

Clinical Roundtable

Researchers Unveil Portrait PSR³ Study Results

Editor's Note: In this Clinical Roundtable, four leading aesthetic clinical researchers shared their experiences with developing a unique plasma-based anti-aging procedure. Rhytec's Portrait® PSR³ technology, which was recently cleared by the FDA for the treatment of facial rhytides, is the result of a lengthy and well-considered research and development project.

Can you explain the Portrait PSR³ technology?

Richard Fitzpatrick, M.D. – Portrait PSR³ technology initiates skin regeneration by delivering millisecond pulses of nitrogen plasma to the skin's surface. This plasma is quite different from any other plasma source that has been used previously in cosmetic surgery or dermatology. The plasma is generated in the handpiece rather than at the tissue surface. Hence, the plasma, an ionized gas, transfers its energy directly to the skin. This results in a very efficient, even delivery of energy that is not chromophore dependent. The way the energy is delivered provides a unique thermal profile that develops in the tissue, resulting in regeneration of new collagen and unexpected improvement in deeper lines.



Richard Fitzpatrick, M.D.

Eric Bernstein, M.D. – There is no chromophore dependency because you are dealing solely with heat generated by the plasma on impact with the skin surface. The Portrait PSR³ provides a qualitatively different effect than laser. Most lasers and intense pulsed light (IPL) devices are absorbed preferentially by both melanin and hemoglobin, for example. Nonetheless, the thermal depth of effect with the Portrait PSR³ is significant: 500 to 600 microns at high energy settings. Temperatures achieved fall just below the threshold for damaging collagen, thus causing neocollagenesis.

How is the procedure performed?

Dr. Fitzpatrick – The nitrogen plasma from the handpiece nozzle is characterized by a lilac glow transitioning to a yellowish light called a Lewis-Rayleigh afterglow. The non-contact treatment consists of holding the handpiece 5 mm from the skin. You then simply apply the plasma energy as a series of spots that are connected and slightly overlapping. The energy is delivered as a pulse because the ultra-high frequency energy exciting the nitrogen is pulsed. Each pulse is delivered sequentially until you cover the entire surface being treated.

Suzanne Kilmer, M.D. – It requires 10 to 15 minutes to perform a full-face treatment with a single pass, whereas a two pass treatment takes between 15 and 20 minutes. Practitioners also have the option of treating regional areas alone, such as perioral and periorbital. But there cannot be too much pigment present on the edge of the regional areas because you will remove any built-up sun damage or actinic bronzing. This is the same issue you have with resurfacing.



Suzanne Kilmer, M.D.

Patients can apply topical anesthesia at home or at the office. The procedure is not as painful as regular resurfacing. Anyone who performs a lot of laser treatments is going to be very comfortable with the procedure. The technology is also a

little more straightforward than for ablative lasers. The Portrait PSR³ was recently FDA cleared for the treatment of facial wrinkles.

What clinical outcomes are you achieving?

Ron Moy, M.D. – When treating perioral and periorbital areas, we're seeing 50% to 70% improvement in the wrinkles. Results are comparable to the older CO₂ lasers. For both dyschromia and wrinkle lines, the Portrait PSR³ has been as effective. The speed of recovery is dependent on the settings, but overall healing appears more rapid than similar settings with the old CO₂ laser.

Although outcomes with the Portrait PSR³ are close to the CO₂ laser, the energy-tissue interactions are different. For example, I think there is more tissue contraction with the Portrait PSR³. This may be from the heat. Plasma energy seems to induce a different type of healing.

Dr. Kilmer – The technology has been in development for five years, including over two years of preclinical and clinical testing. I've personally been involved for the past two years. Three months after treatment, there is already a more normal epidermis, with increased rete ridges and decreased solar elastosis. A single biopsy at one year indicated a more pronounced change in those two parameters and a more dramatic increase in collagen and normal elastin. I plan on biopsying a few more patients. Meanwhile, all my patients feel they have had continued improvement through the first year.

Dr. Fitzpatrick – For full-face, I'm seeing about a 50% improvement in lines. Even deep lines have responded to single pass high energy treatment. You can also eliminate dyschromia and improve texture more significantly than with traditional methods. Skin texture is improved by more than 50%. Patients have also achieved visible tightening in the areas of treatment with long-term follow-up. But we haven't actually measured it.

The degree of collagen remodeling that occurs, even at the lower energies, is striking. We see new activated fibroblasts that are migrating up from the deeper dermis and result in new collagen formation in the papillary dermal area. But this new collagen formation is not a thick, horizontal scar type collagen. Rather it is fine, particulate collagen that is oriented vertically. New elastin tissue regeneration also occurs. This procedure appears to be truly regenerative, resulting in much healthier skin.



Before Tx

Three weeks after three treatments

A clinical study performed by Dr.'s Moy and Tremblay measuring linear contraction following single treatments with Portrait PSR³ showed skin tightening averaging 11.6% at high energy settings. It appears that skin tightening can also be achieved with multiple treatments at low energy settings along with improvements in wrinkles, texture and tone.

We've been able to achieve similar results with repeated non-ablative, low energy settings. Typically, patients achieve at least 50% improvement in their photodamage within 90 days. And that improvement continues for months afterwards, which reflects deeper remodeling of collagen in the dermis. To date, we have not had any incidence of charring or pigmentary changes with any setting on the Portrait PSR³. We have found the treatment to be quite safe.

Dr. Kilmer – Patients do better in their first week after treatment. Patients also appreciate that downtime is limited to one week with aggressive treatment. It is not as bad as resurfacing. Patients appear to be nearly universally happy with treatment.

What does your research reveal about the Portrait PSR³ Tx?

Dr. Moy – To assess skin tightening, J. F. Tremblay, M.D., of the University of Montreal and I conducted a study whereby we tattooed the skin behind people's ears. We measured about 10% to 15% tightening. This, again, is very comparable to CO₂ laser. It may also be comparable to the radiofrequency and infrared heat technology that is currently the vogue.

Dr. Bernstein – I performed a histology study on a few patients at one year follow-up. We saw a reduction in the amount of solar elastosis. We also observed new collagen production, not only beneath the epidermis but in the area deeper in the dermis where the solar elastosis was located. This was a unique feature of this particular study.

In a preclinical *in-vivo* study, we compared CO₂ laser treated skin to skin treated with the Portrait PSR³. In the PSR³ treated skin, new tissue regeneration was much more rapid. In fact, by the time the injured epidermis was ready to slough off, there was already a new epidermis that had grown beneath that barrier. You no longer have a period of an open wound. This occurred well within one week. So, in effect, what you have is the best possible wound dressing. The old surface of the skin – the epidermis – acts as a natural biological dressing. There is no better dressing for your skin than your own skin cells. To me, this is absolutely unique. I had not seen this before with any of the other resurfacing techniques, including CO₂ or erbium.

Dr. Kilmer – Using a patient's own biological dressing makes it much more comfortable for the patient. The dressing stays in place.

I conducted a single pass, full-face treatment study that showed an improvement in dyschromia and mild wrinkling, but not as much as regular full-face ablative resurfacing as with CO₂ laser. A second study involving two passes is ongoing. These patients are achieving even more tightening and increased improvement in wrinkles, dyschromia, and surface changes. Patients also heal as fast as those in the one pass study.

I have also treated eyelids. You do get some improvement. The two pass study will probably indicate more tightening.

What is the thermal effect with Portrait PSR³?

Dr. Bernstein – As with the CO₂ laser, there is a zone of thermal damage. However, in our study, the zone of damage or denatured collagen was much thinner with the Portrait PSR³, on the order of 7 to 10 microns. You also have a transitional zone, whereby collagen is modified, so it becomes antigenic. This modified collagen serves to basically stimulate an inflammatory or healing response. The histology pictures are very dramatic. Overall, you see an effect of collagen remodeling well beyond the zone of thermal damage. There is also a significant healing response well beyond where the visible changes take place. I think this is one of the reasons why the clinical endpoint shows a lot of clinical improvement without much damage to the dermis.

Ten days after treatment, we see a tremendous zone of regeneration just beneath the epidermis. This zone is filled with cells, many times the normal number of fibroblast cells that create collagen. At day ten, we see a completely regenerated epidermis. In other words, the surface of the skin is new, so presumably we've gotten rid of the brown spots and all the other problems

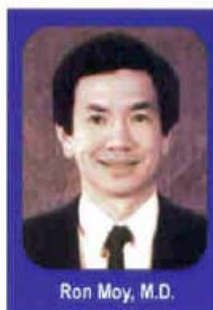
we observe on the surface of sun damaged skin. In addition, just beneath the skin we notice a zone of incredible regenerative activity: fibroblast cells and granulation tissue rich in blood vessels.

The healing response is the same as you get with a wound. Healing occurs at very set stages. It is like a symphony. Each instrument has its own place at its own time. New collagen formation continues for many months after treatment. This is consistent to what we see under the microscope.

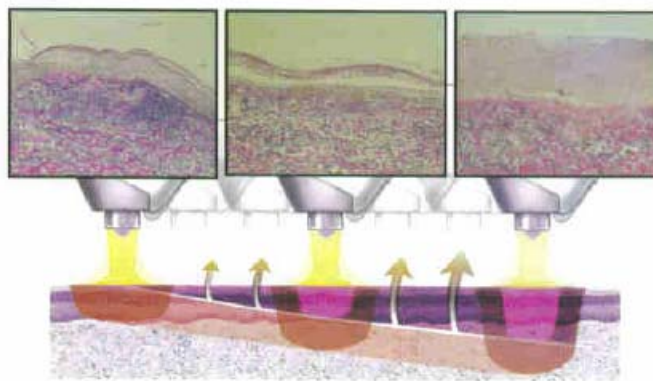
Is the healing time a problem for patients?

Dr. Moy – Patients who are willing to undergo some downtime are thrilled with the treatment. As opposed to procedures with minimal or no downtime, the Portrait PSR³ is a more predictable way of improving wrinkle lines and damaged skin. That said, we do perform the procedure non-ablatively, using minimal settings for a patient who desires a weekend treatment. Most of my patients, though, are willing to have the extended downtime of one week. Many patients combine the Portrait PSR³ with browlifts or facelifts. Overall, patients are universally thrilled.

The Portrait PSR³ has virtually replaced CO₂ resurfacing or erbium resurfacing at our practice. The healing time is quicker, there has been less redness, and the device is easier to use. We also use the Portrait PSR³ instead of non-ablative lasers for a light treatment. But unlike a laser, you don't need to feather. There seems to be a zone of graduated effect around the treatment spot. This actually is an advantage, especially along the jawline. The spots also don't need to be overlapped precisely. This zone appears to be a



Ron Moy, M.D.



Range of Portrait PSR³ energy treatment levels allows control of depth cleavage of skin and subsequent regeneration of skin architecture.

characteristic of the plasma energy. By having this graduated transition zone when treating the eyes or mouth, you do not encounter the really sharp demarcations you see with a laser. The treatment area is naturally feathered into the untreated area.

Dr. Fitzpatrick – For an aggressive treatment, there is about one week of downtime. A dry bronze layer develops which takes between five to seven days to slough off. A single treatment will result in good outcomes. But the Portrait PSR³ also has non-ablative settings with lower energies, thereby avoiding crusting. A series of three to four sessions at three week intervals is recommended.

Any other appealing aspects of this new technology?

Dr. Kilmer – Patients whom I've treated have told me they have received overwhelmingly positive reactions from their family, friends and co-workers. People ask them what they've had done and where they can have it performed.

Dr. Fitzpatrick – The only equipment needed is the device itself. Other than using topical anesthetic, no special patient preparation is needed. There is no dye involved, and no eye protection is required in most instances. If we're treating the eyelids, we'll use protective shields under the eyelids as a precautionary measure.

The patients that I've treated have all been happy with the results and have referred their friends for treatment. It's been a very well received process. You can easily and effectively treat areas with contours; for example, perioral and periorbital areas, plus tight spaces such as folds and deep wrinkles. You are able to provide even coverage. You hold the handpiece much like a wide pencil. There is no bulky device that interferes with placement or movement of the handpiece. The handpiece is very simple and easy to manipulate around areas with complex contours.

What advice would you give to new users of the PSR³ technology?

Dr. Fitzpatrick – It is important to determine the patient's capacity for downtime. This is probably the most important decision to be made. Are you going to try to do everything in a single treatment or use multiple non-downtime sessions? The aggressiveness of the treatment should be totally patient driven. About

half of my patients choose aggressive treatment. On the other hand, there are some patients who do not want multiple procedures, either because of expense or their own schedule. Other patients cannot accept any downtime.

You also need to pay close attention to complete coverage. Be very precise in the placement of the spots. Because the way the plasma reacts to the skin, a kind of cloud spreads laterally. So you need to protect hair. There is a shield that you place along the hairline. This shield can be moved as you treat. The shield also protects the eyebrows and eyelashes.

Do you have any additional comments?

Dr. Bernstein – Rhytec has moved forward very cautiously and deliberately. The company has definitely done its homework. We now have a lot of hard science to demonstrate how the Portrait PSR³ works and the mechanisms of repair. The company has also put together a team of very experienced clinical physicians, particularly in resurfacing, both ablative and non-ablative. I am equally impressed by the scientific and management teams. Because the device has been developed so well, I predict this will pay off tremendously once marketing begins.



Eric Bernstein, M.D.

Dr. Moy – For people who are interested in doing resurfacing, the Portrait PSR³ might be the best technology currently available.

Dr. Fitzpatrick – This is very exciting technology because of the simplicity of the procedure. Single pass lasers can give you significant improvement in dyspigmentation and some improvement in texture. But the Portrait PSR³ is the only treatment modality I have seen that provides significant improvement in deeper lines with a single pass.

Dr. Kilmer – Rhytec is genuinely supportive of clinical research. The company is not trying to get ahead of the game. It is very honest.

I believe the aesthetic community will be receptive to the Portrait PSR³. It is easy to use technology and quick. You can treat anywhere from non-ablative to high energy resurfacing. It is an extremely versatile technology. You can also treat benign skin lesions. This is an FDA indication from two years ago. Patients are very tolerant of treatment and I expect the technology to do well. ■