 14, dermatologist Neal Bhatia, M.D., wrote this on behalf of the Noah Worcester Dermatological Society: “Many of us knew Noah as a presence, a true individual, and one of the nicest guys around. We all knew him as a dermatologist, but he also had a law degree with a sparkling CV and more publications and accolades than we can count. Noah was a real doctor. He took care of patients who needed real help, took on serious medical dermatology diseases, and in many ways made it look easy. He was benevolent as a teacher, masterful as a speaker, and prolific as a writer, just to scratch the surface. His legacy in dermatology will be connected to his work in Hidradenitis Suppurativa, but he was one of the earliest pioneers in the cyber age of dermatology as well. The next time you prescribe any biologic agents for HS, you can thank Noah for opening that door for us because he helped patients this way before we even knew it would be an option.

I always liked Noah, he was kind, he was bubbly, and you always knew he was with us. He was a little quirky, but aren’t we all? And aren’t we going to be worse off without our friend? He came up to me at one of the meetings I was running and said “Neal I want to speak,” and without hesitation I told him “Anything you want my man,” because I knew despite his sometimes off-the-wall behavior, he always brought his best. And we will miss that about him, as well as his innocent smile and kind soul.

When I heard the news of his death, I sat in my office for a few minutes numb — not just because he meant a lot to the society and to dermatology, not just because he was only three years older than me, and not because it was sudden and we may never know the true cause of his passing — but because we lost our friend, and we won’t get to see him again...which is really sad. Please say a few prayers for our lost friend Noah and his family, and for all of us.”

Dr. Bhatia tells Dermatology Times that to honor Dr. Scheinfeld’s contributions to the specialty, Dr. Bhatia is dedicating the session he’s directing, “Advanced Systemic Therapeutics,” July 26, during the American Academy of Dermatology Summer Meeting in New York City to Dr. Scheinfeld.

Contributions in Dr. Scheinfeld’s memory may be made to the Hidradenitis Suppurativa Foundation, according to the New York Times.

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“Homeopathic therapy... has the potential to drive a paradigm shift in medicine...”

by LAWRENCE CHUKWUDI NWABUDIKE, M.D., MBBS, MRCP (U.K.), PHD
Senior Consultant Dermatologist at N.Paulescu National Institute of Diabetes, Bucharest, Romania

Medicine is not just an art and a science, but it is also a calling. It requires the ability to empathize and is always based on principles. A fundamental, driving principle of good medical practice is to take what can potentially help the patient, examine it and apply it — even if it appears to fly in the face of currently accepted principles. We may actually learn something new.

Nowhere in medicine does a therapeutic modality appear to defy current medical precepts than homeopathy. This is because homeopathic medicines (homeopathic remedies as they are often referred to by homeopaths) are often so diluted as to not contain any molecule of the original substance. Also, they are based on the principle of *similia similibus curentur* or “like cures like”, i.e. a substance that can cause symptoms of a disease at a high concentration may cure that disease at a lower concentration.

While these principles appear at first glance to be implausible, one only needs to look at other complementary and alternative medicine (CAM) methods of therapy, such as acupuncture, meditation and prayer.

With acupuncture, needles are regularly inserted into the skin at certain points known as acupoints in order to treat disorders that have no known anatomic connection with the diseased organ, such as the Large Intestine point 4, between the thumb and index finger, which is used to treat headaches, sinusitis, constipation and even to assist in labour. Acupuncture is a widely accepted method of therapy and is even on the latest World Health Organisation (WHO) ICD classification.

**HISTORY OF HOMEOPATHY**

Homeopathy is a system of medicine founded about 200 years ago in Germany, by the physician Samuel Friedrich Christian Hahnemann (10 Apr 1755 – 02 Jul 1843). He studied medicine at Leipzig and Vienna and attained an MD degree at Erlangen in 1779. In Leipzig in 1790, while translating William Cullen’s treatise of *Materia Medica*, he came upon the assertion that cinchona cured malaria because it could induce the symptoms of this disorder. Hahnemann ingested some and developed fever, chills and joint pains, all symptoms of malaria. This led him to believe that a substance that can produce symptoms of a disease in a healthy person, may also do this in a sick person. Due to his disillusionment with the medical practices of his day, such as blood-letting and purging, Hahnemann turned his back on medical practice and chose instead to translate. He was a highly regarded chemist, author and translator; he died a successful and wealthy physician in Paris.

The principle of similars was already espoused well before Hahnemann. Hippocrates reportedly used this principle and treated mania by using Mandrake root, because its can induce symptoms of mania. Paracelsus is also reported to, like Hippocrates, have espoused the principle *similia similibus curentur*. Hahnemann experimented with many different substances; thus, developing a system of dilution and succussion, which helped to eliminate toxicity of the remedies while increasing their efficacy.

Homeopathy was found to be useful during the cholera pandemics that hit Europe, although evidence suggests the medical establishment of the day attempted to suppress these results. Also, it would appear that a precursor of today’s placebo controlled, blinded, randomised trials was a homeopathic trial commissioned by the British government to help it in its search for antidotes to mustard gas exposure, after World War I. Although the trials appeared to have been well done and showed mostly positive outcomes, it is unclear why the British government failed to accept these results.

The oldest national medical society in America is the American Institute of Homeopathy, founded on April 10, 1844, one year after the death of Samuel Hahnemann. It is still in existence and functioning today.
HOMEOPATHIC MEDICINES

Homeopathic medicines come in several forms. They are invariably forms of dilution (potencies, as homeopaths refer to them), principally the D and the C potencies, for dilution orders of 10 or 100, respectively, are in use.

The remedies are prepared from a mother tincture, in which the undiluted substance is diluted by a factor of 10 or 100 to make a D1 or a C1 potency (i.e. 1/10 or 1/100). From these a D2 and C2 potency (i.e. 1/100 and 1/10000) are derived, with D3 and C3 (i.e. 1/10000 and 1/100000000) potencies being derived from D2 and C2 and so on.

Thus, a C12 potency is a 10^12 dilution (1/1,000,000,000,000,000,000,000,000). Hahnemann regularly used C30 dilutions and M (C1000) and higher dilutions exist today.

Each dilution is followed by a process of shaking with banging on an elastic surface, a process known as succussion.

These high dilutions are unlikely to contain molecules of the original substance, yet, the higher the dilution, the deeper the effect of the remedy. Thus, the lower potencies, C12, 15 or 30 address more physical complaints, while the deeper, psychological complaints are addressed by higher potencies such as C200 or M.

Chemistry suggests that there should be no molecules at substance at C12, thus there appears no rational explanation for the effects of homeopathy and this appears to fuel much of the skepticism of this practice.

Nonetheless, homeopaths contend that they work, and more recent evidence suggests that there may be a nanoparticle basis for the functioning of homeopathy.9 There appears also to be evidence from research, clinical and laboratory data to show that homeopathy does exert an effect beyond placebo. Some of this research is listed at the Faculty of Homeopathy website in the UK as well as on the website of the American Institute of Homeopathy.8

These research lists counter the arguments from other studies that appear to show that homeopathy effects are not statistically significant.

Opponents of homeopathy contend that any benefits that may occur from homeopathy are a result of the placebo effect. In other words, an effect based on patients’ expectation of benefit. However, homeopathy is useful in infants,9 animals10 and even in plants,11 all situations in which the placebo effect is unlikely to be significant.

Homeopathic medicines are available as aqueous solutions (alcohol or water), as powders, pellets/granules and tablets.

HOMEOPATHY IN DERMATOLOGY

Many dermatological diseases do not have definitive cures and the available treatments sometimes provide serious potential side-effects. Patients can therefore suffer from these disorders for many years, with corresponding effects on their quality of life over this period. These are some of the reasons why patients turn to CAM methods, including homeopathy.22

Homeopathy is by nature a therapeutic system that is individualised and based on the psyche of the individual. This is in line with evidence from regular dermatologic practice that suggests that many chronic dermatoses have an underlying psychosomatic basis.

The literature suggests homeopathy’s efficacy in the therapy of dermatological diseases is growing and includes research, which suggests its usefulness for acne,13 atopic dermatitis,9,14 lichen planus,15,16 cutaneous lymphoma,17 psoriasis,18,19 rosacea,20 and dermatisis herpetiformis,20 amongst others.

The special characteristic of homeopathic medicines of not having molecules in them makes them attractive for use in pregnancy, as teratogenicity is not likely to be a significant issue.

Allergy and toxicity are also not to be expected with the use of homeopathic medicines. However, following the use of homeopathic remedies, especially individualised treatments, there may be an initial aggravation, followed by an amelioration. Patients need to know this, as an important sign of a correctly selected remedy, but may be a source of anxiety for the patients.

Usually, following the application of properly selected homeopathic treatments there is a tendency to permanent remission.

Homeopathic therapies are very cheap and therefore have the possibility of bringing down healthcare costs, while being at the same time environmentally friendly.

Many physicians have shown a desire to learn about CAM, in order to better advice their patients who may wish these treatments.23

CONCLUSIONS

Homeopathy is a system of medicine, which is gentle and safe for all categories of patients, including infants and pregnant women.

Homeopathic treatment should usually be given by a trained physician, so that the patient’s clinical status can be properly monitored.

Although there have been reports of serious adverse effects, these have often been of products wrongly labelled as being homeopathic.

By its very nature, i.e. treating each person as an individual, homeopathic therapy and research has the potential to drive a paradigm shift in medicine and its approach to health and disease. Empathy is necessary for good medical practice and homeopathy requires empathy in order to achieve good results.

Empathy has been shown to improve patient outcomes, while avoiding burnout in physicians.23 As a result, homeopathy is potentially able to result in a gain for the entire medical system by way of lowering costs, improving patient outcomes and reducing burnout in physicians who practice it.24
**Education or off-label use promotion?**

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

David J. Goldberg, M.D., J.D. is a graduate of Yale University School of Medicine and Fordham University School of Law. He is Chief of Dermatologic/MOHs Surgery at the NJ Medical School and is the Director of the Skin Laser Center of NJ. He is on the faculty of Fordham University School of Law where he teaches Health Care Law. Finally, he is chairman of the Ethics Committee for the American Society of Dermatologic Surgery and serves as legal advisor to the American Society for Laser Surgery and Medicine.

You are a member of your local dermatologic society and attend monthly meetings in order to obtain your desired CME credits. In order to finance the meeting and encourage attendance, the society has the monthly meetings financed by a prominent drug company.

The food is excellent, conforms to pharma guidelines, and the lecture very stimulating. The drug company provides journal articles from the *Journal of the American Academy of Dermatology* at the meeting that document the off-label use of one of their newer biologic agents. You obtain CME credits, read the journal article, and begin prescribing the off-label medication. A fellow dermatologist tells you that the drug company is in violation of the Food and Drug Administration (FDA) rulings against promoting off-label use. He contends you might also run afoul of the regulations.

The FDA derives its authority to regulate various aspects of the pharmaceutical industry from the Food, Drug and Cosmetic Act, 21 U.S.C., section 301. For a prescription drug to be distributed by a manufacturer in interstate commerce, the manufacturer is required to demonstrate that the drug is both safe and effective for each of its intended uses.

As part of the approval process, FDA also reviews the proposed labeling for the drug, which includes all proposed claims about the drug’s risks and benefits. The FDA will only approve a company’s new drug application if the labeling conforms to the uses that the FDA has approved.

In 1962, Congress determined that a manufacturer seeking to market or promote a product for an unlabeled use must resubmit the drug for another series of clinical trials similar to those from the initial approval. Off-label uses include treating a condition not indicated on the label or treating the indicated condition but varying the dosage regimen or varying the patient population. Manufacturer promotion of off-label uses constitutes misbranding and is in violation of the FDA statutes.

Since off-label uses are presently an accepted aspect of a dermatologist’s prescribing regimen, the open dissemination of scientific and medical information regarding these treatments is of great-import. The FDA acknowledges that physicians need reliable and up-to-date information concerning off-label uses. FDA recognizes that sources for such information are varied and include CME lectures and seminars. It specifically recognizes that the need for reliable information is particularly acute in the off-label treatment arena because the primary source of information usually available to physicians — the FDA approved label — is absent.

Off-label prescription practices can be problematic and have, in some circumstances, proven harmful. Therefore, the FDA, has always been concerned about drug company promotion. How far can drug companies go with off-label promotion?

It was the Washington Legal Foundation that sought to set guidelines through a lawsuit they initiated. The Washington Legal Foundation was a non-profit public interest law and policy center that defended the rights of individuals and businesses to go about their affairs without undue influence from government regulators.

In Washington Legal Foundation v. Michael A. Friedman, Commissioner, Food and Drug Administration and Donna Shalala, Secretary of U.S. Dep’t of Health and Human Services, the Washington Legal Foundation contended that peer reviewed journal articles, as scientific and academic speech, are entitled to the highest level of First Amendment free speech protection. There should be no FDA restrictions on the dissemination of such materials. FDA claimed that journal articles represent commercial speech that is not as strictly protected by the First Amendment, as is non-commercial speech.

In analyzing the litigation, the United States District Court for the District Court of Columbia noted that the distribution of enduring materials and sponsorship of CME seminars does constitute speech and therefore is entitled to First Amendment protection.
INDICATION
ALTRENO™ (tretinoin) lotion, 0.05% is indicated for the topical treatment of acne vulgaris in patients 9 years of age and older.

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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%).

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Please see Brief Summary of Prescribing Information on following pages.


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This Brief Summary does not include all the information needed to use ALTRENO safely and effectively. See full prescribing information for ALTRENO.

ALTRENO™ (tretinoin) lotion, for topical use
Initial U.S. Approval: 1973

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

CONTRAINDICATIONS
None.

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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.

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ADVERSE REACTIONS
Clinical Trials Experience
Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in clinical practice.

In 2 randomized, double-blind, vehicle-controlled trials, subjects age 9 years and older applied ALTRENO or vehicle once daily for 12 weeks. The majority of subjects were White (74%) and female (55%). Approximately 47% were Hispanic/Latino and 45% were younger than 18 years of age. Adverse reactions reported by ≥1% of subjects treated with ALTRENO and more frequently than vehicle are summarized in Table 1.

Table 1: Adverse Reactions Reported by ≥1% of Subjects Treated with ALTRENO and More Frequently than Vehicle

<table>
<thead>
<tr>
<th>Adverse Reactions</th>
<th>ALTRENO N=767</th>
<th>Vehicle N=783</th>
</tr>
</thead>
<tbody>
<tr>
<td>Application site dryness</td>
<td>29 (4)</td>
<td>1 (&lt;1)</td>
</tr>
<tr>
<td>Application site pain</td>
<td>25 (3)</td>
<td>3 (&lt;1)</td>
</tr>
<tr>
<td>Application site erythema</td>
<td>12 (2)</td>
<td>1 (&lt;1)</td>
</tr>
<tr>
<td>Application site irritation</td>
<td>7 (1)</td>
<td>1 (&lt;1)</td>
</tr>
<tr>
<td>Application site exfoliation</td>
<td>6 (1)</td>
<td>3 (&lt;1)</td>
</tr>
</tbody>
</table>

Application site pain defined as application site stinging, burning or pain.

Skin irritation was evaluated by active assessment of erythema, scaling, hypopigmentation, hyperpigmentation, itching, burning and stinging.

The percentage of subjects who were assessed to have these signs and symptoms at any post baseline visit are summarized in Table 2.

Table 2: Application Site Tolerability Reactions at Any Post Baseline Visit

<table>
<thead>
<tr>
<th></th>
<th>ALTRENO Mild/Mod/Severe</th>
<th>Vehicle Mild/Mod/Severe</th>
</tr>
</thead>
<tbody>
<tr>
<td>Erythema</td>
<td>51%</td>
<td>44%</td>
</tr>
<tr>
<td>Scaling</td>
<td>49%</td>
<td>30%</td>
</tr>
<tr>
<td>Hypopigmentation</td>
<td>12%</td>
<td>10%</td>
</tr>
<tr>
<td>Hyperpigmentation</td>
<td>35%</td>
<td>35%</td>
</tr>
<tr>
<td>Itching</td>
<td>35%</td>
<td>28%</td>
</tr>
<tr>
<td>Burning</td>
<td>30%</td>
<td>14%</td>
</tr>
<tr>
<td>Stinging</td>
<td>21%</td>
<td>8%</td>
</tr>
</tbody>
</table>

USE IN SPECIFIC POPULATIONS
Pregnancy
Risk Summary
Available data from published observational studies of topical tretinoin in pregnant women have not established a drug-associated risk of major birth defects, miscarriage, or adverse maternal or fetal outcomes. There are no data on ALTRENO use in pregnant women. The systemic levels following topical administration are lower than with administration of oral tretinoin; however, absorption of this product may result in fetal exposure. There are reports of major birth defects similar to those seen in infants exposed to oral retinoids, but these case reports do not establish a pattern or association with tretinoin-related embryopathy (see Data).

Animal reproduction studies have not been conducted with ALTRENO. Topical administration of tretinoin in a different formulation to pregnant rats during organogenesis was associated with malformations (craniofacial abnormalities [hydrocephaly], asymmetrical thyroid, variations in ossification, and increased supernumerary ribs) at doses up to 0.5 mg tretinoin/kg/day, approximately 2 times the maximum recommended human dose (MRHD) based on body surface area (BSA) comparison and assuming 100% absorption. Oral administration of tretinoin to pregnant cynomolgus monkeys during organogenesis was associated with malformations at 10 mg/kg/day (approximately 100 times the MRHD based on BSA comparison and assuming 100% absorption) (see Data).

The estimated background risk of major birth defects and miscarriage for the indicated population is unknown. All pregnancies have a background risk of major birth defects, loss, and other adverse outcomes. The background risk in the U.S. general population of major birth defects is 2 to 4% and of miscarriage is 15 to 20% of clinically recognized pregnancies.

Data
Human Data
While available studies cannot definitively establish the absence of risk, published data from multiple prospective controlled observational studies on the use of topical tretinoin products during pregnancy have
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.

Other topical 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 also been reported in rats 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 pigtailed 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**

Advise the patient to read the FDA-approved patient labeling (Patient Information).

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Bridgewater, NJ 08807 USA

U.S. Patent Number: 6,517,847

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How do you advise patients to select good skin-care on a budget?

Proper moisturizer and cleanser selection are important to patients with a variety of dermatoses; however, cost can be a significant consideration. Patients may mistakenly think expensive products are necessary to maintain control of their disease and prevent recurrence. This is not true. Thus, it is important for the dermatologist to educate patients on selecting OTC products that can improve their skin conditions.

The most important selection for any patient is a good cleanser. Skin cleansing is necessary for good hygiene, but excessive detergency can remove the intercellular lipids and induce barrier damage. The least expensive cleansers are bar cleansers, but many dermatologists confuse a bar cleanser with soap. The only soap bar that is currently widely distributed is Ivory soap, which is a poor choice for most patients with skin disease. Any bar cleanser that is labeled a “beauty bar” can be used by most patients.

Liquid cleansers are more expensive per wash than most bar cleansers. They do not necessarily possess less detergency, they are just liquid forms of the bar cleansers. The only soap bar that is currently widely distributed is Ivory soap, which is a poor choice for most patients with skin disease. Any bar cleanser that is labeled a “beauty bar” can be used by most patients.

Quality skincare on a budget, summer sun protection

What is the difference between lower cost and expensive moisturizers?

After cleansing, the second most important skincare purchase is a moisturizer. There may be formulation differences between lower cost and expensive moisturizers. The primary ingredient in any lotion, the most popular moisturizer formulation purchased, is water. Water does not moisturize the skin, but it is important in getting the moisturizing ingredients on the skin and allowing them to spread to a thin layer. Lower-cost lotions may contain more water, meaning the consumer is getting less moisturization for their dollar. It is best not to purchase the least expensive lotion on the shelf.

Conversely, ultra-high-priced moisturizers may contain more elaborate packaging and better product aesthetics, which do not affect skin moisturization. It is probably best to avoid these expensive boutique moisturizers. The best moisturizers are moderately priced; however, I would recommend the brand name over the house generic because the brand named products have been through more tests, which is not typical of house brands. Even though the labels may read the same, the actual concentration and quality of ingredients may differ, allowing the moisturizers to vary significantly in performance.

Are expensive cosmetics better for skin?

This is a simple question to answer. Expensive cosmetics are not better for the skin. The most expensive part of a cosmetic is the packaging and the fragrance, neither of which have any effect on the functioning of the product.

Why may expired sunscreen be ineffective?

Sunscreens are expensive and seem to last forever, probably because they are seldomly used! It is a shame to throw away perfectly good expired sunscreen. Or, is the expired sunscreen not still perfectly good? Simply stated, the expired sunscreen is no good and should be thrown away.
Many of the newer sunscreen formulations contain inorganic filters, such as zinc oxide and titanium dioxide. These filters are thought to be safer and more natural, since they do not undergo chemical changes when exposed to UV radiation like the organic filters. There are many challenges when formulating with zinc oxide and titanium dioxide, which are minerals ground to a fine powder. The particulate is then added to a lotion base and must remain suspended in the lotion without clumping, a phenomenon known as flocculation, or sinking to the bottom, a phenomenon known as sedimentation. In a stable suspension, the sunscreen active particulate should remain evenly suspended throughout the bottle. However, as the suspension becomes unstable with time, the particles will clump and settle, diminishing the SPF of the sunscreen.

The organic filters, such as oxybenzone, avobenzone, octyl salicylate, homosalate, etc., are chemically reactive substances that undergo structural changes when absorbing UV radiation. Once a photon of UV radiation is absorbed, the filter has been used up and can no longer function as a photoprotectant. These chemical changes can occur in the bottle. Most organic filters are also oily substances that must be emulsified with the water soluble ingredients in the formulation to create stable lotions. Over time the emulsifier may fail and the emulsion will break down.

Expired sunscreens should be discarded because of possible product instability that no longer allows the product to perform up to the labeled SPF. Manufacturers determine expiration dating based on extensive stability testing involving cycling the product between hot and cold temperatures to accelerate instability. The only way for the consumer to determine the inability of the sunscreen to provide the desired photoprotection is to get sunburned! For this reason, all expired sunscreens should be thrown away.

Q. Is there any way to improve the ability of sunscreen to remain on the skin?

Once properly applied, the most common reason sunscreens fail is their inability to remain on the skin. The ability of a product to remain in place once applied is known as substantivity. Sunscreens are designed as substantive formulations and this is now communicated to the consumer as water resistant for a certain number of minutes. The higher the number of minutes, the more substantive the formulation, and the longer the sunscreen will remain in place. Currently, the highest water resistant rating is for 80 minutes.

The condition of the underlying skin over which the sunscreen is placed is also important. For example, a sunscreen will not stay in place on the skin when applied over a moisturizer. Moisturizers place an oily film over the skin preventing the sunscreen from sticking. Sunscreens should be placed on clean skin. After sun exposure, the sunscreen can be washed away and moisturizers applied.

In addition, the sunscreen application method is important. The sunscreen should be rubbed into the skin well and allowed to dry thoroughly. The film is still moveable and can be rubbed away until set. More rubbing is required to achieve an even film in hairy areas.

Q. Can body sunscreens be used on the face?

Sunscreen formulations have been developed for various body areas based on the needs of the particular area. In general, a sunscreen should be used in the area labeled on the packaging. For example, sunscreens for the face should be tested to insure they are noncomedogenic and nonacnegenic. This is not as big a concern for the body so body sunscreens may not undergo comedogenicity and acnegenicity testing.

Drug company promotion has always been a concern of the FDA from page 10
14th World Congress of Cosmetic Dermatology:
A unique and valuable learning experience

by ANNA CHACON, M.D.

One of my great passions is traveling the world and getting to experience a variety of ideas, people and landscapes. My one-of-a-kind experience at the 14th World Congress of Cosmetic Dermatology combined this passion with my passion for dermatology and the treatment of aging skin and skin disease in diverse populations. This is the first of a new ongoing blog in which I will share my experiences as I attend some of these far away meetings and the takeaways against a cultural backdrop.

The 14th World Congress of Cosmetic Dermatology was a wholly fascinating learning opportunity in this way — both in dermatology and in world culture. The congress took place in Lima, Peru, March 28-30, 2019, and was hosted by PeruDerm (Peru’s Dermatology Society) and the International Academy of Cosmetic Dermatology (IACD).

It was my first time visiting the country and I found it to be one of the most attractive tourist destinations in the world. Peru has a wide variety of ecosystems including the desert, mountains and a jungle, and is lined by a beautiful Pacific coastline. Lima is a cosmopolitan capital with more than 10 million people and much to offer including museums, historical sites, and tours.

Additionally, Peru is known as one of the best gastronomic destinations in the world. The food there reflects its indigenous population including the Incas, and has influences from colonizers and immigrants from Europe (particularly Spain, Italy and Germany), Asia (Japanese & Chinese), and West Africa.

In my surroundings, I experienced the unique culture and the influence of the Incas in the architecture, food, and people. Although I did not have a chance to travel to Cuzco or Machu Picchu, the richness of its history can be appreciated within the capital as well.

The academic and community of dermatologists is strong in the country, and the conference attracted world-renowned speakers from many other countries.

The keynote speakers included some of the best dermatologists from around the world: Dr. Francisco Perez Matamoros from Mexico; Dr. Doris Hexsel from Brazil; and Dr. Maritza Kummerfeldt from Guatemala; as well as experts from the United States: Dr. Keyvan Nouri, Miami; Dr. Mercedes Florez-White, Miami.; Dr. Vesna Petronic-Rosic, Washington, DC; and Drs. Paul Benedetto and Anthony Benedetto, Philadelphia, to name a few.

There were also well-known speakers from Chile, Bolivia, Argentina, Ecuador, Egypt, France, Germany, India, Indonesia, Lebanon, Italy, Malaysia, Panama, Spain, Russia, the United Kingdom and Venezuela.

The symposia ranged from dermatology hot topics that spanned all things aesthetics, including anti-aging trends, facial anatomy, minimally invasive treatments like peels and injectables to clinical topics that discussed acne and rosacea, pigimentary disorders, scar management and the treatment of keloids and striae; to business management strategies.

Dr. Anthony Benedetto chaired the full face rejuvenation symposium in which there were live patient demonstrations focused on the use of botulinum toxins in the upper and lower half of the face.

Some of the discussions included, Italy’s professor Leonardo Marinii who offered insight on ablative and non-ablative combination lasers for full-face rejuvenation. Dr. Kummerfeldt, president, Guatemalan Academy of Dermatology, addressed hyaluronic acid fillers, focusing on the differences between the types and how to best use them for facial rejuvenation. Dr. Katherine Barria Steinfort from Santiago de Chile, discussed skin renification strategies for full face rejuvenation and non-hyaluronic acid fillers. Dr. Hexsel offered insight into how to create the perfect lips using fillers, as well as use of botulinum toxin in the trapezius muscle to . . . . , which is a popular trend in Brazil. And, Malaysian dermatologist Dr. Subramaniam educated the audience on how to avoid and manage complications with fillers.

Other sessions included lectures focused on dealing with complications; patient management strategies; gender dermatology; body contouring beyond the face; cosmeceuticals, nutraceuticals and probiotics; facial rejuvenation in men; how to avoid complications with cosmetic procedures; and combined facial contouring procedures.

The congress included a gala dinner with traditional Peruvian food at the luxurious Westin hotel on Friday evening, in which all registering guests were cordially invited. There was also a cultural show with dancing and traditional outfits.

I was very grateful to have the opportunity to attend this conference. The city of choice, Lima, the venue at the Westin, and the keynote speakers could not have been better chosen. The joint organizing institution, PeruDerm was also very hospitable. This was such a unique event combining dermatology education in technology and scientific advances with history, entertainment, cultural exposure, and great food.

As I get the opportunity to share more of these experiences, I hope it encourages you to travel to some of these meetings. I guarantee you’ll come away with a broadened perspective on our specialty and how we can make a positive impact on patient care.
MINOVATION

MinoLira Tablets bring immediate- and sustained-release minocycline together for the first time ever in functionally scored tablets (105 and 135mg) for broad dosing options and safety similar to placebo.³

It’s the active ingredient you know – redefined.

MINOLIRA (minocycline hydrochloride) extended-release tablets

INDICATION AND USAGE
MINOLIRA is indicated to treat only inflammatory lesions of non- nodular moderate to severe acne vulgaris in patients 12 years of age and older. MINOLIRA did not demonstrate any effect on non-inflammatory acne lesions. Safety of MINOLIRA has not been established beyond 12 weeks of use. This formulation of minocycline has not been evaluated in the treatment of infections. To reduce the development of drug-resistant bacteria as well as to maintain the effectiveness of other antibacterial drugs, MINOLIRA should be used only as indicated.

IMPORTANT SAFETY INFORMATION
• This drug is contraindicated in persons who have shown hypersensitivity to any of the tetracyclines.
• Minocycline, like other tetracycline-class drugs, can cause fetal harm when administered to a pregnant woman.
• Minocycline may cause central nervous system side effects, including dizziness, or vertigo.
• Minocycline may cause intracranial hypertension and autoimmune disorders in adults and adolescents. Discontinue MINOLIRA if symptoms occur.
• Minocycline has been associated with anaphylaxis, serious skin reactions, erythema multiforme, and DRESS syndrome. Discontinue MINOLIRA immediately if symptoms occur.
• The most commonly observed adverse reactions are headache, fatigue, dizziness, and pruritus.

To report SUSPECTED ADVERSE REACTIONS, contact EPI Health, LLC at 1-800-499-4468 or FDA at 1-800-FDA-1088 or visit www.fda.gov/medwatch.

To learn more, please visit www.minolira.com

Alternative treatments for PsO

Patients increasingly try CAM; physicians need to ask questions

LISETTE HILTON | Staff Correspondent

More than four in 10 U.S. adults with psoriasis are using alternative remedies in place of traditional allopathic treatments, and nearly 40% report using alternatives to complement the medicines they’re on, ranging from vitamins and dietary changes to yoga, according to results of a survey published online March 29, 2019 in the *Journal of the American Academy of Dermatology*.

When asked why they used complementary and alternative therapies, about 56% of adults said traditional allopathic medicines did not help them or that they had unwanted side effects from traditional treatments. Nearly 23% said they prefer “natural” ingredients. Only about 4% suggested care access was a reason.

“The most important thing to take away from this study is that this is happening,” says the study’s senior author Adam Friedman, M.D., professor and interim chair of dermatology at George Washington School of Medicine and Health Sciences. “They are turning to what some physicians or even patients might not consider are medications as either their sole approach to treating psoriasis or in combination with what we’re giving them. And we have to ask them about it.”

Dr. Friedman and colleagues referred to a survey of psoriasis patients distributed by the National Psoriasis Foundation to nearly 101,000 members, asking about complementary and alternative medicine (CAM) use and motivations for it.

Two hundred-nineteen people completed the survey. Of those, 165 adults, or more than three-quarters, described themselves as having mild or moderate psoriasis. Still, nearly 46% of those surveyed considered their psoriasis to be severe.

Adults surveyed reported using about 100 specific therapies. Oral vitamins led the list of CAM treatments that patients reported taking, with one in five acknowledging it as a chosen therapy. Vitamin D and Omega 3 fish oil were their most preferred treatments.

When you talk about [CAM] it really creates a nice physician-patient relationship because they know [you’re] open to discussing things that are outside the allopathic box.”

Adam Friedman, M.D., George Washington School of Medicine and Health Sciences, Washington, D.C.
8 out of 10 commercially insured lives in the US have preferred access with no biologic step required for Otezla.¹

Otezla is listed as preferred, with no biologic step requirement, on:

- Aetna Prescription Drug Benefit
- Cigna Prescription Drug List
- CVS Caremark Formularies
- Express Scripts National Preferred Formulary
- OptumRx
- Prime Therapeutics
- UnitedHealthcare

Green checkmark indicates no DMARD or biologic step-edit required.

Contact your Otezla representative or visit otezlapro.com for a complete list of plans

*Basic, Standard, and Advanced Control Formularies.
¹SafeGuardRx® Program has 1 biologic step for patients on certain Otezla indications.

DMARD, disease-modifying antirheumatic drug.

Please see accompanying Brief Summary of Full Prescribing Information.

RESULTS—the way THEY WANT THEM

With a proven efficacy and safety profile, oral dosing, and no label-required lab monitoring, Otezla is a treatment experience patients can respond to.*

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

Otezla: the ONLY ORAL treatment indicated for psoriatic arthritis and plaque psoriasis¹

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 were 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; advise patients to contact their healthcare provider. Consider Otezla dose reduction or suspension if patients develop severe diarrhea, nausea, or vomiting
- Depression: 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
  - Psoriasis: 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; Depression was reported as serious in 0.1% (1/1308) of patients exposed to Otezla, compared to none in placebo-treated patients (0/506). Suicidal behavior was observed in 0.1% (1/1308) of patients on Otezla, compared to 0.2% (1/506) on placebo. One patient treated with Otezla attempted suicide; one patient on placebo committed suicide
  - Psoriatic Arthritis: Treatment with Otezla is associated with an increase in depression. During clinical trials, 1.0% (10/998) reported depression or depressed mood compared to 0.8% (4/495) treated with placebo. Suicidal ideation and behavior was observed in 0.2% (3/1441) of patients on Otezla, compared to none in placebo treated patients. Depression was reported as serious in 0.2% (3/1441) of patients exposed to Otezla, compared to none in placebo treated patients (0/495). Two patients who received placebo committed suicide compared to none on Otezla
- Weight Decrease: Monitor body weight regularly; evaluate unexplained or clinically significant weight loss, and consider discontinuation of Otezla
  - Psoriasis: Body weight loss of 5-10% occurred in 12% (96/784) of patients treated with Otezla and in 5% (19/382) of patients treated with placebo. Body weight loss of ≥10% occurred in 2% (16/784) of patients treated with Otezla compared to 1% (3/382) of patients treated with placebo
  - Psoriatic Arthritis: Body weight loss of 5-10% was reported in 10% of patients taking Otezla and in 3.3% of patients taking placebo
- 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
## Significant joint improvement

**In PALACE™ 1**

38% ACR20 response with Otezla® (apremilast) 30 mg twice daily (n = 168) vs 19% with placebo (n = 168) at week 16 (primary endpoint; P = 0.0001)

*The efficacy and safety of Otezla in psoriatic arthritis was evaluated in 3 multicenter, randomized, double-blind, placebo-controlled phase 3 trials in adult patients with active psoriatic arthritis (N = 1493). Patients were randomized 1:1:1 to either Otezla 30 mg twice daily, Otezla 20 mg twice daily, or placebo for 24 weeks, after a 5-day titration period.*

**In PALACE 1**, Otezla significantly increased ACR20 response (n = 168) at week 16 (primary endpoint) vs placebo (n = 168) (38% vs 19%; P = 0.0001).

**Safety profile:** The most common adverse reactions (≥5%) were diarrhea, nausea, and headache.

### PALACE 1-3 clinical development program

- Otezla was studied in 3 randomized, double-blind, placebo-controlled trials of similar design
- Adult patients (N = 1493) with psoriatic arthritis for at least 6 months, now with active psoriatic arthritis (≥3 swollen joints and ≥3 tender joints) despite prior or current DMARD therapy, were randomized 1:1:1 to placebo, Otezla 20 mg, or Otezla 30 mg given twice daily, after an initial 5-day titration.
- Patients who were therapeutic failures of ≥3 agents for psoriatic arthritis (small molecules or biologics) or ≥1 biologic TNF-α inhibitor were excluded.
- Placebo-controlled efficacy data were collected and analyzed through week 24. Placebo nonresponders at week 16 were re-randomized to either 20 mg twice daily or 30 mg twice daily Otezla. At week 24, all remaining patients receiving placebo were re-randomized to either 20 mg twice daily or 30 mg twice daily Otezla. Patients treated with Otezla remained on their initial treatment. Patients entering a long-term extension phase could be treated for 5 years.
- 65% of patients received concomitant therapy with at least one DMARD, including 55% methotrexate.

### Adverse Reactions

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

**Psoriatic Arthritis:** Adverse reactions reported in ≥2% of patients taking Otezla, that occurred at a frequency at least 1% higher than that observed in patients taking placebo, for up to 16 weeks (after the initial 5-day titration), were (Otezla%, placebo%): diarrhea (7.7, 1.6); nausea (6.9, 3.1); headache (5.9, 2.2); upper respiratory tract infection (3.9, 1.8); vomiting (3.2, 0.4); nasopharyngitis (2.6, 1.6); upper abdominal pain (2.0, 0.2)

### Use in Specific Populations

- Pregnancy and Nursing Mothers: Otezla is Pregnancy Category C. It has not been studied in pregnant women. Use during pregnancy only if the potential benefit justifies the potential risk to the fetus. It is not known whether apremilast or its metabolites are present in human milk. Caution should be exercised when Otezla is administered to a nursing woman.

- 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 turn the page for Brief Summary of Full Prescribing Information.**

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**MODERATE TO SEVERE PLAQUE PSORIASIS**

**In ESTEEM® 1**

33% PASI-75 response with Otezla 30 mg twice daily (n = 562) vs 5% with placebo (n = 282) at week 16 (primary endpoint; P < 0.0001)

†The efficacy and safety of Otezla in plaque psoriasis was evaluated in 2 multicenter, double-blind, placebo-controlled trials of similar design. Patients with moderate to severe plaque psoriasis (N = 1257) were randomized 2:1 to Otezla 30 mg twice daily or placebo for 16 weeks after a 5-day titration.

**In ESTEEM 1**, Otezla significantly increased PASI-75 response (n = 562) at week 16 (primary endpoint) vs placebo (n = 282) (33% vs 5%; P < 0.0001).

**Safety profile:** The most common adverse reactions (≥5%) were diarrhea, nausea, upper respiratory tract infection, tension headache, and headache.

### ESTEEM clinical development program

- Evaluated in a multicenter, double-blind, placebo-controlled trial. Patients with moderate to severe plaque psoriasis (N = 844) were randomized 2:1 to Otezla 30 mg twice daily or placebo for 16 weeks after a 5-day titration.
- At week 16, all patients originally assigned to placebo transitioned to Otezla 30 mg twice daily. At week 32, some patients originally randomized to Otezla were, based on clinical response, re-randomized to Otezla or placebo. Those re-randomized to placebo restarted Otezla 30 mg twice daily at loss of response, but no later than week 52.
- Selected inclusion criteria: Age ≥18 years, BSA involvement ≥10%, PASI ≥3, PASI score ≥12, candidates for phototherapy or systemic therapy.
- Patients entering a long-term extension phase could be treated through 5 years.
Adverse Reactions Reported in ≥2% of Patients on OTEZLA 30 mg Twice Daily and 21% Than That Observed in Patients on Placebo on Day 1-5 (Placebo %, OTEZLA %): Diarrhea (1.2%, 9.5%), Nausea (1.4%, 7.4%), Headache (1.6%, 4.8%). Upper respiratory tract infection (0.6%, 0.6%), Vomiting (0.4%, 0.8%), Nasopharyngitis (0.2%, 0.2%). Abdominal pain upper (0.0%, 0.6%).

Adverse Reactions Reported in ≥2% of Patients on OTEZLA 30 mg Twice Daily and 21% Than That Observed in Patients on Placebo on Day 6-112 (Week 16) (Placebo %, OTEZLA %): Diarrhea (1.6%, 7.7%), Nausea (3.1%, 9.9%), Headache (2.3%, 5.5%). Upper respiratory tract infection (1.8%, 3.9%), Vomiting (0.4%, 3.2%), Nasopharyngitis (1.6%, 2.8%). Abdominal pain upper (0.2%, 2.0%).

Of the reported gastrointestinal adverse reactions, 1 subject experienced a serious adverse reaction of nausea and vomiting in OTEZLA 30 mg twice daily. 1 subject treated with OTEZLA 30 mg twice daily experienced a serious adverse reaction of diarrhea. 1 patient treated with OTEZLA 30 mg twice daily experienced a serious adverse reaction of headache. Of the reported adverse drug reactions none were serious.

Other adverse reactions reported in patients on OTEZLA in clinical studies including extension studies:


*1 patient treated with OTEZLA 30 mg twice daily experienced a serious adverse reaction.

Psoriatic Arthritis Clinical Trials

The safety of OTEZLA was assessed in 1426 subjects in 3 randomized, double-blind, placebo-controlled trials in adult subjects with moderate to severe plaque psoriasis who were candidates for phototherapy or systemic therapy. Subjects were randomized to receive OTEZLA 30 mg twice daily or placebo twice daily. Titrations were used over the first 5 days (see Dosage and Administration (2.1)). Subjects ranged in age from 18 to 83 years, with an overall median age of 46 years.

Diarrhea, nausea, and upper respiratory tract infection were the most commonly reported adverse reactions. The most common adverse reactions leading to discontinuation for subjects taking OTEZLA were nausea (1.6%), diarrhea (1.0%), and headache (0.8%). The proportion of subjects with psoriasis who discontinued treatment due to any adverse reaction was 6.1% for subjects treated with OTEZLA 30 mg twice daily and 4.1% for placebo treated subjects.

Adverse Reactions Reported in ≥1% of Subjects on OTEZLA and With Greater Frequency Than in Subjects on Placebo: up to Day 112 (Week 16) (Placebo %, OTEZLA %): Diarrhea (6%, 17%), Nausea (7%, 17%), Upper respiratory tract infection (6%, 9%), Tension headache (4%, 6%), Headache (4%, 6%), Abdominal pain (2%*, 2%), Vomiting (2%, 4%), Fatigue (2%, 3%), Dyspepsia (1%, 3%), Decreased appetite (1%, 3%), Incontinence (1%, 2%), Back pain (1%, 2%), Migraine (1%, 2%), Frequent bowel movements (0%, 2%), Depression (0%, 1%), Bronchitis (0%, 1%), Tooth abscess (0%, 1%), Feliculosis (0%, 1%), Sinus headache (0%, 1%).

*2 subjects treated with OTEZLA experienced serious adverse reaction of abdominal pain.

Severe worsening of psoriasis (rebound) occurred in 0.3% (4/1184) subjects following discontinuation of treatment with OTEZLA.

DRUG INTERACTIONS

Strong CYP450 Inducers: Apremilast exposure is decreased when OTEZLA is co-administered with strong CYP450 inducers (such as rifampin) and may result in loss of efficacy (see Warnings and Precautions (5.3) and Clinical Pharmacology (12.3)).

USE IN SPECIFIC POPULATIONS

Pregnancy: Pregnancy Category C: OTEZLA should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. Pregnancy Exposure Registry: 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 1-888-236-2272. Nursing Mothers: It is not known whether OTEZLA or its metabolites are present in human milk; however apremilast was detected in milk of lactating mice. Because many drugs are present in human milk, caution should be exercised when OTEZLA is administered to a nursing woman. Pediatric use: In a 12-week, randomized, double-blind study, 42 children with psoriatic arthritis (age 6 to 17 years) were treated for 12 weeks with apremilast 0.3 mg/kg twice daily or placebo. Patients treated with apremilast should have their weight monitored regularly. If unexplained or clinically significant weight loss occurs, weight loss should be evaluated, and discontinuation of OTEZLA should be considered.

Drug Interactions: Co-administration of strong cytochrome P450 enzyme inducer, rifampin, resulted in a reduction of systemic exposure of apremilast, which may result in a loss of efficacy of OTEZLA. Apremilast exposure is decreased when OTEZLA is co-administered with strong cytochrome P450 enzyme inducers (e.g., rifampin, phenobarbital, carbamazepine, phenytoin) with OTEZLA (see Drug Interactions (7.1) and Clinical Pharmacology (12.3)).
“Just because something is natural and not a prescription medication, that doesn’t mean that it can’t interact with other medicines and potentially cause some harm. It doesn’t mean that it can’t work, either.”

Adam Friedman, M.D., George Washington School of Medicine and Health Sciences, Washington, D.C.

Complementary treatments may or may not work for psoriasis

Popular supplements in the category of oral vitamins, but flavaseed, type 2 collagen, glutamine and ubiquinol were on the list too.

Almost as many adults said they used dietary changes, led by gluten-free diets, as a psoriasis remedy. Dairy free, low met, elimination diet, Pagano diet and whisky-soaked raisins were among the other dietary attempts at psoriasis relief.

More than 16% reported using topical herbas and botanicals, led by turmeric. Coconut oil and Aloe Vera were also commonly reported therapies in this category. Others reported herbal tar shampoo, bitter gourd juice and castor oil.

Sun exposure and tanning bed use topped complementary and alternative behavioral methods. Nearly 10% used either Dead Sea bath salts or meditation to treat the skin condition. Some other treatments reported in the category included chiropractic care and cryotherapy. More than 8%, or 37 adults, turned to yoga and 37 adults used acupuncture. A few patients (6) reported using cupping.

Some respondents noted trying therapies in the “other” category, such as over-the-counter creams, lotions and ointments. CBD and marijuana use was reported second in that category.

About 67% of the 158 patients who answered the question about how long they had used CAM for psoriasis said it had been at least a year. Yet, about 57% of patients surveyed said they either wouldn’t recommend CAM to others or were unsure if they would.

What does it mean?

Dr. Friedman says it’s important that dermatologists ask each psoriasis patient what he or she is using. One of the big concerns is that some supplements, including vitamin E and fish oil, can increase bleeding time, according to Dr. Friedman.

“So if someone has psoriasis and they’re on a blood thinner and we need to biopsy them, they may not report that they’re on these nontraditional medications, which could cause bleeding issues,” Dr. Friedman explains.

We cannot use the term “medications” when inquiring, he says, because of the fact that patients might not consider these medications.

“We really need to ask about everything … just because something is natural and not a prescription medication, that doesn’t mean that it can’t interact with other medicines and potentially cause some harm. It doesn’t mean that it can’t work, either,” Dr. Friedman says.

Evidence base

While people with psoriasis might take supplements hoping they’ll help, there is no documented efficacy for supplement use, including vitamin D or B12, for psoriasis.

However, Dead Sea treatments, reported by some patients, have reported efficacy in psoriasis, according to Dr. Friedman.

“Oral curcumin, which is derived from turmeric, has been shown to be effective for psoriasis,” Dr. Friedman says. “The problem is it’s not very bioavailable, so you have to give tons of it.”

Dr. Friedman is working on using nanoparticles of curcumin for topical formulation. Curcumin tends to turn everything that it comes in contact with orange. He has shown in published research that by decreasing the size of the curcumin, it doesn’t scatter visible light. That can make the orange invisible, he says.

Research suggests that one CAM treatment that no one who was surveyed mentioned, the plant extract indigo naturalis, which is widely used in Traditional Chinese Medicine, also has efficacy.

“There is some evidence that indigo naturalis has some clinical efficacy in psoriasis as a topical agent,” Dr. Friedman says. “And there is some suggestion that it works on interleukin 17, which we now know is very important for psoriasis.”

Beyond that, dermatologists, researchers and patients have little science backing CAM treatments for psoriasis. And they know little about potential side effects or drug interactions associated in general with CAM,” Dr. Friedman says.

“I think we have to take this study at face value—people were either dissatisfied with traditional therapies or there were side effects,” he says. “Going into the issue of people being dissatisfied with traditional therapies, I would argue that the reason for that is people are being undertreated.”

Communication is key

Dr. Friedman says he spends 45 minutes or so with new psoriasis patients, not only educating them about their psoriasis and potential treatments, but also asking them what they’ve tried to relieve their symptoms.

He’ll then ask more pointed questions, such as: Have you tried vitamins for your psoriasis? Botanicals? Meditation? Etc.

Talking with patients about CAM does more than inform the dermatologist about potential side effects or drug interactions, according to Dr. Friedman.

“It shows that I’m thoughtful about CAM and open to discussing it. A lot of patients are embarrassed to discuss CAM. They think doctors don’t like it. So, they get excited when they can talk about it with me,” he says. “When you talk about these things, it really creates a nice physician-patient relationship because they know I’m open to discussing things that are outside the allopathic box.”

Disclosures
Dr. Friedman reports no relevant conflicts.
Evaluate beyond severity

Randy Dottinga | Staff Correspondent

The evaluation of psoriasis requires more than simply checking the severity and spread of the disease, a new report suggests. Rather, physicians should try to distinguish between stable and active disease with an eye toward the broader body-wide effects of the latter form.

“Stable plaque psoriasis of limited extent can be treated as a cutaneous disease, not impacting comorbidities, whereas more extensive active disease should be regarded as a systemic inflammatory disease, impacting internal diseases, including arthritis and metabolic syndrome,” the authors write. The report was published March 28 in the *Journal of the European Academy of Dermatology and Venereology*.

The authors, led by E. Christophers of the department of dermatology at SH University Clinics in Kiel, Germany, made several points about psoriasis:

- Severity of psoriasis and systemic disease—especially cardiovascular disease (CVD)—are linked.
- In psoriasis, and in RA [rheumatoid arthritis] chronic inflammation with extensive organ involvement predisposes to risk for CVD. In addition, the incidence of psoriatic arthritis is shown to increase with duration of skin disease. In fact, the proportion of patients simultaneously affected by psoriasis and PsA [psoriatic arthritis] increased proportional to the duration of psoriasis.
- In severe psoriasis, systemic inflammation “spills over” via elevated levels of blood cytokine, c-reactive protein, fibrinogen and/or plasminogen activator inhibitor-1.
- There’s a difference between localized and “activated” disease. In 80% of cases, patients have mild psoriasis with stable plaques. “In patients with mild stable disease, lesional pathology is self-sustaining and persists without measurable systemic abnormalities,” they write. “On the other hand, in case of instability of the psoriatic process, a different appearance of the lesions is seen, which can be designated as instable psoriasis or active psoriasis.”
- Why does the distinction between localized and activated disease matter? The authors say differentiating between the two types of immune reactivity may help to further define systemic inflammation in psoriasis.

“Disease severity, simply based on body involvement and the sum of erythema induration and scaling, appears insufficient as it fails to include ‘activity’ which means the inflammatory backbone of psoriasis,” they write.

As such, disease assessments such as PASI [Psoriasis Area and Severity Index], BSA [Body Surface Area], PGA [Physician Global Assessment] fail to show the whole picture.

“Disease assessment in terms of activity comprises the real nature of psoriasis, reflecting the activity of innate and adaptive immunity,” the author stress. “Disease activity is likely to provide a more meaningful approach for treatment management than only disease extent.”

The authors of the report propose that including disease activity in outcome measures for severity may provide a clearer picture of the efficacy of available treatments.

Disclosures
The authors report no study funding or disclosures.

References

Tool may help ID PsA

Dr. David Ozeri | Staff Correspondent

Psoriasis is a chronic prevalent inflammatory disease of the skin that affects approximately 4% of the population. It is estimated that 30% of patients with psoriasis also suffer from psoriatic arthritis. The presence of psoriatic arthritis has implications and treatment joints and morbidity, therefore recognizing psoriatic arthritis is paramount. Unfortunately, several studies have demonstrated that psoriatic arthritis is under diagnosed in patients with psoriasis.

In an article addressing psoriatic arthritis diagnosis, P.J. Mease, M.D., of the Swedish Medical Center, University of Washington, Seattle, and colleagues used the Psoriasis Epidemiology Screening Tool (PEST), a validated short questionnaire to detect undiagnosed psoriatic arthritis. The report was published in the *Journal of the European Academy of Dermatology and Venereology* in January 2019.

The PEST was applied to patients in the Corrona Psoriasis Registry, a large, independent, prospective, observational cohort of patients with psoriasis. Nine hundred and four (56% of the cohort) patients with psoriasis and no diagnosis of psoriatic arthritis at enrollment. Of the patients with no history of psoriatic arthritis, 112 (12%) had a PEST score of three or more, suggesting the need for further psoriatic arthritis evaluation. Elevated PEST score was also associated with nail pitting, elevated BMI which are also risk factors for the development of psoriatic arthritis.

The authors postulate that the PEST can help dermatologists identify which patients need a rheumatology referral. This assists with timely diagnosis of psoriatic arthritis and prevention of erosive disease that occur within the first year of psoriatic arthritis onset, which is associated with more disability.

The authors note that there are several modalities at the dermatologists disposal to identify psoriatic arthritis, such as ToPAS, PASQ, and PACE. More head-to-head comparisons are required to identify which tool performs best.

Still, the observed 12% of patients with a PEST score of three or more reinforces the importance of screening psoriasis patients for psoriatic arthritis.

Disclosures
The authors report no study funding or disclosures.

References
Factors that influence real-world biologic efficacy

WHITNEY J. PALMER | Staff Correspondent

Identifying the right medication for a patient with a skin condition can often be difficult. But, even pinpointing the right treatment doesn’t mean it will work equally as well over time.

With many patients, real-world factors frequently interfere with a drug’s performance.

Stephen Wolverton, M.D., professor of dermatology at the Indiana University School of Medicine, discussed these various factors that could reduce a drug’s efficacy over time during the American Academy of Dermatology meeting in Washington, D.C.

“It’s a very frequent issue for biologics to, after the initial response, lose efficacy,” he says. “So, it’s important for dermatologists to know that there are antibodies to drugs or factors, such as the loading dose versus maintenance dose frequency, that can impact efficacy.”

These factors can affect drug efficacy, Dr. Wolverton says:

1. **LOADING DOSE VS. MAINTENANCE DOSE:**
   It often takes a higher dose of medication to get a skin condition under control than it does to keep it manageable, Dr. Wolverton says. However, analyzing disease presence and medication efficacy can be less than fully objective. For example, it’s possible that PASI scores for erythema, thickness and scaling might not accurately depict medication efficacy, particularly if the score is determined by a provider who doesn’t frequently treat skin conditions.

2. **ANTI-DRUG ANTIBODIES:**
   Over time, he says, it’s possible for patients to develop anti-drug antibodies that can neutralize the efficacy of their medications. Additionally, these antibodies can lead to lower drug serum levels and an increased hypersensitivity to adverse effects.

   This neutralizing effect varies by medication. For instance, TNF inhibitors, including infliximab and adalimumab, experience the most neutralizing effects. However, the neutralizing effect does not affect entercept (Enbrel, Amgen). Among the anti-interleukins (12, 17A, and 23), the neutralizing effect ranges from low-to-moderate. According to existing research data, depending on the medication and the dose, the neutralizing effect can be as much as 83%.

3. **DOsing Gaps:**
   Existing data indicate that gaps in dosing can also be responsible for loss of efficacy because it can open the door to creation of anti-drug antibodies. However, Dr. Wolverton says, it’s unclear whether slow tapering of medication use is responsible for the same effect.

   Overall, Dr. Wolverton says more clinical trials are needed to determine the largest influences over the appearance of anti-drug antibodies. This knowledge could impact how dermatologists decide to change dosing or reduce frequency.

Reference


“...it’s important for dermatologists to know that there are antibodies to drugs or factors, such as the loading dose versus maintenance dose frequency, that can impact efficacy.”

Stephen Wolverton, M.D., Indiana University School of Medicine, Indianapolis
You really have a population who doesn’t feel that their needs for their skin are being met.”

Abby Van Voorhees, M.D., professor and chair of Dermatology at Eastern Virginia Medical School, Norfolk, Va.

Burden of psoriasis may be lowered through new treatment options

Abby Van Voorhees, M.D., professor and chair of dermatology at Eastern Virginia Medical School, Norfolk, Va.

Patients with psoriasis also have an increased risk of early death, particularly from the consequences of cardiovascular disease, such as myocardial infarction. Cardiovascular disease appears to occur earlier in patients with psoriasis — and the increased risk is similar to that related to diabetes, she adds.

A real-world study looking at U.S. patients with psoriasis found the most prevalent comorbidities to be hyperlipidemia (48.6%), hypertension (44.7%), depression (18.7%), type 2 diabetes mellitus (18.3%), and obesity (15.0%).

“An substantial proportion of patients with psoriasis have comorbid conditions that should be considered when formulating a treatment and management plan,” says Steven Feldman, M.D., of the department of dermatology, Wake Forest University School of Medicine, Winston-Salem, N.C., who was a researcher on this study.

“These conditions can complicate treatment of patients with psoriasis. The choice of treatment may have intended or unintended effects on some of the common comorbidities,” he adds.

The presence or absence of certain comorbidities can drive some physicians toward or away from various treatments, according to Dr. Van Voorhees.

For example, if a patient with psoriasis also has an inflammatory bowel disease, such as Crohn’s, she says she will try to avoid using an IL-17 agent because that could potentially make the Crohn’s disease worse. However, if the patient with psoriasis also has psoriatic arthritis, she will actively choose an IL-17 or a TNF inhibitor, because they are known to be as effective as most biologics on the market.

“Patients with psoriasis have lower earnings potential than general population.”

References


Quick Takes

Study: Most prevalent comorbidities are hyperlipidemia, hypertension, depression, type 2 diabetes mellitus, and obesity.

Burden continues on page 31

PSORIASIS TREATMENT OPTIONS EXPAND

By Whitney J. Palmer

PSORIASIS TREATMENT has expanded dramatically over the past decade, and the growth shows no signs of stopping.

Within the next five years, the industry can expect to see potentially three new biologic therapies and one additional oral agent.

Andrew Blauvelt, M.D., a dermatologist with Oregon Medical Research Center, discussed the new drugs in the pipeline during the American Academy of Dermatology Annual Meeting in Washington, D.C.

“Despite the emergence of highly efficacious and safe therapies for psoriasis in the last several years, the psoriasis pipeline continues to be vibrant,” he said.

These potential new treatments are already engaged in human clinical studies.

RISANKIZUMAB

This biologic therapy has been found, in clinical studies, to improve the presence of psoriasis by 38 percent over ustekinumab, he said. Study results indicate it is more efficient than other interleukin (IL)-23 blockers on the market, and it is durable for more than a year. It currently presents no safety concerns and offers convenient dosing every 3 months.

It also has potential efficacy for psoriatic arthritis and Crohn’s disease. However, it does not appear effective for ankylosing spondylitis. The Food & Drug Administration (FDA) approved risankizumab April 24, 2019, he said.

MIRIKIZUMAB

This second biologic has also performed well in clinical studies. Results revealed it creates an 82% improvement in psoriasis symptoms among patients who previously received placebo treatment.

Although initial studies found it to be slightly less effective than other IL-23 blockers, a dose increase in Phase 3 trials improved performance, he said. The therapy is equally durable to risankizumab — more than a year, and it presents no safety concerns. Dosing is set at every 2-to-3 months.

In addition to psoriasis, it shows an indication for ulcerative colitis, and potential FDA approval could come in 2021.

BIMEKIZUMAB

As a biologic, this therapy showed 93 percent to 100 percent of psoriasis patients maintained a PASI 90 response from week 12 to week 60 in clinical studies.

Compared to other IL-17 blockers on the market, bimekizumab is more effective, and it has a durability of more than 1 year. It does present some risk of mucocutaneous candidiasis, but no other safety concerns are identified. Dosing occurs every 1-to-2 months.

Alongside treating psoriasis, it shows relative efficacy in addressing psoriatic arthritis, but it may not be effective in addressing irritable bowel disease. Research anticipate FDA approval in 2020.

BMS-986165

This is the only oral therapy in the pipeline, Blauvelt said. While more effective than most oral therapies on the market, it does not appear to be as effective as most biologics on the market. Currently, its durability is unknown as are the other diseases it could impact. Its safety profile is good, but it can cause some nausea, headaches, acne, and high creatine phosphokinase levels.

If approved by the FDA — potentially in 2021 — it would be dosed daily.

Although these therapies are not yet on the market, it’s important for dermatologists to be aware of the additional treatment options for the psoriasis patients. It will help them prepare to offer the best care possible, Blauvelt said.

“These new additions will give dermatologists a greater set of therapeutic options that are safe and, in some cases, even more efficacious than existing choices,” he said. “These drugs will also enable clinicians greater ability to achieve clear or near-clear skin, the new gold standard in treating psoriasis, in the majority of their patients.”

References

highly effective in both conditions. There also is early evidence to suggest that if patients with psoriatic arthritis are treated with TNF inhibitors it reduces the risk of overall mortality and cardiovascular comorbidity, she adds.

ECONOMIC IMPACT

Aside from the increased morbidity and mortality, psoriasis has a substantial impact on patients’ pockets. Those with severe psoriasis have a much lower earning potential than those in the general population, as they often have to take time out of the workplace to attend doctors’ appointments and treatment and/or take sick leave because their skin is painful, Dr. Van Voorhees says.

“There is no question that this impacts people’s livelihoods quite substantially, and probably part of that is active choices on the part of the patient,” she says.

Psoriasis mostly commonly starts in the late teens or early 20s — a time when people are making their career choices, she says. You can imagine a patient weighing job opportunities that enable them to go to treatments and appointments, whereas someone who does not have psoriasis wouldn’t have the same considerations.

Psoriasis also has a substantial economic impact on the health systems responsible for their care and the wider economy, although the full extent of the economic is difficult to quantify.

One of the most comprehensive analyses to date is a systematic review that attempted to quantify the costs of psoriasis in the United States in 2013. The review evaluated 22 studies and put the cost of psoriasis in the United States in 2013. The economic impact of psoriasis was found to be greatest for patients with more severe psoriasis and comorbidities, in particular psoriatic arthritis, depression or anxiety.

April Armstrong, M.D., of the department of dermatology, University of Colorado, Denver, and a reviewer, says the figures were likely an underestimate of the total cost burden. “A pressing need exists to conduct a comprehensive study from a societal perspective that captures the direct, indirect, intangible, and comorbidity costs associated with psoriasis,” she says.

It is also important for studies examining the costs of systemic therapies for moderate-to-severe psoriasis to take account of their cost-effectiveness, not just their direct costs, she adds.

“A substantial proportion of patients with psoriasis have comorbid conditions that should be considered when formulating a treatment and management plan.”

Steven Feldman, M.D., Wake Forest University School of Medicine, Winston-Salem, N.C.

Burdens of psoriasis carry economic, quality-of-life considerations

“Long-term cost-effectiveness models for systemic and biologic drugs are needed to provide valuable algorithms for treatment selection,” Dr. Van Voorhees says.

Surveys by the National Psoriasis Foundation and formal studies have shown that a large number of patients with psoriasis in the United States are frequently dissatisfied with the medical treatment they receive for their condition.

“It is not surprising,” says Dr. Van Voorhees, chair of the National Psoriasis Foundation medical board, “because even amongst those with very severe psoriasis, most of them are not on any kind of systemic agent at all. Most are using a topical steroid and often not even that. You really have a population who doesn’t feel that their needs for their skin are being met.”

This undertreatment is a combination of patients not being prescribed the most effective drugs because they are not covered by insurance, doctors deciding to offer only a topical because of the difficulties in getting approval for a systemic agent, and patients being concerned about taking systemic agents because of potential side effects, she explains.

“The onus is on us as their caregivers to make sure that we get their skin clear or almost clear and that often requires a systemic agent,” she says. These drugs are generally well tolerated and can be “life changing in terms of the profoundness of the effect they can have on people when their skin clears”.

Phototherapy continues to represent an important mainstay of treatment for patients who do not want to take systemic agents and have the time to attend sessions, Dr. Van Voorhees adds.

“Phototherapy is really like a systemic therapy in my mind, because it really is changing — through the skin — a reduction in the inflammation of the skin. I almost think of it as like a transdermal anti-inflammatory therapy.”

References

A simple neck lift without a facelift works really well,” says Dr. Moy, past president of the American Academy of Dermatology, American Society for Dermatologic Surgery and American Board of Facial Cosmetic Surgery. “It always looks natural, yet it still improves the lower face. It sort of gives you a lower facelift.”

Surgeons can perform a neck lift restricted to the area behind the ear under local anesthesia. The procedure is relatively short — about an hour and a half. Thanks to tumescent anesthesia, there’s little risk of bleeding. And it usually addresses patients’ biggest concerns, according to Dr. Moy. “Generally, it’s the pullback posteriorly — the backward pull — that really does all the tightening. That usually tightens the platysma muscle and tightens the skin,” he says. “We usually don’t have to make the incision in the submental area, where you’d have to suture the bands together or do some type of suctioning. The posterior pull really does all of that.”

Whether he’s operating on men’s or women’s necks, Dr. Moy says he usually removes about 2 inches of skin. “Technically it’s simple — it’s just trimming and suturing. Any dermatologist can do that procedure. And patients are really happy with the results.” — Ronald Moy, M.D., Beverly Hills, Calif.
Building a body business

Interested in getting into the body contouring game? Here’s how

JOHN JESITUS | Staff Correspondent

Just as many body-contouring devices work best in focal areas, practices that enter this market must plan and target their efforts for maximum efficiency, according to one expert. Contrary to some opinions, it’s not too late for board-certified dermatologists to plant their flag in the body-contouring turf.

That’s according to San Francisco-based dermatologist Kathleen Welsh, M.D., who advises any dermatologists who think they’ve missed the body-treatment boat to take heart. “Many dermatologists are afraid to get into this because they think, ‘I’m late to the game. Everybody on my corner has this device. Maybe I shouldn’t join in.’”

However, says Dr. Welsh, dermatologists must remember that many of these competing practices are chains run by business people, not doctors. “We have a huge advantage in getting into this space in that we can properly evaluate the technology. We have the patients. These patients want to see someone they can trust. And if they have the opportunity, they want to see us,” says. Dr. Welsh who spoke on this issue earlier this year at the Generational Dermatology Palm Springs Symposium.

START HERE
Deciding whether to add a body business starts with looking at one’s patient base, she says.

Dermatologists usually have robust medical patient bases whose trust they have earned, and who would likely welcome new services, according to Dr. Welsh. “But you might want to take a brief poll of your patients and see how many might be interested in body services.” She also recommends surveying the local competition and considering how to distinguish your offerings.

Next, consider costs of additional equipment, space and personnel. “We do a very simple return on investment calculation: my office is open about 200 days a year. If I were going to buy a $100,000 piece of equipment, I divide it by 200. Then my overhead is about 50%. So I would have to make $1,000 a day on that piece of equipment to pay it back in one year.”

Next steps include writing a business plan and investigating available technology. Dr. Welsh prefers manufacturers whose other equipment has worked well in her practice. She also scrutinizes the objectivity of a company’s clinical research and researchers. Talking to investigators and peers helps as well, but she advises avoiding a customer provided by the manufacturer. “You don’t know if that person has received compensation for talking to you. You need an unbiased opinion.”

Dr. Welsh began providing body contouring in 2009 with CoolSculpting (Allergan). Being the first adopter of new technology provides a local competitive advantage, she says. “But there’s also a disadvantage to being first in that you’re doing all the marketing for that device. If you’re in the second wave of adopting a new technology, other people have already done that. There’s already a buzz.”

INTERNAL MARKETING IS KEY
Although Dr. Welsh’s practice pays for Google AdWords to boost its search status, most of its marketing is internal. “External marketing is very expensive.” And your billboard

When you have a body business, having a large number of your own before-and-afters is a highly effective marketing tool.”

Kathleen Welsh, M.D., San Francisco
WHAT MOTIVATES WOMEN TO GET THEIR BODIES IN BETTER SHAPE?

By LISETTE HILTON

WHAT MOTIVATES WOMEN to get their bodies in better shape? Inquiring minds at Cynosure wanted to know and surveyed 1,000 women in the UK to find out. Half of them said seeing an unflattering photo of themselves would prompt them to want to make a change, according to the survey. Cynosure is the maker of SculpSure, an FDA-approved light-based fat reduction technology.

A close second, one-third of the women surveyed said getting back into clothes that no longer fit would entice them to do something about unwanted fat.

Much lower on the motivation scale were post-baby bodies, breakups, peer pressure and celebrities.

Post childbirth body changes were an incentive for 8% of those surveyed.

One in 20 women said a divorce or breakup would trigger a desire for body change.

And while peer pressure — meaning seeing their friends shaping up — played a role for some, only 4% said the influence of their peers would prompt the desire for body change.

Finally, a mere 2% said celebrities’ and role models’ bodies would make them want to change their shapes.

The cosmetic industry has recognized the power of photos on self-image for years. In 2014, the American Academy of Facial Plastic and Reconstructive Surgery (AAAPRS) released news about how the rise of selfies was greatly impacting the facial plastic surgery industry. An AAAPRS poll during that time revealed that one in three facial plastic surgeons surveyed saw an increase in requests for procedures due to patients being more self-aware of looks in social media.

“In fact, 13% of AAAPRS members surveyed identified increased photo sharing and patients’ dissatisfaction with their own image on social media sites as a rising trend in practice. As a result, AAAPRS members surveyed noted a 10% increase in rhinoplasty in 2013 over 2012, as well as a 7% increase in hair transplants and a 6% increase in eyelid surgery,” according to an AAAPRS press release.

To support her marketing efforts, Dr. Welsh capitalizes on comarketing dollars available from equipment manufacturers. “If you buy a certain number of their widgets, they’ll give you back a certain number of dollars which you can use for marketing — e-mail campaigns within your practice, posters in your office, Google ads or newsletters. We utilize those comarketing dollars pretty extensively.”

Consultants commonly say that print newsletters are outdated, adds Dr. Welsh. But that hasn’t been her experience. “We do two print newsletters a year, and we have patients coming in clutching that newsletter.” Patients inquire about featured services and grab copies for family and friends. “We try to make our print newsletter extremely educational and downplay the marketing aspect. It’s been a very successful strategy for us. People look forward to it.”

Twice yearly, the practice hosts body events where patients can get on-the-spot consultations and discounts for pre-purchased treatment series. “We’ll also do mini-treatments on patients with some devices. For example, we had an open house where we let patients try our new eMSculpt device (BTL) for five minutes, and then sign up for a series of treatments.”

Once your body business is running, Dr. Welsh advises keeping current with technology and techniques. “If you buy a device and a new handpiece that works faster or better comes out, make sure you’re investing in new technology because everybody around you will have the newer, better device.” By the same token, she says, ongoing staff training, including advanced manufacturer training, helps keep your practice at the top of the field.

Disclosures
Dr. Welsh has been a speaker for BTL (honoraria) and is an Allergan shareholder.

References

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Choosing aesthetic procedures, one must consider the patient as an individual and in the context of their culture and international beauty standards. That’s according to Beverly Hills, California-based dermatologist Ava Shamban, M.D., who spoke on the concept of international beauty at last year’s Fall 2018 Cosmetic Bootcamp.

“Beauty is something that we all recognize, but it’s very difficult to define,” says Dr. Shamban who used The 2018 Winter Olympics as an opportunity to compare and contrast international standards of facial beauty.

Generally, says Dr. Shamban, one can determine an athlete’s nationality from their facial features. For example, German figure skaters’ faces displayed an oval shape consistent with long-held beauty standards. “The Koreans have a bit more defined jawline.” Korean men particularly like a strong V-shaped jawline, she adds, so much so that they sometimes undergo surgery to accentuate or re-create it.

Among the Chinese skaters whose photos Dr. Shamban reviewed, she notes a male’s strong, square jawline versus a female’s more heart-shaped face, with slightly larger proportions for the lips and eyes. As in China and Korea, she says, the Japanese aesthetic favors a strong male jawline, but without the V-shape prized by many Koreans. “The Italian skaters have very beautiful but slightly different physiognomies,” she adds.

A Melting Pot

The U.S. is a melting-pot of beauty aesthetic that encompasses all ethnicities, says Dr. Shamban, while in some other nations, people tend to seek a more uniform look. Nevertheless, she says, the golden ratio or Phi applies equally to beautiful faces across cultures, genders and eras — from Nefertiti to modern-day representatives of all races. “In all the work we do, we want to obey the patient’s ethnicity while still re-establishing a lot of these ratios, whether in two-dimensional or three-dimensional form.”

When actress Reese Witherspoon started out, says Dr. Shamban, she had a distinctly heart-shaped face with a somewhat pointed chin, along with a midface defect. “That’s all been corrected. But it hasn’t changed her appearance. That’s what’s so important.” From Rihanna to Beyoncé, she says, changing a celebrity’s face could hinder her or his career. “I believe it’s the same for everyone. You don’t want to compromise what someone looks like, because then you might as well be working for the witness protection program.”

Along with satisfying universal and cultural beauty standards, Dr. Shamban notes, facial features must match the wearer’s persona. “This is where the actresses — and even the actors — go wrong. Everybody has something special about their persona. Make sure that everything you do is consistent with that.”

The Signature Feature

Considering each person’s signature feature can help guide treatment decisions, says Dr. Shamban. “Use the blink test, because that engages the subcortical area of your brain to identify what’s most prominent — usually eyes or lips.” Reducing facial lines, wrinkles and dyspigmentation dials down background noise to accentuate a patient’s signature feature.

“We want to have memorable faces, because that becomes your calling card. It’s something you wear every day.”

The two facial features that are always unique and immutable are the eyes and mouth, Dr. Shamban says. Michelle Pfeiffer’s widely spaced eyes contrast with those of Jennifer Aniston, which are set more closely together.

“Everyone’s eyes are shaped slightly differently. So in general, we’re trying to highlight or showcase the eyes. The only thing we’re really doing is shaping the brow and making sure the eyes are framed by the lashes and brows. But we don’t change the shape of the eye at all.”

Aesthetic fillers for the nose have sparked substantial debate because these treatments have caused the highest
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Photos provided by Dr. Michael H. Gold, M.D., FAAD
incidence of blindness, and cannulas are not immune, says Dr. Shamban. In a case series published in the June 28, 2018, *Journal of Cosmetic Dermatology*, five of six cases involved cannulas.

“I treat the nose — but very carefully.” One of her favorite procedures is injecting small amounts of filler to give a subtle lift to the nasal tip.

Regarding the lower face, Dr. Shamban says that in her experience, Asian faces tend to have a strong maxilla, and a higher incidence of midface defects that often develop into tear-trough hollows. “In terms of pre-rejuvenation, which is a really important aspect of what we do, a very effective procedure is to support this area in the midface.” The same procedure in the typical Caucasian face likely would produce an overly rounded apple shape, she adds.

Signs of aging in the mid- and lower Caucasian face include thinning lips, drooping corners of the mouth and under-eye hollowing. Volume loss beneath the sub-orbicularis oculi fat pad also can create bulges at the cheek. Other changes include jawline irregularities and neck laxity.

Conversely, Dr. Shamban says that age-related changes in the typical Asian jawline are less severe, as is loss of lip volume, although it definitely occurs in Asian patients. When this happens, the upper lip becomes more prominent. “It’s possible that the patient’s dentition is compromised. So always look inside the mouth.” Injecting in and around the lip can provide the gentle support needed, she says. Similarly, dimpling of the chin responds well to a combination of neuromodulator and filler injections.

**FUNCTIONS OF BEAUTY**

Physical beauty serves several evolutionary purposes. For starters, says Dr. Shamban, beauty contributes to a psychological positive feedback loop. “When we look at ourselves and we look good, we feel better. It’s unclear — do we look good because we feel good, or feel good because we look good?”

Along with making patients feel better about themselves, beauty is a cornerstone of sexual selection. With no physical markers to indicate whether a person will be a loyal partner or great parent, explains Dr. Shamban, people and animals connect with beauty as a surrogate marker. “We know that babies spend more time looking at attractive faces. Since we’re hardwired to appreciate beauty, it is prominent, key and integral not only to our culture, but also as human beings.”

Beauty is also central to nonverbal communication, which is about 90% of human communication, she says. “When you enter a room, you want to be able to judge whether the people there are going to be your friend or foe.” Like recognition of the signature feature, says Dr. Shamban, these instincts occur at the subcortical level.

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**Eye shape: Highlight the eyes by shaping the brow**  
*FROM PAGE 38*

We want to have memorable faces, because that becomes your calling card. It’s something you wear every day.”

Ava Shamban, M.D., Beverly Hills, Calif.

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**recent POLL**

How well versed are you in cultural beauty standards?

*44%*  
Admit their knowledge is limited.

*20%*  
Say they’re international face and beauty experts.

*36%*  
Have a good understanding of the prominent cultural beauty standards in their communities.
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Neck lift experts share techniques from Page 35

ING. ANY DERMATOLOGIST CAN DO THAT PROCEDURE. AND PATIENTS ARE REALLY HAPPY WITH THE RESULTS,“ HE SAYS.

THE SIMPLE NECK LIFT IS RELATIVELY COMPLICATION-FREE, BUT IT’S IMPORTANT FOR DERMATOLOGISTS AND OTHERS TO EDUCATE PATIENTS ABOUT WHAT THEY CAN EXPECT.

“WHEN YOU’RE PULLING FROM BEHIND THE EAR AND THE PATIENT LEANS FORWARD A LITTLE BIT, THE PATIENT STILL MIGHT HAVE SOME LOOSENESS. I THINK IT’S IMPORTANT TO EDUCATE PATIENTS THAT THEY’RE GOING TO GET AN IMPROVED NECK, BUT IT’S NOT GOING TO GET RID OF ALL THE LOOSENESS,” HE SAYS.

A LESS INVASIVE APPROACH USING A RADIOFREQUENCY HEATING DEVICE TO TIGHTEN NECK SKIN OR TO HELP PREVENT THE SKIN FROM GETTING TOO LOOSE REMAINS AN OPTION FOR SOME PATIENTS IN THEIR 40S — EVEN EARLY 50S, ACCORDING TO DR. MOY.

“BIOIDENTICAL HORMONES CAN DECREASE SOME OF THE SAGGING UNDER THE NECK, OR SOME OF THE CREAMS LIKE EPIDERMAL GROWTH FACTOR. THESE AND RADIOFREQUENCY DEVICE TREATMENTS, HOWEVER, ARE NOT FOR SOMEONE WHO HAS [MORE SIGNIFICANT] SAGGING,” DR. MOY SAYS. “GENERALLY, WHEN YOU GET PATIENTS INTO THEIR LATE 50S, YOU’RE MOST LIKELY GOING TO BE DOING THE NECK LIFT.”

THE DEEP NECK LIFT

ST. LOUIS FACIAL PLASTIC SURGEON MIKE NAYAK, M.D., GOES TO GREATER LENGTHS TO RESTORE A YOUTHFUL LOOK TO THE NECK. HE SAYS HIS APPROACH, THE DEEP NECK LIFT, HARKS CONVENTIONAL SURGICAL NECK LIFTING THINKING.

TRADITIONALLY, AESTHETIC SURGEONS APPROACH NECK LIFTS BY SUCTIONING SUBCUTANEOUS FAT, TIGHTENING THE PLATYSMA AREA, THEN PULLING SKIN FROM THE SIDES TO CREATE A “TIGHTER HAMMOCK,” HE SAYS.

“THE REALITY IS THAT THE NECK IS BUILT IN LAYERS AND BY TREATING JUST THE FIRST FEW LAYERS OF SKIN AND SUBCUTANEOUS FAT, THERE IS A FINITE AMOUNT OF CHANGE YOU CAN MAKE,” DR. NAYAK SAYS. “YOU ALSO CAN GET A REALLY OFF-LOOKING RESULT BY OVERTREATING THOSE FIRST COUPLE OF LAYERS AND THEN LEAVING THE DEEPER LAYERS ALONE. YOU CAN GET A VERY DISJOINTED LOOK THAT’S NOT PRETTY, BUT IT IS TIGHT-LOOKING.”

DR. NAYAK SAYS IN RECENT YEARS HE HAS BEEN SAFELY MODIFYING ALL THE LAYERS OF THE NECK. HE REBuilds THE NECK’S DEEPER LAYERS TO THE SHAPE AND FORM OF NOT JUST THE YOUNGER NECK BUT A GENETICALLY GIFTED YOUNGER NECK, HE SAYS.

“SOME PEOPLE EVEN WHEN THEY’RE 20 DON’T HAVE A GREAT SHAPE TO THEIR NECK BECAUSE THEY WERE BORN WITH THE GENETICS FOR A MORE OBLIQUE OR OBTUSE NECK,” DR. NAYAK SAYS. “I ACTUALLY ALSO USE THESE TECHNIQUES IN YOUNGER PEOPLE IN THEIR 20S AND 30S.” SPECIFICALLY, THOSE LAYERS ARE THE DIGASTRIC, MYLOHYOID, GENIOHYOID AND DEEPER MUSCLES OF THE NECK. DR. NAYAK SAYS HE ALSO RESHAPES OVERGrown OR MAL-POSITIONED SUBMANDIBULAR SALIVARY GLANDS. HE THEN SETS THE PLATYSMA MUSCLE AND SKIN SNUGGLY — NOT TIGHTLY — OVER THE NEW FOUNDATION, SO THE NECK HAS NO CHOICE BUT TO FOLLOW THAT NEW SHAPE.

HE TREATS THE SUBCUTANEOUS FAT IN THE NECK CONSERVATIVELY BECAUSE MOST AGING NECKS DON’T HAVE EXCESS FAT.

“YOU WANT TO LEAVE AS MUCH OF THAT AS POSSIBLE TO GET A SOFT, NATURAL LOOKING RESULT, AS OPPOSED TO A SKELETONIZED ANCIENT-LOOKING RESULT,” DR. NAYAK SAYS.

AS FOR SKIN, DR. NAYAK SAYS HE REMOVES WAY LESS THAN ONE MIGHT IMAGINE.

“THE NEW ANGLED CONTOUR IS LIKE TWO LEGS OF A TRIANGLE. IT ACTUALLY IS A LONGER PATH FOR THE SKIN TO FOLLOW NEW, ANGULAR CONTOUR,” HE SAYS. “IN MANY OF MY PATIENTS I DON’T TAKE ANY SKIN. BECAUSE WE REQUIRE ALL OF THAT SKIN TO LINE THE NEW CONCAVE SHAPE.”

SO, WHAT HAS CHANGED AS A RESULT OF THIS SURGERY? ACCORDING TO DR. NAYAK, WHO HAS DONE ABOUT 500 DEEP NECK LIFT PROCEDURES: EVERYTHING.

BUT THE PROCEDURE IS COMPLEX AND REQUIRES A SIGNIFICANT LEARNING CURVE. DR. NAYAK SAYS MOST SURGEONS THINK IT’S TOO MUCH OF A PROCEDURE TO LEARN AND OFFER THEIR PATIENTS.

TREATING THE FIRST FEW LAYERS OF SKIN AND SUBCUTANEOUS FAT IS GENERALLY SAFE.

“THE WORST THING THAT COULD HAPPEN WITH A SUPERFICIAL, TRADITIONAL NECK LIFT IS YOU GET BLEEDING THAT NEEDS TO BE DRAINED OR YOU COULD INJURE THE SKIN AND GET SCARRING, BUT THAT’S PRETTY UNCOMMON,” HE SAYS. “WHEN YOU START GOING TO THE DEEPER LAYERS OF THE NECK, NOW YOU’RE NEAR THE VITAL STRUCTURES. THERE ARE MUCH MORE SIGNIFICANT BLOOD VESSELS. THERE ARE THE NERVES THAT ALLOW YOU TO MOVE YOUR LIPS. THERE ARE THE NERVES THAT ALLOW YOU TO MOVE YOUR TONGUE; NERVES THAT GIVE YOU FEELING IN THE TONGUE AND FEELING IN THE LIPS. THE KEY TO THAT KIND OF SURGERY IS YOU HAVE TO HAVE AN EXCELLENT UNDERSTANDING OF THE LAYERED ANATOMY OF THE NECK AND HEAD AND NECK SURGERY TECHNIQUES. YOU NEED GREAT ASSISTANTS, GREAT LIGHT, GREAT EQUIPMENT AND AN UNHURRIED DAY IN THE OPERATING ROOM.”

THE DEEP NECK LIFT TAKES TWO OR THREE TIMES LONGER THAN MOST COSMETIC PROCEDURES FOR THE NECK.
There is still a role for nonsurgical treatments, but those nonsurgical treatments would usually require some sort of a combination approach to treat the individual layers that they are best at treating.

Mike Nayak, M.D., St. Louis

But if a patient wants dramatic results, there are really no shortcuts, he says.

NONSURGICAL NECK TREATMENTS
Dr. Nayak says nonsurgical treatments have a role in some aspects of neck rejuvenation. He agrees with Dr. Moy that the role is limited.

Fractional laser resurfacing, some kinds of high frequency ultrasound and sometimes radiofrequency can modestly tighten the skin layer. There are some treatments that can modestly thin the subcutaneous fat layer, such as CoolSculpting (Allergan) and Kybella (Allergan), he says.

“In young, fluffy baby fat faces, thinning the fat can actually be helpful. The irony with Kybella and CoolSculpting and sometimes radiofrequency energy is, the patients that are best suited for them are the younger ones with fluffy baby fat in the neck. They often have the hardest time affording $3000, $4000, $5000 worth of repeat nonsurgical treatments. They often end up being a better liposuction candidate, where we liposuction their necks in one setting for $2000,” Dr. Nayak says. High-frequency ultrasound can modestly tighten the platysma area, he says.

“There is still a role for nonsurgical treatments, but those nonsurgical treatments would usually require some sort of a combination approach to treat the individual layers that they are best at treating. It usually requires a budget that by the time you’ve treated those layers and treated them well, it pretty much approaches a surgical budget,” Dr. Nayak says. “Still, you’re left treating those first few layers a little bit unpredictably and incompletely, and completely ignoring the deeper layers.”

The solution, Dr. Nayak says, is to work from what patients want as far as outcomes and decide from there on options that will best suit their lifestyles and budgets.

HIFU OFFERS IMPROVEMENTS IN THE NASOLABIAL, JAWLINE, SUBMENTAL AND NECK AREAS

By: Lissette Hilton

IN A SINGLE-CENTER STUDY of 75 patients, including two men, high-intensity focused ultrasound (HIFU) treatment visibly improved the nasolabial, jawline, submental and neck areas.

Two independent dermatologists who evaluated the HIFU patients three months post-treatment reported that each area improved 80% or more. Patient satisfaction scores at three months were satisfactory or higher.

HIFU induces cellular damage and volume reduction in the treatment area. Delivered noninvasively, HIFU energy causes micro-coagulation zones from the deep dermis to the superficial musculoaponeurotic system, or SMAS. This tightens skin by contracting and remodeling collagen, according to the Turkish researchers.

“Focused ultrasound is superior to other pre-existing skin tightening technologies because of its capability to reach deeper tissues,” they write.

One of the dermatologist authors performed HIFU using the Doublet-S by Hironic device. Using two different probes — one with a focal depth of 3 mm and another with 4.5 mm — the physician delivered one HIFU session for each patient of about 400 to 500 shots, depending on the treatment area size. Patients ranged in age from 37 to 75 years and had Fitzpatrick skin types from II to IV. All complained of wrinkles.

Physician evaluators compared photos of the treated patients at baseline to 90 days post-HIFU treatment of the nasolabial, jawline, submental and neck areas. They used a 4-point scale, with 0 being no improvement and 4 representing excellent improvement. The ratings by both doctors were excellent in nearly 19% of cases, with the best results reported in the neck area. At least 66% of cases moderately improved, according to the evaluators. Patient satisfaction scores were highest, at 86.7% for HIFU treatment results around the jawline.

In no cases did evaluators see no improvement or mild improvement — their evaluations were all in the mild-to-moderate, moderate and excellent categories.

The authors reported no correlation between clinical improvement and age.

Twenty-seven, or 36%, of the 75 patients experienced a treatment-related adverse event, with the most common being pain and transient erythema. One patient had numbness in the mandibular area, which resolved within 10 days without treatment, according to the study. Other researchers have reported rare neurologic complications from HIFU.

“Although the exact mechanism of nerve injury after HIFU treatment is unknown, shrinkage and retraction at SMAS that is caused by the deep penetration of HIFU and the thermal energy may lead to the injury of the nerve branches distributed in SMAS,” they write.

The authors suggest use of moderate energy settings might be safer.

References:
An Overview of Melasma and Its Impact on Today’s Patient Population

Dermatology Times: For those readers who are less familiar with the condition, what is melasma?

Dr. Alexis: Melasma is one of the most common disorders of hyperpigmentation. It primarily affects women, although men can also be affected to a lesser extent. Melasma typically presents with symmetrical, hyperpigmented patches that most commonly involve the cheeks, forehead, and upper lip. Less commonly, sites off the face such as the forearms can be involved.

Despite the relatively common nature of melasma, it is a very challenging disorder to treat in that none of our therapies are curative. Even after visible improvement of a patient’s hyperpigmentation, ongoing management is necessary to treat this chronic relapsing disorder.

Dermatology Times: How does melasma compare to other common chronic skin conditions that dermatologists often see such as acne and rosacea?

Dr. Alexis: Melasma has some similarities to acne and rosacea in the sense that they are all chronic, relapsing conditions. What makes melasma unique is that while it can affect any population, it disproportionately affects patients with Fitzpatrick skin types III, IV, V, and VI. It is our patients with more pigmented skin who tend to be affected the most.

Dermatology Times: Why is that thought to be the case?

Dr. Alexis: As a disorder of hyperpigmentation, excess production of pigment by melanocytes is central to the etiology of melasma. Patients with darkly pigmented skin inherently have melanocyte responses that are more labile. They have a tendency to produce more pigment in response to a variety of stimuli, including light, inflammation, and hormonal factors.

In addition to that, there may be some genetic factors involved that predispose patients with more darkly pigmented skin to the development of melasma. For example, the majority of patients with melasma report a family history of the condition. In one recent review of global epidemiological studies, up to 64% of patients diagnosed with melasma reported having a relevant family history of the condition.

So essentially, there is thought to be an overlap of genetic factors, exposure to ultraviolet and visible light, and hormonal factors that put a patient at risk of developing melasma.

Dermatology Times: What is it about pregnancy that is thought to trigger melasma?

Dr. Alexis: While it is not entirely clear, it is thought that pregnancy-related melasma is caused by the presence of increased levels of progesterone and estrogen that leads to increased pigment production in melanocytes. It is estimated that somewhere between 14% and 56% of cases of melasma are associated with pregnancy or oral contraceptive use, according to recent epidemiological studies.

Dermatology Times: What are the primary steps clinicians need to take to determine the presence or the absence of melasma?

Dr. Alexis: Melasma is typically a diagnosis made by clinical examination. It is rare that a biopsy will need to be performed, although there are other possibilities in the differential diagnosis that some-
times need to be ruled out. But when melasma presents with its characteristic features, further testing — including biopsies — are generally not required.

What is required during the clinical exam is the use of Wood’s light examination to assess the predominant location of the pigment. Is the pigment predominantly epidermal or dermal in nature? It should be noted that the Wood’s light exam is not always reliable, though its results will often have implications as far as the treatment outcomes. Dermal melasma is typically more challenging to treat than melasma that is predominantly epidermal.

**Dermatology Times: Are there any instances where you will require a biopsy in a patient with potential melasma?**

**Dr. Alexis:** Yes, in scenarios where the presentation isn’t 100% characteristic of melasma, biopsy may be required. For example, biopsy is often indicated in a patient who presents with symmetrical hyperpigmentation on the face that has a slightly violaceous or grayish hue that suggests an alternate diagnosis such as lichen planus pigmentosus or medication-induced lichenoid dermatitis. Medication-induced lichenoid dermatosis can be seen with, for instance, as a result of use of calcium channel blockers such as diltiazem.

Exogenous ochronosis is a complication caused by long-term use of hydroquinone that can also present in a similar location as melasma on the face, so that is another possible instance when biopsy is required in a patient who presents with pigmentation that is grayish or blueish in tint.

**Dermatology Times: What would you look for on biopsy that would either point you to melasma or one of these alternate, less common diagnoses?**

**Dr. Alexis:** These other entities such as lichenoid or interface dermatoses, as well as exogenous ochronosis, have specific characteristic findings on histopathology that can be identified on biopsy.

**Dermatology Times: So then is biopsy considered to be a test of exclusion to rule out these less common diagnoses as opposed to being confirmatory of melasma?**

**Dr. Alexis:** Yes, absolutely. In patients with melasma, we will typically see increased pigment in the epidermis as well as in the papillary dermis on biopsy. The melanocytes themselves tend to be larger, have more prominent dendrites, and increased pigment within the melanosomes. In the papillary dermis, there will typically be melanophages as well as features of photo damage such as solar elastosis.

There have been recent studies looking at lesional skin from melasma comparing it to perilesional, uninvolved skin. What these studies have found is that there is increased melanin in lesional skin, as well as hyperfunctional melanocytes and features of increased vascularity and solar elastosis, not all of which are seen in the perilesional skin. 4,5

**Dermatology Times: What sort of impact does melasma have on your patients’ quality of life? What are some of the more common complaints you hear from your patients who are newly diagnosed with the condition?**

**Dr. Alexis:** It cannot be understated how much of an impact melasma can have on quality of life. It can be quite disfiguring to patients, affecting their self-esteem, social functioning, and performance in the workplace. In certain cultures, it can be particularly stigmatizing to have the features of melasma, with brown patches on the face being very visible and difficult to mask with makeup and other cosmetics.

**Dermatology Times: Is it typically a relief to patients to be able to put a name to their condition and then potentially be able to treat it?**

**Dr. Alexis:** Yes, without question. Before a patient actually sees a dermatologist or other healthcare provider who is able to give them a diagnosis of melasma, patients often feel that their condition is due to myriad factors. They might be concerned that it is related to their overall health, including internal diseases. Some patients even worry that it’s something potentially malignant or contagious depending on the culture that they come from and their background level of knowledge.

So yes, it’s often reassuring to our patients to know that this is a common condition that dermatologists can easily recognize. It affects populations around the world, we have a good idea of what causes it, and we have effective treatments.

**References**

National Day Calendar
a novel marketing tactic

LISETTE HILTON | Staff Correspondent

National Day Calendar is a business that tracks and promotes nearly 1,500 National Days, National Weeks and National Months. Companies and organizations can submit applications to have a designated national day, week or month. If the National Day Calendar committee agrees on featuring a company or organization on the calendar, applicants would pay up to $4,500 for a designated day, according to an article published a few years ago on Marketwatch.com.

“… National Day Calendar offers a powerful media mix of digital, radio, social media and television news platforms that reach a hyper-engaged audience of Celebrators across the United States and around the globe,” according to NationalDayCalendar.com.

“Over 20,000 media outlets source their stories from National Day Calendar’s website… Countless newspapers and bloggers write stories for their publications using information from National Day Calendar and millions view it directly every day.”

This year, BTL received its own nationally designated week of May 20. Known as National Emsculpt Week, BTL hopes it will drive annual demand for the device, which noninvasively eliminates fat cells and defines muscle, just in time for the summer kick off.

Competition is high for getting a designated period of time with the organization, which according to John Ferris, vice president of U.S. Marketing at BTL, approves just 20 national holidays a year but receives more than 30,000 applications.

DID IT WORK?
Did having a national week impact business at providers’ offices? Dermatology Times posed the question and this is what some providers had to say:

Dermatologist Dendy Engelman, M.D., says this year’s Emsculpt week drove more patients to her practice.

“For National Emsculpt Week we encouraged our current patients to ‘Em(SCULPT)’ their muscles with a friend, which was a great success. We had many new faces in our office, and the best part is that they were driven by friend referrals, which are more trustworthy than any advertisement,” Dr. Engelman tells Dermatology Times. “In addition to driving more patients into our office, current patients who typically come for other aesthetic treatments were intrigued about Emsculpt and all the hype from National Emsculpt Week. As a result, some of our regulars became new Emsculpt patients too. All around, Emsculpt Week was a huge success for driving new patients to the practice.”

Dermatologist Bruce Katz, M.D., performs Emsculpt at his New York City practice. He says that while he and his staff were not aware that there was a national Emsculpt week, he agrees the device is a patient pleaser.

“… it has definitely lived up to all of the hype about it. It is an amazing new technology. Emsculpt is the first time we can actually build and tone muscle while removing fat at the same time. This hasn’t been done before when performing body contouring,” Dr. Katz says.

Richard Moore, M.D., an internist who uses Emsculpt at his St. Louis, Mo., men’s health practice, says he saw the promotional material on social media for Emsculpt week but did not see an increase in business as a result of it.

“I think Emsculpt is a terrific body sculpting device but in order to raise consumer awareness it will require a larger marketing effort to educate potential clients about its benefits,” Dr. Moore says.

New York City dermatologist Adarsh Vijay Mudgil, M.D., an Emsculpt provider, also didn’t see an uptick in inquiries during Emsculpt week but tells Dermatology Times that having such a designation is an opportunity to create a buzz that could take weeks or months to manifest. Dr. Mudgil is another Emsculpt fan.

“This is great for building abs, buttocks, thighs and biceps. This is an ideal treatment for patients who are not ideal candidates for current body sculpting procedures like CoolSculpting (Allergan),” Dr. Mudgil says.

Emsculpt uses High-Intensity Focused Electromagnetic technology to induce about 20,000 supramaximal muscle contractions during each 30-minute session. Treatment results in a 16% average increase in muscle mass. Providers can use the device to treat the abdominals and buttocks, as well as arms and legs with a small device applicator, according to BTL.

Emsculpt treatment has an 86% Worth It rating on RealSelf as of June 11, 2019.

Disclosures
Dr. Moore and Mudgil report no relevant disclosures. Dr. Katz was an investigator for Emsculpt. Dr. Engelman has consulted for BTL but does not actively consult on behalf of Emsculpt.
FDA clears new fat device

LISETTE HILTON | Staff Correspondent

Dominion Aesthetic Technologies announced in late June that the FDA cleared its eon FR laser energy body contouring device for fat reduction of the abdomen.

“What’s novel about this device is that it has a non-contact automated articulated arm that hovers over the treated area delivering the 1064 nm wavelength energy, while simultaneously cooling the skin with feedback control,” says Suzanne L. Kilmer, M.D., founder of the Laser and Skin Surgery Center of Northern California and clinical professor of dermatology at University of California, Davis. “The device hovers over the patient so nothing is touching the patient or applied to the patient. It automatically moves along the pre-templated area, delivering the heat and cooling while maintaining temperatures that are comfortable for the patient while triggering apoptosis.”

Dr. Kilmer, who was among the investigators for eon FR and is a member of Dominion’s Scientific Advisory Committee, says that fat reduction outcomes with the device are comparable to that of other 1064 nm body contouring technologies, at 11% to 13%. Researchers verified their results with ultrasound, she says.

Most patients describe the treatment as comfortable and were satisfied with results, according to Dr. Kilmer.

“Eon does cover a large area at once—you can actually add in areas, sequentially. So, you can do a smaller correction of fat or an entire abdomen,” she says.

Quick TAKES

The eon FR is a new FDA cleared non-contact device for abdominal fat reduction.

The device allows for small or large abdominal corrections.

Results are seen in 6 to 12 weeks.

In essence, a provider programs the patient’s treatment into the device and the eon FR does the rest. Eon FR treatment takes about 15 minutes to perform, there is no downtime post-treatment and fat reduction takes from six to 12 weeks, according to the company.

As with any noninvasive fat reduction device, it’s important to set realistic patient expectations, according to Dr. Kilmer.

“With body contouring, you can only get rid of so much fat at a given time. Patients’ expectations have to be explained. You could do larger patients, you just have to do multiple treatments,” Dr. Kilmer says.

Disclosures

Dr. Kilmer has received research support from and has been a medical advisory board member with Covidra (stock holder), DermaHarbor (stock holder), Akilex, Allergan, Erasonics, Lipitec Sciences, Lumenis, Lutronic, Mirex, Soliton, Syneron-LumaMed, and Syneron Candela. She has received research support from Gold Alma, BTI, Aestherapeutics, and Strata. She has stock in Auda and HitFMD.

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Imaging evolves to guide Mohs surgery

ILYA PETROU, M.D. | Staff Correspondent

The recent impact of reflectance confocal microscopy (RCM) and optical coherence tomography (OCT) imaging modalities has been viewed as revolutionary in assisting the clinician with accurately diagnosing suspicious lesions and nonmelanoma skin cancers, one expert says.

Combining technologies is considered the next level in state-of-the-art skin cancer diagnosis and management. It may prove to be a useful adjunctive tool to guide Mohs surgery as well as other nonsurgical treatments, says Milind Rajadhyaksha, Ph.D., dermatology service, department of medicine, Memorial Sloan Kettering Cancer Center, New York, who recently spoke at the annual ASLMS conference in Denver.

Mohs surgeons are currently using both RCM and OCT imaging techniques to map out the margins of nonmelanoma skin cancers on patients before the start of surgery. These technologies help them determine the lateral spread of the tumor under investigation. Once the surgeon has a sense of the lateral spread, they then often have a general sense for the depth of the tumor and can better estimate how much tissue needs to be excised, he says.

“Following the example of current therapies used in Europe, some Mohs surgeons in the United States are also beginning to treat these superficial lesions with nonsurgical approaches, such as topical therapy or photodynamic therapy (PDT) or even with laser ablation,” Dr. Rajadhyaksha says. “The imaging and particularly the combination of the technologies can help them guide the choice of treatment, whether to do traditional Mohs surgery or surgical excision, or perhaps they can treat the tumor with topical noninvasive therapies and avoid biopsy.”

Reflectance confocal microscopy creates images at a shallow depth giving the clinician nuclear and cellular level morphologic detail of the targeted lesion, and it has a sensitivity of approximately 80% to 95% and a specificity of 65% to 80%.

The faster OCT device in contrast creates deeper images that allow the clinician to quickly view the structural level morphology and assist in determining the depth and the deep margins of the lesion under scrutiny. In addition, it has a sensitivity of 79% to 96% and a specificity of 58% to 96 percent.

“The confocal microscopic imaging provides a higher resolution than those attainable with OCT, but the OCT images go deeper than confocal microscopy, and it’s the combination of both of these modalities that can really serve as an excellent imaging tool. Moreover, the combination RCM/OCT device is also proving to be very promising as an adjunctive procedure to Mohs surgery,” Dr. Rajadhyaksha says.

Still in early technical development, Dr. Rajadhyaksha and his collaborating team, which includes Nicusor Iftimia, B.Sc., M.S., Ph.D., Physical Science, Inc., and Mr. William Fox, Caliber Imaging and Diagnostics, recently engineered two prototype combination RCM/OCT devices that are currently under investigative research at Memorial Sloan Kettering Cancer Center.

“In the clinical setting, the combination of these two imaging technologies in a single device helps the surgeon to get a better sense for the depth and the deep margins, for example in cases where the tumors are superficial or early nodular (i.e., the tumor depth is within 300–400 microns).”

“In the preliminary data we have with our prototype devices, the in-vivo and ex-vivo imaging approach using the combination RCM/OCT device can be very useful to help guide Mohs surgery as well as to help guide the choice of other nonsurgical treatment modalities,” Dr. Rajadhyaksha says.

The combined RCM/OCT device may take a few more years to commercialize. However, according to Dr. Rajadhyaksha, the promising impact the combination device can have in the treatment and management of this patient population is significant.

Although the dermatoscope remains the right-hand diagnostic tool for skin cancer screening in the dermatologic practice, combination RCM and OCT technologies will bring the advantages of both technologies into one single device, Dr. Rajadhyaksha says, and this may help to prevent biopsy procedures.

Disclosures
Dr. Milind Rajadhyaksha is a former employee of Caliber Imaging and Diagnostics (formerly, Lucid Inc.), the company that manufactures and sells the VivaScope confocal microscope. He owns equity.

The VivaScope is the commercial version of an original laboratory prototype that was developed by Dr. Rajadhyaksha when he was at Massachusetts General Hospital, Harvard Medical School.
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Imaging may speed diagnoses, prevent biopsies

ILYA PETROU, M.D. | Staff Correspondent

Quick TAKES

A new technology based on laser-induced breakdown spectroscopy (LIBS) has demonstrated efficacy in providing quick and accurate imaging of suspicious pigmented lesions and nonmelanoma skin cancers, more so than other leading imaging technology, one expert says.

The Spectra-Scope (Specclipse, Inc., Sunnyvale, Calif.) reportedly allows for real-time, noninvasive in-vivo skin cancer diagnosis utilizing a combination of non-discrete molecular laser spectroscopy and machine learning/deep learning algorithms. The more spectral data is collected, the more accurate the deep learning classification will be, says Boncheol Leo Goo, M.D., Naeum Dermatology and Aesthetic Clinic, Seoul, Korea, and chief medical officer at Specclipse, Inc., who recently spoke at the annual ASLMS conference in Denver.

The device can be helpful in office-based skin cancer screening as well as real-time on-site skin cancer detection during skin cancer surgeries, Dr. Goo says. The LIBS system can be installed as an add-on to any short-pulsed (picosecond and nanosecond) aesthetic laser. It can also be used as a stand-alone model with an integrated small-sized laser source, without the need for any additional equipment.

“This new LIBS technology has shown great promise in the preliminary studies,” Dr. Goo says. “Pathologic diagnosis-based cancer detection is considered to be time and labor consuming. The novel LIBS technique could help clinicians arrive at a quick and accurate diagnosis, potentially preventing unnecessary skin biopsies, which can further help save valuable time and resources.”

A recent study1 utilizing the LIBS device showed highly accurate skin cancer detection outcomes, demonstrating both a high sensitivity (95%) and specificity (87%) for discriminating skin cancers from benign lesions. There were no adverse events or microscopic damage on the irradiated skin.

According to Dr. Goo, other leading imaging techniques can reach accuracy levels of approximately 90% sensitivity and specificity when discerning between benign and malignant lesions, lower than the LIBS diagnostic modality.

The LIBS device can save time for the clinician and patient by creating unique patterns for instant analyzing within a second, without any need for interpretation or any kind of tissue processing procedures, Dr. Goo says. As the technique is completely noninvasive, there is no concern for leaving any scars as is typically seen following conventional biopsy procedures.

“The technique does not cause any trauma to the skin. It has all of the diagnostic benefits of conventional biopsies without any of the risk and aesthetic consequences often associated with them,” Dr. Goo says.

The current goal for noninvasive optical biopsy is to create very accurate imaging that is very similar and can be likened to histologic slides. Other noninvasive imaging technologies such as confocal microscopy have the benefit in diagnostics of being able to image the architecture of the target area in great detail, essentially offering a reconstruction of the histology findings without having a physical biopsy. Compared to LIBS however, Dr. Goo says the image process is slower and physicians need to visit special interpretation training courses to help them learn the RCM procedure and how to best evaluate images.

“I believe clinicians will be very interested in this technology, which is on-course to receive CE-approval this year and in my opinion, LIBS is the best noninvasive imaging technology that has been developed to date. We expect the technique will be very useful in avoiding some of the simple potentially unnecessary shave or punch biopsies. I hope that it will serve as a useful adjuvant diagnostic tool to other diagnostic procedures such as dermoscopy or for quicker staging in Mohs surgery,” Dr. Goo says. ◄

Disclosure
Dr. Goo reports a financial interest in Speclipse, Inc.

References
Various trends in the prevention and treatment of non-melanoma skin cancer—from new chemoprevention agents to the role of telemedicine—were highlighted in a review published in the journal *Current Opinion in Pharmacology*. Many of which have the potential to make a big impact, says Mackenzie Wehner, M.D., M.Phil., a clinical instructor and post-doctoral research fellow in dermatology at the University of Pennsylvania.

Among the most important trends noted are several new or emerging therapies, Dr. Wehner says. “I will be eagerly watching to see new data on medicines for prevention, particularly the over-the-counter nicotinamide, which has shown very promising results in an Australian trial for patients with multiple keratinocyte carcinomas,” she says.

Dr. Wehner also notes the value of vismodegib, checkpoint inhibitors, and programmed cell death 1 (PD-1) blockade, which are transforming the treatment of advanced skin cancers. Specifically, vismodegib or radiotherapy is used to treat inoperable basal cell carcinoma. Immune checkpoint inhibitors, such as nivolumab and pembrolizumab, have proven effective in the treatment of inoperable and/or metastatic squamous cell carcinoma. PD-1 blockade with cemiplimab has been demonstrated to be effective in advanced cutaneous squamous cell carcinoma, with clinical response in about 50% of patients.

With regard to prevention, researchers noted that effective health communication alternatives in rural populations may include teledermatology and teledermoscopy, as well as smart phone apps or text messages.

Jerry D. Brewer, M.D., M.S., a professor of dermatology at the Mayo Clinic in Rochester, Minnesota, says the article does a good job of spreading important messages about non-melanoma skin cancer.

“The field of dermatology is very aware of the trends, and this paper does not have a paradigm-shifting effect on those who are already skin cancer experts. However, it may have an impact on other fields of medicine that are less aware of the health implications associated with non-melanoma skin cancer,” Dr. Brewer says. “The most important thing is that, even though these non-melanoma skin cancers have been traditionally thought of as not a big deal, they can be life threatening and/or debilitating if not treated appropriately.”

Reference:
My thoughts on physical block sunscreen

BY JOEL L. COHEN, M.D. | Contributing Physician

Unfortunately the message that many people heard from the May JAMA article about CHEMICAL sunscreen leading to higher bloodstream absorption of specific chemical ingredients than originally thought — seems to have led to many misperceptions. And the public simply does not realize that this does not apply to all sunscreens, specifically it does not apply to PHYSICAL BLOCK MINERAL sunscreens — that are regarded as safe and effective.

PHYSICAL BLOCK sunscreens, like zinc oxide and titanium dioxide, are specifically regarded by the FDA as generally safe and effective. The ingredients in the serum-level study, however, are all chemical sunscreens, and some of these are now under greater scrutiny, such as oxybenzone — according to the recent FDA guidance.

I have always preferred physical sunscreens for me, my family, and my patients. And my pediatrician wife feels the same way. There is a great deal of literature on the safety and efficacy of zinc oxide and titanium dioxide, as well as the fact that they cover a more broad spectrum of UV A sun exposure than the chemical ingredients. And physical sunscreens have definitely become much more cosmically elegant and rub in very well — no longer looking like lifeguard toothpaste.

Physical block sunscreens also have the advantage of working right away, as soon as they are applied to the skin (vs chemical sunscreens that need about 20 minutes before they are more effective, as they actually work more like a sponge to absorb ultraviolet rays).

Having said that, applying chemical sunscreen in this study amount of 2 mg/cm² to 75% of body surface area and repeated application is really not consistent with typical sunscreen use among my patients, family, friends — even among my extremely diligent skin cancer patients. If we’re fortunate enough to get patients to embrace sun protection, then they often apply sunscreen, at best, to their face, neck, and hands (as the more exposed skin) routinely for most activities — and we recommend that they cover other areas such as the trunk (chest and back) with sun-protective long sleeve shirts, beach rash-guards or long sleeve biking and fishing shirts etc., specifically with UPF rating (ultraviolet protection factor). In addition, the chemical sunscreen article conclusion that serum levels of absorption were higher than originally thought does not equate to these serum levels being known to be harmful. These products have been used for many years, and that next step of saying these chemical sunscreen serum levels are indeed harmful has yet to be proven or even evaluated.

PHYSICAL BLOCK SUNSCREENS are what I recommended to my patients, family and friends. And it is what I personally use every day.

All of us dermatology and pediatrician parents (and every parent really) have rubbed zinc oxide onto our kids with diaper rash, including when almost no barrier of the skin is even apparent, and never worried about absorption nor have we seen any related sequelae. Further, the history of using zinc oxide on skin apparently dates back to ancient India in around 500 BC, with use for burns, wounds and significant skin irritations.

Remember to reapply physical sun-BLOCK every two hours — and more frequently if sweating, swimming, or toweling off. And don’t forget to always wear a wide-brim hat as well as UPF long sleeve shirts.

Active Ingredients Examined in the Study

- avobenzone
- oxybenzone
- octocrylene
- ecamsule

About this author:
Joel Cohen, M.D., is an internationally recognized expert on aesthetics and skin cancer. He is the Director of AboutSkin Dermatology, Greenwood Village and Lone Tree, Colorado and also serves on the teaching faculty of the University of California Irvine as an Associate Clinical Professor. He is Board-Certified by the American Board of Dermatology, and Fellowship-trained in aesthetic dermatology and dermatologic surgery. Dr. Cohen has published over 200 scientific articles and book chapters, and has co-authored 3 academic textbooks. He is the Co-Director of the ASDS Cosmetic Dermatology Fellowship in Colorado. He has also been the recipient of the ASDS Public Service Award, the ASDS Distinguished Service Award, and the ASDS Excellence in Education Award. In 2018, he received the Alabama Dermatology Research Foundation Humanitarian of the Year Award. Dr. Cohen has appeared on many TV shows including Emmy Award Winning The Doctors, and has also been interviewed in many magazines and newspapers including Glamour, Vogue, New York Times, Allure, Shape, Marie Claire, TIME, Allure, InStyle, USA Today, US News and World Report and Consumer Reports.

Joel L. Cohen, M.D., director, AboutSkin Dermatology, Greenwood Village and Lone Tree, Colo.
Survival rates in patients with cutaneous squamous cell carcinoma were similar in those receiving high-dose chemoradiotherapy vs conventional radical surgery, according to the results of a recent study published in the British Journal of Dermatology.

“Although the authors suggest CRT [chemoradiotherapy] offers similar long-term survival, surgery is still the treatment of choice with adjuvant measures, which includes radiation and/or chemotherapy,” notes Jerry D. Brewer, M.D., M.S., a professor of dermatology at the Mayo Clinic in Rochester, Minnesota, in an interview with Cancer Network.

In the current study, Hiura et al retrospectively assessed the cases of 34 patients with stage IV cutaneous squamous cell carcinoma. A total of 21 received chemoradiotherapy while 13 received conventional radical surgery.

Among those who received high-dose chemoradiotherapy, the best overall response rate was 75%, and the disease control rate was 88%. The one-year overall survival rate and the one-year progression-free survival rate were 79% and 44%, respectively, in patients who received chemoradiotherapy vs 82% and 38%, respectively, in patients who received radical surgery.

However, researchers found that overall survival rates were lower among those who received low-dose chemoradiotherapy: median overall survival was 12.5 months in patients who received chemoradiotherapy vs 18.5 months in those who received radical surgery.

On subgroup analysis, patients who were administered low-dose 5-fluorouracil plus cisplatin (FP) exhibited better overall survival than other treatment groups.

The following regimens were employed during chemoradiotherapy: FP [cisplatin 15 mg/m² [Day 1-5]; 5-fluorouracil 800 mg/m² [Day 1-5]; every 4 weeks]; FP’ [carboplatin area under the curve 5 [Day 1]; 5-fluorouracil 600 mg/m² [Day 1-5]; every 4 weeks]; and S-1 ± CDDP [tegafur/gimeracil/oteracil 120 mg/day for 21 days ± cisplatin 60 mg/m² [Day 8]].

With respect to treatment-related adverse events, blood toxicities were most common, especially among patients receiving low-dose FP. These blood toxicities were readily managed with granulocyte colony–stimulating factor injection and/or a blood transfusion.

The current case series builds on previous research that comprised case reports. Despite the low power of the current study, Hiura et al stressed that it is likely the largest study to date.

“The main take home message is that cSCC [cutaneous squamous cell carcinoma] should be treated correctly, promptly, and aggressively the first time,” Dr. Brewer says. “Recurrent cSCC is very challenging. Sometimes a multidisciplinary approach for aggressive cSCC is best, which may include the combination of surgery, radiation, and/or chemotherapy.”

Looking forward, Dr. Brewer sees immunotherapy studies as being more telling.

“It will be interesting and exciting when studies start to look more at immunotherapy, for patients that can tolerate it, as adjunctive measures for aggressive cSCC in terms of survival compared to traditional chemotherapeutic approaches,” he says.  

Reference:


Study compares two therapies on SCC survival

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

One-Year Survival Rate

<table>
<thead>
<tr>
<th>Chemoradiotherapy</th>
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One Year Progression-Free Survival Rate

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<td>44%</td>
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Median Overall Survival Rate

<table>
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<th>Chemoradiotherapy</th>
<th>Conventional Surgery</th>
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<td>12.5 months</td>
<td>18.5 months</td>
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Time to first distant recurrence, survival link

LEAH LAWRENCE | Cancer Network

The time it took for metastatic melanoma to recur was not associated with progression-free survival or overall survival, according to a new study.

The study evaluated progression of metastatic disease in a group of 638 patients with unresectable stage III or IV melanoma from the French MelBase cohort. Included patients were treated with first-line immunotherapies (n = 274), targeted therapies (n = 180), or chemotherapy (n = 132).

"The association of the time interval between the primary excision and first distant relapse with survival has been debated in the literature, and contrasting opinions persist," wrote Anaïs Vallet, MD, of Hopital St-Louis in Paris, and colleagues, in a study published in JAMA Dermatology.

However, in the last decade, the prognosis of patients diagnosed with advanced melanoma has been improved by new therapeutic regimens. In this study, Vallet and colleagues hypothesized that progression of metastatic disease would be associated with time from primary excision to first distant recurrence of melanoma.

The median time from primary excision to first distant recurrence was 25 months, with a median time to treatment initiation of 27 months.

No association was found between time to first distant recurrence and progression-free survival when it was evaluated as a continuous variable (hazard ratio [HR], 0.99; 95% CI, 0.99–1.01) or as a categorical variable (12 to 24 months: HR, 0.75; 95% CI, 0.56–1.03; > 24 months: HR, 0.62; 95% CI, 0.47–1.01).

Similarly, there was no association between time to first distant recurrence and overall survival when it was studied as a continuous variable (HR, 0.99; 95% CI, 0.98–1.02) or as a categorical variable (12 to 24 months: HR, 0.76; 95% CI, 0.54–1.07; > 24 months: HR, 0.61; 95% CI, 0.54–1.03).

Additionally, no interactions were found between time to first distant recurrence and Breslow thickness, or American Joint Committee on Cancer stage at diagnosis.

The researchers acknowledged that one limitation to the study was retrospective collection of dates of primary excision and relapses used in the MelBase cohort. In addition, they did not have an estimation of primary excision and relapses used in the MelBase cohort. In addition, they did not have an estimation of start of the disease from the patient's point of view.

"Indeed, the data concerning the date when the patient first noticed the skin lesion are available for only 62.1% of the patients (396 of 638)," the researchers wrote. "This is the reason why we used the date of primary excision as the earlier event to evaluate time to first distant recurrence."

In an editorial accompanying the study, Daniel G. Coit, M.D., of Memorial Sloan Kettering Cancer Center, pointed out some weaknesses with the data and missed opportunities. However, he added that these data may reflect a change in contemporary treatment of patients with melanoma.

"As complete resection of metastatic disease has always been the most powerful prognostic variable among patients with melanoma undergoing metastasectomy with curative intent, now it is quite likely that a patient’s best response to immune and/or targeted therapy will emerge as much more important than the time it took for stage IV melanoma to become apparent," Coit said. "Response to systemic therapy, seen only anecdotally in the chemotherapy era, is now observed with increasing frequency, with clinical benefit defined as ranging from stabilization of previously progressive disease to increasingly frequent and durable complete remission of all known disease."

INCIDENCE, SURVIVAL STATISTICS REPORTED

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

THE INCIDENCE of melanoma has risen considerably over the past 30 years, and more than 96,000 new cases are estimated to be diagnosed in the United States in 2019, according to the recently published Cancer Facts & Figures 2019 report from the American Cancer Society.

According to the report, from 2006 to 2015, the incidence rate of melanoma increased by 3% each year among men and women age 50 years and older. Incidence rates among adults younger than age 50 years, however, have remained stable.

In total, the incidence rate of melanoma is higher in women than in men before age 50 years. By age 65 years, however, the incidence rate in men is double that of women; by age 80 years, the incidence rate in men is triple that of women. Reasons underlying these trends are secondary to age and sex differences in occupational and recreational exposure to ultraviolet radiation (UV)—such as indoor tanning—as well as detection practices and healthcare utilization, the report found.

The report also noted that while invasive melanoma makes up only about 1% of all skin cancer cases, it accounts for the majority of skin cancer deaths. In addition, most melanoma cases occur among non-Hispanic whites. Specifically, the annual incidence rate of melanoma in non-Hispanic whites is 27 per 100,000 compared with 5 per 100,000 in Hispanics and 1 in 100,000 in blacks and Asians/Pacific Islanders.

Ryan Fields, M.D., a professor of surgery and chief of the Section of Surgical Oncology at Washington University School of Medicine’s Siteman Cancer Center in St. Louis, hypothesized as to why melanoma incidence rates are on the rise in older adults.

"First, we are more vigilant about detecting melanoma. Second, there is a decrease in the protective atmosphere that shields us from UV radiation, which is the leading risk factor for melanoma and all skin cancers. Third, people still use tanning beds..."
Genetic insights are improving tumor classification and treatment. From Page 1

Specifcally, the 5-year relative survival rate for melanoma to metastasize to other parts of the body. If detected early, it is more likely than non-melanoma. However, the death rate for melanoma in 2019. Encouragingly, however, the death rate for melanoma has reported a 2% decrease in US adults age 50 years and older. In adults younger than age 50 years, the death rate decreased by 4% per year.

The American Cancer Society stresses that although melanoma is a treatable cancer when detected early, it is more likely than non-melanoma to metastasize to other parts of the body. Specifically, the 5-year relative survival rate for melanoma is 92%, with 84% of patients diagnosed at a localized stage. At a localized stage, the 5-year survival rate is 98%, according to the report.

Nevertheless, it can still be sometimes challenging for dermatopathologists to accurately classify intermediate tumors by histopathologic features alone, and molecular testing can help stratify melanocytic tumors, Dr. Yeh says.

“Now that an intermediate melanocytic tumor type has been established, one future challenge dermatopathologists will face is refining their ability to categorize tumors and stratify them with respect to risk, for which there is no clear consensus yet. The newly published WHO Classification of Tumors of Skin began to take genetic classifications into account when categorizing tumors, indicating that it is becoming accepted that genetic features can help dermatopathologists more accurately classify tumors into categories such as blue nevus, common acquired nevi, and Spitz nevus. According to Dr. Yeh, this can help clinicians better assess the malignant potential of tumors as well as their appropriate treatment and management.

“It is now clear that there are different subclasses of melanocytic tumors each of which encompasses a continuum from benign to malignant. It has been really nice to see that genetic research has now validated much of the work that was done by dermatopathologists in defining subtypes of melanocytic tumors as we now know these subtypes reflect distinct genetics,” Dr. Yeh says. 

Dr. Yeh reports no relevant disclosures.

Disclosure: Dr. Yeh reports no relevant disclosures.

that concentrates UV exposure, which is essentially a carcinogen that leads to increased risk of skin cancer,” he says.

The report predicts that an estimated 7,230 Americans will die of melanoma in 2019. Encouragingly, however, the death rate for melanoma has reportedly decreased by about 2% per year in US adults age 50 years and older. In adults younger than age 50 years, the death rate decreased by 4% per year.

The American Cancer Society stresses that although melanoma is a treatable cancer when detected early, it is more likely than non-melanoma to metastasize to other parts of the body. Specifically, the 5-year relative survival rate for melanoma is 92%, with 84% of patients diagnosed at a localized stage. At a localized stage, the 5-year survival rate is 98%, according to the report.

“When caught early, meaning prior to spreading to lymph nodes or distant sites, melanoma is very curable with recurrence rates of less than 10%,” said Fields. “When melanoma has spread to lymph nodes or beyond, the rates of recurrence are higher, but the past 5 to 10 years have seen the tables turned on this once untreatable disease,” he says.

With targeted/genetic therapy and immunotherapy, we have many options to treat advanced melanoma. We are seeing durable, long-term remission in patients with advanced disease. And there are many more immune-based therapies and vaccines being studied that will undoubtedly continue this trend towards improved outcomes in all stages of melanoma,” Fields notes.

Fields also stressed the importance of early detection. “We know from many studies that early detection leads to improved outcomes. Through improved education and advocacy, [such as] teaching patients about the A-B-C-Ds of skin lesions and when to be concerned about a mole that is new or changing, we can detect melanoma and other skin cancers at earlier stages, leading to improved outcomes,” he says.
The Value of Combination Therapy for the Treatment of Rosacea

The treatment of rosacea continues to evolve as the dermatology community gains a better understanding of the drivers of this chronic disease. Instead of a broad, overarching approach, clinicians are now able to incorporate specific therapeutic combinations that target individualized symptom profiles.

In this conversation, two experts in the management of rosacea share their insights into effective treatment strategies and ways to overcome common barriers to therapy.

James Del Rosso, DO: Rosacea is recognized as a common inflammatory skin disease that can be addressed with a variety of different treatment options. It has only recently become clearer that we’ve gained a better understanding of the pathophysiology of the disease, allowing us to combine treatment that correlates with some of its clinical manifestations.

Dr. Fromowitz, why do you think it’s taken so long for our community to embrace combination treatment for rosacea?

Jeffrey Fromowitz, MD: When we think about the pathogenesis of acne—a condition for which we’ve used combination therapy for many years—there are a number of factors we are familiar with, including follicular hyperkeratinization, excess Propionibacterium acnes, inflammation, and increased sebum levels. With rosacea, we’re learning that it’s a multimodal condition. It not only involves dysregulation of the immune system and general inflammation but also external drivers such as food, ultraviolet light, stress, exercise and Demodex colonization that may contribute to its development. Better understanding of the drivers of rosacea has helped us understand that combination therapy may be our best approach to treatment.

Dr. Del Rosso: The facial redness associated with rosacea may be due to a variety of different factors. Transepidermal water loss and what I call “rosacea dermatitis” can create some redness. There also may be vasodilation from persistent flushing episodes that leads to persistent facial erythema. Finally, some patients present with papulopustules surrounded by significant redness.

What this means is that we’re slowly moving into an era in which we are able to utilize specific treatment combinations to target the different symptoms of rosacea.

Let’s start our conversation with the treatment of persistent facial erythema. We have several current options, including alpha-2 agonists and intense pulsed light therapy. Which have you found to be the most successful in your practice?

Dr. Fromowitz: The first step in treating patients with rosacea is to improve their barrier function. My go-to agents include subantimicrobial-dose doxycycline, topical azelaic acid in the morning, and topical ivermectin in the evening. That combination tends to be effective in minimizing papules and pustules, as well as quieting down some of the inflammation and perilesional erythema that is often present.

Once the patient’s skin has calmed down, that’s when I will begin to address their background redness. I tend to lean more toward devices versus topical agents in patients with persistent, nondilation-induced background redness once their flaring has quieted down. I have found that these patients will often have a good response to a 595-nm pulsed dye or 532-nm potassium-titanyl-phosphate (KTP) laser. On the flip side, for patients with inducible erythema, alpha-2 agonists can be a great solution to prevent flushing and blushing during the daytime hours when patients are out and about.

Dr. Del Rosso: Subantimicrobial-dose doxycycline is often underestimated in the treatment of rosacea. We need to recognize that because we’re not treating a bacterium, we don’t necessarily need an antibiotic dose of doxycycline and can avoid potential antibiotic resistance, even with prolonged treatment, with a subantibiotic dose. I typically prescribe 40 mg once daily. I find that my patients are more adherent to a once-daily dose than 20 mg twice daily.

Dr. Fromowitz: I agree that the 40-mg dose is a good choice to provide the most predictable outcome for our rosacea patients while allowing us to be antibiotic-resistance stewards. I have found that, if you are only able to choose one agent with which to treat rosacea patients, the evening dose of ivermectin tends to give us the best outcomes. Of course, the combination of subantimicrobial-dose doxycycline, topical azelaic acid in the morning, and topical ivermectin in the evening can be a great solution to prevent flushing and blushing during the daytime hours when patients are out and about.

James Q. Del Rosso, DO, FAOCD, is in clinical practice at Thomas Dermatology and Research Director at JDR Dermatology Research, both in Las Vegas, Nevada. He is an experienced clinician, researcher, teacher, and author, having served as a principal investigator, research protocol consultant, research steering committee member, and publication author for numerous studies. His areas of specialty include acne, rosacea, psoriasis, atopic dermatitis, actinic keratosis, and fungal infections.

Jeffrey Fromowitz, MD, FAAD, is a dermatologist at Dermatology of Boca in Boca Raton, FL, and a member of the teaching faculty at Florida Atlantic University. His areas of specialty include body contouring, laser treatments, tattoo removal, laser hair removal, skin cancer treatment, full body exams, psoriasis, eczema, rosacea, and acne.
The Value of Combination Therapy for the Treatment of Rosacea

Dermatology Times August 2019

Dr. Del Rosso: One thing to consider about topical ivermectin is that clinical studies have shown it is most effective in patients with papulopustular lesions. Topical azelaic acid can also be an option for these patients. Integrating an alpha-2 agonist such as topical brimonidine, when possible, as part of a combination regimen also makes sense.

Dr. Fromowitz: There was a recent study looking at the combination use of brimonidine and ivermectin that did raise concerns about irritability issues with brimonidine. Rosacea patients treated with that combination, however, did see clinical improvement with good overall tolerability.

What’s important to emphasize is that the agents we use to treat rosacea need to be driven by the individual patient’s symptoms. We are at the point where we can tailor our therapies to individual patients based on their skin condition and response to therapies.

Dr. Del Rosso: Let’s return to talking more about the use of pulsed dye laser in the treatment of rosacea. How often do you find you need to repeat the use of pulsed dye laser because of the return of dilated vasculature?

Dr. Fromowitz: That’s a great question. Reuse of the pulsed dye laser tends to be driven in part by the baseline severity of a patient’s erythema, but I find more often that it is driven by the patient’s lack of attention to a follow-up care regimen. I have many rosacea patients whose skin becomes markedly improved with the use of pulsed dye laser, but when they leave my office, they tend to ignore the general skincare lessons we discussed during their previous visit. They start drinking or smoking again, take in a lot of caffeine, eat spicy foods, and forget about a general skincare regimen. Indulging in these behaviors often triggers the return of their rosacea symptoms. I have some patients like that who require monthly laser treatment.

But in a patient who demonstrates good adherence to our after-care instructions, once we complete an initial regimen of 3 pulsed-dye treatments set a month apart to help their background redness and erythema, we’ll typically schedule maintenance treatment once or twice a year, unless there is a need to address individual telangiectasias.

Dr. Del Rosso: It is extremely important to re-inforce with our rosacea patients that if they partake in behaviors that intensify the condition, those behaviors will often overcome the efficacy of any treatment they are prescribed. Our current therapeutic options don’t cure their underlying disease, so if patients don’t control the known triggers of rosacea, they are going to flare. It’s as simple as that. We need to continually remind our patients that they need to be our partners in care.

Are there any specific strategies you utilize to explain to your rosacea patients the importance of adherence to combination therapy regimens? I find that in my practice, despite our staff’s best efforts, adherence is a real issue.

Dr. Fromowitz: Medication adherence is tricky for all of us. The more complicated the regimen, the less likely the patient is going to adhere to it. Again, we explain to the patient that there is no cure to their rosacea and this is a chronic condition they need to partner with us to manage. To keep their symptoms at bay will require making the right choices in terms of any prescription medications, general skincare routine, and device use. They need to know the importance of their role. I will often ask for my patients’ buy-in before we start treatment, so at least they have verbalized their commitment to me.

Being a good listener is one of the keys to helping patients with adherence issues. Show them that you care, that you are hearing them and you acknowledge their issues. That can all positively impact their buy-in and general adherence level.

For the majority of my rosacea patients, I try to give them the simplest regimen possible that includes a bland cleanser, mild moisturizer, and well-tolerated sunscreen in addition to our active medication regimen. We re-educate on the importance of each component at every visit. My nurses are great at reviewing and reinforcing key pieces of information with my patients.

Dr. Del Rosso: Those are all great recommendations. One more thing I want to bring up is that I used to have patients who would come in after 3 months and tell me they aren’t using their medications because it’s too expensive. So now I tell every patient with rosacea before they even leave my office that if for whatever reason they aren’t able to get access to a medication, or if they are quoted a price that sounds unreasonable, let us know and we will work with them to get what they need.

It’s a horrible feeling to work with a patient, figure out a plan, and then essentially lose 3 months because of financial issues. Access to medication is a major issue that is too often ignored, so we’re doing what we can to let patients know upfront that we are here as a helpful resource.

Dr. Fromowitz: Access is the handicapper of innovation. It has become such a significant issue for us that we have one member of our staff whose primary responsibility is to serve as the point person for our patients with financial or other issues that inhibit their access to medication. Just like you, we tell our patients before they leave our office that if they can’t get every medication we agree on in our plan of action, call the medical assistant on our team and we’ll figure out a solution.

We don’t want lost time or productivity for our patients. In the worst case scenario, patients will blame us for lack of access or insurance issues. They think we did something wrong, so they move on to another doctor and start the process all over again.

Dr. Del Rosso: Those are all great points. I hope we’ve been able to offer a variety of helpful pearls for the dermatology community today that will assist them in their treatment of rosacea patients.

References


When something is wrong or perceived to be wrong, people on teams need a psychological safe space to be able to speak up about whatever it is, and that includes healthcare, says Galen Perdikis, M.D., professor and chair of plastic surgery at Vanderbilt University Medical Center, Nashville, Tenn.

“Communication is the most important factor in your success, your malpractice record and your safety profile,” Dr. Perdikis says, “and it is often the last thing you address.”

He often relates the documented failure of communication, or the ability to speak up and stop the line that likely led to the Space Shuttle Challenger explosion on Jan. 28, 1986, to the art of practicing medicine.

“They had been under such pressure with delays,” he says. “The O rings had never been tested below freezing temperature. At that time, there was no ability or resolve to actually ‘stop the line’ and halt the launch.”

Communication is so important because, as earlier data from The Joint Commission confirms, the root cause of sentinel events is lack of communication. The same goes for wrong-site surgery, medication errors and delays in treatment.

“You are the captain, and it is expected that you will have these conversations, and set the standards, systems and procedures for your patient care,” he says. “You need help around you; and if you do not take this on, you will be out on an island by yourself when something occurs.”

This shouldn’t be the case, because communication, when paired with evidence-based medicine, creates a culture of safety.

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This shouldn’t be the case, because communication, when paired with evidence-based medicine, creates a culture of safety, Dr. Perdikis says. That's necessary because in dermatology, there’s a lot going on — doing procedures in clinic, managing pathology specimens, checkouts and timeouts.

“Culture will always triumph over policy, because a culture of safety is the mindfulness by each individual to look for and eliminate risk,” he says. “If, for example, someone is about to perform a procedure but is erring — injecting the wrong product — the culture of safety gives people around the provider the ability to speak up to prevent an error.”

He shares specific recommendations here to bolster that culture, along with this simple equation: Safety = Tech (EBM and Systems) X Culture.

Learn
Physicians suffer from lack of awareness of evidence — most read less than an hour a week, but can suffer from information overload that includes core literature, extended literature and critical evaluation.

“Know the data and apply the data,” Dr. Perdikis says.

Define
The task at hand may not be defined: What is to be done? When? How? Who? What are resource issues or logistic issues? A confirmation checklist can really help with this — the same type used by pilots pre-takeoff. And remember that you are responsible for the systems, so please don’t multitask.

Produce
Dr. Perdikis cites the Toyota production system with its emphasis on continuous improvement, solving root problems, i.e., “Go and see for yourself,” and the belief that the right process will yield the right result. It fosters long-term goal focus, develops people and partners, and maintains respect for them.

Review
A comprehensive plan for systems and processes needs a commitment to review and improve: debriefing, error management, double-loop learning or question the underlying assumptions behind techniques, goals and values, and problem-solving.
10 Apps that can improve care and your life

STEPHANIE STEPHENS | Staff Correspondent

Android users can choose from more than 2 million apps, while Apple offers 1.8 million, according to recent data. You need just a few to improve patient care and your life, says Daniel Mark Siegel, M.D., clinical professor of dermatology at SUNY Downstate. He explained at the Atlantic Derm conference in Washington, D.C. in May.

Remember that the word “app” refers to a software application on a mobile device or website.

1. PRIOR AUTHORIZATION DRUG DENIAL TEMPLATE: Look no further than the free American Academy of Dermatology (AAD) website, where a template works the magic, Dr. Siegel says. If you’re not a stellar letter-writer, the app does it for you, and concisely. It’s easily accessed and takes the emotion out of the process — nicely and politely, he says. “If you’re tired and burned out, this prevents you from taking that out on someone else.”

2. MOHS SURGERY APPROPRIATE USE CRITERIA (AUC) APP: This free workhorse provides decision support on whether Mohs is the right decision for 270 scenarios. It was developed by the AAD, ASDS, ACMS and ASMS using UCLA-Rand criteria, and features 20 pages with 213 references.

The app came to the rescue when Mohs procedures were perceived as being potentially overused. “It pulls the appropriate literature, including controlled trials, extracts the evidence, and parses it,” he says. “Then it allows you to choose the diagnosis and consider criteria. Consider this analogy: If you can catch a mouse with peanut butter and cheese and a mousetrap, why do you need a shotgun? It’s very efficient.”

3. VISUAL DX: This app isn’t free, but it’s worth your investment at the AAD member price of $319. It allows you to build a differential to evaluate possibilities, compare variations and improve diagnostic accuracy. It’s a boon for dermatology.2 “A dermatology-focused support system can narrow down the differential diagnosis,” Dr. Siegel says. That may prevent you from ordering an unnecessary radiation study, an MRI or PET.

“You can look at the picture to determine what you think the patient might have, and the app also shows you diagnoses that could be life-threatening,” he says. The app does offer the world’s largest medical image library, peer-reviewed content, patient engagement tools and handouts, and educational webinars. It’s best known for its Sympticon to visualize symptoms.

4. DERM LITE X AND A CAUTION: Smartphone cameras have made self-documentation of patient’s symptoms easier but are rife with HIPAA-compliance risks for physicians, Dr. Siegel says.

“Secure your own phone and don’t use a four-digit password,” he adds. “Use facial recognition or fingerprint printing for authentication so your passcode is not easily breakable. Lose or misplace your device with protected patient information on it, and you could be liable for thousands of dollars in fines.”

Here’s another tip: “If you set your phone to auto-wipe after a few failed login attempts, you protect your data,” he says. He’s heard from friends that young children at home will keep trying passwords to break in and play games.

DermLite X is a free app that stores all images in a HIPAA-compliant manner.4 “It’s a couple of extra steps versus losing your livelihood,” he says.

Providers can learn more about securing health information at HealthIT.gov.

5. GOOGLE VOICE AND DOXIMITY: Use Google Voice and a permanent number can be forwarded to one or more phones, along with a text and email of the call transcript. Use it on your main office number after hours, and for post-op care handouts. It’s free, more HIPAA-compliant than your own phone, and preserves your privacy, Dr. Siegel says. In any event, consult your own HIPAA compliance officer before using for your practice.

Maybe you still wonder, “How can I call a patient without giving away my number?” Use the free-for-you Doxim-
Take charge of your marketing and get results

STEPHANIE STEPHENS | Staff Correspondent

When considering how to market your practice, “think less about marketing and more about communication overall,” advises Eric F. Bernstein, M.D., M.S.E., Main Line Center for Laser Surgery, Ardmore, Pa.

Communication informs your patients about all of the services you offer, says Dr. Bernstein, a.k.a., “The Dermguy.”

When patients are familiar with your office, and they trust you, they’ll seek other services, he says. Offer easily accessible information about your services around your office.

INTERNAL CONSIDERATIONS

In his 3,600-square-foot office space, Dr. Bernstein discovered that patients didn’t always realize that one floor has most of the laser devices, and the other focuses on injectables and surgical procedures — but it’s all one practice. He placed marketing materials in both patient locations to help clarify.

He also uses video technology judiciously and sparingly, with before-and-after shots of procedures.

“It’s not the same video over and over,” he says. “Patients get iPads that explain our procedures and repeat things I normally say in a patient room.”

He holds events to highlight special procedures.

“Remember that companies you work with will usually help. Sure, they want you to offer discounts to your patients, so why not ask them to offer a discount to you, so they also have ‘skin in the game,’” he says.

Larger expenditures such as advertising, billboards and television really are expensive, Dr. Bernstein says.

“Hire a professional, then track results for a few months,” he suggests. “Device and filler companies may also have co-op budgets and may split marketing costs with you.”

Implementing Your External Message

Take a long, critical look at your website, and if it needs a revamp, do it and include a strong and concise landing page, Dr. Bernstein advises. Then use Google Ads (formerly Google Ad Words) to optimize the site and drive traffic.

If you don’t know how or don’t have time, hire a local company to help you, Dr. Bernstein says.

It’s normal to be hesitant. “Get yourself out there and don’t wait until you have a perfect message,” he says. “Perfect is the enemy of ‘done’ and you can improve your message as you move forward.”

UNDERSTAND WHO USES SOCIAL MEDIA

Everyone isn’t actually “moving away” from Facebook — still the most popular social media platform. Dr. Bernstein says it tells a longer story with larger blocks of space, but some people don’t have the attention span.

He cites these users-per-month for the “big three”:

- Facebook: more than 2 billion
- Instagram: 1 billion
- Twitter: 321 million

Dr. Bernstein shares these tips:

- With both a personal and business Facebook account, do use personal information on your business account to convey a “real person,” says Bernstein. Take advantage of Facebook’s free online courses, use analytics to assess your marketing, and “boost” for more successful posts.

- Instagram is growing fast, he says, with the United States its top consumer. Images get 23% more engagement than on Facebook because of its one or two pictures, a quick movie, or a collage. Younger viewers with short attention spans want a single picture multiple times a day.

- Instagram’s hashtags aggregate images on the same topic. Use them on Twitter and Facebook to find images or videos on similar topics.

- Be smart and careful about choosing influencers to increase your following.

- Competent in-house staff may be able to do social media for you, he says. You may consider a reverse mentorship with a young staffer who teaches you and you do the same for them, he suggests.

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Communication is the most important factor in your success, your malpractice record and your safety profile.

Galen Perdikis, M.D., Vanderbilt University Medical Center, Nashville, Tenn.

Review and improve systems and processes

Assess
Almost 70% of physicians think they’re above-average communicators, while only 50% rate other doctors’ ability to communicate in the above-average category. How are your communication skills?

Listen
Be present. Physicians interrupt the patient 18 seconds after they’ve begun to speak. Uninterrupted patients need about a minute to complete their “list” statement.

“Physicians have two ears and one mouth, so do more reflective listening,” he says. “That means don’t interrupt, limit what you say, stay focused and breathe, take notes, paraphrase and then reflect. Inquire, but don’t dictate or solve.”

Reflect
Know your hooks, those characteristics or habits of others that may get you stuck and cause you to react negatively.

Give
When things get tough, be generous with “PEARLS,” he says. The acronym, coined by the American Academy on Communication in Healthcare, has five components: partnership, empathy, acknowledgement, respect and legitimization. Try “Let’s tackle this together” for partnership, or use empathy this way: “That must be very difficult.”

Slow
Avoid “too-busy, fast words.” Don’t say: “Why don’t you jump up on the exam table and let me do a quick exam?” Try: “Well, why don’t we get you across to the exam table so that we can do a thorough exam?” You are going to perform the same exam, right?

Prepare
Do work before the work, so others can ask for a clarification or discuss a problem. Having team language supports critical communication about important topics, and helps create a safe environment with “speak-up-ability” without fear.

Admit
To promulgate the culture of safety, discuss errors or near misses: Was it the system or the behavior? Individual behavior choices include human error, risky, or reckless behavior. Recognize black holes and brain squirrels.

“These are those things that negatively impact you staying present in the here and now — thoughts that you ruminate over,” says Dr. Perdikis.

Now, you’ll be less likely to say, “What we have here is a failure to communicate.”

Google voice: Forward your number to other phones

ity dialer app and patients see your office phone number instead. It’s ideal since *67 comes up “unknown number” and patients may not answer.

CHARTBUILDER AND CPT QUICK REF:
Marketed as “the best ICD-10 conversion tool ever created,” ChartBuilder builds, saves and prints your own personalized ICD-10 charts — and cross-maps your ICD-9 codes for free.

There’s training, too, Dr. Siegel says.

Don’t miss the AMA’s CPT QuickRef app, and it’s also free.

SKINVISION:
SkinVision uses a complex algorithm to map out features of a lesion to help determine melanoma risk for a patient who’s uploaded a photo of their mole or skin condition. It’s not yet available in the United States, but stay up to date at bit.ly/SkinVisioncomingsoon.

EVERNOTE:
Evernote is like your own private Google-like universe, a note-taking app that helps track most everything. You can save, sync and share — and it’s all secure.

Start with the free option.

EPOCRATES AND GOODRX:
Epocrates from Medscape is the number one medical reference app, with evidence-based guidelines.

It’s free, but there’s a premium version for sale.

Good Rx allows you to look up any drug price and help your patient save; it’s the number one free medical app.

PUBMED:

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Patient experience matters in healthcare collections

NAVEEN SARABU | Medical Economics

The climate in healthcare collections is rapidly changing. While providers are pressured to increase their margins amid evolving value-based care requirements, the expense of medical care is shifting from insurers to patients. According to Bloomberg, in 2017, almost half of privately insured Americans under age 65 had annual deductibles ranging from $1,300 to $6,550. Furthermore, a Kaiser Health tracking poll found that 43% of insured adults said they have difficulty affording their deductibles, while 29% have problems paying medical bills.

As out-of-pocket costs and patient liabilities rise, medical practices struggle to get paid for their services. It’s far more difficult to collect from patients than payers. Therefore, it is important for providers to adjust their workflows to collect at the time of service and enable easier, more immediate payment processes for patients. If weeks and months pass without payment, providers lose money due to rising administrative costs.

Other proactive strategies can help providers with complex claims, unpaid bills, and practice profitability. A practice can reinvent its billing approach with improved patient
“Understanding the practice’s billing specifics and typical workflows and applying technology to automate ... them eases the burden on the practice.”

and payer communication, enhanced engagement, and a precedence for system integration.

**IT’S NOT ONLY HOW MUCH, IT’S WHEN**
For a provider, the true value of a dollar received for services depends on the timing of its collection. According to The Advisory Board Company, providers may be receiving as little as 18 to 34 cents for every dollar billed to those with high-deductible health plans because of additional administrative costs.

When financial responsibility lies with the patient, practices send, on average, 3.3 statements before receiving payment for an outstanding expense, according to Becker’s Hospital CFO Report. Costs of printing and mailing are significant, as are those related to staff time. As much as 42% of providers say it typically takes between one and two months to collect payment from a patient, while 35% say it takes them even longer, says InstaMed’s 2018 report on trends in healthcare payments.

**CREATE AN ENGAGING EXPERIENCE**
First and foremost, providing a positive and engaging patient experience is a good practice. Focusing on patient-centered offerings can lower some of the practice’s costs, generate an increase in patient return rates, and lay the foundation for solid collections. Providers can start by creating a self-service culture.

Practices can make it easy for patients to schedule appointments online, and send text and email appointment reminders to reduce no-shows and encourage mobile pre-check-in. Providers want to consider how to simplify the registration process and include a real-time insurance eligibility check as soon as the appointment is made. Many times, claims are identified as having incorrect insurance. With an automated check upfront, providers can reduce these rejections.

Patients should have the opportunity to fill out intake forms online before their visit or through a patient kiosk just before the appointment. This is a good opportunity to collect any outstanding balances and co-payments for the visit.

It’s also important for providers to communicate with the patient if the benefit has been exceeded or the deductible has not been met. Some practices share procedure codes for non-emergency services with patients in advance so that they could confirm the amounts with their plans directly. Consumers for Quality Care found that 83% of those surveyed said they want more cost transparency from their providers. For the patient to actually “become the payer,” he or she must be aware of the responsibility and, whenever possible, the amount.

On the health plan side, providers also find that claims scrubbing — proactively identifying and performing corrections for errors in billing codes — is advantageous. The process generates cleaner claims, a reduction in denials, and improved payer communication. By getting it right from the outset — and enabling multiple types of edits to the claim before it is submitted — providers will be more efficient and find greater success with reimbursement.

**STREAMLINE PAYMENTS WITH TECHNOLOGY**
To improve upfront collections from patients, practices need to think like retail, not healthcare businesses. It’s all about offering customized, web-based and on-demand services. While patients want easy access to online bill pay, they are not always given that opportunity. It’s reported that while 44% of consumers receive household bills electronically, only 18% get medical bills that way. Patients want multiple ways to pay, and for transactions to be seamless. They also benefit from notifications regarding when payments are due and simple online access to view their balance.

To optimize efficiency, automating as many steps as possible within the practice’s integrated clinical and administrative workflow will both save staff hours and help avoid unwanted surprises in the form of denials, ineligibility, or larger than expected patient responsibility. This includes automating demographic and health plan verification checks, using claims scrubbing technology, and incorporating patient self-service applications, such as portal functionality, E-statements, digital communication access points, and integrated credit card payments.

Other worthwhile tactics include demographic update requests and financial responsibility notifications during — or in addition to — an appointment reminder call. A friendly phone call would include addressing a balance or co-payment due, perhaps with an invitation to pay securely over the phone, put a credit card on file, or discuss a flexible payment plan. Providers can also utilize analytics to identify patient propensity-to-pay behavior, tailoring its strategies for collection calls.

There will always be a need for billing experts in the practice; some claims are far too complex, including in certain specialties such as orthopedics and oncology, or in worker compensation and motor vehicle accident claims. Understanding the practice’s billing specifics and typical workflows and applying technology to automate a large portion of them eases the burden on the practice. However, practices should shift the mindset toward collecting patient responsibility at the time of service to optimize their collections, now and in the future. To make this attainable, providers must elevate the patient experience and remain in touch — consistently and through multiple channels — during the entire patient health journey, not just when patients are in the office.

**Disclosure**
Naveen Sarabu is vice president of product management at AdvancedMD.
Risks of EHRs
Beware of common causes of data errors

JAMES F. SWEENEY | Medical Economics

Originally heralded as a tool that would make healthcare more efficient and effective, EHRs have revealed themselves to be a mixed blessing.

In addition to frustrations over badly designed interfaces and interoperability issues, physicians are coming to realize that the software they rely on to manage their practices can be putting their patients at risk of medical error and themselves in danger of medical liability.

The problems were highlighted in a recent joint Kaiser Health News and Fortune investigation that showed that EHRs are not living up to their promise, but they have been blamed for everything from incorrect prescriptions to patient deaths and serious injuries.

And while many practices have come to working terms with their EHRs, they might be unaware of the malpractice dangers they can pose. “It’s definitely on our radar,” says Robert Hanscom, JD, vice president, business analytics at Coverys, a medical liability insurer. “We are urging [physicians] to pay more attention.”

Three years ago Coverys created a code to flag EHR-related malpractice claims. The number of cases rose from 21 in 2013 to 63 in 2017 and continues to climb, Hanscom says.

In the Medical Economics 2018 EHR Scorecard, dozens of practicing physicians commented on how their EHR systems made them more prone to errors.

“I make more prescription errors with the EHR than I ever did with paper charts,” said one respondent.

UNINTENDED CONSEQUENCES

Many of the problems stem from the fact that EHRs were forced into widespread adoption after the passage of the HITECH Act in 2009. Rather than mandating a universal standard based on design research, best practices and user experience, the government allowed competing vendors to develop their own EHRs. The result is a hodgepodge of systems that creates unnecessary risk, says Hanscom.

User difficulties and risks are compounded for doctors who work on multiple EHR systems, each with its own user interface, quirks and design flaws. “There are components that can come back and bite physicians if they’re not handled correctly,” Hanscom says.

Another insurance executive says he has seen malpractice cases stemming from EHR-related errors that led to incorrect medication doses and even removal of a wrong kidney.
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“Even though the frequency is small, the potential for harm can be catastrophic,” says Darrell Ranum, JD, vice president of patient safety and risk management, The Doctors Company.

EHRs are not going away and the patchwork of competing systems, many of which still don’t work well together, is not going to be replaced anytime soon by a universal, interoperable network. So what can doctors do to prevent errors and subsequent liability?

TEST YOUR EHR
No matter how long they’ve used a particular system or how satisfied they are with its performance, practices should test their EHR’s capabilities, says Lorraine Possanza, DPM, JD, MBE, director of the Partnership for Health IT at ECRI Institute, an independent nonprofit authority on the safety of medical practices and products.

Double check to make sure the system is doing everything it should, such as prescribing the correct amount of drugs, delivering prescriptions to pharmacies and sending orders to labs, she says. “The objective is you don’t want to make a mistake you shouldn’t have made. And you don’t want a system that makes it easier to make a mistake,” she says.

Physicians often have no idea how frequently EHRs can make mistakes, says Zach Hettinger, M.D., MS, medical director and director of cognitive informatics, MedStar Health National Center for Human Factors in Healthcare. The center tests EHRs and one recent evaluation of a common system revealed a 40% error rate in writing prescriptions, Dr. Hettinger says.

The center offers free tools that allow practices to test their EHRs. Its “EHR See What We Mean” program explains many common problems with electronic records and how their designers could avoid errors.

In one example, a physician treating an adult male wants to prescribe Tylenol 500mg and, upon entering “Tylenol”, is confronted by more than 80 options, many of which are not relevant to the patient, such as children’s Tylenol. An attempt to narrow the search by adding “500” after Tylenol fails to turn up anything because the EHR search engine, unlike public search engines, does not recognize near matches and requires exact wording, The doctor returns to the original screen of 80 possible matches and scrolls through to find 500mg, which is the 68th option.

A better system would have screened out options irrelevant because of the patient’s age, gender or other factors and presented Tylenol 500mg, the most common adult dosage, as an easily selected choice.

Possanza also recommends creating backups and contingencies in case an EHR does fail. Common measures include security measures to prevent hacking, data backup and retrieval tools and more.

REPORT PROBLEMS
While some EHRs allow users to modify them, most improvements must be made by the vendor, either through regular upgrades or specific fixes. And a vendor can’t fix a problem if it doesn’t know it exists, says Possanza, so she urges users who notice a persistent or dangerous problem with EHRs to document and report it to the manufacturer. Though not always as responsive as users would like, vendors do want to make their products more reliable and user friendly and eliminate errors, she says.

ECRI formed a patient safety organization, where clinicians and healthcare organizations can report, aggregate and analyze data related to patient safety, including EHR faults. Problems also can be reported to the Office of the National Coordinator for Health Information Technology at the Department of Health and Human Services.

“This is a really complex system we’ve implemented and we need to have a multidisciplinary approach to solving the problems,” says Dr. Hettinger. “Sharing and collaborating on the information is the only way the system is going to get better.”

However, even if an EHR is fully or partially responsible for a medical error, physicians should not think that blaming the software will get them off the malpractice hook.

“It’s never not the physician’s fault,” says Hanscom, adding that many EHR vendor contracts include “hold harmless” provisions that protect the manufacturer. And while some patients have successfully sued EHR vendors in addition to the healthcare providers, the resulting settlements are usually not disclosed.

BEST PRACTICES
Practices should ban copying and pasting information from one form or page to another, says Ranum. This simple function saves time for users in a rush, but it’s one of the worst dangers posed by EHRs.

Copying and pasting on a chart can propagate incorrect or outdated information. Ranum says, a harmful error that can easily spread like a virus as other users do the same. “We want physicians to be extremely careful with copying and pasting. It’s often better to type it in yourself to make sure it’s the most recent,” he says.

Ironically, an EHR feature designed to prevent mistakes is proving to be one of the biggest problems. Systems come with alerts and alarms that appear when a potential problem is indicated by the information entered, such as a drug allergy or incorrect dosage.

However, some users complain that there are so many alerts — many of which are irrelevant — that they are ignored, which can sometimes cause errors. Hanscom cautions users who do ignore or deactivate alarms to document it and explain why in order to protect themselves in the event of litigation.

Some practices employ medical scribes in order to allow physicians to focus on patients during visits. That can avoid data entry mistakes caused by divided attention and reduce the number of users of the EHR system, which could lead to fewer mistakes.

SHARE INFORMATION
Most practices have been working with their EHR systems long enough to have uncovered many of their weaknesses, quirks and blind spots. However, that level of knowledge can vary among users in a practice, depending on their jobs and experience with the system.

Consequently, it’s important that all users in a practice share best practices about the system and know its dangers, says Possanza. Likewise, any workarounds or steps that can prevent errors should be implemented as practice policy, she says, adding that any fixes must be shared among users, as well.

It’s important that new employees be brought up to speed, particularly if they’re used to a different system.
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How to avoid the legal risks of telemedicine

MARY K. PRATT | Medical Economics

Judd Hollander, M.D., holds a medical license in Pennsylvania, where he practices, but to ensure that he could legally treat his patients virtually, even when they’re traveling out of state, he sought out medical licenses in an additional 18 states.

Dr. Hollander obtained those credentials after surveying 3,500 of his patients and asking about their travel showed that obtaining licenses in those 18 states, along with Pennsylvania, would allow him to see his patients nearly any time they needed him.

Dr. Hollander, who in addition to practicing is a senior vice president of Healthcare Delivery Innovation at Jefferson Health, a regional healthcare system based in Philadelphia, says this step allows him to treat his patients without worrying about whether he is legally out of bounds.

Dr. Hollander says that it takes time and effort to manage the requirements associated with all those licenses. “It’s a half-time job keeping up with them,” he jokes, but he says physicians need to take such steps if they want to offer telemedicine services and be compliant with administrative rules and legal regulations.

Patients are increasingly seeking out virtual medical care, while more physicians are working toward providing increased telemedicine services.

However, as physicians add such services to their practices, experts say they need to consider legal and compliance issues around providing such care, from telemedicine-specific regulations to state licensure requirements and even malpractice-related questions.

“You do have to be careful. You can be successful if you’re meticulous, use good resources, have risk managers looking at policies and procedures, and have good technology selection, appropriate documentation and training around telemedicine,” says Neal Sikka, M.D., chief of the innovative practice and telemedicine section at the George Washington University Medical Faculty Associates.

MULTIPLE STATE LICENSES MIGHT BE REQUIRED

Technology now enables physicians to deliver a range of medical services virtually. Experts group these services into two categories: telemedicine, which is when the physician delivers care via telecommunications to a patient located at another site, and telehealth, which includes technology-enabled health services such as remote patient monitoring.

A leading consideration when implementing telemedicine is state licensure, experts say. Telemedicine adds a complication to licensure needs, because the technology enables physicians to see patients who are located in a state where the doctor is not licensed to practice.

As such, physicians and other clinicians will likely need a license to practice in multiple states if they want to treat their patients virtually.

Experts advise physicians to examine their patient panel to determine if they have patients living out of state — for example, in a neighboring state if their practice is near a state line. Physicians may want to determine if they have a significant number of patients who re-locate for part of the year — such as retirees who head to warmer climates during the winter — or if a large percentage of their patients travel extensively.

Thus, a physician seeing a patient via video link needs to know where that patient is located at the time of the visit — known as the “originating site” — and understand that state’s licensure requirements.

Some states are making it easier for physicians to practice in other states. The Interstate Medical Licensure Compact, which encompasses 28 states and the territory of Guam and their 38 medical and osteopathic boards, offers an “expedited pathway to licensure for qualified physicians” seeking to practice in multiple states.

It also offers reciprocity, with the members recognizing each other’s licensing requirements so physicians don’t have to review and meet each state’s requirements to obtain a license, says Steven E. Waldren, M.D., MS, vice president and chief medical informatics officer for the American Academy of Family Physicians.

Dr. Waldren notes that although physicians still need to apply and pay license fees for each member state where they want to practice, the IMLC offers a more efficient way for physicians to obtain additional state licenses.

However, physicians seeking licenses in states that aren’t part of the compact will have to meet the requirements of each of those, Dr. Sikka says.

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Technology can help physicians adhere to the various regulations and laws that govern telemedicine services.

RULES VARY BY STATE
Physicians also need to understand the differences in state regulations governing telemedicine, experts say.

Some require physicians to see patients in person before offering any type of telemedicine service, while some have additional regulations that could apply to physicians billing patients located in those states. Some states have restrictions on asynchronous visits — interactions where the clinician and patient do not interact in real time — while others allow both synchronous and asynchronous visits as well as a broader range of telemedicine services.

States vary in their regulations in other ways, says Rachel Dixon, a consultant and telemedicine expert with the Medical Group Management Association (MGMA). For example, some states allow physicians to prescribe certain controlled substances via telemedicine visits under certain circumstances. Such rules, she says, require physicians to understand such regulatory differences if any of their patients are out of state.

Furthermore, she says, states generally require physicians to obtain consent from patients before treating them, but some states have specific requirements around consent that others do not.

California, for instance, requires the originating site provider to obtain and document patient consent, according to the Center for Connected Health Policy, while Kentucky says the treating site provider to obtain and document patient consent as part of the check-in process, the telemedicine application, do not offer those features.

Medicare rules add another layer of complexity for physicians expanding into telemedicine, says Mollie Gelburd, JD, associate director of government affairs at MGMA.

For example, Gelburd explains, both the originating site and the physician providing the service are expected to submit documentation of the visit. Failure to meet that extra requirement would mean noncompliance with the federal rules.

SECURITY, PRIVACY RISKS
Telemedicine must also meet HIPAA requirements. “The rules are no different for telemedicine than for [in-person visits],” says Ronald Weinstein, M.D., founding director of the Arizona Telemedicine Program.

This means physicians need to ensure they’re in a location where no one can overhear the virtual visits, which would violate HIPAA’s privacy and confidentiality requirements. Additionally, physicians must use technology that’s compliant with HIPAA rules. The technology should have fully encrypted data transmission and provide secure connections. Experts stress that consumer videoconferencing platforms, such as Apple’s FaceTime application, do not offer those features.

Physicians that opt to work with another business or a technology provider to offer telemedicine services to patients must ensure that those partners are compliant with HIPAA regulations, too, Dr. Weinstein says.

“You should have contractual assurances that third parties will follow all the rules around HIPAA,” he adds.

MALPRACTICE CONCERNS?
Experts say physicians offering virtual services don’t face new malpractice rules or risks.

“Telemedicine isn’t really high risk, but you do want to make sure you’re practicing under the board of medicine for the state where the patient is located, and practicing under the terms of your licensure and the standards of care for the conditions and for your practice focus,” Dr. Sikka says.

Physicians who comply with licensing rules, who document appropriately and who follow the same standards of care they would for in-person treatments don’t create additional malpractice risks just because they’re offering their services virtually.

Still, there are risks if physicians don’t diligently adhere to the rules. For example, Dr. Waldren says physicians could face a loss of malpractice insurance coverage if they treat a patient located in a state where they aren’t licensed to practice — even if that error was inadvertent.

As a result of the potential for such situations, Dr. Waldren advises physicians to consult with their attorney as well as with their malpractice insurance company before starting to offer telemedicine services.

TELEMEDICINE TRAINING A MUST
Technology can help physicians adhere to the various regulations and laws that govern telemedicine services.

Some telemedicine applications, for example, allow physicians to incorporate into their telemedicine workflows the appropriate consent forms and checks on patient locations thereby helping them follow the rules applicable to their practice.

Additionally, experts advise physicians to seek out training in delivering telemedicine services to ensure they’re not only following the applicable rules, but also so they’re delivering the best possible care in this new setting. Institutions that offer training in telemedicine services for physicians include the American Telemedicine Association, the American Medical Association, the Arizona Telemedicine Program and Thomas Jefferson University.

Experts say physicians shouldn’t let complicated regulations over licensure, rules and regulations stymie their adoption of telemedicine, because patients will increasingly seek out virtual visits and other technology-enabled care.

At the very least, Dr. Hollander says, physicians should offer telemedicine service to their existing in-state patients if they want to remain relevant in healthcare. “You have to figure out how to do it.”
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MINERAL SUNSCREEN FLUID SPF 50+ has been added to the Avène sun protection line of products, the company recently announced. This daily sunscreen provides protection against UV rays, 80 minutes of water resistance, and is non-comedogenic.

The formula contains 100% mineral sunscreen filters, which are biodegradable. It does not include octinoxate and oxybenzone, which makes the product safer for marine life. Titanium dioxide and zinc oxide provide UVA and UVB protection, and pre-tocopherol (a vitamin E precursor) protects against free radicals. According to the company, the sunscreen also contains Avène’s patented thermal spring water, which 150 studies have shown soothes, softens and calms skin.

A tinted version, which provides sheer coverage, is also available.

The sunscreen is chemical filter-free, fragrance free and paraben free, and can be used on all skin types.

FOR MORE INFORMATION: aveneusap.com

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Vital Body’s CBD EPSOM SOAK is formulated with hemp-derived CBD, essential oils such as lavender, bergamot and rosewood; and mineral compounds designed to relieve foot pain. The product contains magnesium and sulfate, which help to relax sore muscles and calm nerve inflammation as well as itchy, dry skin.

FOR MORE INFORMATION: vitalbodytherapeutics.com

WHEN BEAUTY LAUNCHES ANTI-AGING LINE
When Beauty has announced an anti-aging line that features products made with seanol, a derivative of brown algae. Seanol has anti-inflammatory benefits, protects against free-radicals, and promotes cell health, according to the company.

The line includes:

Toner Mist With Marine Complex: This product is a mist containing sea water to moisturize and calm the skin barrier while supporting cell function. The toner also contains hydrolyzed collagen to plump and improve the look of damaged skin.

Pure Five Serum With Seanol: This fragrance-free serum is meant to improve the look of dull, tired skin.

Ultimate Cream With Seanol: This cream is designed to moisturize and brighten skin while reducing fine lines and wrinkles.

FOR MORE INFORMATION: www.whenbeautyus.com

NEW PSORIASIS LOTION NOW AVAILABLE
Halobetasol propionate and tazarotene lotion, 0.01%/0.045% (Doubri, Ortho Dermatologics) is now commercially available to healthcare providers, according to a press release issued June 25 by Ortho Dermatologics. The topical was approved by the FDA April 25, 2019.

In a phase 2 multicenter, double-blind, randomized, vehicle controlled study, the lotion achieved more effective treatment success than its individual agents and vehicle. Study participants also showed a reduction in psoriasis signs, such as erythema, plaque elevation and scaling at target lesions.

Researchers of two phase 3 prospective, multi-center, randomized, double-blind clinical trials found that the topical was safe and effective in participants 18 years or older with moderate-to-severe psoriasis. A third phase 3 multicenter, open-label study evaluating the long-term safety over the course of a year found the most common treatment-related adverse events were application site reactions such as itching, pain, irritation and folliculitis.

The lotion can be dosed to clearance as long as patients do not experience any local skin reactions; however, treatment should be stopped once clearance is achieved, the company states.

FOR MORE INFORMATION: www.duobrii.com

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FOR MORE INFORMATION: www.whenbeautyus.com
Methotrexate was approved for the treatment of psoriasis in the 1970s, but its widespread adoption for the treatment of severe psoriasis was slow to gain traction.

Krueger JG and Gottlieb AB at Rockefeller University in New York, NY, demonstrated in a paper published in 1990 that psoriasis was likely driven by inflammation, specifically T-cells. The recognition of Krueger's and Gottlieb's findings spurred more widespread use of methotrexate, as well as the investigation of cyclosporine as a systemic therapy, leading to the FDA's approval of cyclosporine for psoriasis treatment in 1997.

The Psoriasis Drug pipeline is focused on small molecules, particularly the Janus kinase (JAK) inhibitors. While tofacitinib (Xeljanz, Pfizer), approved for psoriatic arthritis, did not clear the FDA for psoriasis due to safety concerns, studies showed the 10mg, twice daily dose had similar efficacy to etanercept. Recently phase 2 data for tyrosine kinase 2, or TYK2 inhibitors, has demonstrated remarkable efficacy.

Read the full story at: bit.ly/40yearspsoriasistx
NEW LIP DUO EXFOLIATES, HYDRATES SKIN

IS Clinical recently launched their first products dedicated to promoting healthy lips. The products work together to gently exfoliate and minimize the look of dry lips, according to the company.

THE LIP POLISH: This product is meant to both exfoliate and hydrate. It contains antioxidants from vitamin C and E, as well as botanical butters.

YOUTH LIP ELIXIR: This lip cream contains botanical extracts and antioxidants, including hyaluronic acid, vitamins C, E, and B5, cocoa butter, as well as IS Clinical’s proprietary combination of extremozymes. The product hydrates and plumps the lips, according to the company.

FOR MORE INFORMATION: isclinical.com

AT-HOME TREATMENT FOR BRIGHTENING, EXFOLIATING

Lira Clinical’s PRO ANTI-AGING PADS are designed to brighten and correct skin tone before and after in-clinic treatments. The product uses kojic, azelaic, salicylic, lactic and glycolic acids, as well as Lira’s peptide delivery system. According to a company new release, this combination of ingredients aids cellular turnover, which can decrease the appearance of wrinkles and dark and light spots.

The pads also contain antioxidant botanicals and topical probiotics to support skin health. They are safe for all skin types, including oily and acne-prone skin.

FOR MORE INFORMATION: liraclinical.com

BRIEF SUMMARY OF PRESCRIBING INFORMATION

DUOBRII Lotion contains the active ingredients tazarotene and halobetasol propionate. Tazarotene is a tretinoin-like compound that is a member of the retinoid family and halobetasol propionate is a topical corticosteroid used in the treatment of psoriasis and atopic dermatitis.

PRODUCT INFORMATION

INDICATIONS AND USAGE

DUOBRII Lotion contains the active ingredients tazarotene 0.05%, halobetasol propionate 0.05% (USP), and is indicated for the treatment of psoriasis vulgaris limited to lesions on the flexures, palms, and soles.

CONTRAINDICATIONS

DUOBRII Lotion is contraindicated in pregnant females has not been established. The potential for teratogenicity and embryofetal risk are discussed in the sections Embryofetal Risk and In vitro Studies with Dosing Formulations. It is not known what level of exposure is required for teratogenicity or embryofetal risk.

CONSERVATIVE USE: Because DUOBRII Lotion contains halobetasol propionate, patients with a history of contact sensitization to corticosteroids should be observed for any signs of dermatitis or sensitization.

PRECAUTIONS: Care should be taken when DUOBRII Lotion is applied to sensitive areas of the skin, especially if exposed to sunlight or heat.

PREScribING INFORMATION: DUOBRII Lotion contains tazarotene and halobetasol propionate.
For adults with plaque psoriasis

better together

The first and only steroid/retinoid therapy, allowing halobetasol and tazarotene to work together in an advanced, once-daily lotion that can be dosed to clearance.1,3

Halobetasol (0.01%)

Provides powerful anti-inflammatory effects and reduces skin irritation, which is often associated with retinoids.1,5

Tazarotene (0.045%)

Regulates cell growth and specialization to reduce hyperproliferation, increases collagen, and extends remission post treatment.6,7

The only FDA-approved treatment with a potent-to-superpotent steroid that can be used until control is achieved

Indication

DUOBRII™ (halobetasol propionate and tazarotene) Lotion, 0.01%/0.045%, is indicated for the topical treatment of plaque psoriasis in adults.

Important Safety Information

Contraindication

DUOBRII Lotion is contraindicated in pregnancy.

Warnings and Precautions

• Women of child-bearing potential should be warned of the potential hazard to the fetus.

• Local adverse reactions may include atrophy, striae, telangiectasias, folliculitis, and contact dermatitis. If these effects occur, discontinue until the integrity of the skin has been restored. Do not resume treatment if contact dermatitis is identified.

• DUOBRII Lotion should not be used on eczematous skin, as it may cause severe irritation.

• Avoid exposure to sunlight, sunlamps and weather extremes. Patients with psoriasis should be advised not to use DUOBRII Lotion until fully recovered. DUOBRII Lotion should be administered with caution if the patient is also taking drugs known to be photosensitizers because of the increased potential for photosensitivity.

• Topical corticosteroids may increase the risk of cataracts and glaucoma; advise patients to report any visual symptoms and refer to an ophthalmologist if needed.

Adverse Events

• The most common adverse events in clinical trials were contact dermatitis (7%), application site pain (3%), folliculitis (2%), skin atrophy (2%), and excoriation (2%). To report SUSPECTED ADVERSE REACTIONS, contact Ortho Dermatologics at 1-800-321-4576 or FDA at 1-800-FDA-1088 or visit www.fda.gov/medwatch.

American Academy of Dermatology (AAD) Guidelines give the combination of a corticosteroid and a retinoid an A rating with Evidence Level I for the treatment of psoriasis8

References


Learn more at DUOBRII.com

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