

PRP Pioneers Discuss Controversies in the Market



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When properly harvested and applied, platelet-rich plasma (PRP) and similar products are an extremely safe and powerful tool in the medical and aesthetic armamentarium. However, this growing market of production and application devices is built on a reputation vulnerable to those looking to make a quick buck at the expense of sound medical practice – a potential problem with any aesthetic treatment. This was the motivation for the founding of REVIVE™ Advanced Training Consultants (Laguna Beach, Calif.), an independent CME educational platform that strives to teach aesthetic providers only the safest, most rigorously tested, cutting-edge PRP techniques to ensure the best outcomes for all patients.

***Editor's Note:** With its special edition on Regenerative Aesthetics, The Aesthetic Guide, in partnership with REVIVE, spoke to pioneering clinicians with experience in the use of PRP to hear their opinions about the burgeoning controversies surrounding PRP and the future of regenerative aesthetics. The individual views, thoughts and opinions expressed in this editorial belong solely to the responding physician and are not representative of the entire group.*

The Aesthetic Guide (TAG): What are the ideal characteristics for PRP? Is higher platelet concentration better?

Amelia Hausauer, MD: More characteristics need to be considered rather than only focusing on platelet concentration. In the textbook I co-edited and contributed to with Derek Jones, MD (*PRP and Microneedling in Aesthetic Medicine*; Thieme Publishers LLC, 2019), we set out to educate physicians on the differences between preparatory systems and how to select the right PRP system for a variety of applications.

We also now have the DEPA (Dose Efficiency Purity Activation) classification system, which is helpful in qualifying what is meant by the term “PRP.” It is not a single product, but more a family of products based on the ratios and absolute quantities of platelets, leukocytes and erythrocytes. For the skin and hair

treatments I perform in my practice, I prefer a pure PRP, devoid of contaminating red and white cells.

Gordon Sasaki, MD: Too high or too low of a platelet concentration could negatively affect the result. The maximum benefit for each application is likely found on a bell curve. Total platelet count, not concentration, is the most accurate way to describe dosage. With the support of a grant, we have begun the first investigator-initiated study comparing results with high versus low platelet totals. I think this will add immensely to the field, making it easier to optimize patient results.

TAG: With the New Mexico spa HIV cross-contamination story making national headlines, how can physicians and patients be sure that PRP treatments are safe?

Dr. Sasaki: To the best of my knowledge, the case in New Mexico involved a non-medical spa and a non-medical practitioner. It is important that patients and physicians understand that PRP treatments must be performed with an FDA-cleared Class II single-use disposable tip. Medical providers are trained in handling blood products safely and can therefore perform these treatments using sterile techniques and approved methods for proper patient selection and for disposal of blood products.

TAG: Does PRP need more regulation?

Jeffrey Rapaport, MD: The regulations in place are sufficient. The FDA has provided guidelines for how to determine whether a technology is safe and effective for autologous PRP applications. It's called a 510(k). I'm solicited by companies with non FDA-cleared kits all the time, claiming they are Class I blood collection tubes, but they are selling to physicians illegally and should not be in the U.S. market.

TAG: How can a physician be sure the PRP product they are using is FDA cleared?

Dr. Hausauer: If you simply ask the company for the product's 510(k) number, you can search it on FDA.gov and confirm this for yourself. The trouble is that in

some cases, new PRP products being sold at conferences or featured in magazines are not FDA cleared. This needs to be addressed. We expect patients to do their homework; physicians need to do the same. Jeopardizing the safety of patients or quality of outcomes just to save a buck directly contradicts the Hippocratic Oath. Also, note that PRP production devices are generally cleared for orthopedic indications, so aesthetic use is considered off-label.

TAG: What are the risks for physicians that use non FDA-cleared “do it yourself” methods?

Charles Runels, MD: Unsafe PRP kits of any kind can cause a potentially fatal pyrogen-induced fever. *In vitro* diagnostic (IVD) blood draw tubes are cheap because they are made for lab work, and not produced in a clean room style manufacturing environment, so there could be endotoxins inside the tube. It says right on the packaging that they are not cleared as safe to prepare plasma for injection back into patients. Lawyers would have a field day with a physician that injured a patient with an IVD tube.

TAG: What must be done to educate physicians about this particular issue?

Dr. Runels: We require the members of our group, the *Cellular Medicine Association*, to use legal, FDA-cleared PRP products only. If a member is being cheap and using IVD tubes or non FDA-cleared products, membership is revoked. The success of PRP and branded procedures depends on trained medical providers using good techniques with safe kits. When done correctly, PRP is one of the safest and most profitable treatments you can perform.

TAG: What other risky trends should physicians and patients be aware of?

Dr. Hausauer: The availability of “how-to” PRP and microneedling videos online is disconcerting because people can obtain items to perform this kind of treatment from China through Amazon. Some of these things should not be available to the general public. These are for medical procedures to be performed in a clinical setting under supervision of a highly trained, board certified, licensed physician.

Dr. Rapaport: I am concerned about China entering the U.S. PRP market through a Beijing manufacturing company offering a product for multiple private label American distribution companies. If this is successful and patient outcomes decline, or someone gets hurt, the whole PRP market suffers. From what I have observed, the gel migrates inside the tube without centrifugation, almost behaving like a liquid, and could potentially end up in the final injected product.

Dr. Runels: Many of these Chinese kits aren’t ready for prime time in this market. If you choose a separator gel-based PRP collection system, stick to those having proven safety records with multiple clinical trials supporting their efficacy and safety. If you are trying to save money, companies may work with you.

TAG: How does a provider find safe, effective PRP products and protocols?

Dr. Hausauer: Evidence-based medicine is the core of my cosmetic dermatology practice. Know where your products are manufactured and what techniques yield the best outcomes safely. With controversy in the space, providers must seek unbiased, science-based answers. That is why Dr. Rapaport and I joined the REVIVE faculty. We saw the need for high-level CME programs to demystify PRP and teach up-to-date, proven treatment protocols.

TAG: What about the positive developments that are out there? What is exciting about the future of PRP?

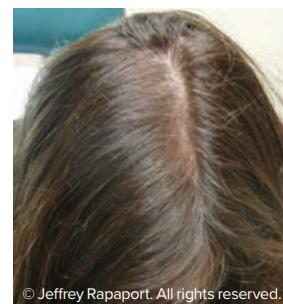
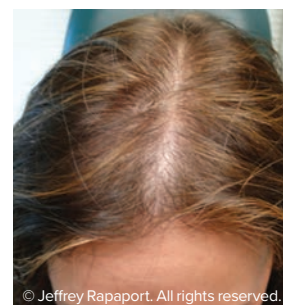
Dr. Sasaki: Companies are working on technologies that will enhance the way we do things. We know so much more than before about how to optimize results. Patient satisfaction with PRP seems to be higher than ever and physicians that are practicing the most up-to-date protocols can achieve more predictable outcomes.

Dr. Rapaport: Several years ago, I started using PRP on friends and family with very little guidance. I had to review the literature and design a treatment plan myself. Today we have literature supporting the injection technique and treatment intervals that I developed with the exact 22 mL PRP kit we use in our practice. As a result, we can better manage patient expectations and often exceed them.



Before and after PRP-based hair restoration treatments

Photos courtesy of Jeffrey Rapaport, MD, PA



Before and four months after three PRP-based hair restoration treatments

Photos courtesy of Jeffrey Rapaport, MD, PA