With an ever increasing number of dermal fillers and neurotoxins on the market, **Wendy Lewis** provides an insight into their evolving role in aesthetic medicine

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ERMAL FILLERS AND NEUROTOXINS have evolved into the ideal gateway to aesthetic medicine. Injectables are taking centre stage in aesthetic practices in new and emerging ways, and the rate of satisfaction among patients is consistently high. Once upon a time, fillers were just for filling in lines and scars, and plumping lips. The realities of modern practice have transformed this category from being thought of as simply adjuncts to surgical enhancements to highly effective treatments using complex techniques that warrant skill and expertise.

global slowdown innovation has created a void in the filler market that has paved the way for practitioners to step up their game in terms of experimenting with advanced techniques, new instrumentation, and unique combinations and layering of products. Fillers containing lidocaine for pain management have become the gold standard. Emphasis on painfree injections using soft or bendable needles, tubes, blunt-tip

cannulas, injector pens, and novel systems that are touted to cause less trauma and bruising are revolutionising the way fillers are being injected. Practitioners are combining fillers in the same syringe, in addition to the same facial region. Another technique often used is to dilute fillers to make them more appropriate for injecting into fine lines.

Fillers are not one size fits all

I have seen the filler market change dramatically over the last 17 years. There was a time when all we had were the line fillers: bovine collagen and autologous fat. Those of us pioneering injection techniques and pan-facial augmentation with fat back then were thought to be radical. I remember going to a lecture by a well-known cosmetic dermatologist in the early 90s who emphatically said 'fillers fill and lifts lift so don't confuse the two'. Now a decade and a half later everyone is using fillers to lift, blend, and smooth. It's really amazing when you think about how this area has evolved,' says New Haven, CT, Dermatologist Lisa M. Donofrio, MD.

Indeed, injectables are useful alternatives as well as

adjuncts to surgical procedures, and are widely considered a mainstay in aesthetic practices. They can prevent wrinkles in younger patients, reduce fine lines, and smooth scars in patients in their 30s, and reverse deeper wrinkles in patients in their 40s and older. Fillers are also valuable tools for reshaping the face, adding enhancing contours, fullness. correcting asymmetries, smoothing out bony irregularities, and solving issues of facial ageing that surgery does not address

effectively. They are also used to correct minor defects post-surgery. Even for plastic surgeons who would rather be operating, injectables have taken on new relevance in today's consumer-driven climate.

Dermal fillers can enhance the results of a surgical facelift nicely, especially in terms of volumisation. But these treatments are also viewed as an alternative in many cases, such as younger patients who do not have significant sagging, and those who are not good candidates for surgery. Injectables buy time until the patient is physically, mentally, and financially ready for a surgical ▷



procedure, says New York City Plastic Surgeon Alan Matarasso, MD, FACS.

'Today's injectable patient may be tomorrow's surgical patient, if their expectations are managed so they understand when surgery is indicated.' he continues.

The evolving menu of injectable agents offers practical solutions for patients seeking non-invasive, affordable aesthetic improvements. In many practices, the most 'bang for the buck' among injectable treatments are neurotoxins. Results are consistent, patients love the subtle improvements that can be achieved; and it is an ideal complement to other treatments such as lasers and fillers.

Far from a 'one size fits all' type of treatment, dermal fillers command skill to create an optimal result. Advanced nonsurgical techniques for facial rejuvenation involve looking at the face in a three dimensional way and using a robust combination of facial-shaping agents.

Knifeless facelifts

Who gets injected with what and where depends largely on the patient's desires, budget, and understanding of their ageing process. High volume injectors do not treat every patient in the same way. They tend to graduate to using more volume to address multiple areas of the face in one session, which has elevated filler treatments to an unprecedented level.

As recently as a decade ago, patients that presented with sagging in the midface and jowls would have been told that they needed a surgical face and necklift under general anaesthesia, and 2 weeks out of work for recovery. They would most likely have been turned away from any non-surgical or minimally-invasive treatments. Today, by using advanced facial contouring techniques, practitioners are able to produce facelift-like results to meet consumers' demands for safe, effective and long-lasting non-surgical options.

Products that stimulate the production

new collagen, of

Injectable landscape

Injectable products cleared by the FDA for aesthetic use as of September 2013¹

- ARTEFILL® (Suneva Medical): bovine collagen with polymethylmethacrylate (PMMA) particles
- BELOTERO® BALANCE (Merz Aesthetics): hvaluronic acid
- BOTOX® COSMETIC (Allergan): botulinum toxin type A
- DYSPORT® (Valeant Aesthetics/Medicis): botulinum toxin type A
- JUVÉDERM® ULTRA XC, JUVÉDERM® ULTRA PLUS XC (Allergan): hyaluronic acid with lidocaine
- **LAVIV™ (Fibrocell Science):** autologous fibroblasts
- PERLANE®, PERLANE-L® (Valeant/Medicis): hyaluronic acid with lidocaine
- PREVELLE® SILK (Mentor): hvaluronic acid with lidocaine
- RADIESSE® (Merz Aesthetics): calcium hydroxyiapatite
- RESTYLANE®. RESTYLANE®-L (Valeant Aesthetics/Medicis): hvaluronic acid with lidocaine
- SCULPTRA® AESTHETIC (Valeant Aesthetics): poly-L-lactic acid
- **XEOMIN®** (Merz Aesthetics): botulinum toxin type A

thereby increasing volume and correction over time, have had a dramatic impact on facial contouring. Unlike hyaluronic acid gels, which offer immediate results, these substances are designed to gradually cause a foreign body reaction to achieve long-lasting effects. According to New York City Plastic Surgeon Bryan G. Forley, Products that are biostimulatory like Sculptra® Aesthetic enhance new collagen production to produce longer-lasting volumetric correction. When combined with skin tightening devices, we can achieve dramatic effects that approximate what a facelift can do in some instances. We now have a range of fillers that are useful to fill an isolated wrinkle, as well as fillers that can be injected into multiple tissue planes to create a change in facial shape and restore volume.

Radiesse® is another popular choice for facial contouring and volumetric lifting owing to its ability to create structural collagen support. Radiesse is a wonderful volume filler. It can correct the hollows that develop in the cheeks, recreate flattened cheekbones, and make the jowls look smoother. Its excellent longevity, versatility, and lifting capacity make it my go-to filler

> for facial contouring, says New City Dermatologist Judith Hellman, MD.

> > When you consider that a typical 'Liquid Facelift' takes about 30 to 60 minutes and patients can wear make-up almost immediately

resume normal activities within 1 to 3 days, this represents a quantum leap over the 'wind tunnel' facelift that was prevalent in the 80s.

A global perspective

When it comes to dermal fillers, Europe leads the way in terms of innovation, and the US lags behind largely based on the stringent clinical data and safety criteria required to bring products to market. In the category of injectables, the EU ranks second behind the US, followed by Asia and Latin America². Although the injectable market is considered to be a more mature market with a lot of small players and a handful of global giants, some privately owned companies in Asia are flooding the market with cheaper products that are starting to show up in clinics throughout Europe and the Middle East. This influx of less expensive products is driving the price down in many markets.

In the US, there are 12 injectable products that currently have the FDA nod and being marketed: three neurotoxins and nine filling agents. As expected, temporary hyaluronic acid gels represent the largest group. Several more products are currently in the FDA pipeline, although the process is notoriously slow. In the US, dermal fillers are often used in an off-label manner. mainly because of the limited indications each product is approved for. For example, although using hyaluronic acid based fillers to enhance the lips is a very common treatment, Restylane® and Restylane®-L are the only fillers that are actually approved for 'lip enhancement in patients over 21 years3.

Each product has its niche. The most recent addition in the US market was Belotero® Balance, manufactured by ▷ **5** Far from a 'one

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▶ Merz Aesthetics, and is widely used in treating superficial lines such as vertical lip lines, as well as the tear trough area, since it is thought to reduce the possibility of a Tyndall effect based on how it integrates into the skin.

As new products continue to gain FDA approval, the question is how many fillers do you really need? All injectors tend to have their favourite 'go to' products on the shelf, but not all fillers can address every area and patient, so having a wide range of tools in the toolbox is necessary. This will become even more important as big players continue to invest in large scale direct-to-consumer marketing programmes to generate awareness of brand name fillers.

Injecting new areas requires a different technique, and in some cases, a lighter touch. Some of the new injectable sites include traumatic scars, eyebrows, temples, jawline, nasal dorsum, earlobes, labia augmentation, the soles of the feet, and dorsal hands. Ageing hands that are

wrinkled. bony. or prominently veined are a arena for promising rejuvenation treatments.

'It takes a lot more experience and expertise to treat the hands because you have to inject deeply and be careful to avoid the veins,' says Forley.

'Cosmetic fillers have a proven safety record when injected by a properly qualified and trained physician in an appropriate medical setting,' says Edwin F. Williams, MD, Group Vice President for Public and Regulatory Affairs of the American Academy of Facial Plastic and Reconstructive Surgery (AAFPRS). While injecting dermal fillers is not surgery, it is still a medical procedure that requires the experience of a physician trained in cosmetic procedures of the face. Patient safety must be paramount. Although complications can occur with any filler substance, using only FDA-approved products and good clinical instruction helps to minimise potential side-effects.'

There are nuances for each dermal filler, including ease of use, location of injection into the skin, versatility, and duration of results, as well as potential risks and the management of adverse events. 'Patient assessment is critical to achieving optimal outcomes with soft tissue fillers. You have to determine what is exactly the problem you are trying to correct, how deep is the fold or wrinkle to be filled, what the ideal options are for each situation, considering the patient's expectations. budget and history,' says Steven Fagien, MD, an Oculoplastic Surgeon in Boca Raton, FL.

Natural born fillers

There is no question that autologous fat transfer and platelet-rich plasma (PRP) take centre stage at aesthetic conferences worldwide, and regenerative medicine is an important segment of the market. This has stimulated a growth industry around fat harvesting tools, innovative centrifuges. fat transfer systems, and syringes. A growing sector of consumers embrace the idea of a more natural approach to antiageing treatments using their own tissues. Many plastic surgeons consider fat grafting to be an integral part of their facelift protocol

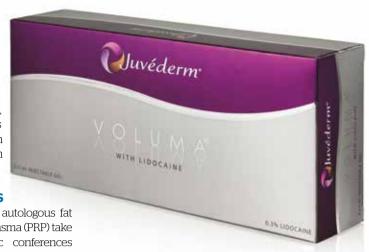
> for most patients, except perhaps those with very full faces.

> Another subset patients also want longer-lasting fillers. Men especially like the idea of treatments that do not require much maintenance.

Longer-lasting products have found their place in facial rejuvenation. There is a group of people who are seeking treatments that last well so they do not have to keep coming back for touch-ups every few months,' says Steven Cohen, Plastic Surgeon, MD, FACS in La Jolla, CA. Yet many practitioners are wary about using a permanent product owing to concerns over granuloma formation, and the fear that the patient may not like the long-term results. There is a decreasing tolerance of risks and side-effects, especially as more products have entered the market that are biocompatible, non-immunogenic, and non-migratory. However, permanent fillers are more accepted and widely used in Asia.

Next kid on the block

On 2 May, 2013 the members of the FDA's General and Plastic Surgery Devices Panel gave their nod to Allergan's Juvéderm® VOLUMA® XC for the correction of age-related volume loss in the midface. VOLUMA is well positioned to be the next



new filler to be launched in the US market.

'With the expanding menu of fillers now available and more products currently under clinical investigation, we are learning to treat the whole face with unprecedented results,' Fagien says. 'Allergan's VOLUMA is the latest advance in larger volume hyaluronic acid gel fillers, and is poised to be the next game changer in facial rejuvenation. The main advantages of VOLUMA include its use in larger quantity facial volume restoration, while enjoying the ability to mold and sculpt with greater precision."

Donofrio agrees with Fagien: 'The demands of patients and doctors to develop better, longer lasting fillers with superior lifting capabilities (high G Prime) has led to products such as Juvéderm VOLUMA coming to market. Those of us that have been volumising with fat for years feel that this will be the closest approximation of the dramatic results we can achieve with fat transfer. I have patients on a waiting list to be called first. It's an exciting time to be a cosmetic sculptor.'

References

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