Charles E. Crutchfield III, M.D., questions whether vendor data-gathering has gone too far, noting tracking software concerns page 46

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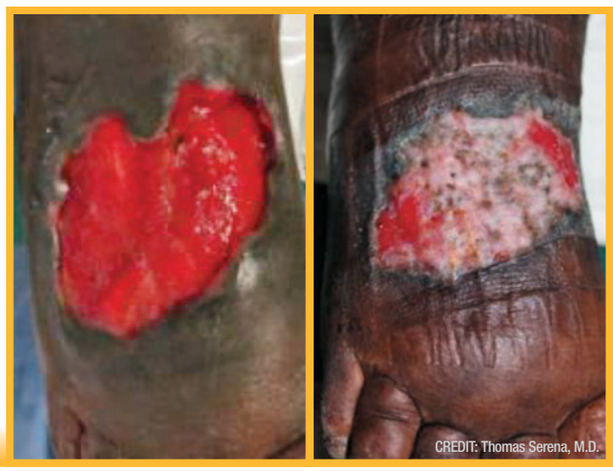
'SMART' SKIN TRANSFERS EVOLVING



A 22-year-old female patient one week after treatment with the CelluTome (KCl) device.

Experts find that innovative grafting techniques for burns, wounds and other skin conditions leave scar-free donor sites, plausible for other organ systems

John Jesitus | Senior Staff Correspondent

INNOVATIVE wound-healing techniques born at the Wellman Center for Photomedicine, Boston, use simple technologies to capitalize on the skin's capacity to heal after fractional injury. Devices under development — and one that's commercially available — make multitudinous miniscule skin grafts that physicians are using to treat burns, chronic wounds and other skin problems without creating scars at tissue donor sites.

Many of these technologies grew from the concept of fractional photothermolysis, also pioneered at the Wellman Center. By creating an array of individual injuries measuring no more than 300 µ across, says R. Rox Anderson, M.D., this approach allows for quick skin healing without scarring. Dr. Anderson is professor of dermatology, Harvard Medical School, director of the Wellman Center for Photomedicine and adjunct professor of health sciences and technology at Massachusetts Institute of Technology (MIT).

The success of fractional ablative resurfacing led Dr. Anderson and his colleagues

GRAFTING see page 32

Also inside: How a Rady Children's Hospital program has adapted protocols pioneered by the U.S. Navy to revolutionize scar treatment. Read more on page 26

Study links immune system, skin microbiota

Bob Roehr | Staff Correspondent

A PROOF-of-concept study has demonstrated for the first time that the complement portion of the immune system and the cutaneous microbiome interact in a symbiotic way to maintain skin health. Better understanding this interaction may provide new targets for interventions to prevent and treat diseases such as atopic dermatitis and psoriasis.

The research was conducted in mice and focused on C5a, the most potent anaphylatoxin produced during complement activation, and on cell receptors for the ligand. The signaling protein triggers multiple proinflammatory and immunoregulatory responses, says dermatologist Elizabeth A. Grice, Ph.D. She was senior author of the

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THE IMPACT OF TECHNOLOGY

New technologies, drugs and devices are evolving to impact nearly every area of dermatologic care, from advances in administrative and operational hardware and software to the connectivity of the Internet to advances in therapeutic devices. This month, we've shaped a discussion around this broader topic, while homing in on the promises and challenges of implementing electronic medical records.

43 PERCENT of doctors agree that EHRs slow them down

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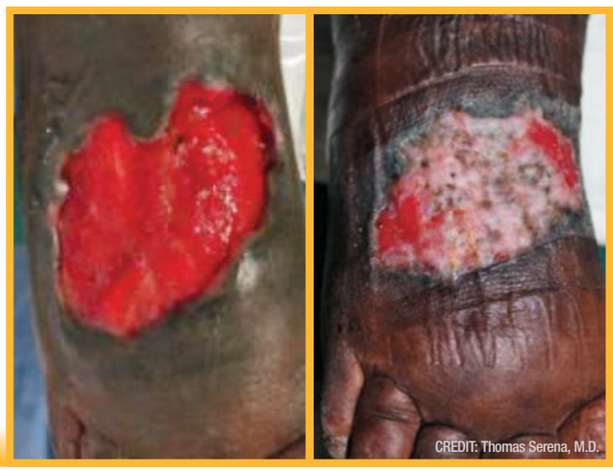

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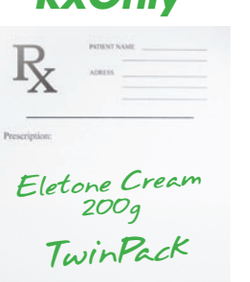

ELETONE® CREAM

Nonsteroidal Atopic Dermatitis Therapy

PRODUCT DESCRIPTION: Eletone® Cream is a non-steroidal, lipid-rich, fragrance free emulsion formulated with Hydrolipid Technology for the management and relief of burning, itching, and redness associated with various types of dermatoses. There are no restrictions on age or duration of use and the product has a low potential for irritation.

INDICATIONS FOR USE: Eletone® Cream is indicated for the management and relief of burning, itching, and redness associated with various types of dermatoses, including atopic dermatitis, allergic contact dermatitis, and radiation dermatitis (post-radiation treatment).

CONTRAINDICATIONS: THIS PRODUCT SHOULD NOT BE USED DURING THE PERIOD OF TIME WHEN RADIATION TREATMENT IS OCCURRING BECAUSE OF THE INCREASED RISK OF SKIN TOXICITY WHEN RADIATING THROUGH PETROLATUM AND OIL. Eletone® Cream is contraindicated in patients with a known hypersensitivity to any of the components of the formulation.

PRECAUTIONS: Eletone® Cream is for external use only.

Eletone® Cream does not contain a sunscreen and should always be used in conjunction with a sunscreen in sun exposed areas.

INSTRUCTIONS FOR USE: Apply liberally to the affected areas three times daily or as needed. If skin is broken, cover Eletone® Cream with a dressing of choice.

INGREDIENTS: Eletone® Cream contains petrolatum, purified water, mineral oil, cetostearyl alcohol, ceteth-20, citric acid, sodium citrate, propylparaben, and butylparaben.

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.

ELE-13102

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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: sthuerk@advanstar.com

Dermatology Times

content

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For eczema-prone skin

TWO ADVANCED TECHNOLOGIES.

ONE REPLENISHING REGIMEN.

Cetaphil® RestoraDerm® products are the first and only regimen with advanced ceramide and Filaggrin technology™

To help restore the skin barrier in dry, eczema-prone skin, recommend the Cetaphil® RestoraDerm® regimen.[1]

Reference: 1. Simpson E, Trookman NS, Rizer RL, et al. Safety and tolerability of a body wash and moisturizer when applied to infants and toddlers with a history of atopic dermatitis: results from an open-label study. *Pediatr Dermatol.* 2012. doi:10.1111/j.1525-1470.2012.01809.x.

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An expert panel discusses best practices and techniques for temple rejuvenation at the 2013 Vegas Cosmetic Surgery and Aesthetic Dermatology meeting.
dermatologytimes.com/temple

Research sheds light on pathophysiology of acne, rosacea
dermatologytimes.com/acne

RUC flawed but functional
modernmedicine.com/tag/ruc-2013

FDA approves Juvéderm for adult midface volume loss
dermatologytimes.com/juvederm

resources in dermatology

Botulinum toxin has a variety of medical uses, including smoothing out frown lines and treating pain. Use these resources to stay informed on the latest in neurotoxins. dermatologytimes.com/injections

Access resources to help you efficiently adopt electronic health record systems and attest to meaningful use requirements. dermatologytimes.com/EHRinvestments

The Business of Dermatology

Obama's new promise: Consumers can keep existing insurance plans

President Barack Obama announced that health insurance companies can delay upgrades to existing plans to meet the requirements of the Affordable Care Act until 2014.

DermatologyTimes.com/insurance

Are insurance exchanges a good option for your practice?

Here is what to assess when deciding whether to buy health insurance for your practice on the exchanges.

DermatologyTimes.com/options

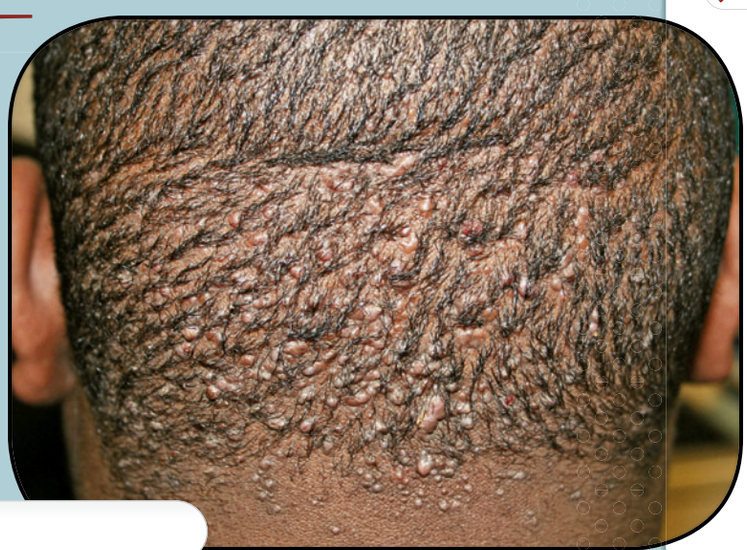
Howto build a budget for your practice in 2014

The looming economic uncertainty of the Affordable Care Act should force physicians to keep a close eye on expenses and income. A practical budget is still one of the most important management tools for a practice owner.

DermatologyTimes.com/budget

What's Your Diagnosis?

A healthy adolescent boy asks you to cure an itchy and painful rash on the nape of his neck that began over a year ago when he had switched barbers. The barber began shaving the back of his neck with a straight razor. What's your diagnosis?



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Help break the unpredictable cycle of rosacea…

CONTAIN THE FLARE OF INFLAMMATION

STRIKE BACK WITH ORACEA®

Oracea® (doxycycline, USP) Capsules, 40 mg:

- Formulated for an effective anti-inflammatory response—30 mg immediate and 10 mg delayed release beads[1]
- Efficacy equivalent to doxycycline 100 mg with fewer GI side effects[2]*
  —In pivotal clinical studies, the most common GI side effect was diarrhea (4.5%)[1]
- No evidence of bacterial resistance in a 9-month safety study[3†]

Important Safety Information

Indication: ORACEA® is indicated for the treatment of only inflammatory lesions (papules and pustules) of rosacea in adult patients. ORACEA® does not lessen the facial redness caused by rosacea. **Adverse Events:** In controlled clinical studies, the most commonly reported adverse events (>2%) in patients treated with ORACEA® were nasopharyngitis, sinusitis, diarrhea, hypertension and aspartate aminotransferase increase. **Warnings/Precautions:** ORACEA® should not be used to treat or prevent infections. ORACEA® should not be taken by patients who have a known hypersensitivity to doxycycline or other tetracyclines. ORACEA® should not be taken during pregnancy, by nursing mothers, or during tooth development (up to the age of 8 years). Although photosensitivity was not observed in clinical trials, ORACEA® patients should minimize or avoid exposure to natural or artificial sunlight. The efficacy of ORACEA® treatment beyond 16 weeks and safety beyond 9 months have not been established.

You are encouraged to report negative side effects of prescription drugs to the FDA. *Visit www.fda.gov/medwatch* or call 1-800-FDA-1088.

Please see brief summary of Prescribing Information on adjacent page.

*A randomized, multicenter, outpatient, double-blind, active-controlled, noninferiority trial of 91 rosacea patients (≥18 years of age) over 16 weeks. Patients were prospectively randomized to receive daily doses of either 40-mg Oracea® or 100-mg doxycycline, each with metronidazole 1%.[2]

†A randomized, multicenter, double-blind, placebo-controlled, parallel-group study of 266 patients (≥18 years of age) was conducted to evaluate the efficacy of 40-mg Oracea® as an adjunct to scaling and root planing for the treatment of periodontitis over a 9-month period. Patients were evaluated at 3, 6, and 9 months after baseline visit.[3]

START WITH
Once-daily 40 mg Capsules*
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AT THE FIRST SIGN OF INFLAMMATORY ROSACEA

IMPORTANT INFORMATION ABOUT

Oracea®

(doxycycline, USP) 40 mg* Capsules

***30 mg Immediate Release & 10 mg Delayed Release beads**

BRIEF SUMMARY

This summary contains important information about ORACEA (Or-RAY-sha). It is not meant to take the place of your doctor's instructions. Read this information carefully before you start taking ORACEA. Ask your doctor or pharmacist if you do not understand any of this information or if you want to know more about ORACEA. For full Prescribing Information and Patient Information please see the package insert.

WHAT IS ORACEA?

ORACEA is a prescription medicine to treat only the pimples or bumps on the face caused by a condition called rosacea. ORACEA is not an antibiotic dose of doxycycline and should not be used for the treatment of infections. ORACEA did not lessen the facial redness caused by rosacea. ORACEA has not been studied for the treatment of rosacea of the eyes or of small blood vessels in the skin. It is not known if ORACEA is effective for use for longer than 16 weeks and it is not known if ORACEA is safe for use longer than 9 months.

WHO IS ORACEA FOR?

ORACEA is for use in adults.

ORACEA should not be given to infants and children 8 years or younger because it may cause staining during tooth development that will not go away.

Also, do not take ORACEA if you are allergic to any medicine known as a tetracycline, including doxycycline and minocycline. If you are not sure, talk to your doctor or pharmacist.

WHAT SHOULD I TELL MY DOCTOR BEFORE TAKING ORACEA?

Tell your doctor about all your health conditions, especially if you

- have had an allergic reaction to doxycycline or other medicines known as tetracyclines.
- are pregnant or planning to become pregnant. ORACEA may harm your unborn baby.
- are breastfeeding. ORACEA passes into breast milk and may harm your baby.
- have kidney problems.
- have liver problems.
- have had surgery on your stomach.
- have or had a yeast or fungus infection in your mouth or vagina.
- spend time in sunlight or artificial sunlight, such as a tanning booth or sunlamp. Although sensitivity to sunlight has not been observed in controlled clinical studies of ORACEA, tetracycline-class products can cause you to get severe sunburns.

Tell your doctor about all of the medicines you take, including prescription and non-prescription medicines, vitamins, and herbal supplements.

ORACEA and other medicines can affect each other causing serious side effects. Especially tell your doctor if you take

- blood thinners (anticoagulants), such as warfarin or Coumadin®. Your doctor may need to change your anticoagulant dose.
- any medicine to treat pimples (acne) or psoriasis.
- birth control pills. Talk to your doctor about other methods of birth control because birth control pills may not work as well when you are taking ORACEA.
- proton pump inhibitors or antacid medicines containing calcium, magnesium or aluminum.
- products containing iron or bismuth subsalicylate.
- any medicine to treat an infection, such as penicillin.
- any medicine to treat seizures.

WHAT SHOULD I AVOID WHILE TAKING ORACEA?

- Although sensitivity to sunlight has not been observed in controlled clinical studies of ORACEA, you should not spend time in sunlight or artificial sunlight, such as a tanning booth or sunlamp. You could get a severe sunburn. Use sunscreen and wear clothes that cover your skin if you have to be in sunlight.
- You should not take ORACEA if you are pregnant or breast feeding or are a man or a woman trying to have a baby.

WHAT ARE THE MOST COMMON SIDE EFFECTS OF ORACEA?

Common side effects of ORACEA are soreness in the nose and throat, diarrhea, sinus infection, high blood pressure, and increase in aspartate aminotransferase in the blood.

ORACEA may also cause

- darkening of your skin, scars, teeth, or gums
- severe headaches, dizziness, or double vision from high pressure in the fluid around the brain

ORACEA may cause serious side effects. Stop taking ORACEA and talk to your doctor right away if you

- have any skin rash, redness, or unusual or severe sunburn
- have an allergic reaction, which may cause a skin rash, swelling, difficulty swallowing, or a feeling of tightness in your throat
- become pregnant
- have stomach cramps, high fever, and bloody diarrhea
- have fever, rash, joint pain, and feel tired. These may be symptoms of a problem where your body is attacking itself (autoimmune syndrome)

These are not all of the possible side effects of ORACEA. For more information, ask your doctor or pharmacist.

You are encouraged to report negative side effects of prescription drugs to the FDA at *www.fda.gov/medwatch or call 1-800-FDA-1088*. You may also contact GALDERMA LABORATORIES, L.P. AT 1-866-735-4137.

HOW SHOULD I TAKE ORACEA?

- Take ORACEA exactly as prescribed by your doctor. Do not change your dose unless told to do so by your doctor. Taking more than the prescribed dose may increase your chance of having side effects.
- The usual dose of ORACEA is one capsule in the morning on an empty stomach. You should take ORACEA at least one hour before or two hours after a meal.
- Take ORACEA with a full glass of water while sitting or standing. To prevent irritation to your throat, do not lay down right after taking ORACEA.
- Do not take ORACEA with or right after taking antacids or products that contain calcium, aluminum, magnesium, or iron. ORACEA may not work as well.
- If you take too much ORACEA, or overdose, stop taking ORACEA and talk to your doctor.
- If you miss a dose of ORACEA, skip that dose and take the next dose at your regular time.
- Do not take ORACEA to treat infections caused by bacteria, germs or viruses.
- Your doctor may do blood tests from time to time to check for side effects of ORACEA.

WHERE SHOULD I GO FOR MORE INFORMATION ABOUT ORACEA?

- Talk to your doctor or pharmacist
- Go to **www.oracea.com** or call **1-866-735-4137**

GALDERMA LABORATORIES, L.P., Fort Worth, Texas 76177 USA

Revised: February 2013

References: 1. Data on file. Galderma Laboratories, L.P. **2.** Del Rosso JQ, Schlessinger J, Werschler P. Comparison of anti-inflammatory dose doxycycline versus doxycycline 100 mg in the treatment of rosacea. *J Drugs Dermatol.* 2008;7(6):573-576. **3.** Preshaw PM, Novak MJ, Mellonig J, et al. Modified-release subantimicrobial dose doxycycline enhances scaling and root planing in subjects with periodontal disease. *J Periodontol.* 2008;79(3):440-452.

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DAVID J. GOLDBERG, M.D., J.D.
is director of Skin Laser & 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.

I'm getting bad reviews on social media. What can I do?

Dr. John has a very busy medical and cosmetic practice. The growth of his practice, and its success, is a testament to the quality of services he provides. Recently, while surfing the Web, Dr. John notes that a recent patient said, "Dr. John was arrogant, insensitive and ran late. The diagnosis he gave me was wrong. And for that, I had to dish out a $50 co-pay. Stay away — forever." Dr. John is incensed. What can he do?

The reality is that most dermatologists go into medicine to help patients. Some dermatologists do provide better care than others. But most are conscientious and wake up every day intending to do the best possible job for their patients. The average experienced dermatologist sees thousands of patients every year. It is impossible to make 100 percent of our patients happy. It is inevitable you will, at some point, receive a bad review. It could be for any number of reasons. What can you do? Do you have legal recourse?

The reality is that if you have an isolated bad review amidst a sea of positive reviews, that is very different than scores of awful reviews. The public generally understands no physician can make everyone happy. But, the public also expects you will make most patients happy. So the first piece of advice is do not sweat an isolated negative review. But can Dr. John fix a negative review?

Unfortunately, most reviews are anonymous, and/or are written under a pseudonym, and/or the review may not give specific information that would allow the aggrieved dermatologist to determine who wrote it. If Dr. John can figure out the author of the review, he should consider reaching out to the patient. If he can fix the patient's problem, he should do so. Sometimes, it's an escalating misunderstanding over a $20 bill. Other times, it's the perception that the physician was rude, does not listen or does not care. These are solvable issues.

> Merely calling the patient and **apologizing** for any misunderstanding may be enough.

Merely calling the patient and apologizing for any misunderstanding may be enough. Most doctors do not call patients about such matters — when YOU do so, it sets you apart from others. It's what top performers in every other industry do. Healthcare should not be an exception.

Take action

More commonly the physician is not sure who the patient is. The complaint is general. If it's a systemic complaint about your office, and you can fix it — do so. Then, tell the world you heard the message and took action. If it's an isolated complaint, consider responding online. You will need to be cognizant of HIPAA issues in doing so. An anonymous post still may contain enough detail to identify the patient. Consider responding online to the post if you can do so in a HIPAA-compliant way.

The more global problem is that every review site has is its own "ecosystem." They have their own guiding philosophies and rules. Most have terms of use. If you believe the review was unfair and violated the terms of use, diplomatically write the site and ask if it will take a look at the post in the context of its terms of use. They may agree with you and remove the post. Remember, each site is run by human beings who are more likely to respond to "please" and "thank you" than to threats. Couch your note as a request and not a demand.

Finally, a high-performing practice can be distinguished online by proactively asking patients for feedback. If you have a great patient safety record, positive clinical outcomes, and great "customer service," your online reputation should mirror your actual reputation. But, you have to be diligent in asking your patients for online feedback. When the inevitable negative review does surface, it will be placed in context of the multitude of positives. Although some social media sites, such as Yelp.com, on the surface seem to highlight negative reviews and discard positive reviews, this is not true for most social media review sites.

Be proactive

Asking your patients for online feedback allows high-performing practices to be fairly represented online. This drives new patient volume and new patient revenue. If a dermatologist has an office, he/she will receive some bad — and even rotten — reviews.

The best way to prepare for that day is for physicians to ask their patients for online feedback each and every day. That way the physician will be defined by hundreds of happy patients instead of two noisy patients with a megaphone. With this, the public will have a representative picture of your practice.

Lastly, Dr. John may wish to sue the website and/or the patient. This attempt is not likely to be successful. The First Amendment right to freedom of speech protects almost all except the most egregious of online complaints. In the end, try to keep most of your patients happy! **DT**

Share your experience

Have you received poor reviews? How did you address it? Tell us: **editor@dermatologytimes.com**

insight & opinion from our advisory board leaders

RONALD G. WHEELAND, M.D.
is a private practitioner in Tucson, Ariz.

Medical, technology advances in dermatology

I have been trying to catalog and assign relative importance to the many changes in the field of medicine that have occurred during my medical career. I first concentrated on the various federal policies and programs that have changed how we practice medicine. This part will review the development of new administrative tools as well as new technologies, drugs and devices that have impacted on dermatologic healthcare delivery.

Administrative tools and software

Computer advances: The "old days" of characterizing patient notes in many physicians' medical offices records as being brief, barely legible and handwritten are really now — thankfully — mostly gone. This is, in large part, due to the introduction of computer technology into medical offices making possible the creation of patient notes that were more complete, more comprehensive and certainly more legible than the formerly handwritten ones.

There are also some potential downsides, however, to using computers in a medical practice, including the potential inadvertent loss of patient digital data, failure of security precautions leading to the loss of patient medical record privacy, as well as the cost of the computer hardware and software.

It has also been my observation that there can be a decrease in the amount of valuable face-to-face personal contact time between the physician and the patient as one tries to simultaneously record the details of the current office visit on the laptop while maintaining eye contact with the patient. However, as improved voice-recognition software becomes available, many of these problems will disappear, making the electronic medical record even easier to utilize to its full potential.

The Internet: That seemingly endless source of information known as the Internet has provided virtually instant access to knowledge. Need a medical reference to care for a patient? Journal access to nearly every publication is available through most individual journals, as well as Grateful Med and a host of other sources.

Online access to the entire electronic Physician's Desk Reference (PDR) with all the drugs, indications, dosages and contraindications approved for use today in the United States is available at your fingertips.

Social media: Once relegated to an almost "gossip column" status, social media (Facebook, Twitter and blogs) have become ideal ways for physicians to provide useful health information on a variety of topics and even carry on a dialogue with interested users. Using social media, it is possible for a physician to seek out individuals who might have an interest in the scope of services provided in their medical office and, thus, increase referrals to the dermatologic practice.

Electronic medical records (EMRs): Although the requirement to establish a secure electronic medical record came as part of federal regulations pertaining to the care of Medicare and Medicaid recipients, it was a logical transition from physicians who were already voluntarily utilizing computer technology to write daily patient visit notes. Justified criticisms of the EMR include: the large financial outlay needed to acquire the necessary equipment, time spent learning to use the software instead of caring for patients, myriad rules and regulations on how to submit bills for payment, and the issue of how to deal with a practices' old handwritten patient records, as well as how best to incorporate them into the patient's electronic file.

While I believe EMRs do increase security and reduce the volume of paper found in most medical offices, I know of several dermatologists who retired early just so they wouldn't have to scan years and years of patient files into the new EMR system in order to meet the regulations.

I also know of one physician who simply pays the penalty for not using an EMR rather than deal with all the associated trouble of implementing it

ADVANCES see page 12

Read Dr. Wheeland's thoughts about important federal policy changes over the past 50 years in the first part of his editorial, now online.

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ADVANCES:

Tools and technologies impacting dermatology from page 10

since most of his patients are young and do not fall under the Medicare guidelines of an EMR. It should be noted that this tactic may well change under the rules of the Affordable Care Act.

Digital photography: Nearly every dermatologist can benefit from having this technology available in his or her office. Not only does digital photography offer a superb way to monitor the success of treatment for a medical problem such as psoriasis or atopic dermatitis, it also is the cosmetic dermatologist's best friend. Most cameras are relatively inexpensive and there is no film to develop. Images can be captured instantaneously and quite effectively in a regular exam room in hand-held fashion, and storage is relatively simple.

Technological advances

Medications: Where would we be without antibiotics, steroids (both oral and topical), biologics, isotretinoin, sunscreens, topical chemotherapeutic agents (5-fluorouracil/5-FU) and local, topical and tumescent anesthetics? With the possible exception of sulfas and penicillin, all of these medications have been developed since the end of World War II and have demonstrated significant advantages in the care of many dermatologic diseases and disorders.

Cosmetic medications: Chemical peels (trichloroacetic acid, phenol, and salicylic acid) for acne scars, rhytids, aging and dyspigmentation, filler substances for depressed scars and onabotulinumtoxinA for rhytids.

Cosmetic procedures: Hair replacement surgery, tumescent liposuction, highly focused ultrasound for subcutaneous fat removal, vein stripping of varicose veins and dermabrasion for scars from acne or trauma.

Lasers and light: Beginning with the ruby laser in 1960, a host of other devices, including: carbon dioxide, argon, Nd:YAG, krypton, copper vapor, erbium:YAG, diode, intense pulsed light (IPL), alexandrite, fractional ablative and nonablative lasers, thulium fiber laser, picosecond lasers and many others have been developed to improve results with greater precision and faster healing than previously possible.

> Social media ... have become ideal ways for physicians to **provide useful health information** on a variety of topics and even carry on a dialogue.

Miscellaneous procedures

Mohs micrographic surgery: The ability to successfully treat most nonmelanoma skin cancers using Mohs micrographic surgery has revolutionized the care of patients with severe sun exposure.

Sentinel lymph node (SLN) biopsy: This widely used procedure has important implications in the management of many cancers. In dermatology, SLN biopsies can be helpful in the treatment of malignant melanoma, squamous cell carcinoma, Merkel cell carcinoma and many others to help determine the best possible treatment for patients with these tumors.

Dermoscopy: These small, inexpensive and portable devices have reduced the number of unnecessary procedures and increase the accuracy of diagnosing melanomas and dysplastic nevi.

Sclerotherapy: A small needle, a bottle of inexpensive saline, some magnification and patience has helped to eradicate unsightly blood vessels with minimal risks.

Synthetic surgical dressings: Use of permeable and semipermeable dressings has improved the rate and quality of wound healing and reduced the amount of care required by patients to obtain the most ideal postoperative or traumatic wound results.

Dermatopathology: Electron microscopy and special tissue stains have largely been replaced by immunofluorescence and immunohistochemistry. Not only do these new techniques provide more accurate diagnoses of many difficult skin tumors or conditions, they permit it to be done faster and easier than before.

What I have attempted to do with this review of the advances that have occurred in the field of medicine over the past 50 years or so is to give my view of the legislative, regulatory, administrative tools, drugs, devices and techniques that I believe have shaped the specialty of dermatology and will continue to provide benefits as well as present challenges to the effective practice of our specialty for decades to come.

While thorough, I have made no attempt to be all-inclusive and would welcome any changes, corrections, additions or deletions that the reader may have to suggest. The number of positive changes in these areas of dermatologic practice, I hope, will continue to help us provide high quality care for our patients with diseases of the skin, hair and nails despite any difficulties produced by current and future changes to the healthcare delivery system in the United States. **DT**

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INDICATION

XEOMIN® (incobotulinumtoxinA) for injection, for intramuscular use is indicated for the temporary improvement in the appearance of moderate to severe glabellar lines associated with corrugator and/or procerus muscle activity in adult patients.

IMPORTANT SAFETY INFORMATION, INCLUDING BOXED WARNING

WARNING: DISTANT SPREAD OF TOXIN EFFECT

Postmarketing reports indicate that the effects of XEOMIN and all botulinum toxin products may spread from the area of injection to produce symptoms consistent with botulinum toxin effects. These may include asthenia, generalized muscle weakness, diplopia, blurred vision, ptosis, dysphagia, dysphonia, dysarthria, urinary incontinence and breathing difficulties. These symptoms have been reported hours to weeks after injection. Swallowing and breathing difficulties can be life threatening and there have been reports of death. The risk of symptoms is probably greatest in children treated for spasticity but symptoms can also occur in adults treated for spasticity and other conditions, particularly in those patients who have underlying conditions that would predispose them to these symptoms. In unapproved uses, including spasticity in children and adults, and in approved indications, cases of spread of effect have been reported at doses comparable to those used to treat cervical dystonia and at lower doses.

CONTRAINDICATIONS

XEOMIN is contraindicated in patients with a known hypersensitivity to the active substance botulinum toxin type A or to any of the components in the formulation and in the presence of infection at the proposed injection site(s), as injection could lead to severe local or disseminated infection.

WARNINGS AND PRECAUTIONS

- The potency units of XEOMIN are not interchangeable with other preparations of botulinum toxin products. Therefore, units of biological activity of XEOMIN cannot be compared to or converted into units of any other botulinum toxin products.
- Hypersensitivity reactions have been reported with botulinum toxin products (anaphylaxis, serum sickness, urticaria, soft tissue edema, and dyspnea). If serious and/or immediate hypersensitivity reactions occur further injection of XEOMIN should be discontinued and appropriate medical therapy immediately instituted.
- Treatment with XEOMIN and other botulinum toxin products can result in swallowing or breathing difficulties. Patients with pre-existing swallowing or breathing difficulties may be more susceptible to these complications. When distant effects occur, additional respiratory muscles may be involved. Patients may require immediate medical attention should they develop problems with swallowing, speech, or respiratory disorders. Dysphagia may persist for several months, which may require use of a feeding tube and aspiration may result from severe dysphagia *[See Boxed Warning]*.
- **Glabellar Lines:** Do not exceed the recommended dosage and frequency of administration of XEOMIN. In order to reduce the complication of ptosis the following steps should be taken:
  - » avoid injection near the levator palpebrae superioris, particularly in patients with larger brow depressor complexes;
  - » corrugator injections should be placed at least 1 cm above the bony supraorbital ridge.
- Individuals with peripheral motor neuropathic diseases, amyotrophic lateral sclerosis, or neuromuscular junctional disorders (e.g., myasthenia gravis or Lambert-Eaton syndrome) should be monitored particularly closely when given botulinum toxin. Patients with neuromuscular disorders may be at increased risk of clinically significant effects including severe dysphagia and respiratory compromise from typical doses of XEOMIN.
- XEOMIN contains human serum albumin. Based on effective donor screening and product manufacturing processes, it carries an extremely remote risk for transmission of viral diseases and Creutzfeldt-Jakob disease (CJD). No cases of transmission of viral diseases or CJD have ever been reported for albumin.

ADVERSE REACTIONS

Glabellar Lines: The most commonly observed adverse reaction (incidence ≥ 2% of patients and greater than placebo) for XEOMIN was Headache (5.4%).

DRUG INTERACTIONS

Concomitant treatment of XEOMIN and aminoglycoside antibiotics, spectinomycin, or other agents that interfere with neuromuscular transmission (e.g., tubocurarine-like agents), or muscle relaxants, should be observed closely because the effect of XEOMIN may be potentiated. The effect of administering different botulinum toxin products at the same time or within several months of each other is unknown. Excessive neuromuscular weakness may be exacerbated by administration of another botulinum toxin prior to the resolution of the effects of a previously administered botulinum toxin.

USE IN PREGNANCY

Pregnancy Category C: There are no adequate and well-controlled studies in pregnant women. XEOMIN should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

PEDIATRIC USE

The safety and effectiveness of XEOMIN in patients less than 18 years of age have not been established.

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BRIEF SUMMARY. Visit www.XEOMIN.com for full Prescribing Information.

WARNING: DISTANT SPREAD OF TOXIN EFFECT

Postmarketing reports indicate that the effects of XEOMIN and all botulinum toxin products may spread from the area of injection to produce symptoms consistent with botulinum toxin effects. These may include asthenia, generalized muscle weakness, diplopia, blurred vision, ptosis, dysphagia, dysphonia, dysarthria, urinary incontinence and breathing difficulties. These symptoms have been reported hours to weeks after injection. Swallowing and breathing difficulties can be life threatening and there have been reports of death. The risk of symptoms is probably greatest in children treated for spasticity but symptoms can also occur in adults treated for spasticity and other conditions, particularly in those patients who have underlying conditions that would predispose them to these symptoms. In unapproved uses, including spasticity in children and adults, and in approved indications, cases of spread of effect have been reported at doses comparable to those used to treat cervical dystonia and at lower doses *[see Warnings and Precautions]*.

CONTRAINDICATIONS

Hypersensitivity-Use in patients with a known hypersensitivity to the active substance botulinum neurotoxin type A, or to any of the excipients (human albumin, sucrose), could lead to a life-threatening allergic reaction. XEOMIN is contraindicated in patients with known hypersensitivity to any botulinum toxin preparation or to any of the components in the formulation *[see Warnings and Precautions]*.

Infection at Injection Site-Use in patients with an infection at the injection site could lead to severe local or disseminated infection. XEOMIN is contraindicated in the presence of infection at the proposed injection site(s).

WARNINGS AND PRECAUTIONS

- **Spread of Toxin Effect-**Postmarketing safety data from XEOMIN and other approved botulinum toxins suggest that botulinum toxin effects may, in some cases, be observed beyond the site of local injection. The symptoms are consistent with the mechanism of action of botulinum toxin and may include asthenia, generalized muscle weakness, diplopia, blurred vision, ptosis, dysphagia, dysphonia, dysarthria, urinary incontinence, and breathing difficulties *[see Boxed Warning (above)]*.
- **Lack of Interchangeability between Botulinum Toxin Products-**The potency Units of XEOMIN are specific to the preparation and assay method utilized. They are not interchangeable with the other preparations of botulinum toxin products and, therefore, Units of biological activity of XEOMIN cannot be compared to or converted into Units of any other botulinum toxin products assessed with any other specific assay method.
- **Hypersensitivity Reactions-**Hypersensitivity reactions have been reported with botulinum toxin products (anaphylaxis, serum sickness, urticaria, soft tissue edema, and dyspnea). If serious and/or immediate hypersensitivity reactions occur further injection of XEOMIN should be discontinued and appropriate medical therapy immediately instituted.
- **Dysphagia and Breathing Difficulties in Treatment of Cervical Dystonia-**Treatment with XEOMIN and other botulinum toxin products can result in swallowing or breathing difficulties. Patients with pre-existing swallowing or breathing difficulties may be more susceptible to these complications. In most cases, this is a consequence of weakening of muscles in the area of injection that are involved in breathing or swallowing. When distant effects occur, additional respiratory muscles may be involved. Deaths as a complication of severe dysphagia have been reported after treatment with botulinum toxin. Dysphagia may persist for several months, and require use of a feeding tube to maintain adequate nutrition and hydration. Aspiration may result from severe dysphagia and is a particular risk when treating patients in whom swallowing or respiratory function is already compromised. In general, limiting the dose injected into the sternocleidomastoid muscle may decrease the occurrence of dysphagia. Patients treated with botulinum toxin may require immediate medical attention should they develop problems with swallowing, speech or respiratory disorders. These reactions can occur within hours to weeks after injection with botulinum toxin *[see Warnings and Precautions and Adverse Reactions in Full Prescribing Information for more information]*.
- **Pre-existing Neuromuscular Disorders and other Special Populations-**Individuals with peripheral motor neuropathic diseases, amyotrophic lateral sclerosis, or neuromuscular junctional disorders (e.g., myasthenia gravis or Lambert-Eaton syndrome) should be monitored particularly closely when given botulinum toxin. Patients with neuromuscular disorders may be at increased risk of clinically significant effects including severe dysphagia and respiratory compromise from typical doses of XEOMIN *[see Adverse Reactions]*.
- **Corneal Exposure, Corneal Ulceration, and Ectropion in Patients Treated with XEOMIN for Blepharospasm-**Reduced blinking from injection of botulinum toxin products in the orbicularis muscle can lead to corneal exposure, persistent epithelial defect and corneal ulceration, especially in patients with VII nerve disorders. Careful testing of corneal sensation in eyes previously operated upon, avoidance of injection into the lower lid area to avoid ectropion, and vigorous treatment of any epithelial defect should be employed. This may require protective drops, ointment, therapeutic soft contact lenses, or closure of the eye by patching or other means. Because of its anticholinergic effects, XEOMIN should be used with caution in patients at risk of developing narrow angle glaucoma. To prevent ectropion, botulinum toxin products should not be injected into the medial lower eyelid area. Ecchymosis easily occurs in the soft tissues of the eyelid. Immediate gentle pressure at the injection site can limit that risk.
- **Risk of Ptosis in Patients Treated with XEOMIN for Glabellar Lines-**Do not exceed the recommended dosage and frequency of administration of XEOMIN. In order to reduce the complication of ptosis the following steps should be taken:
  - » Avoid injection near the levator palpebrae superioris, particularly in patients with larger brow depressor complexes.
  - » Corrugator injections should be placed at least 1 cm above the bony supraorbital ridge.
- **Human Albumin and Transmission of Viral Diseases-**This product contains albumin, a derivative of human blood. Based on effective donor screening and product manufacturing processes, it carries an extremely remote risk for transmission of viral diseases. A theoretical risk for transmission of Creutzfeldt-Jakob disease (CJD) is also considered extremely remote. No cases of transmission of viral diseases or CJD have ever been reported for albumin.

ADVERSE REACTIONS

The following adverse reactions to XEOMIN are discussed in greater detail in other sections of the labeling:

- » Hypersensitivity *[see Contraindications and Warnings and Precautions]*
- » Spread of Effects from Toxin *[see Warnings and Precautions]*

Glabellar Lines In three placebo-controlled trials in 803 subjects with glabellar lines, 535 subjects received a single dose of 20 Units XEOMIN and 268 subjects received placebo. XEOMIN treated subjects were 24 to 74 years old, and were predominantly female (88%). The most frequent adverse reactions in XEOMIN treated subjects were: headache 29 (5.4%), facial paresis 4 (0.7%), injection site hematoma 3 (0.6%) and eyelid edema 2 (0.4%). Four serious adverse events occurred in two placebo-treated subjects. Six XEOMIN treated subjects experienced six serious adverse events. All serious adverse events were assessed as unrelated to study drug. The adverse reactions below reflect exposure to XEOMIN with glabellar lines in placebo-controlled studies. Adverse reactions are adverse events in which there is some basis to believe there is a causal relationship between the drug and the occurrence of the adverse event. 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.

Table 4: Adverse Reactions in Placebo-Controlled Trials

Adverse reactions	XEOMIN (N=535) (%)	Placebo (N=268) (%)
Nervous system disorders	**33 (6.1)**	**6 (2.2)**
Headache[1]	29 (5.4)	6 (2.2)
Facial paresis (brow ptosis)	4 (0.7)	0
General disorders and administration site conditions	**5 (0.9)**	**2 (0.7)**
Injection site hematoma	3 (0.6)	0
Injection site pain	1 (0.2)	0
Facial pain	1 (0.2)	0
Injection site swelling	0	1 (0.4)
Sensation of pressure	0	1 (0.4)
Eye disorders	**5 (0.9)**	**0**
Eyelid edema	2 (0.4)	0
Blepharospasm	1 (0.2)	0
Eye disorder	1 (0.2)	0
Eyelid ptosis	1 (0.2)	0

In open label, multiple dose trials, adverse reactions were reported for 105 of the 800 subjects (13.1%). Headache was the most common adverse reaction, reported for 57 subjects (7.1%), followed by injection site hematoma in 8 subjects (1.0%). Adverse reactions reported in less than 1% of subjects were: facial paresis (brow ptosis), muscle disorder (elevation of eyebrow), injection site pain, and eyelid edema.

Immunogenicity-As with all therapeutic proteins, there is a potential for immunogenicity.

Postmarketing Experience-The following adverse reactions have been reported during post-approval use with XEOMIN. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure: eye swelling, eyelid edema, dysphagia, nausea, flu-like symptoms, injection site pain, injection site reaction, allergic dermatitis, localized allergic reactions like swelling, edema, erythema, pruritus or rash, herpes zoster, muscular weakness, muscle spasm, dysarthria, myalgia and hypersensitivity.

DRUG INTERACTIONS

No formal drug interaction studies have been conducted with XEOMIN. Coadministration of XEOMIN and aminoglycoside antibiotics or other agents interfering with neuromuscular transmission, e.g., tubocurarine-type muscle relaxants, should only be performed with caution as these agents may potentiate the effect of the toxin. Use of anticholinergic drugs after administration of XEOMIN may potentiate systemic anticholinergic effects. The effect of administering different botulinum toxin products at the same time or within several months of each other is unknown. Excessive neuromuscular weakness may be exacerbated by administration of another botulinum toxin prior to the resolution of the effects of a previously administered botulinum toxin. Excessive weakness may also be exaggerated by administration of a muscle relaxant before or after administration of XEOMIN.

USE IN SPECIFIC POPULATIONS

Pregnancy-Pregnancy Category C: There are no adequate and well-controlled studies in pregnant women. XEOMIN should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Nursing Mothers-It is not known whether botulinum toxin type A is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when XEOMIN is administered to a nursing woman.

Pediatric Use-Safety and effectiveness of XEOMIN in patients less than 18 years of age have not been established *[see Warnings and Precautions]*.

Geriatric Use-Glabellar Lines There are limited clinical data with XEOMIN in subjects over 65 years of age and over in clinical studies with glabellar lines. Of the total number of subjects in the placebo-controlled clinical studies GL1 and GL2, 21 (4%) subjects were 65 and over. Efficacy was observed in 20% (3/15) of XEOMIN subjects 65 years and over. For the entire safety database of geriatric subjects, there was no increase in the incidence of adverse events related to treatment with XEOMIN.

OVERDOSAGE

Excessive doses of XEOMIN may be expected to produce neuromuscular weakness with a variety of symptoms. Respiratory support may be required where excessive doses cause paralysis of the respiratory muscles. In the event of overdose, the patient should be medically monitored for symptoms of excessive muscle weakness or muscle paralysis *[see Warnings and Precautions].* Symptomatic treatment may be necessary. Symptoms of overdose are not likely to be present immediately following injection. Should accidental injection or oral ingestion occur, the person should be medically supervised for several weeks for signs and symptoms of excessive muscle weakness or paralysis. In the event of overdose, antitoxin raised against botulinum toxin is available from the Centers for Disease Control and Prevention (CDC) in Atlanta, GA. However, the antitoxin will not reverse any botulinum toxin-induced effects already apparent by the time of antitoxin administration. In the event of suspected or actual cases of botulinum toxin poisoning, please contact your local or state Health Department to process a request for antitoxin through the CDC. If you do not receive a response within 30 minutes, please contact the CDC directly at 770-488-7100. More information can be obtained at http://www.cdc.gov/ncidod/srp/drugs/formulary.html#1a.

Please visit www.xeomin.com for full Prescribing Information.

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PHOTO CREDIT: JOON PARK

Danielle Ofri, M.D., *is a physician at Bellevue Hospital and an associate professor of medicine at NYU School of Medicine, New York. She is also editor-in-chief of the* Bellevue Literary Review. *Her commentary is based on a presentation she gave at the summer meeting of the American Academy of Dermatology.*

Human touch with physical exams will never be obsolete

I recently took off a year from clinical medicine in order to write my book, "What Doctors Feel: How Emotions Affect the Practice of Medicine."

I work in a bustling city hospital, so it felt slightly odd to be out of the fray for 12 months. I certainly didn't mind escaping administrative mandates for a year, but I did miss contact with my patients.

During the year, I interviewed many doctors about the formative experiences that made them who they were as doctors. What was so striking was that every doctor had a story, usually several, of powerful experiences that seared their souls and remained with them forever, often coloring their every future move.

Not one of these stories had anything to do with quality measures, productivity, reimbursement mechanisms, or clinical guidelines. Nobody mentioned state regulations or Medicare rules or coding fraud. EMR, MRI, DRG, JCAHO, HCAHP, and HIPAA never came up.

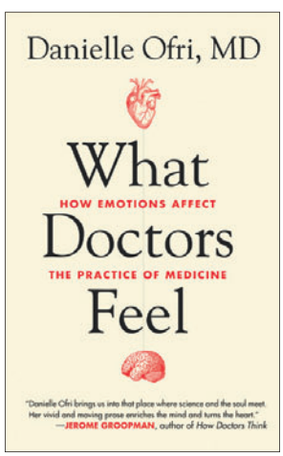
Instead, every single story was an intensely connecting experience between a doctor and patient, even if the story involved conflict, error or regret. Even if no words were spoken between doctor and patient. Even if the doctor and patient crossed paths for only seconds.

What also struck me was how intricately these doctors recalled the stories, many of which took places decades earlier. The detail and specificity of action, dialogue, and setting could be recalled with an almost frightening clarity. This from doctors who, like me, might sneak a peek at the UpToDate app before reciting the differential diagnosis of palpable purpura to a group of medical students.

Technological infiltration

Technology suffuses our every waking moment in medicine. Nearly all of us are (or will be) using an electronic medical record. Screens and computers are part of almost every clinical interaction. We work with medical student and house staff who've never interviewed a patient without an LCD screen humming at hand. We receive reports that calculate the "quality" of our medical care. Every staff member — from the gurney transporter to the unit clerk to the housekeeper — needs a login and password in order to do their job.

And then, God forbid, if the system goes down, an entire medical enterprise can grind to a halt. Nobody, it seems, can register a patient, check a blood pressure or write a prescription without AC current.



Yet, there is still a moment in modern medicine in which technology remains at bay. The physical exam may be the last holdout, the only interaction that takes place between two human beings, conducted only with hands. There is direct touch without — at least for the moment — the intrusion of machines.

The conversation that takes place during the physical exam is entirely different from what occurs during a standard interview with the computer as the go-between. The physical exam is a moment of only talking and touching. Like the stories that doctors related to me during my research, the experience of the physical exam can be profoundly connecting. For that brief moment, the patient has the undivided attention of the doctor, with that most basic of communication systems — touch.

A chance to open up

It is often only during the intimacy of the physical exam that the patient reveals what is truly on his on her mind. There is something about touch that cannot be replicated by even the most advanced simulation systems. It is intensely human, and that human connection can set a tone that makes patients feel comfortable mentioning more vulnerable and frightening issues.

Countless times it is only during physical exams that patients have brought up their true concerns — domestic violence, suicidal ideation, job loss, eating disorders, sexual concerns — things that seemed awkward during the computer-dominated Q&A of the first half of the visit.

Even if the physical exam may have less diagnostic utility as in years past — though this is certainly a debatable point — it still plays a critical role in medicine. I surely wouldn't want to do without MRIs, wireless telemetry, and instant access to lab results and hematology consults, but we should remain cognizant of technology's inherent limitations. I'm grateful that we still have our hands for the rest of the stuff. **DT**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EFFECT.
HALOG Cream and Ointment are designed for a difference your patients can truly feel.
BIPHASIC CREAM for sustained relief.[1,2]
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INDICATIONS AND USAGE: HALOG (Halcinonide, USP) 0.1% is indicated for the relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses.
For topical use only.
For Important Safety Information, please see full Prescribing Information on reverse and also at HalogRx.com.
REFERENCES: 1. Blecker, J. Double-blind comparison between two new topical steroids, halcinonide 0.1% and clobetasol propionate cream 0.05%. Curr Med Res Opin. 1975;3:225-228. 2. Bagatell FK. Halcinonide: a new potent anti-inflammatory drug. Cutis. 1974:14:459-462. 3. Thau P, Fox C. A new procedure for the preparation of polyethylene-mineral oil gels. J Soc Cosmet Chem. 1965;16:359-363.
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HALOG® CREAM or HALOG® OINTMENT is indicated for the relief of the inflammatory and pruritic manifestations of corticosteroid responsive dermatoses.

CONTRAINDICATIONS

Topical corticosteroids are contraindicated in those patients with a history of hypersensitivity to any of the components of the preparations.

PRECAUTIONS

- Systemic absorption of topical corticosteroids has produced reversible hypothalamic-pituitary-adrenal (HPA) axis suppression, manifestations of Cushing's syndrome, hyperglycemia, and glucosuria in some patients.
- Conditions which augment systemic absorption include the application of the more potent steroids, use over large surface areas, prolonged use, and the addition of occlusive dressings.
- Children may absorb proportionally larger amounts of topical corticosteroids and thus be more susceptible to systemic toxicity. Parents of pediatric patients should be advised not to use tight-fitting diapers or plastic pants on a child being treated in the diaper area, as these garments may constitute occlusive dressings.
- Administration of topical corticosteroids to children should be limited to the least amount compatible with an effective therapeutic regimen. Chronic corticosteroid therapy may interfere with the growth and development of children.
- This medication is to be used as directed by the physician. It is for dermatologic use only. Avoid contact with the eyes.
- Patients should be advised not to use this medication for any disorder other than for which it was prescribed.
- The treated skin area should not be bandaged or otherwise covered or wrapped as to be occlusive unless directed by the physician.
- Patients should report any signs of local adverse reactions especially under occlusive dressing.
- **Pregnancy Category C:** Topical corticosteroids 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.
- 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.

ADVERSE REACTIONS

The following local adverse reactions are reported infrequently with topical corticosteroids, but may occur more frequently with the use of occlusive dressings (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.

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(Halcinonide, USP) 0.1%

Federally backed program targets topical nitric oxide therapy for burn wounds

DURHAM, N.C. — The federal government is backing a topical nitric oxide therapy may be the next best thing for treating burns. The Biomedical Advanced Research and Development Authority (BARDA), part of the Department of Health and Human Services, has awarded a two-year, $7.8 million contract to Durham-based Novan Therapeutics to develop a nitric oxide advanced healing (NOAH) technology, a topical treatment for burns. The contract will bolster Novan's ongoing research into NOAH technology for treating combat wounds, multi-drug-resistant infections and chronic wounds.

According to Novan representatives, past studies show that nitric oxide can speed the migration of epidermal cells, stimulate new blood-vessel growth, modulate inflammation and remodel wound beds.

"The link between nitric oxide and the body's ability to heal is well-established," Nathan Stasko, Ph.D., president and founder of Novan, tells **Dermatology Times**. "The challenge is to create stable nitric-oxide drugs that perform on command and deliver a controlled, sustained dose that will supplement the body's ability to regenerate tissue. Our platform technology has allowed us to pursue the development of drugs intended to harness the healing power of nitric oxide."

Joseph V. Boykin Jr., M.D., medical director of the HCA Virginia Wound Healing Centers in Richmond, Va., and well known for his pioneering work in the development of a nitric oxide-based diagnostic for wound healing, says that among its many beneficial attributes, nitric oxide plays a leading role in the release of endothelial progenitor stem cells following injury, and the cellular signaling and mediation of wound repair and regeneration.

"This knowledge base has been achieved through experimental and human research," Dr. Boykin says, "but the clinical implementation of this knowledge has awaited the development of innovative pharmacotherapy capable of precisely reversing critical impairment of nitric-oxide production and providing effective nitric-oxide bioavailability that will mimic natural biological processes."

Dr. Boykin, who is not involved in the current BARDA project, says that with the development of Novan's current platform of nitric-oxide-based therapeutics, the opportunity for significant clinical research and therapeutic advances in the treatment of life-threatening burn injuries may be realized.

"These opportunities to improve the outcomes of burn victims and to better promote the effective physical recovery and rehabilitation of burn-wound victims will be important first steps towards this goal," he says.

One of the potential uses of NOAH is a mass-casualty event resulting in more burn wounds than the current burn-treatment infrastructure can handle effectively.

"Unfortunately, our best efforts to respond to mass-casualty situations with severe burn victims have not significantly improved within the last 20 years," Dr. Boykin says. "It is suggested by experts in burn care that the floor of survival of burn victims has also remained unchanged during this time, while the threat of large-scale thermal injuries with massive casualties appears to be a realistic and growing threat in our society."

BARDA has expressed concern about potential healthcare problems that could be exacerbated due to current limitations of burn care and clinical treatment following a massive thermal catastrophe.

> "We hope to demonstrate that an advanced medical countermeasure can be manufactured that is safe and effective at healing a wide variety of burn injuries — that is our goal."
>
> **Nathan Stasko, Ph.D.**
> President and founder, Novan Therapeutics

"We are also aware of the immense economic and social impact of wounds and wound healing in our society," Dr. Boykin says. "For these reasons, organizations such as the National Institutes of Health are challenged to provide a higher level of resources to understand biological mechanisms underlying cutaneous wound complications that will promote successful wound treatment. It is clear that a sea change in the clinical management of burn victims and effective burn-wound healing is needed. It is also apparent that studies and research of the role of nitric oxide in burn-wound pathophysiology and wound healing may provide the paradigm shift necessary to stimulate the creation of innovative therapies badly needed in this area."

Dr. Stasko says Novan's objective is to tailor NOAH-technology-based products — "ointments, creams, gels, bandages, etc." — for acute and chronic wounds. "We hope to demonstrate that an advanced medical countermeasure can be manufactured that is safe and effective at healing a wide variety of burn injuries — that is our goal." **DT**

Topical mechlorethamine gel for mycosis fungoides launches in U.S.

A TOPICAL GEL, Valchlor (mechlorethamine, Actelion), is now available in the United States for patients with stage 1A and 1B mycosis fungoides-type cutaneous T-cell lymphoma (MF-CTCL).

The topical gel treated is an alkylating drug for MF-CTCL patients who have previously used skin-directed therapy, according to a news release. It is applied once daily. The company states the drug is the first formulation of topical mechlorethamine that is approved by the Food and Drug Administration based on clinical evidence to support its use.

Valchlor, an orphan drug, was acquired by Actelion as the company merged with Ceptaris Therapeutics. The drug is distributed in the United States by Accredo Specialty Pharmacy.

Actelion also launched Valchlor Support, an assistance program for eligible patients starting therapy. **DT**

Laser procedures performed by nonphysicians draw more lawsuits

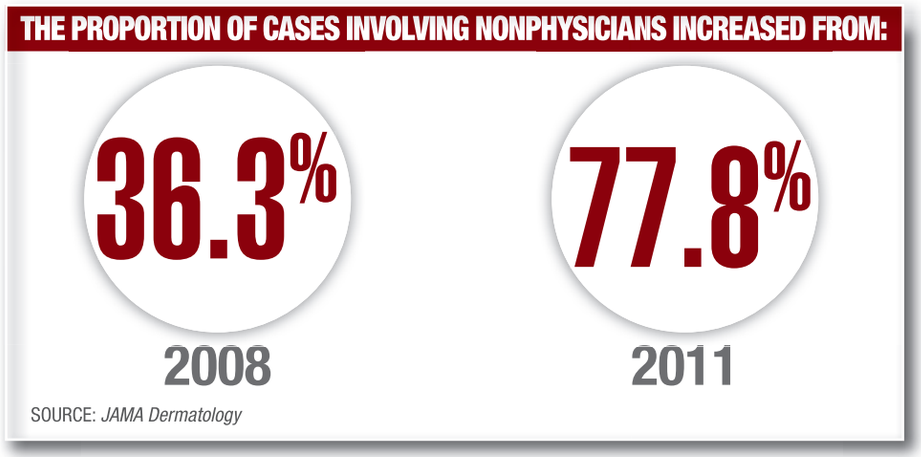
JAMA Dermatology
October 2013

archderm.jamanetwork.com/article.aspx?articleid=1754984

LAWSUITS related to laser procedures performed by nonphysicians are on the rise — particularly those performed outside a traditional medical setting.

According to the study, the nonphysicians included nurse practitioners, registered nurses, medical assistants, electrologists and aestheticians.

A research team led by H. Ray Jalian, M.D., clinical instructor of medicine in the dermatology division at the David Geffen School of Medicine, University of California, Los Angeles, used an online national database to chart the frequency of liability claims stemming from skin-related laser surgeries. They identified 175 cases related to injury from such surgeries between 1999 and 2012. Of those cases, 75 (42.9 percent) involved a nonphysician. The proportion of cases involving nonphysicians increased from 36.3 percent in 2008 to 77.8 percent in 2011.



The study notes that because skin-related laser procedures are increasingly popular, more nonphysicians are performing them in order to meet the demand. The study found that laser hair removal was the most common of these procedures. While only a third of these was performed by nonphysicians, 75.5 percent of hair-removal lawsuits between 2004 and 2012 involved nonphysicians — between 2008 and 2012, that figure had risen to 85.7 percent.

"Procedures performed by untrained individuals, particularly in nonmedical settings, are more likely to result in litigation," Dr. Jalian said in a UCLA news release. "Consumers should be aware that laser treatments are medical procedures and should verify the training, certification and experience of the person performing the procedure."

Dr. Jalian said physicians and others who operate lasers should know their state laws regarding physician supervision of nonphysician laser operators. He also noted that in the correct setting, with close on-site supervision and appropriate training, the use of nonphysician operators can be safe and effective. **DT**

Online skin cancer course improves docs' diagnostic skills

Journal of the American Board of Family Medicine
November-December 2013

www.jabfm.org/content/26/6/648.full

AN ONLINE SKIN CANCER course improved the diagnostic skills of primary care physicians, without impacting dermatology referrals, a recent study suggests.

Researchers with Henry Ford Hospital, Detroit, created a before-and-after evaluation of a one- to two-hour online course on skin cancer detection for primary care physicians (PCPs), according to the study. Fifty-four practicing PCPs volunteered to participate in the course in June 2011, and investigators assessed their ability to diagnose and manage skin cancers in a pre-test, immediate post-test and six months post-test.

Investigators assessed the impact of the online course on practice patterns by tracking participants' patient panels for dermatology referrals and skin biopsies for six months after the course compared to the same period a year later. The Web-based course covered melanoma, basal cell carcinoma and squamous cell carcinoma, plus other benign lesions crucial to differential diagnosis of skin cancers.

Among the participants, 59 percent reported receiving skin cancer education during their residency, but only 15 percent reported that education since beginning their practice. The study suggested the online course improved PCPs' ability to diagnose and manage skin lesions by nearly 30 percent. Participants showed greater improvement with benign skin lesions — immediate post-test scores improved by about 12 percentage points for diagnosis and by 20 points for management.

"The course was particularly effective among participants who reported no previous skin cancer education and those whose pretest scores were in the lower quartile," the study states. "Improvement was still evident six months after taking the course."

Study authors noted PCPs skills at diagnosing skin lesions is important because patients often go to those doctors with questions or concerns about skin conditions.

"A brief, Web-based skin cancer course improved the diagnostic and management skills of practicing PCPs, with improvement still seen at six months, without negative effects on dermatology referrals or visits or skin cancer diagnoses," study authors concluded. **DT**

Twin study shows smoking prematurely ages face

Plastic and Reconstructive Surgery
November 2013

journals.lww.com/plasreconsurg/Fulltext/2013/11000/Facial_Changes_Caused_by_Smoking____A_Comparison.10.aspx

A NEW STUDY of identical twins demonstrates how smoking causes premature aging of the face, causing more wrinkles around the lips and sagging under the eyes.

Researchers led by Bahman Guyuron, M.D., of the department of plastic surgery at Case Western Reserve University and University Hospitals, Cleveland, set out to identify specific components of facial aging secondary to smoking. They did so by identifying 79 pairs of twins in which only one twin smoked or where one smoked at least five years longer than the other.

Participants completed questionnaires, and professional photographers took standardized photographs of the twins. A panel of three blinded judges analyzed the twins' facial features and graded wrinkles using the Lemperle Assessment Scale, then ranked age-related facial features on a four-point scale.

According to the study, which was published in the November issue of *Plastic and Reconstructive Surgery*, twins who smoked compared significantly less favorably to their non-smoking siblings in scores for upper-eyelid skin redundancy, lower-lid bags, malar bags, nasolabial folds, upper lip wrinkles, lower lip vermillion wrinkles and jowls. Lower-lid hyperpigmentation in the smoking group fell just short of statistical significance. There was no statistical difference in transverse forehead wrinkles, glabellar wrinkles, crow's feet and lower lip lines accentuated by puckering.

Among twins with greater than five years' difference in smoking duration, twins who had smoked longer had worse scores for lower lid bags, malar bags and lower lip vermillion wrinkles.

"The most important finding is confirmation of what was assumed to be the aging changes as the consequence of smoking in a scientific manner," Dr. Guyuron tells **Dermatology Times**. "The malar bags and hyperpigmentation of the lower lids seem to be the most common features of the 'smoker face.'" DT

FDA approves luliconazole for tinea pedis

LULICONAZOLE (Luzu Cream, 1 percent, Valeant Pharmaceuticals) has recently been approved by the Food and Drug Administration for the one-week, once-daily treatment of interdigital tinea pedis, tinea cruris, and tinea corporis, caused by the organisms Trichophyton rubrum and Epidermophyton floccosum, in patients ages 18 and older.

Luzu has undergone three positive pivotal studies in the United States that were the basis for approval, according to a news release. The studies were conducted in 679 patients who had either tinea pedis or tinea cruris.

For the two studies in tinea pedis with a treatment duration of two weeks, the primary endpoint was defined as complete clearance at four weeks post-treatment, meaning patients' skin showed no clinical involvement and no evidence of fungus.

In study 1, 26 percent of patients treated with luliconazole demonstrated complete clearance, compared to 2 percent of patients treated with vehicle. In study 2, 14 percent of patients treated with luliconazole were completely cleared, compared to 3 percent of patients treated with vehicle.

For the study in tinea cruris, complete clearance was assessed at three weeks post-treatment. After one week of treatment, 21 percent of patients treated with luliconazole were completely cleared, compared to 4 percent of those treated with vehicle.

Application site reactions — the most common adverse events — were reported in less than 1 percent of patients for both luliconazole and vehicle.

All other approved treatments for these skin conditions require two weeks of treatment, according to the company. Luliconazole has been approved in Japan since 2005. DT

Foam mattresses may prevent pressure ulcers

Journal of the American Geriatric Society
October 2013

onlinelibrary.wiley.com/doi/10.1111/jgs.12440/abstract

USING HIGH-DENSITY foam mattresses, nursing homes may not have to turn residents every two hours to prevent pressure ulcers, a practice that has been used for more than 50 years.

According to a study, led by the University of Texas Health Science Center at Houston (UTHealth), conventional coil-spring mattresses expose residents to higher pressure, which exacerbates the risk of pressure ulcers. High-density foam mattresses create less pressure on the body, which may eliminate the need to turn patients every two hours.

The study — dubbed Turning for Ulcer ReductioN (TURN) — included nearly 1,000 residents from 29 nursing facilities in the United States and Canada, participating over 19,000 resident days. Randomized schedules for turning were set up for study participants who were risk of developing pressure ulcers.

A nurse, blinded to turning frequency, documented skin condition every week, along with type of reposition, heel position, brief condition and skin care at each turn. No serious pressure ulcers developed during the study.

"The TURN Study showed that moderate- and high-risk nursing home residents cared for on high-density foam mattresses could be turned at two-, three- or four-hour intervals and the goal of preventing pressure ulcers can be met," lead author Nancy Bergstrom, Ph.D., UTHealth associate dean, tells ***Dermatology Times***. "There is one very important caveat, though: all of these residents received a safety check at every turning episode. Less frequent turning may promote better rest, but vigilance on the part of staff requires safety observations at each turning episode."

Dr. Bergstrom noted that those episodes include turning position and timing, documenting that heels are up, monitoring skin (red, bruised, open, normal), monitoring briefs (dry, wet, soiled), and brief care (cleaned, barrier cream, dry briefs).

"This one-minute observation check list is an important part of less-frequent turning and brief changes," she says. DT

Dermatology Times

Ablative fractional resurfacing restores form, function after scarring

John Jesitus | Senior Staff Correspondent

NATIONAL REPORT — Being able to open a peanut butter jar may not sound like much. But to a severely burned teenager who couldn't do so before undergoing scar revision with ablative fractional resurfacing (AFR), it's huge.

"Little things make a big difference in your patients' lives," says Andrew C. Krakowski, M.D., who treated the teenager using a protocol adapted from the Navy's Project CARE (Comprehensive Aesthetic Restorative Effort) program for service members wounded in combat. He is assistant clinical professor of pediatrics and dermatology at Rady Children's Hospital, San Diego, and the University of California, San Diego.


Dr. Krakowski

QUICK READ

Ablative fractional resurfacing is revolutionizing the treatment of scars in children and adults. A program at Rady Children's Hospital has adapted protocols pioneered by the U.S. Navy.

"This is probably the biggest thing to happen in scar treatment in decades. I believe it's going to revolutionize the way we treat the traumatically injured," says Cmdr. Peter Shumaker, M.D., chairman of dermatology, Naval Medical Center, San Diego.

After learning the Navy's protocol during a dermatology residency rotation with Dr. Shumaker and Nathan Uebelhoer, D.O., now a dermatologist in private practice in La Jolla, Calif., Dr. Krakowski brought it to the pediatric and adolescent populations served at Rady Children's Hospital. The Kids' Scar Treatment and Revision (STAR) program began in August 2012.

Traditionally, Dr. Krakowski says, "The gold standards for treating painful or itchy hypertrophic scars that impacted function included surgical revision, with or without intralesional corticosteroids."

Ablative lasers have proven very useful for many types of scars, Dr. Shumaker adds. But the compromised skin of large traumatic wounds is susceptible to excessive thermal damage from full-field lasers, he says.

REDUCING COLLATERAL DAMAGE

Conversely, Dr. Krakowski says, "Fractional ablative lasers have allowed scar specialists to deliver a combination of high energy at a

SCARS see page **28**

Quotable

"The use of extracellular matrices for tissue repair has revolutionized wound closure therapy and among other state-of-the-art techniques currently used."

Marco Romanelli, M.D., Ph.D.
Pisa, Italy

On wound healing
See story, page 42

DTExtra

Electrosurgery, pulsed dye laser treatment, and ablative fractional resurfacing, combined with a new targeted therapy — topical sirolimus — may be effective in treating angiofibromas, characteristically seen in patients with tuberous sclerosis, a new study indicates. The authors noted that investigations on the safety of topical sirolimus show that in addition to being safe, **73 percent of patients report that they "got better on treatment."** "Although these responses are not quantitative," they wrote, "they indicate that topical treatment may be an effective adjuvant therapy to laser surgery."

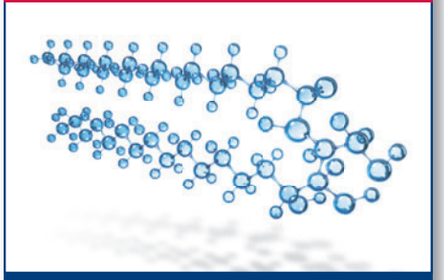
READ MORE: DERMATOLOGYTIMES.COM/ANGIOFIBROMA

THE SCIENCE OF RELIEF

EXPLORING SKIN-SOOTHING AGENTS IN ATOPIC DERMATITIS

How do we deal with the complexities of atopic dermatitis (AD)? Its etiology can include a combination of genetics, environmental triggers, and immunologic and inflammatory pathways. Diagnosis is dependent upon a constellation of both subjective and objective clinical findings. Therapeutic emollients, either as first-line care or in combination with other therapies, have been proven effective in the management and treatment of AD.[1,2] But to truly relieve symptoms and improve the skin barrier for the long term, they should incorporate skin-soothing agents that address the complexities of AD—from the severity of active lesions to the more subtle maintenance of subacute, less symptomatic skin.

CERAMIDES

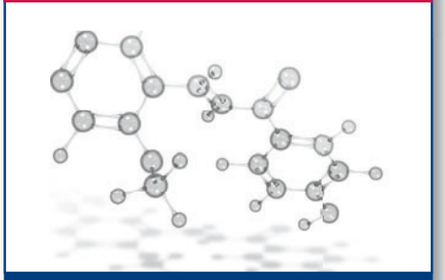


Clinical evidence solidifies the need for ceramides in the treatment of AD: atopic skin, even if non-lesional, usually shows a clear decrease in these intercellular lipids and a consequent increase in transepidermal water loss and impaired barrier. In patients with active lesions in particular, ceramide 3 is significantly lower than in non-symptomatic skin. Impaired skin barrier function leads to increased antigen absorption, which triggers the cutaneous hyperactivity characteristic of AD.[1,3]

COLLOIDAL OATMEAL

With moisturizing, protective, and skin-soothing properties, the active compounds in colloidal oatmeal form an occlusive film, protecting the stratum corneum from outside irritants and allowing for water retention. Proven efficacious and safe in numerous clinical trials, colloidal oatmeal is paramount in relieving one of the most intense symptoms of AD—pruritus. Approved by the FDA, colloidal oatmeal relieves minor skin irritation and itching due to eczema. Clinical trials testing oat-based occlusive creams have improved pruritus as early as 1 week in children and adults.[4,5]

LICOCHALCONE A



Licochalcone A (Lic A), derived from the licorice root *Glycyrrhiza inflata,* is a multipotent ingredient making a powerful impact across the dermatological landscape. A reversely constructed chalcone, or *retrochalcone*, Lic A is a proven inhibitor of proinflammatory reactions, and an antioxidant in both dermal and epidermal cells in vitro. It has served as a skin-soothing agent in emollients, visibly reducing the appearance of redness in razor burn, UV-induced erythema, and in patients with rosacea. Formulations with Lic A, ceramide 3, and oatmeal have eased visible redness and the itch-scratch cycle in adults and children with AD, and improved overall quality of life.[6]

ADVANCING SKIN SCIENCE THROUGH INNOVATION

At Beiersdorf, we are constantly exploring promising ingredients to help improve the quality of life in patients with chronic skin conditions. Our commitment to research has produced a continuous line of innovations that have fueled our passion for skin science for more than 125 years.

1. Leung DY, Boguniewicz M, Howell MD, Nomura I, Hamid QA. *J Clin Invest.* 2004;113(5):651-657. **2.** Buys LM. *Am Fam Physician.* 2007;75(4):523-528. **3.** Coderch L, López O, de la Maza A, Parra JL. *Am J Clin Dermatol.* 2003;4(2):107-129. **4.** Fowler JF, Nebus J, Wallo W, Eichenfield LF. *J Drugs Dermatol.* 2012;11(7):804-807. **5.** Food and Drug Administration, US Department of Health and Human Services. *Fed Regist.* 2003;68(107):33362-33381. **6.** Kolbe L, Immeyer J, Batzer J, et al. *Arch Dermatol Res.* 2006;298(1):23-30.

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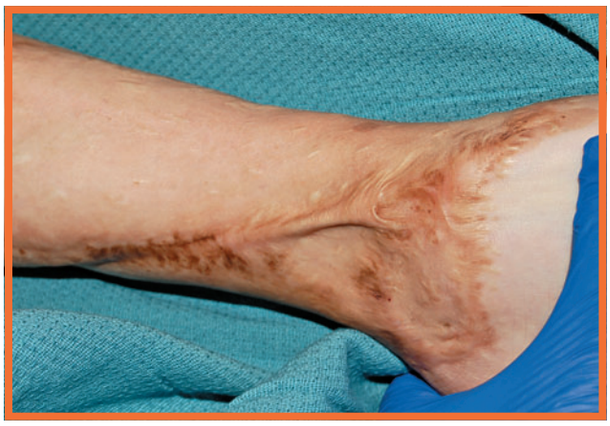
SCARS:

Ablative fractional resurfacing is revolutionizing scar treatment

from page 26



A 12-year-old male patient with a history of a giant congenital nevus that was removed surgically, resulting in a disfiguring contracture scar of the skin of the lower leg. The scar affects his ability to plantar flex his foot

Photo: Andrew C. Krakowski, M.D.

low density, so that treatments can penetrate through thick scar tissue, but with minimal collateral damage."

Treating 10 percent or less of the skin's surface leaves viable tissue between treatment columns, Dr. Shumaker explains. Furthermore, Dr. Krakowski says, the fenestration effect (caused by the microscopic columns) immediately increases the pliability of scar tissue.

"Most importantly, the long-term response that occurs — probably at least in part as a result of the heat shock phenomenon — provides for true wound remodeling that results in skin that is not 'scar' and not 'normal,' but closer to normal," Dr. Krakowski says.

> "It helps to fill the void between physical therapy and surgical revision."
>
> **Cmdr. Peter Shumaker, M.D.**
> San Diego

The protocol's high tolerability allows for earlier treatment. Older paradigms suggested letting scars mature one year before surgical revision, Dr. Shumaker says. However, "Our experience treating battlefield injuries suggests that starting treatment as early as two to three months post-injury can alter the trajectory of scar formation, improving mobility and getting patients into prosthetics earlier and for longer periods of time," he says. This enhances the entire rehabilitative process, even facilitating a return to full active duty after severe injuries in some cases, he says.

In other words, "The sooner you treat after the injury, the better," says Jill Waibel, M.D., a Miami-based dermatologist who was the first physician to use a fractional ablative laser for scar remodeling.[1]

In her experience treating approximately 20 patients shortly after burn injuries, "We get great results." In one such case, a 2-year-old female patient whose treatment started three months after pulling a pot of hot water onto herself experienced approximately 80 percent improvement in scarring of her chest and back after three treatments.

CHANGING THE GAME, CONSERVATIVELY

At Rady Children's Hospital, Dr. Krakowski says, "The techniques we employ vary patient-to-patient, scar-to-scar." Treatment may begin with a pulsed dye laser to minimize redness, or a hair-removal laser to reduce unwanted hair on a graft or flap.

Next comes a fractional CO_2 laser, operating at a treatment depth proportional to scar thickness and a low density.

"Typically," Dr. Krakowski says, "I do a single pass, starting with the most hypertrophic areas first. Then I will go back and feather in lighter settings to thinner scarred portions."

Patients typically require four to six sessions, spaced six to eight weeks apart. Sometimes, Dr. Waibel says, burning, pain and itching can improve 90 percent after just one session.

Immediately after the fractional CO_2 laser, Dr. Krakowski adds, "We have the option of 'dripping in' medications such as intralesional triamcinolone. The laser makes hundreds of micro-channels directly into the skin, and capillary action allows the medications to penetrate the scar evenly and uniformly."

As such, he says, "These newer techniques — along with the ability to apply medications directly through the laser channels — are a total game-changer."

MIDAZOLAM AND MOVIES

Outside of a little candor and TLC, Dr. Krakowski says, children require few adjustments to the original Navy protocol. He tells them the laser "doesn't feel great, but you can get through it." Showing videos of teenagers signaling "thumbs-up" during treatment also helps dispel apprehensions. Because children recognize emotions and body language, he adds, the hospital's STAR team has become adept at calming youngsters' nerves.

Young burn victims almost invariably have post-traumatic stress disorder, Dr. Waibel says. To avoid triggering it, she usually performs AFR in her clinic rather than a hospital. Along with giving patients midazolam pretreatment, she says, "We have iPads with movies, and a toy closet. We make it fun."

To date, Dr. Krakowski has treated more than 100 children. In the past nine years, Dr. Waibel has treated 500 children — and more than 1,000 adults. With multiple military centers providing the treatment to some degree nationally, Dr. Shumaker adds, hundreds and perhaps thousands of service members have undergone AFR as well.

Furthermore, he says, "It's not just for battlefield casualties. These techniques are effective for scars of virtually any type. Millions of people around the world could benefit from them." Worldwide, Dr. Waibel estimates that hundreds of doctors provide AFR scar revision.

FACING THE FUTURE

AFR will not replace surgery, or other interventions such as occupational therapy and physical therapy, say Drs. Shumaker and Krakowski. Rather, Dr. Shumaker says that for scar contractures, "It helps to fill the void between physical therapy and surgical revision."

SCARS see page 31

A CLASS 1, SUPER-POTENT SPRAY

For plaque psoriasis

Topicort®
(desoximetasone)
Topical Spray 0.25%

0.25%
SPRAY

Important Safety Information

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

TaroPharma®

See brief summary of Prescribing Information on reverse side.

AD100-0033 July 2013

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)

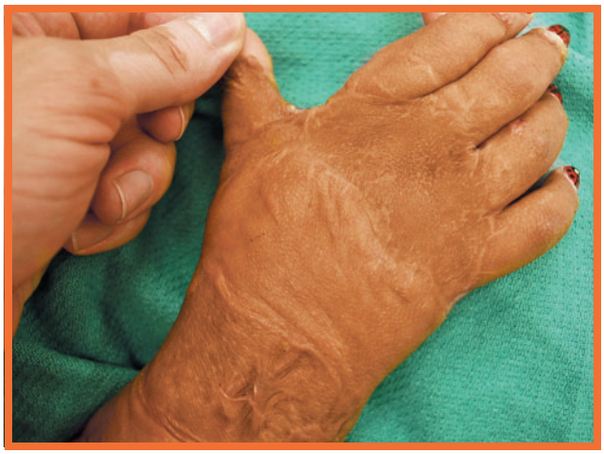
Inform patients of the following:
- Use this medication as directed by the physician.
- Topicort® Topical Spray is for external use only. Avoid use on the face, axilla or groin.
- Do not use this medication for any disorder other than that for which it was prescribed.
- Do not bandage or otherwise cover 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.

Mfd. by: Taro Pharmaceuticals Inc., Brampton, Ontario, Canada L6T 1C1
Dist. by: TaroPharma® a division of Taro Pharmaceuticals U.S.A., Inc., Hawthorne, NY 10532
Revised: April 2013

AD100-0030

SCARS:

Ablative fractional resurfacing is revolutionizing the treatment of scars from page 28



An 8-year-old female patient who as an infant fell into a bathtub filled with hot water and bleach, resulting in severe burns to both wrists and both ankles. Despite the severe contractures she suffered as a result of her injuries, she was most concerned with how her fingernails would look when she was a teenager.

Photos: Andrew C. Krakowski, M.D.

But presently, Dr. Shumaker says, "There is a relative lack of prospective studies in this area. Further study is needed to optimize protocols for different scar types, treatment combinations and other parameters in adults and children." The Navy has multiple studies ongoing to help confirm the efficacy of AFR for scars, he says.

Additionally, Dr. Waibel has a Department of Defense grant at the University of Miami to explore AFR in a preclinical pig model, and was planning to begin a clinical trial in November to investigate the optimum time frame to initiate AFR after burn injuries. Another clinical trial, exploring the treatment's effects on gene expression (NCT01858038), is recruiting patients at Massachusetts General Hospital under the supervision of R. Rox Anderson, M.D., professor of dermatology at Harvard Medical School and director of the Wellman Center for Photomedicine.

Such research already has produced several publications regarding functional improvements co-authored by Dr. Shumaker.[2-8]

"We also have several years of strong anecdotal evidence," he says.

Ultimately, Dr. Shumaker says, "I believe AFR will be incorporated into the standard of care for patients with traumatic scars." To that end, the protocol's proponents are marshaling data to establish a current procedural terminology (CPT) code for the treatment.

Until payers recognize that AFR is not just for cosmetic treatments, Dr. Shumaker says, "It's going to be difficult for it to take off in the civilian world."

Given the current partial freeze on creation of new CPT codes,[9] Dr. Waibel adds, "Unfortunately, it's probably going to take a couple years."

Getting people back to work sooner saves healthcare payers money, Dr. Shumaker says. Accordingly, "Over the next several years, I believe we will see a change in how these procedures are paid for."

For now, Dr. Krakowski says that at Rady Children's, "We try not to turn anybody away." In this regard, donations help provide the treatment regardless of patients' ability to pay.

So far, he says, "Money has not been a large issue — but it will be. The more people who hear about the treatment, the more will come for it. But that will also mean that those resources will be more rapidly depleted. Thus, a CPT code will be essential in the very near future. Whatever happens in this climate of healthcare change, we will find a way to provide these services to the children who require them." **DT**

Disclosures: Drs. Shumaker, Krakowski and Waibel report no relevant financial interests.

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All aboard for AFR

John Jesitus | Senior Staff Correspondent

San Diego — Doctors from the Naval Medical Center (NMC) San Diego have treated children on-site and off. In 2012, dozens of patients received ablative fractional laser therapy for scars aboard the hospital ship USNS Mercy during its deployment to Southeast Asia for Pacific Partnership 2012. Pacific Partnership is the largest annual humanitarian and civic-assistance mission in the Asia-Pacific region, according to its website.

In a related exchange project during 2013, NMC physicians traveled to the National Institute of Burns in Hanoi, Vietnam, for two weeks in April and again in August.

"We worked with Vietnamese doctors treating patients with severe burn scars, including a number of children," says Cmdr. Peter Shumaker, M.D., chairman of dermatology at the NMC. Using ablative fractional resurfacing (AFR) combined with surgical treatments, "We helped restore function and appearance to more than 60 patients suffering from debilitating scars."

One patient, a 3-year-old girl who had suffered burns over 70 percent of her body, could walk more easily after three treatments, Dr. Shumaker says. As such, he says that for patients with severe scarring, "AFR is a life-changing breakthrough." **DT**

For more information: http://www.cpf.navy.mil/pacific-partnership/2012/

Disclosures: Dr. Shumaker reports no relevant financial interests.

GRAFTING:

Innovative grafting techniques leave scar-free donor sites from page 1

to consider what would happen if, rather than burning microscopic columns into the skin, they extracted an array of intact columns of full-thickness skin.

"Now it's a graft. If you get enough of them, you might be able to reassemble them, and they will grow to make skin," Dr. Anderson says.

Over the past three years, "We have shown that you can do this with cold steel, and, as with lasers, you don't get a donor-site scar. It heals rapidly, and recently we have shown in a swine model that those transplanted micro-columns can make new, functional skin (Tam J, Wang Y, Farinelli W, et al. *Plast Reconstr Surg. - Global Open*. 2013 September. 1(6):e47)."

SMART 'SPAGHETTI'

The harvested microcolumns — which Dr. Anderson likens to tiny spaghetti noodles — are "smarter than they look." When placed in a wound bed, "They adhere within five minutes. They know how to orient themselves and make new skin. Each little column is a full-thickness sample of skin that presumably contains many of the 'cues' that cells need to know about their orientation and structure."

Conversely, Dr. Anderson says, skin cells cultured from single cell types "lose sight of where they came from and what they are" when implanted.

Using a double-pointed hypodermic needle to "core" tiny tissue samples, the device's current version can harvest one microcolumn — measuring 200 to 700 μ in diameter — per second.

Over the next five years, he says, "I would like to be able to harvest several thousand columns in 10 minutes and use them for treating larger wounds. I also want this to be a simple bedside procedure that you can do without general anesthesia."

To simplify harvesting and application, Dr. Anderson and his team are exploring the strategy of placing the harvested microcolumns into a biocompatible matrix material that fuels their replication. This would create a more easily handled graft, to which physicians can add drugs or perhaps other cell types as needed, he says.

"The next step is to take it to a human clinical trial to determine the largest harvested skin column that can produce no scarring," Dr. Anderson says. He plans to begin such a trial involving normal, healthy skin by the end of 2013. "Then we'll move into a wound treatment study, probably around the end of 2014. This is going to take us a while because we have both engineering and human studies to do."

To support this project, Dr. Anderson's team recently secured a five-year Department of Defense (Armed Forces Institute for Regenerative Medicine) grant. Its purpose is to devise an alternative to grafting strategies currently used for wounds, says Dr. Anderson, who anticipates performing the first human studies in the grant's second year.

"Instead of making a large donor-site wound that heals with a scar, we would like to make thousands to millions of very small donor-site wounds that heal with no scar," he says.

FRACTIONAL BLISTERING

Regarding chronic wounds, burns and vitiligo, patients already are benefiting from an epidermal grafting device cleared by the Food and Drug Administration — the CelluTome Epidermal Harvesting System (formerly EpiGraft; Kinetic Concepts). It uses heat and suction to create an array of 128 epidermal blisters, each around 2 mm wide, which the device harvests simultaneously for placement onto standard surgical dressings.

"When you place the dressing on the wound, you're placing live epidermis from the normal skin into the wound area. It helps the wound to heal," says Dr. Anderson, the device's co-inventor. Along with being bloodless (because no blood vessels penetrate the epidermis), he adds, "Much to my surprise, the blister harvesting procedure is absolutely painless. The blisters form over 30 minutes, and the transepidermal nerve endings stay on the dermal side."

When covered with an occlusive dressing, donor-site wounds heal in three to four days, adds Thomas Serena, M.D., medical director of the Serena Group, which specializes in chronic wounds.

> "Instead of making a large donor-site wound that heals with a scar, we would like to make thousands to millions of very small donor-site wounds that heal with no scar."
>
> **R. Rox Anderson, M.D.**
> Boston

"Three to four days later, you can harvest the same site again," he says. To date, Dr. Serena has used the device a maximum of twice per patient. "As we gain experience with it, I believe it probably can be used up to three times per patient."

Dr. Anderson adds, "As far as I know, it's the first very practical device for performing an epidermal graft over a reasonably large area, currently about 50 cm^2 for a single dressing. There's no reason the device can't be used to treat a much larger area" with multiple such dressings.

VARIETY OF APPLICATIONS

Because the device is relatively new, Dr. Anderson says, "It's not yet clear what its clinical uses will be. One of the most important next steps is creative clinical learning. It's being

GRAFTING see page 35

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

Introducing

VALCHLOR™
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(commonly known as *nitrogen mustard*)

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CONTRAINDICATION

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

DOSING AND APPLICATION

VALCHLOR is for topical dermatologic use only. Apply a thin film once daily to affected areas of the skin. Caregivers must wear disposable nitrile gloves when applying VALCHLOR. Patients and caregivers must wash hands thoroughly after handling or applying VALCHLOR.

IMPORTANT SAFETY INFORMATION

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:** VALCHLOR is a cytotoxic drug. Avoid direct skin contact with VALCHLOR in individuals other than the patients due to risk of dermatitis, mucosal injury, and secondary cancers
- **Dermatitis:** Monitor patients for redness, swelling, inflammation, itchiness, blisters, ulceration and secondary skin infections. Stop treatment or reduce dose frequency.
- **Non-melanoma skin cancer:** Monitor patients during and after treatment.
- **Embryo-fetal toxicity:** Women should avoid becoming pregnant or nursing while using VALCHLOR due to the potential hazard to the fetus.
- **Flammable gel:** VALCHLOR is an alcohol-based gel. Avoid fire, flame, and smoking until the gel has dried.

ADVERSE REACTIONS

The most common adverse reactions (≥ 5%) are dermatitis, pruritus, bacterial skin infection, skin ulceration or blistering, and hyperpigmentation. These reactions may be mild to severe. Elderly patients may be more susceptible. Depending on severity, dosing changes or discontinuation may be required.

Call your doctor for medical advice about side effects. To report SUSPECTED ADVERSE REACTIONS, contact Actelion Pharmaceuticals US, Inc., at 1-855-4-VALCHLOR (1-855-483-5245) or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Please see **Brief Summary of Prescribing Information** on adjacent page.

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VAL-00025 1113

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VALCHLOR™ (mechlorethamine) gel, 0.016%
For Topical Dermatological Use Only

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

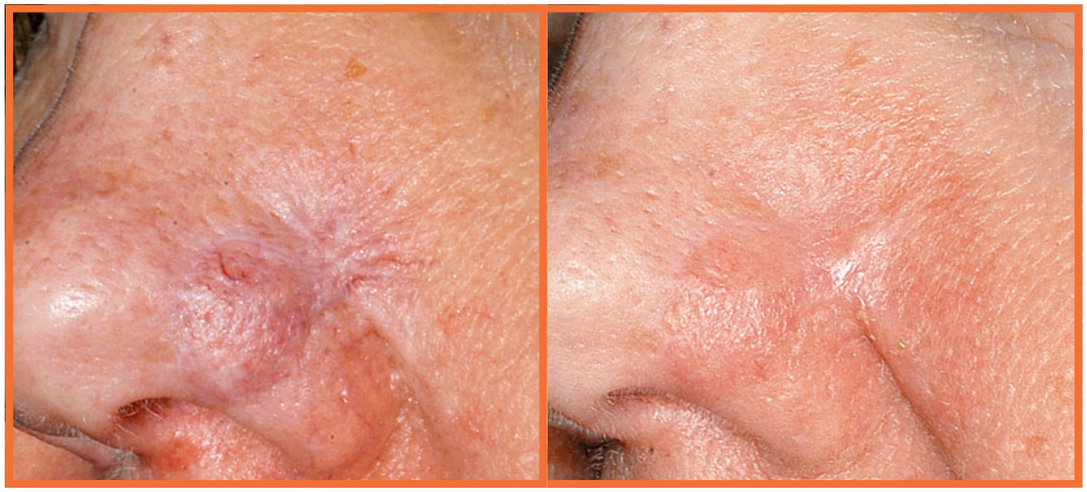
  A total of 79 patients age 65 and older (31% of the clinical trial population) were treated with either VALCHLOR or the comparator in the clinical trial. Forty-four percent (44%) of patients age 65 or older treated with VALCHLOR achieved a Composite Assessment of Index Lesion Severity (CAILS) response 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:
Actelion Pharmaceuticals US, Inc.
South San Francisco, CA 94080, USA

ACTELION

GRAFTING:

Innovative grafting techniques leave scar-free donor sites from page 32



A 59-year-old female patient before (left) and six weeks after one fractional CO_2 treatment of a scar on the nose.

Photos: Suzanne L. Kilmer, M.D.

sold and used for treating wounds, but I believe it will probably have other uses — wherever there's a value in transferring epidermis from one part of the skin to another."

To date, Dr. Anderson says, "I've used it to treat patients with vitiligo. It could also be useful for acute wounds such as burns, abrasions and surgical wounds."

Already, Dr. Anderson has taken this technology to treat children with vitiligo and burns at a clinic that he and his dermatology colleagues established in South Vietnam about five years ago. For vitiligo, physicians also used CO_2 laser resurfacing to remove non-pigmented epidermis from recipient sites.

Similarly, in late 2012 Dr. Serena took the device to Hospital Bernard Mevs in Port-au-Prince, Haiti, to treat chronic wounds caused by Tropical Storm Isaac in seven patients. Due to a local lack of advanced wound care products, he says, "We needed a simple way to perform epidermal grafting. CelluTome is incredibly simple — you perform the treatment in the office," attaching the harvester (which features a metal grate) to the patient's thigh. "After heating the skin to approximately 40 degrees Celsius, I then apply negative pressure to produce the little blisters."

Versus traditional blister grafting, Dr. Serena says, "The treatment is very easy to perform and very easy on the patient." Along with facilitating blister grafts, he adds, the procedure stimulates the entire wound bed to produce growth factors that speed healing. "This dual method of action provides a bonus in chronic wounds. Most advanced woundcare products rely on migration of the skin edges toward the center. But seeding the middle facilitates much faster healing."

Moreover, Dr. Serena says that because the device harvests only epidermis, it makes skin grafting possible for patients with scleroderma or pyoderma gangrenosum. With other grafting devices, he explains, skin grafting in patients with either condition can produce a chronic wound at the donor site.

At press time Dr. Serena was preparing to begin a clinical trial of the CelluTome device in venous leg ulcers. In a small case series he completed in fall 2013, he says it produced "fabulous" results for diabetic ulcers, in combination with hyperbaric oxygen.

HUMAN SKIN COPIES

Another of Dr. Anderson's projects has shown, for the first time, that full-thickness human skin micrografts will grow — complete with sweat glands and the other complex features of human skin — when transplanted onto immunosuppressed mice (Anderson RR. Presented at: Military Health System Research Symposium; Aug. 12-15, 2013; Fort Lauderdale, Fla.).

Instead of transplanting sheets of human skin onto immunosuppressed mice, Dr. Anderson says, "We are transplanting tiny pieces of human skin. We see evidence that the pieces of human skin reorganize themselves and produce complex structures," including human stratum corneum, epidermis, pigment, sebaceous glands and sweat glands, the latter of which mice lack.

Additionally, "The cutaneous immune system was transferred, including human Langerhans cells." The study also demonstrated the first-ever neogenesis of human hair follicles in a mouse, he says, adding that none of these features are transferred with split-thickness skin grafts.

In fall 2013, Dr. Anderson secured a five-year grant to pursue this research. He estimates it will take three to four years to produce the first practical devices for this application.

Along with leaving scar-free donor sites, says Suzanne L. Kilmer, M.D., the beauty of the fractional concept is that "You're taking whole areas of tissue that, when reimplanted, have the ability to reorganize themselves into what they're supposed to be." She is founding director of the Laser and Skin Surgery Center of Northern California and clinical professor of dermatology at the University of California, Davis.

Accordingly, Dr. Kilmer says that along with dermatologic applications, Dr. Anderson has discussed possibly applying the concept to other organs such as the liver, kidney and heart.

"It seems plausible that the same idea could work for other organ systems," she says. **DT**

Disclosures: Dr. Anderson is a co-inventor of all devices mentioned in this article and receives a portion of royalties from patents filed by Massachusetts General Hospital. Dr. Kilmer has been a co-investigator on clinical trials with Dr. Anderson, including early trials of fractional laser technologies. Dr. Serena is a consultant for Kinetic Concepts.

IMMUNE:

Study shows how immune system, cutaneous microbiome interact from page 1

research, which was conducted at the University of Pennsylvania Perelman School of Medicine, Philadelphia.

Disrupting the signaling pathway "decreases cutaneous gene expression of chemokines and cytokines, antimicrobial peptides, and pattern recognition receptors, which parallels decreased lymphocytes and macrophages infiltrating the skin," Dr. Grice tells ***Dermatology Times***. This may, in part, be responsible for shifting the mix of species comprising the skin microbe population without altering its total size.

AN INTERACTIVE RELATIONSHIP

Additional study found a different pattern of cutaneous immune gene expression in germ-free mice, which shifted when the animals were exposed to normal microbiota. This suggests that there is a two-way interaction between the immune system and the organisms colonizing the skin, Dr. Grice says. It confirms an interactive relationship between the microbiota and the immune system that was first demonstrated in the gut.

The past decade has seen an explosion of research into the microbiome — the hundreds of different species of microorganisms that live within and upon all complex organisms — with the number of papers growing by an order of magnitude or more. It has become clear that these ecosystems are complex, very site specific, and can be both the cause and consequence of health and disease.

"It has changed the way we think about disease," Dr. Grice says. "Disease may not necessarily be one single pathogen, as we traditionally think of infectious diseases. It could be more a dysbiotic component, that there is a shift in the whole community, a shift in the balance that could be contributing to the skin disorder, that have been traditionally thought to have some infectious and/or inflammatory component."

Conditions such as atopic dermatitis, acne, and psoriasis clearly fall into this category, and "some people think even diseases such as sarcoidosis and morphea has some sort of microbial trigger," she adds.

"This is a very, very exciting area," says Whitney P. Bowe, M.D., assistant clinical professor of dermatology, Icahn School of Medicine at Mount Sinai, New York. "We used to think, acne — just use an antibiotic and wipe it out. Now we are trying to understand that it is not just about killing harmful bacteria, virus, and pathogens, it is about maintaining or restoring a healthy milieu, a healthy skin barrier where the cross talk between what is sitting on the skin surface and the skin itself is carefully orchestrated or zen-like."

PARADIGM SHIFT

"I think this (paper) will help set the groundwork for a major paradigm shift in the way we think about disease, health and treatment in two broad areas," says Robert S. Kirsner, M.D., Ph.D., vice chairman of the department of dermatology and cutaneous surgery at the University of Miami Miller School of Medicine.

"One is new therapy aimed at altering the microbiome, as we learn more. I don't think we can guess yet exactly what they might be. The other part is, we are going to probably learn optimal ways to maintain the microbiome to prevent disease or maintain health," Dr. Kirsner says.

"It is time we start thinking broader than just about treating disease, especially for people at risk, with a family history of psoriasis or atopic dermatitis," he says. "If we can learn what the optimal microbiome is, perhaps by maintaining that we can prevent, or delay, or lessen development of those diseases."

Research has shown that antibiotic use wrecks havoc on gut microbiota, which in worst case scenarios can open the door to deadly *Clostridium difficile* infection. Gut microbiota recovery can be slow and incomplete; there appears to a correlation between the duration, number, and timing of antibiotic exposure and impact on microbiota.

Whether or not this carries over to the skin compartment and microbiota is an important question for Dr. Grice. "It would be nice to know what's going on when people with acne are prescribed long-term doxycycline. (The antibiotics) are helping acne, but what about other parts of the skin?" she says.

"There is some evidence that people who are on these long-term antibiotics have greater propensities to develop Gram-negative folliculitis," she notes. "There is a reason to think that the antibiotics do something to skin microbiome, we just haven't looked at it with these new precise methods."

ASSOCIATIVE, NOT CAUSATIVE

Dr. Grice says current data on the skin microbiome is more associative than causative. "We don't know if it is the *Staph aureus* (*Staphylococcus aureus*) that is causing the flares in atopic dermatitis or if it is the flares that are selecting for *Staph aureus*. Longitudinal studies will help work out which comes first, the barrier dysfunction or the microbial colonization. Right now it is mostly associative data," she says.

Dr. Bowe says she believes it is possible to identify and develop specific strains of topical probiotics that can 1) interfere with the access of pathogens to the skin through bacterial interference, 2) inhibit inflammatory cell signaling pathways from being activated, and 3) generate the secretion of antimicrobial molecules that target pathogens.

"Ultimately we are going to discover certain bacterial strains — not species but strains — that interact with the skin in ways that calm inflammation," she says. "It may be that one strain can do that for a number of people, or we may need to go to personalized medicine where strain A is capable of calming inflammation in a subcategory of patients who present with X, Y, and Z. And strain B might calm inflammation in other subcategories of people."

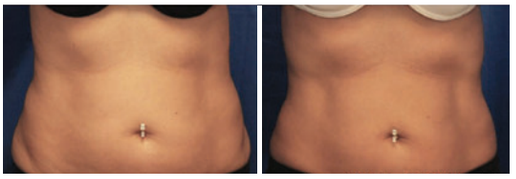
While Dr. Grice hopes that will be the case in the long run, she emphasizes that the current level of understanding of possible beneficial subsets of organisms and their ratios within a health skin ecosystem are quite limited. She is skeptical of claims for probiotics and says, "Unless there is science to back it up, I'd be very careful about those types of products."

Dr. Grice cautions that clinical use of prebiotic and probiotic interventions will require both a greater understanding of the microbiota ecosystem and a new generation of more accurate laboratory diagnostics of those organisms. **DT**

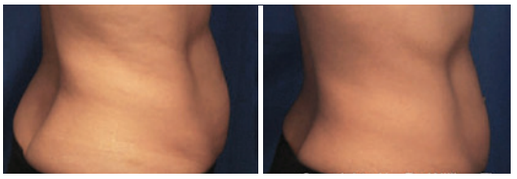
References: Chehoud C, Rafail S, Tyldsley AS, et al. *Proc Natl Acad Sci U S A*. 2013;110(37):15061-15066

Proven and Effective Non-Invasive Body Contouring Results With Liposonix® and VASERshape™

by William Ting, M.D.



Before Liposonix + VASERshape *5 months post treatment*



Before Liposonix + VASERshape *5 months post treatment*

Photographs courtesy of William Ting, MD

As a practicing physician in medical, cosmetic and surgical dermatology, I have seen many patients who live an active lifestyle, yet still struggle with localized trouble spots, i.e., the spare tire or muffin top that diet and exercise alone simply can't improve. Today, more of these patients prefer a non-invasive treatment; they don't want the downtime and risks associated with surgery or minimally invasive procedures like liposuction. For these patients, both Liposonix and VASERshape treatments offer an effective, non-invasive solution.

My interest in these two particular non-invasive ultrasound devices is driven by my patients' demand and by my understanding of how ultrasound works. Both Liposonix and VASERshape are developed with proven ultrasound technology, and are safe and effective treatments with high patient satisfaction. I made the decision to own both devices to provide my patients with different options. I can offer customized body-contouring treatments and target specific trouble spots. I can also offer a more generalized treatment over larger areas, all without damage to the surrounding tissues. Combining both techniques allows me to deliver excellent results for my patients with little to no downtime.

Liposonix is a highly customizable treatment option. The system applies high-intensity focused ultrasound (HIFU) technology to destroy subcutaneous adipose tissue (SAT) without surgery. Destroyed adipocytes and lipids are efficiently removed by normal cellular and tissue response. The handpiece that houses the transducer delivers HIFU energy in a precise and predictable fashion. Custom Contouring™ capability allows me to customize each procedure to the specific curves and contours of a patient's body. In addition, treatment levels can be tailored to ensure patient comfort. It is a single treatment device that typically lasts about one hour, resulting in an average reduction of one dress or pant size. Most patients see maximum results in 8-to-12 weeks. This is how long it takes for the body to naturally metabolize the destroyed fat tissue. Once the healing is complete, I often identify additional spots that can be refined with two VASERshape treatments.

VASERshape is the only non-invasive treatment to combine ultrasound and massage therapy for a safe, effective and relaxing experience with little to no downtime, similar to a hot-stone massage. The ultrasound diathermy treats fatty tissue layers under the skin and can be used in areas with less than one inch of SAT. The vacuum-assisted zonal massage helps to temporarily improve the appearance of cellulite and increase local blood circulation. The massage can be performed pre- and post-ultrasound diathermy. VASERshape requires no pain medication or anesthesia, and patients can immediately return to normal activities. The different Liposonix and VASERshape methodologies work in tandem to achieve the best possible results for my patients.

In my experience, the return on investment for these devices can be as little as six months, but more commonly in the 12-to-18 month range. Offering Liposonix and VASERshape treatments has enhanced my reputation as an industry leader, and distinguishes my cutting-edge practice from others in the San Francisco Bay Area. My practice is well reviewed by my patients; their recommendations and referrals encourage new patients to come from all around the region.

In my practice, Liposonix sets the foundation for body contouring, while VASERshape provides the finishing touches. This powerful combination delivers the results that my patients desire from a non-invasive therapy.

Ustekinumab approval expands options for psoriatic arthritis

Cheryl Guttman Krader | Staff Correspondent

BOSTON — The human interleukin-12 and interleukin-23 (IL-12/IL-23) inhibitor ustekinumab (Stelara, Janssen Biotech) is now approved for the treatment of active psoriatic arthritis (PsA).

Alice B. Gottlieb, M.D., Ph.D., is an investigator and Steering Committee member for the ustekinumab trials and lead author of the 2009 article in *The Lancet* that reported results from the phase 2 study of ustekinumab for active PsA (Gottlieb AB, Menter A, Mendelsohn A, et al. *The Lancet*. 2009;373:633-640).

"It is very important to have therapeutic alternatives to TNF (tumor necrosis factor) inhibitors for psoriatic arthritis as well as psoriasis because there are many patients with those diseases who have either exhausted TNF inhibitor options or cannot receive them because of contraindications," Dr. Gottlieb tells **Dermatology Times**. She is professor and dermatologist-in-chief, department of dermatology, Tufts Medical Center, Boston.

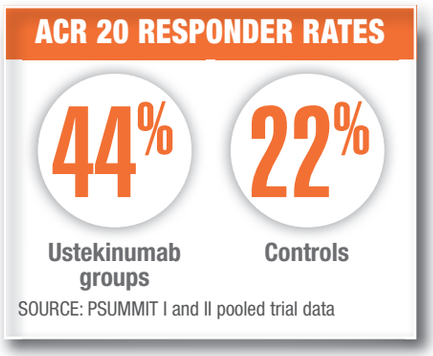
"In addition, it is my opinion that the drugs that work best for psoriatic arthritis are the ones such as ustekinumab that work for both psoriatic arthritis and psoriasis, and the same holds true about the best treatments for psoriasis."

PSUMMIT STUDIES

The Food and Drug Administration approval of ustekinumab for active PsA, on Sept. 20, 2013, was supported by results from two pivotal studies — PSUMMIT I and PSUMMIT II (Phase 3 Multicenter, Randomized, Double-blind, Placebo-controlled trials of Ustekinumab, a Fully Human anti–IL-12/23p40 Monoclonal Antibody, Administered Subcutaneously, in Subjects with Active Psoriatic Arthritis I and II) — that together enrolled 927 patients.

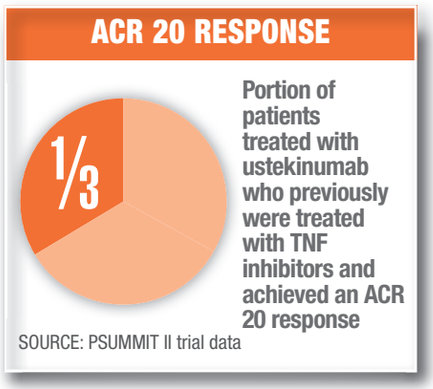
Eligible participants had at least five tender and five swollen joints plus a C-reactive protein level ≥ 0.3 mg/dL; 180 (58 percent) of the 312 patients in PSUMMIT II had a history of prior treatment with between one and five TNF inhibitors.

Both trials randomized patients to initially receive ustekinumab 45 mg, ustekinumab 90 mg, or placebo at baseline, week four, and then every 12 weeks. The primary endpoint analysis was performed at week 24 and looked at the percentage of patients achieving an ACR20 response (≥ 20 percent improvement in signs and symptoms according to the American College of Rheumatology criteria).



With the data from the two trials pooled, the ACR 20 responder rate was 44 percent in both ustekinumab groups and only 22 percent among controls. In PSUMMIT II, about one-third of ustekinumab-treated patients who had previously received a TNF inhibitor achieved an ACR 20 response. It's not known why these patients had a lower response rate, Dr. Gottlieb says. "It could be they represent a naturally resistant population due to some genetic factor or that prior treatment with a TNF inhibitor changes the natural history of the disease, making it more refractory," she says. "However, the same response pattern is being seen with the investigational PDE4 inhibitor, apremilast (Celgene Corporation), such that previous treatment with TNF blockers is also associated with a lower response rate."

A Psoriasis Area Severity Index 75 (PASI 75) response, which was assessed in PSUMMIT in patients with ≥ 3 percent body surface area involvement with psoriasis at entry, was achieved by about 55 percent of patients treated with ustekinumab and < 10 percent of controls. Results from scoring of dactylitis and enthesitis severity as well as for other secondary endpoints also showed statistically significant benefits of ustekinumab, and according to subsequently reported PSUMMIT data, responses to ustekinumab are stable through at least 52 weeks.



CLINICAL DECISIONS

Dr. Gottlieb says she currently would choose a TNF inhibitor as biologic therapy in a patient with PsA, unless there was a contraindication. When prescribing ustekinumab, it is important to set appropriate patient expectations. It takes 24 weeks to achieve maximum benefit, she says. And, patients who have previously failed TNF inhibitor treatment have a lower likelihood of response than TNF inhibitor-naive patients.

Ustekinumab is approved for use alone or with methotrexate when treating PsA. The recommended dose is 45 mg at weeks zero and four, and then every 12 weeks thereafter, although 90 mg is recommended for patients who have coexistent moderate-to-severe plaque psoriasis and weigh more than 220 pounds (100 kg).

Dr. Gottlieb says she was glad the higher dose was approved for use in the latter patients, but thinks it is unfortunate that it was recommended for those individuals only.

"My concern is that especially among rheumatologists who have no prior experience with ustekinumab, skin disease may be undertreated in patients receiving only 45 mg," Dr. Gottlieb says. **DT**

Disclosures: Dr. Gottlieb has served as a consultant and/or advisory board member to Abbott, AbbVie, Acetlion, Amgen, Astellas, Beiersdorf, Bristol-Myers Squibb, Canfite, Coronado Biosciences, Celgene, CSL Behring Biotherapies for Life, Dermipsor Ltd., GlaxoSmithKline, Janssen Biotech, Incyte, Merck, Novo Nordisk, Pfizer, Schering, TEVA and UCB.

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INDICATIONS AND USAGE: Kenalog® Spray (Triamcinolone Acetonide Topical Aerosol, USP) is indicated for relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses.

CONTRAINDICATIONS: Topical corticosteroids are contraindicated in those patients with a history of hypersensitivity to any of the components of the preparations.

For external use only. Please see full Prescribing Information on reverse and also at KenalogSpray.com.

REFERENCE: 1. Fowler J, Fowler L. Physician and patient assessment of triamcinolone acetonide spray for steroid-responsive dermatoses. *J Clin Aesthet Dermatol*. 2010;3:27-31.

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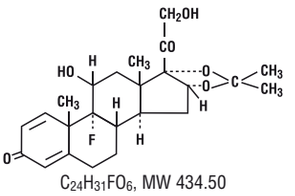
For dermatologic use only
Not for ophthalmic use

DESCRIPTION

The topical corticosteroids constitute a class of primarily synthetic steroids used as anti-inflammatory and antipruritic agents. The steroids in this class include triamcinolone acetonide. Triamcinolone acetonide is designated chemically as 9-fluoro-11β, 16α, 17, 21-tetrahydroxypregna-1, 4-diene-3, 20-dione cyclic 16, 17- acetal with acetone. The structural formula is:



$C_{24}H_{31}FO_6$, MW 434.50

A two-second application, which covers an area approximately the size of the hand, delivers an amount of triamcinolone acetonide not exceeding 0.2 mg. After spraying, the nonvolatile vehicle remaining on the skin contains approximately 0.2% triamcinolone acetonide. Each gram of spray provides 0.147 mg triamcinolone acetonide in a vehicle of isopropyl palmitate, dehydrated alcohol (10.3%), and isobutane propellant.

CLINICAL PHARMACOLOGY

Topical corticosteroids share anti-inflammatory, antipruritic and vasoconstrictive actions.

The mechanism of anti-inflammatory activity of the topical corticosteroids is unclear. Various laboratory methods, including vasoconstrictor assays, are used to compare and predict potencies and/or clinical efficacies of the topical corticosteroids. There is some evidence to suggest that a recognizable correlation exists between vasoconstrictor potency and therapeutic efficacy in man.

Pharmacokinetics

The extent of percutaneous absorption of topical corticosteroids is determined by many factors including the vehicle, the integrity of the epidermal barrier, and the use of occlusive dressings.

Topical corticosteroids can be absorbed from normal intact skin. Inflammation and/or other disease processes in the skin increase percutaneous absorption.

Once absorbed through the skin, topical corticosteroids are handled through pharmacokinetic pathways similar to systemically administered corticosteroids. Corticosteroids are bound to plasma proteins in varying degrees. Corticosteroids are metabolized primarily in the liver and are then excreted by the kidneys. Some of the topical corticosteroids and their metabolites are also excreted into the bile.

INDICATIONS AND USAGE

Kenalog Spray (Triamcinolone Acetonide Topical Aerosol, USP) is indicated for relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses.

CONTRAINDICATIONS

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PRECAUTIONS

General

Systemic absorption of topical corticosteroids has produced reversible hypothalamic-pituitary-adrenal (HPA) axis suppression, manifestations of Cushing's syndrome, hyperglycemia, and glucosuria in some patients.

Conditions which augment systemic absorption include the application of the more potent steroids, use over large surface areas, prolonged use, and the addition of occlusive dressings.

Therefore, patients receiving a large dose of any potent topical steroid applied to a large surface area or under an occlusive dressing should be evaluated periodically for evidence of HPA axis suppression by using the urinary free cortisol and ACTH stimulation tests, and for impairment of thermal homeostasis. If HPA axis suppression or elevation of the body temperature occurs, an attempt should be made to withdraw the drug, to reduce the frequency of application, substitute a less potent steroid, or use a sequential approach.

Recovery of HPA axis function and thermal homeostasis are generally prompt and complete upon discontinuation of the drug. Infrequently, signs and symptoms of steroid withdrawal may occur, requiring supplemental systemic corticosteroids.

Children may absorb proportionally larger amounts of topical corticosteroids and thus be more susceptible to systemic toxicity (see **PRECAUTIONS, Pediatric Use**).

If irritation develops, topical corticosteroids should be discontinued and appropriate therapy instituted.

In the presence of dermatological infections, the use of an appropriate antifungal or antibacterial agent should be instituted. If a favorable response does not occur promptly, the corticosteroid should be discontinued until the infection has been adequately controlled.

Information for the Patient

Patients using Kenalog Spray 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 and inhalation of the spray.
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 wrapped as to be occlusive unless directed by the physician.
4. Patients should report any signs of local adverse reactions.
5. Parents of pediatric patients should be advised not to use tight-fitting diapers or plastic pants on a child being treated in the diaper area, as these garments may constitute occlusive dressings.
6. Do not use Kenalog Spray on the underarms or groin areas unless directed by your physician.
7. If no improvement is seen within 2 weeks, contact your physician.
8. Do not use other corticosteroid-containing products while using Kenalog Spray without first consulting your physician.
9. Kenalog Spray is flammable. Avoid heat, flames or smoking when applying Kenalog Spray.

Laboratory Tests

A urinary free cortisol test and ACTH stimulation test may be helpful in evaluating HPA axis suppression.

Carcinogenesis, Mutagenesis, Impairment of Fertility

Long-term animal studies have not been performed to evaluate the carcinogenic potential or the effect on fertility of topical corticosteroids.

Studies to determine mutagenicity with prednisolone and hydrocortisone showed negative results.

Pregnancy: Teratogenic Effects

Category C. Corticosteroids are generally teratogenic in laboratory animals when administered systemically at relatively low dosage levels. The more potent corticosteroids have been shown to be teratogenic after dermal application in laboratory animals. There are no adequate and well-controlled studies in pregnant women on teratogenic effects from topically applied corticosteroids. Therefore, topical corticosteroids 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.

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

ADVERSE REACTIONS

The following local adverse reactions are reported infrequently with topical corticosteroids, but may occur more frequently with the use of occlusive dressings (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.

OVERDOSAGE

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

DOSAGE AND ADMINISTRATION

Directions for use of the spray can are provided on the label. The preparation may be applied to any area of the body, but when it is sprayed about the face, care should be taken to see that the eyes are covered, and that inhalation of the spray is avoided.

Spray is flammable; avoid heat, flame or smoking when using this product.

Three or four applications daily of Kenalog Spray (Triamcinolone Acetonide Topical Aerosol) are generally adequate.

HOW SUPPLIED

Kenalog Spray (Triamcinolone Acetonide Topical Aerosol, USP)

63 g (NDC 10631-093-62) aerosol can.

100 g (NDC 10631-093-07) aerosol can.

Storage and Handling

Store at room temperature; avoid excessive heat. Contents under pressure; do not puncture or incinerate. Keep out of reach of children.

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

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Quality time with patients improves adherence to medications

Ilya Petrou, M.D. | Senior Staff Correspondent

NEW YORK — Patient compliance to suggested therapy, whether topic or oral, remains the major obstacle in achieving good treatment outcomes in dermatology. Establishing trust with the patient, choosing a treatment plan that the patient likes, and scheduling the follow-up visit soon after first presentation are key steps the physician can take in helping to improve patient compliance and further, treatment outcomes.

According to one expert, there are three major hurdles in getting patients well in the field of dermatology — and making the right diagnosis and prescribing the right therapy are not among those hurdles.

"We as dermatologists know what we are doing, in that we usually recognize the disease as soon as we walk in the room, and we are not prescribing the wrong medications in our patients," says Steven R. Feldman, M.D., Ph.D., professor of dermatology, pathology, and public health sciences, and director of the Center for Dermatology Research at Wake Forest University School of Medicine, Winston-Salem, N.C. "The three hurdles in getting patients well are poor compliance, poor compliance and poor compliance."

QUICK READ

Establishing trust with the patient, choosing an appropriate therapy, and timing of the follow-up visit are important steps dermatologists can take toward improving patient compliance.

ADHERENCE ISSUES

Whether psoriasis, atopic dermatitis, acne or any of the commonly seen dermatologic diseases and conditions, Dr. Feldman says that more often than not, the main reason why patients' symptoms do not improve is because they simply do not adhere to the therapeutic regimens as suggested by their physician.

"The adherence issues in dermatology are probably a lot bigger than they are in other fields of medicine," he says. "That's not to say that they are not big in other fields, but they are even bigger in dermatology because the basis of the vast majority of dermatologic therapies are topical, and therefore, much harder to comply with when compared to oral therapies."

Topical dermatologic therapies typically may last for weeks to even months, or longer. It can be challenging for patients to maintain compliance with topicals for extended periods of time, regardless of the condition or disease for which patients are being treated.

"It's relatively easy to take a pill and patients won't likely forget to take their medicine every day, especially with the help of a seven-day pill box. However, if you're treating foot fungus and you are at the breakfast table and you already put your shoes and socks on, you very likely will not put the cream on that day," Dr. Feldman says.

Aside from patients being forgetful and having concerns over cost, Dr. Feldman says another reason why patients may not take their medications is because of a fear of potential side effects. This is particularly true for corticosteroids, whether topical or oral.

ESTABLISHING TRUST

Establishing a meaningful and close doctor-patient relationship is essential in gaining the patients' trust, Dr. Feldman says, and it is the first crucial step in getting patients to take their medicine as prescribed. Establishing trust does

ADHERENCE see page **44**

VIDEO **dermatologytimes.com/adherence**

Steven R. Feldman, M.D., Ph.D., discusses the role of adherence and how to improve compliance in psoriasis patient care.

Video: DermQuest Video Library

New modalities revolutionize chronic wound management

Ilya Petrou, M.D. | Senior Staff Correspondent

ISTANBUL — New therapeutic modalities such as bioactive extracellular matrices, laser therapy and others have revolutionized the treatment and management of chronic wounds, allowing clinicians to achieve much faster wound closures in their patients.


Dr. Romanelli

Chronic wounds such as venous ulcers and diabetic foot ulcers are two types of cutaneous wounds that have always been historically challenging to treat. In the past, many clinicians relied upon traditional woundcare approaches such as compression, gauze-based dressings, conforming bandages, nonadherent bandages, and other techniques to achieve wound closure. The treatment course with these modalities, however, was typically protracted, resulting in frustration for both patient and physician.

"The use of extracellular matrices for tissue repair has revolutionized wound closure therapy and among other state-of-the-art techniques currently used, this treatment approach has become a mainstay in our modern wound care treatment approach in our patients with chronic wounds," says Marco Romanelli, M.D., Ph.D., professor, department of dermatology, University of Pisa, Italy, and president-elect of the World Union of Wound Healing Societies (WUWHS). He spoke at the EADV Annual Congress in Istanbul.

ADVANCED MEASURES

Diabetic foot ulcers and chronic venous ulcers are considered to be among the most difficult chronic wounds to treat, Dr. Romanelli says, as they typically do not respond well to standard wound closure approaches. A case in point would be patients with venous compartment syndrome, he says, in which approximately 24 percent of patients do not respond to compression and moist wound healing, two cornerstones of wound management.

"In patients with venous compartment syndrome or others in whom standard treatment modalities do not result in an adequate or quick wound closure, we often have to turn to other more advanced measures and treatment approaches," he says. "Here, following a meticulous debridement of the wound, we will often use either extracellular matrices or tissue engineering techniques, or both, to help achieve better wound healing and expedite wound closure."

As head of a large outpatient clinic dedicated to treating chronic wounds, Dr. Romanelli has many different state-of-the-art wound closure products and technologies from which to choose, such as Integra (LifeSciences), a bilayer dermal matrix wound dressing comprised of a porous matrix of cross-linked bovine tendon collagen and glycosaminoglycan, and a semi-permeable silicone layer. While the semi-permeable silicone membrane controls water vapor loss and offers a flexible adherent covering of the wound surface, the collagen-glycosaminoglycan biodegradable matrix is engineered to provide a scaffold for cellular matrix and neoangiogenesis.

Oasis Wound Matrix (Cook Biotech) is another bioresorbable matrix technology product that Dr. Romanelli says he will often choose in his chronic wound patients, consisting of a single layer matrix comprised of porcine small intestinal submucosa (SIS).

WOUND BED PREP

Just prior to the application of these extracellular matrices or other advanced tissue engineering techniques, Dr. Romanelli says it is imperative to perform a meticulous wound bed preparation and debridement of the wound to help improve the efficacy of the product used and to maximize the clinical outcome.

"Crucial in the process is to prepare the wound appropriately and free it from accumulated bacteria. The aim is to restore the wound bed as much as possible to a healthy physiologic state before applying these high-tech and costly tissue repair products," he says. "This will significantly help in the development of healthy granulation tissue and expedite the wound-healing process."

QUICK READ

New emerging therapies used for the treatment of chronic wounds are proving to be quick and effective in achieving wound closure, particularly compared to more traditional closure techniques, raising the standard of care.

> "The aim is to **restore the wound bed to a healthy physiologic state** before applying high-tech products."
>
> **Marco Romanelli, M.D., Ph.D.**
> Pisa, Italy

In addition to extracellular matrices, Dr. Romanelli says the application of topical negative pressure to the wound can also be instrumental in the quick closure of chronic wounds. He says this is a very effective technique in helping to promote granulation tissue in the wound, and is often used for cavity wounds such as pressure ulcers or diabetic foot ulcers with a very large defect.

Topical wound pressure is a technique that results in a negative vacuum pressure to the wound, and it is applied after the wound has been properly sealed with a foam or gauze dressing. According to Dr. Romanelli, the technique assists in the transportation of exudate and admixed bacteria from the wound bed to the vacuum, and helps create a wound bed where the granulation tissue can freely grow.

CHRONIC WOUNDS see page **44**

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Emerging therapies for chronic wounds are proving to be effective from page 42

"We are beginning to increasingly using this treatment modality over the tissue engineering and extra cellular matrices that we have applied to the wounds in order to keep those products better affixed to the wound bed, and to maximize the drainage effect of the fluid which continues to be produced in these wounds," Dr. Romanelli says.

SURGICAL DEFECT TREATMENT

Beyond their use in chronic wounds, extracellular matrices can also be ideal in treating surgical defects such as those after Mohs surgery, he says. According to Dr. Romanelli, the secondary intension healing approach in Mohs surgery often can often result in large defects and here, extracellular matrices can be used to help expedite wound closure.

"In post-Mohs surgery patients or following other surgical procedures that may result in large and deep cutaneous defects, extracellular matrices can be instrumental in a quick wound closure," he says.

The role of lasers and their therapeutic benefits in medicine continue to evolve, as an increasing number of indications for this technology arise spanning many different medical specialties. According to one specialist, this is especially true for the use of lasers in the medical treatment of chronic wounds.

"In addition to the topical therapies used in the treatment of chronic wounds, lasers have also been shown to significantly impact the speed at which these wounds close. In my experience, they can be a great adjunctive treatment approach in wound therapy, particularly in difficult-to-heal cutaneous wounds," says Nicola Zerbinati, M.D., assistant professor of dermatology, department of surgical and morphologic sciences, faculty of medicine and surgery, University of Insubria, Varese, Italy.

One of the central advantages of lasers in chronic wound treatment is that the therapy is not associated with complications, Dr. Zerbinati says. In chronic wounds such as venous leg ulcers and diabetic foot ulcers, Dr. Zerbinati often uses CO_2 lasers to help debride the ulcer and remove the dendritic cells from the wound bed. This treatment approach will invariably result in a stimulation of the fibroblasts, Dr. Zerbinati says, which will help to promote granulation tissue and a re-epithelialization of the wound bed, and result in a faster wound closure.

Though different CO_2 lasers are available on the market for this indication, Dr. Zerbinati says the bottom line is that one should use the laser energy at high power and at very short pulse durations in order to help avoid any risk of coagulative effects in the ulcer bed.

"When employing laser therapy in chronic wounds, it is crucial to induce a 'cold injury' in the wound bed. In my experience, a CO_2 laser that works with a high peak power and short pulse durations is probably one of the most effective treatment options in regards to laser therapy, as its use can significantly help accelerate the closure of chronic wounds," Dr. Zerbinati says. **DT**

Disclosures: Drs. Romanelli and Zerbinati report no relevant financial interests.

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Three steps dermatologists can take toward improving patient compliance from page 41

not necessarily require more time with patients, he says, but instead, it requires spending more quality time with them, which can include giving patients a sense of calm by walking slowly into the examination room, laying hands on the lesion(s), and speaking softly and caringly with them.

"Your initial presentation and how you psychologically handle the patient in the first few minutes you spend with them is crucial in building that bridge of trust," Dr. Feldman says.

"Patients are not going to trust the drug company, and they are not going to trust the drug," he says, and therefore it is essential that they trust the doctor. According to Dr. Feldman, it is absolutely essential to establish that connection with the patient and give them the feeling that you understand what they are going through and truly care, even though you have already mentally decided on how you are going to treat them as soon as you walked in the room.

"If you make sure that they realize you care about them, then they will trust you and follow your instructions in order to please you. If they think you don't care about them, then they very likely are not going to take the medicine," Dr. Feldman said.

NEXT STEPS

After suggesting a given therapy, the next step is to get patients to fill their prescription and use the medicine. According to Dr. Feldman, this can be best achieved by asking to see them back in a week for a follow-up visit, instead of four or eight weeks later.

"Seeing patients after one week will force them to fill their prescription right away. They will begin to use the medicine throughout that first week, right before their second visit, which will invariably bring good therapeutic results and will fuel them to take the medicine long-term," he says.

In more difficult patients and cases such as recalcitrant psoriasis, Dr. Feldman says he will often write down his cell phone number and hand it to the patient prior to leaving the exam room, asking them to call in three days and report on their progress. In the vast majority of cases, Dr. Feldman says patients don't misuse the phone number, and they usually leave a message reporting excellent results because they were quick to fill their prescription and take the medicine as prescribed.

"Patient psychology is a major part of practicing good, effective, and efficient dermatology. Giving patients your personal cell phone number can help establish a very close trust, as it gives patients the feeling that they are special, taken care of, and understood," he says. "It's not difficult to make the diagnosis of psoriasis and prescribe appropriate therapy. What makes dermatology fun and exciting is figuring out how to get patients to use their medications." **DT**

Disclosures: Dr. Feldman reports no relevant financial interests.

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Vendors' data-gathering concerns clinicians

Lisette Hilton | Staff Correspondent

QUICK READ

Device makers seek to capture data to enhance marketing efforts, but some doctors raise concerns about privacy.

NATIONAL REPORT — Charles E. Crutchfield III, M.D., is a fan of CoolSculpting technology, but he says he doesn't like what Zeltiq, CoolSculpting's maker, tried to do after he bought the machine.


Dr. Crutchfield

Dr. Crutchfield claims that a Zeltiq representative told his practice manager several months ago that Zeltiq wanted to install technology on his machine to report data on what his practice was doing to the company.

"I thought, 'That's peculiar,' Dr. Crutchfield says. "They said they'd give us a report that would help us better utilize the machine."

But Dr. Crutchfield, a dermatologist in Eagan, Minn., insisted that he captures his data and doesn't need Zeltiq's help.

"So, I said thank you for the kind offer. We're not interested," he says. "They were relentless. They called every day for several weeks."

Dr. Crutchfield says his manager was unwavering and told the rep to stop calling about the installation. Weeks later, during an office meeting, Dr. Crutchfield says one of his employees said the rep called her and asked if she could come in and install a software update. The unsuspecting employee obliged.

But what the rep really did was install the very technology that Dr. Crutchfield's manager had so consistently declined, according to the dermatologist. The Zeltiq representative later admitted she had installed the modem needed to transmit data from Dr. Crutchfield's machine to the company.

The office manager has since had the modem removed. But the experience so concerned Dr. Crutchfield that he called colleagues, many of who said they were unaware that their CoolSculpting machines might be among those with the modems.

Dermatologists need to be aware, Dr. Crutchfield says.

"It's OK if somebody (is told ahead of time and) wants the report and thinks it's valuable to them. I'm a reasonable person," Dr. Crutchfield says. "I don't know why they're being so heavy-handed — to go into your office and install something on your equipment without your permission. Something's not right about that."

WIDESPREAD PRACTICE?

Some dermatologists contacted by **Dermatology Times** say they suspect other vendors are gathering data, but they're not sure to what extent.

One company responded when **Dermatology Times** queried a few

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Quotable

"The ability of these technologies to deliver higher energy levels ... are giving us much better and more predictable results."

Neil S. Sadick, M.D.
Weill Cornell Medical College, New York

On skin-tightening devices
See story, page 54

DTExtra

Smartlipo (Cynosure) and Vaser (Solta Medical) are two different tools that can be used to aid a surgeon during a tumescent liposuction procedure. Both tools assist in fat removal and both have advantages and disadvantages, says John Bergeron, M.D., a liposuction expert in Houston.

Smartlipo	Vaser
Advantages: Small skin incisions Skin tightening	**Advantages:** Useful on dense tissue (back, male chest)
Disadvantages: Not useful on dense tissue Extra "step" in procedure	**Disadvantages:** Larger skin incisions required Extra "step" in procedure

SOURCE: DERMATOLOGYTIMES.COM/TUMESCENT

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DATA:

Doctors raise privacy concerns after device makers seek to track information from page 46

vendors. According to an Ulthera representative, "The Ulthera System has the capability to process limited procedural data without any patient-identifying information, which is compliant with HIPAA and standard in the industry. Customers consent to this data analysis, which can be useful in providing value to physicians."

Mark D. Kaufmann, M.D., associate clinical professor of dermatology at Icahn School of Medicine at Mount Sinai, New York, says he is not aware of vendors putting tracking software into their devices.

"The laser we have in our office keeps track of how many pulses the machine uses, but that data is only accessed by the technician when servicing the laser," Dr. Kaufmann says.

But if it's true that vendors are using tracking devices, that's a concern, Dr. Kaufmann says.

"... My first concern would be the potential HIPAA privacy breaches. It also troubles me that companies would be installing this software without the doctor's knowledge or permission," he says.

ZELTIQ RESPONDS

Mark Foley, president and CEO of Zeltiq, based in Pleasanton, Calif., says the company has good intentions by installing what he calls a breakthrough data management platform on CoolSculpting machines in doctors' offices.

According to Mr. Foley, the rationale behind the technology — called CoolConnect — is to increase machine usage and more intelligently spend advertising dollars.

"We don't make a lot of money on placing systems in the field, so our long-term growth strategy really depends on happy customers, happy patients and busy machines. And the way that we try to ensure that is we've built out a whole second field organization called Practice Support Specialists, whose sole job and responsibility is to work with our physician customers and the staffs in those accounts, train them, educate them, partner with them," Mr. Foley says.

Zeltiq invests up to half of what it makes from cycle cards into cooperative advertising and marketing to raise awareness and drive CoolSculpting business.

Zeltiq, he says, has always had information about its customers — the doctors who buy the machines. But this new data management platform tells the company more. The CoolConnect device — which costs Zeltiq about $1,000 to install and is free to physicians — gathers real-time data, including the patient's sex, whether it was a first-time or repeat patient, and whether it was a new or existing patient.

GENERIC INFO

He says the data is generic, not patient-

specific, for now. "At this point, I don't know that there's a whole lot of value in linking it to specific patients. And since there isn't that patient-specific identification information, I'm not sure why the physicians would be quite as concerned," Mr. Foley says. "I'm sure there's the ability to do that if that were to be something the physicians wanted. From the company's standpoint, I think that opens a whole new host of issues in terms of how we manage the data, and I'm not sure that's something we want to get into."

The data captured will be put into a form that can help physician practices, he says. Physicians will receive those reports monthly. The trends revealed by the data will help Zeltiq partner with practices that have CoolSculpting machines to increase business or better spend their advertising dollars to promote the technology.

But Mr. Foley admits Dr. Crutchfield's experience was a wake-up call.

"... That maybe we aren't doing as good of a job in educating our physicians," he says. "At a very high level, we are extremely proud about this product and what we're doing, and the innovative nature of this whole thing. If we've done a poor job of installing it or (are) not adequately informing our customers, we're happy to pull this out."

According to Mr. Foley, Zeltiq has more than 1,200 systems in the United States and about half are installed with the modem to transmit data to Zeltiq from doctors' offices. Dermatologists who don't know if the technology is on their machines should ask their Zeltiq representatives or practice support specialists, and they can have those reps remove the modems.

MIXED FEELINGS

Mr. Foley says doctors, for the most part, are fine with and even happy about having the technology installed on their machines.

Plastic surgeon Joseph M. Gryskiewicz, M.D., who has two offices in Minnesota, says he doesn't mind having the modems on his two CoolSculpting machines and the installation was "above board." He says the reporting could be a plus and, if it isn't, he can have the modem removed.

"The other (benefit is) if there is an error code or problem code, this software will immediately send a signal to the company saying there's a malfunction on the machine," Dr. Gryskiewicz says.

One the other hand, dermatologist Neil A. Shah, M.D., says finding out about Zeltiq's tracking software was a deal-breaker for him and his partner.

"My partner and I were looking to purchase the machine over the next six to 12 months. However, once the tracking software came to light we decided to hold off indefinitely on the Zeltiq machine," Dr. Shah says. "For treatment of unwanted fat we will be looking at other therapeutic options. Also, we screened all of our leased equipment now for the presence of tracking software or modems."

> "It troubles me that companies would be **installing this software without the doctor's knowledge** or permission."
>
> **Mark D. Kaufmann, M.D.**
> New York

The discovery that companies install this type of transmission technology was shocking, according to Dr. Shah, who has a practice in St. Anthony, Minn.

"The thought hadn't ever crossed our mind, previously. It has caused us to completely reevaluate our relationship with equipment manufacturers and vendors. One of the first questions we now ask is, 'Does your hardware contain any type of tracking software?'" he says. "Simply put, we will not allow any tracking software or hardware to be installed on any equipment that we own regardless of assurances made my manufacturers."

A PANDORA'S BOX?

Dean Sorensen, principal consultant and CEO of Chicago-based Sorensen Informatics, says this type of data gathering could be a Pandora's box if it transcends into personal health information (PHI).

It's the covered entity's responsibility to find out if the machine is transmitting from the physician's practice to the machine manufacturer. If there is any PHI transmission, the physician must establish a business associate agreement with that vendor, which makes the vendor responsible for any information it collects from the doctor, according to Mr. Sorensen.

Whether the information being transmitted includes any patient-specific data isn't always so clear, according to Mr. Sorensen. Dermatologists and other physicians might use a patient's Social Security number, date of birth or last name to tie that patient's information back to a medical record or chart. All of that is PHI. And if a third-party vendor has access to the information, whether it uses it or not, the physician is in violation of HIPAA without the proper documentation and agreements in place.

"(HIPAA) says that if you create a relationship with someone who is going to have access to your computer systems or any source of information that contains protected health information, you have to create the contract," Mr. Sorensen says.

What should dermatologists do? Mr. Sorensen recommends they need to do a security assessment and identify and track protected health information from the time it comes into their doors to the time it leaves the building — whether that's electronically or physically.

"As a result of that assessment, you need to make sure you've established contracts, or associate agreements, with anybody who touches any of your protected health information," he says. "There has been a trend to try to introduce ways for medical devices to talk to electronic medical record, so it wouldn't surprise me if the information being stored in these devices is commonplace.

"As far as who is able to see what information is being stored on those machines," Mr. Sorensen says. "And whether or not they have established the business associate agreements, or whether or not they have identified to the physician what kind of information they were tracking, that's probably a big unknown." **DT**

Drs. Crutchfield, Gryskiewicz, Kaufmann and Shah report no relevant financial interests.

Q & A

NAVIGATING NEUROTOXINS' DIFFERENCES

An expert panel discusses Botox, Dysport and Xeomin at the 2013 Vegas Cosmetic Surgery and Aesthetic Dermatology meeting.

Q. We now have three neurotoxins in our marketplace. Do you feel that these neurotoxins differ, and if so, how?

Susan Weinkle, M.D.
Dermatologist, Bradenton, Fla.

A. Michael Persky, M.D., plastic surgeon, Encino, Calif.: I'm thankful for all three products that are currently available in the U.S. and I have used all three. I have the most experience with Botox (onabotulinumtoxinA, Allergan) because that was the first one we used. I use Dysport (abobotulinumtoxinA, Medicis), based on the study that Dr. Corey Maas did, for the crow's feet area, because his study showed a little bit of a better and longer-lasting effect on side-by-side comparison versus Botox. I do like all of the available neurotoxins. Again, I don't think it's the product per se, rather it's how the injector uses the product on the patient's face. With Xeomin (incobotulinumtoxinA, Merz) my experience has been that maybe it takes a little bit more than the 1-to-1 unit dose that they recommend.

There's big talk about the ratio of Dysport to Botox: 1-to-2.5 or 1-to-3. Again, I don't put a lot of stock in that. I think the more you use the product, you get a feel for how it works in your individual patients. The ratio may be different in some patients. I don't believe that there's an exact number ratio for everyone. If there's any neuromodulator market companies out there that want to dominate the market make a neurotoxin that is a little less expensive than the others — one product that's maybe $100 or $150 per vial less than the others will dominate all of the market if it's equivalent to the products we have now.

A. Welf Prager, M.D., dermatologist, Hamburg, Germany: I've done quite a few of the studies comparing different neurotoxin products: Botox, Dysport and Xeomin. And when we looked at the results Xeomin to Botox, they are exactly exchangeable in the 1-to-1 ratio and two products compared to Dysport is probably 1-to-2.5 or a 1-to-3 ratio which would apply on the patients.

In Germany the patients do not ask which product we are using. That's why I also exchange the products in my patients. The patients don't notice any difference and I don't notice any difference in coming back. There was the study where 21 doctors in Germany filled out questionnaires and there was no difference in the use these three different products.

A. Derek Jones, M.D., dermatologist, Los Angeles: Excellent question. I'm a data-driven, evidence-based kind of guy. Let's talk just quickly about the three toxins and the data behind them. I think that you can — in most cases — use all three products interchangeably. Dysport I think would be the most different of all three in terms of the dosage required. As you require more units, there does tend to be more spread of effect. So patients and physicians will talk about the sort of stronger freeze that you get with Dysport particularly if you're using it in the crow's feet or in the frontalis.

I think it defuses a bit more and patients will note this sort of more global freeze if you will. That doesn't mean it's a bad product. Sometimes that's what you want. So I think that's one difference.

Now when it comes to Xeomin and Botox Cosmetic, I think that there is enough in the literature right now to suggest that they are pretty equivalent in their clinical response. If you look at the really nice paper by Sattler, Carruthers and Flynn, (Sattler G, Callander MJ, Grablowitz D, et al. *Dermatol Surg.* 2010;36(Suppl 4):2146-2154) in 24 units in the glabella, the efficacy curves and the extinction curves are laying right on top of each other.

There's been a lot of argument that this is a 24-unit and not a 20-unit on-label study. So this has been going back and forth now for a couple of years. I think it's highly likely that we'll see a 20-unit glabella study Xeomin

NEUROTOXINS see page 52

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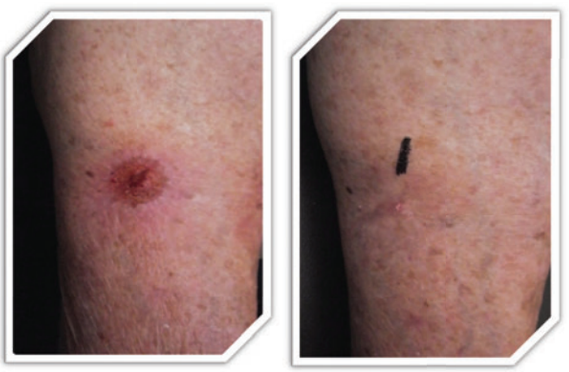

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Dermatology Times **presents a panel discussion (right) at the Vegas Cosmetic Surgery and Aesthetic Dermatology annual meeting. Here, panel members discuss differences, if any, among available neurotoxin products.**

VIDEO dermatologytimes.com/neurotoxins

NEUROTOXINS:

Expert panel discusses product differences, if any from page 50

versus Botox within the next couple of years.

There is this sort of persistent signal out there among users that Xeomin's maybe a bit softer. Whether that's true or not I honestly do not know. I think we need better studies to sort of pick that up. At this point I agree with the other panelists. I've been in practice in L.A. since '97. I have lots of retention in my practice. If the patient is happy with what I'm giving them, that's what I use. With Botox Cosmetic, I have so much experience using multiple dilutions throughout all sorts of areas on the face that I just stick with what I know.

A. Michael Kane, M.D., plastic surgeon, New York: Yeah I carry and use all three toxins that are on the market. And rather than just talk about these, let's talk about the future. You know in a year we'll probably have four toxins and in a couple of years we'll probably have five or six. We may even have a topical toxin. The same thing with fillers.

We're going to have a lot of different fillers besides injectable fillers. We may have solid state HA (hyaluronic acid) threads that you can thread through the skin. I think as we get a bunch of different HA fillers we will see that they are more and more disparate.

We'll have very soft fillers, very stiff, very thick fillers and they're easily differentiated once you inject one person with them. But I think when you look at all the toxins, even when we have seven or eight we will start to realize how similar they are — not identical, not exactly the same, but they will be very similar. And the reason is dissociation — physiologic pH, the complexing proteins fall away.

There's even evidence that suggests in the Eisele paper (Eisele KH, Fink K, Vey M, Taylor HV. *Toxicon*. 2011;57(4):555-565) that as soon as you reconstitute these toxins, a great deal if not total dissociation happens right in the vial. This is a bit controversial due to the amount of centrifugation that the specimens were put through. But most agree, at a physiologic pH, dissociation happens quickly.

That's a little controversial, but I think as you get ease of use with all the different toxins you'll realize how close they are — not identical but very similar.

And, I'm going to be an outlier on this panel. I want the expensive, premium products. If you think that we're immune to market forces and the companies will drop the price and you won't be dropping yours, you are mistaken. I like premium products and my patients do too. I would love to see a differentiated injectable toxin product. Actually there are some animal studies that show that one of the injectable toxins in development right now may last for a bit longer than the others.

Again, that's a very, very early thing. But, again, if something like that were to come to market even with a premium price I think that would be outstanding.

A. Susan Weinkle, M.D., dermatologist, Bradenton, Fla.: I have all the products in my office as well. I think that initially when we started using Xeomin, we did not understand the importance of the swirl. So when I started using Xeomin, some of the patients in my practice didn't think it was as good, and did not think it lasted as long. Unfortunately, we were not inverting the bottle to make sure that we were getting all of the product off that rubber stopper and in the cap. I think we probably were leaving a lot of units in the bottle, not understanding that part of the reconstitution of this product.

Once we started doing that (swirl), I have found all three to be very comparable. Patients often come into my office asking for specific products, so I think that we have to be on the cutting edge and have those things available.

I've used less units, regardless of which product it is, in many locations. I used to use a lot of neurotoxin in the forehead and now I use very little, especially in my older patients that need that frontalis. I believe we've learned that the products are probably more similar than they are different.

I've learned to feather whichever product I am using more than I used to. I use a micro-droplet technique in areas that I never used to — even periorbitally around the eye. I think that less is better than we used to think.

It's an evolution that we're going through with understanding products; with understanding how we use these products.

One thing I do like in my office is to constitute the products in terms of it's volume. So 0.4 in a syringe of one product, I can use interchangeably. So whether it is Dysport, Xeomin, or BOTOX, I know I can utilize that volume the same and I don't have to worry that we've mixed up something. **DT**

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Nonablative skin-tightening devices give good results, but predictability lacking

John Jesitus | Senior Staff Correspondent

New York — Nonablative skin-tightening devices often provide good results, according to an expert, but it's tough to predict which patients will get these results.

Current nonablative skin-tightening devices represent the best option available for patients who do not want surgery, says Neil S. Sadick, M.D., clinical professor of dermatology, Weill Cornell Medical College, New York. These devices provide very good results, he adds, "But results are unpredictable. Some people respond better than others."

To provide more consistent results, he says, "Researchers and developers must optimize treatment parameters with all these technologies."

To that end, additional needs include appropriate temperature monitoring throughout treatment, treatment programs that maximize results, an understanding of the optimal number of treatments required, and the development of effective maintenance regimens.

DEVICE DIFFERENCES

In his practice, Dr. Sadick says, "We like the Thermage (Solta Medical) and Venus Freeze (Venus Concept) devices." His treatment protocol with the former device, which uses unipolar radiofrequency (RF) energy, includes one treatment session.

"The Thermage device can cause some discomfort," he adds, so patients receive oral analgesia (oxycodone and acetaminophen) before treatment.

This device's "super-pass" technique uses a larger tip, which allows one to complete a treatment in one-third the time required with the original tip, Dr. Sadick says. The newer tip requires the vectoring technique: "Use the tip to apply the energy in an upward vectoring fashion to maximize treatment efficacy."

Unlike the Thermage device, he says, "The Venus Freeze causes no discomfort at all, but it requires four to six treatments" for optimal results. For patients, "It's very easy. It almost feels like a spa treatment." The device uses multipolar RF plus magnetic pulses.

With both devices, "There's no recovery time, so people can go right out to lunch afterward if they desire," Dr. Sadick says.

QUICK READ

Nonablative skin-tightening devices represent the best option for patients who do not want surgery, but results can be unpredictable.

WATCH THE TEMPERATURE

With either treatment, "We try to keep the temperature of the epidermis around 42 degrees Celsius." Meanwhile, he says, the reticular dermis must reach a temperature between 55 degrees and 90 degrees Celsius, which he calls the "sweet spot" for collagen denaturation. To maximize efficacy and patient safety, Dr. Sadick adds, target temperatures between 55 degrees and 65 degrees Celsius require longer pulses (measured in minutes), versus the millisecond pulses used when targeting temperatures of 85 degrees to 90 degrees Celsius.

Nonablative skin tightening involves dermal heating to induce new collagen deposition and remodeling without ablating the dermis (Sadick NS. *Aesthet Surg J.* 2008;28:180-188). Immediate effects of such heating include denaturation of the collagen helix, thermally driven collagen contraction, and dermal swelling due to collagen injury, Dr. Sadick says. Longer-term, he adds, these changes induce a wound-healing response, increased expression of transforming growth factor beta (TGF-beta), collagen and elastin remodeling, and reorientation and increased thickness of the papillary dermis.

Broadband devices use intense pulsed infrared light (1100 nm to 1800 nm). They work via cumulative dermal heating to a depth of one to three cm, Dr. Sadick says. Contact cooling protects the epidermis during treatment, he says. His typical protocol for treating facial areas with broadband devices includes two to four passes per session, performed one to three times monthly at energy levels of 30 J/cm^2 to 42 J/cm^2.

Intense focused ultrasound uses short pulses (4 MHz to 4.75 MHz, 0.3 J/cm^2 to 1 J/cm^2), he says. Tissue heating via absorption of acoustic energy creates well-defined zones of thermal damage measuring less than 1 mm^3 in the reticular dermis. Because this treatment spares the epidermis and papillary dermis from damage, Dr. Sadick says, it requires no simultaneous skin cooling.

"These technologies are being used for off-face indications as well." With broadband, for example, body treatments require energy levels of 37 J/cm^2 to 47 J/cm^2.

"We use all these devices for tightening of arms, legs, thighs and in postpartum women," he says. These treatments produce very good results with essentially the same protocols used for the face, according to Dr. Sadick.

MORE PREDICTABLE RESULTS

Overall, he says, "The ability of these technologies to deliver higher energy levels, to reach the desired temperature between 42 degrees and 44 degrees Celsius more rapidly and comfortably, and the availability of improved cooling devices are giving us much better and more predictable results. That's where the evolution of these devices stands."

Dr. Sadick is conducting a clinical study with the Thermage Total Tip 3.0.

"It's a much larger, more powerful tip (3 cm) that requires much less time per treatment," again using the upward vectoring approach. This study should be completed by the end of 2013, he says.

Dr. Sadick soon will start a study with Venus Concept's new Viva technology.

"The Viva device adds sublative rejuvenation for an effective but controlled fractional ablative treatment," he says.

The Viva device's RF pulses can be adjusted by duration, amplitude and the pattern of active pins, adds Dr. Sadick, who anticipates completing this study in spring 2014. **DT**

Disclosures: Dr. Sadick is a researcher and consultant for Cutera, a researcher and speaker for Solta and a consultant and speaker for Venus Concept, in which he also owns stock options.

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58 CUTTING SURGICAL ERRORS
Total body photography may reduce wrong-site surgeries, but clinical value remains unclear

Vismodegib effective for challenging basal cell carcinomas

Ilya Petrou, M.D. | Senior Staff Correspondent

NEW YORK — Vismodegib (Erivedge, Genentech) is demonstrating effectiveness for the treatment of metastatic and locally advanced basal cell carcinoma (BCC), offering hope for patients with this notoriously challenging disease.

The novel oral therapy is approved by the Food and Drug Administration for the treatment of metastatic and locally advanced BCC for which, until recently, the primary treatment options included surgery and/or radiotherapy.

"Until recently, there has been no FDA-approved drug for this specific indication, so vismodegib definitely has a welcomed place in our armamentarium," says Scott W. Fosko, M.D., professor and chairman, department of dermatology, Saint Louis University School of Medicine, St. Louis. "Vismodegib could be an ideal treatment choice in those patients who have failed surgery and/or radiation therapy, in cases of tumor recurrence, or where surgery would be expected to be quite extensive resulting in significant disfigurement."

QUICK READ

Vismodegib is proving an effective option for metastatic basal cell carcinoma and locally advanced basal cell carcinoma, and underscores the therapeutic benefits of targeted dermatologic therapy.

TARGETED THERAPY

Targeted therapy in dermatology is slowly coming of age and vismodegib represents a breakthrough in this field, Dr. Fosko says, as it is the first hedgehog signaling pathway-targeting agent to gain FDA approval for the treatment of metastatic and locally advanced BCC.

The hedgehog pathway is known to be pathogenetically relevant in more than 90 percent of BCCs. Vismodegib acts as a cyclopamine-competitive antagonist of the smoothened receptor, selectively inhibiting the signaling in

"Vismodegib may not necessarily revolutionize the treatment of the majority of BCCs, but it is a great treatment option that we can offer a select group patients."

Scott Fosko, M.D.
St. Louis

Quotable

"(Total body photography) appears to be improving outcomes. The definitive question — do patients randomized to TBP have better outcomes — has not yet been answered."

Anthony Cukras, M.D., Ph.D.
Boston

On biopsy-site photos
See story, page 58

DTExtra

A recent study showed that decreased phosphorylation of the protein S6 after treatment with vemurafenib was associated with responsiveness of BRAF-mutant melanoma cell lines to a BRAF-targeted drug both *in vitro* and in mice. Additionally, researchers found they could reliably assess levels of S6 phosphorylation in tumor cells in fine-needle aspiration biopsies from patients before and during the first two weeks of treatment with a BRAF-targeted drug, and that in these patients, **a decrease in S6 phosphorylation after treatment correlated with treatment response.**

SOURCE: DERMATOLOGYTIMES.COM/BRAF

the hedgehog pathway by targeting the smoothened protein. The inhibition of smoothened causes transcription factors GLI1 and GLI2 to remain inactive, which in turn prevent the expression of tumor mediating genes within the hedgehog pathway.

"This is a very exciting time for all skin cancers and cancer treatment in general, as the current research is focusing more and more on targeted therapies," Dr. Fosko says. "Vismodegib may not necessarily revolutionize the treatment of the majority of BCCs, but it is a great treatment option that we can offer a select group patients."

Vismodegib treatment is associated with side effects, however, the most common of which is muscle cramps, followed by dysgeusia and/or ageusia, alopecia and weight loss. Although these adverse events can lead to the discontinuation of therapy in some patients, Dr. Fosko says that in his experience, the therapeutic benefit of vismodegib often outweighs the associated adverse events — especially in those patients who have tried and failed other treatment approaches.

TUMOR RECURRENCE

The current suggested dose for vismodegib is 150 mg a day, which is to be continued until there are intolerable side effects or the disease starts to progress. According to Dr. Fosko, however, toxicity issues with vismodegib can often be managed well with a drug holiday, which is also allowed in the FDA-approved use.

In a recent clinical trial with vismodegib in patients with basal cell nevus syndrome, researchers found a significant tumor response. More than 50 percent of patients discontinued treatment, however, due to intolerable side effects (Tang JY, Mackay-Wiggan JM, Aszterbaum M, et al. *N Engl J Med*. 2012;366(23):2180-2188).

"In my experience with locally advanced BCC, patients' overall tumors respond well while on drug, and they are very motivated to either stay on-drug or get back on drug. In the basal cell nevus syndrome patient study, however, it was found that some tumors recur once the patients stop treatment," Dr. Fosko says. "Further studies will hopefully help us optimize the treatment protocol and elucidate just how long one needs to take the drug, balancing therapeutic response and potentially minimizing side effects." **DT**

Disclosures: Dr. Fosko is a consultant and on the speakers bureau for Genentech, and is currently receiving funding from Genentech for an ongoing trial with vismodegib.

Clinical photos can cut surgical errors, biopsy rates

John Jesitus | Senior Staff Correspondent

MIAMI BEACH, FLA. — Solid evidence supports the value of biopsy-site photos in preventing wrong-site surgeries, an expert says. The data behind total body photography (TBP) and noninvasive imaging techniques are exciting developments, he adds, but their value in routine practice is less clear.

Of these three techniques, says Anthony Cukras, M.D., Ph.D., "Biopsy site photography — taking a photo of what you're biopsying because you may need to excise that lesion later — has the most evidence behind it. The data show that if patients present for surgery without those photos, there is a significant error rate in site identification." He is an attending dermatologist at Beth Israel Deaconess Medical Center/ Harvard Medical School, Boston.

In particular, studies show that without biopsy-site photos, patients can misidentify their surgical site between 9 and 29 percent of the time.[1,2] Error rates for surgeons in these studies ranged between approximately 5 and 12 percent, says Dr. Cukras, who spoke at the American Academy of Dermatology Annual meeting. Because biopsy-site photos improve patient care, he says, dermatologists and dermatologic surgeons should consider them a necessity.

PHOTO CHALLENGES

Dr. Cukras adds, however, that biopsy-site photos are far from the standard of care because healthcare payers do not reimburse for them.

"It is a lot of work for dermatology offices to photograph every biopsy site, and keep the photos organized and secure," he explains. Accordingly, a survey of 722 Mohs surgeons showed that 88 percent of them receive no biopsy site photographs for three-quarters of their referrals.[3]

"That's surprising. For the good of the patient, we can and should do better," he says. To that end, Dr. Cukras' office automatically incorporates these photos into its homegrown electronic health record (EHR) system. This approach has reduced the proportion of cases in which no biopsy-site photo is available at the time of surgery from 16 to 5 percent, while slashing the amount of time required to upload photos.[4]

Regarding TBP, he says that to date, "No great randomized, controlled trials have been published." But retrospective cohort studies suggest that TBP helps dermatologists find earlier, thinner melanomas, while reducing biopsy rates. Typical biopsy rates without TBP vary from around 8:1 to 30:1 (benign:melanoma), depending on the study, investigator and population, he says. But biopsy rates as low as 3.4:1 and 3.9:1 that have emerged from cohort TBP studies[5,6,7] are "unheard of. Those are incredibly low numbers suggest that these techniques are reducing unnecessary biopsies."

MORE DATA NEEDED

Accordingly, Dr. Cukras says, "TBP appears to be improving outcomes. But the definitive question — do patients randomized to TBP have better outcomes — has not yet been answered." Without randomized, controlled trials, he adds, cohort data might simply reflect exceptional vigilance by these patients and their dermatologists.

"The Holy Grail for dermatology is a noninvasive test to help determine whether a pigmented lesion is benign or malignant," he adds. Presently, only one device (MelaFind, MELA Sciences) is approved by the Food and Drug Administration for this purpose.

"It's a very exciting development. Dermatology has been pursuing such a device for a long time," Dr. Cukras says. However, he adds, the downside of MelaFind is that because its sensitivity had to be extremely high to pass FDA muster, the device offers very low specificity.

In every study published to date, he says, "MelaFind has recommended biopsy on the vast majority of lesions it's placed on." In the device's pivotal trial, he says, MelaFind recommended biopsy on 1,472 of 1,632 lesions, or 90 percent, when only 172 of the 1,472 lesions biopsied actually were melanoma or high-grade (specificity: 10.8 percent).[8]

In a follow-up study, investigators compared the biopsy recommendations of 39 independent dermatologists against those of MelaFind on the same set of 47 lesions. This study showed sensitivity rates of 96 percent versus 80 percent, respectively, and specificity rates of 8 percent versus 43 percent.[9]

"If a clinical tool usually recommends biopsying the lesion, you might as well just biopsy the lesion without using the tool," he says. As such, Dr. Cukras says, dermatologists are concerned about the cost that the device would add to a patient's care without improving outcomes. **DT**

QUICK READ

Evidence shows that biopsy-site photos help prevent wrong-site surgeries. But the clinical value of total body photography and noninvasive imaging techniques remain unclear.

Disclosures: Dr. Cukras reports no relevant financial interests.

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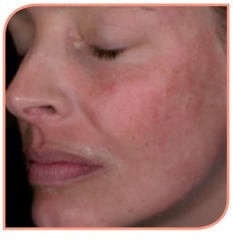

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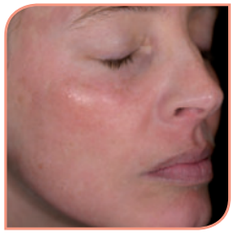

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Pierre Fabre

Consolidation, demand drive EHR market changes

Donna Marbury | Staff Correspondent

QUICK READ

Meaningful use standards will contribute to significant consolidation among EHR vendors; however, opportunity still exists.

In the next few years, the electronic health record (EHR) industry is likely to change rapidly, from a wide variety of choices to just a few key players.

If you take a look at primary care, the number of EHR vendors is already becoming more concentrated, says Jason Mitchell, M.D., director of the Center for Health Information Technology for the American Academy of Family Physicians. He predicts that there will be 20 EHR companies that will make up the majority of the market by 2018.

"Meaningful use 2 (MU2) will be the big shakeout and by meaningful use 3 (MU3) there will be pretty significant consolidation," Dr. Mitchell says. "There will always be a need for boutique systems that offer free EHRs. Larger companies are still having issues wading through lots of code. Even when most of the consolidation occurs, there will always be room for the little guy. There's still room for an innovative player."

In 2007, only 17 percent of physicians used basic EHRs, according to the Centers for Disease Control and Prevention. Now, about 70 percent of physicians are using one of the hundreds of EHR systems currently on the market. Government incentives for usage in 2009 caused a race in the healthcare information technology community to develop and market the next big EHR system.

A study by Kalorama Information — a publisher of market research in medical markets — indicates that six companies make up 58 percent of the EHR market. The remaining 42 percent represent a fractured market that many experts predict is ripe for mass consolidation. However, according to Kalorama, EHR market saturation is still a few years away, and the market could mushroom from $20.7 billion in 2012 to $36.7 billion in 2017.

There are major challenges within the industry — half of practice owners say they are ditching their current EHRs for new ones, while many systems still struggle with interoperability issues as MU2 deadlines approach. If the EHR market is going to shrink and become more efficient, system providers need to balance innovation with government standards and increased specialization in physicians' technology needs.

"Patients and providers are expecting up-to-the-minute access to healthcare data and the government is interested in leveraging this data to improve patient outcomes and to encourage better communication across the healthcare spectrum," says Tim Sayed, M.D., medical director of Modernizing Medicine's Electronic Medical Assistant systems for surgery and cosmetics, and executive committee member of the Healthcare Information and Management Systems Society EHR Association.

"EHR has moved from being a simple concept of a computer-generated text file replacing handwritten chart data to a complex ecosystem of clinical data, patient education, and patient engage-

CONSOLIDATION see page 62

"Just as consumers can self-manage most other aspects of their lives, they expect to take ownership of their medical care."

Kaveh Safavi, M.D., J.D.
managing director, Accenture

Read more on why patients are willing to switch physicians for EHR access: dermatologytimes.com/access

PATIENT EHR ACCESS STILL LACKING

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36% of doctors feel that patients should have full access to records

SOURCE: Accenture

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CONSOLIDATION:

Innovation, evolving technology and standards drive market forces from page 60

ment tools which will increasingly require cross-platform interoperability."

THE NEXT BIG DRIVER

Dr. Mitchell says that the end of government incentives and the beginning of penalties in 2015 won't be a big factor in the EHR industry, though MU2 standards could cause a lot of companies to bow out of the industry.

"Healthcare reform and the transformation in healthcare payment models will be the real drivers," Dr. Mitchell says. "Needing to do data analysis and the switch into value from volume metrics will be important. The payment structure is changing with patient-centered care and accountable care organizations (ACOs)."

Dr. Sayed agrees that MU2 and MU3 requirements will cause many companies with older technology or small marketing budgets to decide between upgrading, merging or closing down.

A big industry shift will result from the transition to Web- and cloud-based systems that can be available in the office or on mobile devices.

According to the Practice Profitability Index released in May 2013 by CareCloud and QuantiaMD, more than 40 percent of physicians say they will be implementing new EHR systems in 2014. Half of the physicians surveyed want to improve operational performance in billings and collection, while 31 percent want to improve their technology overall.

"We are already seeing legacy vendors continuing to merge or go private in order to address various functionally or business model issues," says Albert Santalo, CEO of CareCloud.

IS INTEROPERABILITY POSSIBLE?

Dr. Mitchell says that the industry talks a lot about interoperability, but no company has yet to deliver.

"If we can have general interoperability it will open things up more, but I don't see that happening. There's too much competition. Health systems want to keep patient information within their system — they don't want to share. That's in their business model," Dr. Mitchell says.

The industry has yet to leverage big data to predict and manage outcomes, Dr. Sayed says. "I believe that big data analytics, which allow stakeholders (the government, payers, patient advocates, competing hospital systems, accountable care organizations [ACOs], etc.) to observe patterns of care and outcomes of these different patterns, will be the true vanguard of EHR technology moving forward," he says.

Opportunities to help doctors with existing issues with Health Insurance Portability and Accountability Act (HIPAA) compliancy and communicating with payers in simpler ways are other entry points for small businesses to make an impact in the EHR industry.

"There are many opportunities to make it easier for physicians and patients to communicate in HIPAA-compliant ways, by using tools that are as easy and intuitive as the kinds of tools they are using in their personal lives," Dr. Sayed says. "Integration between EHRs and billing clearinghouses remains somewhat clunky for various systems, and comprehensive practice solutions that include marketing/customer relationship management tools, inventory management, revenue cycle analytics, and human resource business intelligence will increasingly be demanded by high performing practices and enterprise-level organizations like hospitals and ACOs."

ROOM FOR INNOVATION

Though physicians are vocalizing their needs, and the changes in the industry are being outlined, EHR systems are still behind, Mr. Santalo says. This means there is still room for a lot of innovation.

"From a technology standpoint, we are decades behind other industries. Physicians are facing pressures to adopt and use EHRs to comply with various healthcare reform efforts and demonstrate meaningful use. It's clear there is a growing number of providers and groups that signed up for their first EHR in haste and are now entering the market again, wiser about what they need in a clinical system. Specifically, they are looking a more modern, usable, and faster EHR," Mr. Santalo says.

What does EHR innovation look like? Devices such as Google Glass, that could display patient records on eyeglasses, is a likely leap. Wireless and wearable EHR technology will be a necessity in the next few years.

"There are huge opportunities to continue innovating in this field to achieve more transparency and portability of patient data and integration with devices like wearable monitors and mobile apps that track patient health trends and behaviors," Dr. Sayed says. **DT**

5 ways to monitor your EHR vendor's financial health

1. **Set up Google Alerts** to monitor articles and industry conversations on developments, mergers, or sells, says Derek Kosiorek, CPEHR, CPHIT, principal consultant for MGMA.
2. **Ask your EHR vendor** how many installs and de-installs it had in the last year. You may also find data from professional and government organizations, says Peter Basch, M.D., F.A.C.P., chair of ACP's Medical Informatics Committee.
3. **Your EHR vendor** should send updates and developments for the next 18-24 months, Mr. Kosiorek says. Lack of innovation could be a red flag.
4. **A small company** with a strong business model may be more stable than an older company struggling with older technology, Dr. Basch says.
5. **Wait out market changes** before looking for another vendor, Mr. Kosiorek says. Many companies are making too many changes for practices to invest a lot of money right now in a new system. **DT**

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Q&A

TECHNOLOGY STANDS POISED TO TRANSFORM MEDICINE

WITH THE PAIN OF IMPLEMENTATION STILL FRESH FOR MANY PHYSICIANS, SEVEN LEADERS FROM EHR TECHNOLOGY COMPANIES ADDRESS THE FUTURE OF HEALTH INFORMATION TECHNOLOGY IN THE UNITED STATES

Daniel R. Verdon | Group Content Director

TECHNOLOGY'S promise in healthcare was to reinvent, streamline and build new efficiencies among healthcare providers. While the adoption of electronic health records (EHRs) has reached a tipping point, the next phase of its evolution may actually deliver on those promises.

But the process hasn't been without pain for many office-based practices. Why? *Medical Economics* asked

ROUNDTABLE PANELISTS

Jonathan Bush founded athenahealth Inc. in 1997 and serves as its chairman, CEO and president. In 1999, Mr. Bush raised more than $10 million in funding from notable venture capital firms to support the effort. Prior to joining the company, Mr. Bush served as an emergency medical technician for the city of New Orleans, and was trained as a medic in the U.S. Army. He served as a consultant at Booz Allen Hamilton. Bush obtained a Bachelor of Arts in the College of Social Studies from Wesleyan University and an MBA from Harvard Business School.

Matthew Douglass is co-founder and vice president of platform for Practice Fusion. He is credited with creating the SaaS technology framework that enables rapid development of the EHR's national platform, now used by more than 100,000 medical professionals. He has spoken on healthcare technology at SDForum, Health 2.0, the Massachusetts Institute of Technology, Stanford, and Microsoft events.

seven leaders from well-recognized EHR companies to talk about the trends and the future related to technology.

Q. In what ways is technology transforming medicine?

A. Mr. Bush: A critical point to make is that technology, when applied in the right way, has the incredible power to swing the pendulum in healthcare back to where it belongs, with the caregiver and patient. Truly transformative health information technology does not interfere with the sanctity of the encounter between caregiver and patient, but is a smart, elegant tool that doctors don't hate, delivers and enables value, and can be loved, as technology is loved in so many aspects of our lives.

A. Mr. ZoBell: Essentially, if you think about it, physician/patient encounters really have not changed a lot in the last 300 years in the sense that it's a physician interacting with a patient one-on-one, eyeball-to-eyeball. I think technology is transforming medicine in two ways. It helps the physician get to a diagnosis in faster and more reliable ways, whether that's through use of better instrumentation or diagnostic advances. It's also a tool physicians can use to better understand what's going on with their patient panels.

It gives them new ways to better understand longitudinally what's happening with individuals, populations, or even lifetime trends. It's really about data. Advances in technology are also improving access to it.

I think the future power of medicine is all about the physician and the patient. Technology is allowing that patient to really be an active participant in the conversation.

A. Mr. Squire: If you look at the history of medical care, this is the point in time when there's more technology involved in the clinician's life than ever before. I think a part of that has been driven by government incentives to adopt EHR/EMRs, or at least to get everybody out of the filing cabinets and into an electronic playing field. Once you've got a baseline of information captured in electronic format, then the question becomes, "Well, what can you do with that?" One of the things you can do with that, clearly, is to securely share it, exchange it, and have something that approaches a continuum of care between providers. And that's driving health information exchange.

The second thing you get is a bunch of data, which can be analyzed for trends and other metrics.

The third thing I see is the new care models that are possible because you have this electronic infrastructure. Whether you call it a patient-centered medical home or accountable care organization, basically the ability to manage patients between acute episodes, and avoid acute episodes to keep the cost of care down and the outcomes more favorable by more consistent monitoring.

There's also a host of technologies reaching into the home. These technologies are giving physicians and patients a way to monitor these chronic conditions in a way that we never could before, and work that into a care plan that's proactively administrated by a team versus a single clinician trying to keep up with a whole host of patients.

TECHNOLOGY see page **66**

Wyche T. Green III
is president and CEO of Greenway Medical Technologies. He has served in leadership roles since its founding in 1998. Mr. Green started his career in bank operations in 1994. Greenway completed a successful initial public offering on the New York Stock Exchange in 2012. Last month the company announced a definitive agreement that would combine Greenway Medical Solutions with Vitera Healthcare Solutions.

Girish Navani
co-founded eClinicalWorks in 1999 and serves as CEO and president. Prior to founding eClinicalWorks, Mr. Navani led successful information technology and business initiatives at Fidelity Investments, Teradyne, and Aspen Technology. He holds a Masters of Science in Engineering from Boston University.

Michael Nissenbaum
is president and CEO of Aprima. He joined the company in 2004 after stints at Millbrook Corp. and GE Healthcare. During his tenure as president of Millbrook, the company grew from 24 employees to more than 140 employees, supporting over 10,000 physicians in 65 specialties and sub-specialties, across the country. At GE, Mr. Nissenbaum led the commercialization of GE Healthcare–Clinical Data Services. He received an MBA from the University of Chicago and is a certified public accountant and chartered financial analyst.

John Squire
is chief operating officer for Amazing Charts. Most recently, Mr. Squire was senior director of Alliances and Cloud Strategy for Microsoft's U.S. Health and Life Sciences Business Unit. At Microsoft, Mr. Squire was responsible for the partner ecosystem, including all major EHR/EMR solutions and systems integrators. Mr. Squire has previous experience in management roles at IBM, Dassault Systemes, Formation Systems, and Interleaf. He holds a BS in Physics and Computer Science from Ursinus College and an MBA from Harvard.

Steven ZoBell
is vice president of product development for ADP AdvancedMD. Mr. ZoBell has more than 18 years of product development, software engineering and business management experience. Prior to joining AdvancedMD, he was executive vice president and chief technology officer for inContact Inc., a leading SaaS-based contact center software company. During the course of his career, Mr. ZoBell has been involved in the development of more than 25 critically acclaimed, award-winning, commercial software products.

TECHNOLOGY:

EHR leaders address future of healthcare information technology from page 65

A. Mr. Green: I think there has been foundational work over the last decade, and it's all been around this concept of electronification. It's the first step in making information liquid, meaning making information flow from one system to another efficiently.

We are also more able to process clinical transactions. That concept is different than processing administrative and financial transactions. If you think about a financial transaction, regardless of which language, regardless of what country, regardless of really what standard you use, you are processing something that's black and white. It's a debit or a credit in its simplest form.

In healthcare, when I talk about processing clinical transactions, we have to process much more than a yes/no answer. For example, while we have codes for every diagnosis, you still may need to document the fact that the patient's blood pressure was greatly elevated after, say, doing 25 jumping jacks and standing on one foot. In a financial transaction, the jumping jacks and standing on one foot is irrelevant. But in a clinical transaction, it's critical. Today we are able to process clinical transactions, and that's never been possible before. I think that's what's going to change the face of medicine.

Q. If you could think about the delivery of medicine in the next five years, how will it change? How important will technology be in helping to guide this evolution?

A. Mr. Douglass: If we look back 15 years ago, we had almost zero doctors using electronic medical records. We had definitely zero patients being able to access their medical records in any way other than maybe requesting a chart from their doctor.

Prior to 2008 and the American Recovery and Reinvestment Act, we were working with about 7 percent of doctors in the United States using electronic medical records. We had less than 1 percent of patients accessing their medical records online. About $20 billion was earmarked for doctors to adopt systems. That has gotten us, basically, to today where we have about 40 percent adoption in the United States.

Meanwhile, patients were able to access their records online a little bit more often, but I still think we haven't gotten over that hump of true impact of technology with doctors and with patients and with the data that's connecting them.

We're on the precipice. There are a lot of companies working on a lot of big ideas, and we obviously have ours, as well. I think the real power of technology within a practice and within the physician/patient experience is ahead of us; it's in the future. And hopefully, it's not too far off. That's a future that likely consists of patients being able to message with their doctors. Patients able to share data they're collecting about themselves, or home monitoring devices are collecting it about their daily lives and syndicating that information to the doctor. It's not that far off to have basic apps that patients can use powered by their medical charts.

I'm more excited now than I have ever been about the future of technology in healthcare, because it's all coming together.

A. Mr. Navani: Technology will change healthcare delivery. But also I think reimbursement models will create a catalyst for technology to change.

Today's health information technology is too focused on the documentation of the visit. It is changing how technology is being used for coordinating care for patients. Care planning and care management will probably be the focus, and primary care will derive significant benefits as a result of it. That change I think is pretty relevant. And in 2013 we've seen the early stages of it, whether it was the formation of accountable care organizations or patient-centered medical home initiatives.

Technology is going to impact primary care reimbursements in a positive way, as long as it can be used for managing and coordinating care.

I think in 2013 we are still amidst the transition where we now understand that our reimbursements will be tied to outcomes. I don't think we have yet changed the consumers' behavior around looking at those indicators in terms of how and where they derive their quality or care. But if you ask me, the question over the next five years, we're definitely moving to consumer-centered care. The patients will make decisions based on price, quality, and also convenience in terms of how and where they get their care.

Again, it will go faster than you and I expect. My gut tells me if we look back within 12, if not 18 months, we will be pleased that healthcare has moved past digitization of technology to using it as a vehicle for better decision making.

A. Mr. Nissenbaum: Everyone is facing heavy bets that technology is going to be the catalyst for much of the change whether you are talking about the ability to interface with more devices and more instrumentation or to interface with other applications that have information that can be shared.

From my perspective, the whole idea of setting a data standard amongst the different EHRs should have been the very first item coming out of the box of CMS (the Centers for Medicare and Medicaid Services) for Meaningful Use 1 and 2. Because once you do that, you literally set a common denominator throughout our entire healthcare delivery system that people can communicate, share, and ultimately have better outcomes or better patient care.

Going forward, again with a potential reduction in the number of primary care providers, you are going to need technology to step in and fill some of the void. If you have 32 million new patients coming into the healthcare system, you are going to have to be able to train

TECHNOLOGY see page 68

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TECHNOLOGY:

EHR leaders address future of healthcare information technology from page 66

and use physician extenders in the practice and able to share information online. A patient will be able to consult with his or her physician face to face or in video conferencing, for example, and this will continue to push the evolution.

A. Mr. Green: We are eliminating an incredible amount of inefficiency in the system. A lot of my primary care is going to be done from a desk. I am going to interact with my providers electronically, whether it's through smart enabled survey information, working from a mobile platform, or from a video using a mobile platform. All of this will be driven by consumers in the next five years.

I don't know about you, but I haven't gone inside a bank in many years. Banking has become mostly digital. Most patients interact with our healthcare system around common ailments that many patients recognize or have experienced before, like allergies or sinusitis. Many of these cases, patients are looking for validation or medication refills from the provider. I think technology is going to help eliminate incredible inefficiency we have in the delivery of healthcare.

Also, today, a physician may be looking at 30 patients, and the future of medicine is the primary care provider seeing those 30 patients today, and managing 5,000 patients in his or her network. We are moving from this very transactional model to a system that better manages cases the physician hasn't seen in years.

A. Mr. Squire: The idea of electronic decision support at the point of care, I think is now possible. You've got enough of a base of data. Using analytics and other tools that clinicians can be advised on what is the best course of care for a given patient, against an overall patient population, or based on evidence-based protocols that have been derived from a larger population. Now is the time when electronic tools can be used to introduce that at the point-of-care, rather than after some period of study.

I think the catch-all is mobility. We live in a Facebook era. How is this generation growing up surrounded by social media going to receive their care five years from now? How important will telemedicine become? How important will social networks become to gather information and get advice?

Also, our definition of clinician is going to change dramatically. If you look at the trends in primary care — the declining numbers of primary care physicians (PCPs), the increase in patient populations, the increase in insured lives under the Affordable Care Act — clearly, somebody has to be talking to, monitoring, and educating these patients. It cannot be a PCP in every case, and that's why we are seeing the growth in different professions to help — physician assistants, nurse practitioners and others.

The idea of going to see the guy in the white coat, face-to-face in his office is going to become less prevalent and the idea of getting advice and treatment from somebody on the other end of the line becomes more and more pragmatic.

A. Mr. ZoBell: Healthcare is going to be consumer-driven much more so in the future. There is no other business in the world like the healthcare businesses today. I, as a consumer, can walk in to see you as my doctor. I have no real expectations, and I am going to pay hardly any money for the visit. I have no idea what it's going to cost, what you are doing today. Maybe in 30, 60, 90, or 120 days, I will pay you after a third-party entity pays a big chunk of it.

We don't even do that with pizza. I think it's going to change health plans, and it is moving in a way where consumers are going to care more about the cost. With technology — either apps, software or solutions — they are going to take more of an active role in ensuring their wellness or their healing. I think there are going to be many more interactions with the physician. I think there is going to be a lot more interaction with smart technological solutions integrated within their electronic health records.

I think we are going to see a physician going back to a time where they are truly guiding care, and the patient is going to be really a big part of it with their personal devices at home. We fundamentally believe private practice is really a way of allowing the physician and the patient to connect.

A. Mr. Bush: I do think about the delivery of medicine five years from now. Clearly, patient engagement and empowerment are key.

The entire quantified-self movement is gaining traction and will drive mobile technology and tracking innovations that bring together patients and make patients' health records richer. This information will flow from personal devices over the cloud to the provider. I truly believe, and it's why I come to work every day, that the cloud will be our nation's information exchange highway.

Transformative technology is monumentally important in guiding the evolution of medicine five years out and well beyond that. Once technology starts to integrate better, suck less, and be loved more, the delivery of medicine will change and finally, the sanctity to the exam room encounter between caregiver and patient will be returned. **DT**

Read the full interviews with each of these seven leaders on topics including:

- interoperability;
- the mobile revolution;
- growth of personal health technology;
- why it has taken such a massive push to get physicians to adopt EHR systems;
- what happens when incentives to adopt EHRs run out.

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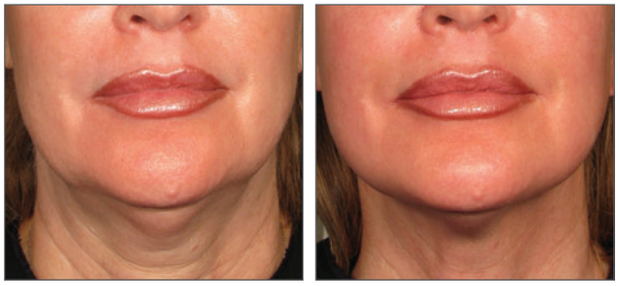

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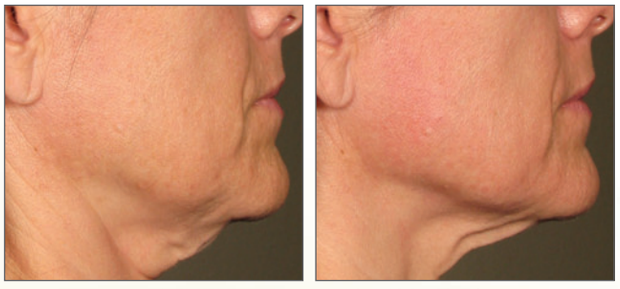

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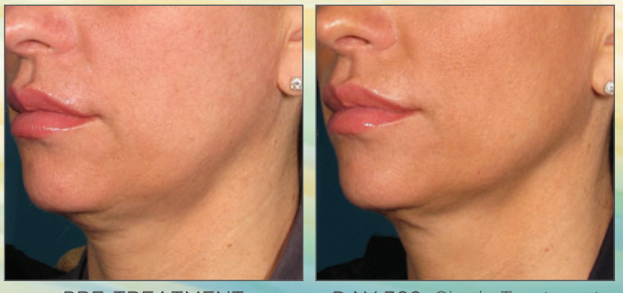

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SEE THE BEAUTY OF SOUND™

Apps make delivery of medicine more personal

Ilya Petrou, M.D. | Senior Staff Correspondent

MIAMI BEACH, FLA. — Smartphone applications (apps) have become very popular in mainstream medicine and dermatology. Though the use of apps can and should not replace clinical judgment or physician interaction, smartphone apps can be practical and helpful in facilitating dermatologic care on both sides of the physician-patient spectrum.

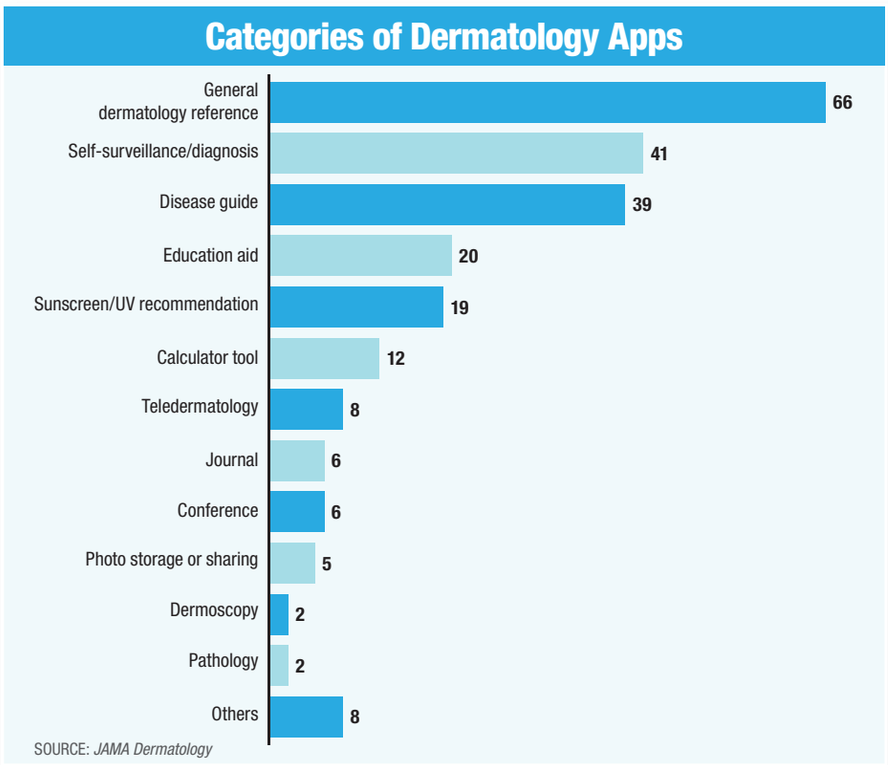
A recent study headed by Ann Chang Brewer, M.D., department of dermatology, Mayo Clinic, Scottsdale, Ariz., looked at a variety of smartphone apps currently available in the field of dermatology, evaluating the app software options offered for Apple, Android, BlackBerry and Nokia/Windows platforms (Brewer AC, Endly DC, Henley J, et al. *JAMA Dermatol*. Epub 2013 Sept 25).

"Many physicians today are using smartphone apps on a daily basis, including apps for dermatology. These apps can be very useful for quick references for physicians in a busy practice as well as for patients who are interested in their own health surveillance," says Dr. Brewer, who spoke at the annual meeting of the American Academy of Dermatology.

Investigators performed an online search in the respective app stores using the terms dermatology, melanoma, skin cancer, psoriasis, rosacea and acne. The apps were categorized by their description and the most popular skin-related apps were ranked according to the number of online reviews.

QUICK READ

Smartphone apps for the field of dermatology can serve as diagnostic tools for physicians, educational resources for students, and health surveillance tools for patients. But not all apps are created equal.



ANALYZING APPS

Dr. Brewer and her fellow researchers identified a total of 229 unique apps for dermatology, of which 117 are intended for patients, 94 for health care providers, and 18 for both. The categories of apps included general dermatology reference (61), self-surveillance/diagnosis (41), disease guide (39), education aid (20), sunscreen/UV recommendation (19), calculator tool (12), teledermatology (8), journal (6), conference (6), photo storage or sharing (5), dermoscopy (2), pathology (2), and other (8). The most reviewed apps included Ultraviolet-UV Index (355 reviews), VisualDx (306), SPF (128), iSore (61) and SpotMole (50). There were 209 unique apps, with 17 apps existing on more than one operating system. More than half of the apps were offered for free (117) and paid apps (112) ranged from 99 cents to $139.99 (median, $2.99). Physicians can benefit from a range of apps including those that list a quick and comprehensive review of commonly used drugs, their dosages and side effects. Apps that offer medical calculation tools help physicians quickly and accurately calculate laser fluence levels, and critical patient parameters and disease severity indices such as psoriasis area and severity index (PASI) and vitiligo area scoring index (VASI).

"Some smartphone apps can quickly help remind you how to calculate things like the body surface area when formulating treatment strategies of topical medications or skin areas of involvement when looking at different diseases," says Girish S. Munavalli, M.D., Dermatology, Laser & Vein Specialists of the Carolinas, Charlotte, N.C., and department of dermatology, Wake Forest University, Winston-Salem, N.C. "They can be useful in the clinical decision making process as well as help to keep track of a patient's

voice of the expert

"Physicians **believe in the benefits of EHRs**, and most do not want to go back to paper charts."

Mark Friedberg, M.D., RAND Corporation,
See **page 72**

progress or manage their therapeutics."

Apps that address sunscreen and UV-exposure are growing in popularity, Dr. Brewer says, particularly for patients. Some apps include timers that remind the patient when to reapply sunscreen depending on the skin type, and provide sun-exposure information in terms of the current UV-index using the smartphone's global positioning system, she says.

"(Apps) give patients and their providers **a tool to help** keep track of their patients' health."

Ann Chang Brewer, M.D.
Scottsdale, Ariz.

"Sometimes the hardest part in dermatology is coming up with the differential diagnosis of a given condition or disease. Apps which aid with this, either by providing lists or access to a bank of images could quickly help in uncertain cases," Dr. Munavalli says.

PERSONALIZING MEDICINE

Although it is not very widely used, teledermatology could play an expanding role in the management of patients. According to Dr. Brewer, teledermatology is a useful way of providing access to dermatologists, particularly in rural or underserved areas where patients often do not have easy access to subspecialists.

"The use of mobile apps has made the access to relevant important information a lot easier, and I think it will make the delivery of medicine a little bit more personal as well. They also give patients and their providers a tool to help keep track of their patients' health," Dr. Brewer says.

Triage apps, such as those that help clinicians assess a patient's moles, can also be a practical way for patients to monitor their own lesions. Mole-tracking mobile apps allow the patient to essentially store photos of moles (that they have taken themselves) as they change over time, which can be sent to the dermatologist for a quick evaluation.

"Patients who just need a spot checked can wait sometimes months for their appointment with their dermatologist. One day, I envision apps that could facilitate teledermatology and save both physician and patient valuable time. Certainly, I wouldn't base any critical decisions strictly on the information gathered from these apps, as a personal consultation is always the preferred approach. However, they can be useful in certain scenarios," Dr. Munavalli says.

Nevertheless, the reliability regarding the information contained in smartphone apps remains a gray area, Dr. Brewer says, as none of

APPS see page **72**

voice of the dermatologist

"Technology, **when applied the right way, has the incredible power** to swing the pendulum in healthcare back to where it belongs, with the caregiver and the patient."

Jonathan Bush, chairman, CEO, president, athenahealth, See page 64

APPS:

Dermatology smartphone apps span categories, but not all equal from page 71

them are scrutinized or approved by the Food and Drug Administration, and one cannot always be sure of the source. Out of the 229 apps studied, Dr. Brewer says most were not developed by medical professionals or did not have clear authorship stated in the developers. There are a few, however, that were developed by academic institutions such as the Mayo Clinic or the University of Michigan, she says.

The apps containing drugs dosing and prescription reference information have been around for a long time and are frequently updated as new information comes along, and, according to Dr. Munavalli, these are usually designed and put together by trusted sources.

"I think the use of smartphone apps is a growing trend and better quality apps are coming out every year. As I tell my patients, (it is) 'buyer beware' in terms of what you are getting and how accurate the app is," Dr. Munavalli says. **DT**

Apps that offer **medical calculation tools help physicians quickly and accurately calculate laser fluence levels**. Triage apps can be a practical way for patients to monitor their own lesions.

Disclosures: Dr. Munavalli reports no relevant financial interests.

EHRs a major cause of physician dissatisfaction

Though physicians understand the benefits of electronic health record (EHR) systems, they "significantly worsen" job satisfaction based on cost, usability, lack of personal contact with patients, and interoperability, according to a recent survey. Older physicians less familiar with technology and without a data entry staff for support were among the most dissatisfied.

The survey was conducted by the RAND corporation and the American Medical Association.

"Physicians believe in the benefits of EHRs, and most do not want to go back to paper charts," says Mark Friedberg, M.D., a RAND scientist and author of the study. "But at the same time, they report that electronic systems are deeply problematic in several ways. Physicians are frustrated by systems that force them to do clerical work or distract them from paying close attention to their patients."

Providing high-quality care was one of the biggest sources of physicians' satisfaction. Those surveyed noted that unsupportive practice leadership and payers not approving medically-neccesary treatment as obstacles in providing quality care.

The survey also cited autonomy, collegiality, work quantity, support staff, pay, liability, and health reforms as other issues affecting job satisfaction. **DT**

43%

of doctors agree that EHRs slow them down. What has your experience been?

SOURCE: RAND Corporation/AMA

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Dermatology Times

12th Annual Caribbean Dermatology Symposium | Jan. 15-19, 2014

The 12th Annual Caribbean Dermatology Symposium gets under way Jan. 15-19, 2014, on Grand Cayman island. Program Director Joseph F. Fowler Jr., M.D., F.A.A.D., says the accredited CME symposium will feature some of the latest information in medical dermatology from expert internationally-known faculty, including discussions of psoriasis, rosacea, acne, atopic and contact dermatitis, and skin cancer.

Hands-on workshops include training in dermoscopy and patch testing. The meeting welcomes dermatologists, dermatology residents, allergists, rheumatologists, family practitioners, physician assistants, nurse practitioners, nurses, and other healthcare professionals.

While on the islands, be sure not to miss Grand Cayman stingray sandbar. Here you can stand or snorkel with friendly southern stingrays for about 45 minutes (www.stingraycitytrips.com). If that's a bit too adventurous, take a stroll instead on one of Grand Cayman's most famed beaches, Seven Mile Beach (www.caymanislands.ky/activities/beaches/sevenmilebeach.aspx). Is history more your thing? Then consider Pedro St. James National Historic Site, the oldest building in the Caymans (www.pedrostjames.ky).

At some point, you'll have worked up an appetite. Options include The Sunshine Grill, where some guests claim they serve the best shrimp tacos, burgers and drinks on the island (www.sunshinesuites.com/restaurant), Ragazzi Restaurante, an Italian place known for its great atmosphere at a great price (www.ragazzi.ky), or the local Caribbean cuisine offered at Tukka (www.tukka.ky).

For more information: help@caribederm.org or visit: www.caribederm.org

upcoming events

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

Orlando Dermatology Aesthetic & Clinical Conference
www.orlandoderm.org/agenda.php
Jan. 17-20, 2014
Omni Orlando Resort at ChampionsGate
Orlando, Fla.

2014 Winter Clinical Conference - Hawaii
www.clinicaldermconf.org
Jan. 17-22, 2014
Fairmont Orchid Hotel
Kohala Coast, Hawaii

10th Annual MauiDerm Conference
www.acmd-derm-hawaii.com
Jan. 26-30, 2014
Grand Wailea Resort
Maui, Hawaii

Dermatology Foundation Clinical Symposia
www.dermatologyfoundation.org
Feb. 5-9, 2014
Ritz-Carlton Naples, Naples, Fla.

2014 South Beach Symposium
www.southbeachsymposium.org
Feb. 13-17, 2014
Loews Miami Beach Hotel
Miami Beach, Fla.

SDEF 38th Annual Hawaii Dermatology Seminar
www.globalacademycme.com
Feb. 16-21, 2014
Hilton Waikoloa Hotel, Big Island, Hawaii

American Osteopathic College of Dermatology 2014 Midyear Meeting
www.aocd.org
Feb. 20-23, 2014
Ritz-Carlton Dallas

17th Joint Meeting of the ISDP
www.intsocdermpath.org
March 19-20, 2014
Westin Denver Downtown, Denver

AAD 72nd Annual Meeting
www.aad.org
March 21-25, 2014
Colorado Convention Center
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SENTÉ

Cream reduces skin irritation following procedures

Senté Dermal Repair Cream works to speed skin healing after sun damage and dermatologic procedures. The cream contains a blend of ingredients including heparan sulfate, a complex of a sugar and glycoprotein, according to the company. Heparan sulfate can gradually deplete from the skin due to aging and sun exposure. The repair cream helps to activate cellular renewal deep in the skin, the company states.

The cream can be used after dermatological procedures such as laser treatments, chemical peels, injectables and intense pulsed light. It helps to diminish the appearance of fine lines and wrinkles, and it helps the skin's ability to heal after sunburns and scarring. The product is available online and in physician's offices.

FOR MORE INFORMATION:
www.sentelabs.com

JF AESTHETIC

Antioxidant cream helps to mask fine lines around eyes

A rich emollient eye cream by Dr. Julius Few is formulated to treat the delicate skin around the eyes. It helps to calm the skin and to mask fine lines, the company states. The cream delivers the hydrating benefits of hyaluronic acid to smooth and plump the skin.

Key ingredients include vitamins A, C and E, Co-Q10 and chamomile extracts. The cream is appropriate for all skin types and can be used once per day.

FOR MORE INFORMATION:
www.drfewbeauty.com

OCUSOFT

Serum enhances eyelash growth cycle

The Zoria Boost Lash Intensifying Serum, available through OCuSOFT's new skincare division, uses patented polypeptide technology to support and enhance the eyelash growth cycle, the company claims. The serum gives consumers longer, fuller and darker-looking lashes.

Consumers can place the product on their lash line before bedtime. The product is nonirritating, the company says.

FOR MORE INFORMATION:
www.zoriacosmetics.com

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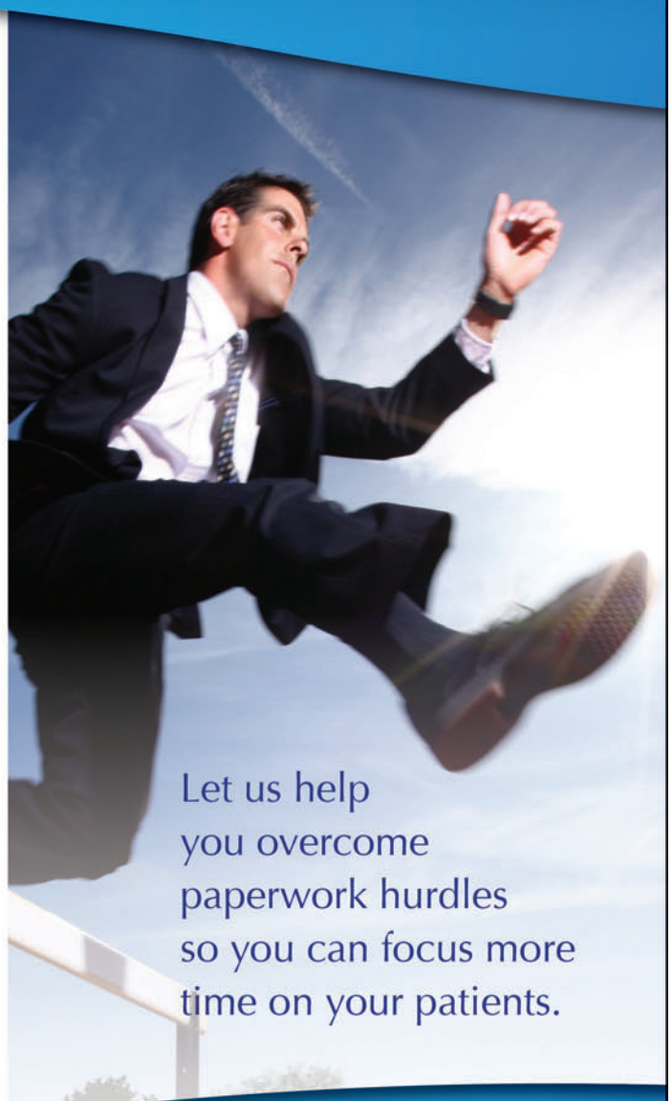

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3 ADMIN APPS TO ENHANCE EFFICIENCY

NEW BACTERIA AND ANTIBIOTIC APP

ATHENAHEALTH INC. and Epocrates have released a new, free mobile app, "Epocrates Bugs + Drugs," to give clinicians geo-located information about bacteria types and resistance patterns, and support appropriate antibiotic prescribing.

Providers can enter their patient's location, view bacteria common to the area and explore potential bacterial resistance patterns. The app features lists of bacteria found in urine, blood and skin for geo-located communities across the United States.

Antibiotic drug options are organized by organism susceptibility and include dosing and contraindication information with links to complete monographs. The app is continually updated through athenahealth's cloud-based electronic health record (EHR) database. The app is available for iOS 7 devices in the Apple App Store.

www.epocrates.com/company
www.athenahealth.com

ENHANCED EMR AND PATHOLOGY LAB INTEGRATION

MODERNIZING MEDICINE, creator of the Electronic Medical Assistant (EMA) — a cloud-based, specialty- specific electronic medical record (EMR) system — and Miraca Life Sciences (MLS) — a developer of subspecialty expert anatomic pathology services — will partner to develop an enhanced diagnostic data bridge. Pathologists normally analyze tissue samples with limited clinical background on patients, which can delay accurate diagnoses.

EMA dermatologists and MLS pathologists will be able to share additional diagnostic information, which can help the pathologist create a more timely, accurate analysis. The user-friendly EMA adapts to style of a practice and integrates into the work flow, saving time and increasing efficiencies.

EMA's cloud-based approach to collecting and storing patient information enables physicians to utilize the EMA Network to provide better care for their patients. The tool is available as an iPad app or on any Web-enabled Mac or PC.

www.modmed.com
www.miracalifesciences.com

APP HELPS TO TRACK SUNSHINE LAW REPORT

DOCTORS concerned about the Physician Payments Sunshine Act can download a new app to see how the reporting process will work before results are made public next year.

The Centers for Medicare and Medicaid Services (CMS) has released two new mobile apps called Open Payments — one for physicians, and one for healthcare industry users — to raise awareness among healthcare providers regarding transactions reported under the Sunshine Act.

The app for physicians will allow them to track payments and other value transfers to drug and device manufacturers.

Physicians will be able to create a profile and track any discrepancies in reporting. The app for industry users, including hospitals and institutions, will have the same features as the physicians' app, but will also be able to store physician profiles.

The Sunshine Act mandates that pharmaceutical and medical device companies report financial relationships with physicians, hospitals, and other healthcare businesses totalling more than $100 per year. Companies began reporting financial data on Aug. 1. The entire list will be published annually beginning in September 2014.

www.cms.gov/Regulations-and-Guidance/Legislation/National-Physician-payment-Transparency-Program/index.html

IMPORTANT INFORMATION ABOUT

Mirvaso®

(Brimonidine) Topical Gel, 0.33%*

*Each gram of gel contains 5 mg of brimonidine tartrate, equivalent to 3.3 mg of brimonidine free base

BRIEF SUMMARY

This summary contains important information about MIRVASO (Mer-VAY-Soe) Gel. It is not meant to take the place of the full Prescribing Information. Read this information carefully before you prescribe MIRVASO Gel. For full Prescribing Information and Patient Information please see package insert.

WHAT IS MIRVASO GEL?

MIRVASO (brimonidine) Topical Gel, 0.33% is a prescription medicine that is used on the skin (topical) to treat facial redness due to rosacea that does not go away (persistent).

WHO IS MIRVASO GEL FOR?

MIRVASO Gel is for use in adults ages 18 years and older.

WHAT WARNINGS AND PRECAUTIONS SHOULD I BE AWARE OF?

MIRVASO Gel should be used with caution in patients that:

- have depression
- have heart or blood vessel problems
- have dizziness or blood pressure problems
- have problems with blood circulation or have had a stroke
- have dry mouth or Sjögren's Syndrome
- have skin tightening or Scleroderma
- have Raynaud's phenomenon
- have irritated skin or open sores
- are pregnant or plan to become pregnant. It is not known if MIRVASO Gel will harm an unborn baby.
- are breastfeeding. It is not known if MIRVASO Gel passes into breast milk. You and your female patient should decide if she will use MIRVASO Gel or breastfeed. She should not do both.

Ask your patient about all the medicines they take, including prescription and over-the-counter medicines, skin products, vitamins and herbal supplements. Using MIRVASO Gel with certain other medicines may affect each other and can cause serious side effects.

Keep MIRVASO Gel out of the reach of children.

If anyone, especially a child, accidentally swallows MIRVASO Gel, they may have serious side effects and need to be treated in a hospital. Get medical help right away if you, your patient, a child, or anyone else swallows MIRVASO Gel and has any of these symptoms:

- **Lack of energy, trouble breathing or stops breathing, a slow heart beat, confusion, sweating, restlessness, muscle spasms or twitching.**

WHAT ARE THE POSSIBLE SIDE EFFECTS OF MIRVASO GEL?

The most common side effects of using MIRVASO Gel include:

- redness, flushing, burning sensation of the skin, skin irritation

Skin redness and flushing may happen about 3 to 4 hours after applying MIRVASO Gel. Ask your patients to tell you if they get skin redness and flushing that is uncomfortable.

MIRVASO Gel can lower blood pressure in people with certain heart or blood vessel problems. See **"What warnings and precautions should I be aware of?"**

These are not all of the possible side effects of MIRVASO Gel. Remind your patients to call you for medical advice about side effects.

You are also encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

HOW SHOULD MIRVASO GEL BE APPLIED?

- Remind your patients to use MIRVASO Gel exactly as you instruct them. They should not use more MIRVASO Gel than prescribed.
- Patients should not apply MIRVASO Gel to irritated skin or open wounds.
- **Important**: MIRVASO Gel is for use on the face only. Patients should not use MIRVASO Gel in their eyes, mouth, or vagina. They should also avoid contact with the lips and eyes.
- Instruct your patients to see the detailed Instructions for Use that come with MIRVASO Gel for information about how to apply MIRVASO Gel correctly.

GENERAL INFORMATION ABOUT THE SAFE AND EFFECTIVE USE OF MIRVASO GEL

Remind your patients not to use MIRVASO Gel for a condition for which it was not prescribed and to not give MIRVASO Gel to other people, even if they have the same symptoms. It may harm them.

WHAT ARE THE INGREDIENTS IN MIRVASO GEL?

Active Ingredient: brimonidine tartrate
Inactive Ingredients: carbomer homopolymer type B, glycerin, methylparaben, phenoxyethanol, propylene glycol, purified water, sodium hydroxide, titanium dioxide.

WHERE SHOULD I GO FOR MORE INFORMATION ABOUT MIRVASO GEL?

- Go to **www.mirvaso.com** or call **1-866-735-4137**

GALDERMA LABORATORIES, L.P.
Fort Worth, Texas 76177 USA
Revised: August, 2013
HCP

MIRVASO® (brimonidine) topical gel, 0.33%

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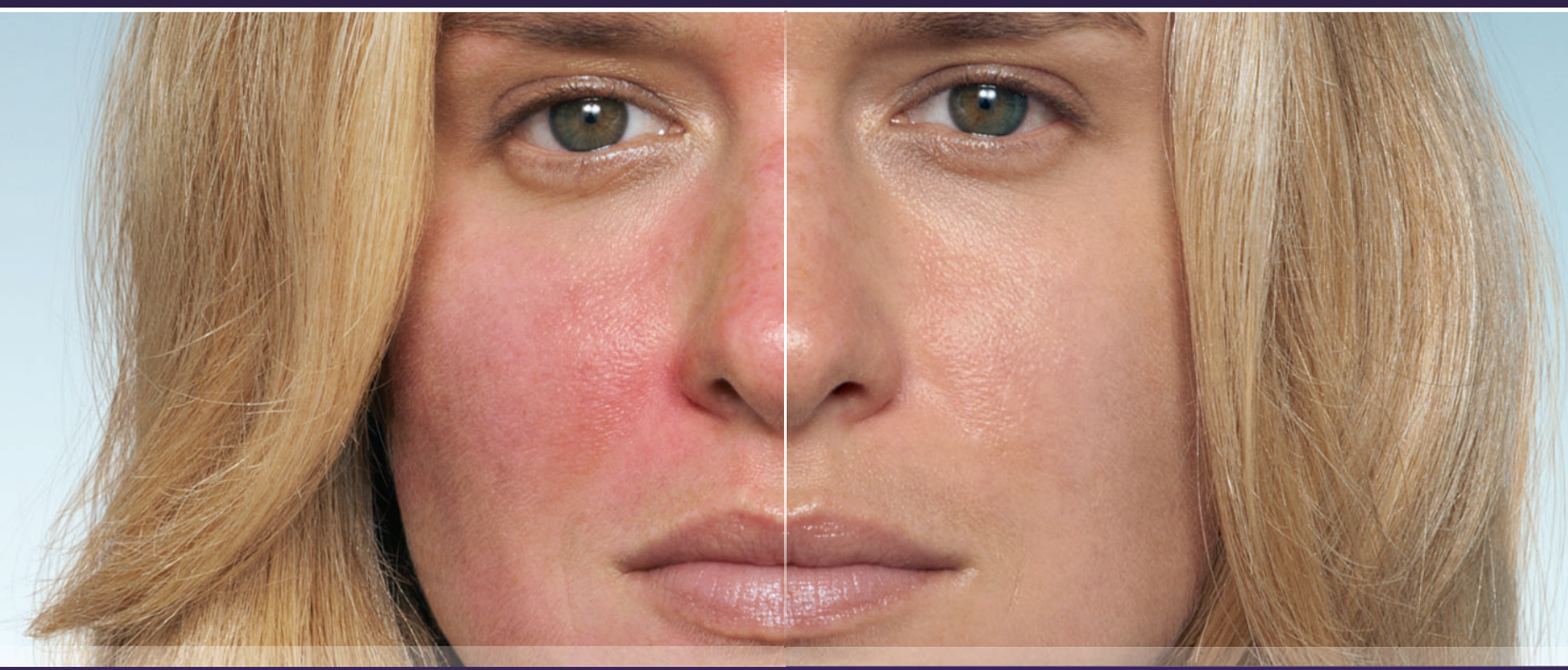
References: 1. Fowler J Jr, Jackson JM, Moore A, et al; Brimonidine Phase III Study Group. Efficacy and safety of once-daily topical brimonidine tartrate gel 0.5% for the treatment of moderate to severe facial erythema of rosacea: results of two randomized, double-blind, vehicle-controlled pivotal studies. *J Drugs Dermatol.* 2013;12(6):650-656. **2.** Mirvaso [package insert]. Galderma Laboratories, L.P. Fort Worth, TX; 2013.

Help your patients with facial erythema of rosacea experience...

THE MIRVASO EFFECT



Not an actual patient. Individual results may vary. Results are simulated to show a 2-grade improvement of erythema. At hour 12 on day 29, 22% of subjects using Mirvaso Gel experienced a 2-grade improvement of erythema compared with 9% of subjects using the vehicle gel.*

RAPID AND SUSTAINED ERYTHEMA REDUCTION BROUGHT TO YOU BY MIRVASO® (brimonidine) TOPICAL GEL, 0.33%†

- The **first** and **only** FDA-approved topical treatment specifically developed and indicated for the facial erythema of rosacea[1]
- Fast results that last up to **12 hours**[1]
- The most commonly reported adverse events in controlled clinical studies included erythema (4%), flushing (2%), skin-burning sensation (2%), and contact dermatitis (1%)[2]

Important Safety Information

Indication: Mirvaso® (brimonidine) topical gel, 0.33% is an alpha-2 adrenergic agonist indicated for the topical treatment of persistent (nontransient) facial erythema of rosacea in adults 18 years of age or older. **Adverse Events:** In clinical trials, the most common adverse reactions (≥1%) included erythema, flushing, skin-burning sensation, and contact dermatitis. **Warnings/Precautions:** Mirvaso Gel should be used with caution in patients with depression, cerebral or coronary insufficiency, Raynaud's phenomenon, orthostatic hypotension, thromboangiitis obliterans, scleroderma, or Sjögren's syndrome. Alpha-2 adrenergic agents can lower blood pressure. Mirvaso Gel should be used with caution in patients with severe or unstable or uncontrolled cardiovascular disease. Serious adverse reactions following accidental ingestion of Mirvaso Gel by children have been reported. **Keep Mirvaso Gel out of the reach of children.** Not for oral, ophthalmic, or intravaginal use.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit *www.fda.gov/medwatch* or call 1-800-FDA-1088.

Please see brief summary of full Prescribing Information on the following page.

See for yourself. Visit **www.mirvaso.com/hcp**.

MIRVASO®
(brimonidine) topical gel, 0.33%

*Phase 3 clinical studies of 553 subjects 18 and older. Subjects were randomized 1:1 to either Mirvaso Gel or vehicle for 29 days. Subjects and clinicians were asked to grade the improvement they saw at 30 minutes and hours 3, 6, 9, and 12 following application.

†Each gram of gel contains 5 mg of brimonidine tartrate equivalent to 3.3 mg of brimonidine free base.