

DermWorld



Sunday • March 19, 2023

meeting news

A Publication of the American Academy of Dermatology | Association



Plenary Lineup

Sunday, March 19 8:45 a.m.–12 p.m. Location: La Nouvelle Orleans BR

8:45 a.m.

Chair's Welcome

Tammie C. Ferringer, MD, FAAD

8:50 a.m.

Clarence S. Livingood, MD, Memorial Award and Lectureship: Ethical Dilemmas Hiding in Plain Site Jane Margaret Grant-Kels, MD, FAAD

9:15 a.m.

President's AddressMark D. Kaufmann, MD. FAAD

9:30 a.m.

Eugene J. Van Scott Award for Innovative Therapy of the Skin and Phillip Frost Leadership Lecture Richard L. Gallo, MD, PhD, FAAD

9:55 a.m.

President-Elect's Address *Terrence A. Cronin Jr., MD, FAAD*

10:10 a.m.

Lila and Murray Gruber Memorial Cancer Research Award and Lectureship: The Road to Single Dose HPV Vaccines

John T. Schiller, PhD

10:35 a.m.

Marion B. Sulzberger, MD Memorial Award and Lectureship: Dermatology, Dermatoepidemiology, and Antibiotic Use

David J. Margolis, MD, FAAD

11 a.m.

John Kenney Jr., MD, Lifetime Achievement Award and Lectureship: Belonging: A Concept for Dermatology Amy J. McMichael, MD, FAAD

11:25 a.m. Keynote Speaker

Safi Bahcall

Hair dos and style don'ts

medication on the scalp, and

morning, that's probably not

going to happen," Dr. Barbosa

said. "It is important that we

Sewn-in weaves, wigs, and

be asked to come to their

to ask about the patient's

exam to avoid surprises.

complex hair styles can limit

a scalp exam. Patients should

in a manner that allows a full

appointments with their hairstyles

scalp examination. It is important

hairstyling, including wigs and

Styling also plays a role in

diagnosis. There is a common

has traction alopecia. Tight

in this area.

assumption that a Black woman

with hair loss at the front hairline

braids and cornrows can generate

traction alopecia, but hairstyling

is not the only cause of hair loss

"You also have to think

alopecia?'" Dr. Barbosa said.

'could this be frontal fibrosing

extensions, before starting an

tailor treatments to the patient."

Styling is another key point.

that it should be rinsed out every

Cultural, health, and other factors in Black women's hair examined

lack hair is unique, often dense, and tightly curled. That distinctive hair has contributed to distinctive cultural preferences, styling practices, and hair care products. It puts a similarly distinctive stamp on alopecia and other familiar hair and scalp disorders.

"It is important that we are prepared to care for a diverse patient population," said Victoria Barbosa, MD, MPH, MBA, FAAD, associate professor of dermatology and director of the Hair Loss Program at University of Chicago. "Particularly when you're talking about hair and scalp disorders, there isn't a lot of information about cultural practices that we learn in textbooks. For Black women. in particular, there are different styling practices and grooming habits that play a role in diagnosis and management as well as in their overall health."

Dr. Barbosa directed the March 18 session, "Uo50 – Hair Care, Hair Loss, and Health in Black Women," with a deep dive into the not-always clear connections between cultural practices, scalp and hair health, and overall health.

Hair habits

Differences start with grooming habits. Dense, curly hair doesn't need shampooing every day or even every week, Dr. Barbosa said. Many Black women shampoo every other week, depending on their hairstyle. This can affect dermatologic treatment choices.

"If a dermatologist suggests that a Black woman put a



"Traditionally, FFA was thought to be seen primarily in white women, but experience tells me we were just misdiagnosing some Black women. You also have to think about ophiasis pattern alopecia areata."

Listen to evaluate and treat

A good diagnosis starts with the patient, she continued. For instance, if there is obvious hair loss at the front hair line, but the patient says no, she never wore braids, wigs, or any other style that might induce traction, then you need to broaden your differential.

"Start by listening to the patient and do a thorough exam," Dr. Barbosa said. "A dermatoscope can help you narrow your differential, and you might need to biopsy to confirm a diagnosis."

Mimicry works both ways. Alopecia areata is usually easy to identify from the coin-shaped patches of alopecia. But traction from braids or other hair styles can cause similar patchy hair loss on the scalp. Alopecia areata at the crown can be mistaken for central centrifugal cicatricial alopecia (CCCA), and vice versa. CCCA is accompanied by follicle loss and scarring and alopecia areata is non-scarring, so dermoscopy can help distinguish the two.

Victoria Barbosa, MD, MPH, MBA, FAAD

Or is it lichen planopilaris? LPP can look very similar to CCCA, Dr. Barbosa said. CCCA is very common in Black women, and LPP much less common, but LPP remains a distinct possibility when examining a scarring alopecia.

"I always encourage people to perform a biopsy when they suspect a scarring alopecia," Dr. Barbosa said. "Sometimes there are clinical clues, but a biopsy can help differentiate between conditions like CCCA and LPP. And that's important because these conditions behave differently, and our treatments differ. It's important to make the right diagnosis."

For more on this story, go to aadmeetingnews.org.

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Who will be the future leaders of the Academy?

The Nominating Committee voted to present the following slate of candidates (listed in random order) for the 2023 Academy election of Officers, Directors, and Nominating Committee Member Representatives (East Region).

Visit the AAD Election Connection at aad.org/election to learn about this year's candidates and to interact with them on top issues via the online Ask the Candidates forum.

Nominating Committee Member Representatives



Anthony Rossi, MD,



Louis Kuchnir, MD, PhD. FAAD

View/print an online ballot book at aad.org/election

President-Elect



Andrew H. Weinstein, MD, MPH, FAAD

Susan C. Taylor, MD, FAAD

Vice President-Elect



MD, FAAD



Kevin D. Cooper, MD, FAAD

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MD, PhD, FAAD



Alexander S. Gross, MD, FAAD

John C. Trinidad,

MD, MPH, FAAD



Howard W. Rogers,



Paul S. Yamauchi, MD, PhD, FAAD



M. Laurin Council, MD. MBA. FAAD

Eligible voting members can vote by using the personalized voting link sent by email or the AAD Election Connection at aad.org/election. You can also print and fax your online secure election ballot starting March 18 to (877) 235-9052. Ballots received at the AAD office will be considered invalid.





TODAY'S HIGHLIGHTS

U058 – Preventing Food Allergy In Pediatric Atopic **Dermatitis: Applying the New Guidelines to Your Practice**

Location: Room 255

U068 - Beyond Skin **Deep: Practical Tips on Management of DRESS/DIHS** 7-8 a.m.

Location: Room 344

AAD/A Annual Business Meeting 8-8:45 a.m.

P151 - Plenary

Location: La Nouvelle Orleans BR

8:45 a.m.-12 p.m. Location: La Nouvelle Orleans BR

DataDerm™ Drop-In Hours 10-11 a.m. Location: AAD Resource Center,

Booth 4039 F088 - Itch Tales: Looking **Beyond Atopic Dermatitis**

1-3 p.m. Location: New Orleans Theater C

S043 - Resident Jeopardy 1-4 p.m.

Location: Room 252

S044 - Skin of Color 1-4 p.m. Location: Room 384

S045 - The 2023 Debates: Controversies in Dermatology 1-4 p.m.

Location: Room 388

S048 - Hot Topics 1-4 p.m.

U078 – The Evolving Toolbox for Treating Difficult Warts

Location: New Orleans Theater B

4:30-5:30 p.m. Location: Room 266

PHOTO GALLERY

Scan the QR code below to view pics from the Annual Meeting



Insects, spiders, and ticks, oh my!

What's bugging a patient might be an actual bug.

issecting the dermatologic significance of exposure to arthropods was the focus of Saturday's session, "Fo6o – What's Bugging You? Arthropods of Dermatologic Importance and Their Management: An Up-to-Date Review," directed by Eric



Eric Hossler, MD, FAAD, a Geisinger Health Systems dermatologist and dermatopathologist



Bethany Rohr, MD, FAAD, dermatologist and dermatopathologist with University Hospitals in Cleveland, Ohio

Hossler, MD, FAAD, a Geisinger Health Systems dermatologist and dermatopathologist. Bethany Rohr, MD, FAAD, joined Dr. Hossler to answer key, clinical questions about the varied cutaneous reactions to arthropods and provided practical management tips.

"Because of the variety of arthropods that can cause dermatologic manifestations."

"Because of the variety of arthropods that can cause dermatologic manifestations, there is a wide diversity of cutaneous findings," said Dr. Rohr, a dermatologist and dermatopathologist with University Hospitals in Cleveland, Ohio. "In many cases, arthropods cause a nonspecific hypersensitivity reaction. However, there are certain clinical clues that help make an accurate diagnosis. In situations where patients bring in the offending arthropod or show a photo, identification of the insect or spider is very helpful." Dr. Rohr added, "Part of a dermatologist's job is to know when a clinical presentation could signify something more sinister, such as an infestation, or when a bite or sting could lead to secondary complications like an infection or internal organ damage."

Confirm your source

Spider bites are notoriously difficult to diagnose with certainty, given the lack of a widely available confirmatory test, Dr. Hossler said. In fact, most "spider bites" are alternative diagnoses, such as erythema migrans, bacterial furunculosis, pyoderma gangrenosum, and other diagnoses; these need to be thoroughly excluded in presumptive spider bites, he said. Recluse spiders are found in the central and southern U.S. as well as many other parts of the

world; most bites are minimally symptomatic, but some bites result in necrotic ulcers with a red, white, and blue appearance.

Some patients experience loxoscelism, characterized by fever, hemolytic anemia, and renal failure.

"Widow spiders, in particular, cause a mild

local reaction, but patients often
experience muscle rigidity and
other systemic symptoms,"
Dr. Hossler said. "Tick
bites are important because
of the potential for disease
transmission. Lyme disease

is predominantly a clinical diagnosis in the dermatology office, with one or more spreading red or violaceous patches. Lab testing is of little value in the acute setting, and histology is often nonspecific." Pyemotes mite bites often cause limited lymphangitis, and cutaneous lesions will show a characteristic comet shape, according to Dr. Hossler.

The distribution of lesions in zoonotic scabies favors the arms, thighs, and other areas that have direct contact with an affected animal.

comet shape, according to Dr. Hossler.

Arthropods may be spineless, but can be aggressive, nonetheless. Insects and arachnids mean business when mingling with humans, and the bite, sting, or irritation radiating from your patient's skin may mean they've made contact with an arthropod.

SEE this, THINK this:

Anemia in a traveler after a trip to the Amazon:
THINK Lonomia envenomation.

Furuncles in a returning traveler: THINK furuncular myiasis

Furuncula

Comet sign: THINK Pyemotes.

Bird mite bites do not have a characteristic morphology, but since the mites bite mostly at night in exposed areas, these can be used as clues to look for an abandoned bird nest around the home.

Dog with mange: THINK zoonotic scabies or Cheyletiella mites.

Red-white-blue ulceration in a patient with hemolytic anemia: THINK recluse spider bite (in an endemic area).

Looks like a spider bite but is actually pyoderma gangenosum

Tram-track purpura: THINK puss moth caterpillar envenomation.

are often nonspecific in appearance, said Dr. Rohr, but puss moth caterpillar stings have a characteristic "tram track" appearance.

The "delta-glider" or

jetliner with contrail"

are signs in scabies,

but you can also see a gray-edged line in

truncal burrows. Nodular

scabies lesions can also show burrows.

covered by tight-fitting

clothing is a clue to

chigger bites.

Arthropod reactions



Burrows on the trunk but not on the hands and feet: THINK zoonotic scabies.

Debugging: The treatment plan

According to Drs. Hossler and Rohr, most arthropod reactions can be managed with local, supportive care. Bed bug and bird mite infestations need to be managed by professional exterminators. Demodex mites can be treated

with topical or systemic antiparasitic agents, such as ivermectin, but many cases can be treated with more traditional rosacea treatments such as metronidazole.

An antivenom is available for lonomia stings. There is evidence of emerging resistance of both scabies and lice to traditional treatments; for scabies, permethrin in traditional doses may be ineffective, and ivermectin or other alternative treatment is an option. Doxycycline for 10-21 days is the

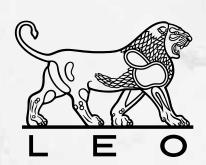
treatment of choice for erythema migrans; it can also be used as prophylaxis in patients bitten by a tick that can be reliably identified as Ixodes in an area with high rates of Lyme disease. Many patients do not recall a tick bite; the index of suspicion must remain high, Dr. Hossler said. •

Most clinicians recognize the grouped urticarial bites from bed bugs, but similar lesions in areas

Bites in areas of tight-fitting clothing: THINK chiggers.

Breakfast, lunch, and dinner bites: THINK bed bugs.







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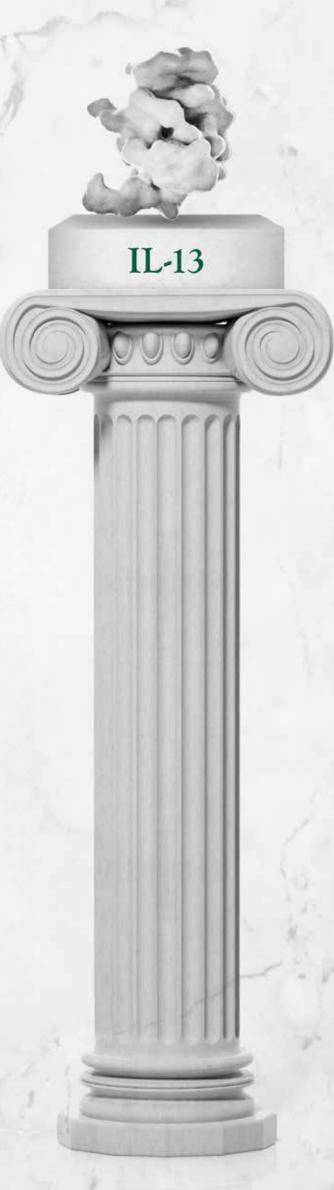
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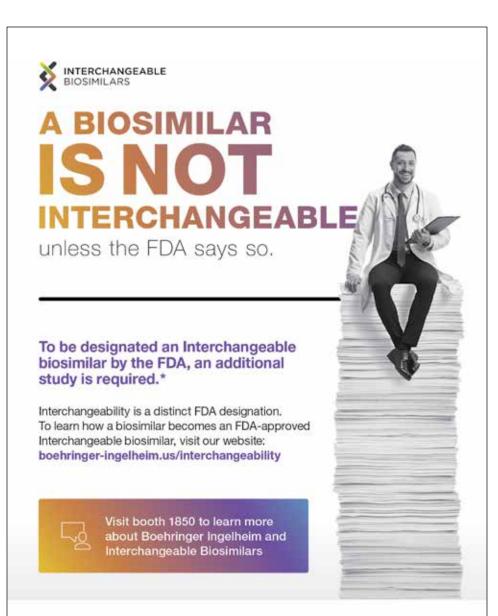




Fox Award: The future of dermatology recognized



Congratulations to all who participated in the 2023 Resident and Fellows Symposium!



*One or more studies may be required by the FDA to

demonstrate Interchangeability

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The Residents and Fellows Symposium was held Saturday, during the 2023 AAD Annual Meeting in New Orleans, led by Cory A. Dunnick, MD, FAAD. Faculty judges selected individuals who presented the most outstanding papers in laboratory and clinical research. The winners of this year's prestigious Everett C. Fox Memorial Award are:

Basic Science Category

Winner Name: Nelson Ugwu, MD

Institution: Department of Dermatology, Yale School of Medicine Title: A gain-of-function somatic mutation in GJA4 underlies venous malformations in the skin and liver, and reveals a novel pathway for therapeutic intervention

Winner Name: Shadi Khalil, MD, PhD **Institution:** University of California, San Diego

Title: Epidermal iron content couples to systemic iron homeostasis

and host defense

Clinical Category

Winner Name: Keegan O'Hern, MD

Institution: Mayo Clinic

Title: Increasing Utilization of Mohs Micrographic Surgery for Melanoma with Improved Survival over Wide Local Excision: A National Cancer Database Analysis

Winner Name: Daniel Joffe, CTCL research fellow

Institution: Department of Dermatology and Cutaneous Biology,

Thomas Jefferson University

Title: Reduced Overall T-cell Receptor Diversity as an Indicator

of Aggressive Cutaneous T-cell Lymphoma

Winner Name: Justin D. Arnold, MD **Institution:** University of California, Irvine

Title: Characteristics and Complications of Anogenital Infantile Hemangiomas

Winner Name: Kun-Lin Lu

Institution: Department of Dermatology, Chang Gung Memorial Hospital,

Linkou branch, Taoyuan, Taiwan

Title: The Role of T helper 17 cells in Paraneoplastic Pemphigus/Paraneoplastic

Autoimmune Multiorgan Syndrome

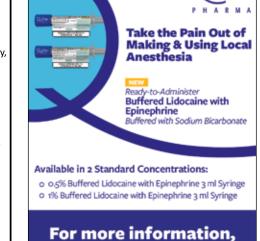
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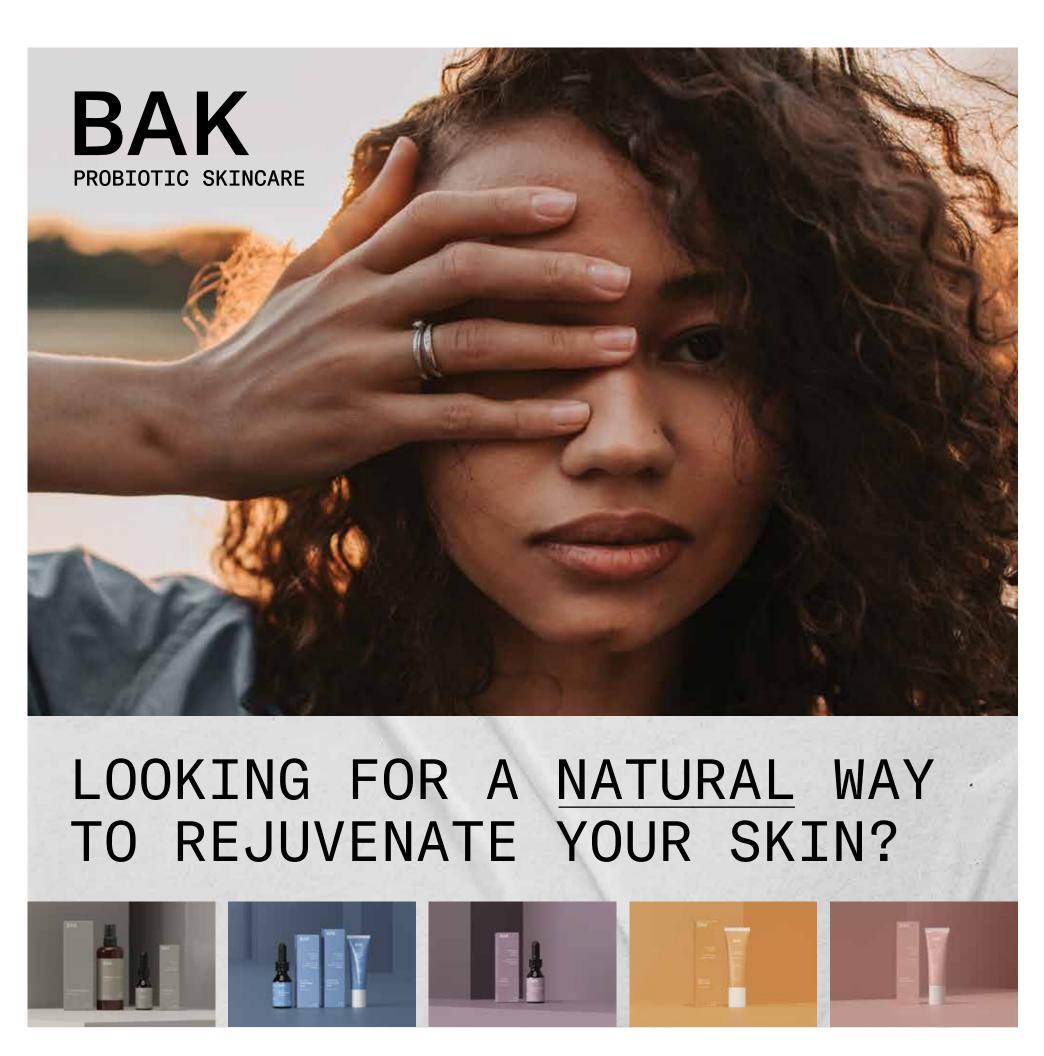
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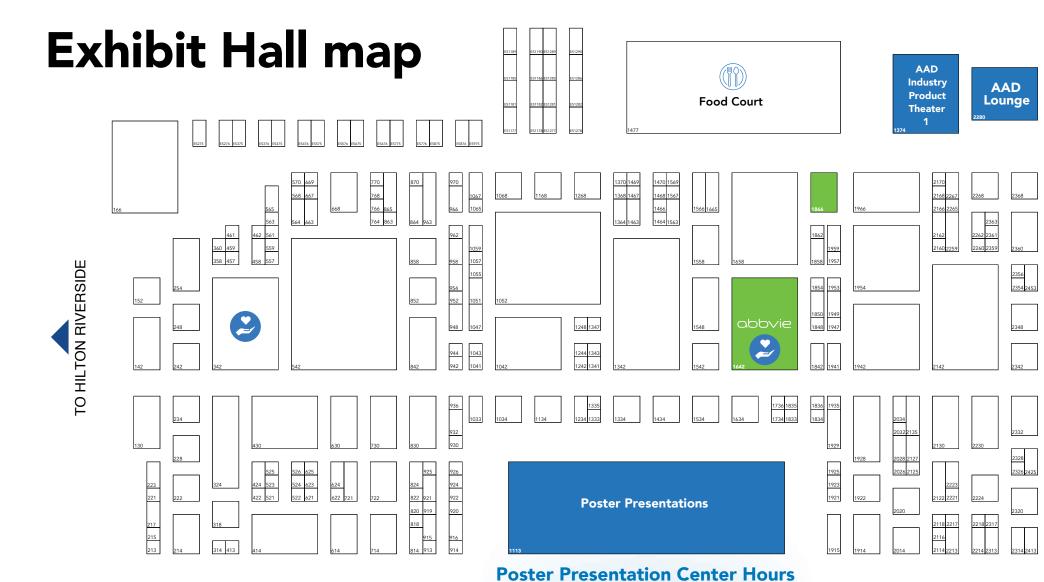
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Exhibitor Listing

Data current as of February 21, 2023. Please use the AAD Meeting App **aad.org/mobile** for the most up-to-date exhibitor list.

ENTRANCE

Friday – Saturday | 8:30 a.m.-5 p.m. Sunday | 1-3 pm.

3Gen, Inc./DermLite	American Society for	Canfield Scientific	Derm Care Billing Consultants 667
5CC (5-Continent-Congress) 1248	Dermatologic Surgery 1736	Cara Therapeutics	Derma Faith, LLC
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AAD Food Court1477	AMLo Biosciences 4541	Casio America, Inc	Dermaesthetics Beverly Hills 926
AAD Industry Product Theater 1 1374	Anne Arundel Dermatology, P.A 1959	Castle Biosciences 4051	DERMAGNOSTIX
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AAD Resource Center 4039	Avante Health Solutions 1041	Clinical Skin LLC	Dermatology Times 913
AAD_Freeman Servicenter 166	Avantik Biogroup 1921	CLN Skin Care (TopMD Skin Care) 2326	Dermavant Sciences, Inc
AbbVie	Baitella AG	Coalition of Skin Diseases 4213	DermCare Management 1047
ABISA 1043	Bank of America Practice Solutions 930	Cobalt Medical Supply, Inc 1563	Dermogalenic Experts SA DE CV 564
Acclaro Medical	Beiersdorf, Inc	COLA Inc	Dermosciences Corp 570
Accurate Manufacturing, Inc 2832	Beijing Sincoheren	Collagen P.I.N	Dermpath Diagnostics 614
AccuTec Inc	S&T Development Co., Ltd 3455	CoNCERT Pharmaceuticals Inc 1534	DermTech
Acuderm	Beijing Syntech Laser Co., Ltd 970	Connect Biopharm 4221	Designs for Vision, Inc
AD Surgical	Belle.ai	Coolibar, Sun Protection You Wear 4231	DiamondTome/Altair Instruments 1055
Advalight	Benev Company Inc 2368	Coous Global Co., Ltd 2314	DOCS Derm Group 4151
Advanced Dermatology	Beutner Laboratories 1467	Coronado Aesthetics LLC 3457	Doctor Multimedia 3920
& Cosmetic Surgery 458	Biodermis	Cortex Technology Aps 1335	Dow Development Laboratories LLC 559
Advanced Dermatology, P.C 663	Biofrontera, Inc	CP Skin Health Group	eClinicalWorks
Aeon Biotherapeutics Corp 1468	BioLab Sciences 4314	Crown Laboratories, Inc 3947	EllaOla Brands Inc 766
Aerolase	Biopark Medical	CryoProbe	Ellis Instruments
Aesthetic Guide, The 525	Bison Medical	CuraScript SD 4227	Elsevier
AIM Medical Inc	Boehringer Ingelheim	Cutera	Eltraderm Skin Care
All States M.E.D1370	Pharmaceuticals, Inc 1850, 4339	Cyspera by Scientis US 459	EMK Medical217
Allergan Aesthetics 1134, 1342	Bristol-Myers Squibb 3147, 2267	Cytrellis Biosystems 565	EPI health
Allstate Medical	Brymill Cryogenic Systems 3339	Daavlin714	Epic
Alma Lasers	BTL 842	Dartmouth Health942	Epionce
ALMIRALL	Burt's Bees	DefenAge	Epiphany Dermatology 865
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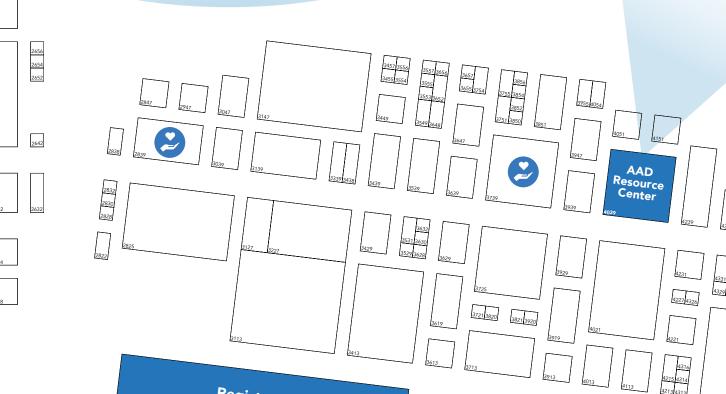
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AAD Industry Product Theater 2

Exhibit Hall hours

Friday – Saturday | 10 a.m.-5 p.m. Sunday | 10 a.m.-3 p.m.





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Focus Medical
Forefront Dermatology 858
Fotofinder Systems, Inc 1922
Fotona Lasers
Foundation for Research
& Education in Dermatology 914
Frontier Derm Partners
Frontline Medical Communications 221 $$

GALDA: Gay & Lesbian Dermatology
Association Found 1244
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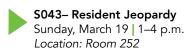
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The question is: What is learning?

Residents put their skills to the test



ontestants representing various residency training programs will face off in a spirited competition based on the iconic, fast-paced game show Jeopardy! Lida Zheng, MD, FAAD, assistant professor of dermatology at Northwestern University's Feinberg School of Medicine in Chicago, will moderate the session at 1 p.m. today.

This fun self-assessment will field queries and image-based inquiries encompassing the breadth of dermatology. Audience members are invited to play along and test their own knowledge. Ultimately, the winning program team of contestants will walk away with the coveted trophy, and the title of 2023 AAD Resident Jeopardy champions!

There is an element of academics involved, of course. Residents will self-assess their core competencies across numerous domains in dermatology, identify gaps in medical knowledge, and interact and network with colleagues at similar career levels from various institutions across the country.

Eligibility requirements: residents had to provide their year of training and email address, register to compete (in-person), create a team of residents, provide an interesting or fun fact about their team or its residents on a wide range of topics from their scariest experience to their most embarrassing moment. In addition to the trophy, each teammate of the winning team will receive a \$15 Amazon gift card and bragging rights for one year.

Dr. Zheng will be joined by Roger Ho, MD, FAAD, Kassandra E. Holzem, MD, FAAD, Kiran Motaparthi, MD, FAAD, Michelle B. Tarbox, MD, FAAD, and Danielle Tartar, MD, PhD, FAAD.

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Warts and all

New approaches, existing therapies tackle those stubborn skin disorders.



Peter Friedman, MD, PhD, FAAD, dermatologist at the Skin Center Dermatology Group in New City, New York; instructor in clinical dermatology at Columbia University – New York Presbyterian Hospital

very dermatologist at some point in their career will run into that most pernicious of protrusions — the stubborn wart that just won't go away.

Peter Friedman, MD, PhD, FAAD, a dermatologist at the Skin Center Dermatology Group in New City, New York, and instructor in clinical dermatology at Columbia University – New York Presbyterian Hospital, said hard-to-manage warts are a daily occurrence in his practice, in part because he sees many children. Dr. Friedman said there are several possible explanations for poor outcomes in managing warts.

Speaking at Friday's session, "Uo28 – The Evolving Toolbox for Treating Difficult Warts," Dr. Friedman took on the tough issues.

Where did that wart come from?

"Sometimes there is an explanation, like the lesions are very big or they are in areas where traditional treatments can't be used to the fullest extent," he said. "The side effects or the logistics associated with traditional treatments can also reduce [patient] compliance, and occasionally underlying medical issues, such as immunosuppression, reduce the efficacy of treatments. However, sometimes there is no obvious reason — the wart just doesn't get better."

Two-fold approach

Dr. Friedman takes a twofold approach when it comes to tackling the toughest warts.

"First, I do not do the 'first-line treatment, second-line treatment after failure' approach," he said. "I try to look at every wart patient with all the treatment options in mind and recommend a plan that uniquely suits their individual scenario."

The second prong of his attack involves a combination of treatments.

"I use the traditional methods — I do freeze many warts and I do recommend using over-the-counter salicylic acid products, but almost never as monotherapy and only when that seems more appropriate for the given patient than anything else I can offer," he said. "It has been my experience, which is also supported by a number of studies, that certain combination treatments can work better than monotherapies."

New treatments now and on the horizon

Dr. Friedman discussed several evolving methods that are showing promising results for wart treatment, along with one new one that he said is matching some traditional treatments in terms of efficacy.

"One of the truly novel methods is cold atmospheric plasma, which was developed by a research team I am part of," he said. "This is a very well-tolerated treatment with efficacy on par with the more traditional treatments. The limitation is that it does require a device to administer the treatment, and it is not yet on the market."

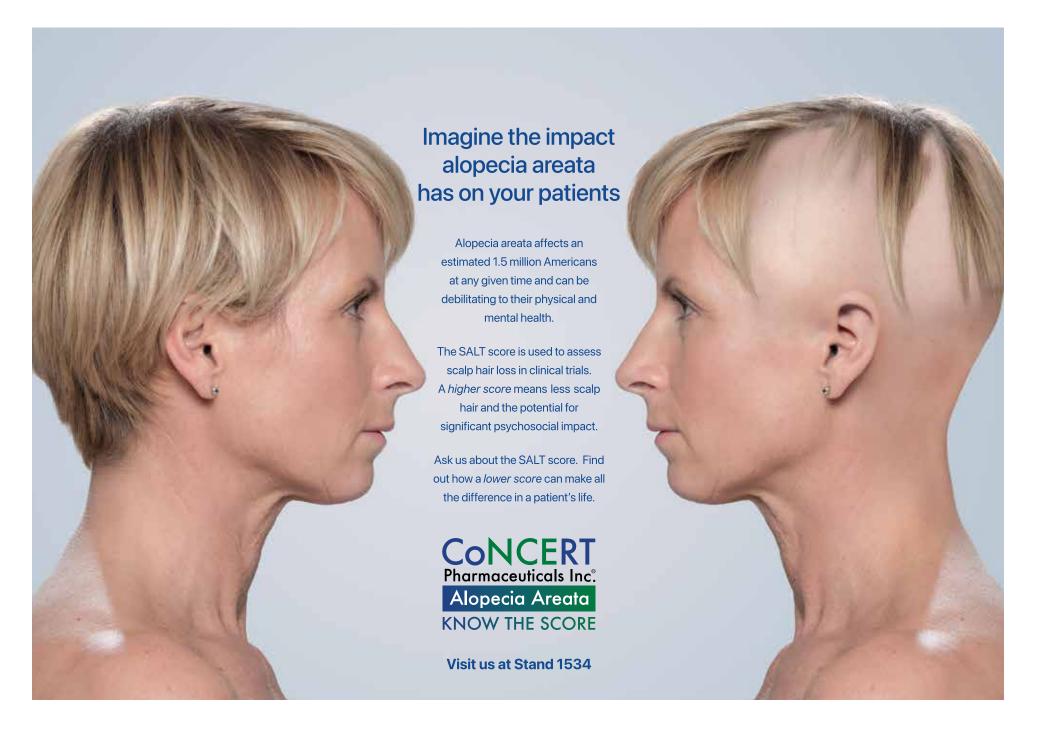
Patient considerations

Ultimately, Dr. Friedman said there are multiple factors to consider when treating stubborn warts, not the least of which is the cost to the patient. "Cost is a very important question and can be a significant barrier," he said. "If we prescribe a medication, the patient may or may not have a co-pay. If they come to the office for treatment, they may or may not have a co-pay or deductible. One part of their benefit package may be more favorable than the other, depending on their insurance. They may live far from the office or work multiple jobs, so it is a big issue to come to see me every three or four weeks for a treatment."

Aside from the cost of the office visit, Dr. Friedman said the cost of just getting to the office and the monetary value of the time patients have to spend on office visits can add up quickly.

"These variables, and not just the purely medical considerations, all factor into the decision process when choosing the best treatment for a patient," he said. "So there really is no one treatment I would recommend above all for all patients.

"We must constantly remind ourselves that our most commonly used first-line wart treatments are far from perfect, as large reviews and analyses have shown time and time again," Dr. Friedman said.





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In DERMIS-1 and DERMIS-2, ~40% of patients achieved IGA Success and ~70% of patients achieved I-IGA Success at Week 8.1

DERMIS-1 and DERMIS-2 were identical Phase 3 randomized, parallel, double-blind, vehicle-controlled, multicenter studies that evaluated ZORYVE over 8 weeks as a once-daily, topical treatment for plaque psoriasis. Subjects (N=881) were randomized 2:1 to receive ZORYVE cream 0.3% (n=576) or vehicle (n=305) applied once daily for 8 weeks. Eligibility criteria included a diagnosis of mild, moderate, or severe plaque psoriasis and an affected BSA of 2% to 20%. Primary endpoint was IGA Success at Week 8 and key secondary endpoint was I-IGA Success at Week 8.1

IGA Success was defined as a score of Clear (0) or Almost Clear (1) and a \geq 2-grade improvement from baseline. I-IGA Success was defined as a score of Clear (0) or Almost Clear (1) and \geq 2-grade improvement from baseline. ZORYVE is not for ophthalmic, oral, or intravaginal use.

BSA = Body Surface Area, IGA = Investigator's Global Assessment, I-IGA = Intertriginous-IGA



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Actor portrayal

INDICATION

ZORYVE is indicated for topical treatment of plaque psoriasis, including intertriginous areas, in patients 12 years of age and older.

IMPORTANT SAFETY INFORMATION

The use of ZORYVE is contraindicated in patients with moderate to severe liver impairment (Child-Pugh B or C). The most common adverse reactions (≥1%) include diarrhea (3%), headache (2%), insomnia (1%), nausea (1%), application site pain (1%), upper respiratory tract infection (1%), and urinary tract infection (1%).

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

References: 1. ZORVYE®. Prescribing information. Arcutis Biotherapeutics, Inc; 2022. 2. Data on File. Arcutis Biotherapeutics, Inc.



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Brief Summary of Prescribing Information for ZORYVE™ (roflumilast) cream, for topical use. See package insert for full Prescribing Information.

INDICATIONS AND USAGE

ZORYVE is indicated for topical treatment of plaque psoriasis, including intertriginous areas, in patients 12 years of age and older.

DOSAGE AND ADMINISTRATION

Apply ZORYVE to affected areas once daily and rub in completely. Wash hands after application, unless ZORYVE is for treatment of the hands.

ZORYVE is for topical use only and not for ophthalmic, oral, or intravaginal use.

CONTRAINDICATIONS

The use of ZORYVE is contraindicated in the following condition:

• Moderate to severe liver impairment (Child-Pugh B or C)

ADVERSE REACTIONS

Clinical Trials Experience

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

In two multicenter, randomized, double-blind, vehicle-controlled trials (DERMIS-1 and DERMIS-2), 881 subjects 2 years of age or older with plaque psoriasis were treated with ZORYVE or vehicle once daily for 8 weeks.

The median age was 47 years (range 6 to 88). The majority of the subjects were male (64%) and White (82%). The median body surface area (BSA) affected was 5.5% (range 2% to 20%).

The proportion of subjects who discontinued treatment due to adverse reaction was 1.0% for subjects treated with ZORYVE and 1.3% for subjects treated with vehicle. The most common adverse reactions that led to discontinuation of ZORYVE was application site urticaria (0.3%).

Table 1 presents adverse reactions that occurred in at least 1% of subjects treated with ZORYVE, and for which the rate exceeded the rate for vehicle.

Table 1. Adverse Reactions Reported in $\geq \! 1\%$ of Subjects Treated with ZORYVE for 8 Weeks

Adverse Reaction	ZORYVE (N=576) n (%)	Vehicle (N=305) n (%)
Diarrhea	18 (3.1)	0 (0.0)
Headache	14 (2.4)	3 (1.0)
Insomnia	8 (1.4)	2 (0.7)
Nausea	7 (1.2)	1 (0.3)
Application site pain	6 (1.0)	1 (0.3)
Upper respiratory tract infection	6 (1.0)	1 (0.3)
Urinary tract infection	6 (1.0)	2 (0.7)

In 594 subjects who continued treatment with ZORYVE for up to 64 weeks in open-label extension trials, the adverse reaction profile was similar to that observed in vehicle-controlled trials.

USE IN SPECIFIC POPULATIONS

Pregnancy

Risk Summary

There are no randomized clinical trials of oral or topical roflumilast in pregnant women. In animal reproduction studies, roflumilast administered orally to pregnant rats and rabbits during the period of organogenesis produced no fetal structural abnormalities at doses up to 9 and 8 times the maximum recommended human dose (MRHD), respectively. Roflumilast induced post-implantation loss in rats at oral doses greater than or equal to 3 times the MRHD. Roflumilast induced stillbirth and decreased pup viability in mice at oral doses 5 and 15 times the MRHD, respectively. Roflumilast has been shown to adversely affect pup post-natal development when dams were treated with an oral dose 15 times the MRHD during pregnancy and lactation periods in mice.

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

Clinical Considerations

Labor and delivery

ZORYVE should not be used during labor and delivery. There are no human studies that have investigated effects of ZORYVE on preterm labor or labor at term; however, animal studies showed that oral roflumilast disrupted the labor and delivery process in mice.

<u>Data</u>

Animal data

In an embryo-fetal development study, pregnant rats were dosed orally during the period of organogenesis with up to 1.8 mg/kg/day roflumilast (9 times the MRHD on a mg/m² basis). No evidence of structural abnormalities or effects on survival rates were observed. Roflumilast did not affect embryo-fetal development at a maternal oral dose of 0.2 mg/kg/day (equivalent to the MRHD on a mg/m² basis).

In a fertility and embryo-fetal development study, male rats were dosed orally with up to 1.8 mg/kg/day roflumilast for 10 weeks and females for 2 weeks prior to pairing and throughout the organogenesis period. Roflumilast induced pre- and post-implantation loss at maternal oral doses greater than or equal to 0.6 mg/kg/day (3 times the MRHD on a mg/m² basis). Roflumilast did not cause fetal structural abnormalities at maternal oral doses up to 1.8 mg/kg/day (9 times the MRHD on a mg/m² basis).

In an embryo-fetal development study in rabbits, pregnant does were dosed orally with 0.8 mg/kg/day roflumilast during the period of organogenesis. Roflumilast did not cause fetal structural abnormalities at the maternal oral doses of 0.8 mg/kg/day (8 times the MRHD on a mg/ m^2 basis).

In pre- and post-natal developmental studies in mice, dams were dosed orally with up to 12 mg/kg/day roflumilast during the period of organogenesis and lactation. Roflumilast induced stillbirth and decreased pup viability at maternal oral doses greater than 2 mg/kg/day and 6 mg/kg/day, respectively (5 and 15 times the MRHD on a mg/m² basis, respectively). Roflumilast induced delivery retardation in pregnant mice at maternal oral doses greater than 2 mg/kg/day (5 times the MRHD on a mg/m² basis). Roflumilast decreased pup rearing frequencies at a maternal oral dose of 6 mg/kg/day during pregnancy and lactation (15 times the MRHD on a mg/m² basis). Roflumilast also decreased survival and forelimb grip reflex and delayed pinna detachment in mouse pups at a maternal oral dose of 12 mg/kg/day (29 times the MRHD on a mg/m² basis).

Lactation

Risk Summary

There is no information regarding the presence of ZORYVE in human milk, the effects on the breastfed infant, or the effects on milk production.

Roflumilast and/or its metabolites are excreted into the milk of lactating rats. When a drug is present in animal milk, it is likely that the drug will present in human milk. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for ZORYVE and any potential adverse effects on the breastfed infant from ZORYVE or from the underlying maternal condition.

Clinical Considerations

To minimize potential exposure to the breastfed infant via breast milk, use ZORYVE on the smallest area of skin and for the shortest duration possible while breastfeeding. Advise breastfeeding women not to apply ZORYVE directly to the nipple and areola to avoid direct infant exposure.

Data

Animal data

Roflumilast and/or its metabolite concentrations measured 8 hours after an oral dose of 1 mg/kg given to lactating rats were 0.32 and 0.02 mcg/g in the milk and pup liver, respectively.

Pediatric Use

The safety and effectiveness of ZORYVE have been established in pediatric patients ages 12 years and older for the treatment of plaque psoriasis. Use of ZORYVE in this age group is supported by data from two 8-week vehicle-controlled safety and efficacy trials which included 14 adolescent patients aged 12 to 17 years, of whom 8 received ZORYVE. Eighteen adolescent patients were treated with ZORYVE in open-label trials of 2- and 24-weeks duration. The adverse reaction profile was similar to that observed in adults.

The safety and effectiveness of ZORYVE in pediatric patients below the age of 12 years have not been established.

Geriatric Use

Of the 881 subjects with psoriasis exposed to ZORYVE or vehicle for up to 8 weeks in 2 controlled clinical trials, 106 were 65 years of age or older. No overall differences in safety or effectiveness were observed between these subjects and younger subjects. Other reported clinical experience has not identified differences in responses between the geriatric and younger patients, but greater sensitivity of some older individuals cannot be ruled out. Based on available data for roflumilast, no adjustment of dosage in geriatric patients is warranted.

Hepatic Impairment

Oral roflumilast 250 mcg once daily for 14 days was studied in subjects with hepatic impairment. The AUC and C_{max} values of roflumilast and roflumilast N-oxide were increased in subjects with moderate (Child-Pugh B) hepatic impairment. ZORYVE is contraindicated in patients with moderate to severe liver impairment (Child-Pugh B or C).

PATIENT COUNSELING INFORMATION

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

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08/2022

A healthy dose of skepticism

The right tools can help you weigh inherent uncertainty in medical research.

he world is filled with uncertainty
— even when it comes to the most
carefully researched medical study.
Learning to recognize that uncertainty is
key to having a better understanding of
those studies and how they can benefit
your patients.

During Friday's new session, "Uo25 – Uncertainties Masquerading as Certainties: Can You Trust the Study You Just Read?" Stephen Malachowski, MD, MS, dermatology resident at Virginia Commonwealth University's Department of Dermatology in Richmond, said using statistical tools and keeping certain ethical and logical considerations in mind can aid in the correct interpretation of medical literature.

"When the goal is to positively impact patient care, clinicians and researchers alike should strive to step outside of their comfort zone to reason with data, and question statistical assumptions," he said.

Assessing the variables

One common mistake people make when developing studies is dichotomizing — or categorizing — quantitative variables.

"An example would be to take age as it is

measured but deciding to classify people as below some age limit or not," Dr. Malachowski said. "This is problematic in many ways. First, information is lost, which mathematically reduces the statistical power of a study. In the case of a randomized clinical trial, the study must now recruit more patients to the trial to reach the same amount of information. If we create information loss that requires us to recruit more people than necessary, this raises the ethical consideration of exposing more people than needed to the risks of the trial."

Dr. Malachowski said dermatologists should review study statistics such as sensitivity (how often a positive test is rendered to patients who have the disease in question) and specificity (how often a negative test is rendered to a healthy patient) with caution.

"The problem with this is inherent in the interpretation," he said. "For a diagnosis, we don't yet know if a patient has a disease, so something like sensitivity or specificity alone cannot tell us much about diagnosis. In fact, sensitivity and specificity are 'backward' for diagnosis because we don't know who has the disease at the time of



Lee Wheless, MD, PhD, FAAD, assistant professor of dermatology and epidemiology at Vanderbilt University Medical Center in Nashville, Tennessee

completing a test. We only know the test result and try to use the result, along with other information, to make a diagnosis."

Limitations at play

Lee Wheless, MD, PhD, FAAD, assistant professor of dermatology and epidemiology at Vanderbilt University Medical Center in Nashville, Tennessee, said when it comes to reviewing a study, it is important to understand the limitations of its p-value (the likelihood that the study will find a particular set of observations to be associated with the outcome if there is no difference among the groups being studied) and its confidence interval (the range of values that are plausible, based on the data).

"It's important to keep in mind that both of these values are really measures of how well a model explains the data in the study," Dr. Wheless said. "A p-value does not reflect the clinical importance of the finding but rather can speak to how likely or not it is the variables in the model describe the relationship with the outcome. Similarly, a confidence interval does not tell us that 'truth' is found 95% of the time within its bounds. Rather, confidence



Stephen Malachowski, MD, MS, dermatology resident at Virginia Commonwealth University's Department of Dermatology in Richmond

intervals give us a sense of how certain we are about the estimates made by the model. Neither a p-value or a confidence interval tells us about the probability or truth of an error, which is a common misconception."

The ripple effect

Drs. Wheless and Malachowski said it is important to recognize uncertainty in medical research because a clinical mistake based on a dermatologist's uncertainty will affect a single patient, but an uncertain measure in a study that becomes accepted as truth has the potential to impact many patients.

Dr. Malachowski echoed that sentiment with an old adage. "There is an old saying: 'The trouble with people is not that they don't know but that they know so much that ain't so,'" he said. "Recognizing uncertainty in medical research is important because the world we live in is filled with uncertainty, even about things we think we understand. Without recognizing uncertainty, patients may receive treatments that appear to work but don't, or we may dismiss treatments that might work but are written off without proper evidence."

In a study of patients with acne, almost 40% of treatment non-adherence was due to side effects¹

Strategic use of OTC skincare, including gentle cleansers and moisturizers, can promote adherence by improving tolerability^{2,3}



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References: 1. Dikicier BS. Topical treatment of acne vulgaris: efficiency, side effects, and adherence rate. *J Int Med Res.* 2019;47(7):2987-2992. **2.** Lain E, Andriessen AE. Choosing the right partner: complementing prescription acne medication with over-the-counter cleansers and moisturizers. *J Drugs Dermatol.* 2020;19(11): 1069-1073. **3.** Dreno B, Araviiskaia E, Kerob Delphine, et al. Nonprescription acne vulgaris treatments: their role in our treatment armamentarium—an international panel discussion. *J Cosmet Dermatol.* 2020;19:2201-2211. Use products only as directed.

Outside the box

It's the great divide. There has long been a fissure among dermatologists when it comes to weighing the use of cosmetic procedures to treat some dermatologic medical conditions. But it doesn't have to be that way.

itchel P. Goldman, MD, FAAD, medical director at Platinum/West Dermatology and Cosmetic Laser Dermatology in San Diego, said many of the treatments that have been developed for things like wrinkles and aging skin have tremendous possibilities for treating other conditions like acne and rosacea.



"The problem we presently have is that academic dermatologists and dermatology residency programs do not cover and do not embrace the concept of nonmedical dermatology," he said. "That's a polarizing statement because academic dermatologists spend almost all the residents' time on severe dermatology diseases which are extremely important. I don't want to disparage in any way the importance of medical dermatology, but I want to highlight the fact that even though we develop cosmetic treatments for wrinkles and aging skin, those cosmetic treatments can cross over into the medical dermatology field."

Available options

There are two types of lasers that are typically used — fully ablative lasers and non-ablative lasers. Newer lasers have also been developed as recently as last year specifically for treating acne and acne scars.

"These scars affect the quality of life for many, many patients because people become self-conscious of the scarred appearance of their faces," Dr. Goldman said. "And that comes from the lack of effective treatments

Rosacea, while not fatal, can also affect the quality of life for anyone on the





spectrum — from mild, acne-like lesions to more severe forms including rhinophyma, which can lead to redness of the face and a bulbous nose.

"We have a variety of lasers and intense pulse-light devices that were developed for the treatment of benign vascular lesions as well as photodamaged skin and have been shown to also effectively treat the redness and acne-like lesions and enlarged glands found in rosacea," Dr. Goldman said. "That improves the quality of life for our patients."

Getting to know Your Dermatologist Knows

AAD members flocked to the Resource Center Friday and Saturday to chat with the social media correspondents who have been creating content in support of Your Dermatologist Knows, the Academy's new consumer positioning strategy. Ronda Farah, MD, FAAD, Sara Moghaddam, MD, FAAD, and Oyetewa Oyerinde, MD, FAAD, discussed the thinking behind the strategy, which is designed to make sure the public knows that dermatologists are the experts in skin, hair, and nail health and address increased willingness among younger demographics to see a non-physician clinician to address skin, hair, and nail concerns. The upbeat, approachable content created by the correspondents is meeting those demographics where they are — on Instagram, Facebook, and TikTok — to spread the word about the full scope of care patients can expect from a dermatologist.

Members who attended the two events created some fun content for their own social media channels, posing in front of Your Dermatologist Knows backdrop with hashtag signs like #SkinExpert, #HairExpert, #NailExpert, #AAD, and even a six-foot #YourDermatologistKnows.





Learn more about the new consumer positioning strategy at aad.org/yourdermatologistknows.



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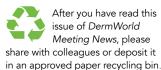
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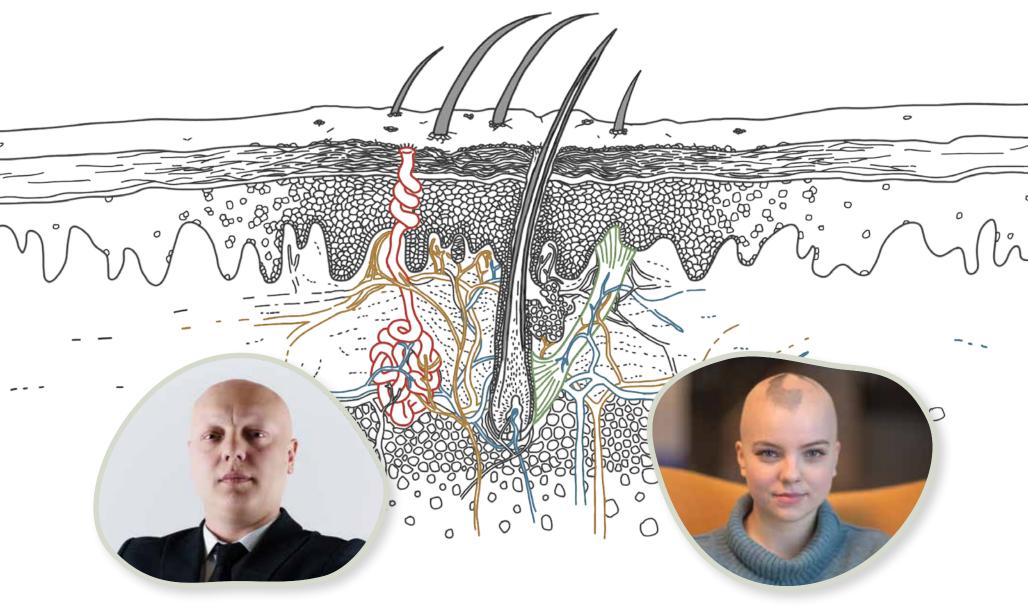
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Re-Examine Alopecia Areata

It's more than just hair loss.

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Hair loss isn't the whole story.

- Alopecia areata (AA) is an autoimmune disease that can also have effects beyond the scalp.¹
- AA has a complex etiology and is rooted in immune system dysregulation, with many patients having a genetic predisposition.^{2,3}
- Patients often experience autoimmune and psychiatric comorbidities, lifestyle disruptions, and psychosocial distress.^{1,2,4}
- The unpredictable course of AA can make disease management difficult for HCPs and their patients.^{5,6}

To re-examine what you know about alopecia areata, visit <u>education.lillymedical.com/advancesinaa</u>



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