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Experts Embrace Comprehensive Injectables Protocol

It is generally accepted that European women are not afraid to age and therefore desire more subtle, natural looking corrections from aesthetic treatments. With a recent market study confirming this attitude, one company has responded to this condition by developing protocols for a holistic approach to facial correction using their three front-line injectable products in concert. According to experts this comprehensive method of treatment has improved overall facial rejuvenation outcomes, resulting in greater patient retention.

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Merz Aesthetics Unveils Holistic Approach to Facial Rejuvenation



Before Tx



After Bocouture, Radiesse and Belotero injections
Photos courtesy of Tatjana Pavicic, M.D.

In response to study findings and current market conditions, Merz Aesthetics, a business unit of Merz Pharma GmbH & Co. KGaA (Frankfurt, Germany) is promoting the use of its injectables portfolio for complete facial rejuvenation. Experts say this holistic approach is made possible due to the complementary characteristics of the company's comprehensive injectables range, which includes Radiesse, a calcium hydroxylapatite (CaHA) dermal filler, the Belotero family of hyaluronic acid (HA) dermal fillers and the neurotoxin Bocouture, also known as Xeomin. In June 2011 this program, which also offers intensive training, was unveiled at the FACE congress in London, U.K.



Jérôme Augustin
Senior Vice President
Merz Aesthetics Europe
President
Merz Pharma France
Frankfurt, Germany

Driving this initiative are the results of a Merz Aesthetics-sponsored market study of women, titled *Face Value*, meant to reveal current conditions in aesthetic medicine and patient attitudes. These findings were also discussed at the FACE congress. "The results of this study are for everyone to take advantage of, and there is a lot of useful information," said Jérôme Augustin, senior vice president of Merz Aesthetics Europe and president of Merz Pharma France. "The study findings reveal a new way of thinking among European women concerning aesthetic procedures, which are no longer considered a luxury but a necessary part of the overall beauty regimen. European women now seek a gentle, full-face holistic strategy for management of facial aging."

"Women want to age beautifully, they believe they can do so, and believe

aesthetic procedures are a natural and acceptable part of this process," Mr. Augustin continued. "The women we surveyed reported a willingness to forego vacations or the purchase of new clothing and luxuries to pay for procedures. While this is a new finding, we in the industry had suspected this for some time." This study of more than 2,900 women included representative samples from the various countries within Europe, so results revealed nation-specific attitudes as well. "The versatility within our injectables portfolio makes it ideal for a holistic full-face approach," Mr. Augustin stated.



Kate Goldie, M.D.
Medics Direct
Glasgow, Scotland, UK

Injectables trainer and aesthetic physician Kate Goldie, M.D., of Medics Direct, an injectables training institute in Glasgow, Scotland, U.K., described the holistic approach as being very natural, in comparison to the common practice of considering individual facial zones for correction. "Systematic facial diagnosis is something aesthetic physicians don't do as well as they could, in my experience," she said. "We need to consider the skin and facial structure, from the top down, noting skin quality, as well as underlying fat and bone resorption. Lines and wrinkles are secondary considerations. Dealing with these various issues requires a variety of tools, so you must have the proper tool for each job. Volumizing, filling in finer lines and relaxing facial musculature are essential to the full-face approach, but there is no single product that can do all of these things."

Correction of the pre-jowl sulcus is a good example of the way this comprehensive



Jawline before Tx



Jawline after lifting of jowls using Radiesse vectoring technique
Photos courtesy of Kate Goldie, M.D.

approach can be more successful. "If you simply fill in that area because you have a dermal filler product that you're comfortable with, you will often get a square jaw because you're so busy filling that you create heaviness in the tissue," Dr. Goldie explained. "Instead, if you work from the temple down using a holistic approach, by the time you get to the jowls you need only a small amount of dermal filler to finish off the area; and you've treated the entire face. You've correctly preserved and perhaps improved the spatial relationships between facial regions. Additionally, you're creating new collagen because the product you used achieves this, so you actually improve the skin as well. Neurotoxin relaxes the appropriate muscles to create a more youthful, relaxed appearance. In the end the patient looks more like a younger or fresher version of themselves. It requires the use of the right products in the right places, thinking in terms of the entire face first."



Tatjana Pavicic, M.D.
Dermatologist
Head of Aesthetic Dermatology
Klinik and Poliklinik for Dermatology
and Allergology LMU
Munich, Germany

Radiesse serves as the volumizer in Merz Aesthetics' portfolio. Its carboxymethylcellulose gel carrier creates the immediate filling effect and CaHA stimulates new collagen growth gradually, so it's a combination stimulatory and volumizing product, according to Tatjana Pavicic, M.D., a dermatologist and head of aesthetic dermatology at the Klinik and Poliklinik for Dermatology and Allergology LMU (Munich, Germany). "The gel is absorbed over three or four months, which is adequate time for growth of the patient's own collagen, providing the more natural result they prefer. It is best injected close to the bone, or at least deep within the dermis and not superficially."

Radiesse's viscosity is another advantage. Recommendations from a 2010 study by Sundaram *et al.*, involving rheological measurements to evaluate deformation and flow characteristics of various dermal filler types, pointed out that products with higher viscosity and elasticity provide the requisite lifting, support and sculpting effects more predictably with less product volume.¹ "These are more resistant to the constant movement within the face, and will stay where they're injected with less spreading," Dr. Pavicic said.

Belotero Basic, Soft and Intense are cross-linked, viscous, gel-derived HA dermal fillers manufactured with cohesive polydensified matrix (CPM) technology so they offer variable densities which improves tolerability and tissue integration. Basic is for moderate lines such as nasolabial folds, while more delicate facial work is handled with Belotero Soft (e.g. perioral lines). Belotero Intense is more ideal for moderate to deep lines, lip augmentation and general volumization. Dr. Pavicic explained that the safety and efficacy of HA with CPM technology for moderate-to-severe nasolabial folds was established in a 2010 open-label extension of a split-face, double-blind trial by Narins, *et al.*² In this trial 95 subjects (predominantly women, enrollment age range 18 to 75 years) were treated. Therapeutic effects persisted for more than 48 weeks in approximately 80% of patients. "These HA dermal fillers serve a variety of needs within the holistic approach."

Dr. Pavicic emphasized that Bocouture is the first botulinum toxin product completely free from complexing proteins, which may play a role in immunogenicity and therapeutic failure. "Although rare, induction of partial or complete secondary therapy failure with aesthetic neurotoxins is described in a 2010 four-case report by Dressler *et al.*³ which appeared in a supplement to *Dermatologic Surgery*."

Bocouture can be stored at room temperature and reconstituted as needed. Another advantage of Bocouture lies in its 1:1 dose ratio with the popular neurotoxin Vistabel / BOTOX Cosmetic from Allergan, Inc. (Irvine, California, U.S.), as suggested by the results of a recent split-face, double-blind, proof-of-concept investigation by Prager, *et al.*⁴ (n=21, 19 women, mean age 44.8±8.7) for the treatment of crow's feet. Another 2010 prospective, multicenter randomized, rater- and patient-blind trial (n=381, all women, age range 18 to 50 years)⁵ examining the non-inferiority of Bocouture to Vistabel found the two products to be equally effective for treating glabellar lines, further advancing the 1:1 dose ratio. "This builds on the familiarity many physicians may have with Vistabel," Dr. Pavicic said. "They can still do what they're used to doing well, just with Bocouture."

According to Dr. Pavicic, the holistic approach first requires a firm foundational understanding of facial anatomy and the way facial aging occurs. This way of thinking is lacking in some physicians who may be used to single-site thinking. "We need to give physicians leeway here because some of this understanding is relatively new. Facial anatomy is very compartmental, and facial aging is a function of the way these compartments change as we age, as suggested in a study by Rohrich and Pessa⁶," she advised.

"An excellent example is the nasolabial fold," Dr. Pavicic began. "It is not skin folding itself that causes the condition, but instead is a result of lipatrophy within the deep fat compartment and resulting diminished support. Accumulation of fat within the more superficial compartment during the aging process will accentuate this effect."

For Dr. Goldie the holistic method is a systematic, stepwise approach. "If you're building a house you start with the foundation,

which is volumization with Radiesse. Strategic vectoring will lift the whole face; therefore, you place volume in the stable and relatively immobile facial zones of the lateral face toward the ear, the hairline and along the sides. The viscosity and elasticity of Radiesse are well suited to the task of structuring the face, malar fat pad, or zygomatic arch when it's placed right above the bone," she said.

Lifting with Radiesse can also be created in the mid- and lower face, Dr. Goldie continued. "In areas where there's no underlying bone you can inject subdermally to fashion viscous and elastic bands anchored in the stable zones at the sides of the face, crossing down to lower problem areas such as the jowls, which will hold tissue up. Here you're lifting not just from the zygomatic arch and malar fat pads, but from carefully-placed subdermal volumization," she noted.

"Radiesse is unusual in its ability to treat the entire face, top to bottom. If placed in the correct location it can completely restructure the face, for example, resetting the bizygomatic distance to a more youthful proportion. In terms of product volume, you can use less because of its viscoelastic properties." She added that Radiesse's alternate role of stimulating collagen generation improves skin quality and additionally firms the area over the next six months and beyond.

While Radiesse serves as the basic scaffolding, Belotero products are for the finesse work, Dr. Goldie continued. "Once you've rebuilt the basic facial structure you attend to other problems. Vectoring and volumization are not the answer to everything. There may be laxity of the skin itself due to aging, genetics or photodamage that is too excessive to be taken up with revolumization. In these cases too much restoration looks unnatural – you must never add too much volume, you must instead restore what used



Before Tx



After Bocouture, Radiesse and Belotero injections
Photos courtesy of Jürgen Huber-Vorländer, M.D.



Before Tx



After Tx

Photos courtesy of Nicola Zerbinati, M.D.

to be there, and no more. If you're left with marionette or nasolabial lines, you use the fine brush of Belotero."

This is where Belotero's ability to integrate with tissue is beneficial. In Dr. Goldie's experience, "When injecting superficially other dermal fillers may create a distinct line of lift. Belotero creates a more natural, less obvious lift that blends well. In addition to augmenting without tissue versus implant demarcation, Belotero will hydrate tissues and enhance skin texture as well," she said.

Dr. Goldie added that the final brushstrokes are laid with Bocouture. "We use neurotoxin more subtly than we used to, maintaining as much natural movement as possible, which is an advancement. We'll use toxin to diminish obvious dynamic lines such as crow's feet or the glabella, with Belotero (usually Basic or Soft) as a second line therapy to smooth things out, improve texture and hydrate skin for a fresher look. We particularly like the effect of using microcannulae to introduce Belotero Basic or Soft, to further improve hydration in the periorcular area before using Bocouture for crow's feet."

Although, Dr. Goldie feels it is in the lower face that Bocouture plays the greatest role in completing the full-face approach. "Hyperactivity in lower face muscles should be addressed to make the most of the rejuvenating effect of the volumization, hydration and microsculpting. A good example of this is where the chin has been sculpted with Radiesse, but a hyperactive mentalis negatively affects the result. Using Bocouture in this area adds the final touches to a holistic facial approach which results in a natural and overall rejuvenated look."

While standards of beauty differ between nationalities, the way these

techniques are employed may not. Differences in perceived beauty begin with gender, according to Dr. Pavicic. "Women prefer more arched eyebrows than men, with the tail a bit higher than the base. Men have a natural ptosis of the eyebrow so it's important that lift be understated in order to look natural. Men will also have a more pronounced but normal jawline, where women want a more pointed look with harder shapes, at least Caucasian women do. I often deal with patients of Slavic origin, who are genetically characterized by a higher cheek with more severe angles; however, some Russian or other European patients prefer the American 'baby cheeks.'"



Jürgen Huber-Vorländer, M.D.
Plastic Surgeon
Fort Malakoff Klinik
Mainz, Germany

Jürgen Huber-Vorländer, M.D., a plastic surgeon at Fort Malakoff Klinik (Mainz, Germany) has experience with the German, Turkish and Spanish aesthetic markets. "We treat the same conditions the same way, but the difference between these markets and the way injectables are viewed is remarkable," he explained. "In Turkey, from the upper middle class to high society, aesthetic treatments are a status symbol. They want to look treated, and if their best friend has a lip augmentation, they want it too, and this drives demand. Most women in Europe would scoff at this attitude. Compared to Germans, Spanish patients will go for a slightly more over-the-top look that's larger and rounder, whether it's lips and cheeks or buttocks and breasts. They also tend to be more open-minded when it comes to new treatments and devices, where Germans are much more conservative."



Nicola Zerbinati, M.D.
Dermatologist
Centro-Medico Clinic
Milan, Italy

According to dermatologist Nicola Zerbinati, M.D., of Centro-Medico Clinic (Milan, Italy), Italian women often look to improve nasolabial folds and increase volume in the zygomatic area. "About half of Italian women want lip augmentation, and half want injections to correct the nasolabial folds. Fewer have problems with periorbital wrinkles. So in our market we're more likely to use Belotero and Radiesse for full-face rejuvenation, and if periorbital wrinkles and forehead lines are a problem, we can add neurotoxin."



Martina Nöhle, M.D.
Head of EU Medical Affairs
Merz Aesthetics
Frankfurt, Germany

Merz Aesthetics' Field Clinical Specialist (FCS) training program for the full-face holistic approach is a powerful and unique method designed to maximize the safe and effective use of the company's injectables product portfolio. Martina Nöhle, M.D., head of EU Medical Affairs at Merz Aesthetics, advised that training begins in larger sessions, and physicians move toward smaller groups. "This forms the foundation of learning, which we expect physicians to have before they enter FCS training."

The FCS program offers a number of advantages. "One-on-one training sessions take place in the trainee physician's own clinical office setting – which they are comfortable with – and involves their patients," said Dr. Nöhle. "In their office, with no other physicians present, trainees

pose questions they would never ask in a group. We are convinced that these one-on-one training sessions are the most impactful way to educate our customers. Nobody else does this."

Dr. Nöhle added that FCS not only promotes the proper use of Merz Aesthetics' injectables, which ensures safety and efficacy, it also promotes the full-face philosophy. "It is about far more than filling wrinkles. This is about improving outcomes well beyond what might be achieved with the individual products by themselves." FCS training, which usually involves two to three sessions and would typically cost between €2,000 and €2,500, is offered to customers at no cost. "Acceptance of the program is high," she said, "because most trainers are dermatologists or plastic surgeons themselves, fostering a peer-to-peer relationship."

This phrase: full-face strategy, applies to more than clinical treatment algorithms and training programs. Findings from the *Face Value* survey are very interesting and useful to physicians, Mr. Augustin noted, and Merz Aesthetics' efforts will capitalize on their ability to educate and inform as they push for an even stronger presence in the injectables market. "Between the economy, shifting attitudes about beauty and facial rejuvenation, and our market position," he began, "I'm very optimistic about the future of Merz Aesthetics' injectables portfolio. Our plan is to spread out everywhere, in all practices and specialties, because clearly there is room for growth in Europe."

For Dr. Huber-Vorländer, the clinically-applied holistic concept for facial injectables represents a great leap forward. "The days of selling single treatments are over because they didn't make people look younger, just different. When we discuss how the patient looked twenty years ago, in comparison, they now look older, tired or unrelaxed, and we can help them look fresher at any age. That's why we do this." ■

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