

Fractional RF Modalities Eliminate Color Barrier

In a global context, the challenge with facial rejuvenation is that the most common therapies rely on thermal damage caused by laser energy. While experts agree that this approach is very effective, it prevents a significant amount of the world's population from receiving treatment since treating dark skin with laser and light energies carries inherent risks such as post-inflammatory hyperpigmentation. Two radiofrequency (RF) based devices are eliminating this color barrier, offering predictable, reproducible results that are both universally accessible and effective.

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Safe Treatment of All Skin Types Drives Global Appeal of eMatrix and ePrime

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Before Tx



One year after eMatrix Tx
Photos courtesy of Michael H. Gold, M.D.

Representing non-laser, non-light fractional rejuvenation, two top-tier technologies from Syneron & Candela (Yokneam, Israel) employ RF energy in distinctly different ways. Safe for all Fitzpatrick skin types, eMatrix and ePrime offer predictable, reproducible outcomes that are unique and universal with little or no risk of post-inflammatory hyperpigmentation (PIH).

According to Lori Brightman, M.D., of the Laser & Skin Surgery Center of New York (New York City, N.Y.), who was involved in some of the seminal work with eMatrix¹, "eMatrix delivers bi-polar RF energy in a novel way for overall facial rejuvenation." The treatment tip contains an array of microelectrodes (in 64- or 144-pin configurations), between which RF energy is predictably delivered. Outcomes include not only superficial tightening and treatment of pigment, but a restoration of luminosity.

Known as Sublative rejuvenation, its unique, inverted-cone shaped delivery of thermal damage minimally disrupts the skin surface while still causing high levels of dermal collagen remodeling. "The ability to treat with far less concern of PIH within the range of skin types opens up a whole new world to us," said Dr. Brightman. "We can rejuvenate or treat scars on the face and body, for example, and perhaps many other indications in the future, for patients of all skin types because RF is color blind. RF energy does not target pigment-making cells in the skin."

The platform itself is easily portable and very user-friendly. A representative for Syneron & Candela revealed that upgraded eMatrix software gives histology-based readings of tissue ablation and coagulation, as well as an integrated

waveform plot to document treatment pulse history and update skin feedback. "This new software with eMatrix makes the device even more user-friendly than it already was," added Michael H. Gold, M.D., director of Gold Skin Care Center and Tennessee Clinical Research Center in Nashville, Tenn.

eMatrix's ability to effectively treat regardless of skin type is a characteristic shared with ePrime, another RF based technology with a novel delivery system. This device features a handpiece containing a series of five pairs of insulated needles that penetrate the skin to a depth of approximately 2 mm, which is where targeted dermal remodeling takes place. Efficacy for the lower face has been demonstrated in literature via elastometry.² Additionally, ePrime's efficacy and safety are enhanced by its Intelligent Feedback System, which allows real-time monitoring of intradermal temperatures to maximize safe delivery of therapeutic energy³ at scientifically-validated doses.⁴

David Eccleston, M.D., an aesthetic practitioner in Birmingham, U.K., trains physicians in the effective use of this device. "ePrime is the first clinically proven method of achieving non-surgical tightening on the lower face," he said. "We can create precise thermal injuries beneath the epidermis, each about the size of a grain of rice, which eliminates the guesswork involved with previous technologies. Until now uncontrolled heating of the skin was the limiting factor, with endpoints based on patient tolerance or surface temperature readings, either of which are vague methods of optimizing therapeutic delivery of energy. I've tried several devices in the past and ePrime is the only one I've actually bought, based



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Before Tx



Three months after one ePrime Tx
Photos courtesy of Taro Kono, M.D.

on the strength of the experience I had within one month of using it. I've documented results using three-dimensional photography and the quality of improvement is quite extraordinary."

In Dr. Gold's opinion, the concept of microneedle treatment is somewhat foreign to Americans but not to the rest of the world. "This sort of technique is being embraced around the globe much more rapidly than in the U.S. Americans will come to understand the concept and its benefits."

Dr. Brightman added that ePrime's fractional RF volume enhancement is unequaled by any energy-based device in the market. "While a variety of quality devices will address tightening, some of them require more than one treatment. Another feature unique to ePrime is the single treatment precision delivery of energy and the real-time feedback. This really sets a new standard for predictability and reproducibility."

In addition, Dr. Brightman feels the methods by which these two devices harness RF simplify treatment. "The technology of RF itself is forgiving compared to laser- and light-based treatments due to the dramatically reduced potential for PIH," she began. "Both eMatrix and ePrime exhibit this characteristic. However, there is still technique and skill involved in delivering consistent and proper outcomes of these technologies in a clinical setting. This is true of any device when you want to deliver the best results for your patients."

Maurice Adatto, M.D., dermatologic surgeon and medical director of SkinPulse Dermatology Center in Geneva, Switzerland, agreed. "It is important to note that parameters with eMatrix, for example, should be

adjusted downward for higher skin types until the physician is very experienced. For the average physician in Europe, care must be exercised; however, I know physicians of Indian decent who treat darker skin regularly and are successful with more aggressive parameters."

"The inverted cone of thermal damage allows for minimal disruption of the epidermis and reduced impact at the dermal-epidermal junction, thus pigmentary problems are less likely."

"No single treatment does everything, and not every physician uses the exact same protocol," Dr. Brightman said. "This is why the global nature of technologies like ePrime and eMatrix is so valuable, so we as a community can communicate to further refine our knowledge base, improve therapies and discover new indications as we grow."

eMatrix's two handpiece configurations are similar in the character of thermal damage delivered, but different in skin surface coverage. "The inverted cone of thermal damage allows for minimal disruption of the epidermis and reduced impact at the dermal-epidermal junction, thus pigmentary problems are less likely," said Taro Kono, M.D., a plastic surgeon in the department of plastic and reconstructive surgery at Tokyo Women's Medical University in Japan. "The 64-pin tip will create only 5% ablation



Before Tx



Five weeks after one eMatrix Tx
Photos courtesy of Taro Kono, M.D.



Before Tx



Eight weeks after Tx
Photos courtesy of David Eccleston, M.D.

at the surface, with strong subsurface impact for which you would need at least 30% ablation with a laser device. Coverage with the 144-pin tip is denser at 12.5% ablation, but the effect is more superficial."

Performing passes with both tips provides multi-layer treatment, Dr. Adatto noted. "We can also perform treatment at two depths with Sublative rejuvenation – superficially for improvements in pigmentation and skin texture, or deeper for scarring or wrinkles. I use this device with excellent results off the face for striae as well, employing the 144-pin tip on the body with lower energies, between 32 mJ and 36 mJ, performing four to six treatments at intervals of about one month to allow for adequate healing. If patients seem to heal more slowly, we will increase the interval by a few weeks. Using three-dimensional imaging we have observed up to 80% improvement."

"You have to be careful with parameters when treating off-face with any technology," Dr. Adatto continued. "There is a higher concentration of sebaceous glands on the face, so that region tolerates more damage. This goes against popular opinion because most consider the face difficult to treat, but it tolerates treatment that the skin on the body cannot."

A study by Dr. Kono, presented in Singapore at the *International Master Course on Aging Skin (IMCAS) Asia Congress* in July 2011, examined the safety and efficacy of eMatrix fractional RF for Sublative rejuvenation in Asian patients. Each of 12 subjects received two to three treatments performed at intervals of one month, using the 64- and/or 144-pin tip at between 32 mJ and 48 mJ per electrode, with

topical anesthesia applied one hour before each session.

Objective evaluation of results was performed via VISIA imaging from Canfield Imaging Systems (Fairfield, N.J.). For all patients, improvement was seen in wrinkles, pore size and elastosis. "Although we did see some incidence of mild hyperpigmentation with the 144-pin tip due to admittedly aggressive settings, complication and downtime were otherwise limited and patient satisfaction was very high," Dr. Kono reported.

Currently, Dr. Brightman is investigating eMatrix for the treatment of port-wine stains for all skin types, comparing it with the gold standard pulse dye laser (PDL). "Although preliminary results show promise combining eMatrix with PDL, what's interesting at this point is that we're seeing clearance with no incidence of PIH so far," she reported. "I am intrigued by the medical indications we have discovered as we learn more, and look forward to discovering what else it can do."

Preliminary results of a study by Dr. Gold using eMatrix for acne scars on subjects up to skin type V are promising as well. "Publication is pending so what I can reveal is limited, but we used a validated scar scale and global position assessment scoring, and saw statistically significant reductions from baseline at one and three months after treatment."

ePrime is an entirely different animal from eMatrix, and gives results not possible with lasers, according to Dr. Eccleston. "With ablative fractional laser resurfacing we have to vaporize a lot of epidermis to deliver energy to the dermis, so one would not be able to reach deep enough to tighten at the layers that ePrime reaches," he explained. "Compared to other RF



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Before Tx



Nine months after third Sublative Rejuvenation Tx
 Photos courtesy of Lori Brightman, M.D.



Before Tx



One month after one ePrime Tx
 Photos courtesy of Lori Brightman, M.D.

devices, ePrime delivers better, consistent, more predictable results because the feedback system allows for optimal delivery of energy. The competition has been successful, but is operator-dependent. With ePrime, each needle pair operates independently, with separate and independent monitoring as well, so if the tissue at one needle site differs from the one next to it the software will still be able to deliver the requisite energy to raise the tissue to the target temperature of exactly 70° C for the exact required time."

Dr. Brightman best describes the character of the ePrime outcome as volume enhancement. She explained that a recent trial by Alexiades-Armenakas *et al.*⁵ compared ePrime directly with a surgical face-lift. After a single treatment results with ePrime demonstrated measurable tightening averaging about one-third of what was seen with surgery. "Histology results showed both neocollagenesis and neoelastinogenesis as well," she said. According to Syneron & Candela, ePrime is the only fractional device currently shown in the literature to produce increases in elastin production at both the RNA and protein levels.

"Having non-surgical alternatives like ePrime is something we see more and more patients asking for," Dr. Brightman continued. "Although ePrime does not replace surgery, it is a viable option for individuals seeking facial rejuvenation who either do not want surgery or simply don't need it yet."

ePrime is an innovative procedure that delivers consistent response for patients and requires local anesthesia for patient comfort and hemostasis. This, along with its feedback system,

involving real time measurements of impedance and internal temperature, facilitated an emerging tumescent technique developed by Mitchell Chasin, M.D., medical director of Reflections Center for Skin & Body in Livingston and Bridgewater, N.J.

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As Dr. Chasin explained, "most physicians are presently using a combination of nerve blocks and supplemental transdermal injections of local anesthesia." Unfortunately patients may experience undesirable levels of discomfort, ecchymosis and needle puncture marks, with unwanted downtime. "If we instead infuse the subdermal space in the treatment area with a diluted, low-volume tumescent solution (including lidocaine, saline, epinephrine and sodium bicarbonate) we can dramatically improve the level of anesthesia, reduce visibility of puncture marks and minimize bruising. Nerve blocks become unnecessary."

To use this method, a 2 mm incision is made in front of the ear so that solution may be introduced through a single entry point. The pain level becomes zero out of ten on the analog pain scale, with 100% hemostasis, enabling most patients to return to full activities the following day. "This protocol has been very well-received because patients



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desire safe treatments and great results, but want to minimize pain and downtime," Dr. Chasin said.

ePrime and eMatrix may be used together as well, and protocols are beginning to emerge with further study and development. "In the future, combination treatment will be the way to go," said Dr. Gold. "It is likely that you will be able to treat volume deficits with ePrime first, then use eMatrix later to address fine lines and wrinkles." Most importantly, combining the two technologies will allow treatment of both the deeper and upper dermis, for better outcomes without the cost of additional downtime.

Dr. Eccleston agreed. "I'm a big believer in getting the foundations right so I like to treat the deeper layers first, and work upward. There is no point in getting nice, clean, smooth exterior skin and then punching holes through it. Therefore, I treat with ePrime first, and if eMatrix is called for I prescribe treatment approximately six weeks later," he noted.

"The advantage of the ePrime compared to lasers is that exactly the same parameters can be used on every single skin color. This means you can treat an African patient with exactly the same parameters as a Caucasian patient or a Hispanic patient because you are measuring the internal temperature of the skin directly," Dr. Eccleston continued. "Any variables depending on the amount of melanin in the skin are completely negated by the fact that the machine is constantly measuring the temperature within the dermis, and unlike a light-based device, the response remains constant and predictable."

According to Syneron & Candela CEO Louis P. Scafuri, the worldwide appeal of these technologies holds

much promise. "As global demand for aesthetic procedures continues to grow, the challenge to treat skin of color with traditional means becomes more apparent. The advance of these two technologies propels the capabilities of our field to now include a safe and efficacious treatment option for all skin types and much broader age groups."

There are major opportunities for innovators like Syneron & Candela. "In emerging markets for aesthetic procedures such as Asia and Latin America, we're partnering with elite local physicians to perform clinical trials and to establish eMatrix and ePrime as the new standard of care available to patients, regardless of skin type," Mr. Scafuri continued. "We are the first company to form an Asian medical advisory board, consisting of Asian thought leaders, formed to conduct clinical trials in local populations, which is substantial when considering the diversity among the peoples in the Pacific Rim. We believe we have the right resources in place to propel and sustain market growth and best serve this segment of the population. This also serves North American interests, as diversity among that population is only increasing."

Ultimately the success of these two technologies rests on three things, in Dr. Gold's opinion. "When presenting new technologies around the world, practitioners listen carefully but have three main concerns, the first being safety and efficacy, the second involving incidence of PIH and the third, the ability to treat skin of color. The literature has shown both eMatrix and ePrime to be safe and effective for all skin types with much less risk of PIH than alternatives. Patients like the results, tolerability and low downtime. It doesn't really get much better than that." ■