NEW THERAPIES IN DEVELOPMENT TO MANAGE ACNE, ROSACEA

WHITNEY J. PALMER | Staff Correspondent

New and innovative therapies for acne and rosacea don’t come around that often. But, occasionally, products emerge that give dermatologists a new arrow in the quiver when it comes to treating these conditions.

According to Diane Berson, M.D., associate clinical professor of derma-

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LASERS

Past, present, future

KAREN APPOLD | Staff Correspondent

The origins of laser technology go back to 1900, when Max Planck, a German theoretical physicist, discovered the relationship between energy and frequency of radiation and concluded that energy could be emitted or absorbed only in discrete chunks, named “quanta.”

In 1905, physicist Albert Einstein proposed how light delivers its energy in chunks, which are represented by photons — discrete quantum particles. Later, in 1916, he introduced the concept of stimulated emission: photons, by interacting with excited atoms or molecules, could stimulate the emission of new photons having the same frequency, phase, polarization and direction of the first one.

American physicist Theodore Maiman was the first to develop a laser used for clinical application. In 1960, he introduced a laser composed of a ruby rod emitting light energy at 694 nm. In 1963, American surgeon Leon...
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**our MISSION**

Provide practical analysis of recent studies, regulatory updates, techniques, devices and business solutions; and facilitate discussion to optimize practice and improve patient care.

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Dermatologists as co-conspirators?

by DR. NORMAN LEVINE, MD

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

A middle-aged patient with a history of coronary artery disease and elevated cholesterol is well controlled with conventional medical therapy. At his last visit with his cardiologist, he is advised that a new class of drug, PCSK9 inhibitor, has revolutionized the treatment of hypercholesterolemia and could decrease his LDL number to remarkably low levels.

The drug is expensive, so insurance carriers will insist that his present drug regimen is ineffective or that he is unable to tolerate the side effects. Since he has never had adverse reactions, he is advised by his cardiologist that he could either lie or he could lower the dose of his present agents which would elevate his LDL above a certain threshold; thus, making him eligible for coverage for the new agent.

He asks my opinion as to what he should do. I recommend that he find another cardiologist.

Even if it may be best for him to go along with this plan, he will be part of a pretty obvious conspiracy with his doctor against his insurance carrier. Why am I relating this story to a readership consisting almost entirely of dermatologists?

Almost unconsciously, many of us may be acting in a similar way with the rationale that all of these appeals that we review involve the use of potentially effective medications by indirectly conspiring with the pharmaceutical industry and against the third-party payers, not only are the insurance carriers well aware of what is going on and act accordingly, but somehow, it diminishes the authenticity of our expertise and further pushes payers to take the advice of independent reviewers or, worse, in-house employees who are not as knowledgeable as we are.

Many would argue that decisions for coverage are arbitrary and are not based on the needs of the patient, so that should give us the excuse to use any means necessary to do what is best for the patient. I would disagree to some extent with that notion. An honest argument of the facts of the individual case may not be as effective, but it will keep our reputations intact and make us more credible the next time we need to appeal an insurance company decision.

I would suggest that if the patient truly prefers one treatment instead of another, state this as the main reason for the appeal. Perhaps he has done well on one therapy and is reluctant to switch medications. This seems to be a very valid argument for continuing that treatment.

Try to avoid dancing around potentially spurious reasons for picking one medication over another.

If it is your belief that the formulary or the stepwise algorithm is inappropriate, make that argument.

If you are of the opinion that immunosuppressive agents are dangerous to use in those with psoriasis, provide data to support that claim.

I would only ask that you represent your patient’s interests in an ethical and intellectually honest way.
Dr. Rash is an internationally recognized expert in psoriasis with a very successful practice. One day a week, he sees lower-income patients at no charge. Many of these patients have been treated for years with a variety of topical agents and UVB.

Dr. Rash is well-versed on the newer biologics used for psoriasis. In fact, he has conducted several of the well-respected clinical trials, and he lectures extensively on these agents at national meetings. Although many of his poorer patients would benefit from the use of biologics, they have little-to-no insurance and cannot afford to purchase them.

Dr. Rash is aware that some states, including his, have taken initiatives to import medications from Canada. But he can get the identical brand name drugs even cheaper from India. He intends to provide the drugs to his patients at no charge, and his patients are eternally grateful.

One of these patients is so happy that he sends a letter to the local newspaper applauding the efforts of his physician. The article, written by a local reporter, is picked up by the national press and covered in the national news.

Three days later FDA agents show up at Dr. Rash’s door threatening him with both civil and criminal penalties. What is the basis? He was only trying to save his patients money. Did Dr. Rash do anything wrong?

What is clear is that prescription drug expenditures are one of the fastest growing segments of the United States healthcare system.

Thus, there is the inevitable desire to import the drugs from abroad where the cost of such pharmaceuticals may be less.

In all fairness, the pharmaceutical industry maintains that the reasons behind the high prices of American drugs are the cost of the research and development needed for new breakthrough drugs. In 1993, the pharmaceutical industry spent $12.7 billion on research and development. A decade later this figure more than doubled to over $33.2 billion. It continues to increase.

With all this said, there is still a natural desire to get the same medications available to our patients from a cheaper source. Dr. Rash turned to India. Other physicians have turned to Canada, Europe and South America. Whatever the source, and despite his admirable intent, Dr. Rash’s actions are illegal.

FDA regulations prohibit the re-importation of exported prescription drugs manufactured in the United States by anyone but the actual U.S. manufacturer. In part, the justification for such laws lies with Congress’ intent to ensure the safety and efficacy of the prescription drugs.

Every prescription, and thus the costs are governed by the laws of supply and demand. Since there is no price ceiling for many of the currently required drugs in the United States, (such as is in place in Canada), prices remain quite high.

Dr. Goldberg is director of Skin Laser and Surgery Specialists of New York and New Jersey, past director of Mohs and Laser Research, Icahn School of Medicine at Mt. Sinai; and, adjunct professor of law, Fordham Law School in New York City.

He was only trying to save his patients money. Did Dr. Rash do anything wrong?”
Every year, the milestones we achieve in the science and delivery of skin health become more significant.”

Innovation dispatches from the AAD

by STEVE XU, M.D., FAAD

Dr. Xu is medical director of the Center for Bio-Integrated Electronics at the Simpson Querrey Institute for Bionanotechnology, Northwestern University, and co-founder of the Advancing Innovation in Dermatology Accelerator Fund. Follow him on Twitter: @stevexumd

The 2019 American Academy of Dermatology (AAD) Meeting in Washington, D.C., is always a wonderful reminder of all of the innovation happening in dermatology. I left the meeting optimistic that our field is moving forward with new disease insights, new therapies, and new diagnostics driven forward by motivated, talented individuals across academia and industry.

But my favorite part of the AAD is the day before. Every year, Advancing Innovation in Dermatology (AID), a 501(c)(3) not-for-profit, hosts a pre-AAD meeting called the Dermatology Innovation Forum. In this one-day conference, I get a frontline seat to founder stories, new innovations and major advances. The smaller, more intimate one-room setting allows for patients to find the cheapest prescription drugs and software do not have a monopoly on innovation. Dr. Klein’s innovations around streamlining prescription topical drug substitutions has a profound benefit on the quality of life for providers and their staff.

James Allred M.D., F.A.A.D., chief clinical officer, RxThat, Inc., is taking on the relentless rise in prescription drug prices in dermatology by offering a transparent digital marketplace for patients. ‘The growth and speed of digital innovations in dermatology is exciting,’ Companies such as Enspectra Health, led by Gabriol Sanchez, Ph.D., are leveraging both diagnostic hardware innovations to image living tissue without a biopsy and digital AI to deliver point-of-care diagnostics. From the industry side, Adrian Rosessler M.Sc., head of Imagine at the Leo Innovation Lab, showed us a sneak peak of the future of skin disease tracking, treatment effectiveness and diagnostics. Lucid Dermatology, founded by two Harvard dermatology residents, Sameer Gupta, M.D. and Tyler Menge, M.D., is disrupting the patch testing experience through software and computer vision.

Therapeutics

Beyond digital innovations, the meeting highlighted new therapeutic advances and major milestones in therapeutics innovation. Doug Lowy, M.D., deputy director of the National Cancer Institute, 2017 Lasker Prize Winner, and a dermatologist, spoke about his journey from studying the HPV virus to the eventual FDA approval of a vaccine for the virus.

Central to this major success was a collaboration between the public and private sectors. We now have a vaccine that, essentially, prevents cancer. In my humble opinion, this represents one of the most important medical breakthroughs in the 21st century.

Dr. Brian Kim, assistant professor of dermatology and co-director of the Center for the Study of Itch, outlined a vision for the future therapeutic landscape of chronic pruritus.

The FDA’s Markham Luke, M.D., Ph.D., and Elektra Papadopoulos, M.D., spoke about the ways the agency is supporting innovation in dermatology and beyond.

Ray Miller, J.D., and Nicole Stakleff, J.D., both partners at Pepper Hamilton LLP, added their regulatory and intellectual property insights, specifically around drug compounding.

At meetings such as the American Academy of Dermatology and the Dermatology Innovation Forum, I am always encouraged and excited about what I see. Every year, the milestones we achieve in the science and delivery of skin health become more significant. I’m already looking forward to next year.

Disclosures:

Dr. Xu is a member of Advancing Innovation in Dermatology, Inc., a registered 501(c)(3) organization designated as a public charity in the United States. He derives no direct financial benefit from his membership.

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**Q.** How do you treat nail ridges?

Nail ridges are a common problem in mature women where the health of individual cells within the nail matrix decreases, resulting in longitudinal ridging. The ridging can become an appearance problem when wearing nail polish, but can be camouflaged with the newer gel nails. There are no treatments for nail ridging, but also no major health concerns.

Recently, a rotating drill tool was marketed in beauty departments that can rapidly remove nail ridges. The device rotates and has different round sandpaper-coated heads that can be removed and replaced. A coarse sandpaper can be used for two strokes longitudinally over the ridge. Holding the sandpaper over the ridge any longer will thin and excessively weaken the nail. Finer sandpaper is then used over the whole nail to blend in the ridge for three strokes. Finally, finishing sandpaper is used to shine the nail for five strokes. The whole procedure takes about three minutes per nail with excellent results and will need to be repeated every two-to-three weeks for new nail growth.

**Q.** Are the newer gel nails safer?

The newer gel nails do not require UV radiation to cure, and deliver vividly colored, chip resistant, long wearing polymer coatings over the natural nails. The gel nails can be applied very rapidly in 20-30 minutes for a complete finger nail set for $40-$80. The procedure is detailed below along with possible side effects:

1. The old gel nail is removed by loosening with a drill, aerosolizing the polymer, which necessitates wearing a mask to prevent particulate pneumonitis.
2. An acetone-soaked cotton ball is placed over the nail and wrapped in aluminum foil to degrade the rest of the polymer dehydrating the natural nail plate.
3. A drill is used to loosen any remaining polymer, but also some of the natural nail plate.
4. The natural nail plate is sanded by hand with sand paper to roughen the surface allowing optimal adherence of the new polymer.
5. The catalyst, containing benzoyl peroxide, is painted on the nail plate.
6. The nail is dipped in clear powdered methacrylate monomer to begin the polymerization process and the creation of a thin plexiglass layer over the natural nail plate.
7. A second layer of catalyst is applied followed by dipping in colored powdered monomer.
8. Third layer of catalyst is applied followed by dipping in the clear powdered monomer.
9. Nail is allowed to dry; then polished with a drill to even the surface and shape the nail.

In summary, gel nails are safe, however they inevitably damage the natural nail plate. It is recommended to remove the nail prostheses every three months for several weeks to allow the natural nail plate to recover.

**Q.** How can the pain of onycholysis be minimized?

The bond between the nail plate and nail bed is weaker than the bond between the gel nail and the natural nail plate. Thus, banging the nail prosthesis can cause painful onycholysis. An easy repair is to put methacrylate super glue between the nail plate and the nail bed and hold the nail plate firmly to the nail bed. This will temporarily close the void and stop the pain until the nail prostheses can be removed and the damaged natural nail trimmed.

**Notes on nails**

by **DR. ZOE DIANA DRAELOS**

Dr. Draelos is a consulting professor of dermatology, Duke University School of Medicine, Durham, NC.
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Photos provided by Dr. Michael H. Gold, M.D., FAAD

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Six healthcare issues to watch this year

PRICE WATERHOUSE Cooper believes 2019 is the year a New Health Economy comes of age, according to its 13th annual report, Top Health Industry Issues of 2019. The company predicts new products, investments and consumer trends will impact healthcare in six key areas.

1. Digital therapeutics
2019 will see new connected health devices and digital therapeutics available to integrate into care delivery and the regulatory process for drug and device approvals. Physicians may have to incorporate new streams of data into workflow processes.

2. Artificial intelligence & automation
As technology advances, organizations will find they need to invest in and train their employees to succeed. While technology can help companies reduce transactional tasks, of those surveyed, 45% of provider executives say their workforce's capabilities are a barrier to organizational change. Training in robotic process automation and artificial intelligence can keep healthcare professionals practicing at the top of their licenses and abilities.

3. Tax reform
The 2017 Tax Cuts and Jobs Act in 2019 will begin to affect the healthcare industry through both new tax savings possibilities and new tax challenges. According to a PwC Health Research Institute and PwC National Tax Practice analysis, the major negative impact to providers will be felt in increased deductions for individuals and may decrease charitable contributions to non-profits. Unrelated Business Taxable Income changes may result in new expenses for non-profits and payers; net investment excise tax on educational foundations may affect academic centers; and a new 21% excise tax imposed on tax-exempt employers that pay "excess" compensation to "covered employees," over $1 million.

4. "Value line" of products & services
As the healthcare industry is pressured to do more with less, some healthcare companies are starting to build lower-cost delivery models to capture consumer patients who are struggling with new higher-deductible health plans or no insurance.

5. Private equity
Acquisitions in the healthcare market have become increasingly diversified and frequent, and this trend is expected to accelerate. The number of deals involving private equity buyers or sellers has steadily increased from 229 in 2009 to a projected 747 deals in 2019. In 2017, there was a total of $1.35 trillion in assets under private equity management.

6. Affordable Care Act
Changes to the law by Republicans will shift who wins and loses. Healthy individuals wishing to purchase and payers buying or selling short-term limited duration insurance may benefit, while middle-class consumers seeking comprehensive coverage, and provider and payers dependent on patients covered by Medicaid or ACA plans living in conservative-leaning states may be challenged.


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achieved a 97% cure rate in older patients (average 82.5 years of age) treated for basal and squamous cell carcinomas on their lower extremities, according to researchers of a recent retrospective study.

"When treating NMSC of the lower extremities, it is critically important to examine every treatment option that doesn't inflict more pain or add potential complications as many of these patients are elderly and present with numerous comorbidities," according to lead author William Roth, M.D., in a Sensus Healthcare press release. "The results of this study highlight SRT as a highly effective treatment option for eliminating basal and squamous cell carcinoma lesions on lower extremities."

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Skin through centuries

JOHN JESITUS AND STEPHANIE STEPHENS | Staff Correspondents

Until recognized as a distinct medical specialty in the 18th and 19th centuries, the study of the skin received scant academic attention, says a recent review. It took the precise taxonomic classification system born during the second century BC, abetted by Enlightenment-era interest in science, for dermatology to begin receiving its due as a specialty. The review appeared in the August 2017 Medicina Historica.

Ancient Greek and Roman medicine considered the skin little more than a surface casing, as evidenced by the terms used to describe it, wrote review author Rosa Santoro, Ph.D., of the University of Messina, Italy. The Greek derma, for instance, originally meant animal hide or vegetable skin.

Rather than appreciating the skin per se, Greek-Roman medicine moreover viewed skin problems as outward representations of internal humoural imbalance. It was Greek medical pioneer Galen (A.D. 129-200) who first recognized the skin—particularly the smooth, hairless surface of the hands—as a tactile organ.

Santoro credits the Byzantines of the fourth through sixth centuries, and their influence on fledgling European universities of the 13th century, for revised interest in Galen’s teachings. This shift allowed human cadaver dissection to become an essential part of academic curricula. The key breakthrough, Santoro wrote, came with 16th-century Flemish physician Andreas van Wesel, who first analyzed the skin’s substance and constituent layers, identifying pores, fat and nerves.

Still, early publications regarding skin diseases focused largely on disfiguring but rarely deadly conditions whose nomenclature sometimes pointed fingers at outsiders for spreading these scourges — 15th-century Italians called syphilis morbo gallico, for example, while the French called it mal napoléotain. Santoro also details the circuitous routes by which labels including leprosy, scabies and herpes evolved from their initial vagueness to characterize the specific conditions they now represent.

Generally, Santoro says, the words used to indicate skin diseases take well-known terms from botany, agriculture or zoology and transform them through a process of metaphorization based on the similarity of the affected skin with objects from everyday life — the term chilblains chosen by Celsus, for example, links back to Cassius Felix’s perniones, which refers to “dried salt pork thigh.”

The cross-pollination of Roman medicine and Greek influences during the second century BC amounted to an epistemological revolution, Santoro wrote.

“In Celsus’ De medicina, the treatment of skin lesions of internal origin betrays the educational intention to transpose Greek knowledge rigorously and systematically, without however stifling the contribution of Latin lexical creativity.”

Much of modern medical terminology, then, marries Latin inventory and classification schemes based on empirical qualities (genre, form, color and seriousness) with authoritative Greek terms to indicate a condition’s degree of aggressiveness (e.g., agrina/savage) or responsivity to treatment.

The modern emphasis on beauty and cosmetic skin improvement represents no less transformative a revolution.

First Inductees to Dermatology Hall of Fame Announced

Sharon Finch, senior vice president and group publisher at Quadrant HealthCom, introduced the Dermatology Hall of Fame and its mission.

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Ancient physicians were constantly concerned with restoring the body to its natural beauty. But in moralistic cultures that equated heavy makeup with lust and prostitution, early dermatological scholars focused largely on natural cures for specific conditions. Not until a growing chorus of female authors such as Trota of Salerno, who unapologetically offered Saracen beauty secrets to women of the Middle Ages, did aesthetic medicine begin to become a noble endeavor.

On the threshold of the 17th century, Gaspare Tagliacozzi in his 1597 De cuturum chirurgia resurrected Galen’s concept of beauty as a reflection of bodily health that should be pursued and restored by every means available. “Although from the Renaissance onwards scientific discoveries progressively saw a rise in specialist medical interest in dermatology,” Santoro wrote, “the greatest acknowledgment to the learning of the Ancients is the fact that the terminology for the classification of diseases remained almost intact.”

THE LANGUAGE OF THE SKIN

In Greek and Latin, the skin was thought of as “a surface casing that comes off easily,” a “surface envelope,” with “purely instrumental function” compared to other organs, reports Santoro. In fact, skin abnormalities were attributed to “an internal imbalance of the humours.”

Galen did identify skin as the organ of touch—especially skin of the hand. Santoro notes that in the early 1300s, physicians cut through skin during autopsy, raised it and moved it aside to access internal organs. In the 1500s, the Flemish doctor, Andreas van Wesel, concentrated on analyzing skin’s substance and layers, and hailed it as the “first barrier” to be incised during dissection. This seemed to confirm that skin had been recognized on its own merit and laid the foundation for future scientific research.

PATHOLOGY

Pliny the Elder (23 A.D. – 79 A.D.) noted that facial diseases, while not painful or fatal, were horribly disfiguring, with those suffering being shunned. The artist and scientific communities were, however, intrigued by them.

Galen is credited with developing “the language of dermatology” as well as of technical medicine in general, which was then annotated and extended by Latin authors. Santoro writes that the Greeks and Romans did try “to develop and differentiate the dictionary of skin diseases.” Alas, they didn’t achieve their goals, instead coming up with “generic and vague” terms for conditions including leprosy, scabies and herpes.

a) Leprosy as we know it today was actually called elephantiasis in the ancient world, which was both serious and fatal. Modern medicine defines the latter condition as a lymphatic condition causing roughness of the tegument caused by infestation of nematode worms from warm regions.

b) Scabies in current terms is contagious, infectious, and caused by the itch-mite Sarcoptes scabiei, replete with itching and skin tunnels. The Latin refers to a “disease that makes you scratch.” Due to a lack of what Santoro calls “distinctive peculiarities,” she notes that recent studies have indicated that “precisely identifying” the scabies of antiquity with modern scabies is basically impossible.

c) Herpes had multiple meanings in ancient medicine. Santoro reports that today, herpes generally indicates “widespread and ulcerative skin lesions rather than a single, specific condition.” A review of documents of the ancients, and of medieval times finds, “a single denomination” for various unrelated diseases.

d) Syphilis was identified in the early 20th century, named for a young shepherd in a Latin poem. In fact, when it comes to the names of skin diseases, “the influence of classical authors has been constant.” From the late 19th century, syphilis spread “like wildfire all over Europe,” (replete with sores, abscesses and ulcers).

COSMETICS

“In the cultural imaginary of every period, attention to skin care and the beauty of the body has represented a form of externalization of the self, through the construction of a bodily image in line with the dominant aesthetic and health parameters,” Santoro says. “Medicine’s interest in beauty finds in cosmetics a legitimate epistemological justification.”

Byzantine (330 A.D. – 1453 A.D.) medicine was aware of society’s penchant for “physical appearance and aesthetic values.” Santoro cites cosmetics applications for wrinkle, stain and hair elimination, along with hair and eyebrow thickening and dying.

Greek female physician Metrodora (200 A.D. – 400 A.D.) wrote about hair removal, facial toning lotions and perfume recipes. Santoro confirms the existence, from the Middle Ages to the Renaissance, of “beauty recipes, essential remedies for blemishes caused by skin diseases.”

In the 16th century, medical cosmetics “passed new milestones.”

In fact, “from the Renaissance onwards, scientific discoveries progressively saw a rise in specialist medical interest in dermatology.” Kudos to the ancients, she says, as “terminology for the classification of diseases remained almost intact. Still today we preserve the same lexical variety that Greek-Roman medicine had adopted and divulged.”

In conclusion, her study “reveals interesting social implications,” she says. Remember the repulsion of ancient dermatological diseases that “heightened the sensitivity of physicians” to cosmetics and aesthetic medicine. Now we achieve results that ancient civilizations could never imagine. And don’t forget the evolution of “the emancipation of women” that care for and respect their bodies.

A final thought: If the study of skin was tardy in achieving specialization, albeit not until the 18th and 19th centuries, the dizzying rate of scientific advances, combined with the extraordinary popularity of elective aesthetic skin procedures, has undeniably picked up the slack for dermatology in 2019.

Reference


cosmetology at the Long View Gallery in Washington, D.C., just before the 2019 American Academy of Dermatology Annual Meeting. Following an insightful presentation by Eve Lowenstein, M.D., Ph.D., on the evolution of humility and error awareness in medicine, Daniel Siegel, M.D., announced the honorees in historical order on behalf of the Dermatology Hall of Fame Board of Directors. The 2019 inductees are:

Marion B. Sulzberger, M.D.
Hermann Pinkus, M.D.
Walter F. Lever, M.D.
Naomi M. Kanof, M.D.
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Stephen I. Katz, M.D., Ph.D.
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Charles Stiefel, former chairman and chief executive officer of Stiefel Laboratories, one of this year’s inductees, has donated a significant amount of money to dermatology research.
HIGH BAR FOR JAK INHIBITORS TO SUCCEED IN PSORIASIS TX

In psoriasis, Janus kinase (JAK) inhibitors must meet a high standard set by existing biologics and systemic agents if they are to gain usage by the dermatology community. “Janus kinases are involved in the Th17 signaling pathway, which is important in the pathogenesis of psoriasis,” said April W. Armstrong, M.D., M.P.H., professor of dermatology and associate dean of clinical research at the University of Southern California, in a presentation made at the 2019 American Academy of Dermatology annual meeting in Washington, D.C. “They help mediate the downstream effects of interleukin (IL)-23. As a result, the Janus kinase pathway is highly relevant to treating psoriasis.”

IL-23 and IL-12 signal through JAK2 and tyrosine kinase 2 (Tyk2), she noted. Oral JAK inhibitors that have been explored for psoriasis include tofacitinib, baricitinib, BMS-986165 and abrocitinib. “They all are variably effective in decreasing psoriasis activity,” Dr. Armstrong said. “What’s different in psoriasis compared to other diseases is that we have many systemic agents, including the biologic medications, that are highly effective. Therefore, for a JAK inhibitor to be competitive, being an oral medication alone is not sufficient. It has to have good efficacy and an acceptable safety profile.”

Tofacitinib underwent extensive studies in psoriasis, but did not complete the approval process, she noted. In separate phase three trials, tofacitinib demonstrated good efficacy and was the first oral medicine shown to be non-inferior to a biologic (etanercept). Tofacitinib-treated patients experienced a 0.8% rate of herpes infections (versus none in placebo-treated patients) and slight abnormalities in creatinine phosphokinase (CPK) and low-density lipoprotein (LDL).

Tyk2 inhibitors represent a novel target and were explored in psoriasis years ago, Dr. Armstrong says. This difference makes it potentially less likely to cause systemic problems in areas such as the hematopoietic pathway.

“Illicit data are limited. Future development of JAK inhibitors for psoriasis will need a higher bar because we have so many biologics that work extremely well and have good safety profiles. It’s a different story than, say, atopic dermatitis.”

But when you look at the mechanism for a JAK inhibitor to be competitive, being an oral medication alone is not sufficient…”

Dr. Armstrong
University of Southern California, California

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In psoriasis, Janus kinase (JAK) inhibitors must meet a high standard set by existing biologics and systemic agents if they are to gain usage by the dermatology community. “Janus kinases are involved in the Th17 signaling pathway, which is important in the pathogenesis of psoriasis,” said April W. Armstrong, M.D., M.P.H., professor of dermatology and associate dean of clinical research at the University of Southern California, in a presentation made at the 2019 American Academy of Dermatology annual meeting in Washington, D.C. “They help mediate the downstream effects of interleukin (IL)-23. As a result, the Janus kinase pathway is highly relevant to treating psoriasis.”

IL-23 and IL-12 signal through JAK2 and tyrosine kinase 2 (Tyk2), she noted. Oral JAK inhibitors that have been explored for psoriasis include tofacitinib, baricitinib, BMS-986165 and abrocitinib. “They all are variably effective in decreasing psoriasis activity,” Dr. Armstrong said. “What’s different in psoriasis compared to other diseases is that we have many systemic agents, including the biologic medications, that are highly effective. Therefore, for a JAK inhibitor to be competitive, being an oral medication alone is not sufficient. It has to have good efficacy and an acceptable safety profile.”

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Tyk2 inhibitors represent a novel target and mechanism of action for psoriasis, Dr. Armstrong said. “That is a promising target, because early studies have shown good efficacy as well as acceptable safety,” she added.

BMS-986165 is functionally more selective than other Tyk inhibitors because it inhibits the regulatory domain rather than the adenosine triphosphate (ATP) binding active domain, Dr. Armstrong says. This difference makes it potentially less likely to cause systemic problems in areas such as the hematopoietic pathway.

Topical delivery of JAK inhibitors could limit systemic absorption and systemic side effects. The topical JAK inhibitor that has garnered the most attention is tofacitinib.

“Topical JAK inhibition has promise because these drugs are not steroids,” she concluded. “But data are limited. Future development of JAK inhibitors for psoriasis will need a higher bar because we have so many biologics that work extremely well and have good safety profiles. It’s a different story than, say, atopic dermatitis.”

Disclosures:
Dr. Armstrong is a clinical researcher and consultant for AbbVie, Johnson & Johnson, Eli Lilly (maker of baricitinib), Pfizer (maker of tofacitinib), Bristol-Myers Squibb (maker of BMS-986165), Novartis, Ortho Dermatologics and Sanofi-Regeneron.

References:

EARLY DATA PROMISING FOR ORAL TYK2 INHIBITOR

Although it’s early, there probably is room in the psoriasis drug market for tyrosine kinase 2 (Tyk2) inhibitors, said an expert at the American Academy of Dermatology (AAD) 77th annual meeting. Phase 2 results for potentially the first oral Tyk2 inhibitor appeared at a meeting. Phase 2 results for potentially the first oral Tyk2 inhibitor appeared at the American Academy of Dermatology (AAD) 77th annual meeting.

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Although it’s early, there probably is room in the psoriasis drug market for tyrosine kinase 2 (Tyk2) inhibitors, said an expert at the American Academy of Dermatology (AAD) 77th annual meeting. Phase 2 results for potentially the first oral Tyk2 inhibitor appear encouraging, he added.

Founder and CEO of the Dermatology Research and Education Foundation in Irvine, Calif, Jashin J. Wu, M.D., said 14 systemic agents have earned FDA approval for plaque psoriasis: four oral drugs and 10 biologics. Approval of risankizumab is expected in April 2019. Janus kinase (JAK) inhibitors being explored for psoriasis carry many potential side effects, he added. “But when you look at the mechanism for a selective Tyk2 inhibitor, it seems to have fewer side effects compared to the JAK inhibitors, because it is more targeted.”

Tyk2 is part of the interleukin (IL)-23 pathway, a key pathway in the pathogenesis of psoriasis, Dr. Wu said. “But Tyk2 is not part of other pathways that may reduce blood counts or worsen cholesterol levels.”

A phase two study of BMS-986165 published in the New England Journal of Medicine in September 2018 produced very promising results, he noted. Among five dosing regimens and placebo, doses of at least six mg daily produced week 12 Psoriasis Area and Severity Index (PASI)
VP-102 PASSES PHASE THREE TRIALS

The success of a novel 0.7% cantharidin solution in phase three trials brings a consistent approach to molluscum contagiosum (MC) closer to U.S. Food and Drug Administration (FDA) approval.

The drug-device combination, VP-102, met all primary and secondary endpoints in the parallel Cantharidin Application in Molluscum Patients (CAMP)-1 and CAMP-2 trials, said principal investigator Lawrence F. Eichenfield, M.D., professor of dermatology and pediatrics at the University of California San Diego and Rady Children’s Hospital, San Diego.

“Molluscum contagiosum is an incredibly common condition, especially in children,” he said. Caused by a DNA poxvirus, MC is highly contagious from contact and has a very high co-infection rate among family members, he added. “While one traditional approach has been waiting for lesions to go away, the data show very clearly that they can persist with an average duration of 13 months.”

While some experts have used cantharidin for MC in the past, Dr. Eichenfield said, physicians now have difficulty accessing it, especially with changes in FDA policies regarding bulk substances and compounding regulations. Cantharidin has never undergone formal clinical trials, he added, or been proven safe and effective for this condition; there has been no clear regulatory framework to support the use of cantharidin in practice.

ABOUT THE TRIALS
In each trial, investigators randomized approximately 150 patients (mean age: 7.5 years) to active treatment and approximately 110 patients to placebo. Mean baseline lesion counts were 19-25.

Patients received treatment or placebo every 21 days until clearance or four applications total. To eliminate cross-contamination concerns, Verrica designed a single-use, squeeze-on applicator that dispenses a consistent strength and concentration of the drug, which patients left on for 24 hours before washing, said Dr. Eichenfield.

At 12 weeks, the proportions of patients in CAMP-1 and CAMP-2 who achieved complete clearance were 46 percent and 54 percent, respectively, versus 18 percent and 13 percent for vehicle (p<0.0001 in both trials). In CAMP-1, Dr. Eichenfield added, there was clear statistical separation at all time periods for the primary outcome — including at three, six and nine weeks. Statistical significance emerged at week 8 in CAMP-2. Week 12 lesion counts decreased 66 percent and 73 percent for placebo. Only three cantharidin-treated patients discontinued treatment due to TEAEs.

Future steps include submission for publication and to the FDA. Approval, if granted, will help drive a more consistent approach to managing MC, Dr. Eichenfield said.

Disclosures: Dr. Eichenfield reports no relevant financial interests. The University of California San Diego received research funding from Verrica Pharmaceuticals for the trials.

Reference: Lawrence F. Eichenfield MD. “CAMP-1 (Cantharidin Application in Molluscum Patients) and CAMP-2: Phase 3, Randomized, Double-Bind, Placebo-Controlled, Pivotal Studies Investigating VP-102, a Drug-Device Combination Containing a Novel Topical Formulation of Cantharidin, for the Treatment of Molluscum Contagiosum,” F078, American Academy of Dermatology, March 2, 2019.

Disclosures: Dr. Wu is a consultant for Bristol Myers Squibb and a consultant or investigator for Celgene, Eli Lilly, Janssen Pharmaceuticals, LEO Pharma, Novartis, Ortho Dermatologics, Pﬁzer, Sanofi Regeneron, and Sun Pharma.


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These new options for the treatment of our patients with acne and rosacea are still being developed, and I think it’s an exciting time.

Diane Berson, M.D., Weill Medical College of Cornell University, New York

Quick Takes

A topical anti-androgen cream in development has demonstrated efficacy on both non-inflammatory and inflammatory lesions.

New formulations of retinoids could also soon be available.

Two new topical formulations of minocycline, previously used only orally, are currently under investigation.

Interest is growing around using natural botanical ingredients, such as honey and cannabinoids, to treat rosacea.

Therapeutic development in acne and rosacea from Page 1

Exciting that we will have new options to offer our patients in the near future.

She discussed these new therapies, including topicals, orals, and medical devices, during the American Academy of Dermatology spring meeting in Washington, D.C.

“This information will increase the tool box of available therapeutic options for patients,” she said. “They will also provide new mechanisms of action.”

Topical Treatment

The most exciting development for treating acne, she said, is the first topical anti-androgen cream. The clascoterone 1-percent cream is a new molecule that targets androgen receptors, preventing the binding of dihydrotestosterone. Clinical studies have already shown it to be effective on both non-inflammatory and inflammatory lesions. If approved, Dr. Berson said, it could be the first topical agent to reduce sebum production.

“Finding a topical agent which actually reduces sebum production has been the holy grail for acne,” she said.

A solution with the same active ingredient is also under investigation for use as a topical treatment for androgenic alopecia.

Alongside clascoterone, new formulations of retinoids could also soon be available. For example, a 0.05-percent tretinoin lotion will likely come to market later this year. The product is unique, Dr. Berson said, because it contains particles that are micronized, making them small enough to penetrate the sebaceous follicles more effectively. With the help of polymerized emulsion technology, the lotion contains a hydrating vehicle with ingredients, such as glycerin and hyaluronic acid, that help the product spread easily, she added.

Other new retinoids under development include trifarotene cream, a selective retinoid that reduces redness, scaling, and dryness by targeting only one retinoid acid receptor. A new tazarotene lotion is also in the pipeline as a minicycline tazarotene combination gel.

Also, two new topical formulations of minocycline that have previously only been used orally are currently under investigation. One is a 1.5 to 4 percent lipophilic gel, and the other is a 4 percent micronized foam. Both are also being examined for use at lower concentrations with rosacea patients, she said.

Berson also mentioned a hypochlorous acid cleaner that offers both antimicrobial and anti-inflammatory properties.

Oral Treatment

Among oral therapies, Berson said, sarecycline is a new chemical entity that recently received approval from the Food & Drug Administration. It’s a tetracycline-derived antibiotic used to treat inflammatory lesions of non-nodular moderate-to-severe acne. The once-daily medication can be taken with or without food and is available in three weight-based doses, 60mg, 100mg, and 150mg. It is approved for use in patients over age 9. In addition, sarecycline is well-tolerated, creates few side effects, and has demonstrated efficacy in treating chest and back acne.

Another study is also ongoing, she said, looking into the long-term efficacy of a lidose formation of isotretinoin. After two years, data shows 83 percent of patients have required no further treatment. She also mentioned another consensus study that unanimously supports the use of non-ablative laser procedures during and soon after isotretinoin treatment. This approval contradicts the current common practice.

Medical Devices

The most significant development in medical devices for treating acne has not yet received approval, Dr. Berson says. The device is a particle-assisted laser treatment where topical suspensions of gold or silver are applied to the skin before radiating it with various laser sources.

She also pointed to a short-pulse 1064nm laser used for treating inflammatory acne and the use of microneedling — alone and in combination with radiofrequency — for treating acne as two newer applications of medical devices.

Rosacea

In addition to the two minocycline re-formulations mentioned earlier, Dr. Berson also highlighted two new rosacea treatments. First, she mentioned a 1-percent ivermectin cream, an anti-parasitic and anti-inflammatory medication, that targets demodex mites. And, second, she discussed the adrenergic agonist 1-percent oxymetazoline cream that has been shown to improve erythema in patients.

Dr. Berson mentioned two studies that are investigating the effects of diet on rosacea. One article, she says, revealed caffeinated coffee may be linked to a decreased incidence of rosacea. However, another study linked white wine and liquor to an increased risk.

But, pharmaceuticals aren’t the only treatment options, she says. Interest is growing around using natural botanical ingredients, such as honey and cannabinoids, to treat rosacea. In the near future, she said she expects to see more studies around how these substances can best be used to treat rosacea, acne, and other dermatoses.

Overall, Berson said, dermatologists should be aware of the newest and energies therapeutic options for treating acne and rosacea. Many of these treatment options could change care delivery, enabling dermatologists to provide the best possible patient outcomes.

“These new options for the treatment of our patients with acne and rosacea are still being developed, and I think it’s an exciting time,” she said. “It’s an exciting time for the development of acne and rosacea therapies as we’re still learning more about the pathogenesis of these diseases.”
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MINOLIRA is indicated to treat only inflammatory lesions of non-nodular moderate to severe acne vulgaris in patients 12 years of age and older.

MINOLIRA did not demonstrate any effect on non-inflammatory acne lesions. Safety of MINOLIRA has not been established beyond 12 weeks of use. This formulation of minocycline has not been evaluated in the treatment of infections. To reduce the development of drug-resistant bacteria as well as to maintain the effectiveness of other antibacterial drugs, MINOLIRA should be used only as indicated.

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

To report SUSPECTED ADVERSE REACTIONS, contact EPI Health, LLC at 1-800-499-4468 or FDA at 1-800-FDA-1998 or visit www.fda.gov/medwatch.

For full prescribing information, please visit www.minolira.com

Energy-based therapies for treating GSM disorders

KAREN APPOLD | Staff Correspondent

In her March 1 presentation at the 2019 American Academy of Dermatology’s annual meeting titled “Women’s Genitourinary Health: Controversies,” Macrene Alexiades, M.D., Ph.D., associate clinical professor of dermatology, Yale University School of Medicine, New Haven, Conn., maintained that proper testing and clearances are needed to ensure the safe and effective use of fractionated and radiofrequency devices for treating genitourinary syndrome of menopause (GSM) disorders, which include atrophic vaginitis, urinary incontinence and pelvic prolapse. “Women’s health technologies shouldn’t be marketed for diagnoses that aren’t yet FDA approved,” she says.

Her remarks were made in light of the FDA’s November 2018 warning letter, which stated, “The use of energy-based devices to perform vaginal ‘rejuvenation’, cosmetic vaginal procedures, or non-surgical vaginal procedures to treat symptoms related to menopause, urinary incontinence or sexual function may be associated with serious adverse events. The safety and effectiveness of energy-based devices for treatment of these conditions has not been established.”

Dr. Alexiades points out, however, that only 14 adverse events from such devices used on vaginal tissue have ever been reported to the FDA. “It is extremely rare to be burned by these technologies; this shouldn’t occur when used appropriately,” she says.

Nonetheless, Dr. Alexiades says she understands the FDA’s need to “pull back on the reigns” until these devices are FDA cleared for additional uses.

In addressing the issue of device safety and efficacy, Dr. Alexiades notes that lasers or energy-based devices have been used to ablate genitourinary (GU) tissue for more than 40 years and that they are FDA cleared for use in that capacity.

Currently, Dr. Alexiades and others in the field are working to attain FDA clearance to apply energy-based devices to treat GSM disorders — which affect up to 50% of women who are post-menopausal, post-oophorectomy, undergoing breast cancer treatment, post-radiation or breastfeeding.

Also noteworthy is that energy-based devices are the fastest growing segment in the device industry for GSM treatments. Global sales for energy-based technologies exceeded $100 million in 2016. “The fee schedule is estimated to exceed $2 billion by 2021,” Dr. Alexiades says. “It is a tremendous area of growth in medical revenue.”

The bottom line, according to Dr. Alexiades, is that women need these treatments. “Their health has been neglected for generations,” she says. “Kegel exercises, the current treatment, aren’t effective; localized estrogen is moderately effective but hampered by a low compliance rate; hormone replacement therapy after menopause is associated with increased breast cancer rates; and surgical approaches, such as slings and meshes, are complicated by mesh erosions and consequent class-action lawsuits. It is absolutely necessary that we find alternative treatments...”
Superficial radiation therapy for keloids

LISETTE HILTON | Staff Correspondent

Researchers found in a retrospective study of 297 surgically excised keloids with superficial radiation therapy around the excision site that only 3% (n = 9), recurred during an average 6-month follow-up, according to a research letter published November 2018 in the online peer-reviewed journal SKIN, The Journal of Cutaneous Medicine.

Study author Brian Berman, M.D., Ph.D., says that he’s cautiously optimistic that superficial radiation could be a game-changing therapy for preventing recurrence of the scars. A longer-term, prospective study is needed to help confirm results, according to Dr. Berman, professor emeritus, Dermatology and Cutaneous Surgery, University of Miami Miller School of Medicine.

THE PROBLEM WITH KEOIDS

Dr. Berman says the first thing he addresses with patients who come in with keloids is whether they really want their keloid removed. “That’s the crucial question because if I can convince the patient that he or she would be satisfied with getting rid of the symptoms and signs — the itching, burning, maybe flattening of the keloid a little — there is a whole set of treatments for that,” he says. “It’s the patients that say they’ll only be satisfied if the keloid is gone that one would have to use a surgical procedure to remove the keloid...The issue and problem is that in the literature the recurrence rate of the keloid after you remove it is in the range of 71%.”

Another problem is that the keloid rarely completely goes away. “That’s why we use superficial radiation therapy after the keloidectomy, in order to reduce the high recurrence rate,” says Dr. Berman, a consultant with Sensus Healthcare, the company that makes the SRT-100 device that was used in the study. The SRT-100 device is FDA approved for the treatment of keloids.

SUPERFICIAL RADIATION THERAPY FOR KEOIDS

When Dr. Berman uses superficial radiation therapy post-keloidectomy, he tries to irradiate a 5 mm margin around the excision site the day after the excision.

“And then we irradiate for three days in a row, on post-operative days 1, 2 and 3,” he says. “We use a biologically effective dose (BED) 30. There are different ways you can achieve that, but we use three fractions of 6 Gy every day for three days in a row, postoperatively.”

Researchers report some patients experience transient hyperpigmentation at the treatment site, but it’s relatively minor because of the fractionation. “In the literature, when you generate a single blast dose of radiation, that’s when you get greater pigmentary alteration. By extending it and fractionating, it offers a more cosmetically pleasing result,” he says.

There are relative contraindications for the use of superficial radiation therapy in general, whether it’s to treat non-melanoma skin cancer or keloids, according to Dr. Berman. These include an implanted pacemaker in the area, re-treatment of a skin cancer or recurrence of the skin cancer or keloid.

“The standard in my mind is to follow patients for a year,” Dr. Berman says. “So take that with a grain of salt. Now we are doing a longer-term retrospective study and planning a prospective study with a one-year follow-up.”

The good news about the retrospective study Dr. Berman and colleagues performed was the low 3% recurrence rate. And even if the recurrence rate with superficial radiation therapy goes up to 10% or so in a longer-term study, that’s still way below the other therapeutic options, he says.

Quick TAKES

Superficial radiation could be a game-changer for preventing recurrence of keloids.

Researchers report a 3% keloid recurrence rate with excision + superficial radiation.

A longer-term retrospective study is underway.
We can achieve beautiful results with less downtime and more efficacy, and with a higher level of safety for more skin conditions, even those we couldn’t treat safely in the past.”

Jason Pozner, M.D., Sanctuary Plastic Surgery, Boca Raton, Fla.

Lasers FROM PAGE 1

Goldman, a pioneer in applying lasers to dermatologic conditions, reported on the effects of Maiman’s ruby laser in the selective photodestruction of pigmented skin elements such as black hair.

“Other developments and clinical applications soon followed in a flurry of published works,” says Melanie D. Palm, M.D., M.B.A., medical director of Art of Skin MD in Solana Beach, Calif., and assistant volunteer clinical professor of the division of dermatology at the University of California San Diego.

Goldman went on to elucidate the use of both ruby and Q-switched lasers for tattoo removal and pigmented lesions while studying the argon laser for vascular lesions and carbon dioxide lasers for skin lesion destruction. Over the next decade, advancements in dermatologic photosurgery developed, including the advent of photodynamic therapy, light-based wound healing and the development of the Nd:YAG (neodymium:yttrium-aluminum-garnet) laser for vascular lesions.

Beyond the 1960s, perhaps the biggest leap forward in the field of cutaneous lasers was the development of the theory of selective photothermolysis by dermatologists Rox Anderson and John Parrish in 1983, Dr. Palm says. Their article elucidated the tissue-laser interaction leading to selective destruction of an intended target structure, termed a chromophore. Laser energy of a predetermined wavelength was preferentially absorbed by a chromophore, creating thermal absorption by the target more so than surrounding structures, leading to selective tissue heating and destruction.

ADVANCEMENTS

In the 1990s, robotic scanning devices were developed, which allowed the laser beam to be moved across the treatment site in a uniform and precise manner. “These scanners helped eliminate excessive tissue injury from over treating tissue by dwelling too long on the same site,” says Matthew Kelleher, M.D., board-certified dermatologist, Premier Dermatology, Crest Hill, Ill. “Scanners also ushered in the next advancement in cutaneous laser surgery—ablative resurfacing.” Resurfacing lasers produced a controlled wound into the epidermis and dermis in order to promote collagen growth, skin tightening and wrinkle reduction. “Dramatic improvements were commonly achieved with these devices; however, the unacceptably high incidence of scarring and hypopigmentation led to a decline in these procedures,” Dr. Kelleher says.

In the ongoing search for laser technology to safely resurface the skin and substantially treat wrinkles and scars, the next major advancement in cutaneous laser surgery was achieved with the development of fractionated laser technology. Fractionated thermolysis (FT) was first described by Huzaira and colleagues and the first devices were available in 2004. Simply put, “FT entails creating a pattern of small laser injuries with intervening ‘skip’ areas to promote wound healing,” Dr. Kelleher says. “This allows deep tissue injury without a long recovery, downtime, scarring and hypopigmentation of previous fully ablative skin resurfacing. Fractionated lasers have transformed our ability to treat wrinkles, skin laxity, tone, texture, dyschromia and scars both safely and effectively.”

LASER TECHNOLOGY TODAY

Nowadays, lasers and light devices have the ability to resurface, rejuvenate and treat vascular lesions of all types, says Mark Nestor, M.D., Ph.D., director at the Center for Cosmetic Enhancement and Center for Clinical and Cosmetic Research in Aventura, Fla. They can also remove and modulate fat, reshape the body, remove unwanted hair and grow hair too.

“We can achieve beautiful results with less downtime and more efficacy, and with a higher level of safety for more skin conditions, even those we couldn’t treat safely in the past,” says Jason N. Pozner, M.D., medical director and plastic surgeon, Sanctuary Plastic Surgery, Boca Raton, Fla. “There are fewertells signs of treatment, which also meets consumers’ demands.” For example, fewer incidences of hypo- and hyperpigmentation have occurred as technologies have become safer to use on more skin types. “These advancements represent a quantum leap over technology we had just a decade or two ago.”

GAPS IN LASER TECHNOLOGY

Despite achievements, there’s always room for advancement. “Patients want better skin tightening options and fat removal that can yield more dramatic results in fewer treatment sessions,” Dr. Pozner says. “More platforms are available for dermatologists and plastic surgeons today that can be customized, expanded and upgraded as new handpieces are added. These systems allow practitioners to stay current with better, faster treatments for a wide range of conditions more cost effectively.”

For laser hair removal, Dr. Palm says the ultimate achievement would be relatively remove melanin-devoid hair follicles such as white, red, grey and blonde hairs. “Currently, no laser hair removal devices can effectively do this,” Dr. Palm says.

And there are still limitations in reju-
venating darker Fitzpatrick skin types rich with melanin. “Currently, we can use longer wavelength laser devices, such as Nd:YAG lasers or infrared lasers, on darker skin types with more conservative laser settings and skin cooling before, after and during treatment to successfully treat skin of color,” according to Dr. Palm.

Treatment time for some procedures is another gap in current laser technology. “The ability to treat an entire face or body in a matter of seconds or minutes has yet to be developed,” Dr. Palm says.

Dr. Kelleher cites multiple areas that need improvement, beginning with the ability to eliminate wrinkles and improve skin tone and texture. “We still can’t substantially tighten skin with lasers,” he says. “A greater ability to target sebaceous glands and successfully treat acne with lasers could potentially eliminate the use of medications such as isotretinoin. The common patient complaint of excessively oily skin still needs to be resolved. The ability of lasers to safely, comfortably and substantially eliminate unwanted fat is lacking. Laser treatment of non-melanoma skin cancer is in its infancy and not widely used. Laser treatment of melanoma is essentially nonexistent.”

A PROMISING FUTURE FOR LASERS

Energy-based devices continue to advance; more developments are coming from different parts of the world, especially Asia. “Better visualization of structures with optical coherence tomography allows us to improve patient outcomes,” according to Dr. Pozner. “We can further customize treatments using the right settings for optimal results for each individual patient. We use combination treatments more widely today and have moved from face to off-face targets (e.g., chest, neck, hands, legs) and often treat more than one area in a single session.”

Another area of potential benefit is the ability to in vivo image tissue with lasers. “This could allow real-time diagnosis without invasively procuring tissue from the patient,” Dr. Kelleher says. “This could allow for more precise and immediate confirmation of tissue margins when treating skin cancers.”

Susan Van Dyke, M.D., medical director and founder of Van Dyke Aesthetics, a Platinum Dermatology Partners practice in Paradise Valley, Ariz., foresees using lasers as drug delivery systems. “Much work is being done to find ways to safely focus highly active drugs and substances to treatment areas,” she says. Examples include steroids to reduce hypertrophic scars, minoxidil to stimulate hair growth, bimatoprost to promote pigmentation, platelet rich plasma to enhance healing and trigger collagen and elastin productions, hydroquinone to reduce melasma, and post-inflammatory hyperpigmentation. “The cosmetic possibilities are endless, as are medical uses such as treating mycotic conditions, cutaneous neoplasms and psoriasis, to name a few.”

Disclosures

Dr. Palm is a speaker, consultant and/or clinical investigator for Lumenis, Lutronic, BTL and Sciton. Dr. Kelleher is an unpaid KOL for Syneron Candela. Dr. Nestor is a consultant, speaker and/or advisory board member for Aerolase, Pulse Biosciences, Rohrer Aesthetics, Sensus Healthcare and Therma, and has received research grants from Aerolase and Pulse Biosciences. Dr. Pozner reports no relevant disclosures.

References

rather than tightening sagging skin with one-dimensional surgical stretching, the combination of fillers and skin tightening devices can safely provide synergistic results, according to dermatologist Susan Van Dyke, M.D.

To explain the dynamics of aging facial skin, Dr. Van Dyke, Paradise Valley, Ariz., uses the analogy of a couch and slipcover.

Over the years, she explains, facial fat — the metaphorical couch — shrinks, while increasing laxity makes the outer envelope of skin — the slipcover — larger.

“We used to take that slipcover and pull it really tight, which never looked good. That was the wind-tunnel effect,” she says. Patients who had undergone multiple surgical facelifts didn’t look younger, just unnaturally tighter.

Instead, says Dr. Van Dyke, aesthetic physicians now seek to shrink the “slipcover” with skin tightening technologies while plumping the “couch” with fillers. When patients look in the mirror, she says, they see loose, sagging skin, but generally fail to recognize the underlying volume loss (although they’re getting more educated in this regard).

“What we know is happening is that we’ve got fat that is not only descending with gravity, but it’s also thinning out,” says Dr. Van Dyke. Ligamental connections eventually stop the descent, resulting in the formation of nasolabial folds.

Most of her patients get a combination of noninvasive procedures. “When you fix one thing, it’s not going to look normal. In my practice, patients want to look like themselves. They don’t want to look like somebody else,” says Dr. Van Dyke, who presented on this topic at Fall 2018 Cosmetic Bootcamp.

She likens her approach of fixing the skin envelope to the process of shrink wrapping. “To that end, we know that heating collagen causes it to contract. And there are significant amounts of collagen in the skin, the dermis and underlying structures including the superficial muscular aponeurotic sys-
A NEW POTENCY CLASS OF STEROID LOTION

CHART A COURSE TO SYMPTOMATIC RELIEF

The efficacy of Class 1 halobetasol with safety proven for up to 8 weeks of dosing1,2

A NEW POTENCY CLASS OF STEROID LOTION

2 PIVOTAL PHASE 3 TRIALS

POTENT TO SUPERPOTENT CLEARANCE1:

Continued results 4 weeks post treatment1

Significant symptomatic relief as early as week 22

No increased epidermal atrophy observed through 8 weeks of treatment2

Local adverse reactions from topical corticosteroids may include atrophy, striae, telangiectasias, hypopigmentation and allergic contact dermatitis. Some local adverse reactions may be irreversible.

STUDY RESULTS: 36.5% of patients in trial 1 and 38.4% in trial 2 achieved treatment success1 at week 8 (primary endpoint) vs 8.1% and 12.0% of patients with vehicle, respectively (P<0.001 in both trials).1

STUDY DESIGN: The safety and efficacy of BRYHALI Lotion were assessed in 2 prospective, multicenter, randomized, double-blind, phase 3 clinical trials in 430 adult patients with moderate-to-severe plaque psoriasis. Patients were treated with BRYHALI Lotion or vehicle lotion; applied once daily. Primary efficacy endpoint was treatment success evaluated at week 8. Secondary efficacy endpoint was treatment success evaluated at weeks 2, 4, 6, and 12 (4 weeks post treatment). Tertiary efficacy endpoint was a 2-grade improvement from baseline at each time point for the individual signs of psoriasis erythema, plaque elevation, and scaling.2

"Treatment success was defined as at least a 2-grade improvement from baseline in the Investigator's Global Assessment score, and a score of "clear" or "almost clear" (primary endpoint) at week 8."


Indication

BRYHALI™ (halobetasol propionate) Lotion, 0.01% is a corticosteroid indicated for the topical treatment of plaque psoriasis in adults.

Important Safety Information

Warnings and Precautions

• BRYHALI Lotion has been shown to suppress the hypothalamic-pituitary-adrenal (HPA) axis during treatment or upon cessation of treatment; periodic evaluation may be required.

• Systemic effects of topical corticosteroids may also include Cushing’s syndrome, hyperglycemia, and glucosuria.

• Children may be more susceptible to systemic toxicity when treated with topical corticosteroids.

• Local adverse reactions may include atrophy, striae, telangiectasias, hypopigmentation, and allergic contact dermatitis. Some local adverse reactions may be irreversible.

• Use of topical corticosteroids may increase the risk of posterior subcapsular cataracts and glaucoma. If visual symptoms occur, consider referral to an ophthalmologist.

• Use an appropriate antimicrobial agent if skin infection is present or occurs, and if prompt response is not seen, discontinue use until infection has been adequately treated.

• Discontinue BRYHALI Lotion if allergic contact dermatitis occurs.

Adverse Reactions

• The most common adverse reactions (≥1%) were upper respiratory tract infection, application site dermatitis, and hyperglycemia.

To report SUSPECTED ADVERSE REACTIONS, contact Customer Service at 1-800-321-4576 or FDA at 1-800-FDA-1088.

Please see Brief Summary of full Prescribing Information on following page.

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BRIEF SUMMARY OF PRESCRIBING INFORMATION

This brief summary does not include all the information needed to use BRYHALI safely and effectively. See full prescribing information for BRYHALI.

BRYHALI™ (halobetasol propionate) lotion, 0.01% for topical use

Initial U.S. Approval: 1990

INDICATIONS AND USAGE

BRYHALI has been shown to suppress the hypothalamic-pituitary-adrenal (HPA) axis. Systemic effects of topical corticosteroids may include reversible HPA axis suppression with the potential for glucocorticosteroid insufficiency. This may occur during treatment or upon withdrawal of treatment with the topical corticosteroid.

CONTRAINDICATIONS

None.

WARNINGS AND PRECAUTIONS

Hypothalamic-Pituitary-Adrenal (HPA) Axis Suppression

BRYHALI has been shown to suppress the hypothalamic-pituitary-adrenal (HPA) axis. Systemic effects of topical corticosteroids may include reversible HPA axis suppression with the potential for glucocorticosteroid insufficiency. This may occur during treatment or upon withdrawal of treatment with the topical corticosteroid.

The potential for hypothalamic-pituitary-adrenal (HPA) axis suppression with BRYHALI was evaluated in a study of 18 adult subjects with moderate to severe plaque psoriasis involving ≥20% of their body surface area (BSA). HPA axis suppression was reported for 1 (5.6%) subject at Week 4 and for 3 (15.8%) subjects at Week 8. All 3 subjects had normal HPA axis suppression test with discontinuation of treatment [see Clinical Pharmacology in full Prescribing Information].

Because of the potential for systemic absorption, use of topical corticosteroids, including BRYHALI, may require that patients be evaluated periodically for evidence of HPA axis suppression. Factors that predispose a patient using a topical corticosteroid to HPA axis suppression include the use of more potent corticosteroids, use on large surface areas, occlusive use, use on an altered skin barrier, concurrent use of multiple corticosteroid-containing products, liver failure, and young age. An adrenocorticotropic hormone (ACTH) stimulation test may be helpful in evaluating patients for HPA axis suppression.

If HPA axis suppression is documented, attempt to gradually withdraw the drug, reduce the frequency of application, or 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. Pediatric patients may be more susceptible than adults to systemic toxicity from the use of topical corticosteroids due to their larger surface-to-body mass ratios [see Use in Specific Populations].

Local Adverse Reactions

Local adverse reactions from topical corticosteroids may include atrophy, striae, telangiectasias, burning, itching, irritation, dryness, folliculitis, acneform eruptions, hypopigmentation, perioral dermatitis, allergic contact dermatitis, secondary infection, and milia. These may be more likely with occlusive use, prolonged use, or use of higher potency corticosteroids, including BRYHALI. Some local adverse reactions may be irreversible.

Concomitant Skin Infections

Use an appropriate antimicrobial agent if a skin infection is present or develops. If a favorable response does not occur promptly, discontinue use of BRYHALI until the infection has been adequately treated.

Allergic Contact Dermatitis

Allergic contact dermatitis with corticosteroids is usually diagnosed by observing failure to heal rather than noting a clinical exacerbation. Consider confirmation of a clinical diagnosis of allergic contact dermatitis by appropriate patch testing. Discontinue BRYHALI if allergic contact dermatitis occurs.

ADVERSE REACTIONS

Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in clinical practice. In randomized, double-blind, multicenter, vehicle-controlled clinical trials, 426 adults with plaque psoriasis were treated with BRYHALI and had post-baseline safety data. Subjects applied BRYHALI once daily for up to eight weeks. Table 1 presents adverse reactions that occurred in at least 1% of subjects treated with BRYHALI and more frequently than in vehicle-treated patients.

Table 1: Adverse Reactions Occurring in ≥1% of the Subjects Treated with BRYHALI through Week 8

<table>
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<tr>
<th></th>
<th>BRYHALI (N=284)</th>
<th>Vehicle (N=142)</th>
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<tr>
<td>Adverse Reaction</td>
<td>%</td>
<td>%</td>
</tr>
<tr>
<td>Upper Respiratory Tract Infection</td>
<td>2%</td>
<td>1%</td>
</tr>
<tr>
<td>Application Site Dermatitis</td>
<td>1%</td>
<td>0%</td>
</tr>
<tr>
<td>Hyperglycemia</td>
<td>1%</td>
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USE IN SPECIFIC POPULATIONS

Pregnancy

Risk Summary

There are no available data on BRYHALI use in pregnant women to inform a drug-associated risk of major birth defects, miscarriage, or adverse maternal or fetal outcomes. In animal reproduction studies, increased malformations, including cleft palate and omphalocele, were observed after oral administration of halobetasol propionate during organogenesis to pregnant rabbits. The available data do not support relevant comparisons of systemic halobetasol propionate exposures achieved in the animal studies to exposures observed in humans after topical use of BRYHALI.

The background risk of major birth defects and miscarriage for the indicated population is unknown. In the U.S. general population, the estimated background risk of major birth defects in clinically recognized pregnancies is 2 to 4% and 15 to 20%, respectively.

Data

Animal Data

Halobetasol propionate has been shown to cause malformations in rats and rabbits when given orally during organogenesis at doses of 0.04 to 0.1 mg/kg/day in rats and 0.01 mg/kg/day in rabbits. Halobetasol propionate was embryotoxic in rabbits but not in rats. Cleft palate was observed in both rats and rabbits. Omphalocele was seen in rats but not in rabbits.

Lactation

Risk Summary

There are no data on the presence of halobetasol propionate or its metabolites in human milk, the effects on the breastfed infant, or the effects on milk production after treatment with BRYHALI.

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 human milk. The developmental and health benefits of breastfeeding should be considered along with the mother’s clinical need for BRYHALI and any potential adverse effects on the breastfed child from BRYHALI.

Clinical Considerations

Advise breastfeeding women not to apply BRYHALI directly to the nipple and areola to avoid direct infant exposure.

Pediatric Use

Safety and effectiveness of BRYHALI in pediatric patients under the age of 18 years have not been evaluated.

Because of higher skin surface area to body mass ratios, 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 also at greater risk of adrenal insufficiency during or after withdrawal of treatment. Adverse reactions including striae have been reported with use of topical corticosteroids in infants and children [see Warnings and Precautions].

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 an absence of response to ACTH stimulation. Manifestations of intracranial hypertension include bulging fontanelles, headaches, and bilateral papilledema [see Warnings and Precautions].

Geriatric Use

Of 284 subjects exposed to BRYHALI in clinical trials, 61 subjects were 65 years or older. Clinical trials of BRYHALI did not include sufficient numbers of subjects age 65 years and older to determine whether they respond differently from younger subjects.

NONCLINICAL TOXICOLOGY

Carcinogenesis, Mutagenesis, Impairment of Fertility

Long-term animal studies have not been performed to evaluate the carcinogenic potential of halobetasol propionate.

Halobetasol propionate was not genotoxic in the Ames assay, in the sister chromatid exchange test in Chinese hamster somatic cells, in chromosome aberration studies of germinal and somatic cells of rodents; or in a mammalian spot test. Positive mutagenicity effects were observed in a mouse lymphoma gene mutation assay in vitro and in a Chinese hamster micronucleus test. Studies in rats following oral administration of halobetasol propionate at dose levels up to 0.05 mg/kg/day indicated no impairment of fertility or general reproductive performance.

PATIENT COUNSELING INFORMATION

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

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By:

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Laval, Quebec H7L 4A8, Canada

U.S. Patent Numbers: 6,517,847 and 8,809,307

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November 2018

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Dr. Susan Van Dyke, Paradise Valley, Ariz.

RF, ultrasound and CO₂ treatments create inflammation in the dermis, which stimulates proliferation of fibroblasts to produce collagen and elastin fibers.

Heating collagen allows for skin tightening in three dimensions

RF, ultrasound and CO₂ treatments create inflammation in the dermis, which stimulates proliferation of fibroblasts to produce collagen and elastin fibers. These results start to become visible three weeks post-treatment and continue for the next year, she adds.

DOES HEAT AFFECT HA?

Some experts have advised against combining fillers with tightening because they believe heating will melt hyaluronic acid (HA) or cause excess inflammation. “That’s not the case,” says Dr. Van Dyke.

A 101-patient chart review² published in 2016 shows that when fillers (HA and calcium hydroxylapatite) and MFUS were performed within six months of each other, in either order, no problems occurred—even with just a two-week interval. “That should give us some confidence in doing these treatments in close proximity.”

MFUS can penetrate to a depth of 4.5 mm, potentially the same depth as a deposit of HA, she says. “When we do Ultherapy, we could go right through filler. I’m sure it happens all the time. And so far I have seen no problems; nor have I seen increase in filler dissolution.”

Heating HA to 65°C does not alter it, says Dr. Van Dyke, because these fillers are routinely sterilized at much higher temperatures. “There are now studies that show that it does not impact the effectiveness of HA.”

A 2007 study² by Goldman et al., showed that laser, RF and intense pulsed light treatment performed immediately after HA injections had no effect on the injections’ effectiveness. A previous trial³ using a porcine model showed that not only did energy-based treatments not hamper HA results, but the combination treatment enhanced collagen deposition. “That’s very exciting, and that study was published 13 years ago. We’ve known that something about this combination is synergistic.”

Additionally, a study⁴ published in 2015 showed that performing ultrasound treatments before poly-L-lactic acid (PLLA) injections during the same session provides safety, efficiency and clinical synergy. Authors suggested performing ultrasound first, stating that the filler volume change could change the depth that the ultrasound penetrated.

Dr. Van Dyke says that she would like to see a similar study performed with PLLA first, because this way, the ultrasound won’t cause as much pain. “And since we can see into the dermis with our ultrasound when we do this procedure, we will still know where the collagen layers are.”

Based on studies and an expert opinion⁵ published in 2016, she says, a consensus to perform energy-based facial treatments first has emerged, although one respected group of authors still recommends injecting fillers first.

Dr. Van Dyke’s practice has performed more than 10,000 filler treatments, and more than 1,500 MFUS treatments. “I’ve not seen and am not aware of any delayed recovery or complications from the combination, or that fillers dissolve faster.” Therefore, she said physicians can be comfortable using these combinations while more research continues to emerge.

References

Cosmeceuticals for skin of color

LISSETTE HILTON | Staff Correspondent

Skin of color patients are less concerned that the cosmeceuticals they use address fine lines and wrinkles. Rather, they're interested in products that minimize and treat hyperpigmentation from melasma or post-inflammatory hyperpigmentation, according to Susan C. Taylor, M.D., associate professor of Dermatology at the Perelman School of Medicine, Philadelphia, Penn.

Dr. Taylor presented “Skin of Color Cosmeceuticals Considerations,” Sunday, March 3, at the 2019 American Academy of Dermatology annual meeting in Washington, DC.

“Skin of color patients are also concerned about the loss of firmness of the skin and with sagging. Therefore, they are searching for products that address this concern,” says Dr. Taylor, who founded the Skin of Color Society. “In the fast-paced world of dermatology and dermatology practice, it is very easy to lose sight of the fact that we see patients with many different skin types and skin tones and skin concerns. One size does not fit all.”

The goal is to carefully consider the needs of individual patients, according to Dr. Taylor. “Many of the needs of the skin of color patient are different from non-Hispanic white patients,” she says. “Even within the group of patients who identify as skin of color, there are differences and different concerns.”

Dr. Taylor refers to a study by Saade DS, et al. published online July 2018 in the Journal of Clinical and Aesthetic Dermatology looking at patterns of over-the-counter lightening agent use among patients with hyperpigmentation in the U.S. The study shows hydroquinone was the most commonly used cream for lightening hyperpigmentation, and more than 36% of those using hydroquinone cream reported improvement. Most of those patients (63.5%) used it for less than six months. On the other hand, kojic acid, azelaic acid, steroids and antioxidants were used by fewer than 15% of patients and were associated with rates of improvement of less than 25% each.

Dr. Taylor is an advisor, speaker, consultant, educator and/or researcher for Aclaris Therapeutics, Aleregen, Avon Products, Beiersdorf, Croma-Pharma GmbH & Co., Eli Lilly and Company, Galderma Laboratories, Neostrata and Unilever. She is an independent contractor with KGL Skin Study Center.

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The evolution of skin cancer

Expanding options offer effective treatment options

ILYA PETROU, M.D. | Staff Correspondent

Recorded history has shown that physicians have always tried to best treat skin cancers with the therapeutic means and medical knowledge of the period. In the more modern era, a myriad of skin cancer treatments has developed and evolved over time including curettage and electrodesiccation, standard surgical excision, Mohs micrographic surgery, radiation therapy, cryosurgery, topical medications, laser surgery, photodynamic therapy (PDT), as well as evolving immunotherapies.

The breakthroughs in both surgical and medical treatments were significant in their own time; however, according to one expert, some advances in skin cancer treatment stand out more than others.

“There have been many important breakthroughs in the evolution of skin cancer therapy; some on the surgical level, such as Mohs surgery, and some on the medical level, such as the dawn of the immunomodulators; all of which have significantly contributed to advancing skin cancer treatment,” said Tobechi L. Ebede, M.D., dermatologist and fellowship-trained Mohs surgeon, Plaza Park Dermatology, Brooklyn, New York.

Historically, skin cancer treatments consisted of some form of destruction or surgical removal of the tumor. From the surgical aspect, Dr. Ebede believes that Mohs micrographic surgery is likely one of the most important breakthroughs in the timeline of skin cancer treatment evolution.

The technique is considered by many as the most effective treatment approach for removing BCC and SCC, and it is being increasingly used as an alternative to standard excision for some cases of melanoma. According to Dr. Ebede, Mohs surgery is proven to have the highest cure rate at 99% for first-time skin cancers and 94% for recurrent tumors.

“Mohs micrographic surgery made a huge impact on the treatment of skin cancer. The procedure can be completed in one visit under local anesthesia, and you can evaluate 100% of the tumor margin while the patient is in the office,” Dr. Ebede said. “With Mohs surgery, dermatosurgeons can spare much of the healthy tissue they normally would be removing via standard excision, leaving only a small scar for the patient who will go home cancer free. Not many other modalities can tout such an effective and efficient procedure for skin cancer treatment.”

Even within Mohs micrographic surgery, there have been recent advancements and refinements of the procedure where dermatopathologists are now staining excised frozen tissue sections with a melanoma antigen recognized by T cells (MART-1) to better identify melanomas such as melanoma in-situ.

According to Dr. Ebede, this significant breakthrough within Mohs surgery will be a catalyst for pathologists to more often use and incorporate the host of immunostains available to them into Mohs surgery.

From the medical treatment aspect, Dr. Ebede believes that immunotherapy is by far one of the most significant skin cancer treatment advances in modern times.

“If you look at past psoriasis and eczema treatments where the immune system was routinely globally suppressed causing so many cutaneous and systemic side effects, compared to the targeted therapy we now have where you can pinpoint specific targets within the immune system, also helping to reduce the side effects of treatment. I believe the same dynamic will also continue to be seen with skin cancer and novel evolving immunotherapies where we can fine-tune our targets without destroying the whole immune system in the process,” Dr. Ebede said.

Another advance in skin cancer immunomodulatory therapy with a novel administration is vismodegib (Erivedge, Genentech), which was a major breakthrough for those patients with advanced BCC. According to Dr. Ebede, being able to offer an oral therapy for those patients...
Adjunct molecular tests aid melanoma diagnosis

ILYA PETROU, M.D. | Staff Correspondent

The increasing incidence of malignant melanoma has led to continued research on innovative diagnostic and prognostic techniques to help clinicians optimize the treatment and management of the disease. As a result, a variety of molecular assays have been developed to help clinicians better treat and manage melanoma patients. One expert expects that these molecular assays will play a central role in the future treatment and management of malignant melanoma.

“We have different molecular tests for different purposes depending on how far along in the process we are when assessing the melanoma,” says Pedram Gerami, M.D., professor of dermatology and pathology, director of the Skin Cancer Institute of Northwestern Medicine (SCIN-med), director of the Melanoma Program of SCIN-med, Northwestern University Department of Dermatology and the Lurie Cancer Center, Chicago. “Those tests, aimed at accurately diagnosing suspicious pigmented lesions, are designed to differentiate between benign versus malignant, while others look at factors related to the prognosis of the tumor, impacting further treatment decisions and outcomes.”

PRE-BIOPSY DIAGNOSTIC AID
One molecular assay developed by DermTech International that assists in diagnosis works by tape stripping. An adhesive strip is applied to the surface of the lesion in question. The top skin cells are then analyzed with PCR tests for expression level of certain genes, including LINC and PRAME, and based on the expression levels of those genes, the scores can indicate whether the lesion favors to be benign or malignant.

The technique has also been shown to be relatively accurate with sensitivity of 91% and specificity of 69%. One limitation of the test is that it can only be implemented in lesions larger than 6 mm and cannot be used on the palms, soles, or face.

According to Dr. Gerami, this technique can be useful for diagnostically challenging lesions and could be considered as a noninvasive type of alternative to a traditional surgical biopsy in select cases.

AUGMENTING BIOPSY
In case a biopsy has already been performed, other molecular tests that can assist clinicians more accurately diagnose suspicious pigmented lesions that may still be ambiguous histologically include those that look at chromosomal copy number changes. Fluorescent in situ Hybridization (FSH) and Comparative Genomic Hybridization (CGH) are two molecular assay techniques that have been studied very extensively for this purpose, Dr. Gerami says. They can be very useful to help predict which indeterminate or borderline lesion may likely have tendency to behave aggressively, he adds.

“Tumors that have clonal segmental or fragments of the chromosome that have extra copies or losses in them is a pattern that is suggestive of melanoma. Both the FSH and CGH techniques are two alternative methods to analyze tumors and see if they have different dosage of or different levels of certain genes, either losses or gains of certain cancer controlling genes that would favor melanoma,” Dr. Gerami says.

Other techniques also useful in morphologically
Advances in SCC management

Better awareness in disease progression and improved understanding of field cancerization has shifted the thinking in patient management

ILYA PETROU, M.D. | Staff Correspondent

Recent advances in how to better stage and treat squamous cell carcinoma (SCC) have changed the understanding and approach of this ubiquitous and potentially deadly disease.

Coupled with the advancement of offering SCC patients more effective targeted immunotherapies, clinicians are also becoming more sophisticated at risk-stratifying patients and more aware of the importance to appropriately stage their SCC patients, said Vishal A. Patel, M.D., FAAD, FACMS, director of cutaneous oncology, GW Cancer Center.

“It’s an exciting time for patients with squamous cell carcinoma, in that many of the lessons learned from the results of immunotherapy and melanoma have now been applied to SCC, particularly those patients with more advanced disease,” said Dr. Patel, who also is assistant professor of dermatology, GW School of Medicine & Health Sciences, Washington, D.C. He spoke at the Orlando Dermatology and Aesthetic Conference.

SCC STAGING

The Brigham and Women’s Hospital or American Joint Committee on Cancer (AJCC) tumor staging systems are currently being readily used to stage patients. Although both are imperfect, Dr. Patel stressed that it is important for clinicians to use one so that they can offer patients the most optimal treatment and management strategies.

“If you’re not staging your SCC patients, you should be. Although both systems need refinement, it has really helped us to take out some of the guess work; to figure out who is going to be among those who may need most extensive treatments now or down the road; and we might now start to look at how to treat that subset patient population earlier,” Dr. Patel said.

It is crucial that physicians get into the habit of staging their patients and to push their histopathologist to report on the mosaic of typical risk factors that have become validated, including perineural invasion and depth of invasion.

According to Dr. Patel, following this approach is not only the best way to be able to provide SCC patients cutting-edge care but also assists in keeping all clinicians on the same page regarding staging and the potential therapeutic options among SCC patients.

“At present, I think the Brigham and Women’s Hospital staging system works a bit better than the AJCC based on what we know; however, I believe the AJCC should eventually become the gold standard staging system once certain factors and parameters are adjusted for. It is an imperfect system but only when you actively use it you can figure out the flaws. We need to all get on the same page and using these staging systems is the first step to help achieve that,” Dr. Patel said.

DISEASE PROGRESSION

A more acute awareness in the progression of disease from actinic keratosis (AK) to SCC and better understanding in the concept of field cancerization has also shifted the thinking in how to approach patients with actinic damage.

Actinic keratosis and field cancerization remain a concern, Dr. Patel said, mostly because of the less than optimal data available on how to best treat and manage these patients. Continued work on field cancerization has led researchers to believe that AKs are possibly simply markers in a complex disease process, not unlike the relationship between heart disease and stroke.

According to Dr. Patel, AKs are markers from an underlying problem and therefore, the underlying problem needs to be treated.

“We are becoming more aware of treating that underlying field cancerization, most recently witnessed in the efforts seen in trials with nicotinamide to potentially reduce the risk of non-melanoma skin cancer formation. As more work is being done into how we can quantify that risk progression from AKs to actual disease, or if there really even is an actual progression, we can approach it in a more sophisticated way using nicotinamide for oral prophylaxis, topical retinoids and topical chemotherapies, as well as rejuvenating modalities such as chemical peels and PDT, giving clinicians a more refined way of treating these patients,” Dr. Patel said.
There have been many important breakthroughs in the evolution of skin cancer therapy, some on the surgical level, such as Mohs surgery, and some on the medical level, such as the dawn of the immunomodulators — all of which have significantly contributed to advancing skin cancer treatment.

Dr. Tobechi L. Ebede, Mohs surgeon, Brooklyn, New York.

Options have expanded in skin cancer treatment FROM PAGE 34

with advanced or metastatic BCC who, prior to this breakthrough, were destined to multiple surgeries and radiation procedures with all of the risk-consequences and adverse events associated with those approaches was more than welcome for this patient population.

“We’ve always known that hedgehog pathway signaling was important in BCC and having such a targeted therapy in pill form is really a significant therapeutic breakthrough. This advance was particularly welcome for patients with Gorlin syndrome who end up developing countless BCCs. Vismodegib helps them reduce the number of BCCs that develop over time, offering them a medical therapy alternative to the traditional cornerstone surgery and radiation approaches,” Dr. Ebede said.

According to Dr. Ebede, combination therapies and a refinement of current modalities are likely the future of skin cancer treatments. Certain patient populations can particularly benefit from combination therapy Dr. Ebede said, such as those with field cancerization. Field cancerization is an aspect the clinician must consider when examining patients with BCC, SCC, and particularly those with multiple actinic keratoses (AK). Dr. Ebede will often combine a surgical removal of the primary tumor followed by field therapy such as ALA-PDT treatment to address the field cancerization lurking in the area. Other field therapy options the clinician can use to address field cancerization include topical imiquimod and 5-fluorouracil.

“These topical immunomodulators activate themselves versus light-activated PDT that help clear the irregular cells in the target area. Among the immunotherapy breakthroughs, these topical therapies have made a big impact in skin cancer treatment in terms of helping patients avoid multiple surgeries,” Dr. Ebede said.

Disclosures:
Dr. Ebede reports no relevant disclosures.

Adjunct molecular tests aid melanoma diagnosis FROM PAGE 35

ambiguous cases under a microscope include the mRNA expression profiling test (Castle Biosciences) and the Myriad Genetics MyPath test (Myriad Genetics), he says.

Similar to the adhesive tape stripping test method, the mRNA expression profiling test also uses PCR and looks for which genes are turned on and which ones are turned off. The Myriad Genetics MyPath test looks at the expression of a total of 23 different genes and which of those genes are turned on or off by the same technique.

“Interestingly, PRAME is also one of those genes analyzed in this test, similar to the target in the adhesive tape stripping test. As such, PRAME appears to be an important gene whether it is turned on or off and can be informative as to whether a lesion is malignant or not,” Dr. Gerami says.

The technique has also been proven in extensive studies to differentiate between benign and malignant lesions with 90% accuracy, Dr. Gerami says. The shortcoming in the testing for this particular technique however is that there has not been any solid validated information for lesions that are completely ambiguous to pathologists.

PROGNOSTIC AIDS
Once melanoma diagnosis has been established, an innovative molecular assay that can be used to help in the prognosis is the Decision-Dx melanoma gene expression profiling test (Castle Biosciences). Prognosis requires traditional staging and includes looking at parameters like Breslow depth and mitotic index to help clinicians discern whether a melanoma is early stage or more advanced in development. Decision-Dx test is a way to use molecular diagnostics to prognosticate or stage the disease as aggressive or not aggressive. Similar to other techniques as far as mRNA expression profiling, the assay of 31 genes also looks at which genes are turned on or off.

“The Decision-Dx melanoma gene expression profiling test has been shown to identify between 75- and 80% of those patients who basically are going to have metastatic disease, but otherwise by their other tests look like they may not have very aggressive stage disease. It is very good at identifying through molecular means looking at the tumor which genes are turned on and off, which of these melanomas is likely to be aggressive even if their traditional staging parameters don’t show it to be,” Dr. Gerami says.

A theoretical limitation of this molecular assay is that, although it has been studied quite extensively with different groups, achieving reproducible results, most of the larger studies were retrospective with only a few small studies with prospective data.

Dr. Gerami says it is important for dermatologists and physicians to embrace these new techniques and not shy away from them perhaps out of concern that such advances could replace them. And, he says, not to worry over becoming proficient with these new methods.

“These molecular assays have already become popular usage in other types of tumors like breast cancer. I believe that it is imperative that dermatologists step up and try to be active leaders in this niche before other specialties in this quickly evolving field,” Dr. Gerami said.

Disclosures:
Dr. Gerami reports having consulted with Castle Biosciences, Inc – C(H); DermTech International – C(H); Myriad Genetics Inc – C(H).
Survival rates in patients with squamous cell carcinoma were similar in those receiving high-dose chemoradiotherapy vs. conventional radical surgery, according to the results of a recent study published in the *British Journal of Dermatology*.

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

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

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

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

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

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

**ADVERSE EVENTS**

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

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

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

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

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

CHRISTINA BENNETT, M.S. | Cancer Network

Among advanced melanoma patients in the CheckMate 511 phase 3b/4 trial, raising the nivolumab dose to 3 mg/kg and lowering the ipilimumab dose to 1 mg/kg leads to a better safety profile without compromising efficacy. The trial results, recently published in the *Journal of Clinical Oncology*, may offer patients with advanced melanoma a safer dosing regimen of nivolumab and ipilimumab.

“This study is an important step towards optimizing combination immunotherapy with ipilimumab plus nivolumab,” Shailender Bhatia, M.D., a medical oncologist at Seattle Cancer Care Alliance, says. He was not involved in the CheckMate 511 trial. “Using a lower dose of ipilimumab at 1 mg/kg appears to lower the risk of severe toxicity, while retaining the efficacy of the combination.”

The CheckMate 511 trial included 360 adult patients with treatment-naïve, unresectable stage 3 or 4 melanoma. Patients were randomly assigned treatment with either the standard approved combination therapy or alternative dosing. The primary trial endpoint was met, showing a statistically significant lower incidence of treatment-related grade 3 to 5 adverse events in the alternative dosing group.

The alternative dosing of nivolumab 3 mg/kg plus ipilimumab 1 mg/kg did not appear to compromise clinical benefit; however, the study was not designed to formally show noninferiority of the alternative dosing compared with the standard dosing. Between the alternative dosing and standard dosing groups, the response rates were similar (45.6% vs 50.6%); complete response rates were also similar (15.0% vs 13.5%). Median progression-free survival (9.9 vs 8.9 months), median time to response (2.83 vs 2.79 months), and proportion of responders (76.8% vs 75.6%) were similar between groups. For both groups, median overall survival and median duration of response were not yet reached.

“The results of [the] CheckMate 511 study should be discussed with the patients who desire aggressive immunotherapy with the combination, as compared to anti-PD1 monotherapy, but are wary of the high rate of severe toxicity with the traditional doses of the combination,” Dr. Bhatia said. “In my practice, I routinely discuss [nivolumab 3 mg/kg plus ipilimumab 1 mg/kg] as an alternative option to [nivolumab 1 mg/kg plus ipilimumab 3 mg/kg] and anti–PD-1 monotherapy, so that my patients can make an informed decision based on their desire for aggressive immunotherapy and risk tolerance.”

The study investigators noted that longer follow-up may be needed to “better characterize efficacy outcomes.”

Quick TAKES

CheckMate 511 trial included 360 patients with unresectable stage 3 or 4 melanoma.

Patients were randomly assigned treatment with standard approved combination therapy or alternative dosing.

Primary trial endpoint was met, showing a statistically significant lower incidence of treatment-related grade 3-5 adverse events in the alternative dosing group.
If you want to get paid promptly in 2019, don’t get too comfortable with biopsy codes you’ve been using for years, said Alexander Miller, M.D., F.A.A.D., and a member of the AMA CPT Advisory Committee. He spoke about coding and office management Saturday, March 2 at the American Academy of Dermatology’s (AAD) annual meeting in Washington, D.C.

“I wanted to provide greater detail and granularity about these codes, which can be confusing,” says Dr. Miller, who practices in Yorba Linda, Calif.

**TOP THREE**

Start with the three types of primary biopsy codes and three kinds of secondary codes, he said. Primary codes remain stratified by technique: tangential, punch and incisional.

“It’s critical to keep the proper hierarchy in mind,” Dr. Miller says. “When more than one biopsy is done on the same patient, on the same encounter date on the same person and should not be appended to additional biopsy codes.

A .59 modifier indicates a separately identifiable procedure done on the same encounter date on the same person and should not be appended to additional biopsy codes.

Use Medicare National Correct Coding Initiative Procedure-to-Procedure Coding Edits as a resource.

‘add-ons’ for tangential,” says Dr. Miller, who emphasized these codes:

- **11102**: Tangential biopsy
- **11103**: each additional
- **11104**: punch biopsy
- **11105**: each additional
- **11106**: incisional biopsy
- **11107**: each additional

**UNDERSTAND ADD-ONS**

A .59 modifier, which indicates a separately identifiable procedure done on the same encounter date on the same person, should not be appended to additional biopsy codes, as their valuation has already been adjusted, he said. Adding a .59 modifier could facilitate a further, inappropriate 50% reduction by insurers.

If more than one procedure, completely different from the biopsy, is done along with the biopsy, know whether that .59 modifier has to be applied to any of the other procedure codes and which code should get the modifier. That’s where savvy use of the Medicare National Correct Coding Initiative (NCCI) Procedure-to-Procedure (PTP) edits comes into play.

“The system determines whether two paired codes,
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RUC ensures physician input

STEPHANIE STEPHENS | Staff Correspondent

Quick Takes

After the RUC submits its recommendations to CMS, which makes a determination.

RUC’s involvement ensures physician input.

100 specialty societies and organizations submit data around valuations for new and revised CPT codes via surveys.

Behind the clever title lay a very practical presentation designed to demystify the American Medical Association (AMA)/Specialty Society Relative Value Update Committee (RUC), first created in 1992.

On March 2 at the annual meeting of American Academy of Dermatology (AAD) in Washington, D.C., Mark D. Kaufmann, M.D., joined four other colleagues fluent in coding and office management, to explain the nuances.

Dr. Kaufmann is also a member of AAD’s Board of Directors. His goal was to “lay out the process” of code valuation, a topic often pondered but not always thoroughly understood. Even if perceived to be somewhat “enigmatic” overall, the RUC is actually a fair and balanced system, he says.

That’s because after the RUC evaluates a procedure code, it sends its recommendations to the Centers for Medicare and Medicaid Services (CMS). The agency then makes the final decision on valuation, but the RUC’s involvement ensures input from physicians who provide invaluable expertise on complex medical procedures.

How CPT codes are ‘valued’

Dr. Kaufmann explained that most commercial insurance fee schedules are based on a percentage of the Medicare Fee Schedule, which is decided with consideration of advice and recommendations of the RUC.

It helps to understand that the total relative value unit (RVU) is comprised of three components: physician work, professional liability insurance, and practice expense. More specifically, the practice expense portion of the total RVU is comprised of physicians’ and nurses’ time, along with supplies and equipment. These are all valued by the expert panel’s assessment as components of a provided medical service. To whittle down further, physician work contains four components: time to perform service; technical skill and physical effort; mental effort and judgment; and psychological stress.

Payment is calculated via an equation of Total RVU X Conversion Factor, the latter number determined by Medicare each year.

Survey says

In addition to physicians and medical advisors, 100 specialty societies and organizations also submit data as follows:

Defining two procedures done during the same encounter, should require a .59 modifier to distinguish the two procedures as distinct services,” Dr. Miller says. “Then, the insurer will be able to adjudicate the claim appropriately, realizing that these two procedures are not integral to each other, but are completely independent and therefore both payable.”

Use Column 2

It’s anticipated that around July of this year, NCCI will adjust policy with Medicare Administrative Contractors (MACs), he notes, so the modifier may be entered on either one of the paired codes in Column 1 or Column 2, and payment will be properly adjudicated.

“Until then, to be paid always append the modifier to the Column 2 code. ’If it ain’t broke, don’t fix it,’ and wait for notification from the AAD before altering your billing processes,” Dr. Miller adds.

Be aware that with new biopsy codes, pairings are “jumbled and not fully predictable” as to which code will be in Column 1 — a biopsy code or another paired code, such as destruction.

“Would be easy to erroneously put the modifier on the wrong code,” Dr. Miller says, adding that the jury’s out as to how private insurers will handle these changes.

Reference:

F048 - Coding and Office Management, Room 201. "What’s the RUC?" Mark D. Kaufmann, M.D. 9 a.m., March 2, American Academy of Dermatology, Washington D.C.
Dr. Brian Biesman and Dr. Michael Gold invite you to the 2019 Music City SCALE Meeting. The meeting is for physicians and clinicians interested in enhancing their practice and learning more about the latest procedures in aesthetic medicine. In addition to the educational sessions, there are live patient workshops and an exhibit hall with the leading members of the industry.

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“Every time something changes in what, when, where, or how a patient chooses to do business with you, use that opportunity to learn something about the patient and about your practice.”

Ryan Suydam, chief experience officer, Client Savvy

Attract loyal patients

Quick TAKES

Customer service and patient experience are different things.

Perfecting client experience requires that you really know your patient’s journey.

Organizations that implement customer experience strategies are more likely to realize revenue growth.

When Ryan Suydam, chief experience officer at Client Savvy, wanted to make an appointment with a local dermatologist, he tried to book his appointment online. He found the practice he wanted to use didn’t offer this option, so he made an appointment with a competing practice. Without even visiting the initial practice, he’s already had a negative patient experience.

Mr. Suydam wants your patients to have an excellent experience. Out of the gate, he also wants to clearly differentiate between customer service and the patient experience.

STEPHANIE STEPHENS | Staff Correspondent

Empathy mapping

a) Break down each patient relationship into five core phases:

- **Entice** (the patient associates his need with your brand)
- **Enter** (the patient engages you for a visit)
- **Engage** (the patient receives your services)
- **Exit** (the patient follows your medical advice after they leave)
- **Extend** (the relationship extends after the visit)

b) For each of these five phases, ask the following questions:

- What questions does the patient have?
- What might they need to answer those questions?
- What might they think (positive and negative)?
- What might they feel (positive and negative)?
- What might they say (positive and negative)?
- What might they do (positive and negative)?

“’The former is very much reactive,’” Mr. Suydam says. “You have to be in the process of being served to have bad customer service. That doesn’t refer to the overall experience that truly high-value clients expect, and that causes them to walk into your practice once and then return on a regular basis.”

KNOW YOUR ‘TOUCH POINTS’

Perfecting the client experience requires you to look comprehensively at your clients’ emotional state that occurs with every touch point with your brand, he says. “In medicine, that can involve a journey that begins when the patient starts thinking about you, then how long they wait, how their records are managed, and how their bills are processed. And of course, it includes their visit with the dermatologist and how they think about the interaction when it’s over.”

Client experience management is about understanding and managing all touch points, he says. “If you identify a weakness, then redesign that touch point so it’s not a frustration,” he says.

EFFECTIVE CUSTOMER EXPERIENCE IS A WINNER

Yes, this is all worth your time, Mr. Suydam says. “Firms that have implemented customer experience strategies are 300% more likely to realize substantial growth in revenue and profit. These firms are more likely to attract and retain both the best clients and the best employees. Employee engagement goes up. Emergencies that interrupt weekends and family vacations go down. Nearly everything in the business improves when everyone knows how to make the clients’ experience a priority.”

He shares his top five tips on how to focus on your patient experience.

1. **INTRODUCE CLIENT EXPERIENCE THINKING.**

   At your staff meeting, introduce a CUSTOMER EXPERIENCE moment, an experience one patient
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- JEANINE DOWNIE, MD

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“This is one of the few meetings that I sit through all of the content because it’s so interesting, innovative and cutting-edge.”

- MATTHEW ZIRWAS, MD

“Part of the benefit of the format is everyone has the chance to weigh in. Often times, you’ll have a speaker giving one viewpoint, and someone in the audience chimes in and offers and alternative viewpoint. That kind of expansive thinking isn’t something you’ll find any place else.”

- CANDACE SPANN, MD

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How does your practice rate on trust?

STEPHANIE STEPHENS | Staff Correspondent

Trust might not be a word you typically consider when thinking about your dermatology practice, but it is an imperative part of all organizations, says Mike Goossen, CPA and CEO of Columns 4 Success.

“When high levels of trust are present throughout an organization, high performance is possible,” Goossen says. “Trusting employees feel their organization, leaders and managers have their interests in mind when making decisions.”

According to the 2019 Edelman Trust Barometer, an international communications marketing firm, trust has changed profoundly in the past year with "my employer" emerging — perhaps surprisingly — as the most trusted institution.

“People have shifted their trust to the relationships within their control, most notably their employers,” the analysis notes. “Globally, 75% of people trust ‘my employer’ to do what is right, significantly more than [non-governmental organizations or] NGOs (57%), business (56%) and media (47%).”

In its trust analysis, Edelman reports that “employees are ready and willing to trust their employers, but the trust must be earned through more than ‘business as usual.’

“The rewards of meeting these [employees’] expectations and building trust are great,” Edelman says.

THE TRUST IMPERATIVE
Trust is critical to organizational success, Mr. Goossen says. When trust is low in an organization, productivity is lower, often with conflict. A high-trust organization makes employees feel they’re supported and taken care of, he says.

“A lack of it means there’s very little opportunity to reach whatever goals that organization has, no matter the size,” says. “It’s the difference between a culture of positivity and a culture of fear and trouble.”

TRUST IN THE BUSINESS CLIMATE
High-performance organizations understand the vital role trust plays within the organization, but maybe you wonder how trust factors into the success of your busy dermatology practice?

Mr. Goossen advises you to first consider business challenges that include

1) environmental demands such as competition, globalization and regulation
2) customer demands for higher quality, lower costs and better delivery
3) financial demands for growth, increased profits and ROI and
4) employee demands for growth opportunities, sense of “partnership” and job challenges.

In the cycle of trust, employees engage in dialogue, see others as allies, commit to win-win outcomes and are trustworthy. Characteristics of the cycle of mistrust are just the opposite, he says. Mr. Goossen urges us to consider our interdependence and that:

- The work of an organization is accomplished through people.
- People are interdependent.
- Interdependence requires collaboration.
- Collaboration is built on a foundation of trust.
- Trust in practice

So now you’ve decided it’s time to build or improve trust. To do that, you need to first provide visionary leadership, because that demonstrates integrity, he says. Consider the quote from John Scully, former CEO of Pepsi and Apple, who said, “The future belongs to those who see possibilities before they become obvious.”

Next, provide continuous learning, because competency is enhanced when you provide leadership by purposefully developing yourself and those around you, says Mr. Goossen. Don’t just say it, but do it when you do things like establish a budget for development organization-wide. You and your colleagues attend professional conferences. You establish a process of sharing what people learn from attending conferences, training seminars and workshops. And this is the clincher: You include a personal development plan as a requirement of employment, so employees keep going and growing.

Mr. Goossen says there’s more. You must also build relationships with doctors, patients and suppliers, but most importantly with your team. To do this, think like a neuroscientist for a moment, understanding that human response modes are either analytical or logical, or automatic and emotional.

“A strong body of research tells us most people all the time
and all people most of the time are in the non-thinking automatic mode, yet most presentations are geared to the heavy-thinking analytical mode,” says Mr. Goossen. “To drill down to the basics, remember that people are, you and I are, emotional beings who think, not thinking beings who feel.”

THEY’RE JUST YOUR TYPE

People employed in a medical office such as your dermatology practice are there, in part, because of their personality profile, Mr. Goossen says.

“You probably work there because you’re a caring, supportive and helpful person. The baseline of the average person in the medical industry is someone who values and wants to be trustworthy. The environment in the office needs to be supportive of that.”

If you identify a potential breach of trust, it’s important to nip it in the bud, and you do that because you’re aware of what transpires among employees — even the smallest things, he says.

Make it clear that discussions about impending problems are welcome at weekly staff meetings. Ask everyone, “Is there any issue that’s occurred during the last 24 hours that has caused a problem? If so, let’s talk about it.”

2. INSTITUTIONALIZE EMPATHY.

All clients have perceptions, sentiments, feelings, wants and needs that you don’t know about. You can gain insight about clients’ potential sentiments with internal reflection, and discover their actual sentiments by asking them directly. Anticipated sentiments are quickly catalogued and understood with a simple process called client empathy mapping. (See sidebar)

Even though a patient visit may only last 15 minutes, it might take your team a few hours to build out a real map of the experience.

“Brainstorm actions you can take to address any negative outcomes and encourage any positive outcomes,” he says. “From there, you can prioritize and design the experience to craft the best one possible.”

3. TRANSFORM EMPATHY INTO LISTENING

Create purposeful or active listening to gain more patient insights, perhaps with client feedback. “With practice, employees become better listeners in meetings and on phone calls, and better observers of writing, while offering empathetic and more complete solutions to problems,” Suydam says.

“Every time something changes in what, when, where or how a patient chooses to do business with you, use that opportunity to learn something about the patient and about your practice,” he says.

4. EMPLOY STRATEGY, DESIGN AND GOVERNANCE.

“Now is time to define a specific strategy that describes the intended patient experience,” he says. “For each strategic goal in your business plan, define exactly how your patient experience supports the overall goal. Create a governance committee to establish the criteria for how patient input and your experience design ideas will be used at the practice. This group should also pursue root causes of failed patient experiences and recommend systemic fixes.”

5. UTILIZE ENCULTURATION.

“To fully enculturate or learn the culture of CUSTOMER EXPERIENCE, ‘experience thinking’ needs to be core to all decision-making processes and initiatives,” says Suydam. “You will make hires through the lens of CUSTOMER EXPERIENCE. You will set firm strategy and promote leaders with CUSTOMER EXPERIENCE in mind. Your team will, on their own initiative, identify experience opportunities. They’ll work in ways that demonstrate patient empathy in everything from marketing, messaging, and brand, through service delivery, accounting, finance, and IT — the use of your EMR or EHR — and will operate in ways that are sensitive to the client.”

Now you have tools to recalibrate the patient experience in your practice, to attract patients there and keep them coming back.
It’s been a long day. You managed to squeeze in three extra patients—and the only thing between you and the door is a few chart updates. Just as you finish, you are alerted to a new email from what looks like a well-known insurance company, complete with a recognizable logo. You recall your office manager mentioning that this company had recently declined several reimbursement claims. The email refers to you and your office manager by name—and informs you that you can clear up your reimbursement issues if you just click a link and provide some extra information. What do you do?

Many healthcare professionals would click without a second thought—and, in doing so, they might very well be inviting a hacker into their networks via a sophisticated electronic communications scam called spearphishing. These personalized attacks are on the rise in healthcare and can have serious consequences for organizations of all shapes and sizes.

“As today’s day and age, hackers are going after people instead of the technology directly,” says Anahi Santiago, CISM, chief information security officer at Christiana Care Health System in Wilmington, Del. “And the breaches that happen as the result of these attacks not only give hackers access to protected patient data but also the ability to disable networks which, essentially, can disable providers and organizations from being able to effectively care for their patients.”

Parham Eftekhari, executive director of the Institute for Critical Infrastructure Technology, a cybersecurity think tank, says hacking a targeted practice called spearphishing. Data breaches give hackers access to protected patient data, as well as the ability to disable networks. Physicians are good targets because they’re busy and implementing new technologies. Educating yourself and your staff can protect your practice.
that spearphishing is a more sophisticated form of phishing, targeting a specific organization or individual.

“With phishing, the hacker doesn’t necessarily care who clicks, he or she is casting a wide net in hopes of getting someone to do so,” he says. “But spearphishing uses a tailored lure—a spear, so to speak—to make the email with those links more appealing to a specific victim.”

In a recent American Medical Association (AMA) survey, 4 out of 5 survey respondents said they had been the target of a cyberattack, with more than half of those stating the attack was the result of a phishing lure. Eftekhari says that is not a surprise—and that providers often are an easy mark for hackers because the healthcare environment is so fast-paced.

“Physicians are busy and their focus is on helping patients. There’s more and more technology in practices, and that technology can often be frustrating for them,” he says. “So if they do get an email, and it looks somewhat legit, it’s not surprising they might click and download and execute a malicious payload.”

Few medical schools discuss the ins and outs of cybersecurity, even though medical practice has become more technology-intensive—and hacks can affect both patient safety and patient satisfaction. James Kaplan, MBA, a partner specializing in information technology (IT) infrastructure and cybersecurity for the management consulting firm McKinsey & Company, says that providers should be concerned about the consequences. Those consequences may include the theft of protected health data—and the consequent fines from the U.S. Department of Health and Human Services’ Office for Civil Rights—as well as the loss of the practice’s financial data.

But more concerning is the possibility of being locked out of EHRs or medical devices and IT systems that play a critical role in providing patient care. The AMA survey reported that the majority of physicians who had been hacked suffered up to four hours of downtime, with many reporting they were unable to provide care for an entire day.

**PROTECT YOUR ORGANIZATION, PROTECT YOUR PATIENTS**

Leslie Saxon, M.D., a cardiologist and executive director at the University of Southern California Center for Body Computing, says that protecting an organization from spearphishing and other cyberattacks starts with education about “cyber hygiene,” or common practices individuals and organizations can undertake to help improve network security.

“It’s hard to create awareness, especially since cybersecurity really is a shared responsibility between providers, clinical and office staff, and even patients,” she says. “That’s why the right education is so important. It’s like handwashing or any other hygienic practice. You have to teach the basics throughout the system in order to be successful.”

The AMA has published specific cybersecurity guidelines for physicians on its website to promote proper cyber hygiene. It also recommends that physicians familiarize themselves with cybersecurity recommendations offered by the Department of Homeland Security. Eftekhari says that provider practices can also benefit from contacting IT organizations that likely have local chapters in their area, like the Healthcare Information and Management Systems Society (HIMSS) or the International Information System Security Certification Consortium (ISC2).

“Cybersecurity can be a challenge for smaller organizations—but that’s no excuse not to practice good cyber hygiene,” he says. He explains that organizations like HIMSS or ISC2 have education materials available that can help educate physicians and their staff, and often hold meetings or seminars to help raise awareness of different cyber threats and how to best deal with them. He says they may also be able to connect your practice with a local expert who can train your staff about appropriate cyber hygiene for a fee.

But Santiago says that practices can adopt cyber hygiene basics before any formal training. She says that provider practices should make sure to keep all network systems patched and updated to help protect them from any potential attacks. Some systems can be set to do so automatically. And she says that maintaining good password hygiene is also critical to success.

“With so many technologies in use, I understand why people want to use one password for a bunch of different systems or keep passwords written on a post-it note somewhere,” she says. “But don’t do it.”

Cybersecurity experts recommend that passwords be difficult to guess—no children’s names or birthdays—and at least eight characters long. Santiago recommends using passphrases so they are easy for physicians to remember but difficult for hackers to crack.

“For an electronic health record system, your password could be a phrase like ‘I love to care for patients,’” she says.

But most importantly, Santiago recommends that physicians and clinical staff always slow down and think before they click. “All it takes is one person to click on the wrong link to result in a breach,” she says.

Kaplan says there are several indicators that an email or social media message may be a spear-phishing attack in disguise. He says that emails telling recipients they need to click immediately, or have return email addresses or web links with 0’s replaced with zeros or L’s with ones mean that recipients are likely clicking at their peril. If it is unclear whether the message is legitimate, Santiago recommends logging into the company’s website or to pick up the phone instead of clicking.

She adds that physicians also need to understand that cybersecurity attacks don’t happen just on laptop and desktop computers. Personal and professional mobile devices can also put their networks—and their patients—at risk.

“Mobile devices are no different than computers. They can be hacked and they can have viruses—many people don’t realize that,” she says. Today, she says, mobile devices often hold more information than desktop computers—and that requires physicians and clinical staff to be vigilant about how they use their tablets and phones. The same guidelines regarding passwords and links apply.

“You really need to guard your phone,” she says. “I like to say ‘treat your phone the same way that you would treat your wallet.’”

What about outsourcing cybersecurity efforts to protect from spearphishing attacks? While many vendors offer cybersecurity solutions, Kaplan says there is often a “security poverty line,” with smaller organizations lacking the resources to hire dedicated information security staff or procure good IT software to support cybersecurity efforts. But with that said, he says that organizations can get some degree of security investment by utilizing cloud-based services.

“When you procure cloud-based services, even if it’s just for your email and calendar, you are also investing in the security infrastructure of the vendor you choose,” he says. “While it doesn’t absolve your organization of responsibility, it does make being more secure less resource intensive.”

There is no one-size-fits-all approach to cybersecurity, but experts agree that good cybersecurity is a community effort. Providers need to make a point of educating and training staff about proper cyber hygiene practices. And as more individuals use their personal devices to interact with EHRs or provide medical information, share those practices with patients, too.

“This is about changing the culture in your practice to promote cyber hygiene and integrate cybersecurity as part of your values,” says Eftekhari. “This goes beyond talking the talk—physicians need to walk the walk to protect their networks and, ultimately, their patients from spear-phishing attacks.”
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Cosmeceutical addresses estrogen-deficient skin

EMEPELLE from Biopelle, Inc., is the first skincare line designed for women with age-related estrogen-deficient skin (EDS). Natural levels of estrogen decline as the body ages, which causes a decline in collagen levels and leads to symptoms such as dryness, atrophy, wrinkling and skin thinning. Emeppelle, which was launched at AAD last month, includes non-hormonal ingredients that help to restore the natural function of EDS and address collagen loss in aging skin.

FOR MORE INFORMATION: emepelle.com

NEOVA launches “after sun” skincare line

Photodamage can continue to happen for up to six hours after sun exposure, according to a recent Yale University study. The DNA DAMAGE CONTROL AFTER SUN BODY REPAIR skincare line from NEOVA SmartSkincare uses three DNA repair enzymes—Photolyases, Endosomes and Mitosomes—to counteract this type of photodamage and accelerate the skin’s natural ability to repair solar DNA damage. The product line was showcased at AAD in March.

FOR MORE INFORMATION: neova.com

RF device offers range of modalities

Cynosure’s TEMPSURE SURGICAL RF TECHNOLOGY, which was demonstrated at AAD in March, uses 300-watt and 4-MHz radiofrequency to allow precise incisions without damage to the surrounding tissue. The new technology extends the capabilities of the existing platform and includes different electrodes that can be incorporated with the main unit. “The cutting-edge technology of the TempSure platform will now allow doctors to transition seamlessly from invasive to non-invasive treatments on one device,” said Kevin Thomal, Hologic’s Division President, Cynosure.

FOR MORE INFORMATION: cynosure.com

Organic mineral foundation provides sun protection

Induction Therapies launched COLOR-LOGIX at AAD last month. It is an organic foundation that provides coverage for skin concerns such as rosacea, post-procedural microneedling, distended capillaries, blemishes and hyperpigmentation. According to the company, both the titanium dioxide and zinc oxide in the product act as a natural sunscreen, while the mica adds softness and radiance to the formula. The iron oxides in the formula deliver the color in the foundation.

FOR MORE INFORMATION: inductiontherapies.com

SENTÉ’s night cream reduces wrinkles, evens skin tone

SENTÉ INTENSIVE BIO COMPLETE CREAM, launched at AAD in March, features exclusive dermatan sulfate analog (DSA), chondroitin sulfate analog (CSA) and 0.5% encapsulated pure retinol, which evens skin tone and texture while also reducing wrinkles with little to no irritation. According to clinical results, 95% of individuals reported improvements in wrinkles, firmness, discoloration and overall skin appearance.

FOR MORE INFORMATION: sentelabs.com

Vitamin C serum fights damage caused by blue light

Revision Skincare’s C+ CORRECTING COMPLEX 30%, which launched at AAD last month, encourages the skin’s natural production of vitamins C and E to enhance skin brightness, tone and firmness. According to the company, it contains a patent-pending MelaPATH Technology, which protects against free radical damage that can be caused by blue light from electronic devices. Results from a clinical study indicated that 87% of participants reported brighter skin, and showed a reduction in fine wrinkles and improved skin smoothness.

FOR MORE INFORMATION: revisionskincare.com
The anti-wrinkle diet

Can your patients eat their way to healthier, more beautiful skin?

Dr. Zoe Draelos, M.D., offered skin care guidance at 2019 AAD for what to eat and how to supplement in her presentation, “Nutraceuticals: Is it Possible to Eat Your Way to Skin Health?” This is what she had to say:

**Eat this**

- 2/3 cup carrots (Vitamin A/ beta carotene)
- 1 raw tomato daily (Vitamin C)
- 1/2 raw avocado, olive oil (Vitamin E)
- 1 slice watermelon (lutein/zeaxanthin)
- 1 raw apple with skin (Combination phytochemicals)
- 1 cup fresh or ½ cup dried blueberries (antioxidant blend)
- Fish, chicken, yogurt, cheese (protein sources)

**Take this**

- Vitamin D (2000 IU)
- 1000 mg flaxseed oil 1-2x per day
- Multivitamin with minerals

**Avoid this**

- Butter, whole milk
- Margarine
- Red meat, processed meat
- Potatoes
- Sugar
- Soft drinks