RESTYLANE SILK SETS A NEW STANDARD FOR LIP ENHANCEMENT

Wendy Lewis reports on Galderma’s launch of Restylane® Silk in the US, the first filler to gain the coveted lip indication from the FDA

WHILE MUCH OF THE COUNTRY was experiencing an arctic freeze, a large group of dermatologists, plastic surgeons, facial plastic surgeons, and nurses made their way to Galderma’s US hometown of Dallas, Texas to get hands on experience with the newest filler of 2015. The company held a training session in January to educate and train healthcare providers on Restylane® Silk to ensure the safe and effective use of the product as they ramp up for launch. Of particular interest, the program provided an overview of the aging lip and perioral area, and of the anatomy and proper assessment of the lip and perioral area.

On June 16, 2014, the US FDA gave its nod to Restylane® Silk Injectable Gel with 0.3% lidocaine, with an indication for submucosal implantation for lip augmentation and dermal implantation for correction of perioral rhytides. At that time, Restylane® and Perlane® products were part of the Valeant Pharmaceuticals Inc. empire, having previously purchased Medicis Pharmaceuticals in 2013. Subsequently, in July 2014, Valeant completed the sale to Galderma of all rights to Restylane and Perlane, along with Emervel, Sculptra, and Dysport to Nestle S.A, which had earlier acquired Galderma.

The Restylane family of products includes Restylane®, Restylane-L®, Restylane® Silk, Perlane®, and Perlane-L®. Restylane, Restylane-L, Perlane, and Perlane-L can be used to add volume and fullness to the skin to correct moderate to severe facial wrinkles and folds. Restylane, Restylane-L and Restylane Silk may also be used for lip enhancement in patients over 21 years, and Restylane Silk can be used to treat lip lines in patients over 21 years.

We are very proud to introduce Restylane Silk—the first and only FDA approved treatment for natural lip enhancement and the smoothing of wrinkles around the mouth—to US healthcare professionals and consumers,’ said Stuart Raetzman, CEO of Galderma Laboratories, L.P. and Vice President North America. ‘Restylane Silk satisfies the market need for a subtle solution that addresses the signs of aging in the lip and mouth area and we are pleased to be able to provide this new and unique offering to the US aesthetics market.’

Restylane® Silk is a crystal clear injectable gel composed of hyaluronic acid, that is non-animal based and free from animal protein, therefore no allergy pretesting is required. It also contains 0.3% lidocaine to reduce the discomfort for patients, which is especially beneficial in the perioral region that is known to be more sensitive in some patients.

The clinical study conducted with Restylane® Silk to evaluate the safety and effectiveness of injections to enhance lip fullness and to improve the wrinkles around the lips. The study included 221 mostly female subjects and evaluated subjects with light and dark skin. Subjects with very dark skin were not studied. Ninety-eight percent (98%) of subjects reported improvement in their lip fullness 14 days after injection and a compelling 76% of study subjects still had lip improvement 6 months after injection. Adverse events reported included mild swelling, bruising, and discomfort.

Rich history of Restylane
Restylane has an impressive track record as a dermal filler globally. Originally launched in 1996 by Q-Med (Uppsala, Sweden) after receiving a CE Mark, it has two decades of research behind the brand, and a well-documented safety
Restylane Silk is definitely an improvement over existing products available in the US market. It is an excellent refiner and definer, and a great finishing agent for the correction of fine lines and the vermilion border.
Restylane® Silk in the lips and perioral lines and 2 ml of Restylane-L® in the nasolabial folds. (A) Before and (B) after of a 46-year-old patient treated with Restylane-L® and Restylane® Silk. Treatment included: 2 ml of Restylane® Silk in the lips in perioral lines and 1 ml of Restylane-L® in the nasolabial fold.

(A) Before and (B) after a 59-year-old patient treated with Restylane® Silk and Restylane-L®. Treatment included: 2.8 ml of Restylane L® in the lips and perioral areas, 2 ml of Restylane® Silk in the lips in perioral lines and 1 ml of Restylane-L® in the nasolabial fold.

The former brand is currently marketed in Canada under the former brand name, and subsequently Restylane Touch®, and is currently marketed in Canada under the brand Restylane® Fine Lines, actually it was originally marketed in the EU under the brand Restylane® Fine Lines, and is currently marketed in Canada under the former brand name.

Restylane Silk is not exactly new. Actually, it was originally marketed in the EU under the brand Restylane® Fine Lines, and subsequently Restylane Touch®, and is currently marketed in Canada under the former brand name.

Restylane Silk is a very versatile filler, which combines smoothness with a good lifting capacity. It is very helpful for perioral lines as well as touch ups after treatment with other Restylane products. The safety and science behind Restylane is very reassuring for practitioners along with the fact that this family of filler has been used successfully for over 20 million treatments worldwide,” said Rajiv Grover, London-based Plastic Surgeon and Past President of the British Association of Aesthetic Plastic Surgeons (BAAPS).

Coming to America
Galderma is rolling out Restylane Silk to injectors who are eagerly awaiting something new and novel for their patients to kick-off the new year.

Steven Fagien, an oculoplastic surgeon based in Boca Raton, Florida says, ‘Restylane Silk is definitely an improvement over existing products available in the US market. It is an excellent refiner and definer, and a great finishing agent for the correction of facial fine lines and the vermilion border. It’s the next generation of the Restylane family of products that definitely fills a niche for fine lines and lip enhancement with its perioral indication.’

With Restylane Silk, Galderma is poised to address some unmet needs practitioners have been clamoring for. From a stand point of the product itself, one of the important points is that it is the first and only injectable filler that has a specific FDA indication for upper lip enhancement and the smoothing of wrinkles around the mouth. In the clinical trials, it was injected into the red lips as well as into the white lips to both restore volume, which was the primary endpoint of the study, but also to smooth wrinkles,” said Dr. Brian Biesman, a Nashville-based oculoplastic surgeon.

According to Washington DC based dermatologist Rebecca Kazin, Restylane Silk is comprised of a smaller particle gel, and was designed specifically for lip enhancement. We as physicians need to demonstrate to patients that lips can be subtly and tastefully enhanced without looking artificial. The product is very easy to inject with a smooth soft consistency that works well for lips of all ages.”

Injection technique pearls
Among the biggest barriers to entry for new patients having dermal filler injections for the first time, is their concern about ending up with a ‘trout pout,’ ‘duck lips,’ or ‘sausage rolls.’ This is largely driven by examples of overfilled lips they are seeing on the silver screen, in reality TV shows, and even at the mall. Restylane Silk offers some advantages that may aid practitioners to achieve a more natural-looking lip.

According to Edward Farrior, Tampa, FL, facial plastic surgeon and Past President of the AAFPRS, Historically the lips have been a challenging area to inject. There is an increasing demand from patients to have a natural looking result, without irregularities, bruising, swelling, downtime, or discomfort during the treatment. This is a tall order but I believe that Restylane Silk can potentially check most if not all of those boxes. In the past, the options for lip rejuvenation, such as tissue grafts and autologous fat grafts, have limitations for lip enhancement. Some HAs on the market can be too hydrophilic or dissolve too quickly. Restylane Silk offers us a new tool in our armamentarium that addresses both volume and perioral rhytides.”

As with every new filler, there is a learning curve for obtaining optimal results. Restylane Silk, like other

Finer fillers

In the US market at present, there is Belotero Balance® (Merz Aesthetics, Greensboro, NC) and Restylane Silk (Galderma). There are some similarities between these two hyaluronic acid gel fillers, however, each product has a place and offers specific benefits. Restylane Silk contains lidocaine, whereas Belotero does not. Belotero Balance is FDA approved to temporarily smooth out and fill in moderate-to-severe nasolabial folds*. Although many practitioners consider the sweet spot for Belotero to be the tear trough area, it is quite popular for treating fine, etched lines around the lips as well. In the Restylane Silk study, the primary focus was volume, and fine lines were a secondary focus.

*For the treatment of the tear trough region, the Belotero Balance® Study used a mean of 1.25 mL of Belotero Balance® per treatment site. However, the amount used per treatment site is product-dependent and can be determined by the physician. The amount used in a treatment setting can range from 0.3 mL to 1.5 mL per treatment site, based on the desired outcomes and the anatomical region to be treated.
injectables, should be injected very slowly. Since the products' advantage is its ability to reduce more superficial facial lines with greater durability, its physical properties, perhaps make it a little more rigid than some other hyaluronic acid fillers. There can be potentially more quickly resolving, yet immediate swelling that can be avoided with some simple maneuvers. Like most filling agents, injection techniques vary with each product for best results so this shouldn’t come as a surprise,’ said Fagien. Another advantage is that it doesn’t overbulk, yet injectors must keep in mind that for volume filling, when being utilized for the correction of fine lines plus volume enhancement, Silk should be used in combination with other products for best results.’

Restylane Silk can also be used in tandem with Restylane and/or Perlane in the same patient as needed. You can use Restylane Silk for the fine line component, and Restylane for deep nasolabial folds for volume. It also works nicely for deep glabellar lines with a neuromodulator to smooth it out first,’ said Fagien. ‘The product seems to flow where it is needed, as if you were to pour a liquid onto something and it flows into cracks and crevices. If you inject it too quickly when you’re injecting lips, you’ll get more swelling than you are used to seeing. The key is to inject submucosal in the lips. If you are injecting the vermilion, it is important not to inject into the muscle because you will get a lot of swelling,’ said Biessman. As Doctor Kent B. Remington in Calgary says, you should treat it like a princess and be a little gentle with it,’ he said.

As we have seen with most injectable products in the US market, experienced injectors inevitably choose different products for specific indications and discover their own personal preferences for how and where they use each product. In some cases, these may include off-label indications.

According to Dr Biessman, ‘Restylane Silk is also beautiful in the tear troughs, which is an off-label use. I have not seen the Tyndall effect to date, but I have seen a Tyndall effect with most hyaluronic acid products and I suspect it could be produced by this one as well. It injects nicely. Restylane has been my go to product for tear troughs for a long time. It is too early for me to say whether Restyline Silk will become my first choice for tear troughs but it is entirely possible,’ he said.

Miami-based dermatologist Jill Waibel, said, ‘Restylane Silk provides excellent results in reducing the appearance of the fine rhytides of the upper lip. The addition of lidocaine allows for a relatively comfortable experience for patients. Restylane Silk provides smooth, natural results and we can treat lip lines with greater precision and subtlety.’

Another benefit of Restylane Silk that practitioners point out is the support of the Galderma organization and its portfolio of dermatology and aesthetic products behind it.

‘I am extremely impressed by the infrastructure that Galderma has built in a very short period of time. From my own observations, they are very serious about growing the marketplace overall which is what all of us really hope for. What physicians want most are good quality products with research behind them and companies that are focused on growing the market. The Galderma team is doing a lot of listening and taking suggestions from experienced injectors. It’s a solid team of good people,’ said Biessman.

**On the horizon**

Targeted dermal fillers attract the interest of many practitioners due to the unique design of the products to address specific indications, especially the delicate eyelid region and the lips. For example, ‘Teoxane® Laboratoires’ PureSense Redensity II is a hyaluronic acid-based gel created to target the tear trough area.

The next lip filler that is anticipated to make its way to US shores is Allergan’s JUVÉDERM® VOLLBELLA with Lidocaine. Part of the JUVÉDERM range of dermal fillers, VOLLBELLA was specifically tailored for the lips for a natural look and feel and gained a CE Mark in 2013. A clinical study showed that JUVÉDERM® VOLLBELLA with Lidocaine is well tolerated and has been demonstrated to provide a smooth and natural improvement in lip fullness that lasts for up to 1 year. In addition, the treatment is associated with high patient satisfaction, with 86% of patients reporting maintained improvement in the look and feel of their lips after 9 months and 57% of patients still reporting maintained improvement after 1 year. This new wave of fillers offer a greater level of sophistication for skilled injectors who have advanced the state of what was once simply considered line filling to pan-facial sculpting and volume restoration. The number of syringes as well as the range of products that may be used for any given patient is subject only to the injector’s aesthetic judgment and the patient’s tolerance for needles, downtime, and budget.

**Further information**

[restylaneusa.com/enhance-lips/first-fda-approved-product.aspx](restylaneusa.com/enhance-lips/first-fda-approved-product.aspx)

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**References**


