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Clinical Roundtable Supplement

Radiesse Raises the Bar in Facial Augmentation

To growing numbers of physicians nationwide, long lasting Radiesse® (Bioform Medical, Inc., San Mateo, Calif.) exemplifies the next generation dermal filler paving the way to the future of facial aesthetics. With its longevity, advanced mechanism of action, volumizing structure and contouring capabilities, Radiesse is ideally positioned to fill the gap between yesterday's short-term fillers and the potential risks of permanent fillers.



Thomas L. Tzikas, M.D.

Facial Plastic Surgeon
Delray Beach, FL

It provides physicians with a superior level of malleability and finesse for facial contouring applications.

According to Thomas L. Tzikas, M.D., the augmentation benefits of Radiesse have been clinically proven to last an average of one year. He credits Radiesse's sustained cosmetic correction to its advanced calcium-based microsphere technology, which creates a scaffold or matrix around which the body generates new collagen. Further, because Radiesse is a robust, full-bodied material, it provides physicians with a superior level of malleability and finesse for facial contouring applications. "Bioform's proprietary microsphere technology is responsible for tissue anchoring as well as preserving

the augmentation to the skin, resulting in both immediate and long-term beneficial effects with a single treatment of Radiesse," explains Dr. Tzikas. "Additionally, the product's dense composition translates to added versatility and value, with one syringe of Radiesse giving a better fill and more correction than similarly priced fillers."

Radiesse has been successfully used off-label in facial aesthetics for over four years to improve the lower third of the face, particularly the nasolabial folds, marionette lines and prejowl sulcus. This product has also been used as a non-surgical, non-implant solution for augmenting cheeks, the sub-malar and zygomatic arch areas.



Nasolabial folds before Tx



Nasolabial folds three months after Radiesse Tx

Photos courtesy of Thomas L. Tzikas, M.D.

Radiesse Clinical Roundtable

Editor's Note: The following Clinical Roundtable was moderated by Thomas L. Tzikas, M.D., who has over four years clinical experience with Radiesse. He has treated more than 2,000 patients with this long lasting filler. Dr. Tzikas and his colleagues share their practical experience with this exciting new filler, which awaits FDA clearance for indications of use in several areas of the face. Radiesse is currently FDA approved for vocal fold augmentation, maxillofacial augmentation and radiographic tissue marking. The FDA's General and Plastic Surgery Devices Panel recommended approval of Radiesse in August.

How does Radiesse fit into your aesthetic practice?

Stephen Mandy, M.D. – A lot of patients treated with collagen or hyaluronic acid ask for a longer lasting filler. Those patients are perfect for Radiesse. It's the best filler for volume, and you get more dollars per cc value. If a patient needs volume, especially for heavy nasolabial folds, marionette lines, or prejowl sulcus, Radiesse is an automatic choice. Radiesse's niche is that of an implant-like filler to augment chins, noses and malar areas. No other filler gets the same firmness and structure.

Devinder Mangat, M.D. – Radiesse fits into my practice extremely well. I've been using it for more than five years. Having tried all the available injectables, I've found that Radiesse is ideal for filling nasolabial folds and marionette lines. Because it's biologically friendly, it blends with tissues very well. Radiesse's biggest plus is that it lasts a long time. We combine Radiesse with other cosmetic procedures frequently. I may use Radiesse in the nasolabial folds right before I do a face-lift.



Devinder Mangat, M.D.

Facial Plastic Surgeon
Mangat-Kuy Plastic Surgery Center
Edgewood, KY

Steven Fagien, M.D. – Radiesse is a good option for those who need more persistence than what they get from hyaluronic acid for the appropriate region. I often inject fillers during surgery so patients have the convenience of soft tissue augmentation at the same time without discomfort.

Rhoda S. Narins, M.D. – Radiesse fits into my practice very nicely. It gives me a new alternative to other products, and it's particularly good for people who want a substance that lasts for a year and gets rid of etched in lines.

Jacqueline M. Calkin, M.D. – Radiesse allows me to offer patients a youthful appearance without invasive surgery. I don't offer face-lifts, rhinoplasty, or chin implants, but I get remarkable improvement in nasolabial folds, marionette lines, prejowl sulcus and nasal defects with a filler like Radiesse.

Thomas L. Tzikas, M.D. – In both men and women, Radiesse is excellent for augmenting deep nasolabial folds, marionette lines, cheeks and for filling deeper lines that are more difficult to eradicate with other fillers. And it's longer lasting, so patient acceptance has been greater. Radiesse is also complementary to surgical procedures such as face-lifts.

Jeffrey M. Kenkel, M.D. – Radiesse gives patients another option that lasts longer. I use it in combination with other fillers if I've got a deep wrinkle. Radiesse works quite well for any type of volume loss. We use it for hollowed cheeks and along the jaw line quite frequently.

What benefits are associated with the calcium-based microspheres?

Dr. Calkin – The microspheres feel soft and natural in the skin and provide more substantial lift and fill than other fillers. There is also evidence that microspheres provide a scaffold for ingrowth of the patient's own collagen. We think this helps to extend the result of the fill. Since the microspheres degrade into calcium and phosphate ions, I feel Radiesse is a safe product.

Dr. Narins – There is very little bruising or swelling, and when an expert lays down an even track of Radiesse, it gives a very smooth result.

Dr. Tzikas – Three to four months after the injection, the gel is absorbed, and then there is a fibroblastic response as the microspheres integrate with tissue. You get a softer effect in the treated area and a longer lasting

result before the product breaks down. The tissue integration gives augmentation as well. Radiesse is biocompatible and very adaptable to the human body.

“Radiesse is biocompatible and very adaptable to the human body.”

Dr. Fagien – This microsphere substance may simply be heartier, so it takes longer for the body to get rid of it. It’s also been shown histologically that scaffolding and deposition of collagen can occur with microspheres. I’m not sure that mechanism is the only basis for its greater persistence, but this filler seems to have more residence time in conjunction with longer clinical effects. With an amorphous gel like hyaluronic acid, when it degrades, it’s gone.



Steven Fagien, M.D.

Oculoplastic Surgeon
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Dr. Mangat – There is ingrowth of fibrous tissue and collagen into the microspheres. Perhaps that’s why it lasts longer. I know that 18 months after injection (when correction has disappeared), you can feel a fibrosis in the tissue when you re-inject the area; the tissues don’t feel as virgin as they did the first time. This implies that the previously injected Radiesse created fibrosis, which is evident with re-injection.

What’s the longevity of Radiesse?

Dr. Mangat – In my experience, Radiesse lasts 12 to 18 months. My patients love that. They don’t have to come back as often as they do with other injectables. I even use Radiesse for lip augmentation. For me the lips have been a good application of Radiesse because I figured out a way to inject it without nodule problems.

Dr. Fagien – A small amount of most fillers placed in the deeper dermis doesn’t last long. With appropriate volumes injected and techniques, Radiesse appears to last at least a year in most areas of the lower face.

This is a big jump, and that’s part of the attraction of fillers like Radiesse. People nearly always like the results of their hyaluronic acid fillers but many wish they’d last longer.

Dr. Narins – Radiesse lasts about a year.

Dr. Kenkel – I get eight or nine months. Often patients with that longevity return for a touch-up. When they get that smaller volume as a touch-up, I’ve seen improvement that lasts 18 months or longer.

Would you say that Radiesse is becoming the new standard for the treatment of nasolabial folds?

Dr. Calkin – Radiesse is my new standard. As others become more familiar with it, I assume it will become the new standard. A lot of dermatologists still haven’t tried it and I hope that will change. It’s a better value for my patients because it lasts longer and goes further.

Dr. Fagien – Radiesse is an attractive alternative, for instance, for those who want treatment of nasolabial folds to last longer than the four to six months they typically get with hyaluronic acid.

Dr. Tzikas – Radiesse is becoming the new standard for the treatment of nasolabial folds because of the way the product is packaged and the instant results you achieve with it. I’ve not seen this with other fillers. What’s nice is that it’s one treatment with Radiesse versus multiple treatments with other fillers.



Before Tx

After Radiesse Tx

Photos courtesy of Stephen Mandy, M.D.

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Dr. Kenkel – I think Radiesse is an appealing option because of its longevity. It's new and a lot of patients are taking advantage of its benefits.



Nasolabial folds before Tx

Nasolabial folds 18 months after Radiesse Tx

Dr. Mandy – Radiesse has raised the bar for nasolabial correction in longevity and volumetric fill. But it can't be the new standard until it has FDA approval and more widespread use.

Dr. Mangat – Radiesse is the new standard for people who have used it. As soon as Radiesse gets FDA approval for use in nasolabial folds, it will replace a lot of other injectables for nasolabial folds. Radiesse is just head and shoulders above any other material purely because of its longevity. Because of its density, it takes me half the amount of Radiesse to bring about a correction as it does a hyaluronic acid product.

What advantages does a versatile, volumizing product like Radiesse offer for facial contouring?

Dr. Mandy – One element is that Radiesse gives more volume correction for the same amount of cc injection. The other is that Radiesse is a firm implant, so it can be used to sculpt the face more effectively than collagen. Although hyaluronic acid has sculpting capacities, I don't think they are as definitive as those of Radiesse.

Dr. Mangat – The advantage is volume replacement. Radiesse has been used for augmentation of large areas such as the cheeks or chin. It's also been used in large amounts to replace volume loss due to HIV lipodystrophy.

Dr. Calkin – Radiesse has a better lift and better structure than some of the other fillers. I can do facial contouring without surgery. In the patient with an obvious jowl and prejowl sulcus, I can mask and almost

eradicate the look of the jowl by filling the prejowl sulcus. Similarly the marionette lines and nasolabial folds can now be treated without surgery. I've also had good results with nasal defects, which in the past may have required rhinoplasty.

Dr. Narins – If an expert lays down a fine, even track of Radiesse, it gives a very smooth result. It will give volume as well as fill in lines and folds. An expert can make the result look natural with any filler, but with one syringe of Radiesse, you get at least 1.5 to 2 times the volume of most other fillers. So you can do a lot with it. For example, you can use Radiesse in a cross-hatched pattern to get volume in the cheeks and along the mandible.

Dr. Tzikas – Radiesse gives an instant long-term result. You can place it almost anywhere in the face for augmentation. It's thicker and not palpable under the skin. Eventually Radiesse degrades in the body so it's very safe.

What are your favorite areas of treatment?

Dr. Narins – Nasolabial folds, puppet folds and oral commissures. I also like to use Radiesse on the sides of the chin where there's volume loss and lines due to peculiar mouth movements.



Rhoda S. Narins, M.D.

Clinical Professor of Dermatology at NYU Medical Center
Medical Director of the Dermatology Surgery and
Laser Center of Manhattan and White Plains, NY

Dr. Calkin – Marionette lines, chin and nasolabial folds first, and then prejowl sulcus and probably nasal defects, cheekbones and occasionally eyebrows. Patients may not be able to articulate what's bothering them around their mouth, so I like to surprise them by turning their mouth back up. This is a wonderful benefit, and Radiesse makes this accessible to the average patient.

Dr. Mandy – Chin, malar, nasolabial, prejowl and marionette lines. I've also used Radiesse to straighten or fill a little nasal defect. These are places where you can expect Radiesse to perform well.

Dr. Tzikas – Nasolabial folds, followed by marionette lines, oral commissures, glabella, cheeks and prejowl areas.

What have you learned about using Radiesse in the lips?

Dr. Kenkel – People should approach the lips with caution. Because of the nature and motility of lip tissue, the product tends to clump. The lips are not an area to inject when first becoming familiar with the product.

Dr. Mangat – Radiesse in the lips is very technique oriented. The key is that the needle always stays in the space between the orbicularis muscle and the submucosa and that the filler is injected very slowly as the needle is withdrawn. Immediately after injection, carry out significant massage to spread the material out evenly and inhibit nodule formation.

Dr. Calkin – I don't use Radiesse in the lips, and rarely use it in the vermillion border. Hyaluronic acid is still my favorite for the lips.

Dr. Mandy – It's ironic because the lips are where I started using Radiesse. You must be cautious because over correction can lead to nodules. If I inject very small amounts of Radiesse in a reverse threading manner just along the lip margin, I achieve nice lip enhancement that lasts longer than that of any other products. As a rule of thumb, I use Radiesse in the lips



Stephen Mandy, M.D.

Dermatologist
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only in patients with injection fatigue. I tell them that this product lasts longer, but there is a small risk of bumpiness even in the most carefully controlled situation. Physicians who use Radiesse in the lips should be really good injectors.

Dr. Fagien – Novice injectors should probably avoid the lips. Even expert injectors have a low level of complications in areas with significant motility such as the lip. I like softer agents like hyaluronic acid for lip volume and collagen products for lip border definition.

Dr. Tzikas – Initially most clinicians injected too much Radiesse into the lips. Since Radiesse coalesces in lips, little nodules — not granulomas — form and may take

a year or more to dissolve. I use Radiesse sparingly and only in the vermillion of younger patients. I use silicone in the lips, and I inject it conservatively with a microdroplet technique.



Lips before Tx

Lips three months after Radiesse Tx

Photos courtesy of Jeffrey M. Kenkel, M.D.

Dr. Narins – I do not use Radiesse on the lips because you tend to get nodules. But if I did, I would use botulinum toxin first to decrease the muscle movement so I wouldn't get nodules. I use hyaluronic acid or silicone in the lips and Radiesse elsewhere.

Do you experience injection fatigue in your patients?

Dr. Kenkel – Injection fatigue is something we present when first counseling patients on the options they have. I haven't seen injection fatigue as a real problem, but patients find it much more appealing to see us every 9 to 12 months as opposed to every three to six months.

Dr. Calkin – We advise patients right off the bat that if I don't use Radiesse they will need to return every four to six months, depending on the treated area and filler used. When I tell patients who have been getting hyaluronic acid that I now have an option that lasts twice as long, they almost always switch and are very pleased.

“Patients find it much more appealing to see us every 9 to 12 months as opposed to every three to six months.”

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Dr. Fagien – Many patients are very happy and don't mind returning every three to six months. Others come in after a few injections and say, "I wish there was something that lasts longer." That's when we discuss other options including Radiesse.

How does patient satisfaction improve with a longer lasting filler like Radiesse?

Dr. Calkin – A longer lasting filler is a better value and offers less downtime out of a busy schedule. Patients appreciate the integrity of our offering a treatment that costs less and requires fewer visits. Although Radiesse lasts twice as long, I don't charge patients twice as much. A year is an ideal amount of time because it becomes affordable to do something once a year. It's also a relief to patients and doctors that if a problem occurs (and thankfully they are rare), it won't be there for five years.



Lips before Tx

Lips after Radiesse Tx

Dr. Fagien – If patients can get the same result with a new filler that they can with a filler they're used to getting and the results are not detectable and the persistence is greater, the satisfaction rate with the new filler is, obviously, extremely high. With Radiesse, the satisfaction rate has been very good.

Dr. Narins – I have patients that still want collagen because they are used to it, but the majority want something that lasts a year and that is what Radiesse does. Other patients just don't like the other products, and Radiesse is a good alternative.

Dr. Kenkel – A longer lasting filler like Radiesse just frees the patient from the office. If you get the result with a longer lasting filler, then patients will be more accepting of that type of treatment.

Dr. Tzikas – We've learned over time that the main thing with patients is the duration of correction. Once they understand that the product lasts a year, they're very fine with it.

Please comment on the comparative amount of Radiesse needed for optimal correction.

Dr. Fagien – You may need to use less Radiesse, in part, due to the absence of need for over correction to improve persistence and also because of the collagen ingrowth that may also work in your favor. With equivalent volumes, the short-term result, assuming optimal injection technique, may be similar to other agents but the persistence can potentially be much greater.

Dr. Tzikas – It depends on the depth of the fold and what you're trying to correct. Some people may require a second syringe or a touch-up three or four months after the initial injection. With a touch-up of Radiesse, the duration often extends to 18 or 20 months.

What's nice about Radiesse is that one cc is roughly equal to more than 2 cc's of collagen and close to 2 cc's of hyaluronic acid. So Radiesse is cost-effective both for the patient and for the physician because you're using less and it lasts longer. The patient is ultimately paying less for correction than they would with other products.

Radiesse is also thicker and expands better in tissue, so you get a better filling effect overall. The other products are more water based and tend to have less structure than Radiesse.

Dr. Mangat – The cost to the patient when I use a single 1.3 cc syringe of Radiesse is about \$1,000 dollars and the result lasts 12 to 18 months. If I use a hyaluronic acid product, I would have to inject it at least two to three times in 12 to 18 months, so the cost to the patient for hyaluronic acid is almost double the cost of Radiesse.

Dr. Calkin – With one syringe of Radiesse, I get the same correction I would get with 1.5 to 2 syringes of hyaluronic acid. Compared to hyaluronic acid, Radiesse is firmer and more substantial so I get more bang for the buck. I can also use less Radiesse in certain areas and get more fill. Three syringes of Radiesse cost maybe \$2,000 for a year's correction, whereas five or six syringes of hyaluronic acid costs \$3,000 for six month's correction.

When do you typically have your patients return to evaluate their Radiesse results and discuss other complementary services?

Dr. Kenkel – We encourage patients to return two to three weeks after the injection so we can assess the results. If we do a small touch-up, patients get persistence for another 9 to 12 weeks. We discuss botulinum toxin or other facial treatments during the initial consultation.



Jeffrey M. Kenkel, M.D.

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Dr. Tzikas – I tell patients to come back early (within a few weeks) if they see asymmetry or have other concerns. Otherwise I see them again in three or four months. If the gel portion has absorbed greatly, they may need another minor injection. BioForm offers a little touch-up syringe. Other than that, most patients come back in a year or so.

Dr. Mandy – For Radiesse patients, most of my discussion goes on in the original consultation. Many Radiesse patients also get botulinum toxin for the forehead, so I reassess their Radiesse result when they come back at three months for another botulinum toxin injection. Most of the time a touch-up with Radiesse is unnecessary.

“Most of the time a touch up with Radiesse is unnecessary.”

Dr. Calkin – I don’t routinely do a touch-up. I tell patients to come back if they see diminution of the fill in two to three months, and I will do a touch-up. They may get a year or more of correction after the touch-up.

I discuss complementary services during the initial consultation, but if patients like the results of the filler and they ask what more I can do, I suggest botulinum

toxin for the upper face since I use Radiesse for the lower face. I sometimes discuss liposuction for the submentum in conjunction with a little filler after that.



Jacqueline M. Calkin, M.D.

Dermatologist
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Dr. Fagien – I think two to four weeks is ideal for them to come back so I can see how they’ve responded. I do a touch-up less than 50% of the time. I most often discuss complementary services only if they ask me questions regarding these or pose the typical question of what else could improve their facial appearance.

Any tips or pearls of wisdom?

Dr. Tzikas – I tell beginners to start with areas such as the deep nasolabial folds. The better the patient’s elasticity, the better the product’s result. For an older person with hanging skin, you need quite a bit of filler, and you can actually palpate it. It’s also very important to inject Radiesse into the subdermal plane. I know physicians have injected it aggressively into the dermis, but Radiesse is white and visible through the skin if injected into the dermis, particularly where the skin is thin. Radiesse must be given by retrograde subdermal injection, putting small amounts in different rows.

Dr. Mangat – For the nasolabial folds and marionette lines, injecting Radiesse is like injecting collagen or hyaluronic acid. Radiesse is perfectly good for lip augmentation, but physicians should get used to injecting it in other areas first. Then when they inject Radiesse into the lips, they should inject slowly and conservatively and with the technique I outlined earlier.

I’ve used Radiesse for various applications because I’m comfortable with it and have used it for so long. I have used Radiesse to correct small post-rhinoplasty defects and to treat acne scars. I’ve also used it to augment the cheek and chin. Although the effects are temporary, injecting Radiesse into the cheek and chin gives the patient an opportunity to see what permanent chin or cheek implants would look like.

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Dr. Mandy – One tip is that Radiesse injections are subdermal to subcutaneous plane. If injected too high, lumpiness may result. It's up to the doctor to choose which contouring technique — criss-crossing, fanning or others — he or she uses. The technique that works best also depends on the area injected. If unsure, you can under inject. With Radiesse, I'm cautious with over correction because the effect doesn't go away quickly. For older people with thin skin, I suggest injecting conservatively. You can always ask them to come back in a few weeks to add more. These skills come with repeated use.

Dr. Calkin – Many patients aren't aware of age-related changes in their faces. When they say, "I don't want to fill my face up," I ask them to bring in pictures taken when they were about 30 and 50 years old so I can show them the volume changes and point out subtle changes such as the marionette lines. By simply filling areas around the mouth, patients suddenly look like they did five or ten years ago.

“Good places to start with Radiesse are to use it as a volume enhancer and use it in nasolabial folds.”

Dr. Fagien – Give your patients a local anesthetic to minimize discomfort. As with hyaluronic acids, precision is much better delivered in a pain-free environment, so I give regional blocks and/or local anesthetic to most of my patients. It also limits bruising and edema and often-times they can look reasonably good even the next day. Also, start slow and until you get more comfortable injecting this or any product, treatments should be directed to areas like the nasolabial fold that are more likely to yield a success before venturing to other facial regions.

Dr. Narins – Radiesse can be used for volume as well as lines, and you get a nice, even result if you use it in a cross-hatch fashion. It took a while for Radiesse to get started because people needed to get experience and make sure there were no problems. But Radiesse has turned out to be a nice filler.

Dr. Kenkel – Good places to start with Radiesse are to use it as a volume enhancer and use it in nasolabial folds. An area to be cautious in is the lips.

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