



## New Horizons for Injectables in 2020

By Kevin A. Wilson, Contributing Editor

While injectable therapies have been a mainstay in aesthetic medicine for decades, this established arena is still an exciting place for physicians and patients alike. While many commonly sought treatments are still in use and have remained relatively unchanged save for refined techniques, additional and expanded indications are expected, new techniques are emerging and novel products are poised to enter the market.

Within the practice of aesthetic medicine, more than just the injectables market is changing, but new neurotoxin, dermal filler and biofiller products may be uniquely situated to have a great impact on transforming paradigms.



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“We’re in the midst of a shift in what we perceive as beauty in this modern era,” said dermatopathologist Gretchen W. Frieling, MD, CEO of GFaceMD (Boston, Mass.). “The challenge is that this differs across geography, not just globally, but within the U.S. Whether it’s Texas or the mid-West vs. Los Angeles or New York, the vibe is very different. People are beginning to realize that they don’t want to look fake, but rather look their best selves, especially among men, which is a growing area of the aesthetic patient population. Less is more. Injectables have been one area of aesthetic medicine where the evolution of this has played out visibly over the last two decades.”

### **Evolving Physician-Patient Relationship**

One factor contributing to the continued growth and stability in the injectables space is that the patient base has expanded to include people at both ends of the age spectrum, but especially on the younger side, according to Rand Rusher, RN, a Beverly Hills, Calif.-based injector and injection trainer. “I’ve discussed this before because it is a key factor in the continued growth of this market,” he said. “We have an established, relatively old class of products in injectables, but as new offerings and techniques emerge, combined with new understanding and a more informed public, we are seeing the younger patients seeking earlier intervention than ever. We have tools at our disposal to effectively do this without causing more harm than good, and this is very much evident with injectables. They tend to not only be less aggressive options, but with things like PRP we have regenerative properties that are useful and appealing to patients of any age.”

In Dr. Frieling’s opinion, another factor is the return of physician expertise. “We are seeing the re-emergence of physician expertise as the driving force behind patient choices,” she explained. “The more informed people became, the more they presented with their own ideas of what treatments they were looking for, and as an industry we were giving it to them, so there was a shift to product-driven marketing.

“Now we’re receiving the informed patient with more of an armamentarium, and they don’t know what we know,” she continued. “It is our expertise they need, not just for undergoing therapy, but in making the best therapeutic choices. This requires the physician to acquire the kind of expertise and reputation that will inspire that kind of patient trust, which is how we focus our practice. The emergence of new offerings makes this even more important, and we are seeing more and more physicians marketing their expertise rather than products.”

### **New Techniques**

Make no mistake, new products and techniques are coming. “There are definitely a variety of injectable offerings in clinical trials that should enter



**Before and after treatment of the undereye region with Restylane Refyne and Restylane Silk, the cheek region with Restylane Lyft and Restylane Refyne to the lips**  
Photos courtesy of Gretchen W. Frieling, MD

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“We’ll be seeing more of a new class of injectables, skin boosters using superficially injected hyaluronic acid to improve fine lines, texture and hydration.”

the marketplace this year or next,” said Jose Raul Montes, MD, an oculoplastic surgeon in San Juan, Puerto Rico.

“We’ll be seeing more of a new class of injectables, skin boosters using superficially injected hyaluronic acid to improve fine lines, texture and hydration,” Dr. Montes expressed. “New indications previously used off label like fillers in the temples or tear trough, the jawline, or the cheek, are emerging as well.”

“Once a new technique or indication is cleared by the FDA, the company can talk about it and teach it officially, which helps the spread of these techniques considerably,” added Heidi A. Waldorf, MD, director of Waldorf Dermatology Aesthetics in Nanuet, N.Y.

“We are poised to see new indications for existing fillers in areas such as the jawline and temple,” she added. “The impact of new indications for approved products tends to be minimal for my practice because they aren’t new to me. However, for other physicians and non-physicians that are not typically able to attend aesthetic meetings it opens the door to education and training. New indications also allow

industry outreach to consumers which may increase demand.”

Further study also enhances understanding of newly emerging, yet safe and effective techniques, Dr. Montes pointed out. “Further study is always needed because otherwise we are uncertain if the way we work with, or sometimes alter (such as during dilution), a product negatively effects the product as it has been studied and optimized by the manufacturer.”

“When you consider something like microdroplet injection techniques that improve skin quality and texture, we have potentially powerful therapies, but we still need to refine the technique,” added facial plastic surgeon Jennifer Levine, MD (New York, N.Y.). “The product may need to be altered or concentrated to provide us with precise, consistent, predictable effects for new applications.”

Many aesthetic treatments rely on the age-old concept that a controlled injury creates a healing effect with an associated aesthetic benefit, Mr. Rusher indicated. “For example, by blending down Radiesse (Merz Aesthetics) calcium hydroxyapatite filler with four more



Before and after treatment of the undereye region with Restylane Refyne and Restylane Silk

Photos courtesy of Gretchen W. Frieling, MD

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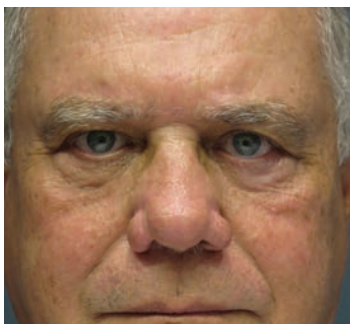
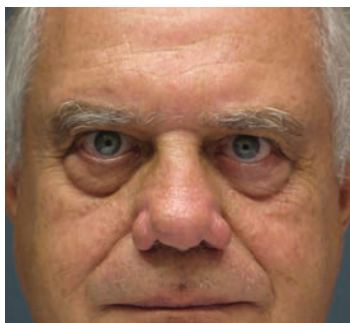
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Before and after treatment of the midface region with facial injectables  
Photos courtesy of Jose Raul Montes, MD

ccs of saline to make a more dilute, less viscous product, we can inject the subsurface to stimulate neocollagenesis. It serves as an irritant to stimulate new collagen," he explained. "We are looking for an effect similar to that seen with Poly-L-lactic acid, but because it is not a foreign substance, there is no chance for granuloma. It is similar to the skin boosting technique where HA fillers are blended down to improve moisturization."

Collagen is a hot topic, Dr. Levine agreed. "We are seeing companies driving new ways to produce collagen with injectables, and some offerings and techniques are already emerging with more on the way," she noted. "Various existing products stimulate different types of collagen, and it will be interesting to see how these products work in combination with energy-based therapies to improve global results for rejuvenation of skin on the face and body."

Another topic gaining attention: the effect of fillers on muscular action. "Now that we have much more experience with fillers, there is a lot of talk being generated about asymmetry from

muscles affected by the implantation of fillers," she said. "In cases where we have perceived facial asymmetry caused by deep volume loss changing the shape of the surface over which a facial muscle contracts, one side may appear more dynamic than the other," Dr. Levine stated. "If we reshape that area the muscular action may appear less dynamic, and we will have volumizing from the filler as well; a sort of two-vector approach to improving facial symmetry in some cases."

## New Product Announcements & Updates

Publication of a non-inferiority trial<sup>1</sup> in December 2019 has bolstered the buzz around Jeuveau, the prabotulinumtoxinA-xvfs neurotoxin product from Evolus, Inc. The study data revealed no significant difference between prabotulinumtoxinA versus onabotulinumtoxin A in the primary efficacy endpoint assessment, with all secondary efficacy outcomes achieved, which adds to an already robust and growing body of literature supporting the product. The neurotoxin is touted as a safe and effective alternative to the "Big Three" neurotoxins, but features a price point up to 25% lower than the industry-leading Botox Cosmetic from Allergan, Inc.

Among new product announcements, Dr. Waldorf focused on the excitement surrounding the imminent launch of Revance neurotoxin from Revance Therapeutics, Inc., "later this year or early 2021."

DaxibotulinumtoxinA for Injection, or Daxi, as it is known, may offer greater longevity of results. "The clinical trials suggested it may produce a more sustained response than competing toxins. I'm looking forward to seeing how it compares once we have the ability to use it off label for other areas and at varied doses," explained Dr. Waldorf,



Before and after treatment of the tear troughs with dermal fillers  
Photos courtesy of Jose Raul Montes, MD





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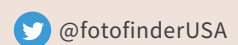
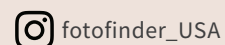
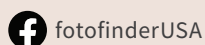


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“We must remember that the excitement about therapies – and sometimes, the financial gains they might bring – can be the things that cause the most problems in our industry.”

who serves on the company’s advisory board and has been involved in clinical trials.

“Also, the unique properties of the Revance neurotoxin will revive the debate about immunogenicity and neurotoxins, similar to what we saw with Xeomin,” Dr. Levine pointed out.

Additionally, Revance recently announced a partnership with TEOXANE SA to market their RHA filler line in the U.S. This collaboration may catapult Revance to measure up to the leaders in the U.S. injectables market.

Restylane Kysse from Galderma, is a new addition to the long-standing filler family and is most akin to Restylane Refyne and Defyne, which are among the more elastic offerings in the line, according to Dr. Waldorf. Like its brethren, the product is a hyaluronic acid-based filler, but is implanted superficially into the lip and vermillion border to provide a defining, plumping effect and more youthful look to the mouth. Lidocaine is incorporated to enhance patient comfort.

According to the manufacturer, Restylane Kysse is clinically demonstrated to last six to nine months, with outcomes seen as far out as 12 months. “We are going to have to wait and see how well this product takes hold in the U.S. market,

but based on my results with Refyne and Defyne, I’m looking forward to getting it in hand,” Dr. Waldorf said. “I think for each physician, the utility of Restylane Kysse will depend on the needs of the patient population.”

Then there is Renuva, an injectable fat alternative derived from cadaver fat, which is reconstituted and used like autologous fat to sculpt and volumize the face, hands or body, Mr. Rusher noted. “The material is injected where you’d place autologous fat grafts, and includes proteins, collagen and growth factors so the body naturally replaces the material with your own fat,” he explained. “There seems to be something causing an additional effect because we are seeing visible brightening of the skin, even in people as old as 70.” Currently the product is employed on a limited basis and should be more widely available over the course of 2020, according to the manufacturer.

Regardless of the excitement generated by new products and possibilities, Dr. Frieling is cautious about the hype surrounding new therapies. “We must remember that the excitement about therapies – and sometimes, the financial gains they might bring – can be the things that cause the most problems in our industry. We need to see what these products can do, even in the case of new neurotoxins, where the likely differences between products are relatively minimal and not expected to impact safety because we have a strong body of knowledge and experience about their use. We still need to exercise prudence.”

#### Reference:

1. Cheon HI, Jung N, Won CH, Kim BJ, Lee YW. Efficacy and safety of prabotulinumtoxin A and onabotulinumtoxin A for crow’s feet: a phase 3, multicenter, randomized, double-blind, split-face study. *Dermatol Surg* 2019 Dec;45(12):1610-1619.