Wart treatment trials hold promise
Effective on-label management options may be coming

INGRID TORJESSEN | Staff Correspondent

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There are several drugs being studied for the viral skin infections that cause warts and molluscum contagiosum, which may provide more effective treatment options than what is currently available.

While these conditions are self-limiting, and will eventually resolve themselves, untreated warts could last two years, and molluscum contagiosum could last one year; although, both conditions could last much longer.

Current treatments have limited effectiveness and are used off label, which can cause additional discomfort through tissue damage. Unless the conditions affect pressure points on the skin and cause discomfort, the biggest concerns for most patients are social and cosmetic. As a result, the best approach may be to let the condition run its course, some experts say.

**PULSED DYE LASER (PDL)** is widely accepted as the gold standard treatment of port-wine stains (PWS), but there is controversy about when to begin treatment and in what setting it should be done.

According to Roy G. Geronemus, M.D., the answer to the first question is, the sooner the better. Earlier treatment allows for better outcomes and avoids the adverse sequelae that accompany a delay. In addition, his experience supports performing the treatment in the office without the use of anesthesia where it can be done very safely andatraumatically for both the child and the parents.

“Infants born with a PWS should go from out of the hospital into the dermatologist’s office,” says Dr. Geronemus, director, Laser & Skin Surgery Center of New York, and clinical professor of dermatology, New York University School of Medicine.

Study examines port-wine stain treatment in infants

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**EARLY INTERVENTION** CONTINUES ON PAGE 33

**TREATMENTS IN DEVELOPMENT**

Clinical trials are primarily examining patients with molluscum contagiosum, which has no current treatment.
DermatologyTimes is guided by a core group of trusted physician experts who review meetings; suggest topics and sources; and conduct interviews.

**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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Medical or surgical intervention is not always the best solution…

First, do no harm

by ELAINE SIEGFRIED, M.D.

Dr. Siegfried is professor of pediatrics & dermatology, Saint Louis University Health Sciences Center, St. Louis, Mo.

W as and molluscum are common, benign and self-limited conditions that are considered much more than a nuisance for the many patients (and parents of pediatric patients) who visit a dermatologist. There is a long list of potential treatments for these conditions because the number of options is often inversely proportional to the efficacy of the best one.

Many patients expect a treatment and are dissatisfied with mere anticipatory guidance about the natural history, iatrogenic risks and lack of a uniformly effective best option. Dermatologists often feel obliged to do something and usually resort to liquid nitrogen cryotherapy, the most efficient in-office treatment, and one which has a defined procedure code. But this approach only satisfies one of the timeless criteria for practicing the art of medicine: “to cure sometimes, to relieve often, to comfort always.”

As healers, our quest to cure can overshadow the fundamental principle of bioethics, “primum non nocere.” Striving to solve problems can also create them. Most interventions have risks and unintended consequences that must be weighed carefully against the risk of the disease. Medical or surgical intervention is not always the best solution for a perceived problem, and every problem is not as easily addressed as a nail that can be driven with a hammer. So, one of my mottos is: never recommend evaluation or treatment with higher risks than the worst possible diagnosis in the differential.

When it comes to easily recognized, benign, self-limited conditions, I have increasingly become a treatment nihilist. This bias is the cumulative result of many memorable patients I have seen in the last 30 years who received treatments with associated risks that far outweighed those of their skin disease.

I have experienced the angst generated by countless benign nevomelanotic nevi (Spitz, congenital, even unwanted IDN on the shoulders/cheat), as well as the disproportionate investment of time and resources, the unfortunate post-operative complications, physical scars and long-term anxiety sustained by children with low-risk lesions and their families. Other benign birthmarks such as nevus sebaceous, epidermal nevus and prominent nevus simplex carry the same management challenges.

My experience as the mother of a child with a facial capillary malformation added heartfelt empathy and long-term follow-up to my perspective. I have also gained enough experience to rely less on the results of invasive tests than my clinical impression. I no longer biopsy typical granuloma annulare, mastocytosis, juvenile xanthogranuloma or pilomatrixoma, and I much less frequently order labs for patients on isotretinoin and methotrexate.

Hemangioma of infancy is an interesting example of the value of an evidence-based, first-line treatment for a generally benign, self-limited condition. An estimated 10% of infants develop at least one of these lesions within the first three months of life, and a significant proportion seek medical evaluation. Prior to the 2008 serendipitous discovery of propranolol, a variety of often costly higher-risk, lower-efficacy treatments were used, including radiation, surgical excision, systemic corticosteroids, vincristine and laser. Clinicians also resorted to using myriad wound-healing techniques — including beca-
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Dr. Toxin, a highly successful cosmetic dermatologist, has heard about an exciting new neuromodulator that is popular in South America, but has not yet undergone clinical trials for the U.S. Food and Drug Administration (FDA). Dr. Toxin traveled to South America and learns that it may be much less expensive than the currently available FDA-approved neurotoxins, and it may last longer. While he cannot use this product in his U.S. office, he discusses the product with the national press at the urging of his marketing department.

Dr. Toxin is excited about the growing number of companies studying and gaining FDA clearance for new neurotoxins. His growing publicity leads to an increase in cosmetic patients requesting appointments. A fellow dermatologist warns that his marketing may lead to the FDA “coming after him.” They are both aware that the FDA had contacted a well-known cosmetic dermatologist in the past about her exuberance in the press over a toxin that was undergoing FDA studies. Does the FDA have jurisdiction over Dr. Toxin?

The FDA receives its authorization under the Food, Drug and Cosmetic Act (FDCA). This regulation both governs interstate distribution of medical products and mandates that both drugs and devices must, through evidence-based studies, be shown to be safe and effective for their on-label purpose.

The underlying purpose of the FDA is to be certain that drugs and devices are safe and effective; and, to ensure that drug/device promotion is not false and/or misleading.

The FDA does this through a variety of methods that directly impact pharmaceutical companies. Included in this oversight is the FDA’s regulation of promotional programs sponsored by the pharmaceutical industry. In fact, in such programs, physician executives who speak on behalf of a pharmaceutical company must provide fair balance, stay “on label,” and be truthful.

Despite these regulations on pharmaceutical companies and their physician executives, the FDA, as well as nearly all insurers, recognize that physician use of drugs and devices in an “off-label” manner is a benefit to patients.

In the end, the FDCA authorizes the FDA to regulate manufacturers’ activities. The FDCA does not authorize the FDA to regulate physician behavior. Having said that, as described above, the FDA can regulate physician executives who work for drug and device companies.

There are also other exceptions when the FDA can regulate physician behavior. In 2004 a drug scandal emerged when four people were temporarily paralyzed after receiving a botulinum toxin that was not approved for human use. The doctor in that case led investigators to a California-based company that sold large volumes of a research grade neurotoxin to TRI, a Tucson, Arizona-based company. This material was, in fact, approved for use in animals by veterinarians; it was not approved by the FDA for human use. The FDA shut down the facility and found a list of some 200 doctors who had used the material. The question raised at the time was whether the FDA had jurisdiction over these doctors.

The FDA does have jurisdiction over promotional comments by physician investigators of drugs even if that physician is not an executive of the pharmaceutical company. One of the FDA-related regulations (21CFR 312.7a) states that “a sponsor, investigator, or any person acting on behalf of the sponsor or investigator cannot promote a drug as safe and effective for the purpose for which it is under investigation.”

If Dr. Toxin had made his promotional comments about a drug that he was personally investigating during an FDA trial, the FDA could stop this behavior. Where Dr. Toxin was “promoting” a drug that was not at all available in the United States, the FDA is unlikely to assert its jurisdiction over him.
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Reflections on the 40th anniversary

by DR. RONALD G. WHEELAND, M.D.

Dr. Wheeland is in private practice in Tucson, Ariz. He is a past president of the American Academy of Dermatology, the American Society for Dermatologic Surgery and the American Society for Laser Medicine and Surgery. He is a member of the Dermatology Times editorial board and a co-medical editor.

For this issue, Norm Levine and I have been asked by the Content Channel Director for Dermatology Times (DT), Heather Onorati, to provide some reflections on the publication for its 40th Anniversary from our many years on the Editorial Advisory Board (EAB). My plan is to review my personal involvement with DT and couple that with a brief summary of what was happening in the dermatologic surgery world over those same years.

Just after having finished my Mohs Surgery fellowship at the Cleveland Clinic Foundation, I was approached to join the DT EAB by one of my patients who, at the time, was the managing editor for DT, which was — and still is — located in North Olmsted, Ohio, a small suburb of Cleveland. He asked me if I would be interested in helping to oversee a new dermatology publication by suggesting additional assistant editors, review content, and write editorials. He vowed to produce a high-quality dermatologic publication that offered practical analysis of recent studies, regulatory updates, articles on new techniques and devices, as well as business solutions to practical problems in the dermatologic office. I was one of several dermatologists asked to be involved, including Norm Levine, a medically oriented dermatologist at the University of Arizona and Larry Schachner, a pediatric dermatologist at the University of Arizona and Larry Schachner, a pediatric dermatologist at the University of Arizona.

My appointment at the Cleveland Clinic put me in close proximity to the DT headquarters, so I got to work closely with the team and was impressed with staff and the effort they were making to live up to the goals as they were originally stated to me.

To give a reference point as to what was happening in dermatologic surgery at that time, the Cleveland Clinic had three full-time Mohs surgeons and also had the two most current lasers, the argon and CO2, at our disposal. Cosmetically, we were performing hair transplants which had been around for a while but also the newer scalp reduction procedure. The only filler agent at that time was purified bovine collagen, Zyderm, and its more concentrated cousin, Zyplast.

In 1984, Dean Celia, the managing editor at that time, asked the three physician editors to review each issue prior to publication for accuracy and quality. We probably did full reviews on only three issues before we all agreed that we couldn’t keep pace with the publishing process in a timely fashion. We switched to a post-publication review for a few additional months before deciding the staff was doing such a good job that our suggestions were only minimal and didn’t provide a substantial improvement over what had been produced.

One of my favorite personal stories from that time involved Dean. He was an avid fan of the Cleveland Indians and would occasionally fly to their spring training in Tucson Arizona, meeting Norm Levine for a game or two and dinner. It is that kind of relationship the physician editors have always had with the DT staff, including getting together annually at the AAD where freelance writers were also in attendance to gather the latest insights for publication. That probably is the single most important aspect of what I appreciate about being affiliated with the publication — they sent their reporters and freelancers to many scientific dermatology meetings, including AAD, ASDS, PDA, EADV, and ASLMS, to obtain the latest information, techniques and devices for publication in the magazine.

By 1987, the surgical world had seen a number of major advances. Not only have new and more precise lasers been added to our treatment options, including the argon-dye laser, pulsed dye laser, Q-switched ruby laser and ultrapulsed CO2 laser, but also soft tissue fillers like Restylane, Juvederm, Sculptra and Radiesse had become available. All of these devices and materials were being reported in DT to keep the readers informed.

In parallel to all of these advances, DT has added expertise to its contributing staff. At present there are four physician editorial advisors and a number of contributing physician board members and columnists. Topics covered now span our subspecialty focal areas and include: clinical dermatology, cutaneous oncology, business solutions, pediatric dermatology, aesthetics, the on-going Legal Eagle column by dermatologist Dr. David Goldberg, J.D., as well as topics like psychodermatology and alternative therapies.

Over the ensuing years surgical and cosmetic dermatology has seen tremendous growth in lasers (diode, Fraxel resurfacing laser and photodynamic therapy), aesthetics (liposuction, ultrasound, CoolSculpting, chemical peels, Botox, and fillers), dressings, oncology and topical anesthetics. Right there by our side there has been a similar growth in a high-quality, unbiased, timely publication—Dermatology Times, a publication that I have been fortunate enough to work closely with since early in its development. Here is my honest tribute to their first forty years and for continued success in the future.
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As dermatology’s scope of practice has evolved, DT expanded to reflect these changes.

Dermatology Times at 40

by NORMAN LEVINE, M.D.

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

As Dermatology Times (DT) celebrates 40 years of continuous publication, it gives those of us who have been expressing our uncensored opinion an opportunity to thank this important magazine for allowing us to say things in public that almost no other similar vehicle would consider.

Very seldom has the managing editor or other staff even suggested that I tone down my sometimes annoying tone, or that I consider avoiding criticism of one or more of their advertisers. I am certain that there was cringing on occasion when my editorial copy was presented to them, but if that was the case, they did not communicate their discomfort to me.

As an example, in 2008 I criticized DT and others for reporting on cosmaceutical agents with scant data to support their claims. They chose not to follow my entreaty to refrain from publicizing so-called therapeutic advances. In retrospect, the marketplace became the final arbiter as new “advances” came and went dependent on the experiences of the consumers of such products.

In an editorial published in celebration of 30 years of DT publication, I marveled at the advances in computer technologies that had made our professional lives more productive. Discussing advances in computers now seems rather quaint 10 years later. Now DT reports on far more advanced technologies, such as new and better laser systems, practice management software and the social media explosion — where computers are merely a means to the end of better information collection and transfer.

For those of us who are technologically challenged, DT reporters have explained these new advances in language that we can all understand.

Who would have predicted 10 years ago that we would become almost indentured servants to some of these emerging technologies? The era of the electronic medical record (EMR) has arrived, and most of us have at least, grudgingly, accepted this as a fact of life.

Early on, DT ran a series of articles describing the various options that were available to dermatologists. I am certain that many practitioners based their decisions on which system to incorporate into their practices — at least, in part, on the clear analysis presented in the pages of DT.

In spite of many pitfalls and hassles associated with the implementation of the electronic medical record, there is little doubt that this technology has improved medical care. If only before the 50 year anniversary of DT, the various EMR’s will be able to share data to make medical records truly portable.

Over the past decade, I have written several articles imploring our specialty to remain mainly interested in patient care. As dermatology, as aesthetic procedural dermatology has become a major component of the services we deliver. As dermatology’s scope of practice has evolved, DT has expanded its capacity to reflect these changes. DT has become a major source for the reporting of new ideas, techniques and products in these areas. It is now clear that this part of dermatology will be a major part of the future of the specialty, and I am pleased that a responsible and even-handed publication such as DT will continue to inform its readers about these matters.

One of the real pleasures of writing editorials for DT has been the feedback that readers have provided about what they like about our opinions and what, in their view, is totally misguided blather. For example, I have been accused of being “cannibalistic” for daring to criticize other dermatologists for practices that seemed marginal to me. A few years ago, I wrote a piece entitled, “If I ruled the (dermatology) world.” In this article, I free-associated about changes in our specialty that I would institute if I had the power to do so. Of all the responses from readers about this and other editorials, my favorite remains a comment made by a physician reacting to that article. His straightforward response went something like this: “Thank God you don’t rule the dermatology world.” Amen, brother.

Over the past four decades, Dermatology Times has brought you highlights from meetings, analysis of research advances, and varying perspectives on the changing regulatory landscape. It has been with our great pleasure and genuine interest that we have participated in shaping a vehicle aimed at offering a platform for insight and a springboard to generate discussion. We have appreciated the feedback over the years, whether it was “Great job!” or “You could’ve done that better.” We’ve valued it all, and we’ve based changes on it all — always striving to provide information geared toward helping you to optimize your practice and improve patient care.

Beginning in this issue, we will include a mix of commentaries and articles reflecting on the past 40 years of our involvement in this ever-evolving specialty of dermatology. If you’d like to contribute, please email us at: editor@dermatologytimes.com.

Thank you for your continued engagement and support!
The case for hackathons in dermatology

by

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In recent years, dermatology has seen significant advancements in understanding and treatment for many skin diseases. Despite these successes, challenges remain for a wide range of actors (e.g., pharma, academic institutions, clinicians, researchers) who struggle to implement collaborative and creative ideation practices and processes that continuously support and nurture innovation.

In many cases, this is the result of a risk-averse mindset that tends to plague organizations and prevent teams from pursuing projects with the potential to disrupt inefficiencies and deficiencies in the status-quo that could drastically improve care for patients.

In the last decade, hackathons have emerged as a popular and productive method to explore out-of-the-box ideas that solve difficult problems. Hackathons are sprint-like events that bring together teams of people from different fields, typically over a three-day period, to brainstorm and design new technology solutions. Originally conceptualized among groups of computer programmers, hackathons have made their way into the medical field.

MIT Hacking Medicine is a student-run group that first brought hackathons to healthcare in 2009. Already, we’ve seen a number of high impact companies, such as PillPack, born out of this group’s hackathons. Hackathons are also a great way for clinicians, including dermatologists, to engage with others who need their domain expertise. Dermatologists get to work with individuals with completely different toolsets in software, engineering, product development, etc. Often, patients are involved in the hacking process as mentors and participants.

Not all hackathons are created equal, and we believe that medical hackathons require a very different approach than the traditional tech-focused initiatives. Hacking Medicine Institute (HMI), an organization founded in 2011 out of MIT, is currently the most influential group working to tackle medical hackathons. In 2018, Advancing Innovation in Dermatology (AID), LEO Science & Tech Hub and Hacking Medicine Institute formed a partnership to establish one of the first ever dermatology-focused hackathons. Hacking Dermatology was designed with a distinct and refined focus on the dermatology industry and diseases of the skin.

Now entering its second year, Hacking Dermatology (September 13 – 15, 2019, Boston) is using a specialized framework and methodology to support the discovery and development of transformative solutions for some of dermatology’s most pressing challenges. This article is a call to action for dermatologists to directly get involved.

PRE-HACK: Setting the stage for success

A central goal of Hacking Dermatology is to build a community of people interested in collaborating to improve the current standards of care for patients with skin disease. The “Frame” or “Pre-Hack” is used to organize the process and align a talented group of stakeholders and participants. Contributing physicians, scientists and business leaders from AID, LEO, and HMI serve as the foundation, and other experts and patients are invited to contribute ideas at this stage. This group comes together at the outset to determine problems worth solving in dermatology based on their expertise and current industry trends.

The “pain points” they identify then evolve into challenge prompts that are introduced to the contestants. In 2018, the challenge statements covered a broad range of topics, including the use of AI in dermatology, measurement and evaluation of chronic diseases, gaps in diagnosis and treatment, treatment costs, and topical delivery of medication.

For example, one statement asked, “How can precision medicine principles and data be applied to help clinicians and researchers better understand chronic skin conditions to detect flares?” In 2019, this process was opened to a wider audience by crowd-sourcing ideas for consideration through online submissions. The results are now on the Hacking Dermatology website.

In addition to establishing expert oversight, the Pre-Hack is also important for securing
One-third of all patients in dermatology have emotional disorders.

Solving the puzzle

Finding the piece that will provide peace

by GINA M. CAPUTO, D.O.

Dr. Caputo is a board-certified dermatologist practicing at Premier Dermatology and Cosmetic Surgery in Newark, Delaware. She is president of the Delaware Academy of Dermatology.

The understanding of the relationship between the psyche and the skin is complex, fascinating, and one that puzzles many physicians.

Many of the chief complaints brought to dermatologists have a psychosocial issue associated with it. Psychodermatology/psychocutaneous medicine encompasses many different types of conditions that are both psychiatric and dermatologic. It is crucial that dermatologists identify these overlapping situations because psychodermatological patients often refuse a psychiatry referral. In fact, often times recommending a referral before trust is formed, can make the patient feel isolated and make the condition worse.

One-third of all patients in dermatology have emotional disorders.¹ The understanding of the relationship between the psyche and the skin is complex, fascinating, and one that puzzles many physicians.

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Psychodermatological disorders can be classified into four different categories: Psychophysiological disorders, primary psychiatric disorders, secondary psychiatric disorders, and cutaneous sensory disorders.

Psychophysiological disorders are true dermatologic diseases that are exacerbated by emotional stressors. Conditions like atopic dermatitis, acne, perioral dermatitis, psoriasis, and hyperhidrosis are all examples of conditions that patients often report worsen when they are under stress. When a patient presents with a flare, it is not uncommon that, when prompted, the patient will report some stressor in his everyday life.

Primary psychiatric disorders, on the other hand, have no real skin disease, but, instead, have serious psychopathology. The classic examples of these conditions are delusions of parasitosis, dermatitis artefacta, and trichotillomania. These patients often present after seeing multiple doctors and have bizarre atypical skin lesions, stories, beliefs and samples for examination.

Secondary psychiatric disorders describe psychological disorders that patients develop in response to their dermatologic disease. Vitiligo, acne, alopecia areata, hidradenitis suppurativa, and psoriasis are all dermatologic conditions that can have a significant impact on the emotional health and well-being of a patient. Due to the severity or believed severity of their disease, many patients develop psychological distress. Cutaneous sensory disorders are akin to chronic pain syndrome. These disorders are the dysesthesias and unpleasant sensations of biting, stinging, burning, and itching without any clear etiology.

Cutaneous sensory disorders often times may present with or without psychiatric disturbances, but depression and anxiety are the most common comorbid conditions.²

There is an enormous amount of pressure put on a dermatologist when patients present to our offices, especially when they have been seen by six other physicians for their complaint. We are often a patient’s last hope. If, after multiple visits, an organic cause has not yet presented itself, it is important that we take the time to shake out the details as to what is the underlying cause of their complaint.

It can be hard to use your “third eye” for these cases when you are 45 minutes behind and there are six drug reps in the hallway harass ing you. Patients simply want to be heard and have their feelings validated. Acknowledging an acne patient’s frustrations, asking a psoriasis patient how they are emotionally dealing with their disease, or simply pausing to acknowledge a patient’s struggles, can help to foster a trusting, safe environment that will allow the physician to ultimately identify the issue and work towards fixing it.

In this upcoming series, my objective is to dive into the different categories of psychodermatological diseases, and discuss how to recognize, address and co-manage each of the different entities.³

References

otherapy may be the most popular treatment, but one round has a 50% success rate, likely no higher than placebo.

For most children, that degree of efficacy does not offset the view, “There is no way to take the ‘cry’ out of cryotherapy.” A long list of other treatments have similar efficacy. As I often tell patients who ask for the best: If there was a single best treatment, there would not be so many choices.

I have seen many physical and emotional scars from patients treated with repeated cryotherapy, radiation and combination cantharidin (including the dreaded ring warts). The most memorable was a 4-year-old who received three rounds of bleomycin injected without anesthesia into her nares rim. She screamed from the moment I entered the room until I left, despite my promise that I would not hurt her. I especially avoid treating anogenital condylomata in children, but do screen for evidence of non-innocent transmission and evaluate for coexisting infections such as chlamydia in symptomatic children.

I also recommend the HPV vaccine for children with widespread warts, or those persisting longer than the average two-year duration, because it suggests immunologic susceptibility to chronic or oncogenic infection.

Based on the available data, the societal financial burden of these infections and their questionably effective treatments is difficult to estimate, but must be staggering. Fortunately, this is an incentive to develop new treatments for these unquestionably unmet medical needs.

There are currently 16 clinical therapeutic trials recruiting patients with warts and the same number active or completed for patients with molluscum.

This issue of Dermatology Times features an update on these conditions, including new treatment options that hold promise for improving QOL for both patients and prescribing physicians.

References

To learn more about Hacking Dermatology 2019, please visit: http://www.hackingdermatology.org/
Self-injection education

Patient training improves confidence, treatment satisfaction

LISETTE HILTON | Staff Correspondent

**Quick Takes**

- There are a few devices on the market, but few patients know how to use them.
- Access to educational material decreases patient injection mistakes.
- Training also decreases patient callbacks and follow-up visits on device use.

**MANAGE INJECTION SITE REACTIONS WITH PROPER TRAINING**

Injection site reactions: There are a number of types with a constellation of symptoms; and they are a local phenomenon!

**INJECTION SITE REACTIONS** can be a major complication of all FDA-approved self-injectable biological agents and biosimilars licensed for dermatological conditions in adults and children. In fact, incidence rate has been put at 40%. However, authors of a recent study, highlighted in this video say almost all injection site reactions can be managed with patient engagement, education, and training around proper injection site techniques.


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Noble conducted a two-week study looking at patient behavior and found that study participants were highly engaged at home with their training materials, and those materials helped them perform better with their actual injections. It also helped increase their overall satisfaction with the therapy, according to Reynolds.

The Noble study included 27 bio-naïve participants. Researchers divided participants into three groups. Participants in the control group only had access to the medication’s instructions for use (IFU). The second cohort received the training device and was trained using Noble materials, in

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43%

Of patients prescribed self-injection devices reported not being trained.3
Atopic dermatitis varies according to onset in kids

INGRID TORJESEN | Staff Correspondent

The disease course of atopic dermatitis in children can vary significantly according to the timing of its onset, and now research published in the Journal of the American Academy of Dermatology has suggested that early-, mid-, and late-onset pediatric AD may be clinically distinct disease subtypes and that age of onset could be used to risk stratify patients.¹

The study used data from the Pediatric Eczema Elective Registry (PEER), which was set up to evaluate the post-marketing malignancy risk associated with pimecrolimus (Elidel, Novartis), a topical calcineurin inhibitor for treating mild-to-moderate atopic dermatitis. Patients included in the study enrolled between November 2004 and September 2018 at a median age of 6.6 years.

Researchers collected patient information on demographics, atopic dermatitis disease and treatment history, including the age of disease onset, upon enrollment. Patients or their caregivers were surveyed about atopic disease control and treatment use every six months for up to 10 years.

While previous studies in British and Dutch children showed similar results for any atopic dermatitis activity,²,³ this study also evaluated the level of disease control.

A total of 8,015 patients (53.3% female) were included in the study for which data on 41,934 person-years of follow-up were available. This data came from 70,841 follow-up surveys—an average of 8.8 surveys per patient.

The median age of atopic dermatitis onset was 0.75 years; 5,770 (72%) children were classified as having early onset with the condition beginning before two years of age; 1,492 (18.6%) children were classified as having mid-onset, with the condition beginning between two and eight years of age; and 712 (8.9%) children were classified as having late-onset atopic dermatitis.

For each additional year of age at disease onset, the adjusted odds ratio (aOR) for poorer control was 0.93, meaning a child whose atopic dermatitis began at age 10 had a 44% lower odds

From a clinical perspective, the age of atopic dermatitis onset may be helpful for risk stratifying and counselling patients about their expected disease course.”

Joy Wan, M.D., University of Pennsylvania Perelman School of Medicine, Philadelphia

Quick Takes

Age of onset could predict which pediatric AD patients are at risk for uncontrolled disease.

Study found patients with disease onset before two years of age were at greatest risk.

Patients with mid- and late-onset were most likely to have good or complete control.
While population studies have indicated that psoriasis occurs less frequently in patients with skin of color, researchers believe the prevalence may be underestimated.\(^1\) There are differences in the presentation of disease in black and Hispanic patients, and the impact on quality of life may be more significant when compared with white patients; however, data on treatment outcomes in this population are limited.

To evaluate the efficacy, safety and health-related quality-of-life outcomes in patients with skin of color, researchers from the department of dermatology at Wake Forest Baptist Medical Center study led by Amy McMichael, M.D., performed a post-hoc analysis of the patients included in two AMAGINE phase 3 clinical trials on patients who were treated with brodalumab (Siliq, Valeant) over 52 weeks. The study was published in April in the *American Journal of Clinical Dermatology.*\(^2\)

According to earlier data published October 1, 2015, in the *New England Journal of Medicine*, both multicenter trials were randomized, double-blind, placebo-controlled and active comparator-controlled, parallel-group designs that enrolled a total of 3,712 patients. Treatment groups received either a subcutaneous injection of brodalumab at either 210 mg or 140 mg on day 1 and weeks 1, 2, 4, 6, 8 and 10 or a subcutaneous injection of ustekinumab at 45 mg (patients with a body weight ≤100 kg) or 90 mg (patients with a body weight >100 kg), on day 1 and week 4 and every 12 weeks thereafter, in accordance with standard dosing regimens. The placebo comparator groups each received a subcutaneous injection on days 1 and weeks 1, 2, 4, 6, 8 and 10 as double-blind, double-dummy injections and corresponding with each randomly assigned treatment group.\(^3\)

Dr. McMichael’s group assessed the subgroup of participants who were self-categorized as black (56), Asian (63) and Hispanic/Latino (200). In this subgroup analysis, patients who received brodalumab achieved higher scores on the Psoriasis Area and Severity Index (PASI) and the Static Physician’s Global Assessment (sPGA) at weeks 12 and 52 compared with those who were treated with ustekinumab (Stelara, Janssen).

The rates of adverse reactions were similar across racial/ethnic backgrounds. The exposure-adjusted event rate per patient year in the black, Asian and Hispanic/Latino subgroups were 222, 301 and 268, respectively.

Patient-reported outcomes were similar across all subgroups. The PSI response rate among the black, Asian and Hispanic/Latino subgroups were 67%, 80% and 55% respectively. Health-related quality-of-life outcomes were assessed using the Dermatology Life Quality Index (DLQI), and were found to be similar across all subgroups with at least a five-point improvement.

This research suggests that brodalumab is effective in black, Asian and Hispanic/Latino patients. This study also suggests that brodalumab may be superior to ustekinumab in these patients.

The authors admit that the study has several limitations. First, it is limited by a small sample size of non-white patients. Second, there is no clear biologic basis for the advantage of brodalumab. The authors suggest that genetic polymorphisms may play a role in differences in psoriasis manifestations and pathogenesis. This may, in turn, provide a biologic foundation for differences in medication efficacy.  

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Energy options to treat hyperpigmentation

WHITNEY J. PALMER | Staff Correspondent

Conventionally, lasers and intense pulsed light (IPL) sources are considered go-to treatments for various pigmentary disorders. But not every energy device works for every condition.

In a new position statement, initiated by the European Society for Laser in Dermatology and published in the European Academy of Dermatology and Venereology, investigators outline recommendations for treating 16 pigmentary disorders.1

“A complete review of the existing data and a consensus statement by experts in the field was highly needed to help physicians to provide optimal care of these lesions,” says Thierry Passeron, M.D., Ph.D., dermatology professor at the University of Nice Sophia Antipolis.

Investigators stress that one therapy does not fit all.

Quick Takes

Researchers discussed treatment options for 16 pigmentary disorders.

Review outlines laser recommendations and efficacy for these conditions.

Investigators stress that one therapy does not fit all.

**Actinic lentigines:** Use ultrashort Q-switched (QS) nanosecond/picosecond laser treatment to treat a small number of actinic lentigines lesions. One or two sessions can completely remove the benign, flat lesions caused by acute, prolonged, unprotected sun exposure.

**Lentil simplex and lentiginosis:** Treat lentigines simplex with QS lasers, such as Nd:YAG, Alexandrite and Ruby, to target melanin with nanosecond pulses. Results are favorable, and recurrence is low, investigators say. If numerous lesions are present, rule out a syndromic association before treating.

**Ephelides:** A 532 nm QS laser can treat ephelides’ high pheomelanin content, but recurrence is inevitable. Laser treatment isn’t highly indicated. Recommend regular sunscreen use instead.

**Café au lait spots:** Laser treatment isn’t recommended. Recurrence within a few months is high, and hypopigmentation is a common side effect.

**Linear & whorled hypermelanosis:** Few treatments exist, but QS lasers appear effective after only one or two sessions, researchers say. Caution patients; recurrences are possible, requiring additional treatments.

**Naevus spilus (NS):** Use QS lasers to treat macules or papules accompanying these lesions. Macular NS responds better to treatment than papular, but recurrences aren’t infrequent.

**Becker’s naevus (BN):** Management is highly variable, and removal carries scarring and dyspigmentation risks. Long-pulsed laser effectively reduced BN-associated hair, but it’s less efficacious in hyperpigmentation treatment. Investigators say advise against treatment because results aren’t predictable and recurrence is high.

**Dermal hypermelanocytosis, Ota, Ito naevus:** The 1064 nm QS laser is the gold standard for Ota and Ito naevus therapy. Pain, swelling and pinpoint bleeding are possible. Consequently, researchers recommend at least two months between sessions to minimize scarring risk.

**Acquired dermal melanocytosis, including ABNOM:** Use the 1064 nm QS laser for treatment. Verify the diagnosis, however, because this condition doesn’t respond to bleaching agents or peeling.

**Congenital nevomelanocytic nevi (CNN):** QS and long-pulsed pigment-specific lasers and fractional lasers can improve a patient’s cosmetic appearance, but they don’t eliminate the malignancy risk associated with bigger, more numerous CNNs. Therefore, discuss laser options among other therapeutic options.

**Postinflammatory hyperpigmentation:** This acquired condition can negatively impact patients’ lives, but eventually laser treatment can provide improvement. However, as it can induce or worsen the condition, test small areas before treating the entire lesion.

**Melasma:** Kligman’s formula is the gold standard treatment for this highly complex hyperpigmentation disorder, but lasers can effectively target melasma’s vascular component, investigators say. Still, consider it only if topical depigmenting agents and peeling fail because relapses and worsening can occur.

**Drug-induced non-melanin pigment:** QS lasers are preferred for clearing these hyperpigmentations caused by drugs or metallic salts. Advise patients to stop using these agents when possible.

**Exogenous ochronosis:** These discolorations are difficult to treat. Use multiple QS laser and/or fractional ablative laser treatments, coupled with high SPF sunscreen protection, to provide improvement.

**Siderosis and hemosiderosis:** Little data is available on treating these iron deposits, but evidence shows fewer than three sessions with a 532 nm QS laser appears to be effective.

**Pigmented seborrhoeic keratosis & dermatosis papulosa:** Good efficacy and safety results indicate a 1064 nm long-pulsed Nd:YAG laser and ablative erbium laser can be added to the cadre of treatments for dermatosis papulosa nigra.

Overall, Dr. Passeron says, clinicians must remember not all devices and therapeutic approaches are effective or appropriate for all conditions. They must be careful to identify the correct diagnosis before prescribing treatment.

Reference

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Rosacea, systemic inflammation may be linked

INGRID TORJESEN | Staff Correspondent

Research suggests that people with rosacea may have a genetic susceptibility to developing the condition and that environmental factors, in particular the microbiome, also play a role. Most importantly, however, there is mounting evidence that rosacea might be an outcome of systemic inflammation.¹

There is a small but significant association between systemic inflammatory diseases, some of which can be potentially serious, and rosacea. The greatest evidence is for links between rosacea and cardiovascular disease and inflammatory bowel disease, but there are also less strongly validated links with certain neurological diseases, in particular parkinsonism, but also dementia and Alzheimer’s.²

A greater understanding of rosacea’s shared etiology will not only aid diagnosis and treatment for patients with rosacea, it could have wider clinical implications. If rosacea is shown to have high predictive value for the development of particular systemic disorders, it could provide a valuable early warning sign for these conditions, says Richard L. Gallo M.D., Ph.D., Irma Gigli Endowed Chair, Distinguished Professor and Founding Chairman, Department of Dermatology, University of California, San Diego.

“We are getting increasing evidence that some of the inflammatory mediators that are released in the skin of rosacea patients, and psoriasis patients as well, can act systemically so something that is produced in the skin may circulate around and act on vessels of the heart or the lumen of the gut,” he says. For example, there is now evidence implicating TH1 and TH17 cytokines and B cells in rosacea.³

Unfortunately, Dr. Gallo adds, “A biochemical marker that would distinguish the inflammation of rosacea from other types of inflammation has not been clearly identified.”⁴

A biochemical identifier unique to rosacea would enable dermatologists to easily confirm a suspected diagnosis and monitor disease progression, and researchers to assess the potential of new candidate therapies. Other than improvements in therapy, this would be the most useful step forward that could be made in our knowledge of the condition, he says.

While, there are many approaches to rosacea treatment, including antimicrobial, vasoactive and physical such as lasers, Dr. Gallo says, “We still could do better, much better.”

Potential new therapies in the pipeline include protease modification. “It is a different approach which could add to the efficacy of existing regimens,” he explains. The rationale of protease modification is to interrupt the signalling pathway that generates the proinflammatory molecules by either blocking the trigger or blocking the pathway.

At present, the pathophysiology of flushing and blushing, the interaction between the nervous and immune systems during neuroinflammation (flushing, erythema), and the immune responses (erythema, papules, pustules) remains unclear.

Dr. Gallo and colleagues presented an abstract to the Society for Investigative Dermatology meeting in Chicago on the mechanism connecting vascular inflammation with increased sensitivity to light. “One of the most common factors that patients report for increased symptoms in rosacea is ultraviolet light exposure and we are reporting on a biochemical explanation for that,” he says.

Dr. Gallo emphasises that rosacea also occurs in individuals with darker skin phototypes but perhaps is more likely to be missed.

“A few reports have suggested that the centrofacial erythema that characterises rosacea has been vastly unappreciated in darker skinned individuals,” he notes. “So, it may not be that the incidence is low in that pigment type but more a diagnostic problem or a detection problem.”

In individuals with darker skin types, erythematous signs can appear as a dusky brown discoloration, so symptoms such as burning, stinging, flushing, papules and pustules might be more appropriate indicators of rosacea than primary centrofacial erythema.

Both the National Rosacea Society and American Acne and Rosacea Society offer funding for research to further understanding and management of rosacea, and Dr. Gallo encourages anyone with ideas for studies to apply for the grants.

References

People forget how to self-inject, and, if they don’t have access to training and education, are more likely to call back with device questions and even schedule follow-up visits.”

Joe Reynolds, research manager, Noble

Injection training may improve adherence, minimize follow-up visits

Addition to the standard IFU. The third group was given the training device and an interactive video, and was trained on how to use the device, in addition to the IFU.

A total of 56% of the subjects in the control group made mistakes when they had to self-administer the injection versus no mistakes in the other two groups. More than 90% of subjects said they preferred to receive a training device to take home and practice with before having to inject the real medication, according to a Noble white paper on the research.4

“We have found that training helps prevent patient callbacks and follow-up visits relating to device use. With many of these medications, there are decay periods between injections. During those time periods, people forget how to self-inject, and, if they don’t have access to training and education, are more likely to call back with device questions and even schedule follow-up visits,” he says. ◆

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Atopic dermatitis appearing earlier was associated with worse disease control

of worse control over time compared to one whose atopic dermatitis began at age 12.

While complete control was more likely to be reported in patients of increasing age in all groups, it was more likely to be reported in the late-onset group than in the mid-onset and early onset groups, and differences were most distinct in the second and third decades of life.

The odds of persistent atopic dermatitis was significantly lower for each additional year of age at onset (adjusted odds ratio 0.84). A child whose atopic dermatitis began at age 10 years, therefore, had a 75% lower odds of persistent disease over time compared to one whose condition began at age two.

“Earlier onset atopic dermatitis was associated with worse disease control and greater persistence over time, independent of sociodemographic characteristics and atopic comorbidities,” Joy Wan, M.D., department of dermatology, University of Pennsylvania Perelman School of Medicine, Philadelphia, says. “Our findings suggest that atopic dermatitis onset age differentiates clinically distinct forms of the disease.”

In all three groups, the proportion of subjects reporting persistent atopic dermatitis generally declined with older age, and differences among the three onset groups were most pronounced from early adolescence onward with a subset of patients with early onset atopic dermatitis experiencing disease resolution, she adds.

“In our early onset group, a continuous decline in reports of persistent atopic dermatitis occurs in early childhood and nadirs at age 13, likely reflecting those individuals whose atopic dermatitis resolved,” Dr. Wan says.

Previous studies have shown that earlier onset atopic dermatitis is associated with a greater risk for asthma, allergic rhinitis and food allergies as well as the presence of genetic risk variants for atopic dermatitis, which suggests that the timing of atopic dermatitis onset is driven, in part, by genetics and is associated with not only atopic dermatitis severity and persistence but also atopic burden overall.

“From a clinical perspective, the age of atopic dermatitis onset may be helpful for risk stratifying and counselling patients about their expected disease course. Although more precise subtypes of atopic dermatitis may be identified by combining clinical, genetic and biomarker data, a simple approach to atopic dermatitis sub-classification remains clinically useful,” Dr. Wan says.

“The timing of disease onset is normally assessed as part of the clinical history for patients with atopic dermatitis while genetic and laboratory tests are not routinely performed. By considering the framework of early onset or late-onset disease, we can identify those patients at greater risk for persistent or poorly controlled atopic dermatitis and whom may benefit from more intensive treatment or monitoring,” she says. ◆

References

Wart treatments in pipeline FROM PAGE 1

Novan is developing SB206 as a topical antiviral gel for the treatment of viral skin infections, with a current focus on the treatment of molluscum contagiosum, a contagious skin infection caused by the molluscipoxvirus, and external genital warts (EGW) caused by human papillomavirus (HPV). SB206 is a topical berdazimer sodium gel co-administered with hydrogel which promotes release of nitric oxide (NO), a free radical gas, which is endogenously produced in human cells. In high concentrations, NO neutralizes many disease-causing microbes and has the potential to treat skin diseases caused by viruses. If approved, SB206 could be a prescription topical treatment for use at-home.

SB206 has entered phase 3 trials (NI-MC301, NI-MC302) in molluscum patients. Plans are to recruit 340 patients aged 6 months and older per trial; patients will receive SB206 12% once-daily or placebo in a 2:1 ratio.5,6

In a phase 2 dose-ranging trial 12% once-daily was the most effective dose with 42% (mITT, p<0.05) and 38% (ITT, p<0.05) complete clearance rates compared to 20% and 18% for vehicle, respectively.5,6

In a phase 2 dose-ranging clinical trial for the treatment of external genital warts, 53.3% of patients achieved complete clearance of baseline warts by week 12 when treated with SB206 12% once-daily, compared to only 4.3% of patients with vehicle once-daily (p<0.010).6

Paula Brown Stafford, chief development officer, Novan, says the treatment showed potential as a once-daily, at-home, safe and well tolerated topical therapy with high complete clearance rates and a treatment benefit as early as week two.

“If approved, [the treatment] would benefit a significant number of patients currently facing an inadequate treatment paradigm,” she says.

The drug which is closest to approval is Verrica Pharmaceuticals’s VP102, a topical application of cantharidin, which is naturally derived from the blister beetle, and has a long track record of treating cutaneous molluscum contagiosum and verrucae,7 reaching as far back as the ancient Egyptians. “Spanish fly” has been also used as an aphrodisiac, most notably the Marquis de Sade, with fatal consequences.

Although not approved by the United States Food and Drug Administration, cantharidin has been available through a variety of compounding sources without standardization of manufacturing, formulation, or method of application.

Both phase 2 and phase 3 trials have been completed. Results from the two phase 3 trials were presented at the 2019 American Academy of Dermatology Meeting in March. A total of 528 patients aged at two years and older with molluscum were enrolled in the two trials (CAMP-1 and CAMP-2). After 12 weeks, 46% and 54% of subjects treated with VP-102 (topical solution of 0.7% cantharidin) every 21 days for up to four applications showed complete clearance of molluscum lesions compared with 18% and 13% of subjects in the placebo groups (p<0.0001).8

If approved, VP-102 will be a product applied by physicians, and likely to be used as an alternative to liquid nitrogen and other cryotherapy. The active ingredient cantharidin 0.7% is presented in single-use containers of a film formulating solution with a violet dye, so that the physician can see where it has been applied.

Ted White, President and Chief Executive Officer of Verrica says VP-102 has the potential to become the standard of care for molluscum.

“Complete clearance of molluscum lesions in a short amount of time is important to patients, especially parents of young children who are impacted by this highly contagious skin infection,” he says.

Veloce BioPharma LLC has tested its topical gel product VBP-245 in a small phase 2 trial at three sites in the United States,9 but the results have not yet been revealed, and Picato, an FDA-approved treatment for actinic keratosis is being tested in an early phase 1 trial in adults with molluscum,10 after case reports suggested it may be effective.11

So what should you offer patients with molluscum and warts now?

For common warts the go-to office treatment is applying liquid nitrogen, although the equipment for this is expensive so some physicians may offer cryotherapies using fluorinated hydrocarbons instead, which is likely to be less effective than applying liquid nitrogen, as they are not as cold.12 Over the counter, the traditional treatments are salicylic acid or cryotherapy based on fluorinated hydrocarbons.

For molluscum, options include liquid nitrogen in the office; topical treatment with podophyllotoxin cream (0.5%), salicylic acid, potassium hydroxide, tretinoin, cantharidin and imiquimod (T cell modifier); oral cimetidine; and even injections of interferon in immunocompromised individuals. However, physicians should take note that an inflamed lesion is often an indication of the beginning of the end — an expected variation in the evolution of immune response to the virus rather than bacterial superinfection.13

Elaine Siegfried, M.D., professor of dermatology and pediatrics at St. Louis University School of Medicine, St. Louis, Mo., says physicians often feel obliged to do something because children’s caregivers want them to do something.

Although the placebo effect of destructive treatments is likely to be strong, unless there is a good reason for treating, such as the site of the wart, it is often better to leave it or do something benign such as covering it with tape, which has been shown to have some effect,14 she advises.

“One of my favorites to use these days as a placebo is garlic, because garlic is cheap and readily available. The only downside of using garlic is that sometimes it’s too toxic to tissue, but it’s not nearly as bad an erosion as cryotherapy or cantharidin,” Dr. Siegfried says.

Dr. Siegfried also sometimes suggests liquid zinc, although it can be hard to come by and hard to use as it usually requires zinc tablets to be crushed, and may cause stomach upsets.

For the paediatric dermatologist, the main issue of offering destructive treatments is that they can often be very uncomfortable for children while offering a low likelihood of success, she says.

“I’ve seen children who have been very negatively impacted by painful treatments,” Dr. Siegfried says. “It is very emotionally scarring.”


Photo: Elaine Siegfried, M.D.
Early intervention of PWS may improve outcome 

FROM PAGE 1

York University Medical Center, New York.

“Parents whose babies have a disfiguring PWS are anxious for options that can eliminate the lesion, and dermatologists who treat PWS need to make the effort to accommodate these families in their appointment schedule. We also need to educate our colleagues in pediatrics about the benefits and safety of early treatment so that they will make the referral.”

ARGUMENTS FOR EARLY INTERVENTION

One of the reasons that favor early initiation of PDL treatment is that it is likely to afford the best outcome.

“Anecdotal evidence shows that the response to PDL is better when the treatment is done in younger versus older children. Earlier treatment results in more complete clearing and requires fewer sessions,” Dr. Geronemus says.

There are several explanations for the better results in younger children. Penetration of the laser energy to its target — the hemoglobin in the PWS capillaries — is better because babies have thinner skin. In addition, the natural history of PWS is that they thicken, darken, and become larger as the child grows, and these features also make clearance more challenging.

Treatment in infancy also enables performance without general anesthesia because it is easier to hold and immobilize a baby than it is an older child.

In addition, as the PWS changes from a flat patch to a thicker plaque, it is at risk for bleeding secondary to physical trauma. There are also psychosocial consequences of delaying treatment that should be considered.

“There is documented evidence that children with a PWS on the face or another cosmetically visible area recognize they are different from their peers and have increased emotional stress and diminished self-esteem,” Dr. Geronemus says.

OFFICE VS OR

Advocates of performing the PDL treatment in a hospital setting under general anesthesia cite concerns over comfort and the need for the child to remain still. However, treatment in the hospital carries a number of drawbacks, Dr. Geronemus explains.

“Treatment in an OR using general anesthesia is expensive, time consuming, not accessible for all physicians and poses a risk for fire due to the interaction between the laser and oxygen and nitrous oxide that are present in the OR,” he says.

“Furthermore, general anesthesia has its own safety risks, and in 2016, the FDA issued a warning that repeated or lengthy use of general anesthetic and sedation drugs in children younger than three years may affect brain development.”

SUPPORTING EVIDENCE

In a paper published in JAMA Dermatology online in March 2019, Dr. Geronemus and colleagues reported their very positive findings from a retrospective cohort study of in-office PDL PWS treatment without general anesthesia.

Results of a retrospective cohort study show PDL treatment of PWS in infants without general anesthesia is safe and effective.

Quick TAKES

Early pulsed dye laser treatment of port-wine stains results in more complete clearing with fewer sessions.

Because infants are easier to hold immobile than older children, earlier treatment can be done without general anesthesia.

Lesions that achieved complete clearance had a smaller average size and required fewer treatments compared with those that had less improvement. Outcome analyses of anatomic location showed the best results were obtained when treating lesions on the first branch of the trigeminal nerve.

“Lesions below the elbows and below the knees can be difficult to treat, and families are informed about the potential for less improvement if the child’s PWS is in one of those locations. Our experience shows that regardless of location, it is possible to get a very good result. However, there are also no guarantees,” Dr. Geronemus says.

He adds that while the study lacks long-term follow-up, his experience indicates that the better the initial result, the lower the chance of recurrence.

“Most of the recurrences I have seen are in patients who did not have a significant response to initial treatment or who were not fully treated. I have seen many patients who had excellent results initially and still look good after 10 to 15 years,” Dr. Geronemus says.

LOGISTICS

In-office treatment without anesthesia requires a team to immobilize the child. Metal corneal shields should be placed to protect the eyes when treating a lesion involving the periorcular region.

Inserting the shields is done after application of an ophthalmic anesthetic solution and can be done safely and quickly with just a little experience, he says.

Ideally, children return for sessions every two to three weeks, although the interval between treatments is extended in children with darker skin. This frequent repeat schedule seems to accelerate the response and therefore minimize the total number of treatments needed, according to Dr. Geronemus.

The treatment is performed using dynamic cooling that minimizes discomfort and with a large spot size (typically 10-mm for face and neck lesions and 12-mm for body PWS) that allows for a shorter treatment session.

Disclosures

Dr. Geronemus is an investigator for and on the medical advisory board for Candela.

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Anecdotal evidence shows that the response to PDL is better when the treatment is done in younger versus older children. Earlier treatment results in more complete clearing and requires fewer sessions.”

Roy G. Geronemus, M.D., New York University Medical Center, New York
A solution for estrogen-deficient skin

ELIZA CABANA | Aesthetic Editor

There’s a new cosmeceutical agent on the market that can benefit estrogen-deficient skin without the systemic effects of estrogen. It’s called MEP, or Methyl Estradiolpropanoate, and studies show that it significantly improves menopausal skin-related symptoms.

According to Diane Berson, M.D., a dermatologist in private practice in NYC, many skin changes seen in aging women are the result of photodamage, environmental exposure and chronological age. However, when a woman loses estrogen after menopause, her skin changes even more.

“Estrogen-deficient skin can be characterized by dryness, wrinkling, thinness and itching. Interestingly, many women don’t associate that with menopause, just with getting older,” says Dr. Berson.

Estrogen is an essential component of skin function, health and wellness. It has been shown to improve skin elasticity, hydration and thickness. Once skin becomes estrogen deficient it undergoes histological changes responsible for decreases in collagen and IGF-1 production, among others, that are associated with the rapid proliferation of unwanted aging skin symptoms.

“[Patients] associate symptoms such as night sweats and difficulty sleeping with menopause. After menopause, skin loses estrogen and, subsequently, estrogen receptors on skin cells such as fibroblasts... Estrogen binding those receptors is responsible for plumping the skin, stimulating the development...”

...of aging skin symptoms from estrogen deficiency. MEP is an estrogen receptor activator. After MEP activates, it becomes a completely inactive metabolite. MEP turns on skin-specific estrogen receptors, but is not a hormone.

MEP turns on skin-specific estrogen receptors, but is not a hormone.

Quick TAKES

MEP is an estrogen receptor activator.

After MEP activates, it becomes a completely inactive metabolite.

MEP turns on skin-specific estrogen receptors, but is not a hormone.
Shining New Light on Poikiloderma of Civatte with the New Vbeam Prima Laser

Have you heard about the study of patients with Poikiloderma of Civatte who were treated with the Vbeam Prima laser?

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Don’t miss this podcast with featured physician Eric Bernstein, MD, MSE, discussing the study in detail, plus the Vbeam Prima laser’s advantages in larger spot size, 50% increased energy, ergonomic improvements, treatment versatility, and more.

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Basically, you are getting the benefit of an estrogen-type product, but with none of the side effects because it is broken down into an inactive ingredient.

Diane Berson, M.D., Private Practice, NYC

Skin loses estrogen and estrogen receptors on fibroblasts after menopause

of glycosaminoglycans, which improve hydration, and also stimulating new collagen and elastin. The loss of that interaction leads to the clinical signs of dryness and wrinkling,” says Dr. Berson, who presented “A New Cosmeceutical for Estrogen Deficient Skin” at the American Academy of Dermatology’s (AAD) 2019 spring meeting in Washington, D.C.

LIFE IN MENOPAUSE
About 6,000 women enter menopause every day in the United States, according to Dr. Berson, and it’s predicted that about 46 million women will be over the age of 55 by 2020. While mean life expectancy has increased by about 30 years since 1900, menopause has only been delayed by about five years. That means women are expected to live postmenopausally roughly 25 years longer than those of previous generations.

“Women are living longer and longer,” stresses Dr. Berson. “We know the lifespan is increasing, but the age of menopause has stayed essentially the same.”

This means that more women are going to be spending a larger percentage of their lives as post-menopausal.

“Women living to 80, 90, 100 who have menopause at 40 or 45 can end up living half of their lives postmenopause,” Dr. Berson says.

Additionally, studies have shown that women lose a significant amount (up to 30%) of collagen in the first five years of menopause, with a 2% loss in subsequent years. So treating estrogen-deficient skin sooner should keep skin looking younger longer.

AN UNMET NEED
Traditionally, women have used either oral or topical estrogen products to help improve the signs and symptoms of menopause. Unfortunately, these options can also result in increased levels of systemic estrogen and the possibility of unwanted hormonal side effects.

“Concerns include hyperplasia of the uterine endometrium, stimulation of breast tissue and cardiovascular disease. Many women don’t want to take hormonal treatments with a potential for side effects,” Dr. Berson points out.

“It would be great if we had something available topically that could be applied to the skin that acted like an estrogen, stimulating estrogen receptors but without potential systemic side effects.”

That ingredient is MEP, she says.

MEP is non-hormonal estrogen receptor agonist (NERA). It is not a hormone and has none of the potential risks of a hormone, and its mode of action is known.

“MEP interacts with the estrogen receptors on the surface of cells such as fibroblasts, stimulating the formation of collagen and elastin and increasing the hydration of the dermis, essentially acting like an estrogen receptor agonist,” explains Dr. Berson.

But unlike estroial, MEP is broken down into an inactive metabolite, which enters the bloodstream and exits the body without being absorbed.

“Basically, you are getting the benefit of an estrogen-type product, but with none of the side effects because it is broken down into an inactive ingredient,” says Dr. Berson.

According to Elliott Milstein, senior vice president of Product Innovation at Ferndale Pharma Group, which manufactures MEP, “Ferndale licensed the basic technology a while ago and spent a lot of time developing the synthesis and scale-up.”

It was up to him to figure out how to bring it to market, he says.

“It sounds simple, but our market research showed that many women are very uncomfortable talking about estrogen and menopause, even when it is only how it relates to the skin,” says Milstein.

The good news is, if a woman begins using MEP before menopause, she can prevent those significant skin changes from happening that begin in early menopause. Women who are already in menopause or post-menopause can also benefit, but results may not come as quickly or be as dramatic.

MEP RESEARCH & RESULTS
In a double-blind, randomized pilot study published in November 2018, investigators evaluated the safety and efficacy of MEP in estrogen-deficient women. The initial safety study included 60 women, all amenorrheic for a minimum of three years and assigned to either MEP (n = 40) or placebo (n = 20) treatment groups. Patients applied product to face twice daily for 12 weeks; blood samples were taken at baseline and week 12 to evaluate presence of MEP and inactive metabolite, with a quantifiable limit set at 20 pg/mL.

“The safety study was done [first] to be sure no active estrogen-like substances were present in the bloodstream, only inactive metabolites,” says study author Zoe Draelos, M.D.

“This molecule is unique in that it is active in the skin and subsequently broken down in the skin such that the active circulating estrogen like substance is not found systemically.”

After 12 weeks of use, only one of the 40 patients in the MEP treatment group had inactive metabolite above the quantifiable limit. There were no adverse events, and both investigators and patients rated product tolerability to be “excellent,” with no related burning or itching.

The efficacy study that followed included 80 women, amenorrheic for three to 10 years, with no history of hormone replacement therapy and assigned to either MEP (n = 60) or placebo (n = 20) treatment groups. Patients applied product to face twice daily for 14 weeks.

ESTROGEN CONTINUES ON PAGE 47  

Dr. Draelos
Dr. Cohen
Mr. Milstein
Bringing Molluscum Contagiosum to Light

While as many as 1 out of every 5 healthy children contract molluscum contagiosum, this disease and the patients it affects receive very little attention.\(^1\) Quality of life can be negatively affected by a molluscum infection.\(^2\) Children with the disease may become stigmatized and experience teasing, embarrassment, and social isolation. Up to 82% of parents and caregivers express moderate to great concern about molluscum.\(^3\) Lesions may be mostly asymptomatic, but reports indicate that patients do complain about itching, burning, and tenderness.\(^3\)

Although lesions can resolve within 6 to 9 months, patients typically have the infection for 13 months, and some infections can persist for 2 years or more.\(^2,\(^3\) Treatment at the time of diagnosis provides the best chance of decreasing the number of lesions and spread of the disease.\(^3\)

No current FDA-approved treatment option addresses the problem of successfully treating molluscum.

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**Striving to Bring Life-Changing Therapies to Market**

- Verrica Pharmaceuticals Inc. is dedicated to identifying, developing, and commercializing novel pharmaceutical products for the treatment of underserved dermatology patients, such as those with molluscum contagiosum. Looking for solutions in this undertreated patient population addresses one of the largest unmet needs in dermatology.

Our proprietary drug-device combination, VP-102, has recently completed its 2 Phase 3 CAMP trials.
While topical products and treatments can address visible signs of skin aging, antiaging regimens also must address internal processes such as chronic inflammation and cell senescence, according to Pamela J. Schell, Psy.D., MSN, ARNP, DNC, who spoke on this issue at the Fall 2018 Cosmetic Bootcamp.

Dr. Schell says evidence supporting the role of chronic inflammation in human aging has grown. Researchers have even coined a term for the process — “inflammaging.” Dr. Schell is director of Werschler Aesthetics in Spokane, Washington.

“Clients always ask me why I look so young for my age. Part of that is I take care of myself from the inside out. It’s not just about getting your Botox (abobotulinum toxin A, Allergan) and Retin-A (tretinoin, Ortho Dermatologics),” she says.

Much of the battle, says Dr. Schell, occurs within the body. “And now we’re finding out that that really is much more the case than we thought.”

Antiaging dermatologic procedures provoke controlled acute inflammation. Conversely, she says, chronic inflammation is long-term, low-grade inflammation that leads to increased levels of pro-inflammatory cytokines including TNF-A, interleukin (IL)-1B and IL-6, even in the skin, which has its own immune response system. Processes affected by inflammaging range from DNA replication to cell senescence, immunosenescence and the skin-gut axis, she adds.

“Our guts do a lot for us — including making many hormones,” Dr. Schell says. The microbiome, which exists mainly in the gut, is also responsible for maintaining a balance of healthy versus unhealthy bacteria — although science has not yet identified which bacteria are which, for which patients. Such determinations depend partly on genetics, she says. “We don’t completely understand everything that our gut microbiome does for us. But we know its function decreases with aging, and it is affected by this chronic low-grade inflammatory process.”

The gut microbiome of elderly patients shows decreased diversity, she adds, with research showing lower amounts of anti-inflammatory microbiota such as *Clostridium cluster XIVa*, *Bifidobacterium spp*, and *Faecalibacterium prausnitzii*.1

LIFESTYLE CHOICES

Even in developing regions, Dr. Schell says the burden of avoidable age-related illnesses has grown as people worldwide eat more processed food and exercise less. Other harmful lifestyle choices include smoking, which increases levels of several pro-inflammatory cytokines and, more importantly, reactive oxygen species.

“Those are all things that we see when the immune system is stressed and trying to fight something,” she says.

Similar dynamics occur in the mouth, as diminished protection against bacterial species that occurs with age can lead to periodontal disease and chronic low-grade inflammation that spreads throughout the cardiovascular system, resulting in cardiovascular disease.

Healthy dietary choices can include the Mediterranean diet, the calorie restriction diet and the ketogenic diet, she says. “I don’t know if the keto diet is going to be a flash in the pan or a long-term solution,” she adds.

Larger studies have suggested that a modified Mediterranean diet that includes some ketogenic elements may be better, she explains.

Dr. Schell also recommends supplementing gut microbiota with probiotics and prebiotics (food sources, such as fiber, in the gut).”

We don’t completely understand everything that our gut microbiome does for us. But we know its function decreases with aging, and it is affected by this chronic low-grade inflammatory process.”

Pamela J. Schell, Psy.D., MSN, ARNP, DNC, Werschler Aesthetics, Spokane, Washington
Medical aesthetics is no longer a “trend,” but a mainstay branch of dermatology. From the drastic increase in preventative procedures for both women, and now men alike, to treatments becoming less and less taboo, the time is now for practices to make investments that will bring in revenue and keep clients returning for more. However, when it comes to selecting those investments, the clear choices are not always so clear.

While there are many options on the market, investing in a device that can seamlessly transition between treatment modalities to address current and future skin concerns, while also shortening patient recovery time, is a game-changing decision for any practice. With endless options available to providers, investing in the right technology is paramount to the success and longevity of a practice. When making aesthetic purchasing decisions, it’s best to take a few key considerations into account:

**Efficiencies**

Equipment requires extensive capital and space, so the ability to perform both surgical and non-surgical aesthetic procedures, all on a single device, could be revolutionary. Instead of investing in multiple tools to perform various procedures, each requiring time to conduct, technology like the TempSure® platform allows providers to seamlessly perform multiple treatments, including aesthetic and surgical procedures, with a single high-value investment. As the patient interest in both surgical and non-surgical procedures increases, the ability to transition between the two on one device, rather than involving the hassle of moving patients from room to room, is key to driving revenue and efficiency. Additionally, for those patients only interested in one type of procedure, the ability to offer both surgical and non-surgical procedures on a single trusted device could very well be the deciding factor for them to move forward with add-on treatments.

With recent advancements in aesthetic technology, instead of working to reverse the effects of aging, providers can proactively slow the aging process for their patients. Thanks to the increasing popularity amongst Hollywood’s elite, patients are seeking out these procedures and asking for specific devices by name, as they now understand and appreciate the value of a preventative approach. By having the most advanced and efficient technology at one’s fingertips, practitioners can capitalize on this “prejuvenation” trend by addressing all areas of concern, and then some. “By investing in both active and reactive beauty maintenance devices, providers can substantially increase the number of patients they’re able to treat, as well as the amount of years they can treat them,” recommends Dianne Quibell, MD, cosmetic laser surgeon, internist and aesthetic physician at MD TLC.

**Patient Satisfaction**

With unrelenting schedules and increasing expectations, the ability to provide patients with tangible results after little to no downtime will keep them coming back for more. Non-invasive skin treatments like the TempSure Envi treatment are a perfect solution, as the patient will only experience a soft glow following the procedure (instead of the oozing and crusting associated with some of the harsher, more invasive treatments), making it easy to integrate into already-established beauty routines. “With dermal collagen loss averaging about one percent per year beginning at age 30 – two percent per year if you live in a sunny area – the ability to receive a quick treatment and get back to enjoying life immediately afterwards is incredibly enticing,” said Dianne Quibell, MD. “Most of my patients do not want surgery to treat cosmetic issues, and now with new devices like TempSure at our disposal, I can offer a combination of safe, effective treatments that keep my patients coming back for more.” When choosing which aesthetic devices to invest in, it’s also important to prioritize those that help reduce downtime as much as possible. The TempSure Surgical device, for example, produces precise incisions with minimal lateral damage. The result: high quality procedures that offer quicker recovery and better healing for patients. “TempSure Surgical technology has allowed me to completely eliminate the scapel in many invasive procedures, and as a result, we’ve also markedly diminished the appearance of visible scars. The platform is truly defining the future of surgical scarring,” added DiBernardo.

**Trusted Manufacturer**

It’s important to align with a trusted company that continually innovates to set itself apart with effective and diverse treatment offerings. The value of a company’s overall commitment to improvement through innovation and client service, as well as their longevity in the space, are key differentiating factors that should be weighed heavily. Cynosure, the makers of the TempSure platform, including the TempSure Surgical and TempSure Envi treatments, is backed by Hologic, a leader in women’s health. “Health is not just about how one feels on the inside, but the outside, too,” said Quibell. “When patients come in for services that help them look their best, they develop confidence in themselves, the practice and the technology.”

Aligning not just with any manufacturer, but one you can trust, will help ensure each investment positively impacts the bottom line. While some companies purposefully design products that force providers to make significant purchases in order to upgrade their equipment, others understand the capital it takes to run a successful practice, and instead aim to produce products that can be seamlessly integrated into previous device iterations. TempSure Surgical RF technology, for example is designed to enhance the existing TempSure radiofrequency platform, which launched in January 2018 with TempSure Envi for facial fine lines and wrinkles, and includes a variety of electrodes that integrate seamlessly with the main unit. New and existing customers now have the opportunity to customize their TempSure Envi system to include TempSure Surgical RF technology to help meet different clinical needs at their practice, rather than being forced to buy a completely new system that would render their previous one useless.

What’s more, companies that offer exceptional customer service and provide service quickly and efficiently to help minimize downtime and lost revenue are worth the investment. “One of the best parts about Cynosure is their service department,” added Quibell. “I think it’s five times larger than the next greatest competitor. When we call for service, we either have a laser or a device shipped to us by the very next morning, or we have a service tech in the office so we can get up and running and we don’t have any time wasted.”

Before purchasing the next best aesthetic device available on the market, take the time to do the homework necessary to ensure it will truly stand the test of time. Gone are the days of touting countless different devices and procedures, each with varying skill requirements and expected results. Less is truly more. Investing in one cutting-edge device from a trusted manufacturer that can seamlessly transition between multiple intended uses all while providing significant ROI will help ensure the ongoing efficiency and longevity of a practice, as well as superior patient results, for years to come.

The TempSure platform, which includes both TempSure Envi and TempSure Surgical applications, has had a huge positive impact on my practice already. The device’s efficiency is truly invaluable to me as a practitioner,” said Barry DiBernardo, MD, medical director of New Jersey Plastic Surgery. “I’m now able to seamlessly transition from aesthetic procedures like wrinkle reduction with TempSure Envi to utilizing TempSure Surgical for more invasive procedures on a single device.
Marketing for anything with hemp is in high gear, fueled by Congress’s passage in December 2018 of the Agricultural Improvement Act, or farm bill, which legalizes production of hemp in all 50 states. According to a Washington Post article on the $867 billion farm bill, hemp is a form of cannabis with lower THC levels than marijuana. The hemp industry could grow to $20 billion by 2022, according to the article.

Companies are touting CBD oil, a hemp-derived cannabidiol (CBD), for a spectrum of health benefits including in the treatment of skin disorders. But the claims are more anecdotal than scientific. It’s hard to find published studies proving CBD is safe and effective. Still dermatologists and others think there’s something to this so-called remedy.

“It’s true, CBD has gone mainstream and is now frequently referred to as a ‘cure-all’ by scientists, doctors and users alike — all because of numerous health challenges that are showing very positive improvements,” says Tina Alster, M.D., clinical professor of dermatology at Georgetown University Medical Center in Washington, D.C.

As a result of the farm bill that legalizes CBD oil, a non-psychoactive (no “high” or intoxicating effect) naturally-occurring compound found in the cannabis plant, each state is responsible for crafting respective legislation to manage the production and sale of CBD within its borders, Dr. Alster says.

CBD FOR HEALTH CONDITIONS

According to Dr. Alster, some believe that CBD may have a positive impact on a variety of health concerns and conditions including chronic pain, joint inflammation, anxiety, insomnia, headaches, memory, nausea, neurological disorders, skin disorders and more. The most scientific evidence for using CBD, however, is in the treatment of some childhood epilepsy syndromes. Studies also suggest that CBD may help with sleep and pain, author Peter Grinspoon, M.D., writes in an August 24, 2018, Harvard Health blog.

CBD FOR SKIN HEALTH

CBD oil has an anti-inflammatory property, which can benefit the skin, and it can also reduce oil production, provide moisture and relieve pain and itching, according to Dr. Alster.

“Topical CBD is safe and works effectively for all skin types. The products are easy to administer. Sufferers of serious medical skin conditions and those who are seeking innovative skincare options can benefit from topical CBD use,” Dr. Alster says.

“Anti-inflammatory properties associated with CBD are beneficial in treating such dermatologic conditions as acne, psoriasis and eczema due to reduction of dryness, irritation and redness. CBD-containing creams, oils, gels and serums not only moisturize and soothe the skin, but are also showing encouraging results in relieving pain caused by certain skin disorders.”

CBD has shown that it exerts antioxidant activity. This could position CBD oil as a treatment that repairs skin from free radicals, which may help to smooth wrinkles and reduce breakouts and blemishes, according to Dr. Alster.

“In addition, CBD-containing products are rich in omega-3 and omega-6 fatty acids which improve overall skin appearance and provide a more youthful glow,” she says.

Topical CBD is considered safe and has no known adverse side effects, according to Dr. Alster.

Dr. Grinspoon writes in his blog that cannabidiol use can result in nausea, fatigue and irritability.

“CBD can increase the level in your blood of the blood thinner coumadin, and it can raise levels of certain other medications in your blood by the exact same mechanism that...
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Optimal uses for 18 popular HA fillers

LISETTE HILTON | Staff Correspondent

Injectable hyaluronic acid (HA) fillers are flooding the market, challenging aesthetic physicians to determine which product is best for an individual patient’s soft-tissue volume loss or facial rejuvenation needs. It’s not so easy. Clinical data looking at product performance is lacking, according to authors of a recent paper published April 2019 in Plastic and Reconstructive Surgery.1 To help aesthetic providers better differentiate HA fillers, the authors collected rheologic and physicochemical measurements on 18 HA filler products, including Belotero Balance (Anteis, S.A. for Merz Pharma); Juvederm products (Allergan); Restylane fillers (Q-Med AB/Galderma); and Teosyal products (Teoxane).

The authors looked at the impact of rheologic parameter elastic modulus (G’) and HA concentration on swelling factor and cohesion to differentiate dermal fillers. They also shared practical experiences about G’-based product selection when considering skin quality, degree of correction, injection depth and anatomical location, according to the paper.

They found G’ is a useful and consistent way to distinguish HA filler products. They observed relationships between G’ and swelling factor and G’ and cohesion among products manufactured by the same crosslinking technology and the same concentration. But there was no apparent relationship between isolated HA concentration and swelling factor or cohesion.

Higher G’ fillers tend to be firmer, with a more elastic compression response. Lower G’ fillers tend to be softer and less elastic.

“… in general, higher G’ products are better suited for thicker skin and deeper injection planes, whereas lower G’ products are better for more superficial planes, although exceptions to these trends are also made based on technical experience,” according to the authors.

"IN A RECENT POLL, WE ASKED OUR ONLINE READERS: Do you find G’ value an important part of the HA filler decision-making process?"

NO ONE FILLER DOES IT ALL
Aesthetic clinicians are using HA fillers in many ways to rejuvenate the face — from primary uses such as injections into the superficial to mid dermis to address perioral rhytids, to more recent uses, including correction of the temple and infraorbital hollows. No one filler does it all, they say. And those clinicians who understand how to select products based on G’ can use that knowledge to better correct soft-tissue volume loss and rejuvenate faces, according to the paper.

Of the 18 fillers studied, the filler with the lowest G’ was Restylane Lyft, which they say is good for injecting into the deep dermis, to treat moderate to severe nasolabial folds, for midface volume loss, for cheek augmentation and to build volume in the dorsal hand.

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**RECOMMENDED OPTIMAL HA FILLER USES**

<table>
<thead>
<tr>
<th>PRODUCT</th>
<th>TECHNOLOGY</th>
<th>APPLICATION AREA</th>
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<tbody>
<tr>
<td>Restylane Silk</td>
<td>Vycross crosslinking technology</td>
<td>Lateral canthal lines (superficial to deep dermis)</td>
</tr>
<tr>
<td>Restylane Refyne</td>
<td>XpresH4 crosslinking technology</td>
<td>Nasolabial folds and perioral area (superficial to deep dermis to subcutaneous)</td>
</tr>
<tr>
<td>Juvederm Ultra XC</td>
<td>Hylacross crosslinking technology</td>
<td>Nasolabial folds (mid to deep dermis)</td>
</tr>
<tr>
<td>Juvederm Volbella</td>
<td>Vycross crosslinking technology</td>
<td>Lateral canthal lines (superficial to mid dermis)</td>
</tr>
<tr>
<td>Belotero Balance</td>
<td>CPM crosslinking technology</td>
<td>Lateral canthal lines (superficial to mid dermis)</td>
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**IN A RECENT POLL, WE ASKED OUR ONLINE READERS: Do you find G’ value an important part of the HA filler decision-making process?**

| 61% | 17% | 22% |
| YES | NO | IT DEPENDS |

**CHOOSING HA FILLERS**

Aesthetic clinicians are using HA fillers in many ways to rejuvenate the face — from primary uses such as injections into the superficial to mid dermis to address perioral rhytids, to more recent uses, including correction of the temple and infraorbital hollows. No one filler does it all, they say. And those clinicians who understand how to select products based on G’ can use that knowledge to better correct soft-tissue volume loss and rejuvenate faces, according to the paper.

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FILLERS CONTINUES ON PAGE 47
"...clinicians should look to products with higher G′ values for deeper planes of injection and a greater degree of correction, and to lower G′ fillers for more superficial planes of injection and less severe correction."

Fillers: Higher G′ good for injecting into deep dermis

The authors report swelling factor data indicate that lower G′ products tend to have higher swelling factor and higher G′ fillers often have lower swelling factor. They found nonanimal stabilized HA and Vycross products have the lowest capacity to take up additional fluid, versus Cohesive Polydensified Matrix product (Belotero Balance) and XpresHAn crosslinking product (Restylane Fynesse), which had the highest swelling factors.

Another finding: As G′ decreases, gel appears to have more cohesive properties, or a higher drop weight. But that relationship seemed to exist only with products produced by the same technology. Gel cohesion’s importance is not yet clear but is evolving, according to the researchers.

PRODUCT SELECTION TIPS
The authors point to other factors that are important for product selection, including skin quality. "The contributing authors agree that for patients with thinner skin, where product palpability/visibility is an important consideration, products with lower G′ values are generally most appropriate."

When considering a product based on degree of correction and plane of injection, clinicians should look to products with higher G′ values for deeper planes of injection and a greater degree of correction, and to lower G′ fillers for more superficial planes of injection and less severe correction, according to study authors.

When selecting G′ based on anatomical location, the authors offer a few examples such as considering lower G′ products for areas such as mild tear troughs in patients with thin or transparent skin and higher G′ products with greater lift capacity for deeper tear troughs. "The data and discussion topics presented here represent a source of practical information intended to educate and assist clinicians and injectors in selecting the products best suited to the needs of each patient. Some author recommendations may include off-label use of products, they conclude. ◼

Disclosures
G Medi AB/Galderma, Uppsala, Sweden, for provided data for all products presented. Åke Öhrlund and Per Winlöf (G Medi Galdermo) provided technical expertise and scientific input, and Alessandra Nogueira, M.D., and Lynette Artadi, M.S., F.A.P.A.C.C. (Galderma Laboratories, L.P., Fort Worth, Texas), shared clinical expertise for the article. The paper's authors S. Fagien is a paid speaker, consultant and clinical trial investigator for Galderma and a paid speaker, consultant and clinical trial investigator for Allergan. V. Bertucci is a paid clinical investigator, consultant and speaker for Galderma, Allegan and Mezard and a consultant for Prolenium and Reese; E. Von Stechow; and J.H. Mashburn were employees of Galderma Laboratories, L.P., (Fort Worth, Texas) at the time of article preparation.

Reference

Estrogen: MEP product well tolerated in safety study

At week 14, investigators found significant improvement in MEP vs placebo for skin dryness, dullness, thickness, laxity, erythema, atrophy and fine lines. The study was designed such that MEP could be responsible for the observed results.

“We wanted to be sure that the effect we were observing was due to the active MEP and not due to moisturizing substances in the vehicle,” says Dr. Draelos. “We tried to create as close to a placebo as possible in the vehicle. This is important because the moisturizing vehicle is the active in many cosmeceutical formulations.”

DIGGING DEEPER INTO THE DATA
“When they did the studies of MEP and then performed biopsies of the skin that had been treated with MEP after 14 weeks, they looked for estrogen receptors on fibroblasts,” says Dr. Berson.

After 14 weeks of treatment, investigators found estrogen receptors on fibroblasts where they had previously disappeared. Essentially, says Dr. Berson, MEP actually stimulated estrogen receptors to reform on dormant fibroblasts.

“We know that the presence of estrogen stimulates receptors to increase on the cells, but MEP similarly did this. So you could have a woman who’s been postmenopausal for five years, give her this product and she can actually reform estrogen receptors on her fibroblasts,” says Dr. Berson, thereby stimulating receptors and subsequently increasing collagen and skin hydration.

“As dermatologists, I think we will be treating a larger percentage of postmenopausal women. We can reverse the signs of estrogen-deficient skin by using this product but yet not have to worry about any of the potential hormonal side effects because it is not a hormone,” Dr. Berson says.

Joel Cohen, M.D., a dermatologist in Denver, Colo., tells Dermatology Times that he recently completed a 20-week open-label study of the MEP technology.

“In the study, many younger patients seem to show significant improvement by about eight weeks, documented in photos. Some older patients, who presumably have been in menopause longer, seem to have taken longer, but by 20 weeks some have shown very significant improvement,” says Dr. Cohen.

Importantly, “Patients really liked the formulations — which are what is now currently available: the day serum and the night cream,” he says. ◼

Disclosures
Dr. Berson, Draelos and Cohen have received grants and/or research funding from Ferndale Laboratories.

References
Researchers’ knowledge of how to counter chronic low-grade inflammation continues to evolve."

Probiotics and prebiotics can supplement gut microbiota. From Page 42

For probiotics), because it remains unclear which probiotic species provide maximum benefits in which patient groups, says Dr. Schell, gastroenterologists and rheumatologists often recommend rotating several strains monthly.

Stress affects the skin

Stress also impacts the skin through the brain-skin connection. Along with immediately perceiving external stressors such as heat, cold, pain and mechanical tension, she says, the skin is a target of stress responses. Various receptors transmit these external signals to the spinal cord. Once these signals reach the brain, it responds by triggering the release of stress hormones such as corticotropin-releasing hormone (CRH), glucocorticoids and epinephrine. While stress impacts the skin mainly through the hypothalamic-pituitary-adrenal (HPA) axis, she adds, the skin also contains a fully functional peripheral HPA system in which CRH, adrenal corticotropin and their receptors are produced in skin cells.

Additional skin stress comes from the release of catecholamines (epinephrine and norepinephrine) through the sympathetic-adrenal-medullary axis, and from the effects of neuropeptides (such as substance P) and neurotransmitters (such as prolactin) secreted by peripheral nerves within the skin, Dr. Schell says. Meanwhile, external insults including UV radiation accelerate the skin’s natural aging process, producing evidence of chronic low-grade inflammation including coarse and deep wrinkles, mottled hyperpigmentation, sallowness and telangectasias.

Cellular senescence is driven by mechanisms including telomere shortening, genotoxic stress, mitogen stimuli and inflammatory cytokines, all of which can activate the p53 tumor suppressor and/or the cyclin-dependent kinase inhibitor p16, Dr. Schell adds. Clearly, she says, the number of senescent cells, which secrete multiple inflammatory cytokines, in several organs increases with age.

“This phenotype of senescent cells is called the senescence-associated secretory phenotype (SASP), which recently has been proposed (in this review) as the main origin of inflammation in both aging and age-related diseases such as atherosclerosis, cancer and diabetes,” Dr. Shell adds.

Immunosenescence (age-related dysregulation of the innate immune system) is both characterized by persistent inflammatory responses and accelerated by the presence of chronic inflammatory illness.

“Along with cell senescence, dysregulation of immunological imprinting mediated by trained innate immunity might also contribute to persistent low-grade inflammation that occurs even after the initial stimulus has been removed,” Dr. Schell says.

Conversely, she adds, a recent study has shown that the catecholamines released during exercise may reduce chronic inflammation. In this study, 20 minutes of moderate exercise suppressed monocytic TNF production via B2 androgen receptors.

Battling cell senescence can be as easy as taking oral supplements, Dr. Schell says. Natural anti- senescence compounds with senolytic effects include tocotrienols, quercetin and piperlongumine.

Natural polyphenols (flavonoids and non-flavonoids) also combat senescence, she says. “We’ve known about natural polyphenols for a while. That’s why people juice. It’s probably better to eat the vegetable or fruit, instead of just doing the juicing, and get the cellulose with it. People don’t want to eat a lot of fruit and vegetables anymore.” Additionally, synthetic compounds including dasatinib, navitoclax, panobinostat, Hsp90 inhibitors, FOXO4-p53 targeting peptide and 2-deoxy-D-glucose also provide senolytic activity.

To combat the SASP, Dr. Schell says, natural options range from curcumin to catchines, genistein and resveratrol. Synthetic SASP fighters include metformin, rapamycin, JAK inhibitors and aspirin.

Presently, she says, researchers’ knowledge of how to counter chronic low-grade inflammation continues to evolve.

“We don’t really know the correct pathways or how it’s going to work. Right now everything is just a big open-minded experiment for people who are interested in this topic.” Yet the necessity of reducing chronic low-grade inflammation could hardly be clearer, she says.

Disclosures
Dr. Schell reports no relevant financial interests.

References

Cannabidiol use can result in nausea, fatigue and irritability. From Page 44

Grapefruit juice does. A significant safety concern with CBD is that it is primarily marketed and sold as a supplement, not a medication. Currently, the U.S. Food and Drug Administration does not regulate the safety and purity of dietary supplements,” explains Dr. Grinspoon.

CBD is being tested in numerous laboratories around the world for its health-enhancing properties and its effects on a plethora of diseases and conditions, according to Dr. Alster.

“The CBD skincare industry is still very young, so further research and experimentation is needed,” she says.

Disclosures
Dr. Alster reports no relevant conflicts of interest.
Sunsreen is in the news. The FDA is proposing researchers, manufacturers and consumers take a hard look at how some sunscreens don’t have the data needed to show they’re safe.1 A recently published paper in the *Journal of the American Medical Association* (JAMA) suggests that active ingredients in commercially available sunscreens quickly enter the bloodstream at levels far exceeding the recommended threshold.2 And, mainstream media and grassroots bloggers are covering the news with headlines suggesting the products consumers trust to protect their skin might be hurting their health.

Through it all, the U.S. Food and Drug Administration (FDA), American Academy of Dermatology, researchers and physicians are urging Americans to continue using sun protection, including sunscreen, until more is known.

It’s a challenging situation for dermatologists, according to Henry W. Lim, M.D., chair emeritus of the department of dermatology at Henry Ford Hospital in Detroit.

“Dermatologists and the public in general have to make sure not to lose sight of the importance of photoprotection. We all know the side effects of UV exposure, and we know photoprotection does decrease the development of skin cancer,” Dr. Lim says. “We need to continue to emphasize that photoprotection is important and sunscreen is one part but not the only part of photoprotection. We also need to continue to emphasize that while the FDA is requesting more data, the FDA has also been very clear that people should continue to use sunscreen. The data that they got on the *JAMA* article — the clinical significance of that requires further study.”

**FDA’S PROPOSED RULE**

In late February 2019, the FDA publicly issued its proposed rule — one it calls a significant action to bring nonprescription, over-the-counter sunscreens that have, until now, largely escaped the FDA’s radar under greater scientific scrutiny. The final rule would impact how industry markets sunscreens.

“The agency is issuing this proposed rule to put into effect final monograph regulations for OTC sunscreen drug products as required by the Sunscreen Innovation Act,” according to the FDA. “OTC monographs establish conditions under which the FDA permits certain OTC drugs to be marketed without approved new drug applications because they are generally recognized as safe and effective (GRASE) and not misbranded.”

**ACCORDING TO THE PROPOSED RULE:**

Zinc oxide and titanium oxide are the only two of 16 marketed active ingredients, or filters, that are GRASE.

On the other side of the safety spectrum, aminobenzoic acid (PABA) and trolamine salicylate should not be used in sunscreens due to safety issues.

That leaves 12 active sunscreen ingredients: cinoxate, dioxybenzone, ensulizole, homosalate, meradimate, octinoxate, octisalate, octocrylene, padimate O, sulisobenzone, oxybenzone and avobenzone.

There isn’t enough data to classify these as GRASE, so the FDA has published guidelines for industry to ensure sun...
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Recent advancements in noninvasive imaging modalities are making an impact on dermatological care. Techniques such as reflectance confocal microscopy (RCM), optical coherence tomography (OCT), and the various innovative spectroscopies have all proven to be useful adjunctive tools in the diagnosis and management of suspicious pigmented lesions and nonmelanoma skin cancers — whether used alone or in combination.

According to Anthony M. Rossi, M.D., FAAD, it is in the combination of these technologies where the future of skin cancer management lies.

“Noninvasive imaging is not just an idea in the future; but, rather, already in current practice used across the world. Noninvasive imaging is something that we need to understand, and we should own it as dermatologists because it really is imaging of the skin. We use dermatoscopes and digital photography, so confocal microscopy is the next adjunctive tool that we should be using in skin cancer management,” says Dr. Rossi, a Mohs surgeon in the department of dermatology at Memorial Sloan Kettering Cancer Center, New York. He spoke to colleagues during the Annual Conference of the American Society for Laser Medicine and Surgery, Denver.

Dr. Rossi says there is a push to integrate these imaging techniques into clinical practice where they can potentially serve as helpful tools to reduce biopsy procedures. The limitation of RCM is that it only images 200 microns into the skin, reaching into the papillary dermis. In his current research, Dr. Rossi and his team utilize a clinical confocal microscope that combines both OCT and RCM. According to Dr. Rossi, it is the integration of RCM with OCT that gives you more of a depth of resolution, allowing a user to see both superficial and deep structures.

“We can now image the depth as well as the breadth of the lesion, translating into a virtual 3D landscape of the area/lesion under scrutiny. In our patients, we’re using this technique for any suspicious lesion that we believe is amenable to it. We can actually estimate how deep a basal cell carcinoma is running in the skin, noninvasively,” Dr. Rossi says.

Another imaging technique they’re implementing is the use of video mosaics. Using confocal microscopy and a hand-held microscope (visoScope 3000), Dr. Rossi’s team creates real-time videos, imaging the lesion and the lesion margin status. These video images are then translated into a mosaic, similar to the panorama mode found on smartphones to create panoramic images.

“Video mosaic imaging with the confocal allows us to actually assess the whole margin status and view the image in real-time. We routinely found this technique to be very useful in accurately diagnosing suspicious lesions, but in particular, for the correlation of margin status to the actual lesion. In contrast to the old method of static confocal, video mosaicking lets you be more free form and allows you to correlate the mosaic image back to the actual patient,” Dr. Rossi says.

The integration of such new and innovative imaging technologies in widespread clinical practice is perhaps less of a financial issue, Dr. Rossi says, and more of a question of affinity and adoption by dermatologists. Perhaps at first perceived as a daunting task, Dr. Rossi says that the learning curve is manageable and concerns of learning to appropriately use and implement these technologies can be overcome after visiting device-respective teaching courses and workshops.

“We are seeing more interest and resources being devoted to technologies such as RCM. In my opinion, these advanced technologies are here to stay, and the more people adopt and embrace it the better chances we have to really own it,” Dr. Rossi says.
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Lasers aid AK treatment

ILYA PETROU, M.D. | Staff Correspondent

A s most dermatologic therapies are administered topically, adjunctive modalities used to enhance the uptake of the topically applied medication can help improve treatment outcomes, one expert says.

For example, Andrés Már Erlendsson, M.D., Ph.D., has found that laser-assisted drug delivery (LADD), used to fractionally ablate the target area prior to topical medical treatment, is particularly useful in patients with widespread actinic damage. He recently shared insights during the Annual Conference of the American Society for Laser Medicine and Surgery, Denver.

Other drug delivery techniques that can be used to help increase the topical delivery of the drug to the target area include microneedling, nonablative fractional curettage and microdermabrasion; however, the novel ablative fractional laser technique (using erbium:YAG or CO2 lasers) not only creates a greater uptake of the drug, but there is a more homogenous uptake of the topically applied drug in the skin compared with other modalities, says Dr. Erlendsson, a research fellow in the department of dermatology at Memorial Sloan Kettering Cancer Center, New York.

Patient populations that can significantly benefit from the LADD technique are those presenting with widespread actinic damage, in part, characterized by multiple and coalescing actinic keratoses (AKs), as well as organ transplant recipients (OTRs) who, because of their immunosuppression, will often develop multiple AKs in terms of field cancerization. According to Dr. Erlendsson, performing a field therapy in such patients can be more effective and efficient if the target area is pretreated using the LADD treatment technique. A metaanalysis study summarizing the data of seven recent randomized controlled studies using the LADD technique with photodynamic therapy (PDT) in patients with AKs showed a 33% increase in AK clearing when the target area was pretreated with the fractional ablative laser, he says.

“When a patient comes in with a lot of severe actinic damage, you can target the AKs with the fractional ablative laser and then perform a PDT treatment on that entire treatment field,” Dr. Erlendsson says. “In those areas where you have done the laser pretreatment, you will get a more robust treatment response. Laser-assisted drug delivery is not for every AK patient that comes through the door but for those with widespread severe actinic damage, it can be a very useful method to help better clear the cancerization field.”

The characteristics of the laser channels, such as depth and density, are key to maximizing drug delivery, Dr. Erlendsson says. When performing laser-assisted PDT in thicker, hyperkeratotic AKs (i.e., Grade II-III), a recent clinical study found that using deeper channels, 350-500-micron, appear to increase the clearance rate of targeted lesions compared to superficial channels.

“In terms of channel density, there’s plenty of data showing that you do not need more than 5% to 10% density when performing the LADD treatment. The overall uptake increases with density but it plateaus at around 5% to 10% density. LADD is a very effective and promising therapy, but one should also use it with measure according to the targeted lesion,” Dr. Erlendsson says.

Although a few studies with the LADD technique have already been performed for patients with basal cell carcinoma (BCC) and squamous cell carcinoma (SCC), Dr. Erlendsson says the results have been mixed and, as such, he does not recommend LADD treatment for those nonmelanoma skin cancers. In contrast however, the treatment is very amenable and welcome for those patients with multiple AKs.

“Using the topical drugs that we have at our disposal, particularly PDT, LADD is an off-label treatment technique that can significantly help increase the efficacy of our topicals and achieve a higher clearance of targeted lesions,” Dr. Erlendsson says.

Disclosures
Dr. Erlendsson reports no relevant financial disclosures.

References
New immunotherapy medications have shown a durable clinical benefit in cancer patients, including those with malignant melanoma. It is important for clinicians to understand the intricacies of the immune mechanisms driving these evolving immunotherapies in order to provide guidance when patients seek advice on best treatment and management strategies, one expert says.

“Melanoma is one type of cancer that is most relevant when it comes to tumor immunology since it is one of the most immunogenic tumors. As such, it should be one of the central goals of dermatologists to gain a better understanding of immunologic pathways as well as the mechanisms of new and evolving immunotherapies, as these are key for understanding many current and emerging treatments,” says Delphine J. Lee, M.D., chief of dermatology and residency program director at Harbor UCLA Medical Center, Los Angeles.

There are several melanoma immunotherapies that have been approved by the U.S. Food and Drug Administration (FDA), including immune checkpoint inhibitors, adoptive cell transfer, as well as vaccines like Bacillus Calmette–Guérin and cytokines that can be used to enhance the host’s immune response to fight the tumor.

Antibodies against the immune checkpoint regulators, such as ipilimumab (Yervoy, Bristol-Myers Squibb), nivolumab (Opdivo, Bristol-Myers Squibb) and pembrolizumab (Keytruda, Merck) have all shown benefit in survival.

According to Dr. Lee, adjuvant immunotherapy is an exciting area of treatment. Just a few years ago those patients who had lymph node involvement (stage 3 disease) were either observed, received interferon alfa or radiotherapy, or could hope to enter a clinical trial after their definitive surgery.

Today, melanoma patients have an increasing variety of immunotherapy medications that can be wisely chosen once they are considered NED (No Evidence of Disease), which will hopefully prolong survival.

“In the past, we just didn’t understand how to manipulate the immune system in the right way. Back when we were making the vaccines in the 1980s, we did not know about immune checkpoint molecules. Now that we understand so much more about the immune system and how it is regulated, we are able to offer our patients advanced immunotherapies that help them improve their survival. It’s just so amazing and great to witness the positive changes that have happened in melanoma therapy in the last few years,” Dr. Lee says.

FUTURE OPTIONS
Future treatment approaches may consist of personalizing therapy one step further. For example, a patient’s novel tumor neoantigens would be identified and, after determining which ones are most highly expressed, vaccines would be developed against those tumor antigens so the patient’s immune system could recognize them.

“I consider dermatologists as the primary care physician for melanoma patients and, as such, it is good for us to be well versed in this specific field,” Dr. Lee says.

Disclosures
Dr. Lee reports the following disclosure: Biogen—SH(NC).
Rosacea as an Inflammatory Disorder

James Del Rosso, DO: Hello. I am Jim Del Rosso, a dermatologist in private practice in Las Vegas and research director at JDR Dermatology Research, and am joined by Linda Stein Gold, the director of dermatology clinical research at Henry Ford Health System in Detroit. We are discussing rosacea as an inflammatory disorder.

Rosacea has been the subject of basic science and clinical research. It is now considered a chronic inflammatory dermatosis involving the face. Dr. Stein Gold, can you give me some thoughts based on this research?

Linda Stein Gold, MD: Rosacea has gone through an explosion in terms of understanding it. It is not acne, in which an organism is central to pathogenesis, but again, an inflammatory disorder. I think of it as the innate immune system overreacting to certain stimuli. At the center is the cathelicidin pathway, the antimicrobial peptides, which should be our first line of defense. Instead of protecting us, though, it starts to spark a chronic inflammatory condition. Do you think the cathelicidins are important?

Dr. Del Rosso: There are different circuits: neurovascular dysregulation, with different neurotransmitters and chemical mediators that trigger flushing and some stinging and burning, and the cathelicidin pathway. The cathelicidin pathway is involved in the development of background erythema and inflammation, but it does not explain the entire story. Immune dysfunction and neurovascular dysregulation lead to signs and symptoms that can vary over time and among patients as to what is dominant.

This is what makes it complicated. We used to mix everything together regarding clinical presentation, but now we look at individual features because we have different therapies to target them. It has helped me in evaluating patients. Let’s say a new patient comes in who has not used therapy in a long time, their face is red with diffuse erythema, papules and pustules, and they are in a flared state. How you evaluate and explain it to the patient is important.

Dr. Stein Gold: Yes, the whole process is complex. We have different factors that go into pathogenesis, the neurovascular pathway, cathelicidin pathway, and triggers. All come into play when we see a patient. In the past, it didn’t matter what signs or symptoms they had, we wrote for topical metronidazole.

We know now that’s not the best approach. When I see a patient, I say, “Okay, what exactly am I treating?” If someone presents with papules and pustules, they need a topical or oral anti-inflammatory drug. If they also have background erythema, they’ll probably need a topical alpha-adrenergic agonist. If they have scattered broken blood vessels, the patient isn’t going to be happy because I made their bumps and redness go away, as those blood vessels remain.

Dr. Del Rosso: When they’re flared, it may take several steps to address. If they have a lot of background erythema, I might integrate the alpha agonist early or wait to calm it down. I explain we might need to use things at different times, but first I calm down the flare with the papules and pustules to see everything better.

I use topical ivermectin, which data show is an excellent drug. I also use azelaic acid and metronidazole along with oral doxycycline. I like to use subantibiotic-dose doxycycline to avoid the resistance factor, but I may not use both long term, depending on how the patient does and how I integrate the alpha agonist. I use more oxymetazoline, because I have less issue with worsening erythema, although brimonidine works on many patients. When they’re really flared, I get that perilesional erythema under control as quickly as possible.

Dr. Stein Gold: Often with patients who are really inflamed, a lot of papules come in. They have not only perilesional erythema but also background erythema. Once you calm everything down, they are not as red as you might have thought.

But I agree, we tell them this is a staged approach. Once we get the initial condition under control, I explain that the blood vessels will be treated separately. I ask about eye symptoms with these patients. Many have ocular rosacea that goes undiagnosed.

Dr. Del Rosso: It is important to ask about ocular symptomatology. They could have allergies or itchy eyes and not equate it with rosacea. They’ll often improve, especially on an oral drug.

Dr. Stein Gold: As to using lower- or submicrobi-al-dose doxycycline, this goes back to rosacea being an inflammatory disease. We don’t need higher-dose antibiotics because these are not being used as antibiotics but for their anti-inflammatory properties.

Dr. Del Rosso: Let’s take the patient without papules and pustules who comes in with diffuse central facial erythema and tells you when it intensifies, but their cheeks stay red. But you are seeing them in a nonflared state. They have persistent facial erythema and may or may not have ocular symptoms. How do you approach that?

Dr. Stein Gold: If I see just background erythema, I go with a topical alpha-adrenergic agonist.
If I’m going with oxymetazoline, I wait to use it in patients, especially if they have papules, in combination with the topical ivermectin.

**Dr. Del Rosso:** Another agent, brimonidine, initially came in multiple pea sizes and was being overused. Skin care was not recommended. I use it in a very thin amount, and with some moisturizer, many patients do well. But it’s very potent, the highest concentration of that drug. Oxymetazoline has a middle concentration that doesn’t blanch out the skin as intensely. Having both options lets you judge how much erythema you’re going after.

**Dr. Stein Gold:** And it’s individualized for each patient. Brimonidine has a more significant effect, while that with oxymetazoline is gentler.

**Dr. Del Rosso:** With oxymetazoline, there is less chance of paradoxical erythema, but both are very helpful in patients if used consistently and they know the erythema will come back in about 12 hours. I tell the patient the first time you use one, we don’t know how it’s going to kick in. We need to learn how it’s going to work for you so you’ll know how to apply it and how long it will last.

**Sometimes I have trouble explaining rosacea to patients. What are key things you say to patients to get them to understand rosacea?**

**Dr. Stein Gold:** First, it’s not your fault. People want to know what they are doing wrong or if they are not eating right. Rosacea is a complicated condition. For many patients it’s inherited. It commonly occurs, more in women and in Caucasians, but we can see it in anyone. I explain there’s nothing you’re necessarily doing wrong, but many people have triggers that can make it worse. So although it’s not spicy or hot foods causing you to flare up, maybe you don’t want to go out on a first date and order hot chicken soup and turn red. And you need to have sunscreen on.

I explain this is a process, an inflammatory condition many have throughout their adult life. You learn how to control it and deal with it.

**Dr. Dell Rosso:** What you said is important, to let them know it’s not their fault. We have treatments to help control it even long term if they’re compliant and work with us. You develop that partnership when they’re not looking for a quick cure because it’s not curable. Although they can have prolonged periods during which they don’t flare, it varies. Data show we can decrease flushing episodes by using anti-inflammatory agents like ivermectin and doxycycline.

**Dr. Stein Gold:** This is a holistic approach to skin care. It’s not just that I can give you a pill to take and it will make you better. You have to be an equal partner in getting your skin under control, not buying toners and scrubs, and using gentle cleansers.

**Dr. Del Rosso:** What about management of phymas? In early phymas that are inflammatory, the topical agents effective against papular pustular disease like doxycycline can improve that inflammation. Do you use isotretinoin in early phymas or in more difficult cases of rosacea?

**Dr. Stein Gold:** I have. Sometimes though, a patient will come in with severe rosacea, and I’m thinking we have to use oral isotretinoin. I start them on oral doxycycline and a potent topical. Some respond nicely without having to go to isotretinoin.

**Dr. Del Rosso:** I am more aggressive with isotretinoin when seeing sebaceous hyperplasia with inflammation developing that will lead to a phyma before it becomes fibrotic or mucinous. I may prevent that if I catch it early enough with isotretinoin. Then patients can be on intermittent low doses to control it.

**Do you have any other suggestions in managing rosacea?**

**Dr. Stein Gold:** Very commonly, I use monotherapy. Now that we have topical ivermectin, monotherapy works in many cases. But when do you start with combinations?

**Dr. Del Rosso:** It’s based on severity of disease. There are patients for whom I’ll try topical alone, ivermectin or azelaic acid. In clinical studies, topical ivermectin went after a higher severity based on lesion counts. So it works well as monotherapy. But some patients have too much inflammation to depend on one treatment. I get them on subantibiotic-dose doxycycline with the topical. After a couple of months, we’ll look at monotherapy. If any persistent facial erythema is minimal, they may not need the alpha agonist or a device.

**Dr. Stein Gold:** Sometimes, I’ll use a combination to make sure it kicks in faster to get the patient more rapidly and completely under control.

**Dr. Del Rosso:** Data support it’s quicker to use doxycycline and topical ivermectin or metronidazole or azelaic acid, but not every patient needs that depending on severity.

**Dr. Stein Gold:** It’s important to have all these drugs. We need them because for every patient, we can’t predict who’s going to do well with which drug.

**Dr. Del Rosso:** Each patient is different and requires assessment of their manifestations. We select treatment based on what’s bothering them most, but some therapies are not used all at once. We might have to stagger in different treatments depending on the manifestation being targeted.

**What about the time course of response? When starting a treatment, we need to let a patient know how long it’s going to take before a change is visible.**

**Dr. Stein Gold:** People see drugs advertised as getting them better overnight, so setting realistic expectations is huge. Also, when we do clinical trials, we study drugs for 3 or 4 months, but some patients do not hit their peak by then. I’ll say they may be on this medication for a long time because I didn’t cure you, just controlled it.

**Dr. Del Rosso:** Data from long-term studies show more endpoint success with patients continuing to use treatment. More patients do better if they’re consistent over a longer time.

**Dr. Stein Gold:** Absolutely. For most patients, we’re going to have to use it for longer periods. What about maintenance therapy after the patient gets clear?

**Dr. Del Rosso:** If patients continue to apply medication or stay on a regimen like subantibiotic-dose doxycycline, they will reduce flares. It doesn’t mean they’re never going to get a flare or need more medication. I encourage them to stay on long-term treatment, but it costs. Refill data show that when better, they forego it. We may want that Nirvana of having patients on therapy long term, but often that’s wishful thinking.

**Dr. Stein Gold:** Right, but it is important to reinforce that I didn’t cure you. I feel better if a patient is not on an antibiotic for long periods. If the patient’s on submicrobial-dose doxycycline, I am okay saying this is a long-term control. I’m not concerned we’re doing anything to negatively affect overall health.
Dermatologists and the public in general have to make sure not to lose sight of the importance of photoprotection.”

Henry W. Lim, M.D., Henry Ford Hospital, Detroit

Sunscreen guidance hasn’t changed while FDA questions data

Screen manufacturers understand the data FDA needs to evaluate the safety and efficacy of these ingredients.

FDA also proposes GRASE dosage forms for different ways of applying sunscreens, including sprays, oils, lotions, creams, gels, butters, pastes, ointments and sticks.

“Powders are proposed to be eligible for inclusion in the monograph, but additional data are requested before powders can be included in the monograph. Wipes, towelettes, body washes, shampoo and other dosage forms are proposed to be categorized as new drugs because the FDA has not received data showing they are eligible for inclusion in the monograph,” according to FDA.

FDA proposes the maximum SPF value on sunscreen labels be raised to SPF 60+, from SPF 50+. Other issues in the proposed rule address labeling requirements; differentiating products that combine sunscreen and insect repellants as not GRASE; and more.

Steven Wang, M.D., a dermatologist at Memorial Sloan Kettering Cancer Center, says this is a proposed and not a final rule. The FDA was still seeking public comment through June at the time of this publication.

“The FDA is requesting the industry to submit proposed study proposals and results demonstrating the safety. Most of the safety data is looking at absorption and toxicity,” Dr. Wang says. But the timeline for the data isn’t enough to conduct research, according to Dr. Wang.

“In November of this year, the FDA needs to finalize the monograph on sunscreen, and that puts time pressure on this entire process. These absorption and safety studies take time. It is very doubtful that it can be completed within the next six months. It’s going to take a few years to sort through this process,” Dr. Wang says.

There are a few implications of the proposed ruling in the meantime, according to Dr. Wang. While the FDA is saying there’s insufficient data for safety, consumers should know that doesn’t mean sunscreens are unsafe, he says.

“It’s important to be reminded that sunscreens formulated with these 12 UV filters have been in use for [more than] 30 years. Millions of people are using these products every day. So far, there are no reported systemic side effects,” Dr. Wang says.

Sharyn A. Laughlin, M.D., a dermatologist, who specializes in laser and cosmetic dermatology in Ottawa, Ontario, Canada, says ignoring the FDA’s concerns is akin to putting one’s head in the sand.

Dr. Laughlin says that there are not only strong signs that some sunscreen chemicals harm humans and the environment, but these soluble organic hydrocarbon filters delisted by the FDA have little effect on lowering skin cancer rates.

“Even with avobenzone (the main UVA filter in the group of 12) they give UVB-BIASED protection where the sunscreen transmits up to 10 times more UVA than UVB to your skin — similar to the radiation profile of a tanning bed, which every dermatologist knows is carcinogenic. These UVB-BIASED sunscreens have dominated global sunscreen markets for 50 years and paralleled the rise in skin cancer rates that have doubled or tripled in many countries, including North America,” Dr. Laughlin says. There are perfectly good and safe options in sunscreens if consumers know where to look, says Dr. Laughlin, who is a research consultant to Cyberderm, an Ottawa-based sunscreen company. Dr. Laughlin started Cyberderm in 1995 to research and develop high UVA mineral sunscreens, she says.

There are no perfect sunscreen active ingredients with systemic absorption above 0.5 ng/mL should undergo non-clinical toxicology assessment, including systemic carcinogenicity and developmental and reproductive studies, according to the FDA.

When researchers studied 24 healthy partici-
pants applying four commercially available sunscreen formulations, in spray, lotion and cream formulations, they found the maximum plasma concentrations for avobenzone, oxybenzone, octocrylene and ecamsule (a filter not included in the FDA’s proposed rule) far exceeded the threshold, according to the FDA-funded study published online May 6 in JAMA.4

One glaring example: The geometric mean maximum plasma concentration of oxybenzone was 209.6 ng/ML for one of the sprays. And those in the study who applied sunscreens with oxybenzone had plasma concentrations of more than 0.5 ng/ML within two hours after a single application on the first day, according to the study.

Whether human health suffers with high plasma concentrations of these and other sunscreen chemicals remains unclear. The authors cite research that oxybenzone, octocrylene and other active sunscreen ingredients have been found in human breast milk. Oxybenzone has been detected in amniotic fluid, urine and blood and studies have raised questions about whether oxybenzone impacts endocrine activity.

The authors write that their findings are not definitive. Joshua Zeichner, M.D., a dermatologist at Mount Sinai Hospital in New York, agrees. “In this preliminary study where high levels of sunscreen were applied to 75% of the body, low levels of chemical sunscreen filters were shown to be absorbed through the skin. In the real world, consumers do not apply as much sunscreen as they should, and they do not reapply every two hours. So, it is unclear whether there is absorption with every day, real world use,” Dr. Zeichner says. “We need more data to understand this issue fully. Based on what we know today, the benefit of wearing sunscreen in protecting the skin against skin cancer and premature aging outweighs the potential risks. If anyone is concerned with the use of chemical blocker sunscreens, mineral options that contain zinc oxide alone or in combination with titanium dioxide are a great option.”

Dr. Wang says the fallout from this controversy could be fewer UV filters available for US sunscreen manufacturers and potentially less sunscreen use among consumers. “By the time this process is completed we might have fewer filters in the U.S.,” Dr. Wang says. “The industry might say we will not perform the necessary experiments for all 12 UV filters.”

The United States needs more of the UV filters currently available in other parts of the world, Dr. Wang says. Dr. Laughlin says new technologies are making even some zinc sunscreens more cosmetically pleasing.

“Zinc and titanium sunscreens which are what we call the insoluble, inorganic sunscreen filters, cannot get absorbed into the body,” Dr. Laughlin says. “What has happened over time is the molecule — the zinc itself — is milled very fine and it’s processed. The particles are actually lighter, which gives you better attenuation of light, and they’re not white anymore. They’re actually clear. It’s what we call index matching of the skin, so you see your own skin tone through. And, also, they don’t wash off with the water because they’re adherent to the dead skin.”

There are other newer molecules coming out which are insoluble but are not yet available in the United States, according to Dr. Laughlin.

“They may be carbon-based, but they are insoluble and cannot enter through the skin. They cannot enter into blood. They don’t cross the blood-brain barrier or the placenta to get into the fetus. Plus, they’re excellent filters for UVA,” Dr. Laughlin says. “For example, Tinosorb S and Tinosorb M, which provide UV absorption and reflection. Health Canada just approved those but in concentrations that are pretty low. We’ve formulated a 21% zinc sunscreen with Tinosorb S (1%) and M (9%) at higher concentrations. And that probably is the highest UVA protection factor at 45 in the world.”

For now, Dr. Wang says his message to patients is the message he has always given: “Sun avoidance, seeking shade, clothing, hat, use sunscreen. That sequence of protection has always been consistent.”

Dr. Laughlin says that even people with darker skin should try newer versions of zinc oxide sunscreen.

“Many zinc oxide sunscreens even at 20% to 25% apply clear and do not leave even dark skin looking white,” she says. “People need to use sunscreen, but they need to use good sunscreen with large insoluble UV filters that do not permeate; thereby avoiding all the controversy and bioavailability to the unborn, likely safer for humans and the environment and with higher UVA protection.”

Disclosures

Dr. Laughlin is a shareholder and consultant for The Sunscreen Company (Cyberdeem) No disclosures for Dr. Zeichner or Wang. Dr. Lim reports research grants from Henry Ford Hospital from Estee Lauder, Ferndale, Unigen. Dr. Lim is a consultant for Pierre Fabre and ISDIN.

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Another consideration when using sunscreens is the potential impact on the environment.

The sunscreen chemicals oxybenzone, benzophenone-1, benzophenone-8, OD-PABA, 4-methylbenzilidene camphor, 3-benzylidene camphor, nano-Titanium dioxide and nano-Zinc dioxide can harm marine life, according to the National Ocean Service.

Sunscreen chemicals become environmental hazards when they wash off skin and enter waterways. The marine life impacted includes green algae, coral, mussels, sea urchins, fish and dolphin. These chemicals impair marine life fertility and reproduction, induce defects in young creatures and even kill, according to the National Ocean service, which recommends that people choose sunscreens with chemicals that don’t harm marine life.

Studies implicating nanoparticle mineral sunscreens were carried out with true nanoparticles from industrial dispersions at less than 50 nm in size, says Sharyn A. Laughlin, M.D., a dermatologist, who specializes in laser and cosmetic dermatology in Ottawa, Ontario, Canada.

“Commercial sunscreens rarely if ever use true nanoparticles, which tend to forcibly agglomerate into larger particle dimensions. Most mineral products use size distributions of 200 to 15,000 nanometers,” she says.

Reference

The generational dermatology practice

JOHN JESITUS | Staff Correspondent

Treating patients of all ages does more than grow individual practices. Practicing dermatology across generations can also help the specialty regain its rightful medical and aesthetic leadership, experts say.

“A generational practice encompasses medical, aesthetic, cosmetic, oncologic and general pediatric dermatology,” says Wendy E. Roberts, M.D., who presented “Building a Generational Practice & Why You Should,” earlier this year at the Generational Dermatology Symposium. She is a Rancho Mirage, Calif.-based dermatologist whose practice is approximately 60% aesthetic and 40% medical.

“It’s a multi-decade approach to the evolving aging patient, using medical observations and family history,” says Dr. Roberts. For example, a mother in her 40s presents with melasma that developed during her first pregnancy. “After physical examination, you determine she does have melasma, and then you ask about her children.”

Perhaps the patient’s 21-year-old daughter takes oral contraceptives and has noticed skin darkening on her upper lip.

“You then start seeing this daughter for prejuvenation to decrease the risk of melasma,” she adds. Another daughter could be a teenager starting to experience acne.

“The patient who knows you treat hair loss also sends in her husband who is experiencing male-pattern hair loss.”

Dr. Roberts’ generational philosophy grew out of her desire to address aging proactively, and her observation that during her 25 years in practice, academic centers failed to embrace cosmetic treatments and skincare. These circumstances allowed other practitioners to position themselves as experts in these areas.

According to Dr. Roberts, “We dropped the ball. We didn’t maintain leadership in those subspecialties.”

BE THE EXPERT

The situation at academic centers is changing as people realize how much science supports cosmetic surgical dermatology, Dr. Roberts says. Still, dermatologists commonly complain about losing business to medspas, and about the commoditization of their specialty.

“We can’t complain — we must act. Just be the expert,” she says.

According to Beverly Hills, Calif.-based dermatologist Ronald L. Moy, M.D., “Other specialties are moving into injectable treatments with a 30-gauge needle or by pressing a laser button.”

With more general physicians branding themselves as cosmetic physicians, he says, injectable and minimally invasive treatments will become increasingly competitive.

Conversely, says Dr. Moy, hormone replacement therapy (HRT), DNA repair and nutritional supplementation are growth areas that dermatologists should consider. These patients are also his happiest. Compared to having a tighter neck or periorcular skin, Dr. Moy explains, HRT can be life-changing, while nicotinamide and DNA repair creams can halt development of skin cancers.

By adopting a generational approach, says Dr. Roberts, one might acquire every member of a patient’s family — by questioning not only the patient, but also inquiring about other family members, as family doctors do.

“This approach brings everything from simple skincare advice to skin cancer back into your practice,” she says.
PREVENTION ACROSS GENERATIONS
For Dr. Moy, generational dermatology includes a heavy focus on prevention for patients in their 20s.
“The average dermatologist just says, ‘wear sunscreens to prevent skin cancer and aging,’” he says. “We give people supplements and creams that increase DNA repair, which prevents aging and skin cancers.”

A study published in the September 2015 *Journal of Drugs in Dermatology* showed that a sunscreen with DNA repair enzymes performed significantly better than traditional sunscreen in reducing field cancerization of actinic keratoses and formation of cyclobutane pyrimidine dimers.1 A phase 3 study published in the October 2015 *New England Journal of Medicine* showed that oral nicotinamide significantly reduced nonmelanoma skin cancer development vs placebo.2

A small study published in the March 2001 edition of *The Lancet* showed that DNA repair enzymes dramatically decreased formation of basal cell carcinomas in sun-damaged skin of patients with xeroderma pigmentosum. These evidence-based discoveries have not received the attention they deserve, says Dr. Moy, because they involve inexpensive off-patent ingredients.

Dr. Moy also treats many postmenopausal women whose needs have been ignored by OB/GYNs.
“We see them in dermatology because so many people want to look better,” he says. “And the best way to make your skin look better is to be on hormones like estrogen, DHEA and testosterone, which tighten and thicken skin.”

HRT also prevents illnesses ranging from Alzheimer’s and cardiovascular disease to osteoporosis, he says, and HRT can improve mood and mental health.

“We should be better at preventing these medical problems. And we have the studies to do it,” he says. “It’s just that our education is so biased toward synthetic, patentable things because so much of our conferences are sponsored by the pharmaceutical industry.”

REFERENCE


$200

THE AMOUNT DR. ROBERTS AVERAGES EXTRA PER PATIENT BY ASKING A COUPLE OF QUESTIONS.

“It’s letting people know what services you offer, and making them come to life, not just on paper or a website,” she says.

A head-to-toe patient questionnaire includes questions like, “Are you or anyone in your family experiencing hair loss?” To go beyond the presenting complaint, Dr. Roberts sits with each cosmetic consultation patient and discusses challenges related to their skin and age.

“I look for subtle signs of hair loss, earlobe laxity, eyelid laxity, neck laxity, photodamage and other signs of aging,” she says.

She then crafts a treatment plan that encompasses the patient’s current and future needs. Dr. Roberts also explains to patients that relying on her aesthetic expertise will reduce costs, complications and time spent researching and trying procedures and products that may not work.

With HRT, says Dr. Moy, patients’ biggest concern is cancer. However, he tells patients that most publications linking HRT with cancer were older studies involving synthetic hormones.

“The use of bioidentical hormones doesn’t cause cancer,” he says. “I could bring out 40 articles that show no increased risk of breast cancer, for example.”

The same is true in prostate cancer, he adds, because many studies show that men with low testosterone are more likely to get prostate cancer than those who undergo properly administered testosterone replacement.

Challenges for Dr. Roberts include treatment costs and helping patients understand that completing a comprehensive plan takes more than one or two visits. However, she says, about 50% of cost-conscious patients overcome their reluctance after thoroughly discussing a procedure and seeing compelling before-and-after photos. She’s also had patients call or meet previous patients to discuss their experiences.

“A generational practice is a decision to make a custom practice. It can be very rewarding, and it’s not a mill. You will work hard in a different way. You could scurry and see five individual patients, or sit with one person and wind up treating them and their entire family. I probably make an average of about $200 extra per patient, just by asking a couple questions,” she says.

The generational approach also boosts patient loyalty, she adds. ✷

Disclosures
Dr. Roberts is founder of the Generational Dermatology Palm Springs Symposium but reports no other relevant financial interests. Dr. Moy is scientific director for DNA EGF Renewal Cream, which markets a nicotinamide supplement and products containing DNA repair enzymes.

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"After physical examination, you determine she does have melasma, and then you ask about her children."

Wendy E. Roberts, M.D., Rancho Mirage, Calif.
5 Insights on launching a new practice

For many dermatologists, the idea of starting a practice is a dream. While the concept of leaving the security of a hospital, health system or group practice can create feelings of freedom and independence, there can also be fear and plenty of “What ifs?”

Terrence Keaney, M.D., FAAD, co-founder and director of SkinDC in Arlington, Virginia, knows it’s a big step. He tells colleagues, however, that he practices with “no regrets” about his decision to open his practice in July 2017. He works in all of his chosen areas of expertise. “I wanted to create something bigger than myself,” he says.

The practice has seen more than 8,000 patients. Dr. Keaney says his practice breaks out into about 40% cosmetic and 60% medical. He currently employs five practitioners: the two co-founding dermatologists, two physician assistants and one aesthetician. He’s now doubling his office size to 18 rooms with cosmetic and medical wings, and he’s adding another dermatologist.

Dr. Keaney, who is assistant clinical faculty member with George Washington Hospital, Howard University Hospital and the Washington, D.C., VA Medical Center, says his office also is a study site for four clinical trials.

He shares five things he’s learned.

1. **KNOW WHY YOU WANT YOUR OWN PRACTICE AND WHAT YOU WANT IN THAT PRACTICE.**
   You must determine if you prefer medical or cosmetic dermatology, Mohs surgery or clinical research — or maybe a combo. Also, do you want a small or large practice?
   **The pros:** You have control of the schedule, the staff and the practice mix, and, ultimately, there is a long-term financial benefit.
   **The cons:** Human resources headaches can abound, along with unpredictability, a lot of pressure and “work upon work.” You run a business and see patients, which is two jobs.

2. **THERE ARE VARIOUS OPTIONS TO FINANCE YOUR BUSINESS.**
   You can either self-fund (Good for you!), seek investors — knowing you’re selling equity and losing control — or pursue a loan from a small, local bank or a larger one. Your start-up capital determines office space and medical device capability, while what you want to do determines how much capital you need. Remember to factor in soft costs of practice consultants, an attorney, an accountant and architects.

3. **THINK “LOCATION, LOCATION, LOCATION.”**
   Take a macro-level view and consider city vs urban environments, also look at the neighborhood. Evaluate the parts of town where people live or work and what kinds of other businesses are around: medical office vs commercial. You also want to know who the other dermatologists in the area are and where they are located. You can use the American Academy of Dermatology’s Find a Dermatologist tool and search the locations for the nearest dermatologists on Google Maps.

Dr. Keaney says he is positioned near the State Department offices and thriving security consulting firms, as well as organizations like Nestle, Amazon and Georgetown University. The closest dermatology practice is a few miles away.

4. **DON’T BE AFRAID TO BUILD OUT AN OFFICE.**
   It isn’t cheap to build a new office, but it may not be as expensive as you think, due, in part, to more sophisticated, but less expensive, building materials. Hint: Use your architect as your interior designer.
   You can buy or lease a space and use an attorney or tenant broker for detailed lease negotiations such as term, security deposit, tenant improvements and more. Go bigger than you need so you can expand. You don’t have to be in a medical building. Also, consider retail space, parking availability and convenience.
   Take your time, he cautions. He took more than a year to secure and build out his space. “The landlord would only lease us part of what we wanted,” he says. “It took time, patience and persistence, and the downside was that it delayed my opening, but I was the only dermatologist to push for this location.”

5. **DON’T BE AFRAID TO PARTNER.**
   As in any relationship, tread carefully. Select a partner you know well and trust. Think of this as a “professional marriage” with shared costs and responsibilities.
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Tips for making large capital investments

STEPHANIE STEPHENS | Staff Correspondent

**Quick Takes**

Dermatologists have an advantage when determining which devices to invest.

Patients present with a problem and ask for a solution.

When considering devices, consider your space, your budget and your long-term plans for the device.

Finally, you have options from outright purchase, to renting and leasing.

When considering incorporating devices into your practice, you should look at the patients you treat and their typical presenting complaints, one expert says.

Dermatologists have an advantage when determining which devices to invest in, says Anne Chapas, M.D., of Union Square Laser Dermatology in New York City. We’re always performing skin examinations. Patients don’t usually ask for specific devices, they present with a problem and ask for a solution.

“It’s our job to use the best evidence to help patients get the best results,” Dr. Chapas says. “The best investments address sun damage, pigmentation and vasculature, and there are lots of different options.”

She says you should consider your space, your budget and your long-term plans for a device. And then look at the conditions you’re treating and whether you’d prefer one device or several targeted devices.

For example, there are at least a dozen new innovations in the radiofrequency microneedling category, she says; but, these are more efficacious for fine lines and scaring; not as effective for targeting pigment.

**OPTIONS**

First, take a hard look at costs, either fixed or variable, she says.

- Fixed includes the laser purchase price, warranty and maintenance, office staff and lease.
- Variable includes the costs of consumables, and physician salary compensation.

The simplest move is an outright purchase, if you have cash flow to put down $100,000 on a laser, she says. There’s also the average 10 percent-of-purchase-cost annual warranty fee to consider.

“The outlay can be significant compared to making a $10,000 purchase of injectables,” Chapas says.

In lieu of an outright purchase, consider lease-to-own options from the company or from an outside bank, Dr. Chapas says.

“The interest rate usually fluctuates throughout the lease and is initially front-loaded.”

Another option is to rent a device for a day — but, she says, make sure all of your relevant patients are available the day the device is in your office.

**DON’T RUSH**

Shop smart at the end of the quarter or year and watch for floor-model sales and resale-market bargains, she says.

**TRY BEFORE YOU BUY**

“Ask the manufacturer to bring the device in and show you the features, then try it on staff,” Dr. Chapas says. “We tried one...”
A ccording to HubSpot, marketing statistics for 2019, 97% of consumers have searched online to find a local business. That’s not all: 46% of all searches on Google are from potential buyers seeking information, and 88% of consumers will typically use the internet to find a local business and visit them within 24 hours.

For your practice, it’s never been more critical to establish an online presence to attract leads and foster meaningful relations with potential patients. One of the first steps to generating online leads in local search is setting up your Google My Business (GMB) profile, customizing it, and gearing it towards online success for your healthcare marketing program.

Dermatology practices that employ high-performance GMB growth tactics can rank at the top of Google’s map pack, a rectangular box (example below) that displays nearby businesses in a searcher’s area. As a result, the practice at the top of Google’s map pack receives the lion’s share of consumer clicks. Google’s top map result has a 30% click-through rate (CTR), according to Smart Insights. Considering that thousands of people in your local area currently use search engines to find local businesses, that statistic is huge.

Fortunately, you can successfully increase your GMB ranking by using a methodical approach backed by proven industry techniques. Below are 9 tips you can use to leverage your GMB profile as a lucrative extension of your digital marketing strategy.

Tip #1: CLAIM AND VERIFY YOUR GMB LISTING
Did you know that 32% of U.S. businesses haven’t claimed their GMB listing? If you haven’t taken a few minutes to claim and verify your listing, then you’re missing out on lead opportunities.

Setting up your GMB profile is simple, and you only need to follow these four steps:
2. Fill out your name, address, phone number, (NAP) etc. and ensure that it’s correct.
3. Verify your GMB profile either on your phone or online using the verification code sent to you. Most likely, you’ll need to complete a two-step verification process.
4. Google will send you a postcard that contains your verification code. When you receive this postcard, login into your profile and verify your account.

Following these steps will ensure that your GMB is both accurate and verified.

Tip #2: COMPLETELY FILL OUT YOUR GMB PROFILE
Your GMB is essentially the liaison between you and a patient. Therefore, you must be sure that the information on your profile is accurate. These areas of your profile need to be explicit so prospects can contact you whenever they need to schedule an appointment, obtain information, etc.

- **Category** - Your category describes what your business is, not what it does or sells. This area of your profile needs to tell people what type of practice you’re running. If your niche is broad, you can add additional categories to narrow down your practice and increase your chances for showing up in more queries. If possible, add five categories (but ONLY if they fit your business appropriately).
- **Service Area** - This field is only used for those who don’t operate out of a physical location, but rather a geographical area. You can set your service area if you don’t wish for your physical address to show up in your listing or you handle services on location.

GMB CONTINUES ON PAGE 70 ▶
GMB acts as a liaison between you and potential patients

**Tip #3: CREATE AN SEO OPTIMIZED BUSINESS DESCRIPTION**

Writing a compelling, SEO optimized business description is integral to ranking well in local search queries. There are several essential items you need to include in the first few sentences of your description, primarily because 250 words (out of 750 words) show up instantly.

Here is a breakdown of how your GMB business description should be structured:

**First sentence: Main Keyword + city**
- We are a dermatology practice in Los Angeles.
- ABC is the leading dermatologist in New York.

**Second sentence: 3 to 5 of your most important service level keywords**
- We offer a range of dermatology services including treatments for acne, psoriasis, eczema, skin cancer, anti-aging and more!

Your first two sentences should quickly get to the point, while exploiting your core focus keywords. Structuring your business description this way will help your practice appear in more queries and provide people with useful takeaways of what you're all about.

**Tip #4: ADD A GMB MAP TO YOUR WEBSITE**

Having a map on your website is one thing, but featuring your GMB map on your site is much different. Often, developers will SEO shortchange their clients by including a map that is not the actual Google My Business embedded map.

Doing so will tie in your website’s map with the one on your listing and help Google know that your listing is associated with that page. Also, your GMB map has your vital information on it, which is more useful to your website visitors than a plain map. It is a critical aspect to establishing business proximity, which is one of Google’s top ranking factors.

**Tip #5: GROW YOUR REVIEWS**

According to BIA/Kelsey, 97% of people consult online reviews for local businesses, and 91% of 18 to 34 year olds trust online reviews as much as personal recommendations.

If you don’t have any online reviews, patients will often hesitate to make an appointment and go to practices with stellar reviews instead.

The best way to grow your reviews is to simply ask your patients to leave one. According to BrightLocal, 68% of consumers will leave a review if they’re politely asked.

Consider incorporating a review generation software that can automate the review request process via email or text message.

**Tip #6: OPTIMIZE YOUR WEB PAGES FOR SEO**

You can’t count solely on your GMB profile to generate leads and website traffic. Your website will have to be carefully optimized to ensure that your pages are found near the top of search engine result pages (SERPs).

The first step to optimizing your website for SEO is conducting keyword research. There are various online keyword research tools you can use, such as Google Keyword Planner, Ahrefs and Moz that will allow you to identify popular search terms people are using to find practices like yours.

The key to implementing an effective keyword strategy is to:
- Map important keywords to relevant pages.
- Don’t include the keyword “dermatologist Los Angeles” on a web page that doesn’t mention anything about dermatology.
- Don’t just focus on the search volume of keywords. Take the time to observe factors that include competition, user intent and specificity.
- Develop a healthy mix of short and long-tail keywords. Make sure to include LSI keywords or Google’s version of essential synonyms for your focus keyword.

Your website and GMB listing ideally work hand-in-hand. Having a website that’s correctly optimized will steadily increase your traffic and contribute to the growth of your listing as well.

**Tip #7: ADD SCHEMA MARKUP TO YOUR WEBSITE**

Adding schema markup to your website improves the way it is displayed in the SERPs by providing users with quick information about your business.

You can use schema markup to communicate specific information about your business to Google, such as your review rating on products or services, location information, NAP and thousands of other data points.

Adding schema markup is essential to help search engines learn more about your business so it can pair your website accurately with corresponding queries. The more search engines know about your practice, the better.

**Tip #8: RESPOND TO QUESTIONS**

Google My Business allows people to ask businesses questions. It’s in your best interest to answer these questions to assist the person who asked the question, and others.

You can view all of the questions people are asking about your practice by logging into your profile, navigating to your listing and clicking “see all questions” under the “questions and answers” section.

**Tip #9: BUILD LEGITIMATE BACKLINKS**

One of the significant drivers for local SEO in 2019 is backlinks or links to your site from other websites. Search engines weight backlinks heavily when they rank websites, so it’s important to build backlinks from high-authority websites. Follow these tips to help you get started:
- Start guest posting. If you’re a medical expert, you can provide your commentary on an educational website to showcase your expertise and gain a link back to your site.
- Commit yourself to creating quality content. This is most natural way of convincing other websites to link back to your site. Content creators strive to back up their facts and provide context, so if you’re providing exceptional content, you’ll be more likely to catch their eye.

**WRAP UP**

Increasing your GMB ranking is pivotal for your practice, especially since people are using search engines more than ever to find local businesses. As you can see, there are many things to consider if you want to leverage your profile for success.
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Healthcare policy in 2019: A look ahead

JEFFREY BENDIX | Medical Economics

Doctors rarely have the time or inclination to follow developments in federal healthcare policy, but 2019 may well be a year where physicians start paying more attention to events in Washington. That’s because lawmakers, judges and regulators are poised to take—or at least consider—steps that could affect the nation’s $3.5 trillion healthcare system for years to come.

Here’s a look at what 2019 may hold in four areas of healthcare policy of importance to doctors: the future of the Affordable Care Act, expanding healthcare insurance coverage, the cost of prescription drugs and changes to accountable care organizations.

THE FUTURE OF THE AFFORDABLE CARE ACT
Since becoming law in 2010, the ACA has survived several near-death experiences, including a 5-4 U.S. Supreme Court vote to uphold it in 2012, an effort to defund the law via a government shutdown in 2013, and a 51-49 vote in the U.S. Senate against repealing it in 2017.

The latest threat to the ACA came in December 2018, when a federal judge in Texas, ruling on a lawsuit brought by a group of Republican attorneys general and governors, declared the law unconstitutional. The judge agreed with the plaintiffs that when Congress zeroed out the financial penalty for not having health insurance (which was part of the 2017 tax reduction law) and because the Supreme Court had previously ruled that the penalty was actually a tax, both the tax and the entire statute unconstitutional doesn’t really work.

A group of Democratic attorneys general is appealing the judge’s decision to the U.S. Supreme Court. If the Supreme Court decides to hear the case—which Gary says is not certain—it could wind up issuing its ruling just before the 2020 presidential election.

Gary attributes the courts’ frequent involvement with the ACA to Congressional dysfunction, noting the long and often convoluted process the required to get the law passed, and the fact that no Republicans voted for it.

“When Congress can’t make decisions, the courts step in to try and do that, and courts aren’t particularly well-suited to the task,” he says. “And what you end up with is a lot of surprise.”

EXPANDED HEALTHCARE INSURANCE COVERAGE
In the wake of Democrats gaining control of the U.S. House of Representatives following the 2018 Congressional elections, and with the 2020 presidential election already in full swing, the possibility of extending healthcare insurance to more Americans is again being widely discussed.

For many in the public and the media—and some Democratic presidential candidates—the discussion translates into some version of “Medicare-For-All,” a slogan popularized by Vermont Sen. Bernie Sanders during his 2016 bid for the Democratic nomination. And while that term does apply to some of the ideas being floated for expanding coverage, others are more limited in scope.

In a study published late last year, the nonprofit Kaiser Family Foundation identified eight pieces of legislation aimed at making insurance more widely available, which the study groups into four categories:

- Two proposals for instituting single-payer coverage for all Americans—in effect, Medicare For All.
- Three plans for creating a Medicare-like “public option” that would be available to all individuals and some or all employers via the ACA insurance exchanges.
- Two bills enabling Americans younger than 65 to buy into Medicare. One proposal would allow buy-ins starting at age 55, the other at age 50.
- One proposal allowing states to offer their residents a Medicaid buy-in option through the ACA marketplaces.

A ninth bill, the Medicare for America (MFA) Act of 2018.
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“This is a yearly trip for me. CSF is very cutting-edge and forward thinking with great faculty, plus audience participation and interaction. That’s why I value it so much.”
- JILL FICHTEL, MD

HONEST
“The meeting evolves in such a wonderful way. We never shy away from controversy, and this year was no exception.”
- S. MANJULA JEGASOTHY, MD

“I like the back and forth discussion that’s candid and honest. I’m looking forward to more intense discussions. They stay respectful but elevate our learning platforms and learning processes, so I think they’re necessary.”
- JEANINE DOWNIE, MD

INSIGHTFUL
“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

“This 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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When Congress can’t make decisions, the courts step in ... and courts aren’t particularly well-suited to the task. And what you end up with is a lot of surprise.”

C. Timothy Gary, J.D., Dickinson Wright, Nashville, Tenn.

A single-payer system would be the most difficult to navigate
[Drug price] is an issue that is on Congress’ mind, and public support for government action ... is pretty clear and crosses party lines.

Tricia Neuman, Sc.D., M.S., Kaiser Foundation, San Francisco

generic drugs in cases where there aren’t enough competitors to keep prices down;
- Letting Medicare negotiate directly with drug manufacturers;
- Prohibiting drug companies from pricing their drugs higher than the median prices charged in Germany, France, Canada, Japan and the U.K.;
- Allowing drugs to be imported from Canada, and possibly other countries later on; and
- Abolishing the practice whereby manufacturers of brand-name drugs pay generic producers to keep competing drugs off the market.

“[Drug prices] is an issue that is on Congress’ mind, and public support for government action in this area is pretty clear and crosses party lines,” says Neuman.

Meanwhile, the Trump administration has announced its own plan for lowering drug prices. In early February it released a proposed rule that would prohibit pharmaceutical companies from offering rebates to pharmacy benefit managers who administer drug plans under Medicare Part D or Medicaid managed care organizations, but could offer rebates directly to patients.

CHANGES TO ACCOUNTABLE CARE ORGANIZATIONS (ACOS)
For doctors in ACOs, the biggest issue in 2019 almost certainly will be the impact of “Pathways to Success,” the CMS rule overhauling the Medicare Shared Savings Program.

Released at the end of 2018, the “Pathways” rule takes effect July 1. It reduces the length of time an ACO can remain on the program’s “upside only” track, where it shares in savings if its spending is lower than its benchmark, but does not incur losses if its spending exceeds its benchmark. Currently, an ACO entering the program can be on an upside only track for up to six years. The rule lowers that to two or three years, depending on the ACO’s revenue.

“Pathways” consolidates the program’s four tracks into two — a “basic” track that allows new ACOs to start by sharing only in savings and begin transitioning after two years to a model where it also incurs financial risk, and an “enhanced” track that provides an ACO with potential for greater financial rewards, along with greater financial risk.

In addition, the rule creates a distinction between “low revenue” and “high revenue” ACOs, extends the length of ACO contracts from three years to five, and reduces the percentage of shared savings available to newly formed ACOs from 50% to 40%.

Clif Gaus, Sc.D., president and CEO of the National Association of Accountable Care Organizations, says that while it will take time for the effects of the “Pathways” rule to play out, the association is concerned that the lower shared savings and decreased time allowed for transitioning to a risk-sharing model could inhibit the formation of new ACOs.

“We believe two years is too short a time for ACOs to get their bearings in no-risk models before they’re forced to take on risk,” he says.

“Studies show it takes three or four years before ACOs are fine-tuned enough to operate with the necessary degree of efficiency.”

Capital investments should be considered carefully from page 68

device a few years ago that was too painful, with significant recovery time, and realized it wasn’t going to work in our practice.”

DO YOUR HOMEWORK
“Survey your patients and see what they care about, which will usually be out-of-pocket expenses for them,” she says. “Maybe you have 100 patients complaining about redness or veins or acne scars. That knowledge helps you go forward as you choose devices.”

Ask your peers’ opinions, she advises. Find out how long they’ve used a device and their opinions on things like the company’s response if the laser breaks down, she says.

Talk to the company about their trade-in specifications and about whether they provide training, she adds.

Do your own research and review evidence-based journal articles to confirm whether the device works as the company claims, she advises. Also, evaluate devices in action when you attend conferences.

Once purchased, expect to get five-to-seven years out of a device, until a “newer, better” model comes along.

“It’s possible to be in perpetual trade-in mode, or to have a laser graveyard of obsolete devices,” Dr. Chapas says.

Once you have your device in place, you want to spread the word. Update your website and begin reaching out to your patients. The laser company also should include you and your marketing message in their links to “find a doctor.”

You can also conduct target-based marketing, Dr. Chapas says. This is where you reach out to a group of potential patients who may desire your services.

However, she advises, don’t pre-determine what age demographic wants what.

“Millennials are starting preventive skin procedures early, even in their 20s, and some of my oldest patients are in their 90s,” she says.

Finally, don’t bother with Groupon or Living Social offers. These attract one-time patients who move on to the next special, she says.

Disclosure
Dr. Chapas reports no relevant financial disclosures.
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<th>City</th>
<th>Type</th>
<th>Contact Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>VIRGINIA</td>
<td>NORFOLK, VIRGINIA</td>
<td>Full-time/part-time</td>
<td>Karey, (866) 488-4100 or <a href="mailto:dermatologist@mydermgroup.com">dermatologist@mydermgroup.com</a></td>
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</tr>
</tbody>
</table>

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<table>
<thead>
<tr>
<th>Advertiser</th>
<th>Product</th>
<th>Website</th>
<th>Pages</th>
</tr>
</thead>
<tbody>
<tr>
<td>ASDS</td>
<td></td>
<td><a href="http://www.asds.net/medical-professionals/annual-meeting">www.asds.net/medical-professionals/annual-meeting</a></td>
<td>27</td>
</tr>
<tr>
<td>Cynosure</td>
<td></td>
<td></td>
<td>43</td>
</tr>
<tr>
<td>Epi Health</td>
<td>MINOLIRA</td>
<td><a href="http://www.minolira.com">www.minolira.com</a></td>
<td>57</td>
</tr>
<tr>
<td>Epiphany Dermatology</td>
<td></td>
<td><a href="http://www.epiphanydermatology.com">www.epiphanydermatology.com</a></td>
<td>25</td>
</tr>
<tr>
<td>MTF Biologics</td>
<td>RENUVA</td>
<td><a href="http://www.mtfbiologics.org">www.mtfbiologics.org</a></td>
<td>14-Feb</td>
</tr>
<tr>
<td>Ortho Dermatologics, LLC.</td>
<td>DUOBRII</td>
<td><a href="http://www.ortho-dermatologics.com">www.ortho-dermatologics.com</a></td>
<td>CV TIP</td>
</tr>
<tr>
<td>Sensus Healthcare</td>
<td></td>
<td><a href="http://www.sensushealthcare.com">www.sensushealthcare.com</a></td>
<td>9</td>
</tr>
<tr>
<td>Verrica Pharmaceuticals</td>
<td></td>
<td><a href="http://www.verrica.com">www.verrica.com</a></td>
<td>41</td>
</tr>
</tbody>
</table>

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Dermatology Times | new products | JULY 2019

NUTRAFOL LAUNCHES ‘HAIRBIOTIC’

HAIRBIOTIC from Nutrafol is a physician-formulated probiotic with 2 billion CFUs of specific probiotic strains that aims to address the gut stressors that can affect hair health.

The product includes strains such as L. Reuteri, L. Rhamnosus GG, L. Helveticus, L. Plantarum and L. Acidophilus, as well as the company’s patented PreforPro Prebiotic. L. Reuteri has been shown to support hair quality and growth cycle through the modulation of expression of IL-10 and IL-17 in the gut and skin, according to the company.

Gut disrupters such as stress, antibiotic use or poor diet can influence healthy hair production by increasing gut permeability, inflammation and malabsorption. The product is enclosed in acid-resistant capsules to ensure probiotics aren’t damaged by stomach acid and they can effect the deeper digestive tract.

FOR MORE INFORMATION: nutrafol.com

ORGANIC ANTI-WRINKLE CREAM PROMOTES SMOOTH SKIN

Big River Silk Skincare, Inc., offers a variety of organic skincare for individuals with sensitive skin, including GLYCOSHEA FACIAL & NECK CREAM.

This product is an organic, hypoallergenic anti-wrinkle cream, which contains glycolic acid (GA), an alpha hydroxy acid.

GA encourages the outermost layer of the skin to shed dead cells, which can decrease the appearance of fine lines and wrinkles, according to the company. GA is a natural ingredient, found originally in pineapple, sugarcane and citrus fruits.

The cream also contains organic shea butter and water from the Memphis Aquifer. The formula does not contain sulfates, dyes, propylene glycol or fragrances.

FOR MORE INFORMATION: bigriversilkskincare.com

COLORSCIENCE OFFERS BRUSH-ON SUN PROTECTION

SUNFORGETTABLE TOTAL PROTECTION BRUSH-ON SHIELD SPF 50 from Colorscience consists of a 100% mineral, chemical-free formula that can be applied directly to the skin or over makeup.

According to the company, the product features EnviroScreen technology, which protects skin from harmful environmental factors that could damage skin, including pollution exposure. The formula is also water resistant for up to 80 minutes, protects against 93% of blue light and minimizes damage caused by infrared radiation.

The product dispenses from a portable brush for convenient reaplication and is available in four shades for all skin types.

FOR MORE INFORMATION: colorscience.com

BRIGHTEN SKIN WITH ANTIOXIDANT SERUM

The A-OXITIVE ANTIOXIDANT DEFENSE SERUM from Avène is a fast-absorbing serum that works to hydrate, plump and brighten skin, according to the company.

The formula contains the time-released vitamin C and E precursors, preynocopheryl and ascorbyl glucoside, an antioxidant booster, GAG, and hyaluronic acid. The stable form of vitamin C and E protects against free radicals, helps to gently nurture collagen production, and brightens skin, the company says.

The product is available online on the company’s website.

FOR MORE INFORMATION: aveneusa.com
Identifiers that distinguish molluscum from imitators

Distinguishing BOTE

Sheila Fallon Friedlander, M.D., professor of dermatology and pediatrics, University of California San Diego and Rady Children's Hospital, offers this at-a-glance information about common molluscum mimickers and how to make the right diagnosis.

Photo: Elaine Siegfried, M.D.

Dermatology Times

Rashes that can occur with molluscum

IN 2012, JV Shaffer et al. published a paper in JAMA Dermatology looking at inflamed molluscum contagiosum lesions, molluscum dermatitis, reactive papular eruptions resembling Gianotti-Crosti syndrome and atopic dermatitis in patients with molluscum contagiosum. The authors found three rashes commonly occurred in molluscum contagiosum patients:

- molluscum dermatitis
- inflamed molluscum dermatitis lesions
- Gianotti-Crosti syndrome

The authors concluded that cell-mediated immune responses that may lead to viral clearance.

Imitators

FOLLICULITIS

The best thing dermatologists can do to distinguish molluscum from anything else is to reach for their dermascopes. With folliculitis, a hair should be present at the center of the lesion — often a vellus hair surrounded by erythema without a central core. A pustule may be present but this should be soft and compressible — indicating it's folliculitis. An umbilicated core in the center suggests molluscum.

CYST

Cysts generally don't have an epidermal component, other than a central pore. Cysts often are mobile, and more of the lesion is beneath the surface than above it (molluscum sits in the epidermis and dermis).

PAPULAR ECZEMA

Papular eczema usually manifests as small papules pretty much the same size and color, often grouped into plaques. Molluscum lesions can present in varying sizes with various colors — some are flesh colored, some are white, some are red. Papular eczema usually is either all red or all flesh color.

METHICILLIN-RESISTANT STAPHYLOCOCCUS AUREUS (MRSA)

MRSA lesions are often softer, compressible and will sometimes have compressible purulence. They can resemble bug or spider bites. In contrast, molluscum lesions are firm.

FLAT WARTS

Flat warts and molluscum are often confused. Molluscum is more dome shaped and the surface of flat warts is generally somewhat verrucous.

SMALL MILIA

Milia lesions are white, globoid and monomorphous. There is no central umbilication.

REFERENCES: