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FDA Approval Advances Aesthetic Hand Augmentation

Along with facial revitalization procedures, increasingly patients are demanding treatments to reverse the aesthetic effects of aging hands. As hands age, veins, tendons and bony structures become evident. While there are numerous approaches to volume restoration that can address the loss of elasticity and atrophy of the underlying tissues, physicians have reported high success with a very efficacious treatment for hand augmentation that uses calcium hydroxylapatite (CaHA).

Physicians Report High Success with Radiesse for Hands



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Before treatment



Immediately after treatment (half of 1.5 mL syringe)
Photos courtesy of Tatjana Pavicic, M.D.

By Jeffrey Frentzen, Executive Editor

Radiesse®, the popular CaHA-based biocompatible dermal filler from Merz Pharmaceuticals GmbH (Frankfurt, Germany), was first approved by the U.S. FDA in 2006 for the treatment of facial wrinkles and folds and has now received clearance for the treatment of hands.

"This indication is not something new in clinical practice," noted Lawrence Bass, M.D., a plastic surgeon in New York City, New York, U.S. "However, what this indication means is very compelling data convinced a FDA committee that Radiesse for Hands is both safe and effective."

According to some clinical studies, Radiesse for Hands consistently delivers smooth, natural-looking results that can last up to one year. For instance, in a recent U.S.-based clinical trial, 98% of patients treated with Radiesse reported an improvement in the appearance of their hands at three months. In the follow-up trial, 86% of Radiesse patients receiving treatment in their hands continued to report an improved appearance after one year.

"Patients are always looking for aesthetic procedures that will have a positive impact on their confidence when they're out socially or in work situations," noted Dr. Bass. "Taking care of areas off the face has become a rapidly growing segment of medical aesthetics, particularly treating the hands. We might spend only a week or two in a bikini during summer, but we're definitely showing off our hands, face and neck every day."

Tatjana Pavicic, M.D., a cosmetic dermatologist in Munich, Germany, has been using Radiesse to treat both the face and the hands since 2009. "When patients come to me for anti-aging treatments, the first concern is the face," she said. "After we address facial rejuvenation they look around for new indications. Even if they decide to do the underarm, or the thighs and buttocks, eventually we come back to the hands. With Radiesse, hands are very easily fixed with predictable results."

Hand augmentation using Radiesse for Hands can be addressed in a number of ways but primarily volume loss needs to be managed, as well as pigmentation and vascularity, advised Andreas Nikolis, M.D., a plastic surgeon in Montreal, Quebec, Canada. "This procedure makes the hands look pliant and more youthful, reducing the 'bony' look. This material is much longer lasting than hyaluronic acid (HA)-based fillers. Also, its color is white so you don't observe a Tyndall effect," he said.

Upon being asked if Radiesse is as usable and effective on hands as it is in the face, Mitchel Goldman, M.D., a dermatologist and cosmetic surgeon in San Diego, California, U.S., responded; "It is, if not more so. For instance,



Before treatment



Immediately after treatment

Photos courtesy of Michael E. Jasin, M.D.

before Radiesse for Hands, my associates and I would do fat transfer to this area or use HA fillers. But since Radiesse for Hands has been available, it is now the only filler we use. It is much more reproducible and gives better results than HAs and / or fat transfer."

When injected into the hands, Radiesse creates natural scaffolding within the soft tissues, explained Gabriele Muti, M.D., a plastic surgeon in Milan, Italy. "The product's collagen stimulation aspect allows the patient's own tissues to grow and sustain the volume, which is important and a particular characteristic of Radiesse," he said. "In older skin that might show many wrinkles and sun damage, the collagen stimulation aspects of Radiesse can improve and maintain the appearance of natural youthfulness in the hands."

Treatments allow patients to forgo surgery now and advance in age before more intervention is needed, Dr. Bass reported. "A successful Radiesse for Hands treatment uses relatively modest amounts of product compared with what we have had to inject around the cheeks or along the jawline at times. The hands take some volume, but not a massive amount."

Identifying the ideal patient for Radiesse for Hands, therefore is very easy, noted Dr. Goldman. "It's basically any hand that looks old, in which the veins and tendons are visible."

Dr. Muti agreed, adding, "These are people that are usually in their 40s or 50s and older. When evaluating the patient you need to feel the space between the vein and the tendon. The most important thing to look for is the loss of volume."

Interestingly, many fit and athletic people that have remained healthy overall ask for Radiesse for Hands, Dr. Bass pointed out. "They are using their extremities in a lot of sports and eventually they can get pretty stringy looking in those areas. Their hands start showing accumulated sun damage and other aging changes. These people look good, are fit and active, but they also want their hands to look young and energetic."

A number of injection techniques are available to practitioners when treating the hands. "There's the bolus technique, which uses a single insertion point to inject the product in one area and then massage it in order to cover the entire area of the dorsum," Dr. Nikolis stated. "With the micro droplet technique, you find out where the deficiencies are and then inject accordingly."

A key technical challenge in treating this area is getting the material into the right plane, Dr. Bass advised. "There's this loose area over the plane between the skin and the tendon sheaths. That's where you want to inject, and after just a bit of practice you get the feel for when you have your needle in that space. After injection, you then can gently massage and spread the material evenly across

the back of the hand. You want to get good coverage as that will cause collagen stimulation,” he said.

As with the facial indication, Radiesse is mixed with lidocaine prior to injection, “But when it comes to the hands the volume used is different,” Dr. Muti stated. “Some physicians stick with the 0.2 mL when mixing Radiesse with lidocaine. Others go up to 0.5 mL or a one-to-one dilution ratio. There’s no right or wrong, but the physician’s decision should be based on providing the best outcome for the patient.”

Radiesse for Hands is so moldable that practitioners can achieve a major improvement very simply, Dr. Muti added. “The treatment is easier if one knows the anatomy of the hand. I use a technique that I have employed successfully when doing lipofilling – a small, blunt cannula and just a single point of injection. You tent the skin just a bit, introduce the cannula and gently add product. You can see the skin bulge when you deliver the filler to the subcutaneous space that protects the veins and the tendons, and you can inject freely.”

The treatment is easy to administer and patients experience no pain during injection, with the use of lidocaine, Dr. Muti continued. “In addition, this procedure is much more acceptable to my patients than any type of surgery, such as lipofilling of the hands. Patients can see results immediately, but are also grateful for the longevity of the outcomes.”

With Dr. Pavicic’s approach to injecting Radiesse into the hands, she dilutes the filler material more than when she prepares to inject in the face. “The standard FDA approved dilution is 1.3 mL of Radiesse mixed with 0.2 mL of 2% lidocaine, and what I usually do for the hands is dilute Radiesse and lidocaine one-to-one,” she said. “Sometimes, I dilute a 1 mL mixture of lidocaine and saline solution. In this manner, I inject a more fluid product that is less viscous. I can then more evenly and easily distribute it throughout the tissues. If we have really even distribution during treatment and don’t inject tremendous amounts of the material in one session, we also don’t see swelling.”

Using lubricant or emollient can help make the spreading of injected filler material more pleasant and less aggressive for the patient, described Dr. Nikolis. “Fat transfer could be done and some physicians report good outcomes with that, but doing so requires an invasive procedure to collect the fat from one area, such as the abdomen, and using a larger cannula to inject it with the possibility of more bruising and swelling. It just seems so much easier to take a long-term, prepackaged filler from the shelf than to do fat transfer,” he noted.

Each physician tends to use his or her own technique, Dr. Goldman elaborated. “The FDA approved on-label method is one approach. But like many things, including botulinum toxin, physicians rarely use the pure on-label technique. In our



Before treatment



After treatment

Photos courtesy of Ulrich Kühne, M.D.



Before treatment



After treatment

Photos courtesy of Ulrich Kühne, M.D.

practice, we've been using a process where we dilute the Radiesse almost one-to-one with bacteriostatic normal saline. We add some Triamcinolone solution, as well, which decreases the edema."

Currently, Dr. Goldman is conducting an investigator-initiated study on the combination of Triamcinolone with Radiesse for treating the back of the hands. "The only real complicating factor that we see when treating hands can be edema that may last a few days or as long as a week or two," he noted, "and preliminary indications are good for using Triamcinolone."

Employing Radiesse for Hands with other modalities to achieve certain results is a common and successful practice. "The hands can take the full brunt of environmental dangers, such as sun damage. Physicians combine Radiesse for Hands with other treatments that target solar lentigines, photodamage and other pigmentary problems on the surface of the hands," Dr. Goldman reported. The objective is to make the surface more youthful looking in all ways, he continued. "It's a wonderful protocol to inject the Radiesse first and then follow with laser treatment. The patient still has numbness after the Radiesse for Hands procedure, and that helps facilitate a better intense pulsed light or other secondary therapy."

Likewise, Dr. Pavicic performs skin resurfacing using a CO₂ laser after two or three applications of Radiesse into the hands. "We should execute this sort of multiple treatment approach more and more," she advised.

As long as injectors apply Radiesse properly into the hands, adverse events are rare, Dr. Pavicic emphasized. "I have personally never seen any complications, swelling, nodules or aesthetically dissatisfying effects, such as discoloration or induration. This is very likely because I inject Radiesse diluted with lidocaine according to the FDA approval."

"We caution patients of the possibility of swelling, which can last for a few days or longer in some cases," Dr. Nikolis shared. "However, there is no restriction on activities of any kind, after treatment, and patients have not reported any pain. Ice and compression wraps or gloves can be used to reduce any swelling and make the recovery more comfortable. As with any filler, the most concerning risk is the development of a lump or nodule, but this is very rare when using proper injection techniques."

Dr. Bass reported that in the FDA's clinical study, the safety data in terms of adverse events was extremely good. "This matches my clinical experience over the last couple of years. I really have not had a problem that I had to go back and see a patient for. In skillful hands, the treatments are very safe."

Merz has produced numerous clinical studies that back up claims made about Radiesse, Dr. Pavicic pointed out. "When I look at the entire market and the

safety data floating around with regards to many other aesthetic technologies, Radiesse is one product with the largest amount of scientific documentation.” She added that practitioners should always review clinical studies prior to buying an aesthetic device or product. “One thing I appreciate about Merz is the amount of time they invest in producing clinical studies and publishing the data. I will not try something new if a sales representative cannot show me a clinical study.”

In the aesthetic market, safety is more important than efficacy, Dr. Nikolis advised. “This is what our patients want. Merz does a lot of research and puts a lot of effort into the development of guidelines aimed at physicians that are not heavily involved in the scientific work. They are too busy building their practices to attend every conference.”

In Dr. Pavicic’s opinion, the company does much to support physicians in everyday practice. “Merz offers us valuable information on how to treat patients and how to combine therapies within a variety of time periods. These are the areas in which they are leading in the industry. They support the products they make. Radiesse is a really good product and very effective in terms of hand regeneration. This is what differentiates an authentic aesthetic company from the ones that just want to make a profit.”

The balance of return on investment offered by Radiesse – and this new, FDA approved hand indication – is a win-win for both physicians and patients. For the patient, in addition to the clinical value of this efficacious treatment and the documented outcomes, there is also the economic value of the procedure itself and the product’s longevity. “When you’re a patient and you’re trying to allocate your aesthetic budget, efficient treatments are always a crowd pleaser,” said Dr. Bass. Conversely, the practitioner benefits from implementing a reliable practice builder.

As conveyed by Dr. Pavicic, “Radiesse is a unique product that produces immediate results, along with long-term positive effects on skin quality due to the production of new collagen and a big improvement in superficial skin structures for the hands. All of this is achieved without the kinds of complications that you see with other approaches.” ■

Manufacturer’s note: Product selection and treatment approach are the responsibility of the quoted physicians and not necessarily recommended by Merz. Please note that Radiesse mixed with lidocaine is FDA approved only. Please check local regulations for the combined use of Radiesse and lidocaine.



Before treatment



Immediately after treatment (half of 1.5 mL syringe)

Photos courtesy of Tatjana Pavicic, M.D.