Dermatology Times®
Clinical Analysis for Today's Skincare Specialists
October 2014 | VOL. 35, NO. 10

Conventional criteria falls short with kids

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Tech fuels skin reactions

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For a detailed program agenda, visit dermatologyfoundation.org/symposia.

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Conventional criteria falls short with kids

Researchers find evolution key to identifying pediatric melanoma

Lisette Hilton | Staff Correspondent

Children are not small adults, even when it comes to the way they present with melanoma.

Kelly M. Cordoro, M.D., and colleagues recently reported on how common it is for children to present atypically with melanoma. Dr. Cordoro is associate professor of dermatology and pediatrics at the University of California, San Francisco.

The study, published June 2013 in the *Journal of the American Academy of Dermatology*, looks at whether using the conventional ABCDE criteria adequately detects the skin cancer in children.

Researchers conducted a retrospective study looking at 70 patients under age 20. Sixty of those were diagnosed with melanoma; the other 10 had ambiguous melanocytic tumors treated as melanoma. They divided patients into two groups by age at diagnosis, including an ages zero to 10 years group, representing 19 children, and an 11-to-19 years group.

"The 19 prepubertal patients in this study represent one of the largest series reporting detailed clinical and histopathological features of melanoma in this age group. Large national cancer databases and registries provide summary statistics such as age of presentation, melanoma subtype, site, treatment and outcomes, but lack detailed information about the presenting features and recent history of the melanoma," Dr. Cordoro says. "This is critically important information for clinicians because we need to know what we should be looking for in order to not miss this diagnosis in children. In fact, 86 percent of children less than 10 years old in this study had a greater than six-month delay in diagnosis, most likely due to a low index of suspicion and atypical clinical presentations common to this age group."

They found 60 percent of the younger group and 40 percent of the older children did not present with conventional ABCDE criteria. Rather, their lesions tended to be characterized by amelanosis, bleeding bumps, uniform color, variable diameter and de novo development, according to the study.

Not only were the clinical characteristics different but histopathological subtypes varied between groups. The histopathologic differences from adult melanoma identified in these patients seemed to parallel the non-ABCD morphology observed clinically, according to Dr. Cordoro.

Nearly half (44 percent) of the lesions were not classifiable by experienced dermatopathologists into conventional adult subtypes (e.g., superficial spreading, nodular, acral lentiginous, lentigo maligna). Very likely, the

PEDIATRIC MELANOMA see page **59**

A statistical snapshot

- **Ninety percent** of pediatric melanoma cases occur in patients ages **10 through 19**
- Melanoma in children is more likely to occur in people of darker skin types than in adults, with **6.5 percent of pediatric melanomas occurring in non-Caucasians**
- Melanoma accounts for up to **3 percent of all pediatric cancers** (6 percent of cancer cases in teens 15 to 19 years old)

Source: www.skincancer.org/skin-cancer-information/skin-cancer-facts#pediatrics

Clinical

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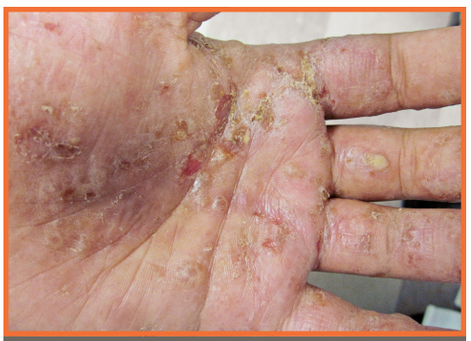

A teenager with allergic contact dermatitis of the hands from a rubber cell phone case.
Photo: Jonathan Silverberg, M.D., Ph.D., M.P.H.

Lisette Hilton | Staff Correspondent

New sources of pediatric contact dermatitis are found in many of the products used by children, parents and even dermatologists. Recognizing these and other emerging allergens could spell fast, effective relief for pediatric patients, as well as prevent misdiagnoses and long-term unnecessary treatments, an expert says.

Nickel and methylisothiazolinone are among today's most important pediatric allergens, according to Jonathan Silverberg, M.D., Ph.D., M.P.H., assistant professor of dermatology, preventive medicine and

CONTACT DERMATITIS see page **32**

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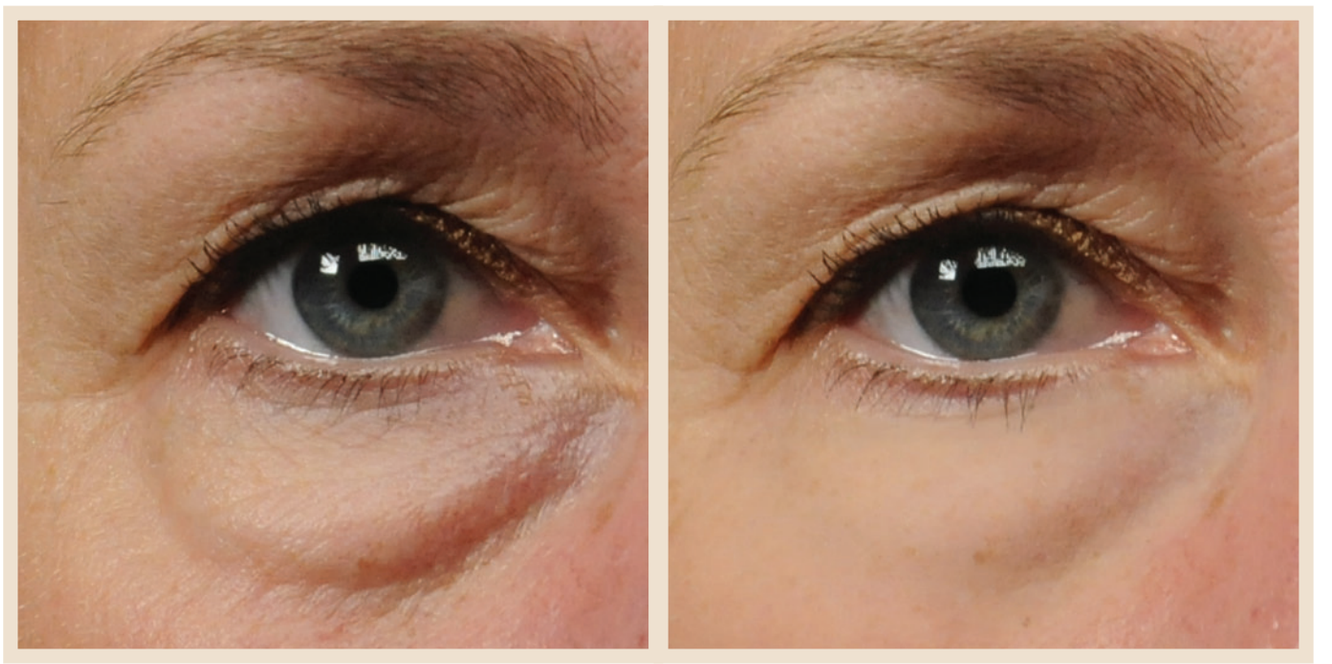
Q&A THE TAKEAWAY | **STEVEN FELDMAN, M.D.** talks about incentives to encourage medication adherence. SEE PAGE 74



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‡Study results for once-daily application of Neotensil in a 2-week pilot study; N=25.

References: 1. Data on file, Living Proof, Inc. **2.** Draelos ZD, Investigator. Strateris 16-hour durability study, DCS-105-13. Data on file, Living Proof, Inc. **3.** Kauvar A, Kilmer S, Ross EV, et al. A pilot study of a novel non-invasive topical under-eye contouring technology. Poster presented at: 71st Annual Meeting of the American Academy of Dermatology; March 1-5, 2013; Miami, FL.

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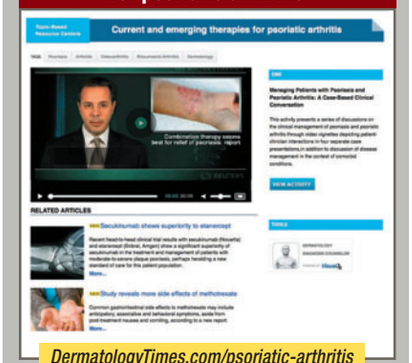
Best practices in the evaluation and management of actinic keratoses

DermatologyTimes.com/actinickeratoses

Current and emerging therapies for psoriatic arthritis



DermatologyTimes.com/psoriatic-arthritis

Fillers and Toxins: Cosmetic and Therapeutic Options

DermatologyTimes.com/injectables

Insights into managing atopic dermatitis and acne

DermatologyTimes.com/atopicdermatitis

What's your diagnosis?

A 65-year-old woman reported that she had stepped on something three years earlier, and it just never healed.

CHOOSE ONE:

- **SQUAMOUS CELL CARCINOMA**
- **PYOGENIC GRANULOMA**
- **MELANOMA**

bit.ly/octoberdiagnosis

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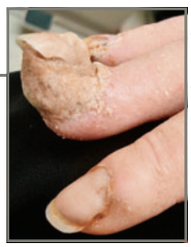

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VIEW ON DEMAND

Formula Matters:
Implications for Patient Compliance

Zoe Diana Draelos, M.D.
Clinical Research Dermatologist

dermatologytimes.com/ranbaxywebinar

Blog

Cosmetic Considerations: Can trauma displace fillers?

bit.ly/trauma-fillers

Jason Emer, M.D.

It's a question asked recently on realself.com by a patient who explained that after undergoing a filler injection procedure, an at-home traumatic event in the same area caused a large bruise that resulted in a permanent indentation. This patient wants to know, can trauma displace fillers?

While filler rarely migrates, it has been reported at distant sites and in different planes (superficially) from injection.

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Dermatology Times is the only clinical news resource serving a readership of more than 14,000 dermatologists and other professionals focused on skincare. Through unbiased reporting, we strive to help practitioners put into perspective developments that affect their business. Our goal is to provide practical information that will help them to better understand clinical, regulatory and financial issues, as well as chart business growth.

Let your voice be heard, contact us: editor@dermatologytimes.com

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Childhood skin disease has unique challenges

I am pleased to introduce this issue of **Dermatology Times**, focusing on topics related to pediatric dermatology.

I became aware of pediatric dermatology as a medical student. Way back then, I chose an elective in dermatology because I thought it would support my goal of becoming a well-rounded pediatrician. In 1984 the University of Missouri-Columbia Medical School offered only a two-month rotation, because our chief, Dr. Phil Anderson, accepted nothing less. Fortunately, that interval gave me the opportunity to fall in love with dermatology. And it gave Dr. Anderson a chance to recognize my interest. At the time, he advised me against pursuing a residency in pediatrics, because he knew it could negatively impact my chances of winning a residency in dermatology. But while I loved dermatology, I was also committed to caring for children. So, although the great majority of Dr. Anderson's advice was sage, I chose to complete a residency in pediatrics.

2 PERCENT of us are board-certified in pediatric dermatology

At the end of two years, I recognized my interest in subspecialty, rather than general pediatrics. But there was no established route to becoming a pediatric dermatologist, so I had to bushwhack my own. Luckily, Dr. John Strauss gave me a chance to train in the department of dermatology at the University of Iowa. Among the faculty, Dr. Mary Stone served as my strongest pediatric guide and support to help fill a much needed niche for treating children with skin disease. In the two-plus decades since, I have been very busy learning, adapting and doing my best to meet the clinical demand.

The subspecialty has dramatically evolved since its inaugural meeting in 1972.[1] We earned ACGME recognition in 2000, and established board certification with the first examination held in October 2004. The body of knowledge is large and growing, in contrast to the workforce. Many dermatologists are rewarded by the privilege of seeing children, but only about 2 percent of us are board-certified in pediatric dermatology. The group may be small, but the collegiality is outsized.

First-time attendees to the annual meeting of the Society for Pediatric Dermatology often comment on the unique ambience. For most of the other participants, it is our favorite conference. Every year that I attend, I am humbled by the new insights, and the brilliance of my colleagues. We have long-recognized that children are not simply small adults. While they sometimes suffer similar diseases, the spectrum of pediatric illness and abnormality is often unique, as documented by an expanding foundation of abstracts, journal articles and textbooks.

Therapeutics is one of the most significant challenges in pediatric dermatology. Children have been identified as "therapeutic orphans," with few options that have pediatric indications approved by the Food and Drug Administration (FDA). Access to new and novel treatments like biologics is especially limited. Supportive legislation, beginning with the Best Pharmaceuticals for Children Act (bpca.nichd.nih.gov), has marked the dawn of a new era.

Recent FDA approval of propranolol for infantile hemangioma (Hemangeol, Pierre Fabre) is a game-changing therapeutic advance.

This issue of **Dermatology Times** includes information on many other important innovations in the field, including approach to woundcare for epidermolysis bullosa, update on atopic dermatitis, new sources of pediatric allergic contact dermatitis, review of the recently published guidelines for acne in children, aesthetic trends for adolescents and how to weigh the risk-benefit ratio for anxious patients and their parents, the rising incidence of pediatric melanoma, and skin findings in kids with cancer. Enjoy. **DT**

1. Prindaville B, Antaya RJ, Siegfried EC. Pediatric Dermatology: Past, Present, and Future. *Pediatr Dermatol.* 2014, 31(6) [Epub ahead of print]

Elaine C. Siegfried, M.D.

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David Goldberg, M.D., J.D.,
is director of Skin Laser and Surgery Specialists of New York and New Jersey; director of laser research, Mount Sinai School of Medicine; and adjunct professor of law, Fordham Law School.

Can my text pose a legal risk?

A 2-year-old patient, Danielle, is brought by her distraught mother to see Dr. Derm. Apparently she is concerned that her infant's perianal warts have some connection to her estranged husband. Dr. Derm agrees that this may be a possibility and reports his findings to the state child welfare bureau. Danielle's mother has been family friends of Dr. Derm for years — as has her husband. They both have his cell number.

Three weeks later, Dr. Derm receives a question about the warts by way of text message from a person whom he assumes to be Danielle's mother. It is really from the father. Dr. Derm responds by text message and states that he has filed a concern with the state. The mother, although acknowledging that both parents have joint custody of the child, is furious that Dr. Derm texted his actions to the father. She sues Dr. Derm for a HIPAA violation. Dr. Derm has never heard of such a lawsuit. Should he be worried?

Texting has become so popular because it is instantaneous, convenient and direct. Without appropriate safeguards, though, texting can lead to violations of the Health Insurance Portability and Accountability Act (HIPAA).

Dermatologists are smartphone "superusers." According to Manhattan Research, more than 81 percent of physicians now use a smartphone to communicate and access medical information. The attractions are clear-cut. Phone applications put libraries full of information at our fingertips. Texting reduces time waiting for our patients and our peers to call back and may expedite and improve patient care.

CONVENIENCE AT A COST

The very convenience that makes texting so inviting may create privacy and security violations if messages containing protected health information (PHI) are not properly safeguarded. Text messages to our peers and patients should be encrypted and exchanged in a closed, secure network.

However, according to a member survey conducted by the College of Healthcare Information Management Executives, more than 95 percent of those surveyed said their physicians texted; more than 57 percent did not use any form of encryption software. The underlying reasons for poor compliance with encryption could be due to lack of technical knowledge or to avoid the inconvenience of sending a message to someone who may not be able to unencrypt it.

With penalties starting at $50,000 per HIPAA violation, safeguarding texts should be of utmost priority. In addition to encrypting texts, dermatologists may want to consider installing auto-lock and remote wiping programs. Auto-lock will lock the device when it is not in use and requires a password for unlocking. Wiping programs can erase data, texts and email remotely. Both types of safeguards provide additional protection in the event a device is lost or stolen.

A cavalier attitude when composing a text message can also pose a legal risk. The informal nature of text messaging may lead to the use of abbreviations which is bound to have potential for miscommunication. Furthermore, a deleted text is never fully deleted, and the metadata (data left behind) is almost always available in a lawsuit.

In the end, the following steps are recommended: Enable encryption of your mobile device. Have a texting policy that outlines the acceptable types of text communications and when perhaps a phone call is instead warranted. Install auto-lock and remote wiping programs to prevent lost devices from becoming data breaches. Know your recipient and double check the "send" field to prevent sending confidential information to the wrong person. Avoid identifying patient details in texts. Lastly, assume that your text can be viewed by anyone in close proximity to you.

Thankfully, Dr. Derm's phone was fully encrypted and protected. Although one might question the wisdom of his discussion with Danielle's father, Dr. Derm is not guilty of a HIPAA violation. **DT**

STATE YOUR CASE What scenarios keep you guessing? Pass them along in confidence to: ***editor@dermatologytimes.com***

August 'teledermatology' headline misleading

IN RESPONSE to the August 2014 article "Teledermatology fraught with liability issues," Dr. Goldberg cites an example case of medical negligence for a patient that died of a rare melanoma. Regardless of the delivery mechanism, this instance being teledermatology, I agree this case is fraught with liability issues. Teletriage, teleconsultation and direct-to-patient teledermatology services are not fraught with liability issues as long as the deliverer of these services understands the parameters of delivering such care with regard to state licensure, establishment of a physician-patient relationship, obtaining the proper informed consent, enabling continuity of care and referrals for emergency services, understands applicable state medical board statutory language on e-prescribing, supports exchanging information and maintaining patient records in a private and secure manner, and having medical liability coverage. I enjoy reading Dr. Goldberg's commentary on a regular basis and appreciate his willingness to share his legal expertise combined with the practice of dermatology. I feel compelled, however, to point out that the title of this article is misleading and the cited patient case is a mischaracterization of teledermatology in general especially with the tremendous body of supporting medical literature demonstrating the diagnostic reliability of teledermatology. **DT**

—Mark P. Seraly, M.D.

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HOW SUPPLIED: Eletone® Cream is available in a 100 gram tube **NHRIC** 0178-0368-01.

Store at 25°C (77°F); excursions permitted to 15-30°C (59-86°F) [see USP Controlled Room Temperature].

CAUTION: Rx only. Federal law restricts this device to sale by or on the order of a physician.

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Sunscreen allergies contribute to photosensitivity in children

British Journal of Dermatology
August 2014

onlinelibrary.wiley.com/doi/10.1111/bjd.13003/abstract

IT'S NO SECRET that chemicals used in sunscreens can cause photoallergic (PA) contact reactions in adults. However, there's sparse research on the extent to which sunscreen chemicals cause PA reactions in children.

With that in mind, researchers from the Dermatology Centre at the University of Manchester in England assessed the frequency of sunscreen PA and contact allergy (CA) in children younger than 18 who'd been examined for potential photosensitivity.

The researchers did a retrospective analysis of data on 157 children — 69 male, 88 female — who from 2000 to 2011 had undergone photopatch testing for nine ultraviolet (UV) filters and for sunscreen products. Duplicate series of UV filters and the children's own sunscreen products were applied to their back, with readings taken at sample removal and at 24 and 48 hours after UVA exposure of one series.

A total of 10 children (6.4 percent) showed positive photopatch responses to UV filters and/or their sunscreen products (4.5 percent to the former, 5.7 percent to the latter). The responsible UV filters most often identified were benzophenone-3 and octyl methoxycinnamate. Also, the researchers identified CA reactions in nine children (5.7 percent), with 16 children (10.2 percent) showing PA and/or CA to UV filters and/or sunscreen products.

"Dermatologists should consider that photocontact allergy to sunscreens may be causing or contributing to the photosensitive symptoms presenting in children," study author Lesley Rhodes, M.D., tells **Dermatology Times**. DT

Jury out on efficacy of cantharidin in treating molluscum contagiosum

Pediatric Dermatology
July 2014

http://bit.ly/1yimsbj

RESULTS of a recent study suggest that while cantharidin is safe for treating pediatric molluscum contagiosum (MC), more research is needed to measure its efficacy.

Researchers from the University of Miami, Florida, and the University of North Carolina, Chapel Hill, conducted a placebo-controlled, randomized clinical trial to evaluate the safety and efficacy of topical cantharidin for treatment of pediatric MC in an ambulatory care center. They enrolled 29 patients with MC, ages 5 to 10 years, to receive treatment with cantharidin or placebo over a two-month period.

The study results demonstrated complete clearance of all molluscum lesions. In contrast to previous retrospective observational studies, however, the performance of cantharidin treatment over two months was about the same as that of placebo. The authors suggested that a longer follow-up period might have identified a greater effect of cantharidin.

The patients experienced minimal side effects when treated with cantharidin.

"The most significant finding from our study was prospective data showing cantharidin is a safe treatment for molluscum," study author Jacquelyn Coloe Dosal, M.D., of the University of Miami's department of dermatology and cutaneous surgery, tells **Dermatology Times**. "While our efficacy rates were lower than expected, and there may be several reasons for this including study design, we were able to show the safety and tolerability of cantharidin.

"This is significant because we are at a time when many institutions are having difficulty procuring cantharidin due to confusing regulations. Having safety data is paramount to protect dermatologists' access to cantharidin. I continue to use cantharidin in my practice as a first line treatment for molluscum." DT

Researchers report positive findings about propranolol

Journal of Investigative Dermatology
September 2014

www.nature.com/jid/journal/v134/n2s/full/jid2014340a.html

A FRENCH research team has issued an encouraging report on a cohort of children who underwent propranolol therapy for severe infantile hemangioma (IH).

Over the past few years, propranolol has emerged as the gold-standard treatment for IH, despite the fact that there's relatively little data regarding the safety of beta blockers for pediatric use.

In an effort to provide more data, researchers from the University of Bordeaux and pharma/cosmetics firm Laboratoire Pierre Fabre analyzed the prospective cohort of the French compassionate use program (CUP) for a new pediatric formulation of oral propranolol from 2010 to 2013. The database included patients with proliferating IH who required systemic therapy. Safety information was collected during intake and for two years after treatment began.

The CUP included 922 pediatric patients — 74.9 percent female — with a median age of 114 days at inclusion. Forty percent of target IH were ulcerated, 72.4 percent led to functional impairment and 16.2 percent were life-threatening. The median daily propranolol dosage was 2 mg/kg, and median exposure duration was 6.5 months. Propranolol was discontinued following good efficacy in 83.7 percent of the patients.

The researchers found 104 adverse events (AE) in 81 patients, with 24 patients (2.6 percent) experiencing serious adverse events (SAE). The most frequent AE (slightly more than 38 percent) were respiratory, mainly bronchiolitis and bronchitis. Other AE included sleep disorders (24.7 percent), vascular (11.1 percent) with hypotension and acrocyanosis, and digestive (11.1 percent), mainly diarrhea. Slightly more than 41 percent of all SAE were respiratory, with 16.7 percent metabolic, 12.5 percent cardiovascular and 8.3 percent peripheral vascular. Most AE were transient and allowed maintenance or reintroduction of propranolol.

According to the study, this first large cohort of children tolerated the propranolol treatment well. "However," the authors wrote, "prescribers and caretakers must consider carefully the potential severe risk of bronchoreactivity during bronchial infection, and the risk of hypoglycemia in case of low food intake or fasting." DT

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Report looks at links between breast-feeding, pediatric AD

Journal of the American Academy of Dermatology
August 2014

www.eblue.org/article/S0190-9622(14)00980-3/abstract

OVER THE past few decades, efforts to slow the increase in cases of pediatric atopic dermatitis (AD), combined with a focus on the health benefits of breast-feeding, have led to the question of whether breast-feeding can reduce the risk of AD.

Researchers Jenny E Murase, M.D. of the University of California, San Francisco, and Collin M. Blattner, of Des Moines University in Iowa, investigated the question and reported the results in the August issue of the *Journal of the American Academy of Dermatology*.

They found evidence that breast-feeding during the first four months of life appears to help reduce incidence and severity of atopic disease, but that the effect appears to be limited to high-risk infants, defined as a those who have a first-degree relative with AD.

In addition, there appears to be no difference in atopic risk reduction between infants exclusively breast-fed for six months, as recommended by the World Health Organization, and those in whom breast-feeding is supplemented with, for example, formula.

"There is strong evidence to support that breast-feeding during the first four months of life results in an approximately 33 percent reduction in the incidence and severity of atopic disease in high-risk infants," Dr. Murase tells **Dermatology Times**. "Mothers can also be reassured that they do not have to exclusively breast-feed to achieve the desired risk reduction, since supplementing with formula will not lessen the benefit to the baby."

The authors addressed another issue related to breast-feeding: whether antigen avoidance during pregnancy and while breast-feeding can minimize the baby's risk for developing AD. Citing the results of three recent studies, the authors conclude that dietary antigen avoidance during pregnancy has no effect on the incidence of AD during the first 18 months of life. Indeed, two of the studies they cite suggest that dietary modification during pregnancy should not be recommended as it may hinder fetal growth and increase the risk of prematurity.

"More data are necessary to determine the potential adverse effects of maternal antigen avoidance during pregnancy on gestational weight gain, fetal growth and preterm birth," the authors wrote. **DT**

Corticosteroids top emollients in wet-wrap study

Journal of the American Academy of Dermatology
June 2014

www.jaad.org/article/S0190-9622(14)01029-9/abstract

WET-WRAP TREATMENT (WWT) has long been known as an effective therapy for children with severe atopic dermatitis (AD). But is it more effective when used with diluted corticosteroids or with emollients?

Researchers from Erasmus University Medical Center Rotterdam, Netherlands, evaluated the use of WWT with diluted corticosteroids in comparison with emollient in children with severe AD over a four-week schedule during which the frequency of corticosteroid applications was tapered.

Their randomized, placebo-controlled study involved pediatric patients ages 6 months to 10 years with severe AD. The researchers compared WWT with diluted corticosteroids (1:3 mometasone furoate 0.1 percent ointment and, for the face, 1:19 mometasone furoate 0.1 percent ointment under a mask) with emollient (petrolatum 20 percent in cetomacrogol cream). Their goal was to improve SCORAD (SCORing Atopic Dermatitis), the Patient Oriented Eczema Measure and the quality-of-life index.

"WWT with diluted corticosteroids acted faster and was more efficacious than WWT with emollients," the authors wrote. "Best results were obtained in age groups 6 to 9 years and 0 to 3 years. The difference in efficacy evaluated by objective SCORAD was significant at all measuring points. This also applied to the quality-of-life index." **DT**

Study finds ties between childhood obesity, skin disorders

Pediatric Dermatology
March/April 2014

onlinelibrary.wiley.com/doi/10.1111/pde.12271/abstract

CHILDHOOD OBESITY is a major—and well-documented — public-health concern in the United States. What isn't so well-known, however, is whether there's a correlation between childhood obesity and cutaneous disorders—and, if there is, how to best treat them.

With that in mind, researchers affiliated with the Kaiser Permanente Northern California Managed Healthcare System undertook a study to determine the prevalence of various groups of cutaneous disorders in obese children and adolescents, and to compare the use of dermatology services for obese children with those for nonobese kids.

The researchers did a retrospective, population-based study involving a total of 248,775 subjects. The main outcome measures were: relative risk of cutaneous disorders associated with insulin resistance; androgen excess; bacterial and/or fungal infection; viral infection; inflammation; mechanical changes and other skin conditions such as hidradenitis and hyperhidrosis. Also measured were the subjects' weight profile (normal, overweight, obese) and the number of dermatology visits.

After analyzing the data, the researchers found that a greater proportion of insulin-resistance disorders, bacterial infection, fungal infection, inflammatory disorders, mechanical changes and other skin conditions were present in obese subjects as compared with those who had a normal body mass index (BMI). An excess of androgen and viral infections were significantly less common in obese subjects.

In addition, obese subjects had significantly lower odds of having at least one dermatology encounter than subjects with a normal BMI. Heightened recognition and further analysis of adipose tissue as an endocrine organ capable of affecting the skin is warranted.

"Obesity is a significant issue among our pediatric patients — almost one-fifth of the children in this cohort were obese," study author Paradi Mirmirani, M.D., tells **Dermatology Times**. "Dermatologists should consider excess adipose tissue as a powerful endocrine organ capable of impacting the skin." **DT**

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Massage gently upon application to loosen and help wash away flakes.

For more information, please visit www.Promiseb.com.

Promiseb® Topical Cream

For Topical Dermatological Use Only
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Rx only

Product Description:
Promiseb® Topical Cream is an off-white, steroid-free, fragrance-free, water-based emulsion.

Indications for Use:
Under the supervision of a healthcare professional, Promiseb Topical Cream is indicated to manage and relieve the signs and symptoms of seborrhea and seborrheic dermatitis such as itching, erythema, scaling and pain. Promiseb Topical Cream helps to relieve dry waxy skin by maintaining a moist wound & skin environment, which is beneficial to the healing process.

Directions for Use:
Apply Promiseb Topical Cream to the affected skin areas 2 to 3 times per day (or as needed), and massage gently into the skin. If the skin is broken, cover Promiseb Topical Cream with a dressing of choice.

Ingredients:
Promiseb Topical Cream is comprised of Purified Water, Isohexadecane, Butyrospermum parkii, Pentylene glycol, Ethylhexyl palmitate, Cera alba, PEG-30 Dipolyhydroxystearate, Bisabolol, Polyglyceryl-6 polyricinoleate, Tocopheryl acetate, Hydrogenated castor oil, Acifructol complex, Butylene glycol, Magnesium sulfate, Piroctone olamine, Allantoin, Magnesium stearate, Disodium EDTA, Vitis vinifera, Ascorbyl tetraisopalmitate, Glycyrrhetinic acid, Propyl gallate, and Telmesteine.

Caution:
The use of Promiseb Topical Cream is contraindicated in any patient with a known history of hypersensitivity to any of the ingredients. Promiseb Topical Cream does not contain milk, wheat, peanut or animal derivatives. Promiseb Topical Cream does contain shea butter (Butyrospermum parkii), a derivative of shea nut oil (not peanut oil). Patients with a known allergy to nuts or nut oils should consult their physician before using this topical preparation.

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30 g tube, 67857-803-30

To Open: Puncture seal with pointed end of cap.
Important: The opening of this product is covered by a metal seal. Do not use if seal has been punctured or is not visible.

Store at controlled room temperature 68° to 77°F (20° to 25°C), excursions permitted between 59° and 86°F (15° and 30°C).

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Children can suffer from excessive sweating

Dermatologic Clinics
July 2014

derm.theclinics.com/article/S0733-8635(14)00072-2/abstract

PEDIATRIC patients can present with hyperhidrosis, and it can greatly impair quality of life, according to a recently published manuscript that discussed special considerations for managing hyperhidrosis in children. The authors noted that about 1.6 percent of adolescents and 0.6 percent of prepubertal children are affected by primary hyperhidrosis, and that children who experience the disease often experience social distress.

"The implications for children can be evidenced in daily activities," says Adelaide A. Hebert M.D., professor of dermatology and pediatrics, University of Texas Medical School, Houston. "Their hands may be sweating, and they cannot participate fully in games with other children. The affected children may not be able to hold a bat to play baseball or have other children agree to hold their hands when playing ring around the rosy." Children who have plantar hyperhidrosis may not be able to wear footwear such as flip-flops because their feet slip out of them, Dr. Hebert says.

One of the most common therapies to treat pediatric patients with primary, focal hyperhidrosis is oral glycopyrrolate. Patients must continue the therapy, otherwise the excessive sweating will return, Dr. Hebert says. There may be some undesirable side effects with therapies like glycopyrrolate such as constipation or dry mouth, she notes.

Another option for children with plantar and/or palmar hyperhidrosis is iontophoresis, which exposes patients to a low-level, well-tolerated electrical current that lessens the sweating of the palms and soles. If children have severe plantar and/or palmar hyperhidrosis, glycopyrrolate tablets may be dropped in the iontophoresis trays to increase the robustness of therapy, Dr. Hebert says.

If hyperhidrosis is not well-controlled in pediatric patients with therapies like oral anticholinergics or with iontophoresis, clinician may look to botulinum toxin injections to manage the condition, says Dr. Hebert. Such therapy is considered off-label.

Newer treatments such as miraDry (Miramar Labs), which uses noninvasive microwave technology, was approved by the Food and Drug Administration in 2011 to treat hyperhidrosis. The device, however, has not been studied in the pediatric population, Dr. Hebert says.

The disease remains idiopathic, but research may lead to newer treatments that target the cause of the condition, Dr. Hebert says. **DT**

Read more of this story at:
bit.ly/kids-sweat

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But with just 1 revealing question, you can uncover the dissatisfaction your patients may have trouble expressing and help make a real difference in managing their PsO.

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References: 1. Data on file. Kantar Health 2013. Novartis Pharmaceuticals Corp; 2014. **2.** Gupta MA, Gupta AK, Watteel GN. Perceived deprivation of social touch in psoriasis is associated with greater psychologic morbidity: an index of the stigma experience in dermatologic disorders. *Cutis*. 1998;61(6):339-342. **3.** Schmid-Ott G, Jaeger B, Kuensebeck HW, Ott R, Lamprecht F. Dimensions of stigmatization in patients with psoriasis in a "Questionnaire on Experience with Skin Complaints." *Dermatology*. 1996;193(4):304-310. **4.** Armstrong AW, Schupp C, Wu J, Bebo B. Quality of life and work productivity impairment among psoriasis patients: findings from the National Psoriasis Foundation survey data 2003-2011. *PLoS One*. 2012;7(12):e52935.

Dermatology Times

Study: Bleach-based gel wash improves atopic dermatitis severity

Cheryl Guttman Krader | Staff Correspondent

DENVER — Positive results of an open-label, multicenter trial support the use of a gel body wash containing 0.006 percent sodium hypochlorite (CLn Body Wash, Top MD Skin Care) as an adjunct in the management of atopic dermatitis (AD), according to researchers who presented their findings at the 2014 annual meeting of the American Academy of Dermatology.

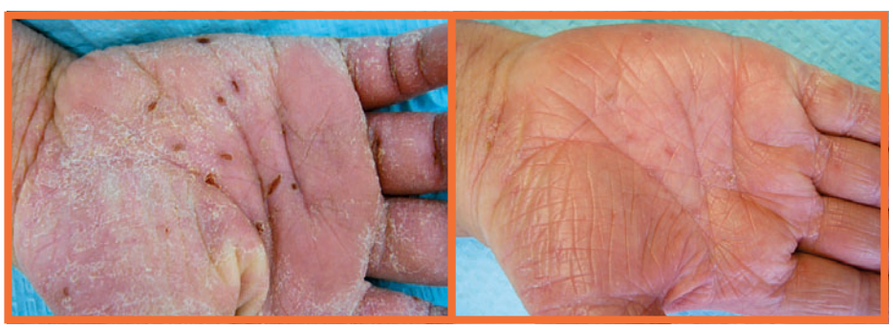
QUICK READ

Pediatric patients with moderate-to-severe atopic dermatitis and culture-confirmed *S. aureus* colonization achieved significant improvements in AD severity after daily use of a sodium hypochlorite gel body wash.

The study recruited pediatric patients from the outpatient dermatology clinics of the University of Texas Health Science Center, Houston, and Northwestern University Feinberg School of Medicine, Chicago. Eligible criteria required presence of moderate-to-severe AD and culture-confirmed *Staphylococcus aureus* colonization of affected skin without active infection. Patients were to use the gel body wash daily in the bath or shower with instructions to lather it on and wait one to two minutes before rinsing. Existing treatments for atopic dermatitis were continued unchanged during the six-week study.

Forty patients were enrolled (mean age 8.5 years) in the study. Changes in the Investigator's Global Assessment, Eczema Area and Severity Index score, pruritus visual analogue scale, and body surface area of involvement were assessed to determine benefit. At a follow-up visit after two weeks, all of these standard parameters of AD severity as well as measures of quality of life (Children's Dermatology

GEL WASH see page **21**



A patient with atopic dermatitis of the dorsal hands is shown at baseline (left) and two weeks after treatment with sodium hypochlorite wash. (Photos: TopMD Skin Care, Clinical Trial CLN003.7)

Quotable

"You can overuse corticosteroids, but if you don't use them at all, it can be very difficult to keep the disease under control."

Elaine Siegfried, M.D.
St. Louis

On atopic dermatitis therapies
See story, page 26

DTExtra

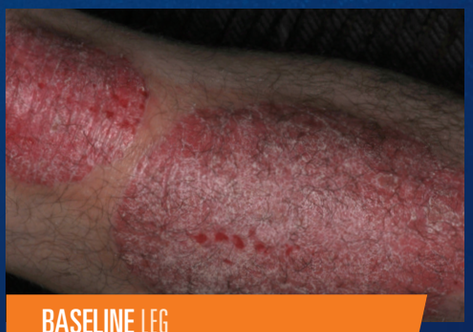
Researchers from Harvard Medical School, Boston, compared the efficacy of antibiotics and oral contraceptives (OCPs) in managing acne. The review of 226 publications included 32 randomized, controlled trials. At three and six months, both antibiotics and OCPs led to a greater percent of reduction in inflammatory, noninflammatory and total lesions compared to placebo. At three months, antibiotics (48 percent) outperformed OCPs (37.3 percent) in percent reduction of total lesions. At six months, OCPs generated a 55 percent total-lesion reduction rate, oral antibiotics, 52.8 percent, placebo 28.6 percent.

READ MORE: BIT.LY/OCPSACNE

ONE TOUGH SPRAY

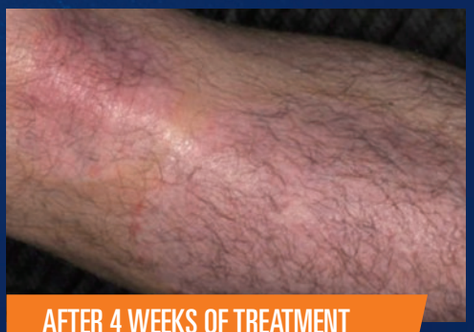
A super-potent spray for moderate to severe plaque psoriasis

Patient pictured was not a participant in the Phase 3 clinical studies for Topicort® Topical Spray. Individual results may vary. Photos and notes provided by J. Bikowski, M.D.[1]



BASELINE LEG

Erythematous, scaling plaques on anterior left leg.



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(desoximetasone)
Topical Spray 0.25%

0.25%
SPRAY

CLASS 1 *STRENGTH*

Topicort® Topical Spray is a topical corticosteroid indicated for the treatment of plaque psoriasis in patients 18 years of age or older.

Important Safety Information

- Topicort® Topical Spray is a topical corticosteroid that has been shown to suppress the hypothalamic-pituitary-adrenal (HPA) axis.
- Systemic absorption of topical corticosteroids can produce reversible HPA axis suppression with the potential for glucocorticosteroid insufficiency. This may occur during treatment or upon withdrawal of the topical corticosteroid.
- Because of the potential for systemic absorption, use of topical corticosteroids may require that patients be periodically evaluated for HPA axis suppression.
- Local adverse reactions may be more likely to occur with occlusive use, prolonged use or use of higher potency corticosteroids. Reactions may include atrophy, striae, telangiectasias, burning, itching, irritation, dryness, folliculitis, acneiform eruptions, hypopigmentation, perioral dermatitis, allergic contact dermatitis, secondary infection, and miliaria. Some local reactions may be irreversible.
- Safety and effectiveness of Topicort® Topical Spray in patients younger than 18 years of age have not been studied; therefore use in pediatric patients is not recommended.

1. Data on file, Taro Pharmaceuticals U.S.A., Inc.

TaroPharma®

See brief summary of Prescribing Information on reverse side.

AD100-0036 June 2014

TOPICORT® (desoximetasone) Topical Spray, 0.25%
Rx Only

BRIEF SUMMARY

1 INDICATIONS AND USAGE
Topicort® Topical Spray is a corticosteroid indicated for the treatment of plaque psoriasis in patients 18 years of age or older.

4 CONTRAINDICATIONS
None

5 WARNINGS AND PRECAUTIONS

5.1 Effect on Endocrine System
Topicort® Topical Spray is a topical corticosteroid that has been shown to suppress the hypothalamic-pituitary-adrenal (HPA) axis.

Systemic absorption of topical corticosteroids can produce reversible HPA axis suppression with the potential for glucocorticosteroid insufficiency. This may occur during treatment or upon withdrawal of the topical corticosteroid.

In a study including 21 evaluable subjects 18 years of age or older with moderate to severe plaque psoriasis, adrenal suppression was identified in 1 out of 12 subjects having involvement of 10-15% of body surface area (BSA) and 2 out of 9 subjects having involvement of >15% of BSA after treatment with Topicort® Topical Spray twice a day for 28 days. [*see Clinical Pharmacology (12.2)*]

Because of the potential for systemic absorption, use of topical corticosteroids may require that patients be periodically evaluated for HPA axis suppression. Factors that predispose a patient using a topical corticosteroid to HPA axis suppression include the use of high potency steroids, larger treatment surface areas, prolonged use, use of occlusive dressings, altered skin barrier, liver failure and young age.

An ACTH stimulation test may be helpful in evaluating patients for HPA axis suppression.

If HPA axis suppression is documented, an attempt should be made to gradually withdraw the drug, to reduce the frequency of application, or to substitute a less potent steroid. Manifestations of adrenal insufficiency may require supplemental systemic corticosteroids. Recovery of HPA axis function is generally prompt and complete upon discontinuation of topical corticosteroids.

Cushing's syndrome, hyperglycemia, and unmasking of latent diabetes mellitus can also result from systemic absorption of topical corticosteroids.
Use of more than one corticosteroid-containing product at the same time may increase the total systemic corticosteroid exposure.
Pediatric patients may be more susceptible to systemic toxicity from use of topical corticosteroids. [*see Use in Specific Populations (8.4)*]

5.2 Local Adverse Reactions with Topical Corticosteroids
Local adverse reactions may be more likely to occur with occlusive use, prolonged use or use of higher potency corticosteroids. Reactions may include atrophy, striae, telangiectasias, burning, itching, irritation, dryness, folliculitis, acneiform eruptions, hypopigmentation, perioral dermatitis, allergic contact dermatitis, secondary infection, and miliaria. Some local adverse reactions may be irreversible.

5.3 Allergic Contact Dermatitis with Topical Corticosteroids
Allergic contact dermatitis to any component of topical corticosteroids is usually diagnosed by a failure to heal rather than a clinical exacerbation. Clinical diagnosis of allergic contact dermatitis can be confirmed by patch testing.

5.4 Concomitant Skin Infections
Concomitant skin infections should be treated with an appropriate antimicrobial agent.
If the infection persists, Topicort® Topical Spray should be discontinued until the infection has been adequately treated.

5.5 Flammable Contents
Topicort® Topical Spray is flammable; keep away from heat or flame.

ADVERSE REACTIONS

6.1 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 practice.

In randomized, multicenter, prospective vehicle-controlled clinical trials, subjects with moderate to severe plaque psoriasis of the body applied Topicort® Topical Spray or vehicle spray twice daily for 4 weeks. A total of 149 subjects applied Topicort® Topical Spray.

Adverse reactions that occurred in ≥ 1% of subjects treated with Topicort® Topical Spray were application site dryness (2.7%), application site irritation (2.7%) and application site pruritus (2.0%).

Another less common adverse reaction (<1% but >0.1%) was folliculitis.

Table 1. Number (%) of Subjects with Adverse Reactions Occurring in ≥ 1%

	Topicort® Topical Spray, 0.25% b.i.d. (N = 149)	Vehicle spray b.i.d. (N = 135)
Number of Subjects with Adverse Reactions	13 (8.7%)	18 (13.3%)
Application site dryness	4 (2.7%)	7 (5.2%)
Application site irritation	4 (2.7%)	5 (3.7%)
Application site pruritus	3 (2.0%)	5 (3.7%)

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy
Teratogenic Effects: Pregnancy Category C
There are no adequate and well-controlled studies in pregnant women. Topicort® Topical Spray should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Corticosteroids have been shown to be teratogenic in laboratory animals when administered systemically at relatively low dosage levels.

Desoximetasone has been shown to be teratogenic and embryotoxic in mice, rats, and rabbits when given by subcutaneous or dermal routes of administration at doses 3 to 30 times the human dose of Topicort® Topical Spray based on a body surface area comparison.

8.3 Nursing Mothers
Systemically administered corticosteroids appear in human milk and could suppress growth, interfere with endogenous corticosteroid production, or cause other untoward effects. It is not known whether topical administration of corticosteroids could result in sufficient systemic absorption to produce detectable quantities in breast milk. Because many drugs are excreted in human milk, caution should be exercised when Topicort® Topical Spray is administered to a nursing woman.

If used during lactation, Topicort® Topical Spray should not be applied on the chest to avoid accidental ingestion by the infant.

8.4 Pediatric Use
Safety and effectiveness of Topicort® Topical Spray in patients younger than 18 years of age have not been studied; therefore use in pediatric patients is not recommended. Because of a higher ratio of skin surface area to body mass, pediatric patients are at a greater risk than adults of HPA axis suppression and Cushing's syndrome when they are treated with topical corticosteroids. They are therefore at greater risk of adrenal insufficiency during and/or after withdrawal of treatment. Adverse effects including striae have been reported with inappropriate use of topical corticosteroids in infants and children. [*see Warnings and Precautions (5.1)*]
HPA axis suppression, Cushing's syndrome, linear growth retardation, delayed weight gain, and intracranial hypertension have been reported in children receiving topical corticosteroids. Manifestations of adrenal suppression in children include low plasma cortisol levels and absence of response to ACTH stimulation. Manifestations of intracranial hypertension include bulging fontanelles, headaches, and bilateral papilledema. [*see Warnings and Precautions (5.1)*]

8.5 Geriatric Use
Clinical studies of Topicort® Topical Spray did not include sufficient numbers of subjects aged 65 years and over to determine whether they respond differently from younger subjects. Other reported clinical experience has not identified differences in responses between the elderly and younger patients. In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy.

10 OVERDOSAGE
Topicort® Topical Spray can be absorbed in sufficient amounts to produce systemic effects. [*see Warnings and Precautions (5.1)*]

17 PATIENT COUNSELING INFORMATION
See FDA-approved patient labeling (Patient Information and Instructions for Use)

Inform patients of the following:
- Use this medication as directed by the physician.
- Topicort® Topical Spray is for external use only. Avoid use on the face, axilla or groin.
- Do not use this medication for any disorder other than that for which it was prescribed.
- Do not bandage or otherwise cover or wrap the treated skin so as to be occlusive.
- Report any signs of local or systemic adverse reactions to the physician.
- Do not use other corticosteroid-containing products with Topicort® Topical Spray without first consulting with the physician.
- Discontinue therapy when control is achieved. If no improvement is seen within 4 weeks, contact the physician.
- This medication is flammable; avoid heat, flame, or smoking when applying this product.
- Discard this product 30 days after dispensed by pharmacist.

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AD100-0030

voice of the dermatologist

"For most kids with atopic dermatitis, nighttime is the worst. They have trouble falling asleep, and if they fall asleep, they sleep miserably."

Amy Paller, M.D.
See story, page 26

GEL WASH:

Daily use of sodium hypochlorite gel body wash significantly improved AD severity from page 18

Life Quality Index and Family Dermatology Life Quality Index) showed statistically significant improvements from baseline.

Further benefit was observed at the six-week follow-up. At study completion, scores for all of the endpoints had improved by between 34 and 44 percent from baseline. In addition, the product was well-received, particularly by patients who were poorly compliant with previous recommendations on using bleach baths, researchers noted.

33-44 PERCENT
Improvement from baseline in scores for all endpoints

"Sodium hypochlorite body wash offers a convenient alternative for extending the benefits of bleach baths to a broader population."

Amy Paller, M.D.
Chicago

MAINTAINING DISEASE CONTROL

"We established in a previous randomized, double-blind study (Huang JT, et al. *Pediatrics*. 2009;123(5):e808-e814) that dilute bleach baths can be very helpful in decreasing the severity of AD in patients with clinical signs of secondary bacterial infections, and this modality has become an important part of our recommended strategy for maintaining disease control," says Amy S. Paller, M.D., principal investigator and Chair and Walter J. Hamlin Professor of Dermatology, Northwestern University Feinberg School of Medicine, Chicago. "However, not all households have bathtubs, and not everyone likes to take baths. In particular, older children, teens, and adults generally prefer showering over baths."

The study results reflect findings from another, smaller trial, Dr. Paller says.

"The positive results of our study are consistent with those from a previous smaller open-label trial conducted by Fred Ghali, M.D., and colleagues (Ryan C, et al. *Pediatr Dermatol*. 2013;30(3):308-315), and together they indicate the sodium hypochlorite body wash offers a convenient alternative for extending the benefits of bleach baths to a broader population," she says.

Dr. Paller notes that when the body wash is diluted with water for lathering, the concentration of sodium hypochlorite on exposed skin is similar to that achieved in a commonly recommended regimen for preparing a dilute bleach bath (one-fourth cup household bleach per half tub of water).

ADJUNCTIVE CARE

Further research is needed to determine the underlying mechanism(s) for the benefits of topical sodium hypochlorite in patients with atopic dermatitis.

"In addition to being antimicrobial, a recently published paper describing results from a series of preclinical studies indicates that sodium hypochlorite has anti-inflammatory effects mediated by modulation of nuclear factor-kappaB signaling (Leung TH, et al. *J Clin Invest*. 2013(12):5361-5370)," Dr. Paller says.

"Bleach can be especially helpful for those who have a tendency to develop infections or crusting in areas prone to scratching."

Amy Paller, M.D.
Chicago

Dr. Paller reiterates that the role of dilute bleach baths or use of the sodium hypochlorite body wash in AD patient management is as an adjunct in maintenance care for certain patients.

"The skin of most patients with AD is colonized with *S. aureus*, but bleach can be especially helpful for those who have a tendency to develop infections or crusting in areas prone to scratching. The body wash or dilute bleach baths are important as maintenance therapy rather than just for acute flares," Dr. Paller says. **DT**

Disclosures: Top MD Skin Care provided funding for the research. Dr. Paller reports no other relevant financial interests.

VALCHLOR® (mechlorethamine) gel is an alkylating drug indicated for the topical treatment of Stage IA and IB mycosis fungoides–type cutaneous T-cell lymphoma (MF-CTCL) in patients who have received prior skin-directed therapy

WHEN IT'S TIME TO MANAGE THE CHALLENGES

VALCHLOR

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

VALCHLOR is contraindicated in patients with known severe hypersensitivity to mechlorethamine. Hypersensitivity reactions, including anaphylaxis, have occurred with topical formulations of mechlorethamine.

WARNINGS AND PRECAUTIONS

- **Mucosal or eye injury:** Exposure of mucous membranes to mechlorethamine such as the oral mucosa or nasal mucosa causes pain, redness, and ulceration, which may be severe. Exposure of the eyes causes pain, burns, inflammation, photophobia, and blurred vision. Blindness and severe irreversible anterior eye injury may occur. Should eye exposure or mucosal contact occur, immediately irrigate for at least 15 minutes with copious amounts of water, followed by immediate medical consultation
- **Secondary exposure:** Avoid direct skin contact with VALCHLOR in individuals other than the patients due to risk of dermatitis, mucosal injury, and secondary cancers
- **Dermatitis:** Dermatitis may be moderately severe or severe. Monitor patients for redness, swelling, inflammation, itchiness, blisters, ulceration, and secondary skin infections. Stop treatment with VALCHLOR or reduce dose frequency
- **Non-melanoma skin cancer:** Monitor patients during and after treatment with VALCHLOR
- **Embryo-fetal toxicity:** Women should avoid becoming pregnant while using VALCHLOR due to the potential hazard to the fetus. For nursing mothers, discontinue use of VALCHLOR or nursing
- **Flammable gel:** VALCHLOR is an alcohol-based gel. Avoid fire, flame, and smoking until the gel has dried

Please see additional Important Safety Information on adjacent page.

OF STAGE IA AND IB MF-CTCL

IS ON IT

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DOSING AND APPLICATION

VALCHLOR is for topical dermatological use only. Apply a thin film of gel once daily to affected areas of the skin. VALCHLOR is a cytotoxic drug and special handling and disposal procedures should be followed during use. Caregivers must wear disposable nitrile gloves when applying VALCHLOR. Patients and caregivers must wash hands thoroughly after handling or applying VALCHLOR.

ADVERSE REACTIONS

The most common adverse reactions (≥5%) were dermatitis (56%), pruritus (20%), bacterial skin infection (11%), skin ulceration or blistering (6%), and skin hyperpigmentation (5%). These reactions may be moderately severe or severe. Elderly patients aged 65 and older may be more susceptible. Depending on severity, treatment reduction, suspension, or discontinuation may be required.

To report SUSPECTED ADVERSE REACTIONS, contact Actelion Pharmaceuticals US, Inc., at 1-855-4-VALCHLOR (1-855-482-5245) or FDA at 1-800-FDA-1088 or visit www.fda.gov/medwatch.

Please see Brief Summary of Prescribing Information on adjacent page.

REFERENCE: 1. VALCHLOR [package insert]. South San Francisco, CA: Actelion Pharmaceuticals US, Inc.; 2013.

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BRIEF SUMMARY OF FULL PRESCRIBING INFORMATION

This brief summary does not include all the information needed to use VALCHLOR safely and effectively. See Full Prescribing Information for VALCHLOR.

- **INDICATIONS AND USAGE**

  VALCHLOR is an alkylating drug indicated for the topical treatment of Stage IA and IB mycosis fungoides-type cutaneous T-cell lymphoma in patients who have received prior skin-directed therapy.

- **CONTRAINDICATIONS**

  The use of VALCHLOR is contraindicated in patients with known severe hypersensitivity to mechlorethamine. Hypersensitivity reactions, including anaphylaxis, have occurred with topical formulations of mechlorethamine.

- **WARNINGS AND PRECAUTIONS**

  >> Mucosal or Eye Injury

  Exposure of the eyes to mechlorethamine causes pain, burns, inflammation, photophobia, and blurred vision. Blindness and severe irreversible anterior eye injury may occur. Advise patients that if eye exposure occurs, (1) immediately irrigate for at least 15 minutes with copious amounts of water, normal saline, or a balanced salt ophthalmic irrigating solution and (2) obtain immediate medical care (including ophthalmologic consultation).

  Exposure of mucous membranes such as the oral mucosa or nasal mucosa causes pain, redness, and ulceration, which may be severe. Should mucosal contact occur, immediately irrigate for at least 15 minutes with copious amounts of water, followed by immediate medical consultation.

  >> Secondary Exposure to VALCHLOR

  Avoid direct skin contact with VALCHLOR in individuals other than the patient. Risks of secondary exposure include dermatitis, mucosal injury, and secondary cancers. Follow recommended application instructions to prevent secondary exposure.

  >> Dermatitis

  The most common adverse reaction was dermatitis, which occurred in 56% of the patients. Dermatitis was moderately severe or severe in 23% of patients. Monitor patients for redness, swelling, inflammation, itchiness, blisters, ulceration, and secondary skin infections. The face, genitalia, anus, and intertriginous skin are at increased risk of dermatitis. Follow dose modification instructions for dermatitis.

  >> Non-Melanoma Skin Cancer

  Four percent (4%, 11/255) of patients developed a non-melanoma skin cancer during the clinical trial or during one year of post-treatment follow-up: 2% (3/128) of patients receiving VALCHLOR and 6% (8/127) of patients receiving the mechlorethamine ointment comparator. Some of these non-melanoma skin cancers occurred in patients who had received prior therapies known to cause non-melanoma skin cancer. Monitor patients for non-melanoma skin cancers during and after treatment with VALCHLOR. Non-melanoma skin cancer may occur on any area of the skin, including untreated areas.

  >> Embryo-fetal Toxicity

  Based on its mechanism of action, case reports in humans, and findings in animals, VALCHLOR can cause fetal harm when administered to a pregnant woman. There are case reports of children born with malformations in pregnant women systemically administered mechlorethamine. Mechlorethamine was teratogenic and embryo-lethal after a single subcutaneous administration to animals. Advise women to avoid becoming pregnant while using VALCHLOR. If this drug is used during pregnancy or if the patient becomes pregnant while taking this drug, the patient should be apprised of the potential hazard to a fetus.

  >> Flammable Gel

  Alcohol-based products, including VALCHLOR, are flammable. Follow recommended application instructions.

- **ADVERSE REACTIONS**

  In a randomized, observer-blinded, controlled trial, VALCHLOR 0.016% (equivalent to 0.02% mechlorethamine HCl) was compared to an Aquaphor®-based mechlorethamine HCl 0.02% ointment (Comparator). The maximum duration of treatment was 12 months. Sixty-three percent (63%) of patients in the VALCHLOR arm and 67% in the comparator arm completed 12 months of treatment.

  The body system associated with the most frequent adverse reactions was skin and subcutaneous tissue disorders. The most common adverse reactions (occurring in at least 5% of the patients) are shown in Table 1.

Table 1. Most Commonly Reported (≥5%) Cutaneous Adverse Reactions

	VALCHLOR N=128 % of patients		Comparator N=127 % of patients	
	Any Grade	Moderately-Severe or Severe	Any Grade	Moderately-Severe or Severe
Dermatitis	56	23	58	17
Pruritus	20	4	16	2
Bacterial skin infection	11	2	9	2
Skin ulceration or blistering	6	3	5	2
Skin hyperpigmentation	5	0	7	0

In the clinical trial, moderately-severe to severe skin-related adverse events were managed with treatment reduction, suspension, or discontinuation. Discontinuations due to adverse reactions occurred in 22% of patients treated with VALCHLOR and 18% of patients treated with the comparator. Sixty-seven percent (67%) of the discontinuations for adverse reactions occurred within the first 90 days of treatment. Temporary treatment suspension occurred in 34% of patients treated with VALCHLOR and 20% of patients treated with the comparator. Reductions in dosing frequency occurred in 23% of patients treated with VALCHLOR and 12% of patients treated with the comparator.

Reductions in hemoglobin, neutrophil count, or platelet count occurred in 13% of patients treated with VALCHLOR and 17% treated with Comparator.

- **DRUG INTERACTIONS**

  No drug interaction studies have been performed with VALCHLOR. Systemic exposure has not been observed with topical administration of VALCHLOR; therefore, systemic drug interactions are not likely.

- **USE IN SPECIFIC POPULATIONS**

  >> Pregnancy

  Pregnancy Category D

  Risk Summary

  Mechlorethamine can cause fetal harm when administered to a pregnant woman. There are case reports of children born with malformations to pregnant women systemically administered mechlorethamine. Mechlorethamine was teratogenic in animals after a single subcutaneous administration. If this drug is used during pregnancy or if the patient becomes pregnant while taking this drug, the patient should be apprised of the potential hazard to a fetus.

  Animal Data

  Mechlorethamine caused fetal malformations in the rat and ferret when given as single subcutaneous injections of 1 mg/kg. Other findings in animals included embryolethality and growth retardation when administered as a single subcutaneous injection.

  >> Nursing Mothers

  It is not known if mechlorethamine is excreted in human milk. Due to the potential for topical or systemic exposure to VALCHLOR through exposure to the mother's skin, a decision should be made whether to discontinue nursing or the drug, taking into account the importance of the drug to the mother.

  >> Pediatric Use

  Safety and effectiveness in pediatric patients have not been established.

  >> Geriatric Use

  A total of 79 patients age 65 and older (31% of the clinical trial population) were treated with either VALCHLOR or the comparator in the clinical trial. Forty-four percent (44%) of patients age 65 or older treated with VALCHLOR achieved a Composite Assessment of Index Lesion Severity (CAILS) response compared to 66% of patients below the age of 65. Seventy percent (70%) of patients age 65 and older experienced cutaneous adverse reactions and 38% discontinued treatment due to adverse reactions, compared to 58% and 14% in patients below the age of 65, respectively. Similar differences in discontinuation rates between age subgroups were observed in the comparator group.

Manufactured for:
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ACTELION

Epidermolysis bullosa presents unique woundcare challenges

Louise Gagnon | Staff Correspondent

TORONTO — It's advisable for clinicians to release the fluid in blisters that develop in children with epidermolysis bullosa (EB), but they should aim to keep the roof of the blister intact, an expert recommends.

"You want to release the fluid, but the roof of the blister serves as a biological membrane," says Elena Pope, M.D., M.Sc., F.R.C.P.C., head of the section of dermatology, Division of Pediatric Medicine, Hospital for Sick Children in Toronto. She is also associate professor, department of paediatrics, University of Toronto. Dr. Pope spoke at a pediatric wound symposium organized through the Hospital for Sick Children.

A consideration in woundcare for EB is to alternate therapies such as topical antimicrobials, to avoid possible sensitization.

Woundcare in EB — a cluster of genetic conditions causing the skin to be fragile and blister easily — is a complex aspect of the management of the condition, Dr. Pope notes. As with general woundcare, local and systemic factors have to be taken into account. Age is a factor that needs to be considered when developing a woundcare plan for a pediatric patient with EB, as each age presents its own challenges, she says. The severity and extent of the wounds depends on the type of EB.

QUICK READ

When faced with patients who have EB, clinicians should attempt to reduce the total bioburden in wounds and consider variables such as exudate and critical colonization in woundcare management.

TYPES OF EB

EB simplex is characterized by blisters on the palms and soles and mild thickening of the soles, but there is no adverse impact on the life span of patients, Dr. Pope says. Another form of the condition Herlitz junctional EB, however, can shorten the lives of patients and carries a high-risk of complications. It is characterized by periorificial blistering, hypergranulation tissue and periungual involvement, as well as nail shedding. Patients can experience poor growth and there can be significant airway involvement, she says.

Recessive dystrophic EB is another form of the condition, and it presents with chronic blisters and wounds; scarring and contractures can develop, and it is associated with an increased risk of skin cancer.

"The majority of the patients die secondary to squamous cell carcinoma," Dr. Pope says.

To minimize trauma in EB, physicians are urged to apply dressings that are described as "non-stick," Dr. Pope says.

"We usually use silicone dressings," she says. "You also want to avoid adhesives, such as tapes, stick probes at any cost."

Moreover, the choice of a dressing is affected by parameters such as the presence of exudate, degree of exudate, and critical colonization, Dr. Pope explains. There are medical adhesive sprays that can be employed to remove dressings in an atraumatic fashion.

PROMOTING WOUND HEALING

When wounds present in patients with severe forms of EB, they can become "stuck," or non-healing. In such instances, it may be a wise step to administer a therapy such as low-dose tetracycline.

Recessive dystrophic EB presents with chronic blisters and it is associated with an increased risk of skin cancer.

"Such a treatment will reduce inflammation and promote wound healing in wounds that are stuck," Dr. Pope says.

Aiming to decrease the total bioburden should be an objective in wound care in EB. Bathing is a means of achieving that. Another consideration in woundcare for EB is to alternate therapies such as topical antimicrobials, to avoid possible sensitization and the potential for resistance to treatment, Dr. Pope says.

"Be mindful of your overall use (of therapies)," she says.

EB can be more challenging to treat on some sites of the body. The diaper area, for example, is complex to treat because of the presence of urine and feces. As in the management of diaper dermatitis, the generous application of zinc oxide in the diaper area is an effective management practice, particularly with junctional EB. **DT**

Disclosures: Dr. Pope reports no relevant financial interests.

Research holds promise for atopic dermatitis

Lisette Hilton | Staff Correspondent

San Diego — Research on new agents for atopic dermatitis holds promise for children with the skin disease. This is while dermatologists continue to face challenges in effectively managing eczema in their pediatric patients.

"Atopic dermatitis is the most prevalent chronic inflammatory skin condition in children. In the United States and other industrialized countries, the estimated prevalence of atopic dermatitis (AD) is between 10 and almost 20 percent in the first few years of life," says Lawrence F. Eichenfield, M.D., chief of pediatric dermatology and professor of pediatrics and medicine (dermatology), at University of California, San Diego, and Rady Children's Hospital San Diego. Dr. Eichenfield is an author on atopic dermatitis guidelines released this year by the American Academy of Dermatology (*see: bit.ly/ADguidelines*).


Dr. Eichenfield

QUICK READ

Pediatric dermatologists say a renewed interest in studying atopic dermatitis treatments could lead to improved quality of life for children suffering from the skin disease.

BIG STRIDES

Among the strides in atopic dermatitis: an improved understanding of the epidemiology and pathogenesis of the disease.

"Over the last several years, identification of mutations in the skin responsible for skin barrier dysfunction, associated with the dry skin of eczema, as well as a set up for its inflammation, have been emphasized," Dr. Eichenfield says. "Research has shown there are mutations in certain genes expressed in the epidermis that fundamentally influence the skin barrier function."

Filaggrin gene mutations have been shown to have a strong predictive value for higher risk of atopic dermatitis development. The gene mutations are also associated with increased rates of asthma, allergic rhinitis, IgE sensitization, as well as more severe atopic dermatitis that can persist into late childhood and adulthood, according to Dr. Eichenfield.

"…In the U.S., David Margolis evaluated DNA from almost 900 children and found that about 16 percent of them had filaggrin mutations while less than 6 percent of African-Americans had these mutations," Dr. Eichenfield says (Margolis DJ, Gupta J, Apter AJ, et al. *J Invest Dermatol*. 2014;134(8):2272-2274).

From a clinical standpoint, the knowledge about skin barrier dysfunction helps to reassure dermatologists that an approach emphasizing good skin care and liberal moisturizer use can help to minimize the disease's impact, Dr. Eichenfield says.

RESEARCH see page **28**

AD's psychosocial side

DERMATOLOGISTS have long known atopic dermatitis takes a huge psychological toll on children and their families. New research shines a light on the aspects of life most affected by the skin disease. Getting enough and quality sleep is a big issue for children with atopic dermatitis, according to Amy Paller, M.D., professor and chairwoman of dermatology and professor of pediatrics at Northwestern University Feinberg School of Medicine, Chicago. "It's difficult in school because they're falling asleep and that makes them different. They have attention issues at school," Dr. Paller says. Children with atopic dermatitis might not engage in playing with others because of the disease.

An issue that researchers are studying, she says, is neurocognitive issues with atopic dermatitis, which come at least in part from sleep deprivation. Findings from quality of life studies on children with atopic dermatitis speak loud and clear about the condition's impact. "In fact, the quality of life reported (by these children) is what we see with many of the chronic diseases, such as diabetes and seizures," she says. "That's important for people to know." What isn't as clear is eczema's impact on families. Dr. Paller says the negative repercussions from the disease are significant and far-reaching. "For most kids with atopic dermatitis, the nighttime is the worst. They have trouble falling asleep, and if they fall asleep, they sleep miserably. All the sleep studies have shown incredible dysfunction in a wide range of areas," she says. "So many parents say, 'I just stay up all night trying to keep him from scratching.' That, alone, risks having a profound effect on the relationship between the parent and the child in ways that are not the healthiest," Dr. Paller says.

SOURCES FOR QUALITY OF LIFE

Researchers in this study report atopic dermatitis greatly affects the quality-of-life of affected children and their families. "The burden of atopic dermatitis can likely be improved by identifying parents and their caregivers with impaired quality-of-life and providing appropriate education and psychosocial support," according to the abstract (Chamlin SL, Chren MM. *Immunol Allergy Clin North Am.* 2010;30(3):281-288). Epub 2010 Jul 1. Review). Authors of this study investigated prevalence of symptoms of depression, anxiety and stress and, if the symptoms are associated with disease severity, quality of life and skin biophysiology in childhood atopic eczema. They concluded that quality of life impairments correlate with disease severity, aberrant skin biophysiology, depression, anxiety and stress symptoms in adolescents with the disease. "Physicians caring for these patients must evaluate the different but inter-correlated medical, biophysiological and pertinent psychosocial domains. These significant correlations imply that a holistic approach should encompass psychotherapy, behavioral therapy and coping strategies in conjunction with dermatologic therapy," according to the abstract (Hon KL, Pong NH, Poon TC, et al. *J Dermatolog Treat.* 2014 Feb 20. [Epub ahead of print]). Researchers of this study found health-related quality of life (HRQL) " … Impairment in children with chronic skin disease is at least equal to that experienced by children with many other chronic diseases of childhood, with AD and psoriasis having the greatest impact on HRQL among chronic skin disorders and only cerebral palsy scoring higher than AD (Beattie PE, Lewis-Jones MS. *Br J Dermatol.* 2006;155(1):145-151)." **DT**

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Preliminary List – more faculty added soon!

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RESEARCH:

Renewed interest in AD therapies could improve quality of life for patients

from page 26

SKIN COLONIZATION

Another area of interesting research relates to colonization on the skin and infection of atopic dermatitis.

"It has been well known that *Staph aureus* (*Staphylococcus aureus/S. aureus*) is a bacteria that commonly colonizes atopic dermatitis, and can impact atopic dermatitis with clinical infection and flaring of the disease," Dr. Eichenfield says. "Recent studies using techniques to assess genetic material of microbes is helping to show the tremendous diversity of microorganisms on normal and clinically impacted skin."

Studies have shown that the diversity of microbes decreases during AD flares, as *S. aureus* increases, he says.

"Generally in nonaffected atopic dermatitis the broad use of antibiotics is not recommended. However, infected eczema might benefit from systemic treatments," Dr. Eichenfield says. "In the future, there might be studies that look at both skin colonization as well as the potential of course of gut colonization in the development of atopic dermatitis and/or its course."

An area related to colonization of the skin is the use of bleach baths as adjuvant therapy in atopic dermatitis. Dilute sodium hypochlorite soaks can decrease skin colonization and have been shown to be useful in improving AD.

"Interestingly a set of studies by Thomas Leung at Stanford and published in the *Journal of Investigative Dermatology* showed that sodium hypochlorite solution may be anti-inflammatory, influencing N F kappa beta expression. Dilute sodium hypochlorite solution also decreased radiation dermatitis in a rat model," Dr. Eichenfield says.

NEW MEDS ON THE BLOCK

There are new topical and systemic agents in the drug development pipeline, several of which are in advanced clinical trials, including a boron-based phosphodiesterase inhibitor (PDE4, AN2728), studied by Anacor, and a biologic agent being developed for atopic dermatitis, studied by Regeneron/Sanofi.

Dr. Paller

"We've spent more than a decade studying the underlying pathogenesis of psoriasis and translating that information into new therapies," says Amy Paller, M.D., professor and chairwoman of dermatology and professor of pediatrics, Northwestern University Feinberg School of Medicine, Chicago. "Now it's time for atopic dermatitis … and a growing number of pharmaceutical companies are taking an interest. It's going to be extremely exciting."

PDE-4, the boron-based phosphodiesterase inhibitor in phase 3 trials in adult patients, looks promising for mild-to-moderate atopic dermatitis and has not shown evidence of toxicity, according to Dr. Paller. Anacor Pharmaceuticals announced positive results from a phase 2 trial in December 2012, following a trial on adolescents with mild-to-moderate atopic dermatitis using its PDE-4 inhibitor, AN2728.

"One of the most exciting new developments in atopic dermatitis is the testing of the first biologic designed based on our understanding of the mechanism underlying atopic dermatitis," she says. "And the clinical results look so promising. It's called dupilumab and continues in trials in adults right now. Once safety is established in adults, dupilumab can be tested in pediatric patients as well."

Dupilumab, a human monoclonal antibody that blocks interleukin-4 and interleukin-13, showed promising results from a trial of adult patients with moderate-to-severe atopic dermatitis in a July 2014 paper published in the *New England Journal of Medicine* (Beck LA, Thaçi D, Hamilton JD, et al. *N Engl J Med*. 2014;371(2):130-139).

Beck et al concluded, "Patients treated with dupilumab had marked and rapid improvement in all the evaluated measures of atopic dermatitis disease activity. Side-effect profiles were not dose-limiting."

Dr. Siegfried

There's more research on atopic dermatitis going on in the areas of AD biomarkers, triggers and better tools for judging treatment efficacy in research trials, according to Elaine C. Siegfried, M.D., professor of pediatrics and dermatology, Saint Louis University, St. Louis.

"A sizable group of dedicated clinicians and investigators is working with various agencies to try to define the best measure of atopic dermatitis improvement," Dr. Siegfried says. "Implementing a uniform measure into new clinical trials protocols is very important in order to have a uniform measure to compare different drugs."

PRESCRIBING CAN BE A CHALLENGE

Topical anti-inflammatory therapy is still a standard approach for the inflammation of atopic dermatitis, focused on use of topical corticosteroids and topical calcineurin inhibitors, Dr. Eichenfield says.

"As emphasized in the new American Academy of Dermatology Atopic Dermatitis guidelines, both sets of agents may be used as proactive therapy, rather than reactive therapy. The principle of proactive therapy is that the use of intermittent topical corticosteroid or calcineurin inhibitors to clinical normal skin may be useful to decrease flares of the disease and render the patient relatively pruritus or inflammation free," he says.

The biggest breakthrough in atopic dermatitis treatment has been the development of topical corticosteroids, Dr. Siegfried says.

"Before (topical corticosteroids), treatment was incredibly difficult. After topi-

RESEARCH see page 34

Alternative therapies in eczema care

Peter Lio, M.D., assistant professor of clinical dermatology and pediatrics, Northwestern University Feinberg School of Medicine, Chicago, and director of the Chicago Integrative Eczema Center, says eczema patients and their families often come to him looking for alternative treatments.

Dr. Lio

"Sometimes people come in and say, 'I don't want to use any Western medicine,' and I'll say if it's the mildest eczema, perhaps we can get by. But for anything more severe, we really need to do this as part of a plan with the hopes of minimizing the amount of more powerful medicines by strengthening the skin and doing these other good things," Dr. Lio says.

Read more on what advice Dr. Lio gives patients, including what's "thumbs up," "jury's out" and "thumbs down," at: bit.ly/integrativederm

PROVEN EFFICACY WITH CUSTOMIZED, WEIGHT-BASED DOSING[1,2]

- Significant reduction in inflammatory lesions at ~1 mg/kg/day in SOLODYN®-treated patients[1,2]
  - In a dose-ranging study, a 56.8% reduction from baseline vs placebo (39.4%)*
  - In 2 phase 3 trials, mean percent improvement from baseline was 43% and 46% vs placebo (32% and 31%, respectively)†
- Once-daily dosing, with or without food[1]
- No generic equivalent

*Phase 2 study; N=233 subjects.
† N=924 subjects.

Indication and Usage

SOLODYN is indicated to treat only inflammatory lesions of non-nodular moderate to severe acne vulgaris in patients 12 years of age and older.

Important Safety Information for SOLODYN Tablets

- The most commonly observed adverse reactions are headache, fatigue, dizziness, and pruritus
- Minocycline like other tetracycline-class drugs can cause fetal harm when administered to a pregnant woman
- Tetracycline drugs should not be used during tooth development (last half of pregnancy and up to 8 years of age) as they may cause permanent discoloration of teeth
- Pseudomembranous colitis has been reported with nearly all antibacterial agents and may range from mild to life-threatening; therefore, it is important to consider this diagnosis in patients who present with diarrhea subsequent to the administration of antibacterial agents
- Central nervous system side effects, including light-headedness, dizziness, and vertigo, have been reported with minocycline therapy
- In rare cases, photosensitivity has been reported
- Should not be used during pregnancy or by individuals of either gender who are attempting to conceive a child; concurrent use of tetracyclines with oral contraceptives may render oral contraceptives less effective
- This drug is contraindicated in persons who have shown hypersensitivity to any of the tetracyclines
- Safety beyond 12 weeks of use has not been established
- Cases of anaphylaxis, serious skin reactions, erythema multiforme, and drug rash with eosinophilia and systemic symptoms have been reported postmarketing with minocycline use. Discontinue SOLODYN immediately if symptoms occur

Please see Brief Summary of full Prescribing Information on the following pages.

References: 1. SOLODYN Tablets Package Insert. Scottsdale, AZ: Valeant Dermatology; February 2012.
2. Data on file, Valeant Pharmaceuticals.

VALEANT® Dermatology

DM/SDN/14/0005

SOLODYN®
(MINOCYCLINE HCl, USP)
EXTENDED RELEASE TABLETS

BRIEF SUMMARY
(see package insert for full prescribing information)

SOLODYN®
(minocycline HCl, USP) Extended Release Tablets

Rx Only
KEEP OUT OF REACH OF CHILDREN

INDICATIONS AND USAGE

Indication
SOLODYN is indicated to treat only inflammatory lesions of non-nodular moderate to severe acne vulgaris in patients 12 years of age and older.

Limitations of Use
SOLODYN did not demonstrate any effect on non-inflammatory acne lesions. Safety of SOLODYN 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, SOLODYN should be used only as indicated *(see Warnings and Precautions)*.

CONTRAINDICATIONS

This drug is contraindicated in persons who have shown hypersensitivity to any of the tetracyclines.

WARNINGS AND PRECAUTIONS

Teratogenic Effects

A. MINOCYCLINE, LIKE OTHER TETRACYCLINE-CLASS DRUGS, CAN CAUSE FETAL HARM WHEN ADMINISTERED TO A PREGNANT WOMAN. IF ANY TETRACYCLINE IS USED DURING PREGNANCY OR IF THE PATIENT BECOMES PREGNANT WHILE TAKING THESE DRUGS, THE PATIENT SHOULD BE APPRISED OF THE POTENTIAL HAZARD TO THE FETUS.

SOLODYN should not be used during pregnancy or by individuals of either gender who are attempting to conceive a child *(see Nonclinical Toxicology & Use in Specific Populations)*.

B. THE USE OF DRUGS OF THE TETRACYCLINE CLASS DURING TOOTH DEVELOPMENT (LAST HALF OF PREGNANCY, INFANCY, AND CHILDHOOD UP TO THE AGE OF 8 YEARS) MAY CAUSE PERMANENT DISCOLORATION OF THE TEETH (YELLOW-GRAY-BROWN).

This adverse reaction is more common during long-term use of the drug but has been observed following repeated short-term courses. Enamel hypoplasia has also been reported. TETRACYCLINE DRUGS, THEREFORE, SHOULD NOT BE USED DURING TOOTH DEVELOPMENT.

C. All tetracyclines form a stable calcium complex in any bone-forming tissue. A decrease in fibula growth rate has been observed in premature human infants given oral tetracycline in doses of 25 mg/kg every 6 hours. This reaction was shown to be reversible when the drug was discontinued.

Results of animal studies indicate that tetracyclines cross the placenta, are found in fetal tissues, and can cause retardation of skeletal development on the developing fetus. Evidence of embryotoxicity has been noted in animals treated early in pregnancy *(see Use in Specific Populations)*.

Pseudomembranous Colitis

Pseudomembranous colitis has been reported with nearly all antibacterial agents and may range from mild to life-threatening. Therefore, it is important to consider this diagnosis in patients who present with diarrhea subsequent to the administration of antibacterial agents.

Treatment with antibacterial agents alters the normal flora of the colon and may permit overgrowth of clostridia. Studies indicate that a toxin produced by Clostridium difficile is a primary cause of "antibiotic-associated colitis".

After the diagnosis of pseudomembranous colitis has been established, therapeutic measures should be initiated. Mild cases of pseudomembranous colitis usually respond to discontinuation of the drug alone. In moderate to severe cases, consideration should be given to management with fluids and electrolytes, protein supplementation, and treatment with an antibacterial drug clinically effective against Clostridium difficile colitis.

Hepatotoxicity
Post-marketing cases of serious liver injury, including irreversible drug-induced hepatitis and fulminant hepatic failure (sometimes fatal) have been reported with minocycline use in the treatment of acne.

Metabolic Effects
The anti-anabolic action of the tetracyclines may cause an increase in BUN. While this is not a problem in those with normal renal function, in patients with significantly impaired function, higher serum levels of tetracycline-class drugs may lead to azotemia, hyperphosphatemia, and acidosis. If renal impairment exists, even usual oral or parenteral doses may lead to excessive systemic accumulations of the drug and possible liver toxicity. Under such conditions, lower than usual total doses are indicated, and if therapy is prolonged, serum level determinations of the drug may be advisable.

Central Nervous System Effects
Central nervous system side effects including light-headedness, dizziness or vertigo have been reported with minocycline therapy. Patients who experience these symptoms should be cautioned about driving vehicles or using hazardous machinery while on minocycline therapy. These symptoms may disappear during therapy and usually rapidly disappear when the drug is discontinued.

Benign Intracranial Hypertension
Pseudotumor cerebri (benign intracranial hypertension) in adults and adolescents has been associated with the use of tetracyclines. Minocycline has been reported to cause or precipitate pseudotumor cerebri, the hallmark of which is papilledema. Clinical manifestations include headache and blurred vision. Bulging fontanels have been associated with the use of tetracyclines in infants. Although signs and symptoms of pseudotumor cerebri resolve after discontinuation of treatment, the possibility for permanent sequelae such as visual loss that may be permanent or severe exists. Patients should be questioned for visual disturbances prior to initiation of treatment with tetracyclines. If visual disturbance occurs during treatment, patients should be checked for papilledema. Concomitant use of isotretinoin and minocycline should be avoided because isotretinoin, a systemic retinoid, is also known to cause pseudotumor cerebri.

Autoimmune Syndromes
Tetracyclines have been associated with the development of autoimmune syndromes. The long-term use of minocycline in the treatment of acne has been associated with drug-induced lupus-like syndrome, autoimmune hepatitis and vasculitis. Sporadic cases of serum sickness have presented shortly after minocycline use. Symptoms may be manifested by fever, rash, arthralgia, and malaise. In symptomatic patients, liver function tests, ANA, CBC, and other appropriate tests should be performed to evaluate the patients. Use of all tetracycline-class drugs should be discontinued immediately.

Photosensitivity
Photosensitivity manifested by an exaggerated sunburn reaction has been observed in some individuals taking tetracyclines. This has been reported rarely with minocycline. Patients should minimize or avoid exposure to natural or artificial sunlight (tanning beds or UVA/B treatment) while using minocycline. If patients need to be outdoors while using minocycline, they should wear loose-fitting clothes that protect skin from sun exposure and discuss other sun protection measures with their physician.

Serious Skin/Hypersensitivity Reaction
Cases of anaphylaxis, serious skin reactions (e.g. Stevens Johnson syndrome), erythema multiforme, and drug rash with eosinophilia and systemic symptoms (DRESS) syndrome have been reported postmarketing with minocycline use in patients with acne. DRESS syndrome consists of cutaneous reaction (such as rash or exfoliative dermatitis), eosinophilia, and one or more of the following visceral complications such as: hepatitis, pneumonitis, nephritis, myocarditis, and pericarditis. Fever and lymphadenopathy may be present. In some cases, death has been reported. If this syndrome is recognized, the drug should be discontinued immediately.

Tissue Hyperpigmentation
Tetracycline-class antibiotics are known to cause hyperpigmentation. Tetracycline therapy may induce hyperpigmentation in many organs, including nails, bone, skin, eyes, thyroid, visceral tissue, oral cavity (teeth, mucosa, alveolar bone), sclerae and heart valves. Skin and oral pigmentation has been reported to occur independently of time or amount of drug administration, whereas other tissue pigmentation has been reported to occur upon prolonged administration. Skin pigmentation includes diffuse pigmentation as well as over sites of scars or injury.

Development of Drug Resistant Bacteria
Bacterial resistance to the tetracyclines may develop in patients using SOLODYN, therefore, the susceptibility of bacteria associated with infection should be considered in selecting antimicrobial therapy. Because of the potential for drug-resistant bacteria to develop during the use of SOLODYN, it should be used only as indicated.

Superinfection
As with other antibiotic preparations, use of SOLODYN may result in overgrowth of nonsusceptible organisms, including fungi. If superinfection occurs, SOLODYN should be discontinued and appropriate therapy instituted.

Laboratory Monitoring
Periodic laboratory evaluations of organ systems, including hematopoietic, renal and hepatic studies should be performed. Appropriate tests for autoimmune syndromes should be performed as indicated.

ADVERSE REACTIONS

Clinical Trial Experience
Because clinical trials are conducted under prescribed conditions, adverse reaction rates observed in the clinical trial may not reflect the rates observed in practice.

The following table summarizes selected adverse reactions reported in clinical trials at a rate of ≥1% for SOLODYN.

Selected Treatment-Emergent Adverse Reactions in at least 1% of Clinical Trial Subjects

Adverse Reactions	SOLODYN (1 mg/kg) N=674 (%)	PLACEBO N=364 (%)
At least one treatment-emergent event	379 (56)	197 (54)
Headache	152 (23)	83 (23)
Fatigue	62 (9)	24 (7)
Dizziness	59 (9)	17 (5)
Pruritus	31 (5)	16 (4)
Malaise	26 (4)	9 (3)
Mood alteration	17 (3)	9 (3)
Somnolence	13 (2)	3 (1)
Urticaria	10 (2)	1 (0)
Tinnitus	10 (2)	5 (1)
Arthralgia	9 (1)	2 (0)
Vertigo	8 (1)	3 (1)
Dry mouth	7 (1)	5 (1)
Myalgia	7 (1)	4 (1)

Postmarketing Experience
Adverse reactions that have been reported with minocycline hydrochloride use in a variety of indications include:

Skin and hypersensitivity reactions: fixed drug eruptions, balanitis, erythema multiforme, Stevens-Johnson syndrome, anaphylactoid purpura, photosensitivity, pigmentation of skin and mucous membranes, hypersensitivity reactions, angioneurotic edema, anaphylaxis, DRESS syndrome *(see Warnings and Precautions)*.

Autoimmune conditions: polyarthralgia, pericarditis, exacerbation of systemic lupus, pulmonary infiltrates with eosinophilia, transient lupus-like syndrome.

Central nervous system: pseudotumor cerebri, bulging fontanels in infants, decreased hearing.

Endocrine: brown-black microscopic thyroid discoloration, abnormal thyroid function.

Oncology: thyroid cancer.

Oral: glossitis, dysphagia, tooth discoloration.

Gastrointestinal: enterocolitis, pancreatitis, hepatitis, liver failure.

Renal: reversible acute renal failure.

Hematology: hemolytic anemia, thrombocytopenia, eosinophilia.

Preliminary studies suggest that use of minocycline may have deleterious effects on human spermatogenesis *(see Nonclinical Toxicology)*.

DRUG INTERACTIONS

Anticoagulants

Because tetracyclines have been shown to depress plasma prothrombin activity, patients who are on anticoagulant therapy may require downward adjustment of their anticoagulant dosage.

Penicillin

Since bacteriostatic drugs may interfere with the bactericidal action of penicillin, it is advisable to avoid giving tetracycline-class drugs in conjunction with penicillin.

Methoxyflurane

The concurrent use of tetracycline and methoxyflurane has been reported to result in fatal renal toxicity.

Antacids and Iron Preparations

Absorption of tetracyclines is impaired by antacids containing aluminum, calcium or magnesium and iron-containing preparations.

Low Dose Oral Contraceptives

In a multi-center study to evaluate the effect of SOLODYN on low dose oral contraceptives, hormone levels over one menstrual cycle with and without SOLODYN 1 mg/kg once-daily were measured. Based on the results of this trial, minocycline-related changes in estradiol, progestinic hormone, FSH and LH plasma levels, of breakthrough bleeding, or of contraceptive failure, cannot be ruled out. To avoid contraceptive failure, female patients are advised to use a second form of contraceptive during treatment with minocycline.

Drug/Laboratory Test Interactions

False elevations of urinary catecholamine levels may occur due to interference with the fluorescence test.

USE IN SPECIFIC POPULATIONS

Pregnancy

Teratogenic Effects: Pregnancy category D (see Warnings and Precautions)

SOLODYN should not be used during pregnancy. If the patient becomes pregnant while taking this drug, the patient should be apprised of the potential hazard to the fetus and stop treatment immediately.

There are no adequate and well-controlled studies on the use of minocycline in pregnant women. Minocycline, like other tetracycline-class drugs, crosses the placenta and may cause fetal harm when administered to a pregnant woman.

Rare spontaneous reports of congenital anomalies including limb reduction have been reported with minocycline use in pregnancy in post-marketing experience. Only limited information is available regarding these reports; therefore, no conclusion on causal association can be established.

Minocycline induced skeletal malformations (bent limb bones) in fetuses when administered to pregnant rats and rabbits in doses of 30 mg/kg/day and 100 mg/kg/day, respectively, (resulting in approximately 3 times and 2 times, respectively, the systemic exposure to minocycline observed in patients as a result of use of SOLODYN). Reduced mean fetal body weight was observed in studies in which minocycline was administered to pregnant rats at a dose of 10 mg/kg/day (which resulted in approximately the same level of systemic exposure to minocycline as that observed in patients who use SOLODYN).

Minocycline was assessed for effects on peri- and post-natal development of rats in a study that involved oral administration to pregnant rats from day 6 of gestation through the period of lactation (postpartum day 20), at dosages of 5, 10, or 50 mg/kg/day. In this study, body weight gain was significantly reduced in pregnant females that received 50 mg/kg/day (resulting in approximately 2.5 times the systemic exposure to minocycline observed in patients as a result of use of SOLODYN). No effects of treatment on the duration of the gestation period or the number of live pups born per litter were observed. Gross external anomalies observed in F1 pups (offspring of animals that received minocycline) included reduced body size, improperly rotated forelimbs, and reduced size of extremities. No effects were observed on the physical development, behavior, learning ability, or reproduction of F1 pups, and there was no effect on gross appearance of F2 pups (offspring of F1 animals).

Nursing Mothers

Tetracycline-class antibiotics are excreted in human milk. Because of the potential for serious adverse effects on bone and tooth development in nursing infants from the tetracycline-class antibiotics, a decision should be made whether to discontinue nursing or discontinue the drug, taking into account the importance of the drug to the mother *(see Warnings and Precautions)*.

Pediatric Use

SOLODYN is indicated to treat only inflammatory lesions of non-nodular moderate to severe acne vulgaris in patients 12 years and older. Safety and effectiveness in pediatric patients below the age of 12 has not been established.

Use of tetracycline-class antibiotics below the age of 8 is not recommended due to the potential for tooth discoloration *(see Warnings and Precautions)*.

Geriatric Use

Clinical studies of SOLODYN did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. Other reported clinical experience has not identified differences in responses between the elderly and younger patients. In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and concomitant disease or other drug therapy.

OVERDOSAGE

In case of overdosage, discontinue medication, treat symptomatically and institute supportive measures. Minocycline is not removed in significant quantities by hemodialysis or peritoneal dialysis.

NONCLINICAL TOXICOLOGY

Carcinogenesis, Mutagenesis, Impairment of Fertility

Carcinogenesis—Long-term animal studies have not been performed to evaluate the carcinogenic potential of minocycline. A structurally related compound, oxytetracycline, was found to produce adrenal and pituitary tumors in rats.

Mutagenesis—Minocycline was not mutagenic *in vitro* in a bacterial reverse mutation assay (Ames test) or CHO/HGPRT mammalian cell assay in the presence or absence of metabolic activation. Minocycline was not clastogenic *in vitro* using human peripheral blood lymphocytes or *in vivo* in a mouse micronucleus test.

Impairment of Fertility—Male and female reproductive performance in rats was unaffected by oral doses of minocycline of up to 300 mg/kg/day (which resulted in up to approximately 40 times the level of systemic exposure to minocycline observed in patients as a result of use of SOLODYN). However, oral administration of 100 or 300 mg/kg/day of minocycline to male rats (resulting in approximately 15 to 40 times the level of systemic exposure to minocycline observed in patients as a result of use of SOLODYN) adversely affected spermatogenesis. Effects observed at 300 mg/kg/day included a reduced number of sperm cells per gram of epididymis, an apparent reduction in the percentage of sperm that were motile, and (at 100 and 300 mg/kg/day) increased numbers of morphologically abnormal sperm cells. Morphological abnormalities observed in sperm samples included absent heads, misshapen heads, and abnormal flagella.

Limited human studies suggest that minocycline may have a deleterious effect on spermatogenesis.

SOLODYN should not be used by individuals of either gender who are attempting to conceive a child.

HOW SUPPLIED/STORAGE AND HANDLING

How Supplied

SOLODYN (minocycline HCl, USP) Extended Release Tablets are supplied as aqueous film coated tablets containing minocycline hydrochloride equivalent to 55 mg, 65 mg, 80 mg, 105 mg or 115 mg minocycline, are supplied as follows.

The 55 mg extended release tablets are pink, unscored, coated, and debossed with “DYN-055” on one side. Each tablet contains minocycline hydrochloride equivalent to 55 mg minocycline, supplied as follows:

NDC 99207-465-30 Bottle of 30

The 65 mg extended release tablets are blue, unscored, coated, and debossed with “DYN-065” on one side. Each tablet contains minocycline hydrochloride equivalent to 65 mg minocycline, supplied as follows:

NDC 99207-463-30 Bottle of 30

The 80 mg extended release tablets are dark gray, unscored, coated, and debossed with “DYN-080” on one side. Each tablet contains minocycline hydrochloride equivalent to 80 mg minocycline, supplied as follows:

NDC 99207-466-30 Bottle of 30

The 105 mg extended release tablets are purple, unscored, coated, and debossed with “DYN-105” on one side. Each tablet contains minocycline hydrochloride equivalent to 105 mg minocycline, supplied as follows:

NDC 99207-467-30 Bottle of 30

The 115 mg extended release tablets are green, unscored, coated, and debossed with “DYN-115” on one side. Each tablet contains minocycline hydrochloride equivalent to 115 mg minocycline, supplied as follows:

NDC 99207-464-30 Bottle of 30

Storage

Store at 25ºC (77ºF); excursions are permitted to 15º-30ºC (59º-86ºF) [See USP Controlled Room Temperature].

Handling

Keep out of reach of children

Protect from light, moisture, and excessive heat.

Dispense in tight, light-resistant container with child-resistant closure.

Manufactured for:
Medicis, The Dermatology Company
Scottsdale, AZ 85256

02/2012

17110264

CONTACT DERMATITIS:

Pediatric skin reactions stem from new technology, accessories

from page 1

medical social sciences at Northwestern University, Chicago.

TECHNOLOGY FUELS NICKEL EXPOSURE

Nickel has been the most common patch test positive for children and adults for many years. But recently, there has been an explosion of nickel use, Dr. Silverberg says.

"Going back about 10 years, we saw a lot of nickel positive patch tests, but they weren't always relevant," he says. "Nowadays, we're seeing a lot more relevant reactions. The metal exposures are coming from technology, including telephones, iPads, tablets, laptop cases."

Even children who might not be old enough to use phones or computers are at risk. Toys have become more sophisticated, with electronic components that contain metals, including nickel, Dr. Silverberg says.

And while nickel allergies traditionally occur more often in girls than boys (because girls are more likely to have piercings and get exposure from jewelry), boys seem to be closing the gap.

Allergic reactions from nickel exposure is significant from a public health standpoint because not only has nickel triggered reactions in people who are at risk, but it may be that ongoing nickel exposure in children might predispose them for nickel allergies down the road.

IT'S NOT JUST NICKEL

Pediatric skin reactions from cell phones and other devices are not just from the nickel in devices, but also from the many accessories that go along with these technologies, according to Dr. Silverberg.

"We're seeing (skin reactions from) rubber and dyes that are used on key pads for cells phones. The rubber and plastic cases are a source of allergens. Headphones and ear buds — there's rubber and plastic in them. The leather casings … all of these can be sources of allergens that can cause allergic contact dermatitis," he says.

The American Contact Dermatitis Society named methylisothiazolinone Contact Allergen of the Year for 2013 (Castanedo-Tardana MP, Zug KA. *Dermatitis*. 2013;24(1):2-6. Review).

"This is something that entered the marketplace 10 or 20 years ago and is ubiquitous. There's basically no skincare category that doesn't use it in one form or another," Dr. Silverberg says.

Methylisothiazolinone, a preservative that increases shelf life and prevents bacterial growth, is commonly combined in products with methylchloroisothiazolinone. The mixture, called Kathon CG, is a known to cause allergic contact dermatitis. Researchers reported increases in Kathon CG-associated allergies in the 1980s.

"In unselected eczema patients subjected to routine patch testing, the number with positive reactions to Kathon CG 100 ppm increased from none in 1983 to 0.7 percent in January-August 1985, and to 4.6 percent in September 1985 to March 1986," according to the study (Hannuksela M. *Contact Dermatitis*. 1986;15(4):211-214).

In Europe, the documented frequency of allergy to Kathon CG is about 1.5 percent, according to the study by Castanedo-Tardana and Zug.

"The frequency of allergy to this preservative in the United States is unknown. If you are not testing for allergy to this preservative, you may be overlooking the importance of a very relevant preservative allergen that, to date, has managed to stay under the radar in the United States," Dr. Silverberg says.

SEEING REACTIONS 'EVERYWHERE'

While it's useful as a preservative, methylisothiazolinone alone can be irritating and allergenic, he says. As a result, Dr. Silverberg is seeing cases of allergic contact dermatitis where they don't usually occur.

"We're seeing a lot of perianal reactions to baby wipes. In young kids, we're seeing those reactions particularly in children known to have inflammatory bowel syndrome or any other causes of diarrhea," Dr. Silverberg says. "We're seeing facial reactions and hand eczema due to a number of moisturizing creams and lotions and kids being cleaned with wipes by their parents. We're seeing generalized reactions from shampoos and conditioners. It's just everywhere."

Methylisothiazolinone is an ingredient that dermatologists might not think about. But, the fact is, it's even in some of the prescription topical medications they prescribe, Dr. Silverberg says. These include crotamiton (Eurax, Ranbaxy), halobetasol propionate 0.05 percent cream (Ultravate, Ranbaxy) and some triamcinolone cream preparations, which are mainstays of treating inflammatory skin disease.

CONTACT DERMATITIS see page 34

QUICK READ

Nickel and methylisothiazolinone are among the most prevalent causes of pediatric allergic contact dermatitis today, an expert says.

Top pediatric allergen sources

JONATHAN SILVERBERG, M.D., PH.D., M.P.H., assistant professor of dermatology, preventive medicine and medical social sciences at Northwestern University, Chicago, says the following are novel sources of common skin allergies among pediatric patients:

☑ ***MOISTURIZERS:*** "There are a lot of people using moisturizers more and more on their own — even without a recommendation. There's evidence that parents might be able to prevent eczema in early childhood if they lather on moisturizers, early and often," he says. "But many of the new moisturizing products, particularly the ones that are being marketed as being more elegant and less greasy, are loaded with different preservatives that can be both irritants and allergens. We're starting to see some of those reactions, now. But I think one can expect that we'll start to see a lot more reactions in the next five to 10 years because of increased use of these products."

☑ ***BOTANICALS:*** "Everyone loves natural products. It's a big fad. And many companies are jumping on the bandwagon and adding a number of botanical ingredients to their products, like aloe, green tea, chamomile — all kinds of plant extracts," Dr. Silverberg says. "Some of these have beneficial properties for the skin, but many are potent irritants and allergens. I've seen a number of cases with severe blistering rashes from some of these botanical products. Sometimes, not everything that's natural is going to be good, especially if you're allergic to it."

☑ ***SUNSCREEN:*** "One of the biggest public health discussions in dermatology is in … how important it is to use sunscreen in early life. But as kids use sunscreens more and more, they're also exposing themselves to the potential of developing irritation of their underlying eczema and sensitive skin or even allergies," Dr. Silverberg says. "I'm really a minimalist. I try to recommend products that have fewer ingredients, no fragrances, less of the preservatives — even if it means a shorter shelf life. Because I really want to avoid sensitizing these kids down the road." **DT**

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RESEARCH:

Renewed interest in AD therapies could improve quality of life for patients from page 28

cal corticosteroids were developed, acute relief was possible for the majority of patients," she says.

But long-term use of topical corticosteroid monotherapy carries the risk of side effects. Potential problems include cyclic rebound of the skin disease, cutaneous atrophy and corticosteroid contact allergy. Compounding the reality of side effects is a prevailing phobia surrounding topical corticosteroid use. "Steroid phobia," or "corticosteroid phobia" is more fear-based than research-based, according to Dr. Siegfried.

ADDRESSING NONCOMPLIANCE

The perceived dangers of topical corticosteroids often lead to noncompliance. According to research, parents and adult atopic patients surveyed reported fearing topical corticosteroids, and more than a third admitted nonadherence to treatment (Aubert-Wastiaux H, Moret L, Le Rhun A, et al. *Br J Dermatol*. 2011;165(4):808-814).

"You can overuse corticosteroids, but, if you don't use them at all, it can be very difficult to keep the disease under control," Dr. Siegfried says. "In my practice … corticosteroids are always first-line. They're the most well studied and have been around for the longest period of time. But … in people whose disease can't be controlled on a safe amount of corticosteroids, you have to add a steroid-sparing agent. Options include a calcineurin inhibitor or phototherapy. Some people still use tar, although most patients don't like it and there's a concern about carcinogenicity."

Calcineurin inhibitors, she says, are safe and well tolerated.

"… It's wonderful to have those options. The most well-studied are the topical calcineurin inhibitors, Elidel (pimecrolimus, Valeant) and Protopic (tacrolimus, Astellas)," Dr. Siegfried says. "They don't work as fast or as dramatically as corticosteroids but they maintain skin health and help control inflammation long term, without causing cutaneous atrophy."

But there is the black box warning on tacrolimus ointment and pimecrolimus cream, which limits access to the options for children with atopic dermatitis, Dr. Siegfried says.

The warning states the use of these medications may increase the risk of certain cancers, specifically skin cancer and non-Hodgkin's lymphoma. The American Academy of Dermatology, however, published this quote by Dr. Eichenfield: "… Patients should know that studies have not demonstrated an increased cancer risk from (topical calcineurin inhibitor) use."

"New drug development for atopic dermatitis suffered from the black box warning on calcineurin inhibitors, so there were no drugs in the pipeline for a long time," Dr. Siegfried says. "Finally, people are starting to recognize the epidemiologic importance and unmet medical need of (atopic dermatitis)." **DT**

Read more on patient education at:
bit.ly/ADresearch

CONTACT DERMATITIS:

Pediatric skin reactions stem from new technology, accessories from page 32

Methylisothiazolinone is also in over-the-counter products dermatologists might recommend to pediatric patients, such as Dove Soap, Dove Body Wash and Head & Shoulders shampoo.

These products might not be irritating, initially. However, one of the major risk factors for developing contact dermatitis is frequency of use.

"Or, if patients have an allergy to methylisothiazolinone, providers need to be aware that they can't be using these creams and topical prescriptions or make over-the-counter recommendations where they might be directly exposing patients to these allergens."

REBOUND RESPONSE

Often patients who are using topical agents and are allergic or develop an allergy to methylisothiazolinone will experience some improvement initially because the steroid suppresses inflammation. But, almost immediately after, they get a worsening because they've been exposed to an allergen.

"When you see that kind of rebound, you really need to think about some kind of allergen," he says.

Dermatologists can check product inserts for methylisothiazolinone, and should refer patients for patch testing if they suspect a skin allergy.

"If you're really suspicious, don't hesitate. It's better to refer for patch testing and be certain about it. Otherwise, some of these patients will go on for years or decades with a chronic disease, where it's never well controlled. It might be as simple as changing around some products and avoiding some allergens and everything gets better or goes away," Dr. Silverberg says.

He admits finding products without the preservative might be a challenge, but he says it's worth it for patients.

AVOIDING ALLERGENS

Dermatologists should at least entertain the possibility of a methylisothiazolinone-related or another contact dermatitis every time they see a child with an eczema-like rash.

"It can show up commonly in … those localized eczema reactions. So, really tough hand eczema or eczema that just keeps coming back that's localized to a particular body," Dr. Silverberg says. "Nummular or coin-shaped eczema — a number of studies have shown that to be highly related to contact allergies. Even just the garden variety of atopic dermatitis can be confounded by contact dermatitis."

Some dermatologists still believe in the conventional dogma that atopic dermatitis somehow cancels out an increased risk of allergens. But recent research tells a different story.

"This year, at the American Contact Dermatitis Society meeting, there were (many) studies that presented higher rates of contact dermatitis in atopic dermatitis," he says. "So, even for those garden variety eczema cases, if you're thinking about putting them on prednisone, systemic agents or phototherapy, you're really obligated to patch test them first, to make sure that it's not some reversible thing."

In one of those studies, researchers reported evidence from the U.S. and Europe that suggests people with atopic dermatitis have similar if not higher rates of positive patch test results to common contact allergens, including metals and fragrance, than people without atopic dermatitis (Aquino M, Fonacier L. *J Allergy Clin Immunol Pract*. 2014;2(4):382-387). **DT**

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References:
1. Elias PM, Sun R, Eder AR, et al. Treating atopic dermatitis at the source: corrective barrier repair therapy based upon new pathogenic insights. *Expert Rev Dermatol.* 2013;8(1):27-36. **2.** Kippenberger S, Loitsch SM, Grundmann-Kollmann M, et al. Activators of peroxisome proliferator-activated receptors protect human skin from ultraviolet-B-light-induced inflammation. *J of Investigative Dermatology.* 2001;117(6):1430-1436. **3.** Bikowski J. Understanding the structure, function, and strategies for repair of the epidermal barrier. *Practical Dermatology.* 2009; May:17-18. **4.** Data on File. South Plainfield, NJ: PuraCap Pharmaceutical, LLC; 2013. **5.** Kircik L, Hougeir F, Bikowski J. Barrier dysregulation, atopic dermatitis, and the role for a ceramide-dominant, physiologic lipid-based barrier repair emulsion. *J Drugs Dermatol.* 2013;12(9):611-614.

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Instructions for Use
Apply in a thin layer to the affected skin areas two times per day (or as needed) and massage gently into the skin. If the skin is broken, cover EpiCeram® Controlled Release Skin Barrier Emulsion with a dressing of choice.

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Aesthetic trends among teens

Lisette Hilton | Staff Correspondent

TEENS MAY represent only a small percentage of cosmetic patients at dermatologists', cosmetic and plastic surgeons' offices, but they are by no means simple cosmetic cases. Often driven by hormones, social pressure, short-term desires and the belief they're invincible, teens tend to be challenging patients for physicians who are trying to help, not harm.


Dr. Diller

"Adolescents are actually most similar to perimenopausal women in certain ways because of their fluctuating hormones," says Vivian Diller, Ph.D., a psychologist in New York City who works with adolescents and does research on the psychology of beauty and aging. "I often will talk to those women (mid-lifers), reminding them that this is a phase of their life, probably most similar to adolescence because so much is in transition. Plastic surgery is one of the things the aging woman has turned to, to try to stop time. For adolescents, it's actually one of the ways they want to control the changes they are experiencing."

QUICK READ

Thorough consultations are critical when assessing teenage patients seeking aesthetic procedures, experts say.

Adolescents are strongly influenced by unsettling internal and external change, including raging hormones, according to Dr. Diller.

"As a dermatologist or plastic surgeon, you have to consider not just what you see, but what's going on inside the adolescent," she says.

Demand for cosmetic procedures is on an upward trend, in general, but not among teens.

The American Society for Aesthetic Plastic Surgery (ASAPS) released its 2013 multispecialty statistics (including plastic surgeons, dermatologists and otolaryngologists) in the United States and reported a 12 percent overall increase in cosmetic procedures. In 2013, Americans spent the most on cosmetic procedures since the recession in 2008.

In the same year, cosmetic procedures among patients ages 18 and younger reached a low, at 1 percent of total surgical and nonsurgical procedures. The 113,924 procedures in this age group, according to the 2013 ASAPS Cosmetic Surgery National Data Bank Statistics, is a far cry from the 220,000 aesthetic procedures 18-and-unders had in 2002.


Dr. Welch

The most recent statistics suggest the top nonsurgical procedures among teens are: hair removal, chemical peels and microdermabrasion. The most popular surgical procedures in the younger set are ear surgery, nose surgery and breast revision (not augmentation, which registered as zero procedures in 2013 among patients ages 18 and under).

Michelle Welch, M.D., a dermatologist practicing in Lexington, S.C., says she sees a lot of teenagers.

"I think for the majority of teenagers, they are concerned with their facial skin (acne, bumps, acne scars). I

TRENDS see page **43**

Quotable

"I'd advise any physician to give the family and teen an honest answer and describe their reservations about proceeding with the aesthetic intervention."

Gia Washington, Ph.D.
Houston

On how to say no
See story, page 44

DTExtra

A nonablative fractional laser improves the appearance of mature burn scars, according to investigators with the University of Copenhagen, Denmark. Researchers evaluated the clinical and histological long-term outcome of the 1,540 nm fractional Er:Glass laser on superficial and deep components of mature burn scars. Scar appearance in scars treated with the laser improved (P=0.001 versus untreated) and histology at six months supported collagen remodeling.

READ MORE: BIT.LY/NONABLATIVELASERSTUDY

TRENDS:

Experts discuss teenage patient requests for aesthetic procedures from page 36

would say (I see) a majority of female versus male patients. But we're having an increase in the amount of male patients," Dr. Welch says.

Very rarely will Dr. Welch get a teen who is requesting something she thinks of as an "adult" procedure, such as Botox (onabotulinumtoxinA, Allergan) injections for wrinkles.

"I've had a few ask for that and, to be honest, I was floored. A beautiful young person, no. (She) doesn't need something like that," Dr. Welch says.

John M. Hilinski, M.D., a facial plastic surgeon in San Diego, says his cosmetic teen patients typically request nose reshaping or cosmetic ear surgery.

"Rhinoplasty is hands-down one of the most popular that we're seeing in the late teen patients coming out of high school — mostly, in seniors going off to college who want to have their noses redone before going off to a new environment," Dr. Hilinski says.

And while cosmetic ear surgeries come in a close second, it's not only ear pinning that Dr. Hilinski says is popular among people in the younger set.

"In the last couple of years, I've been doing a lot of gauge repairs," he says.

Gauge repairs are an emerging need among teens who want or need to repair earlobes damaged by the big holes, according to Dr. Hilinski. He says teens do their research to find physicians like him, who have developed a reputation for restoring natural-looking lobes.

"You can do gauge repairs and, if you're not very good at it, you can make the lobes ... look like an earlobe, but not really. If you really want to do it right, and you finesse it, and you do a lot of them, you learn how to make a natural looking earlobe," Dr. Hilinski says. **DT**

3 tips for evaluating teens for aesthetic treatment

1 ASSESS PHYSICAL MATURITY **Operating on a feature that has not yet fully developed could interfere with its growth, and continued growth could negate the benefits of surgery in later years, according to the American Society of Aesthetic Plastic Surgery (ASAPS).**

2 EXPLORE EMOTIONAL MATURITY AND EXPECTATIONS **As with any patient, the young person should appreciate the benefits and limitations of the proposed surgery, and have realistic expectations, according to ASAPS.**

3 EDUCATE, EDUCATE, EDUCATE **Teens and their parents should understand the risks of surgery, postoperative restrictions on activity, and typical recovery times, according to ASAPS. Adolescents should fully understand how invasive a procedure is (by use of visual models, graphics, etc.) and have a good understanding of what type of procedure may be reversible, according to Gia Washington, Ph.D., a clinical psychologist at Texas Children's Hospital and assistant professor at Baylor College of Medicine, Houston.**

What's right, wrong among aesthetics for teens?

Lisette Hilton | Staff Correspondent

WHAT'S RIGHT and wrong in terms of cosmetic procedures for teens is not black and white, experts say. There are no formal guidelines to determine whether a teen should have a cosmetic procedure. So, often, it's left up to the discretion of the physician consulting with the patient.

"Most would agree that any aesthetic procedure with a negative or unexpected outcome could potentially be damaging to an adolescent's self-esteem or body image," says Gia Washington, Ph.D., a clinical psychologist at Texas Children's Hospital and assistant professor at Baylor College of Medicine, Houston. "Certainly a reconstructive surgery (breast, facial, removal of excess skin after excessive weight loss) would be considered acceptable and safe for an adolescent's emotional development."


Dr. Washington

While Michelle Welch, M.D., a dermatologist practicing in Lexington, S.C., says it is her personal opinion that Botox (onabotulinumtoxinA, Allergan), facial fillers and lip augmentation are among the cosmetic procedures that are inappropriate for teens, it may be important to address physical scars from a major trauma. And some skin conditions need to be cosmetically addressed. For example, Dr. Welch says, she strives to help patients with acne feel better about themselves.

"You can imagine, if people make fun of (kids with acne), or they feel like people are going to make fun of them. I've had kids come in and say so-and-so didn't want to be their boyfriend because they had pimples all over their face," Dr. Welch says.

Among the procedures she uses to smooth skin damaged from acne: microdermabrasion and light chemical peels.

"Microdermabrasion is a wonderful treatment to help slough off those surface layers and help open their pores. Products can get in the skin better," she says. "There are some chemical peels that are very light and very mild that may help them if they have a lot of redness. And if they already have scarring and you're trying to improve their skin, there are some (light chemical peels) that would be beneficial for teenagers, but not the deep, invasive chemical peels that older people might get."

Some procedures seem perfectly reasonable for some kids, but not for others.

Even age itself isn't always a good indicator whether a cosmetic procedure is appropriate for a teen, according to Vivian Diller, Ph.D., a psychologist based in New York City.

"You have to look at the maturity of the patient that you're talking to," Dr. Diller says. "You can find a 16-year-old who is extremely mature, who has been thinking about a particular feature they want to change; has done their research; is thinking for themselves. Then, you find a 50-year-old who is being highly influenced by someone other than themselves (it could be a mate, a parent, a movie star). Really, I tell physicians to think less about chronological age and more about maturity."

The trick for physicians and surgeons consulting with these patients is to be objective; not judgmental, Dr. Diller says.

"When an adolescent approaches you about wanting surgery, they're suffering a great deal. I've had the experience of talking to an adolescent who has been bullied or who has required reconstructive surgery as a result of an accident or injury. And to judge that young person that they're too young for that surgery, I think is unfair to them," Dr. Diller says. "I'd rather talk to them in great depth about how they're thinking about it."

For example, Dr. Diller says, a teenager who wants Botox for wrinkles isn't appropriate in most cases — unless that teen is under the spotlight, in the media, or whose income may depend upon maintaining a certain look, perhaps. Breast surgery is another example. Adolescents' bodies are changing and they're still evolving mentally and socially. Breast augmentation during the teen years is a clear red flag. Breast surgery to correct uneven breasts, however, might be a different story.

"To provide that kind of normalization can sometimes truly help a child going into adulthood feel much more confident about themselves," Dr. Diller says. **DT**

Teens & cosmetic procedures: How to say 'no'

HONESTY IS THE BEST policy when consulting with a teen about whether you will perform a cosmetic procedure, according to Gia Washington, Ph.D., a clinical psychologist at Texas Children's Hospital and assistant professor at Baylor College of Medicine, Houston.

"I'd advise any physician to give the family and teen an honest answer and describe their reservations about proceeding with the aesthetic intervention," Dr. Washington says. "Most adolescents and families would be receptive to a physician saying something like, 'I'm not advising this procedure now because of the risks, your age, expected changes in your body, etc. Consider revisiting this in a few years in your 20s. If it's still really important to you then, we can meet again.'"

When patients have what doctors think might be a mental illness, a firm "no," an explanation about why and a referral to a mental health professional can be what's most appropriate. However, if a physician thinks a cosmetic procedure might be appropriate for a teen but isn't sure, a "Let's think about this a little longer" approach could be the answer. Vivian Diller, Ph.D., a psychologist in New York City who works with adolescents and does research on the psychology of beauty and aging, suggests saying the patient should come back in a month, maybe two.

"Giving an adolescent time to think about it, will give the doctor a clear idea how important it is to this patient. It will give them an idea about whether this patient has done research. It will give the doctor a greater clarity whether this is just a passing fantasy," Dr. Diller says. "The doctor needs to say, 'I want you to be happy. I don't want you to do something that will make you unhappy. That's why I'm sending you home. I know that if I send you home and you come back in a month or two, there's a greater likelihood that you will be satisfied with the results.'" **DT**

For more on when cosmetic treatments may be appropriate in the adolescent population, read our online tips: "Reasons to say 'yes' to cosmetic surgery":
bit.ly/teencosmeticsurgery

"Rhinoplasty for teens":
bit.ly/teenrhinoplasty

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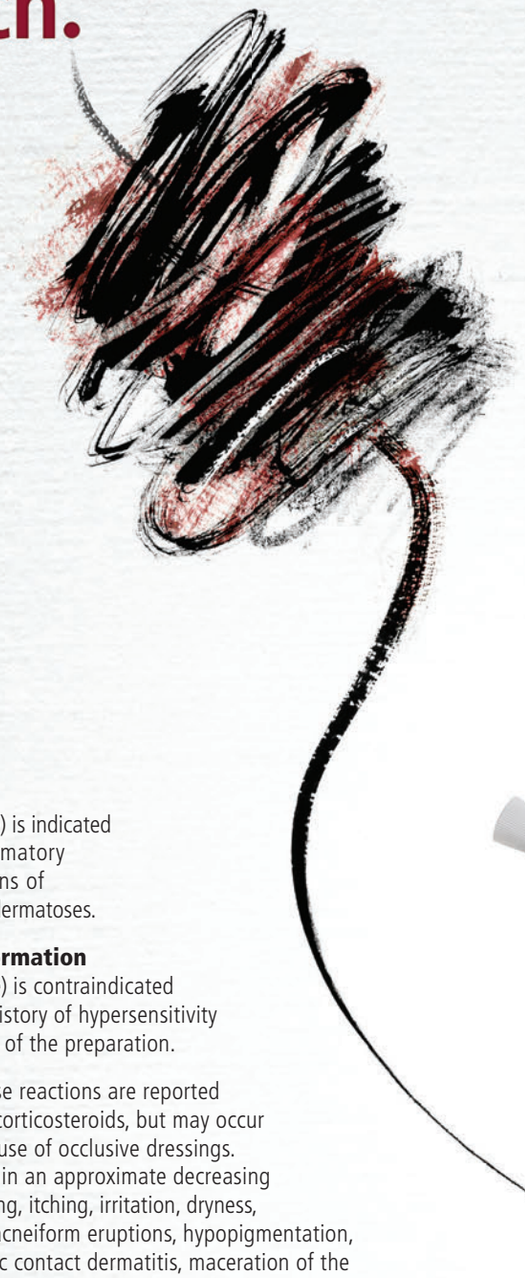

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Pediatric patients may demonstrate greater susceptibility to topical corticosteroid-induced HPA axis suppression and Cushing's syndrome than mature patients because of a larger skin surface area to body weight ratio.

Hypothalamic-pituitary-adrenal (HPA) axis suppression, Cushing's syndrome, and intracranial hypertension have been reported in pediatric patients receiving topical corticosteroids. Administration of topical corticosteroids to pediatric patients should be limited to the least amount compatible with an effective therapeutic regimen. Chronic corticosteroid therapy may interfere with the growth and development of pediatric patients.

References: 1. Topicort® Cream 0.05% Prescribing Information. Taro Pharmaceuticals U.S.A., Inc. **2.** Topicort® Ointment 0.05% Prescribing Information. Taro Pharmaceuticals U.S.A., Inc.

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PRECAUTIONS
General
Systemic absorption of topical corticosteroids can produce reversible hypothalamic-pituitary-adrenal (HPA) axis suppression with the potential for clinical glucocorticosteroid insufficiency. This may occur during treatment or upon withdrawal of the topical corticosteroid.

Because of the potential for systemic absorption, use of topical corticosteroids may require that patients be periodically evaluated for HPA axis suppression. Factors that predispose a patient using a topical corticosteroid to HPA axis suppression include the use of more potent steroids, use over large surface areas, use over prolonged periods, use under occlusion, use on an altered skin barrier, and use in patients with liver failure.

An ACTH stimulation test may be helpful in evaluating patients for HPA axis suppression. If HPA axis suppression is documented, an attempt should be made to gradually withdraw the drug, to reduce the frequency of application, or to substitute a less potent steroid. Manifestations of adrenal insufficiency may require supplemental systemic corticosteroids. Recovery of HPA axis function is generally prompt and complete upon discontinuation of topical corticosteroids.

Cushing's syndrome, hyperglycemia, and unmasking of latent diabetes mellitus can also result from systemic absorption of topical corticosteroids.

Use of more than one corticosteroid-containing product at the same time may increase the total systemic corticosteroid exposure.

Pediatric patients may be more susceptible to systemic toxicity from use of topical corticosteroids.

Local Adverse Reactions with Topical Corticosteroids
Local adverse reactions may be more likely to occur with occlusive use, prolonged use or use of higher potency corticosteroids. Reactions may include atrophy, striae, telangiectasias, burning, itching, irritation, dryness, folliculitis, acneiform eruptions, hypopigmentation, perioral dermatitis, allergic contact dermatitis, secondary infection, and miliaria. Some local adverse reactions may be irreversible.

Allergic Contact Dermatitis with Topical Corticosteroids
Allergic contact dermatitis to any component of topical corticosteroids is usually diagnosed by a failure to heal rather than a clinical exacerbation. Clinical diagnosis of allergic contact dermatitis can be confirmed by patch testing.

Concomitant Skin Infections
Concomitant skin infections should be treated with an appropriate antimicrobial agent. If the infection persists, Topicort® (desoximetasone cream USP) 0.05% or Topicort® (desoximetasone ointment USP) 0.05% should be discontinued until the infection has been adequately treated.

Information for the Patient
Patients using topical corticosteroids should receive the following information and instructions:
1. This medication is to be used as directed by the physician. It is for external use only. Avoid contact with the eyes.
2. Patients should be advised not to use this medication for any disorder other than for which it was prescribed.
3. The treated skin area should not be bandaged or otherwise covered or 4. wrapped as to be occlusive unless directed by the physician.
4. Patients should report any signs of local adverse reactions, especially under occlusive dressings.
5. Other corticosteroid-containing products should not be used with Topicort® (desoximetasone cream USP) 0.05% or Topicort® (desoximetasone ointment USP) 0.05% without first consulting with the physician.

As with other corticosteroids, therapy should be discontinued when control is achieved. If no improvement is seen within 4 weeks, contact the physician.

Laboratory Tests
The following tests may be helpful in evaluating the hypothalamic-pituitary-adrenal (HPA) axis suppression:
Urinary free cortisol test
ACTH stimulation test

Carcinogenesis, Mutagenesis, and Impairment of Fertility
Long-term animal studies have not been performed to evaluate the carcinogenic potential or the effect on fertility of topical corticosteroids.
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Corticosteroids have been shown to be teratogenic in laboratory animals when administered systemically at relatively low dosage levels. Some corticosteroids have been shown to be teratogenic after dermal application in laboratory animals. Desoximetasone has been shown to be teratogenic and embryotoxic in mice, rats, and rabbits when given by subcutaneous or dermal routes of administration in doses 15 to 150 times the human dose of Topicort® (desoximetasone cream USP) 0.05%, or Topicort® (desoximetasone ointment USP) 0.05%.

There are no adequate and well-controlled studies in pregnant women on teratogenic effects from topically applied corticosteroids. Therefore, Topicort® (desoximetasone cream USP) 0.05% or Topicort® (desoximetasone ointment USP) 0.05% should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. Drugs of this class should not be used extensively on pregnant patients, in large amounts, or for prolonged periods of time.

Nursing Mothers
It is not known whether topical administration of corticosteroids could result in sufficient systemic absorption to produce detectable quantities in breast milk. Systemically administered corticosteroids are secreted into breast milk in quantities not likely to have a deleterious effect on the infant. Nevertheless, caution should be exercised when topical corticosteroids are administered to a nursing woman.

Pediatric Use
Pediatric patients may demonstrate greater susceptibility to topical corticosteroid-induced HPA axis suppression and Cushing's syndrome than mature patients because of a larger skin surface area to body weight ratio.
Hypothalamic-pituitary-adrenal (HPA) axis suppression, Cushing's syndrome, and intracranial hypertension have been reported in pediatric patients receiving topical corticosteroids. Manifestations of adrenal suppression in pediatric patients include linear growth retardation, delayed weight gain, low plasma cortisol levels, and absence of response to ACTH stimulation. Manifestations of intracranial hypertension include bulging fontanelles, headaches, and bilateral papilledema.
Administration of topical corticosteroids to pediatric patients should be limited to the least amount compatible with an effective therapeutic regimen. Chronic corticosteroid therapy may interfere with the growth and development of pediatric patients.

ADVERSE REACTIONS
The following local adverse reactions are reported infrequently with topical corticosteroids, but may occur more frequently with the use of occlusive dressings. These reactions are listed in an approximate decreasing order of occurrence:

Burning, itching, irritation, dryness, folliculitis, hypertrichosis, acneiform eruptions, hypopigmentation, perioral dermatitis, allergic contact dermatitis, maceration of the skin, secondary infection, skin atrophy, striae, and miliaria.

In controlled clinical studies the incidence of adverse reactions were low (0.8%) for Topicort® (desoximetasone cream USP) 0.05% and included pruritus, erythema, vesiculation, and burning sensation. The incidence of adverse reactions was low (0.2%) for Topicort® (desoximetasone ointment USP) 0.05% and included mild burning sensation at the site of application.

OVERDOSAGE
Topically applied corticosteroids can be absorbed in sufficient amounts to produce systemic effects (see **PRECAUTIONS**).

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Issued: April 2014

Psychology tips when consulting with teens

Lisette Hilton | Staff Correspondent

THE TEEN YEARS are a time of mental and physical development according to Gia Washington, Ph.D., a clinical psychologist at Texas Children's Hospital and assistant professor at Baylor College of Medicine, Houston.


Dr. Washington

"Dermatologists and surgeons should be aware of the stages of adolescent cognitive development," Dr. Washington says. Most adolescents between the ages of 15 and 19 can think abstractly and consider hypothetical situations, therefore they are likely able to understand how the particular procedure affects most people.

"However, many adolescents may still be in the concrete operational stage and be so concrete in their thinking about the outcome of the aesthetic intervention, they would be unable to adequately understand the risks and benefits of the intervention and identify a realistic expectation about the outcome," Dr. Washington says.


Dr. Diller

Issues that might seem minor to adults are magnified to an adolescent based upon the perception that everyone notices their aesthetic issue, Dr. Washington says.

"Adolescents may believe that the guidelines for recovery or treatment don't apply to them. … They often perceive themselves as being impervious, invulnerable and invincible," Dr. Washington says. "For this reason, physicians may often see adolescents not adhering to their recommendations for follow-up care and maintenance."


Dr. Welch

When it comes to assessing teen patients, Michelle Welch, M.D., a dermatologist practicing in Lexington, S.C., says she is on alert for patients of all ages who show signs of body dysmorphic disorder. John M. Hilinski, M.D., a facial plastic surgeon in San Diego, says he asks adults and teens similar questions during consultations. One of the most important questions, he says, is what motivates them to have surgery.

"If something comes up that hints at a body dysmorphic disorder, then I will not (go forward)," Dr. Hilinski says.

Asking the right questions can help a physician determine whether a teen patient should have a cosmetic procedure, wait or would be better off seeing a psychologist or other mental health expert.

"Not every patient needs to be referred to a psychologist," says Vivian Diller, Ph.D., a psychologist based in New York City. "(But) there are key things that you want to look for that you say to yourself as a doctor, 'I think you should talk to a counselor.'" For example, when you think you have a patient who might have body dysmorphic disorder, bipolar, depression, addiction or an eating disorder.

This is especially important during adolescence. All adolescents tend to be emotionally labile. "It's really important to distinguish between the adolescent who has low self-esteem versus the adolescent who is suicidal," she says.

It could help to ask patients to write out their reasons for requesting the aesthetic intervention and explain their expectations for the results, Dr. Washington says.

Dr. Welch says she uses the consultation to not only assess patients and educate, but also to emphasize what's positive about patients' features and overall beauty.

"If we push cosmetic (procedures) on young people who may be insecure, I think we run the risk of making those young people insecure in other aspects of their life or in their beauty," Dr. Welch says.

It's important that teens know that the near-perfection they see online and in magazines is altered to look that way, Diller says. **DT**

Acne guidelines aim to improve patient care

Cheryl Guttman Krader | Staff Correspondent

MAUI, HAWAII — Guidelines for the diagnosis and treatment of pediatric acne developed by the American Acne Rosacea Society (AARS) and endorsed by the American Academy of Pediatrics (AAP) provide the AAP with its first-ever evidence-based guidelines for the management of this very common pediatric condition.

Released in May 2013, the guidelines present an age-based categorization of acne and a set of severity-based treatment algorithms, says Lawrence F. Eichenfield, M.D. He is president of the AARS and co-chaired the panel that developed the guidelines. He spoke to the impetus for the project and highlighted some of the key recommendations at the Maui-Derm 2014 meeting.

Dr. Eichenfield

"The onset of acne is occurring earlier now than in the past, and one goal of the guidelines was to get physicians to recognize that early significant acne is a predictor of worse acne over time. In addition, numerous articles have identified a huge gap, essentially a chasm, between the way dermatologists and pediatricians manage children and teens with acne," says Dr. Eichenfield, professor of pediatrics and dermatology, University of California, San Diego, and Rady Children's Hospital.

DIAGNOSTIC ISSUES

The age-based categorization divides acne type into neonatal, infantile, mid-childhood, preadolescent and adolescent acne. Dr. Eichenfield points out that neonatal acne usually represents some non-acne pustular eruption whereas acne in infants tends to be a true acneiform condition. Acne during the mid-childhood years, ages 1 to <7 years, is a condition that should raise concern about an underlying endocrinologic cause.

"Acne in a child this age, even when it appears mild, is worrisome because it may be a sign of hyperandrogenism associated with Cushing syndrome, premature adrenarche, congenital adrenal hyperplasia, or adrenal tumors," Dr. Eichenfield says.

"The guidelines recommend that children with mid-childhood acne be referred for evaluation by a pediatric endocrinologist."

Preadolescent acne, with onset between ages 7 and 12 or prior to menarche in girls, is now very common, and unless there are other findings to suggest an endocrine-related or other systemic problem, there is no need for these children to undergo work-up beyond history and physical.

"Acne can precede other signs of pubertal maturization, and we know that the average age of puberty is now about one year younger than it was a decade ago for both males and females," Dr. Eichenfield says.

QUICK READ

New guidelines on diagnosis and treatment of pediatric acne feature severity-based treatment algorithms and aim to improve acne patient care.

OPTIMIZED REGIMENS OF CARE

Severity-based treatment algorithms represent the crux of the guidelines. Adherence to the recommendations should eliminate important practice gaps that include low retinoid prescribing rates with over-reliance on antibiotics as monotherapy.

"One goal is to be able to successfully maintain patients on topical treatment with a retinoid alone or in combination with a topical antimicrobial, even in moderate patients who may use oral antibiotic for a few months. Therefore, one should not be treating acne using an oral antibiotic alone," Dr. Eichenfield says.

He notes the guidelines also emphasize the use of a topical retinoid alone or in combination for all severities of acne in pediatric patients of all ages, even though per the prescribing information for individual products, use in children younger than ages 9 or 12 years is off-label. In addition, they make benzoyl peroxide a priority in regimens of care.

"Benzoyl peroxide should be prescribed whenever using a topical or oral antibiotic to decrease the development of bacterial resistance," he says.

Highlighting some of the key points within the individual algorithms, Dr. Eichenfield notes that as a departure from prior acne guidelines, the AARS guideline recommends that benzoyl peroxide may be considered as initial monotherapy for mild acne. Other options for initial treatment include a topical retinoid alone or topical combinations including benzoyl peroxide with an antibiotic and/or retinoid. Topical dapsone is also identified as a monotherapy option or to be used in place of a topical antibiotic, although topical antibiotics are not recommended as monotherapy.

MODERATE ACNE THERAPIES

Treatment for moderate acne is initiated with a combination regimen that should always include a topical retinoid and benzoyl peroxide with an oral or topical antibiotic. Again, topical dapsone can be substituted for a topical antibiotic.

"Oral antibiotics are reasonable for treating moderate or worse inflammatory acne at any age, and the guidelines note that second generation tetracyclines are sometimes preferred based on absorption and dosing frequency. However, tetracyclines should not be used in children younger than 8 years of age," Dr. Eichenfield says.

The treatment regimen can be modified for inadequate responders by altering the topical components or substituting an oral antibiotic for a topical agent. If there is still insufficient control, the guidelines recommend considering hormonal therapy for females or oral isotretinoin along with dermatology referral. Consideration of referral to a dermatologist is also recommended for any patient with severe acne.

Dr. Eichenfield notes there is controversy on the appropriate age for initiating hormonal therapy. The group's consensus recommendation was that a combined oral contraceptive (OC) can be used as second-line therapy for pubertal females with moderate-to-severe acne and note the need to assess tobacco use and family history of thrombotic events. It is also noted that due to concerns about potential effects on bone, some experts recommend withholding OCs to treat acne in girls until they are at least one year past onset of menstruation. **DT**

Disclosures: Dr. Eichenfield is a clinical investigator for and past consultant to companies that market products for treatment of acne.

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Reference: BENSAL HP [prescribing information]. Easley, SC: 7 Oaks Pharmaceutical Corp; 2010.

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Bensal HP® Ointment should be applied twice a day for best results.

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Microorganism	QRB-7	Microorganism	QRB-7
Microorganism	*Parts Per Million*	*Microorganism*	*Parts Per Million*
Staphylococcus aureus, ATCC 6538	25,000	Pseudomonas stutzeri, ATCC 17588	50,000
Salmonella choleraesuis, ATCC 10708	25,000	Salmonella typhi, ATCC 6539	12,500
*Enterococcus faecalis, ATCC 19433	50,000	Enterobacter aerogenes, ATCC 15038	25,000
Pseudomonas cepacia, ATCC 10856	3,125	Group D enterococcus	50,000
Staphylococcus epidermidis, ATCC 17917	12,500	Trichophyton mentagrophytes CDC y68+	50,000
Alcaligenes faecalis, ATCC 8750	25,000	Rhodotorula rubra HTB Isolate	50,000
Streptococcus uberis ATCC 27958	12,500	Enterobacter cloacae, Hosp/Envi isolate	25,000
Escherichia coli, ATC 25922	25,000	Escherichia coli, Hosp/Envi isolate	25,000
Klebsiella pneumoniae, ATCC 13883	25,000	Pseudomonas cepacia, Hosp/Envi isolate	25,000
Pseudomonas aeruginosa, ATCC 10145	25,000	Klebsiella pneumoniae, Hosp/Envi isolate	25,000
Shigella flexneri type 1A ATTC 9199	12,500	Staphylococcus aureus, Hosp/Envi isolate	50,000
Pseudomonas paucimobilis, ATCC 29837	1,563	Acinetobacter calcoaceticus, ATCC 17961	25,000
Streptococcus sanguis, ATCC 10556	12,500	Alcaligenes faecalis, ATCC 337	25,000
Acinetobacter lewoffii, ATCC 9957	25,000	Enterobacter cloacae, ATCC 23355	25,000
Pseudomonas putida, HTB Isolate	6,250	Achromobacter xylosoxidans, HTB isolate	25,000
Aeromonas sobria, ATCC 9071	25,000	Salmonella typhi, ATCC 19430	25,000
Staphylococcus hominus, ATCC 27844	12,500	Listeria monocytogenes, ATCC 15313	12,500
Staphylococcus haemolyticus, ATCC 29970	25,000	Serratia marcesans, ATCC 14756	25,000
Staphylococcus saprophyticus, ATCC 15305	25,000	Serratia marcesans, ATCC 13880	25,000
Staphylococcus simulans, ATCC 27848	25,000	Candida albicans, ATCC 10231	12,500
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Streptococcus agalactiae ATCC 13813	12,500	Salmonella enteritidis, ATCC 13076	25,000
Streptococcus equisimilis ATCC 9542	12,500	Escherichia coli, ATCC 11229	25,000
Pseudomonas alcaligenes, ATCC 14909	25,000	Proteus mirabilis, ATCC 9240	25,000
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Experts clarify verrucous hemangioma confusion

Louise Gagnon | Staff Correspondent

QUEBEC CITY, QUEBEC — The diagnosis of angiokeratoma circumscriptum should be supplanted with verrucous hemangioma, and the lesion should be treated with surgery in most cases, according to a retrospective case series presented at the annual meeting of the Canadian Dermatology Association.

"The reason we undertook this study is that there was confusion about what was an angiokeratoma, which could be better treated with laser, and the verrucous hemangioma, which could be better treated with surgery," says Catherine McCuaig, M.D., F.R.C.P.C., a pediatric dermatologist at CHU Sainte-Justine in Montreal, and an associate professor of dermatology and pediatrics at the University of Montreal.

The series included 20 cases, which had been referred to the tertiary care institution. All of the lesions in the series were biopsied, and the mean age of the patients was 4.1 years old. The lesions were located mainly on the lower extremities, in some cases on the forearms, and on the abdomen.

20 CASES All of the lesions in the series were biopsied, and the mean age of the patients was 4.1 years old

QUICK READ

The diagnosis of angiokeratoma circumscriptum should be supplanted with verrucous hemangioma, and the lesion should be treated with surgery in many cases, according to an expert.

DEFINING DISTINCTIONS

The two lesions have very similar clinical presentation, but Dr. McCuaig drew several distinctions between angiokermatomas and verrucous hemangiomas. Verrucous hemangiomas are always congenital, well-circumscribed, and thicken with time. There is often oozing and/or bleeding present. Their incidence is very rare.

By contrast, angiokeratomas are acquired dermatoses that are smaller, superficial and occasionally bleed. They can feature superficial, crusted papules.

"Verrucous hemangioma is always congenital while the angiokeratoma, for the most part, is quiet and often overlies another vascular formation, primarily a lymphatic malformation," says Dr. McCuaig, adding that a histopathological examination should be performed to confirm the diagnosis of verrucous hemangioma. "We think the term angiokeratoma circumscriptum should be let go."

There are no guidelines outlining the most efficacious treatment for verrucous hemangiomas, Dr. McCuaig says.

Another difference between the two types of lesions is their depth: angiokeratomas only involve the papillary dermis while with verrucous hemangiomas, the blood vessels extend into the dermis and subcutaneous fat. This difference between the two entities underlines the need for a biopsy of sufficient depth, for a biopsy that consists of a superficial tissue sample can result in an incorrect diagnosis.[1]

TREATMENT OPTIONS

Surgery effectively treats the verrucous hemangioma with no recurrence and patients satisfaction. When the surface area of a verrucous hemangioma is extensive and it is too large to resect, laser therapy should be the management choice. Not all lasers are effective in managing these hemangiomas, Dr. McCuaig says.

A pulsed dye laser eliminates keratotic papules, but the overall improvement in treating verrucous hemangiomas is somewhat limited, according to Dr. McCuaig.

"If you are trying to palliate a verrucous hemangioma, and you use a pulsed dye laser, it doesn't go particularly deep, and the treatment might not be definitive," she says. "Some patients (in this series), were satisfied enough with the pulsed dye laser because it stopped the bleeding. These were hemangiomas that were too big to excise."

The CO_2 laser, while effective in treating an angiokeratoma, did not effectively treat verrucous hemangiomas, Dr. McCuaig says. With one of the patients in the series, there was clearance of the lesion followed by recurrence of the hemangioma one month after treatment with the CO_2 laser. Although it is not their own clinical practice, Dr. McCuaig points to experience in the published literature that demonstrates efficacy with the Nd:YAG laser to manage larger verrucous hemangiomas.[2]

A pulsed dye **laser eliminates keratotic papules**, but the overall improvement in **treating verrucous hemangiomas is somewhat limited.**

"In some ways, we are reporting negative results for us (clinicians) all to better learn," she says. "The surgical approach would have been better from the beginning (in the case where there was recurrence). Choosing the laser route, the Nd:YAG laser is preferred. You need to know full well that there can be significant scarring (after laser treatment)."

Complications such as bleeding, pain and infection arise with either surgical or laser treatment.

"Complications are inherent to any surgery or the use of a laser," Dr. McCuaig says. **DT**

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1. Pavithra S, Mallya H, Kini H, Pai GS. *Indian J Dermatol.* 2011;56(5):599-600
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Dermatology Times

Incidence of pediatric melanoma on the rise

Louise Gagnon | Staff Correspondent

BANFF, ALBERTA — Clinicians have to consider actions to avoid the potential for mortality if melanoma is suspected in pediatric cases, and they should be cognizant that pediatric melanoma cases represent a very heterogeneous group of patients, according to the chairman of the department of cutaneous oncology at the Moffitt Cancer Center, Tampa, Florida.

"There are a growing number of children, some as young as 4, who have melanomas that seem to behave and seem to be identifiably different than what we are used to with adults," says Vernon Sondak, M.D., a surgical oncologist, discussing pediatric melanoma here at the 8th Canadian Melanoma Conference.

But melanoma that occurs in individuals in late adolescence appears more similar to melanoma that occurs in adults, Dr. Sondak says.

The incidence of melanoma is going up in children, especially teenagers, and clinicians such as Dr. Sondak believe the use of tanning beds is implicated in this rising incidence. "The rise (in melanoma) is greater in places that do not have high ultraviolet (exposure) versus areas of the U.S. where there is higher UV," Dr. Sondak says.

QUICK READ

If melanoma is in the differential diagnosis of a skin lesion in a pediatric patient, clinicians should remove the lesion and might also consider checking the sentinel lymph node.

RISING RATES OF MELANOMA

A study published last year found that, indeed, melanoma is occurring more often in children. The rate rose about 2 percent in newborns to age 19 from 1973 to 2009. The largest increase was amongst adolescents, ages 15 to 19, particularly girls. Investigators found living in northern latitudes, being female, and being age 15 to 19 were all linked to the greatest spikes in incidence (Wong JR, Harris JK, Rodriguez-Galindo C, Johnson KJ. *Pediatrics*. 2013;131(5):846-854).

The finding about living in more northern latitudes being associated with the largest increase was of special interest since it points a finger at artificial sources of UV radiation such as tanning beds rather than natural sources. While very rare, neonates can develop melanoma through placental transmission from a mother with widespread melanoma, Dr. Sondak says.

"It is extremely rare, but it can happen," he says. "Additionally, neonates who are born with a very large congenital 'bathing trunk nevus' can develop melanoma in the first year or two of life. Pediatricians now recognize that patients with a bathing trunk nevus are at high risk (of developing melanoma). These infants are watched more carefully, and the nevus removed surgically when appropriate."

Another observation by Dr. Sondak is that children ages 13 and under who have Fitzpatrick skin types IV, V and VI are being diagnosed with melanoma,

PEDIATRIC MELANOMA see page 55

Quotable

"This is a generation that doesn't trust marketing due to the fact that it has let them down in the past. They trust themselves and the 'crowd' opinion."

Joel Schlessinger, M.D.
Omaha, Neb.

On reaching young people
See story, page 56

DTExtra

The Food and Drug Administration has granted accelerated approval to pembrolizumab (Keytruda, Merck) for treatment of advanced or unresectable melanoma in patients who have stopped responding to other drugs. Keytruda is the sixth new melanoma treatment approved since 2011 and the first that blocks a cellular pathway known as PD-1, which restricts the immune system from attacking melanoma cells. For patients whose tumors express the BRAF V600 gene mutation, Keytruda is intended for use after treatment with ipilimumab and a BRAF inhibitor.

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Rash treatment can have long-term implications

Lisette Hilton | Staff Correspondent

A DERMATOLOGIST'S first instinct to relieve a pediatric patient's rash might be to try topical or oral treatments or address the skin manifestation's potential cause. But in a child undergoing cancer treatment, even a seemingly straightforward treatment or modification could have long-term health implications.

Melinda Chu, M.D., resident and clinical trials fellow in the department of dermatology at Saint Louis University, St. Louis, says dermatologists should be aware not only of the common cancers among children and how pediatric cancer treatment might result in skin conditions, but also of how treating the skin condition might impact cancer treatment and the child's long-term health.

CHILDREN AND CANCER

According to the American Cancer Society, the most common cancers among children are leukemias (which account for 31 percent of all cancers in children), brain (and other central nervous system tumors), neuroblastoma, Wilms tumor, Hodgkin or non-Hodgkin lymphoma, rhabdomyosarcoma, retinoblastoma and bone cancers (source: http://www.cancer.org/cancer/cancerinchildren/detailedguide/cancer-in-children-types-of-childhood-cancers).

"Because leukemia is the most common cancer in pediatric patients, stem cell transplants are performed in children more commonly than what might expect," Dr. Chu says.

In children, as well as adults, it's important for dermatologists to recognize that their input can alter cancer treatment regimens, she says.

"Some rashes can be impressive on presentation, but may not be life-threatening. So, I think it's important to distinguish that before dermatologists recommend altering treatments, especially in terms of affecting the chemo regimen as disrupting the chemo regimen has the potential to impact response and survival," Dr. Chu says.

Rashes might result from chemotherapy drugs.

"It is important to know the exact drugs that are part of a patients' cancer regimen to recognize common dermatologic side effects," she says.

Skin rash in pediatric cancer patient: A case in point

MELINDA CHU, M.D., St. Louis, points to an example of how looks can deceive when deciding whether to treat skin rashes in pediatric patients undergoing cancer treatment.

She saw a patient who presented with yellowish hyperkeratotic plaques — evidence of graft versus host disease (GVHD). The flaky rash covered the patient's face. GVHD often is considered life-threatening.

"However, there are different grades of GVHD. While it definitely can kill people with leukemia, oncologists can actually see a low-grade GVHD as a good thing," Dr. Chu says. "Low-grade GVHD means that the patient's immune system is active. And when there's graft versus host there's also graft versus leukemia going on."

Dr. Chu and colleagues considered aggressive treatment to get rid of the skin manifestation, but the rash wasn't bothering the patient. Medications to treat it would increase immunosuppression, which would have affected all of the patient's other defense systems and increase risk of infection.

Without therapy to treat the rash, the patient has improved but is not completely clear, according to Dr. Chu. **DT**

QUICK READ

Treating a rash in a pediatric patient undergoing cancer therapy can have long-term health implications.

For example, carboplatin (Paraplatin, Bristol-Myers Squibb) used in pediatric patients to treat low-grade glioma is known to cause skin reactions.

"Though we may be quick to ascribe any new rash to a chemotherapy or cancer treatment. Drug rashes are more likely caused by the common culprits of drug rashes — antibiotics — used to prevent opportunistic infections in these children's weakened immune systems," Dr. Chu says. "Even if there is a rash associated with medication, I would caution dermatologists from putting medications on pediatric patients' allergy lists, pending a full investigation."

Pediatric cancer patients might make several trips to the hospital. Before adding a medication, such as penicillin, to a patient's allergy list, dermatologists should think about the long-term therapeutic consequences. In particular, adding antibiotics, such as penicillin, to an allergy list may greatly limit antibiotic options as physicians may be hesitate to prescribe any penicillin or cephalosporin in the future, she says.

"There are definitely a few rashes that can be life-threatening, like Stevens-Johnson syndrome, toxic epidermal necrolysis (TEN) or drug rash with eosinophilia and systemic symptoms (DRESS). In general, the most common, which is the morbilliform drug eruption, is not life-threatening. But it can be really uncomfortable for the patient," Dr. Chu says.

It is important to recognize that a past history of rashes that are common in all children, like pityriasis rosea due to HHV-6 or "slapped cheeks" due to parvovirus, may have important future implications for pediatric patients with cancer.

RASH see page **56**

PEDIATRIC MELANOMA:

Childhood melanoma represents a challenge to pathologists from page 52

and clinicians don't have an explanation for the phenomenon. It is also clear that melanoma in younger children often fails to demonstrate the classic "ABCDs" that are associated with melanoma in adults. Pediatric melanomas seem to be more often amelanotic, nodular and even verrucous in appearance, Dr. Sondak says.

One possible explanation for the overall increase in cases is increased awareness. There has been a rise in pediatric patients having unusual moles biopsied, owing to this increased awareness.

"More of these moles are being biopsied, and more questionable lesions are being put in front of pathologists," he says.

'DIAGNOSTIC UNCERTAINTY'

Pediatric melanoma represents a challenge to pathologists, and pathologists often label suspected melanoma in children as atypical melanocytic neoplasms, he says.

"Pathologists often have difficulty in definitively diagnosing melanoma in a child such as 'atypical melanocytic neoplasms' or 'melanocytic tumor of uncertain biologic potential,'" Dr. Sondak says. "We have to understand it is a complex situation. There is a degree of diagnostic uncertainty about what the lesion is and how it will behave."

Given the potential for uncertainty about the prognosis of pediatric melanoma and atypical melanocytic neoplasms, clinicians need to consider making treatment decisions based on what are the worst-case scenarios, Dr. Sondak says.

"We have seen some of the atypical tumors, where the pathologist cannot make a definitive diagnosis, lead to widespread metastatic disease or even death," he says. "If we have an atypical skin lesion where melanoma that could potentially kill the child is in the differential diagnosis, then we will take precautions to deal with it that are basically the same as when a formal diagnosis of melanoma is rendered. That will mean removing the lesion with a margin of about 1 cm, and when appropriate, checking the sentinel lymph node."

In some cases where a sentinel lymph node biopsy is not performed, regional nodal ultrasound would be performed, and the child would continue to be followed, Dr. Sondak says.

If the sentinel lymph node is positive, management is generally identical to that for an adult with stage 3 melanoma. Management could include doing a complete lymph node dissection and/or giving the patient interferon, according to Dr. Sondak.

"Children tolerate interferon better than adults tolerate it," he says. "No one wants to over-treat, but the uncertainty (of a diagnosis) should be acknowledged and addressed head-on." **DT**

Disclosures: Dr. Sondak reports no relevant financial interests.

Study reveals teens' indifference to sunscreen, video may help educate

Bill Gillette | Staff Correspondent

A NEW STUDY reveals an alarming statistic about sunscreen : its use by young people has declined significantly.

According to research conducted by Corey H. Basch, Ed.D., an associate professor of public health at William Paterson University, Wayne, N.J., the number of young people who reported wearing sunscreen declined from 67.7 to 56.1 percent from 2001 to 2011. The study also found that there was little decline in the use of tanning devices among adolescents, and that the use of such devices was highest among white females (29.3 percent).

According to a news release, Dr. Basch's research focuses on health communication, cancer education and cancer screening. The release quotes her as saying, "This research suggests that adolescents continue to put themselves at risk for skin cancer. Future prevention efforts definitely need to be focused at young people."

"I totally am in agreement as to the study findings," Helen M. Torok, M.D., a dermatologist in Medina, Ohio, tells **Dermatology Times**. "I discuss sunscreen in patients over 30 about 80 percent of the time but fail to really educate the younger population. Thus, the fault lies with us, the dermatologists, for failing to stress the importance of photoprotection to our teenage acne patients. We have a captive audience when we are treating the younger population for acne, so we should take advantage of this opportunity and educate them."

This video, created by photographer/artist Thomas Leveritt, went viral on YouTube. The video is titled "How the Sun Sees You" and is hailed by science-news website redorbit.com as "the best argument ever in support of sunscreen."

Some dermatologists believe such efforts will be most effective if delivered via social media.

"This is a generation that doesn't trust marketing due to the fact that it has let them down in the past," says dermatologist Joel Schlessinger, M.D., Omaha, Nebraska. "They trust themselves and the 'crowd' opinion more than an ad or campaign. This works better than all the shouting, exhorting and pleading we can do as dermatologists."

An example is a video that went viral on YouTube. Created by photographer/artist Thomas Leveritt, the video is titled "How the Sun Sees You" and is hailed by science-news website redorbit.com as "the best argument ever in support of sunscreen."

"The video is a wonderful tool, and I would use it in my exam rooms as I am now installing TVs in all my exam rooms and will place leading stories for my patients," Dr. Torok says.

Dr. Schlessinger agrees. "This video is a great example of ways that we have to interact with teenagers and millennials," he says. "We won't get to them unless we do this, but as in the case of this video and the ALS Ice Bucket Challenge, it is possible to reach them, just not via normal — read old-style — marketing methods."

Dr. Basch's study appears in the August issue of the Centers for Disease Control and Prevention journal Preventing Chronic Disease. **DT**

RASH:

Consider long-term implications when treating rash in pediatric cancer patients

from page 54

"Usually when pityriasis rosea occurs in a healthy kid, we don't think of it as a problem or as having any future consequence," she says. "For patients with cancer, it is important to know about past rashes and viral exanthem. In these immunosuppressed patients, their new eruptions may be caused by viral reactivation."

In addition, there is increasing evidence that demonstrates that systemic symptoms of severe drug rashes such as DRESS may in some cases be related to reactivation of HHV-6 and EBV, Dr. Chu says.

WEIGHING TREATMENT OPTIONS

Treating rashes in pediatric cancer patients is complex. One example: traditional treatments for rashes in adults, such as prednisone or even antihistamines to help with itch, can result in side effects that mimic cancer progression.

"Prednisone can alter mood and make you irritable. But when that's a kid that it's happening to, it can be challenging for the kids and the parents and doctors to tell if the child is getting sicker or if it's a side effect of the medication. Antihistamines can make children really sleepy, which can be interpreted as a mental status change and could lead doctors to believe the disease is getting worse," Dr. Chu says.

Dermatologists can minimize complications, drug interactions or long-term consequences from skin treatments by knowing a child's cancer treatment regimen, including specific medications and time lines for treatment, according to Dr. Chu.

"Dermatologists should talk with other physicians on the team, including pediatric oncologists, about how the dermatologist's role would affect the management versus the patient's overall health," Dr. Chu says.

AFTER CANCER TREATMENT

The good news is children with cancer are living longer thanks to medical advances. The bad news is many of the medicines used to treat cancer have long-term side effects, including an increased risk for skin cancer.

The antifungal medication, voriconazole, for example, is known to increase risk of squamous cell carcinoma in adults. Recent research suggests it also increases skin cancer risk in children.

Dermatologists should keep this in mind when treating children who have been on voriconazole, and realize they might see a precancer or even skin cancer in a pediatric patient, Dr. Chu says. **DT**

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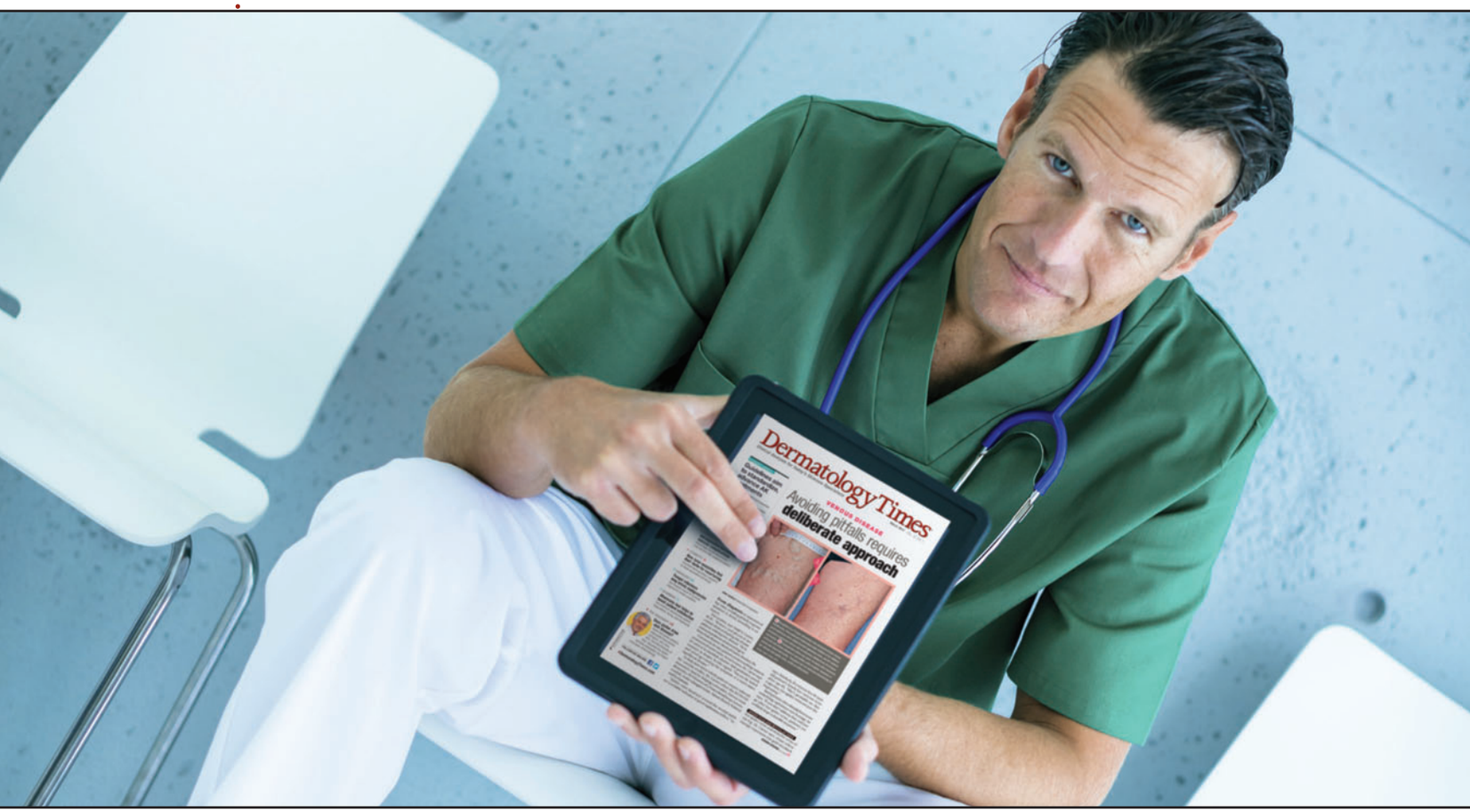

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voice of the dermatologist

"Though we may be quick to ascribe any new rash to a chemotherapy or cancer treatment. Drug rashes are more likely caused by the **common culprits of drug rashes — antibiotics —** used to prevent opportunistic infections in these children's weakened immune systems." Melinda Chu, M.D.
Saint Louis University, St. Louis

On the long-term implications of rash treatment in children undergoing cancer treatment. See PG 54

PEDIATRIC MELANOMA:

It is common for children to present atypically from page 1

histopathological complexity of these lesions contributed to the diagnostic delay, she says.

More than 90 percent of the younger patients had stage 2a disease or higher, compared to 46 percent of the older children.

INADEQUATE CRITERIA?

The conventional ABCD criteria (asymmetry, border irregularity, color variation and diameter >6 mm) were largely inadequate for detecting melanoma in especially younger children. The "E" for evolution proved to be the more sensitive indicator, according to Dr. Cordoro.

"The criterion of evolution was universally valuable, capturing nearly 100 percent of the entire cohort of pediatric melanomas. We must remain mindful of this as we interview and examine our patients. Though growth is a form of evolution, nevi in children are often changing with age and dermatologists are very good at recognizing these banal transitions," Dr. Cordoro says. "More important are new, persistent pink or red papules or nodules or pigmented nevi that have developed new symptoms such as itching, crusting or bleeding. The latter are warning signs, and warrant biopsy."

QUICK READ

Researchers have found that many children do not present with conventional ABCDE criteria. Their lesions tend to be characterized by amelanosis, bleeding bumps, uniform color, variable diameter, and *de novo* development. Dermatologists should be aware of the alternate presentations.

"In adults we generally think of melanoma as being a brown spot or coming from a mole, **but in children it can be a skin-colored lesion that bleeds a lot…**"

Melinda Chu, M.D.
St. Louis

The presentation of melanoma in children can mimic a benign pyogenic granuloma, according to Melinda Chu, M.D., resident and clinical trials fellow in the department of dermatology at Saint Louis University, St. Louis.

"In adults we generally think of melanoma as being a brown spot or coming from a mole, but in children it can be a skin-colored lesion that bleeds a lot that looks like a pyogenic granuloma," Dr. Chu says.

Still, the modified criteria are not meant to replace the conventional ABCDs because many children will still present with typical melanomas, according to Dr. Cordoro. Rather, A for amelanotic; B for bleeding, bump; C for color uniformity; and D for *de novo*, any diameter are meant to raise awareness and serve as a reminder of the alternate presentations of melanoma in children, she says. **DT**

Reference:
Cordoro KM, Gupta D, Frieden IJ, et al. *J Am Acad Dermatol.* 2013;68

The challenges of healthcare price transparency

Lisa Zamosky | Staff Correspondent

THE PUSH for greater price transparency in healthcare has become a movement. There is widespread belief that with access to information about the cost and quality of healthcare services, patients will be more cautious about their use of medical services and competition among healthcare providers will increase. But concerns remain about whether transparency can achieve its goals.

Transparency proponents say giving patients more information about cost will lead to lower costs and higher quality healthcare throughout the system. In fact, a recent analysis from the West Health Policy Center estimates that increasing price transparency in health care could save more than $100 billion over 10 years.

Historically, price information has been difficult for patients to come by, but now such information is increasingly available. Insurers and independent vendors offer tools that show patients average prices in their area. Groups such as Castlight Health provide employers with sophisticated technology allowing employees to view a range of price and quality information about local providers and to learn how much their care will cost based on personalized insurance information.

QUICK READ

A growing demand for improved access to cost information presents opportunities for practicing physicians

"What the users really want to know is how much they're going to pay out of pocket," says Jennifer Schneider, M.D., vice president of strategic analytics with Castlight Health.

While most price transparency tools available to patients today lack this level of sophistication, the raw data required to power them are being made available at rates never before seen. The Centers for Medicare and Medicaid Services (CMS) recently released another batch of claims data that enable comparisons of spending across the country. States are passing laws that require providers to post price information. Large employers, as well as organizations such as the Health Care Cost Institute, are partnering with insurers to develop tools that allow patients to tap into price and quality information.

MARKET DYNAMICS ENCOURAGING PRICE TRANSPARENCY

Because Americans traditionally have obtained health insurance through their employers, which picked up a large portion of their health insurance costs, patients have long been shielded from the true cost of their care. This has allowed a system of secrecy around healthcare prices to grow up. Even today, it's very diffi-

PRICE TRANSPARENCY see page **68**

Quotable

"A good way to measure the loyalty of your readers is to check your repeat visits. This tells you how 'sticky' your blog is."

Patricia Redsicker
Baltimore

On blogging metrics
See story, page 64

DTExtra

The Affordable Care Act (ACA) imposes new taxes on higher earners. It adds a new Medicare tax on earned income as well as a new net investment income tax on unearned income. These may have an impact on your bottom line. If you have modified adjusted gross income (line 37 of Form 1040) exceeding $250,000 if married or $200,000 if single, you are now subject to two additional taxes. Prior to year end, it would make sense to confer with your tax counsel to review whether there are opportunities to minimize or eliminate these new taxes or other options to enable you to pay the least tax permitted under the law.

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OAT: Maintaining A Healthy Skin Moisture Barrier

The key to maintaining healthy skin is maintaining a healthy skin barrier. Colloidal oatmeal's enriched chemical composition helps protect and maintain a healthy skin moisture barrier by providing a number of skin care benefits. (Table 1)

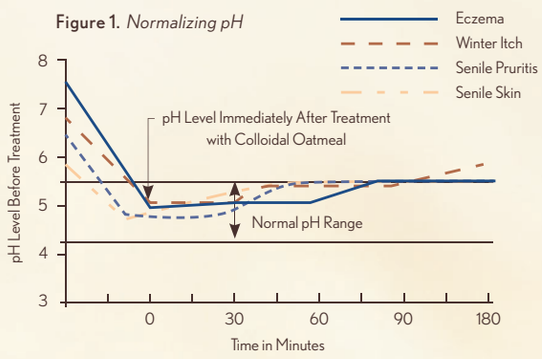
Table 1: *Composition and beneficial properties of colloidal oatmeal*[1]

COMPONENT	BENEFIT
Proteins	Moisturizing, water-binding
Polysaccharides	Soothing, form protective barrier
Lipids	Barrier replenishment
Saponins	Cleansing
Vitamin E & Enzymes	Antioxidants

COLLOIDAL OAT

The great viscosity of colloidal oatmeal when mixed with water derives from the high concentration of highly hydrophilic polysaccharides.[2] The occlusive and water-binding colloidal film holds moisture in the stratum corneum, thus helping to replenish the barrier.[3] Colloidal oatmeal also acts as a buffer system to both acids and bases, helping to normalize the skin's pH.[4] (Figure 1) The moisturizing and protective properties of colloidal oatmeal help promote a healthy skin barrier, prevent water loss, and relieve itch.

Figure 1. *Normalizing pH*



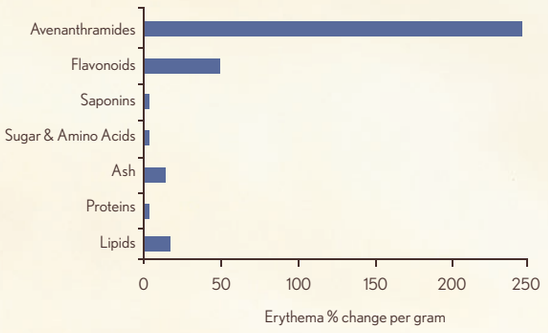
AVENANTHRAMIDES

Avenanthramides are the main polyphenolic antioxidants in oat grains, demonstrating greater antioxidant activity (10-fold to 30-fold greater) than that of the other oat phenolic compounds such as vanillin or caffeic acid and five-fold greater than that of oat flavonoids.[5,6]

This antioxidant activity has been linked to structural factors such as the presence of amine bonds and number and position of hydroxyl groups. Vollhardt et al[6] compared the functional properties of seven oat fractions (avenanthramides, flavonoids, saponins, sugar and amino acids, ash, proteins and lipids) in reducing UV-induced skin erythema, as measured by change in skin color, 24 hours after application and found avenanthramides to have the greatest activity against erythema. (Figure 2)

Avenanthramides also demonstrate potent anti-irritant properties. Published data suggests this anti-irritant effect may result in decreased contact hypersensitivity. It may also reduce the scratching-induced secondary irritation that can occur in extra dry, itchy skin, preventing disruption of the skin barrier function.[11]

Figure 2. *Comparison of seven oat fractions in reducing erythema*[6]

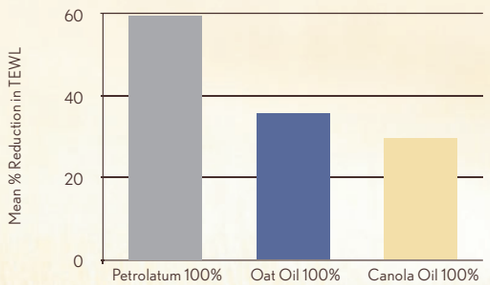


OAT OIL

When fractionated, whole oat oil is composed of a mixture of lipids, falling into four main lipid classes: triglycerides, diacylglycerol, phospholipids, and free fatty acids, with smaller amounts of sterols, phosphatidylethanolamine, and other compounds. Oat lipids contain about 80% unsaturated fatty acids, which in turn are about 42% to 52% linoleic acid. Linoleic acid has been shown effective in reducing transepidermal water loss and restoring the skin permeability barrier.[7,8] (Figure 3)

Oat oil treatment in primary human keratinocytes has also been shown to significantly increase total ceramide levels by 3-fold compared to untreated control, which may lead to improved epidermal barrier functions.[9]

Figure 3. *Oat oil reduces TEWL compared to controls*[10]



SAFETY

There is a long-standing history of safety for colloidal oatmeal as a topical treatment to relieve itch and irritation associated with various xerotic dermatoses. In a recent series of studies, the safety of personal care products containing oatmeal (creams, cleansers, lotions) was tested by assessing their irritant/allergenic potential on repeat insult patch testing, in safety-in-use and ocular studies using subjects with nonsensitive and sensitive skin. The studies showed that the irritation and allergenic potential of a diverse range of oatmeal-containing personal care products was very low demonstrating that colloidal oatmeal is a safe and effective ingredient in personal care products. No allergies were reported by consumers of 445,820 products sold during a 3-year period. [10]

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Melanie D. Palm, M.D.,
is director of Art of Skin MD
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Front office signals first impressions

WITH AUTUMN upon us, perhaps it's time to "fall" into some good habits and brush up a bit on what is happening in your reception area. When is the last time you took a good look at what your waiting area is signaling to the outside world? It is, after all, the first physical impression of your clinic. Perhaps it is time to make some changes, or improve on some already excellent practices. Read on to hear how the experts weigh in on flare for the front desk.

A valuable tip I gained from a practice management series was to see your clinic periodically through the five senses — sight, sound, smell, touch and taste. Try to look at your office space through new eyes, and critically identify any unwanted appearances, noises, clutter or odor. Is there furniture that appears tattered and needs refurbishing? Old marketing materials or dust on display cases? A squeaky fan or vent in the back office? Aroma of a microwave meal emanating from the staff room?

> "Try to **look at your office space through new eyes,** and critically identify any unwanted appearances, noises, clutter or odor."

If you don't find yourself to be objective enough to find the cracks in your clinic's glossy veneer, perform the task with a trusted "outsider" to the clinic or with your staff. For example, once a year I actually make this a part of our staff meeting — identifying needs for our handyman to address in our clinic while I am away at meetings.

ELIMINATE CLUTTER

What physically makes for a good clinic entrance area? According to Catherine Maley, practice consultant and author of Your Aesthetic Practice, it is an open space with no clutter.

"Less is more, visiting patients will be more comfortable with less chairs." She also suggests readily accessible product displays with testers. Risa Goldman Luksa, founder and president of Goldman Marketing Group, recommends channeling beauty counters such as those at Nordstrom for retail displays.

"This allows patients to touch, feel, and smell products as they shop," Ms. Luksa says.

Other quick changes for a pleasant reception area can be implemented even if you are not planning a space renovation. Remove clocks from the area, offer wireless Internet access, add live plants or flowers, or consider offering refreshments to patients. Remember that personal touches are everything in creating a great patient experience. Keep conversations private, and if possible, greet patients by name as they enter the premises. This is a simple but effective tool that is used frequently in the hotel and restaurant industry and easily translatable to a patient visit.

MARKETING PLACEMENT

So now with repair work and the physical assessment of the reception area complete, how does one determine if the reception area is best enhancing the practice offerings? This is a more challenging task and one wants to strike a balance between educating the patient yet not inundating the patient with marketing materials.

Thoughtful placement of marketing education is key.

"Remove magazines from the waiting area and replace them with branded materials such as hardback or iPad before-and-after picture books," Ms. Luksa says. Ms. Maley recommends using silent PowerPoint presentations to display before-and-after success stories.

"Visitors can see themselves if you use photos of different ages, ethnicities, etc., and patients will ask you for more information during their consultation," she says. Ms. Maley cautions, however, the "need for a balance between educating the public about services and pummeling them with vendor brochures and promotional materials."

Ms. Luksa echoes the importance of tailored electronic interactions, favoring "something custom on TVs as opposed to TV shows that have commercials or potentially inappropriate subject matter."

AVOID THESE 'NO-NO'S'

There are also some absolute "no-no's" when it comes to front office etiquette. According to our experts, many of these mistakes boil down to creating patient discomfort. Importantly for privacy matters, patient conversations should be conducted confidentially and out of earshot from others in the office, according to Ms. Luksa. If possible, do not use the same area for patient check-in and check-out.

Patients should not wait long in the reception area, but if there is a delay, "touch base with patients on a regular basis to remind them you have not forgotten about them," Ms. Luksa says.

Ms. Maley recommends doctor's offices avoid deluging patients with overstimulation.

"A clipboard full of redundant forms with today's technology is not necessary," she says. "Use technology to prepopulate forms (name, address, phone, etc.) so patients fill out only what is necessary." Beyond the paperwork, Ms. Maley also cautions avoiding overuse of promotional materials including repetitive videos. This is likely to annoy both patients and staff.

So consider a little "spring cleaning" of your reception area, even if it is a little out of season. Creating a clean, inviting, engaging, and respectful sanctuary for patients may be just what the doctor ordered. **DT**

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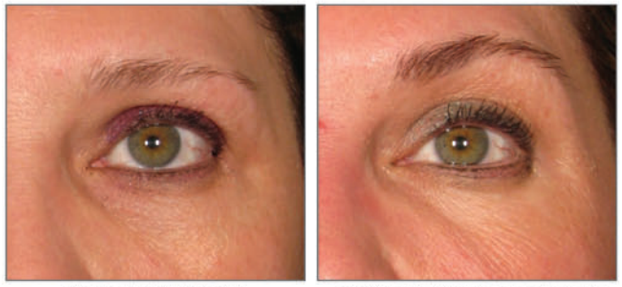

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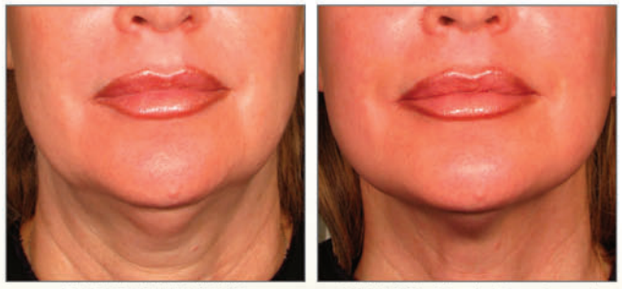

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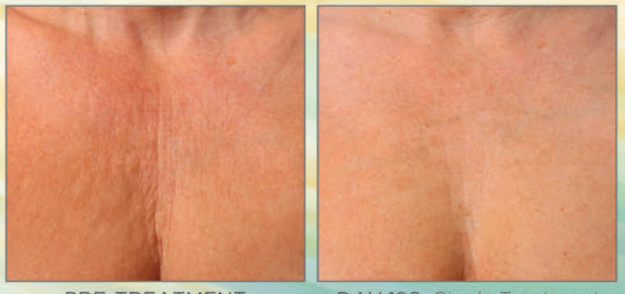

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Patricia Redsicker is a healthcare content marketing consultant and principal at Wordview Editing in Baltimore

5 key metrics to measure physician blog success

Are you dermatologist who blogs? Wondering how to measure your blog's performance or success?

Many physicians have discovered that blogging is a great way to build a community, target a specific audience, share professional opinions about health and healthcare and establish thought leadership in a specific area within healthcare.

Those who blog have probably realized, however, that it's difficult to quantify and measure the success of a business blog. With so many different blog metrics out there, how do you figure out which ones to focus on?

Here are five key metrics that every blogging physician should pay attention to:

1 **Repeat visits** A good way to measure the loyalty of your readers is to check your repeat visits. This tells you how "sticky" your blog is (i.e., prospects find your content interesting and they keep coming back for more).

If you see that your repeat visit rate (on Google Analytics) is in the single-digits, your blog might not be offering enough content to keep readers coming back.

If your repeat visit rate is above 30 percent it could be that you're not growing your audience base enough to generate new readership. According to Hubspot, the sweet spot for repeat visits is about 15 percent.

2 **Average length of stay** How long do readers stay on your blog before leaving? The answer is almost the same for everyone — not very long. On average, page visits last just a little less than a minute according to research by Nielsen Group.

But don't feel bad — while it depends to some extent on the quality of your content, it's also influenced by industry type. Some industries just aren't "sexy" and there's nothing you can do about that.

Here's what you can do: As readers rush through a massive amount of content on the Web, it'll take some pretty compelling articles to keep their eyeballs glued on yours. Try these tips to help your readers linger on your blog:

- Include lots of images or visual content on your blog;
- Make sure your writing is clear, concise and very informative;
- Make sure your website does not take too long (i.e., more than three seconds) to load;
- Add video content every now and then;
- Enable comments on your blog so that readers can have a reason to linger and converse.

3 **RSS or email subscribers** First of all, you should give readers an opportunity to subscribe to your blog via RSS (Really Simple Syndication) or email subscription. That's because it takes multiple encounters with your content for readers to develop a connection with your ideas, expertise and credibility.

So take a look at how many people are subscribing to your blog on a weekly or monthly basis, as this is a direct indicator of the quality of your content. Remember too that existing subscribers can share your content with their friends and thus help to boost your subscriber base and your community.

4 **Comments** When you see a successful blog, one of the first things you'll notice is the number of comments it receives. The more comments you get, the more popular your blog is.

A large number of comments show that your content is compelling and that readers are engaged. A blog post with 50 comments "looks better" than a blog with two comments.

Since most dermatologists are trying to build a community around their blog, more comments indicate that more prospects are reading your content and that interesting conversations are taking place.

5 **Referrals from social media outposts such as Facebook or Twitter** Monitoring the sources of your blog traffic can give you valuable insights about your community. For example, if you notice Facebook sends you more traffic than other social media sites, you can focus on boosting your Facebook posts rather wasting too much time on less valuable platforms.

Google Analytics has a built-in feature that allows you to see where your traffic is coming from (including the volume coming from desktop versus mobile devices).

For a step-by-step walk-through on how to do this, check out this post (www.socialmediaexaminer.com/measure-social-media-traffic-using-google-analytics) by Liz Lockard of Social Media Examiner.

If you're a dermatologist who has just started blogging, remember that blogging is a slow march to success. As long as you're constantly updating your blog with fresh, interesting content for your readers, your blog will eventually do well.

In the meantime, the best way to stay on course is to keep an eye on these success metrics to ensure that you finally meet your goals. **DT**

What do you think?

Which of these metrics have you been focusing on? Please share what your experience has been like so far, contact us at editor@dermatologytimes.com

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Adam DeGraide is CEO and founder of Crystal Clear Digital Marketing

Mobile searches offer risk, reward for your practice

THE MODERN patient's acceptance and use of mobile technology is growing faster than ever before. But we all know that, right? For the purpose of this article, let's define mobile as any device other than a laptop or desktop computer (i.e. tablets and smartphones).

Consider these statistics:

- Forty-six percent of online searchers now use mobile exclusively to research (start their search) on the Internet;
- According to Google's new Multi-Screen Study, 65 percent of all online searches began on a mobile device;
- In the first 10 quarters after Apple introduced the iPad, it shipped nearly 100 million units, nearly four times more than the first 10 quarters after the introduction of the iPhone.

This is crystal clear proof that adoption of mobile technology is the future of your practice's ability to stay connected with your patients. But as I said, everybody knows that, right?

KNOWING AND DOING AREN'T THE SAME

In speaking with physicians across the country, it is obvious to me that as a group they understand the impact of mobile search trends on their ability to find, serve and keep new and existing patients. Physicians by nature appreciate innovation and possess an above-average understanding of technology.

If we can all agree that the math and science support the hypothesis that the majority of future, present and past patients utilize a mobile device to search for a local practice, and we agree that inexpensive technology exists to build highly effective mobile responsive web platforms, then there is a strong research based case for widespread adoption (Let's define mobile responsive as any website, email or other online marketing message that automatically formats to the screen size of the user's device, i.e., iPhone, iPad, Android, etc.).

It would therefore be a reasonable assumption that every medical practice either is now or has in the recent past taken the time to integrate mobile responsive technology into their online marketing efforts.

You either believe it, or you don't. There is no in-between.

IN THE PATIENT'S SHOES

Clinicians must put themselves in the shoes of the patient. What are reasonable expectations/intentions of someone launching a search from a mobile device? Consider these statistics:

- Fifty-seven percent go directly to an app or the website being searched;
- Sixty percent expect to be within walking distance or local driving distance;
- Thirty-three percent search specifically for contact information (i.e. maps, directions, phone numbers);
- From a conversion perspective, 80 percent (4/5) of local searches launched on a website result in a conversion (purchase of the searched product/procedure).

These are not "tire-kickers." Most know exactly what they want and when they want it. This represents highly qualified traffic for your practice.

THE RISK, THE REWARD

Mobile searchers will be quickly turned off by a website that it is not easy to find or navigate, or does not quickly provide the information they are looking for in the exact format of their screen. There is nothing more disappointing to mobile searchers than to find the site they're looking for only to discover they have to tap, expand, pull, pinch, squint and scroll to find what they want. We have all been in that situation, and it is not pleasant. Lack of an effective mobile responsive platform will absolutely negatively impact your ability to convert searchers to paying patients. This is a risk not worth taking.

A well thought-out mobile responsive platform combined with a solid local search strategy can dramatically increase your ability to attract and convert mobile searchers. Hint: the No. 1 influencing factor on a patient's decision to choose a provider is the amount of experience of the physician.

74 PERCENT
of people ages 30-49 own a smartphone

So, in addition to all relevant contact information, what would be something to consider in the navigation of your mobile site? Exactly!

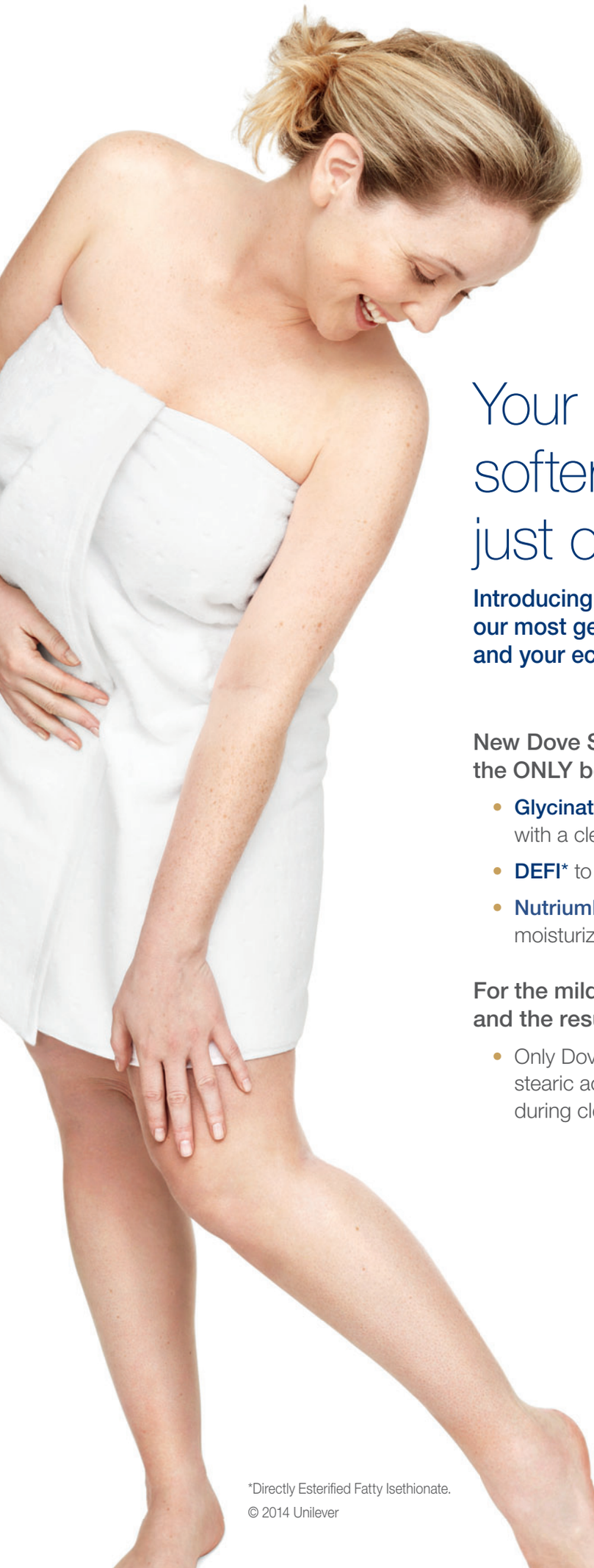
By the way, your mobile site alone has a 9.2 percent influence on the searcher's decision to contact the practice. This translates to big rewards given the volume of mobile searches conducted daily. They are rewards worth pursuing.

THE BOTTOM LINE

Acceptance and wide spread adoption of mobile search technology is here to stay. And no, it's not just kids playing on Twitter and Instagram. In the 30-49 age bracket, 74 percent own a smartphone. From ages 50-64, the number is just under 50 percent. And they use them for everything. The demographics line up well — for people with incomes over $75,000, the number is 81 percent.

The reality is mobile searchers pose an incredible opportunity for physicians to increase market share. Consider the success of the iPod. Nearly 13 years after being introduced in 2001, the good, old iPod still controls 90 percent of the market for hard drive-based players. The lesson there is that those who are first to market usually win.

The million-dollar question is: Now that you know it, what are you going to do about it? **DT**



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PRICE TRANSPARENCY:

Improved access to cost information presents opportunities from page 60

cult, and in some cases impossible, for patients to get a straight answer when they pose the question to their doctor, "How much will this cost?"

"Today, bills are completely inscrutable, says James Caillouette, M.D., surgeon in chief for Hoag Orthopedic Institute in Newport Beach, California. "Patients can't tell what they're paying for and there is no other industry where that is the case," he says.

The tide is quickly turning, however, and patients are increasingly becoming consumers of healthcare rather than passive recipients. For physicians this means a growing imperative to begin thinking about how to make price and quality information readily available to their patients — not only for the services they provide but also for those to which they frequently refer patients.

"Everyone recognizes that it's a challenge for many physicians to provide that kind of information to patients at the point of service," says Bill Kramer, M.B.A., executive director for national health policy at the Pacific Business Group on Health. "But from the patient perspective they ought to know about that before they go for services, for lab tests, radiology, follow up or specialty visits."

The expectation is that patients will continue to demand information about how much their care costs and what they're getting for the price. That's largely because they are being forced to take on more responsibility for the cost of their medical care through higher deductibles, copayments and coinsurance.

High-deductible health plans that require patients to pay thousands of dollars before receiving help from insurance are the fastest-growing type of benefit design. According to a report from America's Health Insurance Plans, the insurance industry association, as of January 2013, nearly 15.5 million Americans were covered by a high-deductible health plan, an increase of 2 million from the previous year.

That number is expected to grow in the coming years. That's because employers increasingly are shifting costs to workers to keep their own costs down, and many health plans sold through the public insurance exchanges set up under the Affordable Care Act are high-deductible policies.

It's not only fair that physicians have price information readily available for their patients, it's also good business, Dr. Caillouette says. "Our job is to deliver a great experience at the lowest cost possible. We have to be willing to compete on outcomes where the doctors that provide the best experience and best outcomes for patients ... and do it in the most cost effective way will attract patients."

A RAPIDLY-CHANGING LANDSCAPE

"The incentives to continue to perform services and be paid based on volume are still there and it can still be barrier to" price transparency, says Andrea Caballero, program director with Catalyst for Payment Reform in San Francisco. "That's why Catalyst for Payment Reform is challenging payers to contract with physicians on value," she says.

Payers are increasingly doing just that. Tiered and narrow provider networks are already showing up on insurance exchanges, and although some insurers have said recently that they are increasing the number of providers in their networks, narrow networks are likely to become a fixture of insurance policies as a way of managing cost. "We'll see more of that and price is an element," Mr. Kramer says.

In addition, large employers, such as the supermarket chain Safeway and the California Public Employees' Retirement System have instituted reference pricing. Under this model, employers establish a base price for certain services. Employees who choose providers charging above the reference price will have to pay the additional cost of those services.

Experts say reference pricing is not yet widespread, but is likely to become much more so in the coming years. That will place additional pressure on providers not only to know what their services cost but to compete on price and quality.

THE CHALLENGE AND OPPORTUNITY

The growing demand for price transparency in healthcare presents challenges and opportunities for practicing physicians, experts say. For example, incorporating price into discussions with patients about their medical care represents a major shift for many physicians in how they practice. "There's nothing in medical education that talks about cost," Dr. Schneider says.

Many physicians feel uncomfortable talking about price and would prefer not to, Mr. Kramer says. In addition, he notes, with primary care physicians so pressed for time, "it's hard to imagine spending even another five minutes discussing cost."

Dr. Caillouette, whose organization made a decision to publish its rates for orthopedic procedures on its website, acknowledges that it's easier to provide a flat, global rate for knee and hip replacements than for office-based services. "We have not done this yet on the physician side because it's far more complicated to do," he says.

In reality, however, the push for price transparency will only grow, and physicians must figure out how best to provide that information to their patients.

Ms. Cabellero says there are advantages to doing so, not the least of which is high-quality customer service. "The more reviews people do on individual physicians and word of mouth spreads that they provide good service and information is a good thing," for doctors, she says.

Dr. Schneider says that "exposing prices is hugely advantageous for providers because they can help their patients pay less money, and they can make more money if they're bearing more of their risk in such an ACO model." In addition, she says, physicians can use the growing availability of pricing information in their market to help negotiate their own fees with insurers.

The bottom line, Mr. Kramer says is that "transparency is a tide that can't be turned back. Patients expect it, and they'll be frustrated by physicians who say they don't know the price."

The best doctors, he says, will embrace price transparency. "They'll be proud to provide the information and patients will choose those physicians for their care." **DT**

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[1]Bhatnagar A. Electronic Brachytherapy for the Treatment of Nonmelanoma Skin Cancer: Results at 3 Years. Int J Radiat Oncol Biol Phys 2013;87:S65

Bottle cap helps to curb non-adherence

REMIND-A-CAP, a patented pill bottle cap, helps patients to remember to take prescription medication. The device allows individuals to set the next date of intake by turning a knob. The founder hopes the cap will promote better health outcomes by simplifying and regulating the patient's scheduled medication intake.

REMIND-A-CAP
www.remindacap.com

CREAM ENHANCES SKIN RENEWAL, REPAIR

DERMWORX Professional Skincare has introduced a single-dose topical antioxidant. CerumWorX Stable 10 percent Vitamin C + Biopeptides is formulated with three forms of vitamins C, E and a dual-biopeptide blend to help reduce the appearance of fine lines and wrinkles, the company states. The blend comes in individual capsules delivered in a silky powder-based cream, according to the company.

DERMWORX
www.dermworx.com

EXFOLIATING SCALP MASK PROMOTES SCALP HEALTH

PHILIP KINGSLEY has introduced an Exfoliating Scalp Mask that is designed to restore skin and promote scalp health. The product is formulated to effectively remove dead skin cells and excess oil, according to the company. The mask clears and soothes irritated skin, fortifies hair follicles and promotes healthy hair growth.

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CLINIQUE Smart Custom-Repair Serum uses 37 patents to repair damaged skin and is suitable for all skin types. After a 12-week study, results showed visible improvement in treating uneven skin tone, dark spots, dullness, lines and wrinkles, and skin firmness, according to the company.

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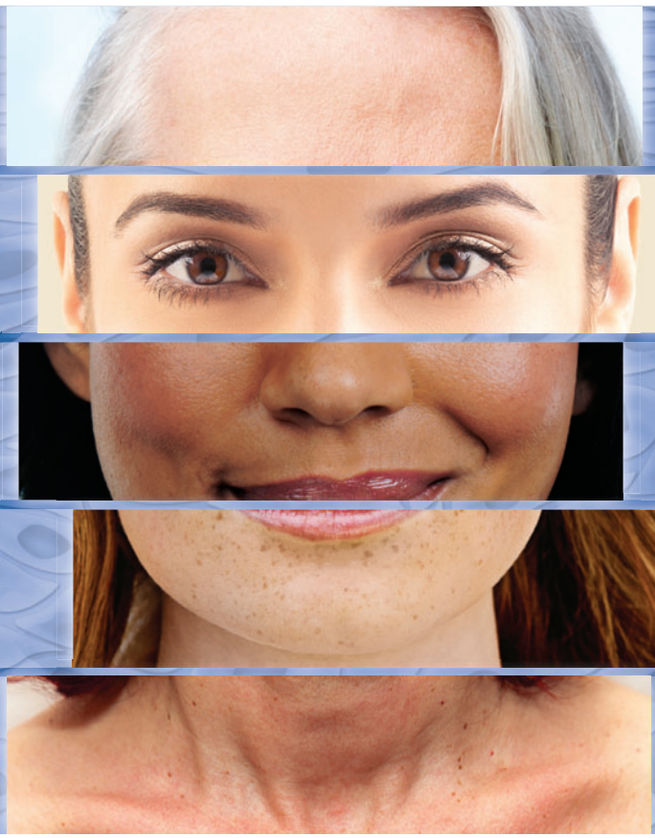

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BY ZEIN OBAGI, MD

Dermatology Times

WEBINAR

Formula Matters:
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Featuring **Zoe Diana Draelos, M.D.**

Clinical Research Dermatologist
***Dermatology Times* Editorial Advisory Board Member**

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INCENTIVES TO ENCOURAGE PATIENT ADHERENCE

Q&A

ELAINE SIEGFRIED, M.D.

In the third and final part of our discussion on patient adherence, Dermatology Times editorial adviser Elaine Siegfried, M.D., continues the discussion with Steven Feldman, M.D., on assessing adherence and intervening to encourage the best possible treatment outcomes. They discuss a method for developing patient accountability, clinical trial results versus real life, and whole health system incentives for focusing more research in this area. Dr. Feldman is a professor of dermatology at Wake Forest University School of Medicine, Winston-Salem, N.C.

Adherence to medication is a critical factor in treatment success. This is the final part of the discussion from Dr. Siegfried's interview with Dr. Feldman regarding the factors he sees as influencing whether a patient will use medication, incentives he uses to encourage patients to use medications, and projects he's been involved with for measuring factors that influence patient adherence. This discussion concludes with a look into a project that seeks to better understand incentives for encouraging adherence, as well as Dr. Feldman's thoughts on the importance of patient adherence to the health system as a whole. To read or listen to this discussion in its entirety, you can find the first two parts at: ***bit.ly/patientadherence***

DR. SIEGFRIED: Can you talk about your current work with Causa Research, what it is and how it came to be?

Dr. Feldman: Causa comes out of what I've learned from treating patients with scalp psoriasis. This condition has taught me so much about adherence, because scalp psoriasis is the *mother* of all compliance problems. In treating patients with this condition, I found that getting patients to use the medicine was possible if I only asked them to do it for a few days. First, I found that if I brought people back in three days after starting treatment, they'd get well. Then, I found if I gave just them my cell phone number and had them call me in three days, they did well. So, I thought we might be able to have them fill out an online survey shortly after starting treatment as a way to get them to feel like they were reporting, being watched over, and well-cared for.

I liken this project to piano lessons. Weekly piano visits force the kids to practice. In the clinical studies on which drugs are approved, they bring the patients back at weeks one, two, four, six, eight and 12 and those return visits force patients to use the medicine. But doctors say, "OK, here's the medicine, see you in eight to 12 weeks."

> "Patients are going to take their medicines much better knowing that ... they're going to be reporting the results."
>
> **Steven Feldman, M.D.**
> Winston-Salem, N.C.

There's nothing that assures accountability. This is an online attempt at creating accountability.

We studied this by randomizing kids with acne into two groups: one group was given the medicine and told to come back in six to 12 weeks; the second group was given the medicine and told to come back in six to 12 weeks, but they were also given a weekly survey to fill out on how well the medicine was working. The group that received the weekly Internet surveys used the medicine about *three times* as often. The compliance rate went from 30 percent with standard of care to around 85 percent to 90 percent with the surveys.[1]

In theory, I think it should work not just in dermatology.

DR. SIEGFRIED: Are there any other types of data that you're collecting that look at interventions and how they're impacting adherence?

Dr. Feldman: With Causa Research and our Internet surveys, we're at our local university enrolling teenagers with ADHD (attention deficit hyperactivity disorder) and depression to see if we can improve their use of medication. We're also in our pharmacy here at the medical center looking to see if we can improve adherence to medicines for depression, hypertension and diabetes.

INCENTIVES see page 86

Dermatology Times®

WEBINAR

New Approaches in Enhancing Patient Access:
A Focus on Steroid Responsive Dermatoses and Severe Recalcitrant Nodular Acne

Featuring **Mark D. Kaufmann, MD**

Associate Clinical Professor, Department of Dermatology
Icahn School of Medicine at Mount Sinai

Promius Pharma is exploring new ways to enhance patient access, including the implementation of a specialized distribution platform and an authorized generic version of one of their products.

In this free, 60-minute webinar, Dr. Kaufmann will discuss with you the potential benefits of these developments.

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upcoming events

Dermatology Times lists meeting announcements for the following three months in our print issue.

American Society for Dermatologic Surgery Annual Meeting
www.asds.net/annualmeeting
Nov. 6-9, 2014
Manchester Grand Hyatt
San Diego

American Society of Dermatopathology 51st Annual Meeting
www.asdp.org
Nov. 6-9, 2014
Chicago Hilton and Towers
Chicago

Alabama Dermatology Society — Seminar at Sea
www.alabamaderm.org
Nov. 13-24, 2014
Auckland, New Zealand

Inflammatory Skin Disease Summit: The Translational Revolution
www.oeaw.ac.at/isds2014
Nov. 19-21, 2014
Festive Hall of the Austrian Academy of Sciences
Vienna

New Frontiers in Cosmetic Medicine Symposium
www.cosmeticfrontiers.com
Nov. 22-23, 2014
Hekemian Conference Center Auditorium
Hackensack, N.J.

12th International Darmstadt Symposium for Dermatologic and Cosmetic Surgery
www.live-symposium.de
Dec. 4-7, 2014
Kempinski Hotel Gravenbruch-Frankfurt
Gravenbruch-Frankfurt, Germany

ASDS Cosmetic and Reconstructive Anatomy Course and Cadaver Lab
www.asds.net/CadaverLab
Dec. 6-7, 2014
Hyatt Regency Coral Gables
Coral Gables, Florida

ad index

Dermatology Times®

WEBINAR

Improving Patient Adherence and Cost-Efficiency of Treatment for Inflammatory Skin Diseases

Featuring

Steven Feldman, M.D., Ph.D

Professor of Dermatology
Wake Forest University School of Medicine

Patient compliance is fundamental to treatment success, yet many dermatologists lack key management methods to ensure that patients follow treatments.

In this webinar, Dr. Feldman will show you how to:

- Consistently develop doctor-patient trust
- Turn improved adherence into cost savings
- Reduce post-checkup information loss
- Address specific challenges of psoriasis & eczema

Tues., Nov. 18, 2014 6:00 PM EST | **Wed., Nov. 19, 2014** 8:30 PM EST

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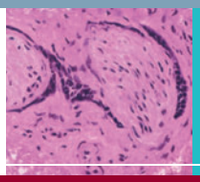

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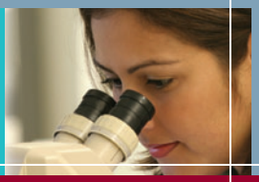

UPCOMING CME ACTIVITIES

Basal and Squamous Cell Cancer Pathology for Mohs Surgeons and Fundamentals of Mohs Surgery

DoubleTree Hotel San Diego, Mission Valley – San Diego, California

November 5, 2014 – Basal and Squamous Cell Cancer Pathology
This one-day course will be a practical "pure pathology" experience for physicians who are interested in understanding all the subtle characteristics of basal cell and squamous cell carcinoma, the most common tumors treated with Mohs surgery. Course will prepare attendees to accurately read and interpret BCC and SCC in all its variations as well as differentiate these tumors from background findings and reactive changes commonly seen at the site of recent biopsies.

November 6-9, 2014 – Fundamentals of Mohs Surgery
Course provides basic surgical, histopathology, and laboratory skills required to perform the Mohs procedure. It is designed to prepare a solid foundation upon which both physicians and technicians may build to become more proficient Mohs surgery practitioners. Microscope lab sessions will feature several hundred Mohs cases to be read as "unknowns," as well as small group discussions of important Mohs pathology-related topics. Separate cryostat lab instruction is available for Mohs technicians at all levels of training and experience, and very much emphasizes the team approach integral to successful Mohs surgery.

Closure Course and Dermatologic Surgery: Focus on Skin Cancer

Hyatt Regency Grand Cypress – Orlando, Florida

May 20-21, 2015 – Closure Course
This intense learning experience provides didactic instruction and practical demonstrations of multiple closure techniques, anatomic site-specific discussions and valuable pearls, designed to take dermatologists to the next level of derm surgery practice. An elective lab featuring realistic visco elastic models will allow participants to practice new and complex closures, proctored by highly experienced Mohs surgeons. The material presented in the Closure Course is unique and will perfectly complement the topics and activities included in Dermatologic Surgery: Focus on Skin Cancer, immediately following.

May 21-24, 2015 – Dermatologic Surgery: Focus on Skin Cancer
Top experts in cutaneous oncology, dermatologic surgery and dermatopathology will provide updates on a wide range of surgical and Mohs topics. Interactive forum and panel members will discuss appropriate repair strategies for different types of surgical wounds, as well as innovative approaches to melanoma treatment and medico legal controversies in dermatologic surgery. A separate session is offered for "veteran" Mohs lab personnel, covering more advanced topics than those included in the Fundamentals of Mohs Surgery technician training.

For additional information, please contact:
Novella M. Rodgers, ASMS Executive Director
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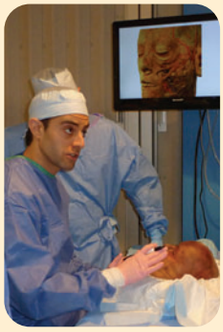
Directors: Stephen H. Mandy, MD and Gary Monheit, MD
Faculty: Adam M. Rotunda, MD; Julie E. Spielman, PhD; Daniel I. Wasserman, MD and Susan Weinkle, MD



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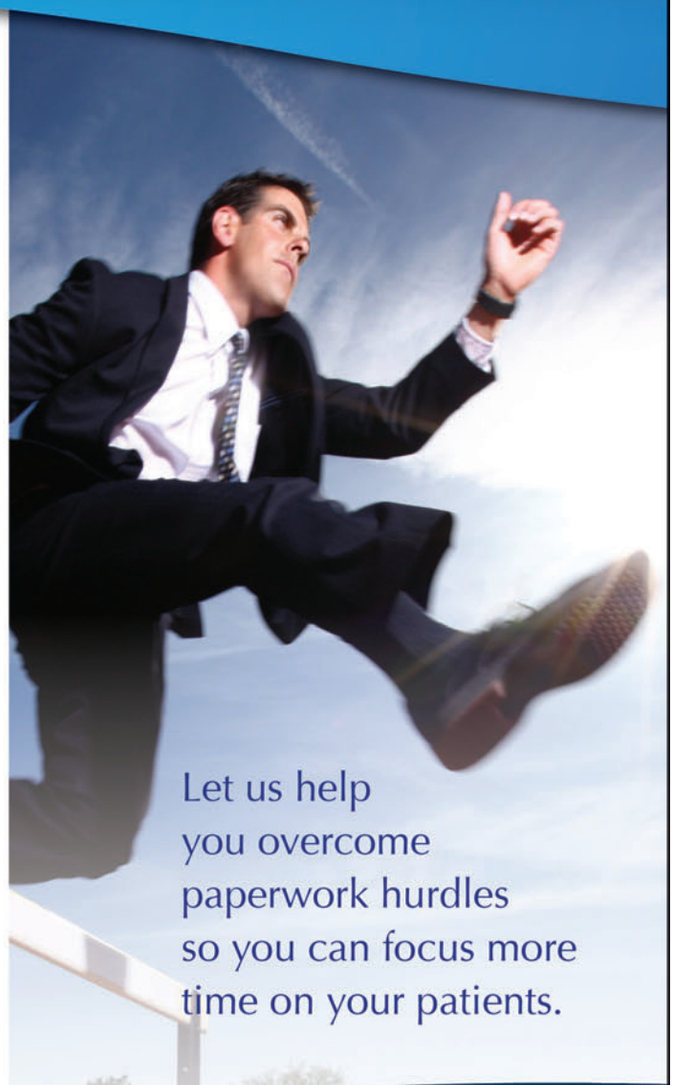

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INCENTIVES:

Intervention ideas to encourage patient adherence from page 74

DR. SIEGFRIED: Do you have any ideas about models to incentivize the healthcare industry to support or turn more focus to adherence?

A Dr. Feldman: I look at this a little differently. The No. 1 factor that drives me in medicine is the joy that I get out of getting patients well. I can't believe that isn't the No. 1 factor that drives every other dermatologist. I feel fabulous when I take a kid with atopic dermatitis who's scratching and itching and has already seen other doctors but hasn't gotten well, and with a few adherence tricks, I get them clear. That affects me far more than my bank account. I don't think money is what drives physicians to enjoy work the way they do. There was a study published that said that 90 percent of physicians would not recommend medicine as a career.[2] We asked the same question to dermatologists and 90 percent of them said they would recommend dermatology.[3]

It is a joy and a pleasure.

Just the way we spend time on CME to understand the diseases we're seeing and to stay up-to-date on treatments, I think dermatologists will find themselves highly incentivized to incorporate strategies for adherence.

That said, hospitals get dinged for their readmission rates, and so they are actively interested in seeing patients use their medicine better after discharge. Insurance plans get scored on their covered lives' adherence to treatment as measured by pharmacy records and so they're incentivized. You don't have to incentivize drug companies and pharmacies, because they only get paid when patients buy the drugs, and so they're interested in adherence. Adherence is the one thing that I think all the players in the healthcare system can get behind trying to improve.

DR. SIEGFRIED: Are you aware of any Food and Drug Administration requirements that incorporate adherence or take adherence into account in any way during the drug development process?

A Dr. Feldman: There are good ways of assessing patients' adherence to treatments. One of my research colleagues here at Wake Forest mentioned a company that sold medicine bottle caps containing computer chips that record the day and time the patients take the medicine. However, in clinical trials, they include patient diaries, they count pills — which is totally unreliable because patients chuck the stuff in the toilet — but to some extent the clinical trial is giving you somewhat of a real-life sensor. If the clinical trial controlled adherence too much then you wouldn't find out what things are like in real life. So if you do put those caps on containers for FDA studies and you show the FDA the data on the drug with the additional data that patients weren't really using it, I don't think they would know how to interpret that. So my sense is that neither the companies nor the FDA, at this point, really want detailed adherence data in those clinical trials.

DR. SIEGFRIED: It's difficult to interpret, but as you mentioned, clinical trials are a best-case scenario, because of more frequent visits and medication use monitoring. Although as your classic microchip study showed that even in a best possible case scenario, adherence is not great and probably worse for topicals than for pills, so that's an area that definitely needs more understanding.

A Dr. Feldman: When I was a first-year dermatology resident, I remember that the chair of our department at the time, Dr. Wheeler at the University of North Carolina, Chapel Hill, told us — and I've heard other dermatologists say they were taught the same thing — that "when new drugs are approved, use them fast before they stop working." In the clinical trials, these drugs work great and then in the real life they don't work so well, and I think it's because of all those factors in the trials that lead to better adherence. **DT**

1 Yentzer BA, Wood AA, Sagransky MJ, et al. *Arch Dermatol.* 2011 Oct;147(10):1223-1224

2 http://www.thedoctors.com/ecm/groups/public/@tdc/@web/documents/web_content/con_id_004676.pdf

3 http://www.the-dermatologist.com/content/would-you-recommend-dermatology-career-family-member

Dermatology Times
ADDITIONAL TAKEAWAYS

A CHANGING LANDSCAPE

The landscape of dermatology is rapidly changing and every practicing dermatologist will almost certainly be affected. **Dermatology Times** asked Dirk Elston, M.D., president of the American Academy of Dermatology, to address some of these issues so that we may all have a better idea of what lies ahead for the specialty.

DermatologyTimes.com/changinglandscape

VALUE OF COSMECEUTICALS

Among the difficulties faced by consumers is the blitz of advertising of new and presumably revolutionary products that can rejuvenate and preserve the youthful appearance of the skin. Many products make what sound like medical claims about efficacy. Zoe Draelos, M.D. — the foremost authority on this subject — discusses these issues with **Dermatology Times.**

DermatologyTimes.com/cosmeceuticals

DOES GLUTEN DRIVE SKIN DISEASE?

Gluten and gluten-sensitive enteropathy have become hot topics among the lay public and in medical practices. Dermatologists have historically concerned themselves with gluten only as it relates to dermatitis herpetiformis. This may be changing. John Zone, M.D., from the University of Utah, Salt Lake City, discusses how gluten sensitive enteropathy may impact many areas of dermatology.

DermatologyTimes.com/gluten-sensitivity

ADVANCEMENTS IN PSORIASIS TREATMENT

The past few years have been an exciting time for those who treat psoriasis and for many patients with severe disease because of excellent new therapies for this often intractable problem. Alan Menter, M.D., Baylor University Medical Center, Dallas, shares insight into recent developments in the treatment of psoriasis.

DermatologyTimes.com/psoriasisadvances

STRATEGIES FOR MANAGING LEG ULCERS

Leg ulcers are a common and difficult management problem for all dermatologists. Robert S. Kirsner, M.D., professor and vice chairman of dermatology, University of Miami Miller School of Medicine, and director of the University of Miami Hospital Wound Center, elucidates the diagnosis and management of these challenging skin problems.

DermatologyTimes.com/legulcers

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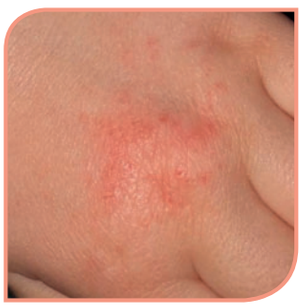

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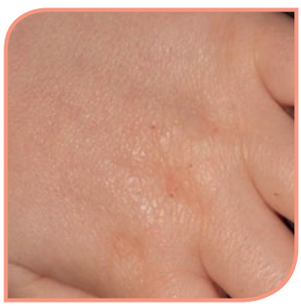

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[1]Results from 32 subjects (ages 7 months to 9 years). Application of XeraCalm A.D Lipid-Replenishing Cream twice daily for 4 weeks.
[2]Results from 55 subjects (ages 1 to 4 years). Application of XeraCalm A.D Lipid-Replenishing Balm twice daily for 28 days.

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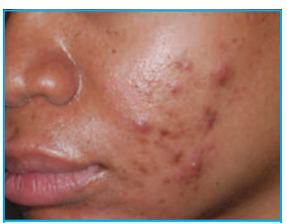
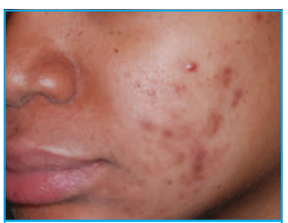
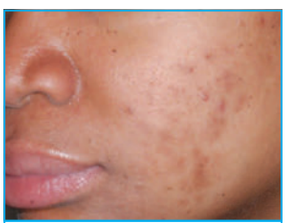

Baseline


Week 2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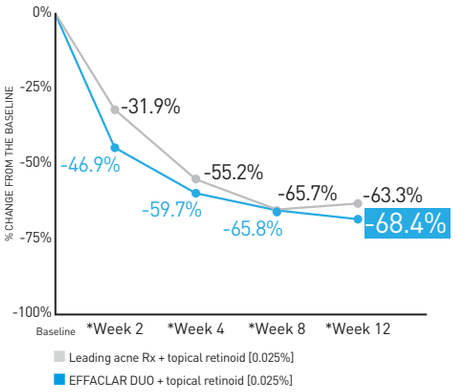
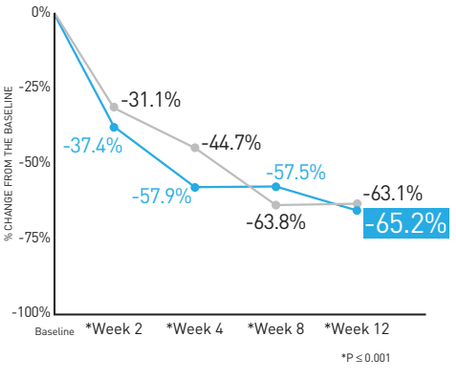


NON-INFLAMMATORY LESION COUNTS[2]



*P ≤ 0.001

(1) Dual action acne treatment stems from Benzoyl peroxide.
(2) Protocol: A 12 week dermatologist controlled, multi-center study: double blind clinical trial to evaluate safety and efficacy of two acne creams in subjects with mild to moderate acne vulgaris. 61 patients, ages 18–50, multi-ethnic skin, all skin types. 2 cell study: Cell 1, 27 patients, [EFFACLAR DUO]+ 0.025% Topical Retinoid vs. Cell 2, 34 patients, [a leading topical Benzoyl peroxide prescription] + 0.025% Topical Retinoid. Results measured at mean % change from baseline at 12 weeks of use. Application of topical retinoid applied once a day in PM and application of Effaclar DUO or a leading topical prescription Benzoyl peroxide twice a day. Inclusion criteria: ≥ 15 inflammatory lesions and ≥ 20 non-inflammatory lesions.

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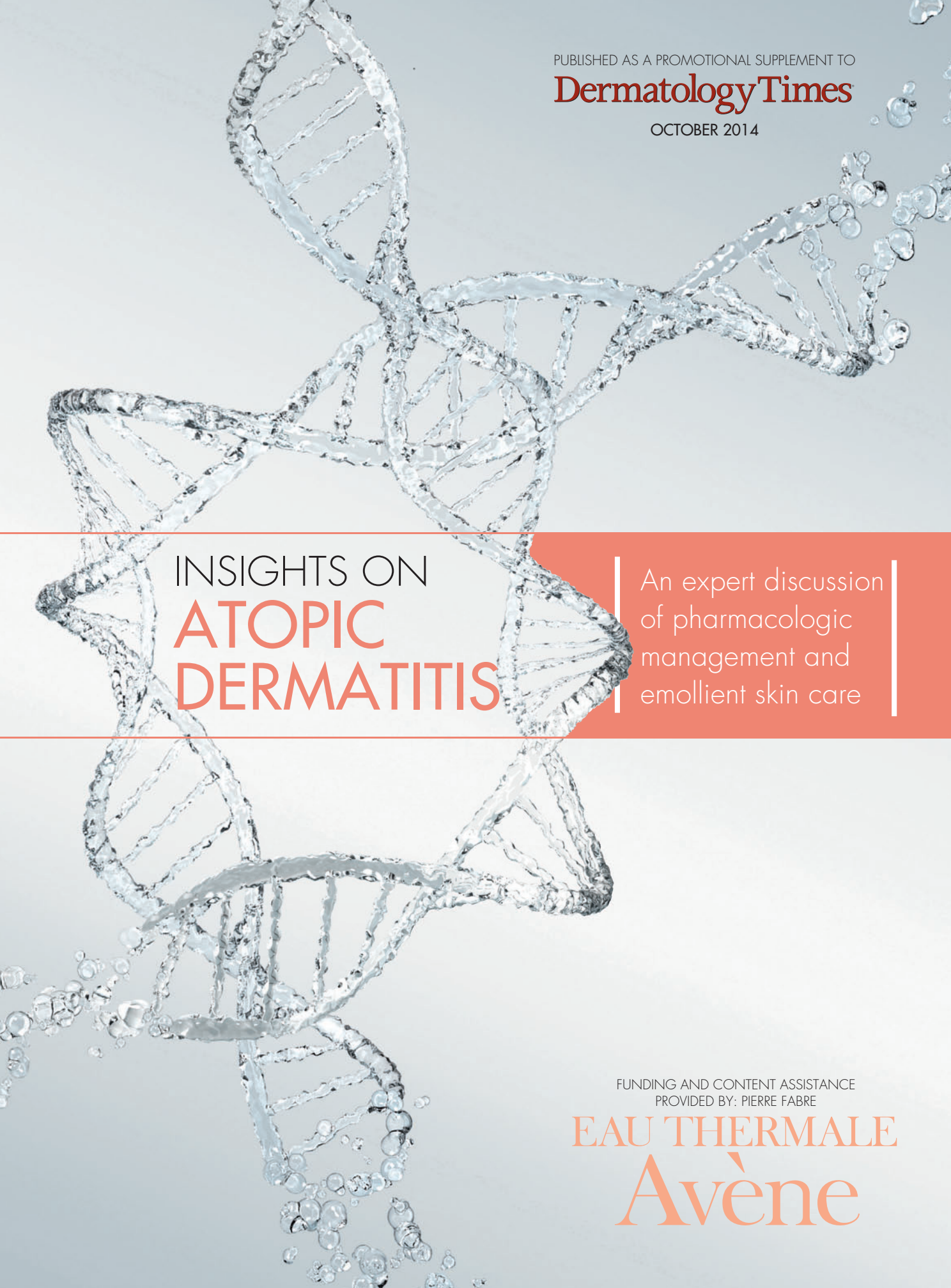

INSIGHTS ON ATOPIC DERMATITIS

An expert discussion of pharmacologic management and emollient skin care

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INSIGHTS ON ATOPIC DERMATITIS

An expert discussion of pharmacologic management and emollient skin care

Xerosis is a hallmark feature of atopic dermatitis (AD) and is the result of skin barrier dysfunction that is now considered a factor in the pathogenesis of the disease. Recently released guidelines of care for the management of AD strongly recommend the use of moisturizers to treat xerosis based on Level I evidence showing that they can reduce disease severity and the need for pharmacologic therapy.[1] There are a host of moisturizer options for patients to choose from, and they encompass both over-the-counter products, which are formulated with different emollient, occlusive, and/or humectant ingredients, and prescription medical device creams.[2]

In January, 2014, Eau Thermale Avène introduced three new products intended for the hygiene and care of dry skin prone to AD or itching: XeraCalm A.D Lipid-Replenishing Cream, XeraCalm A.D Lipid-Replenishing Balm, and XeraCalm A.D Lipid-Replenishing Cleansing Oil. Appropriate for use by individuals of all ages, both on the face as well as on the body, the XeraCalm A.D products came to the over-the-counter market after more than a decade of research and development, offering unique ingredients and other formulation characteristics desirable in topical agents for patients with AD [Table 1].

Recently, a group of leading dermatologists convened to discuss these new products in the context of understanding AD pathophysiology, principles of AD management, the findings of in vitro and clinical studies pertaining to the XeraCalm A.D product line, and early patient experience. Following are the highlights of their conversation.

FACULTY

Lawrence F. Eichenfield, MD (Moderator)
Professor, Pediatrics and Medicine (Dermatology)
University of California, San Diego School of Medicine
Chief, Pediatric and Adolescent Dermatology
Rady Children's Hospital, San Diego
San Diego, California

Gary Goldenberg, MD
Assistant Professor, Dermatology and Pathology
Mount Sinai School of Medicine
Medical Director
Dermatology Faculty Practice
Mount Sinai Medical Center
New York, New York

Peter A. Lio, MD
Assistant Professor, Clinical Dermatology and Pediatrics
Northwestern University Feinberg School of Medicine
Co-founder and co-director
Chicago Integrative Eczema Center
Chicago, Illinois

Dr. Eichenfield has been an advisory board member and received honoraria from Pierre Fabre.

Dr. Goldenberg has no financial conflicts of interest to disclose.

Dr. Lio has been a speaker and advisory board member and received honoraria and travel support from Pierre Fabre. He has also served as an investigator for studies that have had funding and materials provided by Pierre Fabre.

ISSUES IN AD MANAGEMENT

Dr. Eichenfield: Atopic dermatitis (AD) is a common pruritic inflammatory skin disease that has increased in prevalence in much of the industrialized world.[3] It usually begins in infancy and often resolves or goes into sustained remission by adulthood. Recent data from the United States and other industrialized countries indicate that AD affects between 15% and 30% of children and 2% to 10% of adults.[3]

AD is well known to have a profound negative impact on quality of life, both for patients and the families of affected children, related to the signs and symptoms of the disease, particularly the itching and rashes, and its association with sleep disruption and secondary infections.

Dr. Goldenberg, do you want to emphasize other features of AD that are important issues for our patients?

Dr. Goldenberg: I think the cyclical nature of the disease is something that a lot of patients struggle with and that many physicians fail to clearly explain. Due to the nature of my university practice setting, many of the patients I see with AD are coming in for a second or third opinion, and in my conversations with them, it is clear that they don't understand the relapsing and remitting nature of their disease. I think it is very important to bring that point home to patients so that they will expect to have periods of good control and periods of worsening.

Dr. Lio: I totally agree with that. Something that I like to emphasize is the fruitlessness of trying to identify a single trigger for AD flares. Patients with AD may be sensitive to a variety of triggers, which might include emotional stressors, weather changes, and environmental irritants. That knowledge establishes a foundation for understanding the importance of a maintenance care regimen that will optimize the skin barrier and keep it fortified, so to speak, even between flares. That is where the use of moisturizers to improve skin hydration has an essential role in the care of AD.

"Patients with AD may be sensitive to a variety of triggers, which might include emotional stressors, weather changes, and environmental irritants. That knowledge establishes a foundation for understanding the importance of a maintenance care regimen that will optimize the skin barrier and keep it fortified, so to speak, even between flares. That is where the use of moisturizers to improve skin hydration has an essential role in the care of AD."
—Peter A. Lio, MD

Dr. Goldenberg: Those are great points. I primarily treat adults in my practice, and I often see patients in my population with AD who have been trying to achieve disease control by focusing on a specific trigger. Some patients have been identified as allergic to various substances through patch testing and swear that they have been avoiding exposure to those agents. Therefore, they are puzzled and frustrated that they are still experiencing AD flares. So, it is extremely important that patients realize that there are numerous triggering factors for AD.

Dr. Eichenfield: The potential for AD to be a persistent disease is another feature that I think is not completely appreciated by some physicians, particularly primary care physicians. There is a subset of patients with AD who have active disease for months, and occasionally years, at a time. Although their disease may be fairly well controlled with a variety of therapies, these patients still have some burden of disease that mandates a level of care different than what would be used in patients who are able to achieve sustained clearing.

Table 1. XeraCalm A.D Product Line

Product	Key Ingredients	Main Characteristics
XeraCalm A.D Lipid-Replenishing Cream	Avène Thermal Spring Water 66% I-Modulia 0.4% Cer-Omega 2.3% Lipid phase 20%	Formulated for moderate dryness Fragrance-free Preservative-free Sterile formulation DEFI packaging system maintains sterility and prevents retrocontamination during use
XeraCalm A.D Lipid-Replenishing Balm	Avène Thermal Spring Water 56% I-Modulia 0.4% Cer-Omega 2.3% Lipid phase 30%	Formulated for severe dryness Fragrance-free Preservative-free Sterile formulation DEFI packaging system maintains sterility and prevents retrocontamination during use
XeraCalm A.D Lipid-Replenishing Cleansing Oil	Avène Thermal Spring Water 78.6% Gentle cleansing base 14% I-Modulia 0.4% Lipid phase 7% Cer-Omega Preservatives: caprylyl glycol, citric acid	For use in the shower or bath Physiological pH Soap-free Fragrance-free

DEFI = Device for Exclusive Formula Integrity

AD PATHOPHYSIOLOGY

Dr. Eichenfield: Now, let's discuss the pathophysiology of AD because understanding it guides our treatment.

Dr. Lio: The pathophysiology of AD is complex and multifactorial, and that is why it can be a therapeutic challenge. In my mind, I don't think about AD as being a single disease, but rather as a heterogeneous disorder with multiple underlying causes that can result in a similar clinical manifestation. The concept that there are likely different subtypes of AD is something that I am increasingly coming to terms with because I think it may explain why patients with refractory disease are not responding to our standard therapies.

We know that impaired skin barrier function is a major factor in the pathophysiology of AD, and in that regard, it has been very exciting to learn more about the role of filaggrin gene mutations in skin barrier dysfunction. There is also a proinflammatory, immunologic component, but I think any discussion about whether the impaired skin barrier or an immunologic abnormality is the primary factor in AD pathophysiology is like talking about which came first, the chicken or the egg. We know that both are involved and need to be addressed from a therapeutic standpoint

Dr. Eichenfield: I agree with those concepts. It is interesting that our insights on the pathogenesis of AD change based on emerging research and that there may be a focus on a particular area for perhaps years at a time, but then the emphasis may shift when new findings are reported. However, we can say there is evidence that a significant subset of patients with AD have a fundamental genetic defect in their skin barrier that explains the dry skin and, to some degree, their susceptibility to develop a proinflammatory response to exogenous agents. There is still a lot of conversation about the genetic aspect of the pathogenic pathway. At the same time, with the advent of advanced laboratory tools, including genomic profiling, researchers are taking a more extensive look at the immunologic characteristics of lesional and non-lesional skin in patients with AD and skin of normal controls.

Another area of active research is evaluating microbial colonization. Findings from some recent studies have suggested new ideas about how colonization with *Staphylococcus aureus* drives inflammation in AD, and I believe we are entering into a period that will, at least initially, be very confusing as researchers try to figure out if and how microbial colonization of both the skin and the gut influence each other and impact the immune system. There is also interest in sorting out whether or not mediating exposure to microbes early in life, or in patients with established AD, affects the onset and course of disease.

The bottom line in terms of translating current scientific understanding about the pathophysiology of AD into clinical practice is that management must account for the fact that AD is a multifactorial disease. Meanwhile, we will stay tuned for new research advances that elucidate the contributions and interactions between genetics, immunology, and environmental factors.

"Management of AD requires a multipronged approach involving four major areas that may all need to be addressed for optimal disease control. Skin hydration is the first aspect, and it is an integral part of the management regimen for all patients, whether or not they have active disease."

—Peter A. Lio, MD

AD MANAGEMENT PRINCIPLES

Dr. Eichenfield: Let us shift now to the management of AD. Dr. Lio, could you please talk about the standard goals?

Dr. Lio: Management of AD requires a multipronged approach involving four major areas that may all need to be addressed for optimal disease control.

Skin hydration is the first aspect, and it is an integral part of the management regimen for all patients, whether or not they have active disease. Secondly, there is anti-inflammatory treatment. Topical corticosteroids are the mainstay, but there is a need to balance their benefit and potential risks, and so there is also a role for use of nonsteroidal medications, such as topical calcineurin inhibitors.

The third area relates to antimicrobial management, and that is important not only with respect to treating secondary infections, but also because of evidence that bacterial colonization may be promoting disease activity through a variety of mechanisms. For example, a recent paper described delta-toxin released by *S. aureus* as a potent inducer of mast-cell degranulation,[4] and it is already known that various staphylococcal exotoxins can act as superantigens stimulating T cells to cause inflammation. Because abnormal microbial colonization appears to be fueling the disease more generally, the strategies have been forced to change from those used for simply treating an infection. While topical and oral antibiotics may still be helpful, decreasing colonization through the use of broad antiseptics, such as dilute bleach baths, may be more appropriate and carry less risks for some. Information is also emerging about probiotics for rebalancing the bacterial flora,[5] and while exciting, their use is something that we currently have limited data on.

Finally, we need to think about management of pruritus. Sometimes AD is referred

to as "the itch that rashes." Itch is not only a bothersome symptom affecting quality of life, but the scratching it induces promotes inflammation that exacerbates both the rash and the itch. Unfortunately, finding effective antipruritic agents to break the itch-scratch cycle remains the Holy Grail for effective management of AD. Part of the challenge has to do with the fact that the itch is mediated by multiple mechanisms involving neural pathways and immunologic factors.

Dr. Goldenberg: It is important that we also mention the potential need for more aggressive treatment with phototherapy or systemic immunomodulating agents. The nature of my practice in an academic setting is that I tend to see mostly patients who have very severe or refractory disease, and for that group of patients, there is an important role for more aggressive therapies. I think we need to highlight their role, recognizing that today in the United States, a lot of medical dermatology patients are being seen by physician assistants and nurse practitioners who, while working under the supervision of a dermatologist, may not be familiar themselves with the role of systemic medications.

Dr. Eichenfield: It is important to realize that systemic therapy may sometimes be needed for the management of AD. I think that experts in AD management understand that patients will do much better in the long run if they receive treatment that is appropriately aggressive to control their inflammation. The analogy I like to use is that effective anti-inflammatory treatment reboots the system. When there is significant persistent inflammation, even focally, the burden of the disease ends up being much higher.

Dr. Goldenberg: I totally agree with you. I think it is easier and better to use whatever treatment we need to achieve disease control and then maintain the improvement with topical agents than to be relying only on topical medications and having the disease wax and wane for years, never really getting the patient to a state of good control. I think we should also mention that there are several investigational agents for AD in the pipeline, including new biologics and small-molecule therapeutics. Dr. Eichenfield, I believe you have said that dermatology has seen a decade of drug development for psoriasis and that now we can anticipate a decade of new therapies for AD. I think it is important for physicians and patients to understand that there are new treatments coming around the corner.

Dr. Eichenfield: It is certainly helpful for patients to know that there is a lot happening, and a lot of promise, in the area of new treatments for AD. Dr. Lio and I have discussed the idea that the lack of advances in pharmacotherapy for AD is one of the reasons why patients are often seeking out alternative or complementary medicine options. The situation is changing, and we are now in a time of rapid development, with emerging systemic agents and other modalities that will give us new tools to help control the disease.

XeraCalm A.D — RESEARCH & DEVELOPMENT

Dr. Eichenfield: While we have just emphasized the importance of anti-inflammatory agents in treating AD, as Dr. Lio stated previously, management of xerosis is a mainstay of care for all patients with AD, regardless of their disease severity. Increasing skin hydration will help improve the skin barrier and help control pruritus and inflammation.[1] To address this need, Pierre Fabre has introduced its new line of XeraCalm A.D Lipid-Replenishing products consisting of a cream preparation, a balm, and a cleansing oil. These products have an interesting development history, and based on their ingredients and other features, they seem very well suited for patients with AD.

All three products contain a high concentration of Avène Thermal Spring Water plus I-Modulia and Cer-Omega. I-Modulia is a patented complex of lipopolysaccharides, amino acids, and sugars derived from a natural microflora species found in the thermal spring water. Cer-Omega is a proprietary complex of ceramide-like molecules and omega-6 fatty acids that has been shown to restore the skin barrier and reduce xerosis.[6]

For hundreds of years, and to this day, patients with dermatological diseases have gone to the Avène Hydrotherapy Center for treatments with thermal spring water, and there are clinical and in vitro study data showing its benefits.[7,8]

Pierre Fabre has been incorporating Avène thermal spring water into their skin care products for years, but about a decade ago, scientists at the company's research center began undertaking studies to better understand what active ingredients in the water, in addition to its mineral content, might explain its benefits. Their work led to the identification of a bacteria, *Aquaphilus dolomiae*, which is part of the water's microflora, and the determination that compounds produced by *A. dolomiae* were biologically active.

Pierre Fabre was able to scale up production of the extraction of the active substances to produce the complex they named I-Modulia. Subsequently, results

> "Management of xerosis is a mainstay of care for all patients with AD, regardless of their disease severity. Increasing skin hydration will help improve the skin barrier and help control pruritus and inflammation."
>
> **—Lawrence F. Eichenfield, MD**

XeraCalm A.D Clinical Trials

The effects of XeraCalm A.D products when used by patients with AD were investigated in a series of clinical studies.[6,12,13] Patients entered in all protocols had to have discontinued corticosteroid use for at least 8 days and used the XeraCalm A.D product twice daily.

A controlled study enrolled 54 children ages 1 to 4 years old with mild AD (SCORAD 5 to 20) who were randomized to use of a hygiene product alone or combined with XeraCalm A.D Balm.[6,13] The children had a mean age of 2.5 ± 1.0 years, and a mean baseline SCORAD of 10.98+/–3.26.

Changes in the SCORAD and pruritus severity scores are depicted in Figures 1 and 2. After 2 weeks of treatment using XeraCalm A.D Balm, patients had significant improvements from their baseline SCORAD and pruritus scores (–36% and –49%, respectively). Further improvements were recorded after 28 days of treatment, and there were statistically significant differences favoring the group using XeraCalm A.D Balm compared with the controls for change in SCORAD (–48% vs. –20%; P = .0009) and pruritus (–75% vs. –36%; P = .0599) scores. In addition, use of the XeraCalm A.D Balm was associated with significant improvement in transepidermal water loss at both 14 and 28 days (–35.2%; P<.0001), indicating improvement in skin barrier function. Mean xerosis severity grade was also significantly improved at both follow-up visits in patients using XeraCalm A.D Balm (P≤.0001), and at study conclusion, xerosis severity was rated as improved from baseline in 97% of patients using XeraCalm A.D Balm.

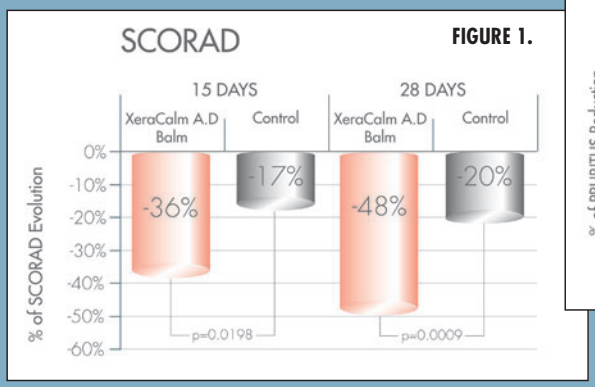

FIGURE 1.

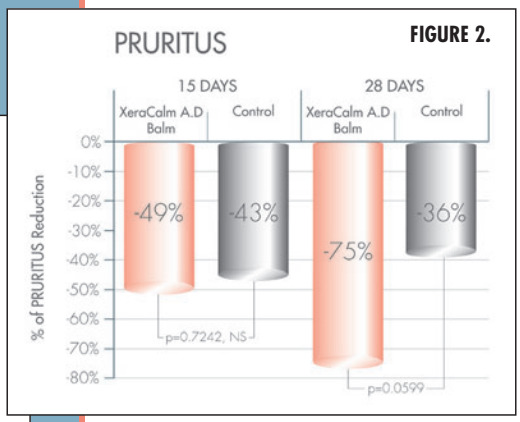

FIGURE 2.

XeraCalm A.D Balm was also investigated in a study including 33 children and 12 adults with AD who had a xerosis grade ≥2 (scale 0 to 3) and SCORAD of 15 to 25. After 3 weeks, mean SCORAD scores were reduced by 80% from baseline in the pediatric subgroup and by 75% in the adults. Mean pruritus and xerosis scores were reduced by 81% to 99% from baseline, and the treatment effects were maintained or further improved at the end of the 3-month study.

XeraCalm A.D Cream was evaluated in a study enrolling 44 patients ages 7 months to 60 years. Patients eligible for this trial had a xerosis grade ≥1 (scale 0 to 3) and SCORAD ranging from 15 to 25. After 4 weeks of treatment in the pediatric subgroup, mean SCORAD was reduced by 55% from baseline, mean pruritus score was reduced 97%, and mean xerosis grade was reduced 69%. Among children younger than 2 years of age, mean SCORAD was reduced 65% from baseline, and xerosis and pruritus were completely resolved.

In all of the above studies and for patients of all ages, investigator ratings showed very good skin tolerance with use of the XeraCalm A.D products. Images from clinical trial participants treated with XeraCalm A.D products are seen in Figures 3 and 4.

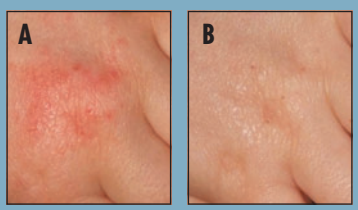

FIGURE 3. Images of a child's hand before (A) and after 10 days of application of XeraCalm A.D Cream twice daily (B). This child was a participant in a study that enrolled 32 children, ages 7 months to 9 years, with mild to moderate AD.

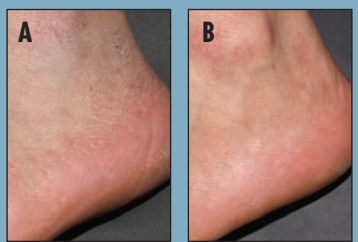

FIGURE 4. Images of an adult's foot before (A) and after 21 days of application of XeraCalm A.D Balm twice daily (B). This patient was a participant in a study that enrolled 50 adults, ages 19 to 50 years, with mild to moderate AD.

"So, overall I think we can say there exists a broad set of data from a number of studies that establish tolerance and utility for the XeraCalm A.D products."
—Lawrence F. Eichenfield, MD

from a series of in vitro studies conducted using a variety of models showed that I-Modulia may have anti-inflammatory and antipruritic properties.[9-11]

Acknowledging that data were limited to in vitro studies, the information did provide an evidence base for Pierre Fabre to pursue developing a set of products containing I-Modulia that could be useful for patients with AD.

In addition to the in vitro tests with I-Modulia, Pierre Fabre conducted clinical studies with the XeraCalm A.D products. The clinical research program included a series of studies using standard protocols to document tolerance in both healthy individuals and patients with AD. Additionally, there were clinical tolerance and efficacy studies in both adults and children with AD.[6,12,13] [SEE SIDEBAR]

Dr. Lio: In first learning about the XeraCalm A.D products, I was very impressed by the work undertaken by Pierre Fabre to isolate, identify, and characterize the active biologic component in the Avène thermal spring water and by the extent of the clinical research performed. The development program was much more comprehensive than we might expect to see for a non-prescription product, but I believe Pierre Fabre decided not to pursue medical device approval in order to make the products more affordable and more easily accessible for patients.

The fact that the cream and balm products are sterile and contain no preservatives is something I think is particularly exciting, and Pierre Fabre should be congratulated for its innovative manufacturing and packaging methods that make it possible for these products to be preservative-free.

Dr. Eichenfield: The clinical research program involved almost 1300 subjects, of whom more than 650 were patients with AD. The tolerance studies established gynecologic and eye tolerance in addition to skin tolerance, and benefits in patients with active AD were demonstrated using a number of standard assessments. The clinical studies showed patients using the XeraCalm A.D products had decreased transepidermal water loss and improvements in the SCORing Atopic Dermatitis (SCORAD) index, as well other ratings specific to xerosis, pruritus, and quality of life. So, overall I think we can say there exists a broad set of data from a number of studies that establish tolerance and utility for the XeraCalm A.D products.

XeraCalm A.D — USER EXPERIENCE

Dr. Eichenfield: We have all had the opportunity to use these products on our patients. Let's talk about that experience. Dr. Goldenberg, please begin.

Dr. Goldenberg: Before I do, I also want to mention how impressed I was with the research commitment Pierre Fabre made to develop these skin care products and by the amount of data that is available. The in vitro data on the effects of I-Modulia on inflammation and itch are particularly interesting.

In terms of my personal experience, I have a handful of patients who have used the XeraCalm A.D products so far. A few of those patients had more severe AD and did not achieve much improvement after just a couple of weeks of use.

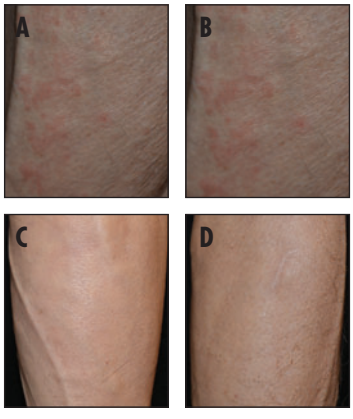

FIGURE 5. A 58-year-old male with a lifelong history of AD who presented with a flare-up on his arms and legs (Arm Images: A and B: before, C and D: after). Prior treatments included multiple topical steroids and antibiotics. Two weeks after starting twice daily XeraCalm A.D Cream and XeraCalm A.D Cleansing Oil, he achieved almost total clearing.

In contrast, patients whose disease was more moderately severe achieved greater benefit. One patient with a particularly good response had moderate disease that was being treated with a topical corticosteroid, and he achieved complete clearing at 2 weeks after starting use of XeraCalm A.D [Figure 5].

However, regardless of the extent of their improvement, most patients preferred XeraCalm A.D over the moisturizer they were previously using. And, the patient I discussed who had such a great response continues to call my office periodically to see if any samples are available.

Notably, some of my patients seemed to particularly like the balm, which is a thicker product and seems more protective than some other moisturizers that are available.

Dr. Eichenfield: My experience with the XeraCalm A.D products includes several patients with moderate to severe AD who showed improvement when they returned for follow-up after 2 weeks. They still had some persistent disease, but I would say that their AD was more in the mild category and generally under excellent control with minimal use of mild topical corticosteroids.

Other patients who used the products already had controlled severe disease and were being maintained on a moisturizer. These patients continued to have good disease control without any need for topical corticosteroids after switching to the XeraCalm A.D products. I also had a few patients who were on intermittent topical corticosteroid treatment, using them once or twice a week on hot spot areas, and had a very good experience with the XeraCalm A.D products when they were substituted for their usual moisturizer and cleansing products.

> "Some of my patients seemed to particularly like the balm, which is a thicker product and seems more protective than some other moisturizers that are available."
>
> **—Gary Goldenberg, MD**

The products seemed very well tolerated, and I got excellent feedback about them from patients and their families. Variation in patient preference for a particular product due to differences in the vehicle or other product characteristics is something we see with all topical modalities, and we also see variability among patients in terms of how they respond to a particular preparation. As we gain more experience using the XeraCalm A.D products, it will be interesting to see if we can identify any subsets of patients who may do particularly well on a given product.

In addition to needing information on the use of the XeraCalm A.D products in more patients and for a longer term, ideally we'd like to see them evaluated in controlled studies with an active comparator.

For now, we have to think about how the XeraCalm A.D products fit into our management regimens for patients with AD, taking into account the features of these products, their scientific background, and our early clinical experience.

Dr. Lio: Based on my experience, I think these products are great for addressing xerosis (Figures 6 and 7), which is a cardinal clinical feature of AD. They are not a replacement for our standard anti-inflammatory medications, but I believe that they can be a valuable addition to our management plan.

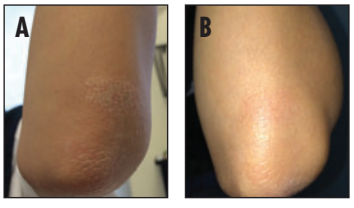

FIGURE 6. Elbow area of 12-year-old girl with mild atopic dermatitis and severe xerosis before (A) and 3 weeks after (B) switching from her previous moisturizer to XeraCalm A.D Balm.

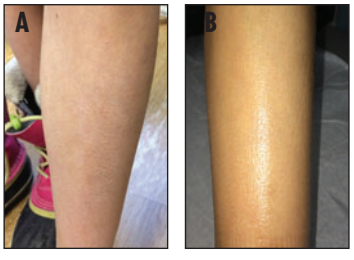

FIGURE 7. Left pretibial area of 9-year-old girl with mild atopic dermatitis and moderate xerosis before (A) and 4 weeks after (B) switching from her previous moisturizer to XeraCalm A.D Balm.

Dr. Goldenberg: I also think the cream and balm products can be considered an excellent moisturizer option, and in patients with mild or moderate disease who need anti-inflammatory treatment, perhaps they may be combined with an intermittently used topical corticosteroid or calcineurin inhibitor.

"The fact that the XeraCalm A.D Balm and Cream contain no preservatives really distinguishes them from other moisturizers. Some products may be paraben-free, but still contain other preservatives, such as BHT." **—Gary Goldenberg, MD**

The fact that the XeraCalm A.D Balm and Cream contain no preservatives really distinguishes them from other moisturizers. Some products may be paraben-free, but still contain other preservatives, such as BHT.

Dr. Goldenberg: I agree that it would be especially nice to see head-to-head comparisons between the XeraCalm A.D products and available OTC bland emollient products, which may be less expensive. Price is not a major sticking point for a sizeable segment of the patients I see in my Manhattan practice. However, it may become a bigger issue in the future as insurers are increasingly pushing the costs of AD care onto the patients. In that regard, the prescription emollient devices that can be used for AD management are almost never covered by insurance. Compared to agents in that category, the XeraCalm A.D products are more accessible to patients and perhaps more affordable.

Dr. Eichenfield: It is nice to have products that patients can directly purchase so that we can avoid issues with formulary restrictions. Cost is something that physicians should always be conscious about whether we are prescribing medications or recommending OTC products to our patients. We also need to consider whether or not a more expensive product has benefits that justify or outweigh a higher cost for a particular patient. Pricing of the XeraCalm A.D products compared to some other OTC moisturizers likely reflects the investment spent on research and development, and the costs of the sterile manufacturing process and novel packaging.

While we don't have any information from comparative studies with the XeraCalm A.D, these products do appear to stand out from some of the OTC competitors based on their being preservative-free, the wealth of tolerance data, and the science behind the natural ingredients. As we see how the products fit into the maintenance regimens that are so important for our patients, perhaps we will find that they enhance control of the disease and lessen the development of flares requiring treatment with prescription medications, which could be a cost-saving advantage.

Sterile Cosmetics is a unique process developed by Pierre Fabre Research teams to provide ultimate efficacy and safety by providing 100% sterile formulas containing only essential ingredients

To conclude, I think our discussion highlights the features of the XeraCalm A.D line and puts that information into perspective in terms of our understanding of AD pathophysiology and our needs for management options to control inflammation by optimizing the skin barrier. This review should be helpful to dermatologists to familiarize them with these new products as they explore how the products may fit into their clinical practice.

"As we see how the products fit into the maintenance regimens that are so important for our patients, perhaps we will find that they enhance control of the disease and lessen the development of flares requiring treatment with prescription medications, which could be a cost-saving advantage." **—Lawrence F. Eichenfield, MD**

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