

## T H E

# AESTHETIC GUIDE

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sure to be an exciting year filled with promise.



## What's the Big Idea? The New Year Offers New Paths to Success

While social media has changed marketing and delineated the divide between generations, cultural shifts have brought previously taboo topics, such as sexual health, to the forefront.

Powerful forces within our own bodies are being harnessed to regenerate and restore. The doctor-patient relationship is changing, as is the system itself, driven by social, governmental, economic and industrial factors. R&D is bringing new and exciting technologies to bear, which seem right out of science fiction, whilst proven and popular techniques and technologies are being further refined.

### Generational aesthetics

As aesthetic medicine has become more accessible to and accepted by the average consumer, the patient base has expanded. In addition, affordability and media exposure, specifically the rise of social media, has coupled with development and refinement of modalities providing less aggressive, but effective therapies that stave off the need for more drastic measures.

All of these changes have contributed to the wider age range of patients seeking aesthetic enhancements. Understanding the significance of generational aesthetics will prove critical to our industry in all aspects, including creation of a wider potential patient base, evolution of technology and changing the ways in which you market to and communicate with patients.

Shrewd practice owners know they must strategically offer treatments that appeal to different generations and market them accordingly.

"The term 'prejuvenation' has been coined to describe the increasing use of small, subtle, less aggressive, minimally or non-invasive therapies to slow the appearance of aging in younger patients," said Joel L. Cohen, M.D., director of AboutSkin Dermatology and DermSurgery in metropolitan Denver, Colo.

Millennials, or Generation Y (born between 1980 and 1995), are more comfortable with – and expect – an 'experience,' as well as a result. They seek solutions and digest information quickly. Their relative youth and resilient skin make them ideal for less aggressive therapies and any level of body contouring.

Conversely, older patients and baby boomers need more aggressive therapies and respond to more traditional marketing.

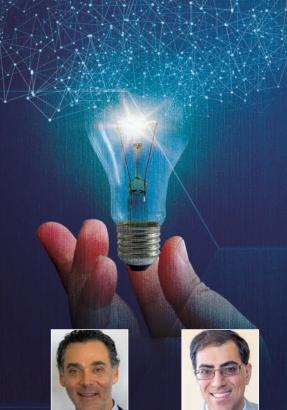
However, the bulk of patients in a practice will be from Generation X (born between 1965 and 1979). These patients are more media savvy and skeptical, but in a prime position to benefit from a variety of therapeutic options.

The most recent addition to the aesthetic patient population is Generation Z, also known as the iGeneration (mid 1990s to mid 2000s). This group may seek body contouring and milder therapies. They are most comfortable with the Internet, open to new ideas and treatments, and hungry for information, while being put off by more traditional marketing.

### Regenerative medicine

While it is still early in the game, the use of adipose-derived stem cells (ADSCs), platelet-rich plasma (PRP), platelet-rich fibrin matrix (PRFM), stromal vascular faction (SVF) and growth factors are being applied safely and effectively in a myriad of ways, both as stand-alone therapies, as well as to enhance results and speed healing after other treatments. The number and variety of products and applications is growing exponentially, almost faster than science can keep up.

Experts agree that regenerative medicine holds a tremendous amount of potential to dramatically transform the future of aesthetic medicine by changing the way physicians approach anti-aging and other indications. Examples include, autologous products that implement the use of a patient's own cells in surgical products, products that utilize amniotic fluid, epithelial growth factors and stem cell tissues, as well as adipose stromal connections. Other sources include cord blood, bone marrow and stem cells for the heart.1



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### **Facial injectables**

Injectable neurotoxins are the backbone of aesthetic medicine, with Botox Cosmetic from Allergan, Inc. (Irvine, Calif.), being largely responsible for the explosive growth of the aesthetic industry. For years there have been three main neurotoxin offerings in the U.S., but this is about to change, according to Dr. Cohen. Three competitors are on the radar and the potential market is still huge.

After overcoming FDA-clearance hurdles, Evolus (Newport Beach, Calif.) is expected to disrupt the current market as an aesthetic-only neurotoxin that is as good as rivals, but most likely offered at a much lower price. While the product has received a lot of backing by KOL physicians, some of these KOLs also are investors in Strathspey Crown/Alphaeon, which is a 50% owner of Evolus. Despite this detail, the buzz is still growing.

Revance Therapeutics, Inc., (Newark, Calif.) has completed Phase III trials on the long-acting neurotoxin product DaxibotulinumtoxinA for Injection (RT002) for the treatment of glabellar lines. The product is in clinical development for a broad range of aesthetic and therapeutic indications, including glabellar lines. Data presented by industry luminaries throughout 2018 strongly supported the product's potential of longer duration.

In addition, Croma-Pharma GmbH (Leobendorf, Austria) has partnered with Hugel, Inc. (Seoul, South Korea) to bring Botulax to the U.S. market soon, along with its unique saypha brand of HA-fillers and family of PDO threads.

"These are all type-A neurotoxins, with some variations in formulation, so I expect some heavily-marketed differentiating features, such as price and studies on longevity," said Dr. Cohen, who has been an investigator in trials of all three of these new neurotoxin products, but is not an investor in Revance Therapeutics.

"Patients are becoming more comfortable with the concept of injectables — even from a younger age, so the market is growing significantly. Thus, there are certainly opportunities for new players, products and procedures," Dr. Cohen said.

Collagen restoration is another popular characteristic being offered by many soft-tissue augmentation agents, such as poly-L-lactic acid (Sculptra, Galderma Laboratories), but lesser known products, such as Polycaprolactone (PCL) fillers (Ellansé, Sinclair Pharma, plc), take it to the next level. Ellansé is touted as a high viscosity, easy-to-inject biostimulator with a longevity outcome that relies on a specific neocollagenesis effect.

"We've been talking about fillers inducing collagen stimulation for a long time, and there have been studies in the literature, but now we are seeing more specific pathways and mechanisms of action reported to explain this," Dr. Cohen stated. "There is definitely something to it, with both established and emerging biostimulatory fillers."

### Integrative customized care

In aesthetics, integrative customized care denotes a modified approach to patient care that comes with unique benefits, said Farhan Taghizadeh, M.D., medical director of Arizona Facial Plastics (Scottsdale, Ariz.). This concept marries the whole-person approach with multi-vector treatment, some of which may seem to fall outside the purview of aesthetic medicine at times.

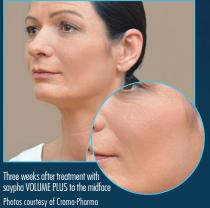
"A healthy lifestyle is better medicine than anything we can prescribe," Dr. Taghizadeh pointed out. "Diet, exercise, and supplementation when necessary, can go a long way to improving health and allows patients to maximize results.

"Everyone knows that lifestyle profoundly affects health, healing and aging," he continued. "Consider the role of inflammation, which we're learning more about every day. And what better example is there of the opportunity to affect outcomes with a healthy lifestyle than among body contouring patients?"

Lifestyle coaching, plus the use of combination therapies, especially non- or minimally invasive therapies, is a big part of this approach, but it is more than that.

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According to Dr. Taghizadeh, the resulting patient trust and loyalty has numerous benefits. Compliance is higher, and a loyal patient refers their friends.

"We provide a caring atmosphere and we're interested in how they are doing. They sense this," he explained. "Patients who trust us are more likely to do what we ask of them. We give options and explain thoroughly that we are with them every step of the way. And, in this business, reputation is everything. You can't buy the kind of advertising that a happy, trusting patient provides by word of mouth."

In many cases, this kind of 'multi-specialization' isn't nearly as far a stretch as it may seem, he added.

"It makes sense when you think about it," he began. "We are in the quality-of-life business. Aesthetic medicine is about outcomes that improve self-image and wellness. Any physician should understand the role of nutrition, hormones and exercise in day-to-day health.

"Wellness isn't just about how you look, it is about how you feel," he continued. "Thus, there are areas in which we're addressing issues from several angles, which is only natural, but goes against – and is ultimately changing – the paradigm of modern medicine."

### Skincare advancements

Personalization is also a growing trend within the segment of topical skincare, according to Dr. Taghizadeh.

"What we are seeing, and doing, is individualized skincare from one of two vectors. On one side, you have a patient undergoing a survey of their skin and being given a personalized combination of proven ingredients designed specifically for their needs," he expressed. The other side involves the harvest and application of a patient's own growth factors and platelets.

Dr. Taghizadeh is currently performing research on skincare products derived from autologous platelets. "This is inexpensive and effective, but I think it's only the beginning," he said. "Aesthetic medicine has been extracting growth factors and stem cells in a variety of ways and who knows how these could be incorporated into valid, accessible topical skincare therapies?"

Among the currently available topicals that work with growth factors or signal stem cells are products like Tensage from Biopelle, Inc., (Ferndale, Mich.) and DefenAge from Progenitor Biologics, LLC (Carlsbad, Calif.). Each have unique formulations and supporting studies.

These products are being used as part of daily skincare regimens and adjunctively with in-office procedures.

"After laser resurfacing, I have patients use Tensage Serum, which I believe can help jump-start the fibroblasts to aid in the repair process, augment wound healing and be overall synergistic with the procedure," said Dr. Cohen, who has done research for Biopelle on Tensage. He also has resurfacing and peel patients use Senté Dermal Repair cream from Senté Laboratories (Carlsbad, Calif.). "The proprietary Heparan Sulfate Analog (HSA) technology uniquely supports the extracellular matrix milieu."

Among some of the more recent ingredients being introduced for use in topical formulations, orchids, more associated with traditional or 'folk' medicine in Asia, may have a promising future. A 2018 investigation reported that dihydrostilbene derivatives (known as stilbenoids) from two orchid species offer anti-melanogenic and anti-oxidative effects, potentially making them extremely useful in skincare products.<sup>2</sup> These could provide further mitigation of undue oxidative stress and manage age-related pigmentary disorders when used regularly in effective formulations.

According to an article in *Dermatology Times*,<sup>3</sup> probiotics may have dermatologic applications, but this has become problematic. A plethora of products from cleansers

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"Microneedling is a very immature technology. We know it works, but we don't yet know how to make it work better. There is a lot of research going into three key areas: needle type and depth for other applications, automation of the device to treat larger areas more rapidly, and integration of microneedling with lasers. The last one is huge because we know they are very complementary."

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to creams have arisen that all claim to nurture and promote the proliferation of a natural, healthy microbial ecosystem of the skin.

Many products have been tagged as 'probiotic.' The issue: There are no regulatory guidelines, few definitions of beneficial processes, few demonstrated mechanisms of action, and no real standards on which claims can be based. However, there is still plenty to keep an eye on as researchers continue to expand our understanding of the role of our body's microbiome, inside and out.

Cannabis-based skin therapies that harness anti-inflammatory and other properties of derived compounds are on the way, and a 2017 review paper discussed their potential in dermatology.<sup>4</sup> However, while cannabis has many potential medicinal uses, there is still significant controversy.

"The public seems enthralled with marijuana right now, and I come from a state where it is legal and sold openly," said Dr. Cohen. "Nevertheless, we have much work to do as far as dosimetry, ideal routes of administration, and formulations are concerned. And given the hype these days, we must be cautious and thorough. I don't think concerns will apply to topical formulations, but we really need the research and the time for that to happen on a comprehensive scale to properly investigate cannabis."

Non-hormonal estrogen receptor activators (NERA) are an emerging class of cosmeceuticals. Emepelle topical skincare from Biopelle, Inc., which incorporates this technology, will launch at AAD in March 2019. A November 2018 study of 79 patients<sup>5</sup> produced impressive data.

"Estrogen deficiency causes accelerated loss of collagen and speeds aging of skin in women who may not actually correlate increased dryness, inhibited wound healing, or other changes with declining estrogen levels," said Dr. Cohen, who is currently involved in clinical trials with Emepelle.

"In fact, women may lose significant collagen within the first five years post-menopause, leading to wrinkles and thinning skin," he added. "Emepelle has been shown clinically to reduce these effects without causing untoward systemic effects, leading to smoother, more luminous skin with potential improvement in lines and wrinkles."

Amino acids, which have long been known to have beneficial effects on skin, stimulate fibroblasts, improve skin quality and hydration, as well as revive natural anti-oxidants in skin. "This is decades-old knowledge," Dr. Taghizadeh indicated. "Amino acids penetrate well, and the skin knows what to do with them. The issue is how should they be prepared."

### Microneedling advances and delivery systems

"Microneedling is a very immature technology," Dr. Taghizadeh said. "We know it works, but we don't yet know how to make it work better. That is why it is so often paired with other therapies, such as PRP.

"There is also a lot of research going into three key areas: needle type and depth for other applications, automation of the device to treat larger areas more rapidly, and integration of microneedling with lasers. The last one is huge because we know they are very complementary, we just need to find out what lasers work well with it," Dr. Taghizadeh stated.

Another area of investigation is unique uses of microneedling on and off the face, including post-traumatic burn scarring, hyperhidrosis and stretch marks, to name a few.

Furthermore, in addition to the wound healing response, "microneedling creates channels to allow entry of compounds into the skin, so companies are developing products specifically for use with microneedling," Dr. Taghizadeh elaborated.

With the proliferation of new compounds for skincare, other delivery systems, such as RF microneedling, iontophoresis and combination plasma/ultrasound, are becoming more prominent. These are designed to facilitate minimally invasive penetration of compounds and can be used with proprietary sera, as well as existing compounds.



Abdomen before treatment



After fourth Emsculpt treatment
Photos courtesy of Katerina Fajkosova, M.D.

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### Sexual Health

Concepts common in aesthetic medicine have driven recent advancements in sexual health, an equally popular and controversial topic. Despite the scrutiny being placed on the emerging therapies in this segment and their proposed efficacy, to the doctors who perform them, home runs are being hit daily.

"When you have patients who come back and talk about how happy they and their partners are, detailing their renewed interest in sex and more gratifying experiences, that's hard to argue with," said Dr. Taghizadeh. "It goes back to total wellness, regardless of gender. That's why we offer the P-Shot and O-Shot therapies," Dr. Taghizadeh said, referring to PRP injections designed to improve sexual function, "as well as lasers for cosmetic and functional therapies."

According to Dr. Taghizadeh, recent advancements in sexual health therapies use concepts harnessed in aesthetic medicine, which is why many practitioners have adopted them. "While gynecologists and related specialties can and do perform these treatments, they are often not readily set up to do so," he noted.

"We in aesthetic medicine have a cash-pay, fee-for-service business model, and they do not. Our patients expect the fee, while their patients expect a co-pay," he explained.

"For the most part, the current system does not provide for insurance reimbursement for preventative measures, and, in many ways, this is punitive to core specialists," Dr. Taghizadeh observed. "Also, we've been using these technologies in other ways for a while, and they have not. Frankly, patients should be able to go to their specialist for these therapies, but they come to us because we are performing these therapies, we've adopted them and the specialists, in general, are behind and trying to get into the game."

Another emergent therapy involves the application of acoustic sound waves from various existing devices to genital tissue. This non-invasive procedure breaks up plaque formations in local blood vessels and stimulates neovascularization for increased blood flow and sexual function. Treatment is intended for erectile dysfunction in men and orgasmic dysfunction in women, and it is often given in conjunction with PRP injections.

### Unique uses of thread lifts

Polydioxanone (PDO) thread lifts are gaining popularity, with subtler outcomes being a fair trade-off for the easy implantation and relative safety compared to surgery.

According to a 2018 consensus paper,<sup>6</sup> the procedure is very technique dependent, but provides results safely, which can easily be combined with energy-based therapies and/or injectables for improved global outcomes.

Physicians are now exploring off-face applications for thread lifting, such as the neck and chest, arms, buttocks and thighs, and even the abdomen. Some physicians already offer these therapies, but in Dr. Taghizadeh's opinion, there is much work to be done before these become a new standard.

"I don't use threads myself because, while they work, I don't believe they provide better or more lasting results than other tools currently available," he elaborated.

Furthermore, "Expectations management is as important with PDO threads as anything else, even more so for off-label uses such as on the body," he added. "And again, we must ask ourselves, are they truly equal to or better than other options out there?"

### **Advancements in Body Shaping**

While traditional liposuction and related therapies are still the gold standard in fat reduction and body shaping, non-invasive modalities are proliferating.

What began with cryolipolysis has expanded with the advent of non-invasive laser and radiofrequency therapies that melt fat all over the body, some of which can be used on larger patients to great effect.



Axillary fat before treatment



Three months after Kybella injections Photos courtesy of Stephan J. Finical, M.D.

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Recently, electromagnetism and microwaves have entered the arena. Most notably, the EMSCULPT from BTL Aesthetics (Marlborough, Mass.) uses non-invasive high-intensity focused electromagnetic (HIFEM) technology to stimulate the underlying musculature, inducing intense muscular contractions. According to BTL, studies using MRI, CT, ultrasound and histologic evidence have demonstrated significant fat reduction and increases in muscle mass, with high patient satisfaction.

"This isn't hype, this is reality," said Edward M. Zimmermann, M.D., medical director of Las Vegas Laser & Lipo (Las Vegas, Nev.). "We build muscle while permanently destroying fat through apoptosis. This technology was born as a mode of physical therapy to rehab muscles. The repeated contractions are so strong that the energy uptake required to sustain them destroys surrounding fat cells."

Microwave energy is another recently introduced technology that non-invasively disrupts fat cells. While not yet available in the U.S., Onda Coolwaves from DEKA M.E.L.A. srl (Florence, Italy) is the first device to feature microwaves for fat reduction and skin tightening. During treatment the generated heat destroys fat cells and tightens connective tissue while cooling the dermis.

The increasing popularity of Kybella (Allergan) for submental fat reduction injections has led to its use on other parts of the body. The product uses synthetic deoxycholic acid, a naturally-occurring molecule that helps the body break down and absorb dietary fat.

Stephan J. Finical, M.D., medical director of Charlotte Plastic Surgery (Charlotte, N.C.), has observed successful outcomes using Kybella on small areas of localized fat such as bra-rolls and the pre-axillary region above the breast, among others, but sees an emerging benefit as an adjunct to cryolipolysis.

"Kybella dissolves adipose tissue, there's no question, so it is ideal for small pockets of fat," Dr. Finical stated. "One limiting factor in cryolipolysis is cost of treatment, so Kybella is a relatively inexpensive way to improve results or smooth out suboptimal outcomes. It is perfect for this.

"Mesotherapy has been around a while and Kybella is effective when used properly," said Dr. Taghizadeh. "So off-label use is going to increase, but we need more research before we get ahead of ourselves. Some therapies like fillers or lasers lend well to off-label use, but even with decades of science about mesotherapy we need more studies on the long-term impact of Kybella on body fat."

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