

# AESTHETIC

BUYERS GUIDE



## Juvederm Raises Standards

Following the success of Botox Cosmetic, Allergan, Inc. (Irvine, Calif.) has developed two new facial dermal fillers, Juvederm™ Ultra and the more robust Juvederm Ultra Plus, shown in clinical trials to provide long lasting correction with unprecedented smoothness. These next-generation hyaluronic acid (HA) based fillers are currently FDA approved for moderate-to-severe facial wrinkles and folds.

As with similar fillers, the HA in Juvederm products binds with water to create volume that temporarily corrects facial rhytides. It is the concentration of HA that sets Juvederm apart from competitors, according to Robert Grant, president of Allergan Medical, a division of Allergan. "Juvederm contains 24 mg/mL of non-animal HA, which is the highest concentration you'll find in the U.S. market," he said.

Juvederm is produced through HYLACROSS™ technology creating a high degree of cross-linking and promoting duration. HYLACROSS technology results in a uniformly consistent gel, which is a primary factor in the long-lasting, smooth, natural look and feel that is a hallmark of Juvederm wrinkle correction, according to Ahmet Tezel, Ph.D., director of research and development at Allergan. "Basically the way we cross-link it and

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**Pearl Grimes, M.D.**  
Dermatologist  
Los Angeles, CA



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**Mary Lupo, M.D.**  
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make it soft and malleable differentiates Juvéderm from other fillers. It’s what we call HYLACROSS technology,” Dr. Tezel explained. “It allows us to cross-link higher concentrations of HA and still end up with a low-viscosity gel, which improves the smoothness of both the injection and the correction.”

“It’s well documented that cross-linking decreases the rate of degradation, and obviously we wanted Juvéderm to show dramatic persistence,” Dr. Tezel said, adding that Allergan also wanted to create a filler that was easy to inject and more comfortable for the patient. “We form a blend of particle sizes to give us a continuum of particle dimensions and ultimately, a gel that looks almost like a moisturizing cream. Other fillers have a discernable average particle size, which gives them a more granular consistency.”

Clinical trials were performed at 11 U.S. sites and included a total of 439 patients. The nasolabial folds of each patient were treated with Juvéderm on one side and the collagen filler Zyplast (the gold standard filler at the time of the trials) on the other side, according to Dr. Tezel. “HA fillers had not yet established themselves in the market, and thus were not used for comparison,” he said. Patients were followed each month after treatment and evaluated through six months. Los Angeles based dermatologist and study investigator Jessica Wu, M.D., said, “We found that after six months, up to 88% of the Juvéderm treated nasolabial folds still showed a significant clinical improvement.”

Some trial patients enjoyed correction without requiring touch-up injections long after the study’s completion. “At two years these people still had significant correction,” reported Pearl Grimes, M.D., another Los Angeles based dermatologist

and study investigator. “I injected more women of color than any other group. Although there may be a better collagen base in these women, even one of my Caucasian patients who received a touch-up at six months still had correction at two years, so Juvéderm lasts,” she said. “Juvéderm was also extremely well tolerated, as the side effects profile for Caucasians vs. non-Caucasians was pretty much the same.”

According to Dr. Tezel, biocompatibility results for Juvéderm products have been excellent so far; no patient has developed an immune response. He added that while darker skin types generally have more hyperpigmentation and hypertrophic scarring, Juvéderm is the only approved HA filler proven safe and effective for people of color. That’s why New Orleans based dermatologist and trial investigator Mary Lupo, M.D., recommends Juvéderm for new patients with dark skin. “To be on the safe side, you should use Juvéderm because it’s actually been tested for these patients,” she said.

Photos courtesy of Jessica Wu, M.D.



Nasolabial folds before Tx



Nasolabial folds after Juvéderm Tx

Safety is not the only revolutionary characteristic generating a buzz within the aesthetic community. The smoothness of Juvéderm sets it apart from other fillers such as Restylane (Medicis, Scottsdale, Ariz.). “Juvéderm flows from the needle like butter,” remarked trial investigator Mark Pinsky, M.D., a



**Mark Pinsky, M.D.**  
Plastic Surgeon  
West Palm Beach, FL

“Many of my patients maintained significant improvement at nine months or even a year after treatment. And in the study, 82% to 88% of patients still felt they had significant correction at six months based on wrinkle severity score.”

plastic surgeon in West Palm Beach, Florida. “It takes far less pressure to push the material out, which also means you can be extremely precise with the tip of the needle.”

A variety of injection techniques may be practical for first time users. “I see less bruising with a cross-hatching technique than I do with Restylane, and I think that’s one of the advantages of Juvéderm,” said Dr. Lupo. Technique can also depend on the location of the treatment area. “If I’m injecting melo-mental lines,” said Dr. Grimes, “that’s when I choose serial puncture over linear threading because it allows me to buttress a bit more.” Fanning is another common practice. “I use a fanning technique around the malar facial groove,” said Dr. Pinsky, “Sometimes I use cross-hatching with fanning.”

“Because Juvéderm requires much less force to depress the plunger of the syringe, it’s easy to use,” explained Dr. Wu.



**Jessica Wu, M.D.**  
Dermatologist  
Los Angeles, CA

“Less force translates into less tissue trauma and ultimately, less patient discomfort.” She added that experienced injectors should have no problems. “Juvéderm is more forgiving regardless of technique because it fills the space much more uniformly than Restylane.”

Patient discomfort is always an issue with cosmetic procedures, though Juvéderm products are at least as tolerable as other fillers and require minimal pre- and post treatment care. Some patients don’t need anesthesia, according to Dr. Wu, but a nerve block or a topical anesthetic may be appropriate. Other trial investigators agree, and said that ice is a simple and common post treatment solution. “It is normal for the

injection site to be somewhat red, tender and swollen for several hours and bruising is possible,” said Dr. Lupo. “I ice the area for one to three hours at 15 minute intervals and avoid non-steroidal anti-inflammatory medications for four hours.” Dr. Pinsky uses ice both before and after treatment. “If the patient doesn’t want a dental block,” he said, “we’ll alternate between a cream and an ice cube. After treatment everyone is instructed to apply ice to the treated site.” Dr. Grimes has no set pre-treatment regimen, but agrees that ice should be applied for a couple of days.

Photos courtesy of Jessica Wu, M.D.



Lips before Tx



Lips after Juvéderm Tx

Although the study tested Juvéderm only in the nasolabial folds, trial investigators are finding that these new fillers show promise for volumizing the lips as well. “The biggest advantage of Juvéderm is in the lips,” said Dr. Wu. “Lips are always moving and people don’t want any lumps. Juvéderm almost melts into the skin and looks so natural, and patients appreciate that.” She added that anesthetic is almost always necessary when treating the lips, but “inflammation also appears to be lower in lips treated with Juvéderm.”

Overall, physicians are excited about the future of fillers with the addition of the Juvéderm product line. “Many of my patients maintained significant improvement at nine months or



**Robert Grant**  
President  
Allergan Medical  
Irvine, CA

"We've demonstrated our commitment to safety, quality assurance, and patient care. This creates trust, which in turn builds brand loyalty. At the end of the day, this trust will position us and our product as number one in the category."

even a year after treatment," said Dr. Pinsky. "And in the study, 82% to 88% of patients still felt they had significant correction at six months based on wrinkle severity score. Even a one point difference is significant."

"In my opinion, Juvéderm is a welcome addition to our filler armamentarium," said Dr. Grimes. "When patients return for follow-up evaluation, the correction with Juvéderm is natural looking. It's an amazing filler for patients who want more than six months of correction. It's good for mild, moderate and severe lines, and in my experience works great for nasolabial folds and melomental lines. I think the Ultra Plus is going to be great for facial contouring. It may well become my workhorse."

Currently the number of dermal filler procedures performed to date in the U.S. is only half the number recorded in Europe, according to Mr. Grant. "We believe this is due in part to the limited choices of collagen and HA fillers in the U.S., and that fewer investment dollars have been directed to consumer advertising, which we believe will expand this segment of the market," he said. "While medical aesthetics and rejuvenation are among the fastest growing sectors in healthcare, this market is largely untapped. We're looking at a pool of about 28 million women who can afford this type of treatment, and yet we've only penetrated about 3% of that here in the U.S."

To fulfill this market potential, the Juvéderm product line is priced at a premium to Restylane, which is considered to be Juvéderm's major competitor. "Juvéderm is priced on the quality of the product, which we believe is very strong, as well as market demand for new and innovative products," explained Mr. Grant. "Juvéderm is a unique, science based, next-generation product and as such, it's priced at a slight premium to Restylane."

Peter Bye, director of equity research at Wachovia Corporation, believes Juvéderm will return Allergan's dermal fillers franchise, which has declined since the introduction of Restylane. "You'll get an initial spike, say for three months, then a little drift down as doctors go back to other fillers, then steady growth after that," he explained. "It's two-fold. One, there's the hyaluronic acid market today, which they will capture a certain share of. But the bigger factor will be what Allergan can do to grow that slice of the pie. Although there are differences, Juvéderm and Restylane are similar in that they are a step above everything else on the market. Allergan is going to work to change that perception and try to elevate Juvéderm. I think they have a lot of work to do to get there."

Photos courtesy of Mary Lupo, M.D.



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Nasolabial folds after Juvéderm Tx

According to Mr. Bye, the growth of Juvéderm may follow the pattern of Botox Cosmetic if similarly managed, especially if the scientific rigor is apparent. "As far as ophthalmologists, OB/GYNs and general practitioners doing Botox treatments, these specialists didn't begin until Botox was well-established in the marketplace. So those physicians may add to the growth four or five years down the line. But in the next two years, I will be surprised if we see meaningful growth from that segment. It's tougher for fillers to get that kind of expansion outside of dermatologists and plastic surgeons. If you look at

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lasers and Botox, they’re generally easier procedures to do. So that’s more of an opportunity for those subsegments of aesthetic medicine than it is for fillers. But it’s very possible that we’ll see similar growth.”

Although cautious, Mr. Bye sees big potential for Juvéderm in a growing U.S. aesthetic market. “The launch of Juvéderm will help the overall market expand, though it’s hard to say by what percentage,” he observed. “Being a major player in the industry with their fillers, botulinum toxin and implants, Allergan has the opportunity to set the tone for the marketplace. They have power to dig below to the bulk of the

opportunity over the next several years, and the wherewithal to increase consumer demand for these products as well.”

“The FDA approval and launch of Juvéderm is exciting for both Allergan and the aesthetic community,” said Mr. Grant. “For us, it complements Botox Cosmetic in our total facial rejuvenation portfolio. For the community, it offers another choice – a smooth, long lasting, natural looking correction for patients. We’ve demonstrated our commitment to safety, quality assurance and patient care. This creates trust, which in turn builds brand loyalty. At the end of the day, this trust will position us and our product as number one in the category.”

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