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SPECIAL REPORT

Lights, Lasers, Actions: Highlights from ASLMS

The annual meeting of the American Society for Laser Medicine and Surgery (ASLMS) is and always has been considered the premier laser medicine show in the dermatology and aesthetics space—and 2018 was no exception.

The newly re-christened Candela went all out to introduce the Vbeam Prima at an exclusive reception. (Access this issue online to see photos of their big event; Turn to page 12 for our exclusive Take 5 interview with new CEO Geoffrey Crouse.)

The Vbeam Prima is a next generation pulsed dye laser with 595nm and 1064nm wave lengths, contact and spray cooling, and a smart dye life management tool. It's got a lot of the perks that will make it a true workhorse, says Eric Bernstein, MD, Director of Laser Surgery and Cosmetic Dermatology Centers at Mainline Center for Laser Surgery in Ardmore, PA. "The new laser enables a 15mm beam-diameter, a very big spot size for a vascular laser," says Dr. Bernstein, also the new ASLMS President.

BTL came out of the gate strong with HIFEM technology to address muscle and fat including Emsculpt for abs and buttocks and Emsella for strengthening the pelvic floor.

"This is the first time that we have actually been able to address muscle," says Bruce E. Katz, MD, Clinical Professor at the Icahn School of Medicine at Mt Sinai, Director, Juva Skin & Laser Center, Director, Cosmetic Surgery & Laser Clinic Mt. Sinai Hospital in New York City. "Until now, we could tighten skin or take away fat minimally invasively or non-invasively but we have never had anything to address the muscles."

Emsculpt is akin to doing 20,000 sit-ups in 30 minutes. Dr. Katz recommends four treatments every two to three days to tighten the abs. The device is user-friendly with little to no learning curve for doctors.

HIFEM is also helping to lift buttocks, and in the future may shape and sculpt other areas where muscles need tightening along with fat reduction such as the thighs.

With Emsella, "you sit on a chair fully clothed and it does to pelvic floor muscles what Emsculpt does to ab muscles," he says. "With stress urinary incontinence, muscles get lax. This is like doing kegels on steroids."

Lumenis treated attendees to the soft roll out of their Legend Pro, a tripollar radiofrequency (RF) device with RF-assisted microneedling that can resurface the upper layers of the skin and generate collagen and elastin below the skin's surface using a smart tip design for an even distribution of energy.

Cutera celebrated its 20-year anniversary with a party at the Dallas Cowboys Stadium. They also announced the global launch of the enlighten SR, a new picosecond platform for skin revitalization and the treatment of benign pigmented lesions.

Sciton unveiled a new and improved Halo Hybrid Fractional Laser with such bells and whistles as Tempo technology for even treatment; new software templates for off-face treatments; Adjustable Beam Placement technology to treat areas with distinct edges or smaller zones; and Customizable Pass Selection, which puts the practitioner in control of the treatment speed and energy density.

MORE THAN JUST LASERS...

A topical that can delete or fill wrinkles as well as injectables is considered a holy grail in aesthetics—and Dyve Biosciences' technology may pave the way toward such advancement. The company developed a hydrophilic molecule that gets through the skin barrier where it absorbs water and expands. It fills from the inside out to thicken the dermis. The company is looking at ways to harness the technology to treat hyperpigmentation, fat and wrinkles.

Currently, Dyve Biosciences is introducing topical lidocaine that can be delivered using their technology. Dyve Comfort (the next generation of what was previously Procicept), is an FDA-cleared topical analgesic. Melanie Palm, MD, founder of the Art of Skin MD in Solana Beach, CA, shared positive results from a blinded comparison of Dyve Comfort versus compounded lidocaine/tetracaine (23 percent/7 percent) for pain reduction during Ultherapy treatments.

Pulse Biosciences presented the first multi-center study of its Nano-Pulse Stimulation (NPS) technology for the treatment of seborrheic keratosis lesions (SKs) in humans.

The technology, delivered via micro needles, induces delayed cell death. In pre-clinical research models, this gentler method of slowly killing cells was shown to also trigger an immune response that teaches the immune system to recognize the offender, when it is reintroduced—resulting in a vaccine-like effect that prevents recurrences of new cancer cell introductions.

NPS offers cellular specificity. "Unlike non-specific thermal technologies, which affect everything they touch, NPS targets cellular structures and doesn't affect tissue types that

don't have cells," says Ed Ebbers, Vice President and General Manager of its dermatology products. On a histological level, the cell membrane is intact, but the nuclei disappear. "The cell is not viable, but it's not expelling its contents and triggering a severe inflammatory response," he explains.

This cell specificity has the potential to reduce the collateral damage that can occur when treating lesions that are surrounded by less cellular dermal tissue. The company has near-term plans to investigate NPS in treating hard-to-treat cellular targets that protrude into the dermis, like sebaceous hyperplasia (SH), keloids, and other common lesions like warts.

In support of its long-term goals in immune-oncology, Pulse Biosciences has announced plans to submit investigational device exemption (IDE) to the FDA for a study in melanoma, and is also developing protocols for treating nonmelanoma skin cancers.

Daily Aspirin Linked to Higher Melanoma Risk in Men

Men who take once-daily aspirin have nearly double the risk of melanoma compared to men who don't, reports a new Northwestern Medicine study. Women, however, do not have an increased risk in this large patient population.

The study, published the *Journal of the American Academy of Dermatology*, collected medical record data comprising almost 200,000 patients who were aspirin-exposed or aspirin-unexposed, ages 18-89, with no prior history of melanoma and with a follow-up time of at least five years.

Take 5

WITH GEOFFREY CROUSE, CHIEF EXECUTIVE OFFICER OF CANDELA

It was a big night for Candela. The annual American Society for Laser Medicine and Surgery, Inc. (ASLMS) meeting was in full swing, the brand was rolling out the Vbeam Prima to a room filled with brand loyalists and enthusiasts, and Geoffrey Crouse, Candela's new Chief Executive Officer, took the stage to share his vision for the new, old company. Mr. Crouse took time out to talk to Practical Dermatology® about Candela's future.

1. A WHOLE NEW WORLD

"I've been at Candela for nine months. Physicians who are driven by self-pay are much more business savvy and aware. This was not the case in diagnostic medicine, where I was for 15 years. These physicians understand that to have a thriving successful practice, you need partnerships. We all do better when we work together. We will leverage all of our resources to build business for our doctors."

2. WHAT'S IN NAME?

"We are focusing on Candela and the ethos that made Candela great: Science, results and trust. This is an incredible brand with incredible history and great people."

3. ONE VISION

"We are one company and will operate under one vision. We will offer a rational product portfolio, which may involve getting rid of suboptimal devices. We will go back to the drawing board to make sure that we feel confident that we can put a device in our doctor's hands. This will include understanding results from the basic science level including histology on up. We will also be announcing a new advisory board."

4. RAISING THE BAR

"We plan to reinvest and redouble our efforts with physicians and key opinion leaders. We will get our investigators back on the podium and develop clinical protocols for our devices."

5. FOSTERING FUTURE LEADERS

"We are sponsoring investigator awards that will be focused on reflecting the Candela mission. These awards will be open to healthcare professionals—anywhere from residency to 10 years post-graduation. The awards will be launched in time for ASLMS 2019, and ASLMS will build an award committee to review and make the final decision. Grants will be awarded to physicians for clinical research that has an effect on changing human life. This will be specific to ASLMS membership, and three winners will be honored as ASLMS awardees at an award ceremony every year during the annual meeting."

CLOSE UP

PD Gets the Inside Scoop on New AD Research

With Emma Guttman-Yassky, MD, PhD,

Practical Dermatology® spoke with Emma Guttman-Yassky, MD, PhD, Vice Chair, Department of Dermatology at the Icahn School of Medicine at Mount Sinai in New York City, about results of her newly published study in *The Journal of Allergy and Clinical Immunology* and the findings that just may change how we treat pediatric atopic dermatitis (AD).

PD: Why is this topic important to study?

Dr. Guttman-Yassky: Just seven percent of adults have atopic dermatitis, while 15-20 percent of children have AD. Thus, there is a very high prevalence of AD in children. However, all discoveries are based on adult data. There has been very little, if any, investigation in children, and particularly children's skin at the time of disease initiation. This is really important as we need to see if children with AD have the same skin phenotypes as adults, and if the same treatments that apply in adults can also be good for children.

PD: Describe the research and your findings.

Dr. Guttman-Yassky: We looked at 19 children who were diagnosed with AD within the past six months, and with very early disease. Most of these children were two or three years of age, and all were under five and with moderate-to-severe disease (mean SCORAD 57.8, range 33-84). Control skin was collected during routine surgical procedures from a group of 18 healthy children matched for age, gender, and ethnicity, without personal/familial atopy. Skin biopsies of both children and adults with similar disease severity (lesional and non-lesional adult (AD) tissues (n=20; age range 18-73yrs) and matched control skin (n=11; age range 38-57yrs; SCORAD mean 62.4, range 44-97) from previously reported cohorts from my group were analyzed using gene expression studies, as well as immunohistochemistry and immunofluorescence. The results were compared to lesional and non-lesional adult AD tissues and matched control skin.

We did not expect to find thickened skin in early pediatric AD, but when we looked under the microscope, we found that children with AD had very thickened lesions, similar to adults with long-standing disease. Both patient populations exhibited TH2-centered inflammation. Unlike adult AD, however, pediatric AD showed significant TH17/TH22 skewing. Importantly, pediatric AD patients lacked the TH1 upregulation that characterizes chronic adult AD skin. On the other hand, pediatric AD skin exhibited relatively normal expression of epidermal differentiation and cornification products, which we know are significantly downregulated in adults.

The barrier differences left us puzzled, as the dogma has been that filaggrin is the driver of AD and instigator of the atopic march, but we must remember that children have intact filaggrin expression. We did find some defects in epidermal barrier, which largely focused on lipid and tight junction abnormalities (claudins 8 and 23), which were shared in both children and adults. These findings overall suggest that early AD disease at the initiation stages in children shows a phenotype that is somewhere in between AD and psoriasis, with possible therapeutic complications.

PD: What is the next step?

Dr. Guttman-Yassky: These children with moderate-to-severe AD have huge immune activity and a severe phenotype already very early on in the game. We thus may need heavy guns to treat the disease and prevent the atopic march. We may also want to consider some of the psoriasis treatments for this age group based on the phenotype.

And we need to follow the clinical trials with dupilumab, and see if this treatment may be able to not only treat AD effectively but also reduce risk for asthma and other atopic manifestations that characterize the atopic march. It's an exciting time for AD.

When the groups were separated into men and women, men exposed to aspirin had almost twice the risk for diagnosis of melanoma (adjusted relative risk: 1.83) compared to other men.

"Given the widespread use of aspirin and the potential clinical impact of the link to melanoma, patients and health care providers need to be aware of the possibility of increased risk for men," says senior study author Beatrice Nardone, MD, research assistant professor of dermatology at Northwestern University Feinberg School of Medicine, in a news release.

She suggested increasing patient education about sun exposure, avoiding tanning beds, and getting skin checks.

"This does not mean men should stop aspirin therapy to lower the risk of heart attack," she stresses.

FDA Approves Tafinlar Plus Mekinist

The FDA approved Novartis' Tafinlar (dabrafenib) in combi-

nation with Mekinist (trametinib) for the adjuvant treatment of patients with melanoma with BRAF V600E or V600K mutations and involvement of lymph node(s), following complete resection. Breakthrough Therapy Designation was granted in October 2017 and Priority Review in December 2017.

FDA: Priority Review for Cemiplimab for Advanced SCC

The FDA has accepted the Biologics License Application (BLA) for cemiplimab for the treatment of patients with metastatic cutaneous squamous cell carcinoma (CSCC) or patients with locally advanced CSCC who are not candidates for surgery. The BLA will receive priority review. Cemiplimab is an investigational human monoclonal antibody targeting the checkpoint inhibitor PD-1 and was granted Breakthrough Therapy designation in September 2017. The target action date for the FDA decision is October 28, 2018.

The BLA is based on a Phase 2 pivotal, single-arm, open-label clinical trial of cemiplimab for advanced CSCC (EMPOWER-CSCC 1) in addition to Phase 1 data from two advanced CSCC expansion cohorts. Both clinical trials enrolled patients with metastatic CSCC and patients with locally advanced CSCC who were not candidates for surgery.

Encore Launches Impoyz Cream

Encore Dermatology Inc. launched Impoyz Cream, indicated for the topical treatment of moderate to severe plaque psoriasis in patients 18 years of age or older. Impoyz Cream is the only FDA-approved high-potency topical corticosteroid with 0.025% clobetasol propionate. Impoyz Cream is available in the US by prescription only in a 60g tube.

Hair Products for Black Women May Contain Hazardous Ingredients

Black women are potentially exposed to dozens of hazardous chemicals through their hair products, finds a new report in the journal *Environmental Research*.

The study, led by scientists at Silent Spring Institute in Newton, MA, is the first to measure concentrations of endocrine-disrupting chemicals in a variety of hair products marketed at Black women. The findings could help researchers understand why Black women have higher exposures to hazardous chemicals than other groups and how these elevated exposures contribute to health disparities in the US population.

The new study looked at 18 different hair products including hot oil treatments, anti-frizz hair polishes, leave-in conditioners, root stimulators, hair lotions, and hair relaxers. The products were chosen based on results from a survey of black women asking them about their product use.

A total of 45 endocrine disruptors were detected in total, with each product containing anywhere between six and 30 of the target chemicals Although the chemicals detected in the new study are not unique to hair products used by black women, the levels measured were generally in the higher range compared with other hair products, the researchers note. ■

MORE HEADLINES FROM DERMWIRE.COM

Sensus Appoints Rita Gable VP of Sales, Oncology

As Vice President of Sales-Oncology, Rita Gable, will report to Joe Sardano, Sensus CEO. She has 15 years of sales experience, specializing in the oncology market.

Cellulite Market Expected to Grow

The cellulite treatment market is expected to grow worldwide, says a comprehensive research report by Future Market Insights entitled "Cellulite Treatment Market: Global Industry Analysis 2013-2017 and Opportunity Assessment 2018-2028." North America shows the strongest prospects with an expected market value of over $2.1 million by the end of 2028.

First Androgenetic Alopecia Patient Dosed in a Pilot Study with Aclaris' ATI-502 Topical

Aclaris Therapeutics, Inc. initiated a Phase 2 open-label study of ATI-502, a topical Janus Kinase (JAK) 1/3 inhibitor (ATI-502 Topical), in patients with androgenetic alopecia (AGA), a condition characterized by a genetically determined male/female-pattern baldness. This trial will evaluate the safety, tolerability and effect of ATI-502 Topical applied twice daily in 24 adults (12 male and 12 female) with androgenetic alopecia.

AAD Awards 26 Shade Structure Grants to Protect America's Youth

The American Academy of Dermatology (AAD) has awarded Shade Structure grants to 26 schools and nonprofit organizations across the country. For organizations interested in offering a sun safety program, the AAD has developed a curriculum for eight- to 13-year-olds to promote healthy self-esteem through education about skin, hair, and nails. The Good Skin Knowledge lesson plans and accompanying activities include sun safety education, which meets the Shade Structure Grant Program's sun safety requirement when in place for one year prior to application.