

# ePrime Raises Minimally Invasive Facial Volumization to New Heights

By Kevin A. Wilson, Contributing Editor



Before Tx



Three months after single ePrime Tx of lower face  
Photos courtesy of Andrea Willey, M.D.



Before Tx



Three months after ePrime Tx  
Photos courtesy of James Newman, M.D.

Offering a new dimension in facial volumization, ePrime from Syneron, Inc. (Irvine, Calif.), utilizes novel fractional bi-polar RF technology to deposit energy right where it's needed to stimulate not only neocollagenesis, but elastinogenesis as well. Other features, such as real-time treatment temperature feedback, mean reliable, reproducible outcomes even after a single painless treatment, according to experts, which translates into dermal volumization with improved skin tone.

Bypassing the epidermis, this device relies on a matrix of paired 32 gauge electrodes inserted into the dermis to create a pattern of precisely defined thermal lesions within the target tissue. "Previous technologies delivered energy through the epidermis to the papillary dermis to cause the denaturation and contraction of collagen," said Macrene Alexiades-Armenakas, M.D., Ph.D., F.A.A.D., an assistant clinical professor at Yale University School of Medicine (New Haven, Conn.), who is involved in the clinical study of ePrime and development of its protocols. "We've pretty much exhausted surface-applied technologies, so ePrime takes us to the next level."



**Macrene Alexiades-Armenakas, M.D., Ph.D., F.A.A.D.**  
Assistant Clinical Professor  
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Another unique feature is the wound healing response created by ePrime. "ePrime causes very precise dermal injuries that arouse an anabolic wound healing response which stimulates the growth of collagen and elastin in a way that we've not seen before," said Andrea Willey, M.D., of the Laser and



**Andrea Willey, M.D.**  
Laser and Skin Surgery Center of  
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Skin Surgery Center of Northern California (Sacramento, Calif.). "We are consistently able to create younger, more elastic skin, in addition to improving volume."

ePrime's ability to deliver energy directly to target tissue and monitor tissue temperature response in real-time using its patented Intelligent Feedback System is the driving force behind its impending success. Facial plastic surgeon James Newman, M.D., medical director of Premier Plastic Surgery in Palo Alto and San Mateo, Calif., has been directly involved in the development and study of the ePrime device. "We all know that the key to maximizing results is the ability to maximize the delivery of adequate treatment energy to achieve the desired effect," he said. "There are numerous obstacles to this. Patients don't want any pain or downtime. It's easy for us to tell how much energy we're using, but how do we know if it is being delivered to the target, and is it enough to help us achieve the desired result? ePrime answers those questions, so users can rest on more-than-reasonable expectations."



**James Newman, M.D.**  
Facial Plastic Surgeon  
Medical Director  
Premier Plastic Surgery  
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Dr. Alexiades-Armenakas echoed this viewpoint. "Instead of being hampered in one way or another by the need for



Before Tx



After ePrime Tx

Photos courtesy of Macrene Alexiades-Armenakas, M.D., Ph.D., F.A.A.D.



Before Tx



After ePrime Tx

Photos courtesy of Macrene Alexiades-Armenakas, M.D., Ph.D., F.A.A.D.

energy to penetrate the surface, or the need for epidermal cooling, or the potential for burning, we bypass these issues and deliver the RF energy directly to the reticular dermis, which is the target," she said. "We also have real-time feedback of target tissue temperature and delivered energy, so we can control how much energy we deliver, as well as achieve and maintain a therapeutic temperature level exactly where the energy is supposed to go."

"Before ePrime, temperature measurements during treatment were just estimations based on Monte Carlo simulations (a class of computational algorithms)," Dr. Alexiades-Armenakas continued. "This is the first time that we have actual real-time feedback, and it's the first time we can pinpoint exactly what temperature is achieved and for how long it is maintained. It's a huge breakthrough." Software helps the user achieve and maintain treatment temperature settings, as well as prevent over-treatment, she pointed out. "This device is by far the most effective for minimally invasive dermal volumizing from a single treatment. Also, it's perfect for the lower face, where many other technologies are not effective, so there's little or no competition for this right now."

According to Dr. Newman, it takes approximately 45 to 60 minutes on average to treat the entire face. Target temperature and length of time on temperature can be adjusted for each treatment pulse. Temperature is assessed in real-time via thermocouples inside the electrode needles. "The kind of uniform precision this affords users is extraordinary, but more than that, it allows us to standardize treatment protocols much more effectively than we're used to with previous skin tightening modalities," he said. "This is a direct window into what's happening within the target tissue. Furthermore,

since we bypass the epidermis, the treatment is viable for all skin types."

Successful ePrime treatment requires adequate delivery of energy to raise dermal temperatures from 68°C to 72°C for about four seconds. According to Dr. Alexiades-Armenakas this is standard. "You don't want to be overly aggressive in the beginning. Over time we'll continue to work out protocols, as with any other device."

While ePrime's intradermal delivery of RF energy would normally be painful for patients, Dr. Alexiades-Armenakas has developed a protocol that's absolutely painless. "I numb my patients with EMLA cream for 75 minutes, then infiltrate locally with dilute lidocaine and epinephrine so that they don't feel a thing when treatment time comes. When treatment is finished they have little poke marks and some mild edema and erythema which may last for a few days, but usually patients return to normal activities within 24 hours. I have also found that an antihistamine will help with the swelling."

Clinical studies of ePrime include an investigation by Dr. Alexiades-Armenakas and colleagues<sup>1</sup> featuring the first quantitative, blinded independent evaluation and comparison of surgical face-lift and fractional RF in conjunction with a validated grading scale for laxity. "If you want to truly evaluate a new modality you compare it to the gold standard, which in this case is a surgical face-lift," she explained. "Until recently we didn't have an adequate quantitative grading scale. Here, we took a minimally-invasive technology and compared it directly with the gold standard."

Patients in the fractional RF group (n=15, all female, mean age 59.7 years, skin types I through IV [mode

II]), and the surgical face-lift group (n=6, all female, mean age 54.0 years, skin types I [three patients] and II [three patients]) presented with similar, moderate laxity grades (2.76 and 2.47, respectively).

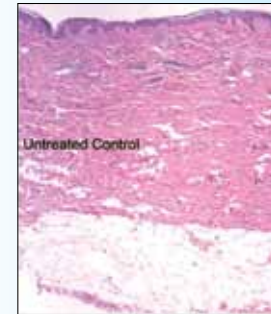
Of the fractional RF group, 93% of patients said they were satisfied or very satisfied with treatment. Average percentage improvement in laxity score from baseline with fractional RF was 37% of that seen with surgical face-lift (improvement by .45 points versus approximately 1.2 points on the 4-point laxity grading scale, respectively). "Overwhelmingly, our patients are very pleased with the results we've been getting," Dr. Alexiades-Armenakas reported. "No adverse events or complications other than transient erythema, swelling and ecchymosis were observed in the fractional RF group from the study conducted in my research clinic. In contrast, four of six patients in the surgical group experienced hypertrophic scarring of the pre- and post-auricular regions, with ecchymoses and edema resolving in two to four weeks."

One key to the unique efficacy of ePrime is elastinogenesis. "Over the years we've discovered that laxity is an issue in itself, separate from wrinkling and other aspects of skin aging, and there is a largely associated genetic component," Dr. Alexiades-Armenakas said. "There are a great many genetic conditions and mutations involved, and the majority of them appear to be in the genes that deal with elastin. This gives us a strong rationale that any device stimulating elastinogenesis will be much more effective than a modality promoting neocollagenesis alone. I believe ePrime is so effective for laxity reduction because it promotes both."

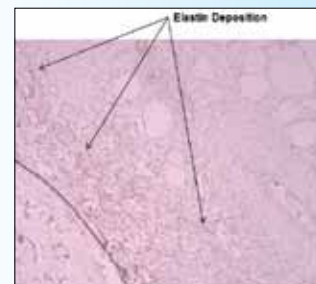
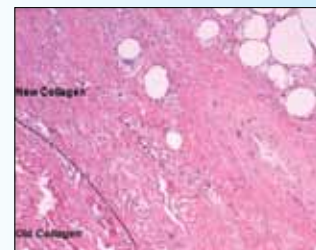
Dr. Willey is also involved in trials with ePrime, and recently studied clinical improvement and skin elasticity<sup>2</sup> with this device. "We treated the lower faces of 44 patients with ePrime and evaluated improvement in skin laxity and elasticity, a technique typically used to measure loss of skin elasticity due to photodamage. This is the first time elastometry has been used to measure increases in elasticity due to elastinogenesis." Dr. Willey reported that three month follow-up showed statistically significant improvement correlating to a reduction in skin age of 2.6 years. "We also saw averages of 1.42 grade improvement on the Fitzpatrick wrinkle scale and 0.66 point improvement on the Alexiades laxity scale, with even greater improvement seen at six months. About 90% of patients were either satisfied or very satisfied with treatment."

Dr. Newman believes ePrime will soon be established as the gold standard for energy-based dermal volumization, and an essential component of a complete rejuvenation regimen. "ePrime gives us actual subsurface tightening, which is a niche. Other technologies can address surface manifestations of photodamage and aging such as pigment. Additionally, you could pretreat with a few sessions of pulsed light therapy or very superficial fractional CO<sub>2</sub> resurfacing. I think physicians would be comfortable with ePrime as a key adjunct to minimally invasive face-lift procedures because of the nominal injury to the epidermis."

According to Dr. Willey, ePrime can also be used with submental liposuction, with the added advantage of being able to treat the whole face, which even laser lipolysis cannot do. "Another nice aspect to ePrime is that it can be used on patients of all ages and skin types," she added. "We've seen that



New Dermal Volume – Ten Weeks



Neoelastogenesis – Ten Weeks

“We’ve seen that you still have robust collagen and elastin production at ten weeks following treatment, and clinical improvement at six months.”



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Three months after ePrime Tx of the lower face  
Photos courtesy of Suzanne Kilmer, M.D.



Before Tx



After ePrime Tx  
Photos courtesy of James Newman, M.D.

you still have robust collagen and elastin production at ten weeks following treatment, and clinical improvement at six months. Due to this, even patients in their thirties could periodically turn back the clock on early laxity and loss of volume, perhaps staving off the need for dermal fillers for a time. This is important because dermal fillers last for maybe a year while the collagen and elastin generated by the body after ePrime therapy is yours to keep, although patients do continue to age. Results are seen with more advanced photo-aging as well, and complement surgical modalities. Competing technologies often require multiple treatments and can be less reliable. In a sense, there really isn't any direct competition for ePrime because other devices don't do what ePrime does."

Furthermore, the cost of treatment with ePrime is easily manageable when compared to other devices, Dr. Willey pointed out. "As with many other devices there is a disposable treatment tip, which is comparable in cost. There is also the benefit of minimal necessary post-procedural care." Dr. Willey added that it's vital to protect results with sunscreen and a skin-care regimen.

Dr. Newman also suggests sunscreen and moisturizers to patients, especially for the first day or two, with little else – no antibiotics or antivirals are needed. "Essentially, the skin puncture sites are healed within 24 hours so aftercare beyond that is unnecessary, and patients can wear make-up because the barrier function is intact thereafter."

Overall, however, what separates ePrime from the pack is what makes any device great: dependable delivery of results. "What ePrime gives you is different and better," Dr. Newman emphasized. "Other devices that require

repeated treatments have been trying for years to do what ePrime does more predictably with a single treatment," he continued. "In comparison to other single modality therapies, the results are unsurpassed. When patients can come in and get visible, satisfying results in a single, painless treatment with virtually no downtime, this will set that practice apart from the rest."

"Essentially, the reason ePrime will be a success is that it provides truly personalized, individualized treatment to patients without fail," Dr. Newman noted. "You don't need to figure out how to deliver enough energy depending on the patient's unique skin profile, because the feedback mechanisms assure it. Nothing else does that; instead you have indirect feedback, with therapeutic energy delivered according to scientifically-determined, but generalized, less reliable protocols that cannot be as easily and accurately individualized. With ePrime, once the target temperature has been achieved and maintained, the rest is a matter of time." ■

#### References:

1. Alexiades-Armenakas M, Rosenberg D, Renton B, *et al.* Blinded, randomized, quantitative grading comparison of minimally invasive, fractional radiofrequency and surgical face-lift to treat skin laxity. *Arch Dermatol.* Apr 2010;146(4):396-405.
2. Willey A, Kilmer S, Newman J, *et al.* Elastometry and clinical results after bipolar radiofrequency treatment of skin. *Dermatol Surg.* Jun 2010;36(6):877-84.