

latelet-rich plasma (PRP) has been used for many years for a wide variety of indications in medicine. Blood products, such as PRP, fall under the jurisdiction of the FDA's Center for Biologics Evaluation and Research (CBER). CBER is responsible for regulating human cells, tissues, and cellular- and tissue-based products. The regulatory process for these products is described in FDA regulation 21 CFR 1271. Under these regulations, certain products, such as PRP, are exempt from certain FDA guidelines and therefore do not follow the FDA's traditional regulatory pathway that includes animal studies and clinical trials. A premarket notification 510(k) can be used to bring PRP preparation systems to the market. In short, once a device is submitted for a 510(k) and shown to be "substantially equivalent" to a similar currently marketed device predicate, 510(k) clearance will allow the new device to be marketed in the United States. There are numerous PRP preparation systems available today with FDA clearance; however, these systems have 510(k) clearance for producing platelet-rich preparations intended to mix with bone graft materials to enhance bone graft handling properties in orthopedic practices. The use of PRP outside this setting, eg, injection for androgenetic alopecia (AGA) or topical application post-procedure, would be considered "off-label."1

The concept behind PRP is to harnesses the power of the body's own growth factors to renew and stimulate tissue. Platelets are known to contain a cornucopia of growth factors active in hair growth and wound healing. Specifically, platelet-derived growth factor stimulates stem cell mitosis, transforming growth factor  $\beta$  activates the dermal papilla and inhibits apoptosis during the cell cycle, and vascular endothelial growth factor helps promote microcirculation.  $^{2\text{-}4}$ 

In recent years, PRP has catapulted into the aesthetic dermatology space for different uses, such as hair restoration, scars, striae, and wound healing, as well as an adjunct to several types of microcolumn treatments, including fractional (ablative and nonablative laser, bipolar radiofrequency, and microneedling)

treatments.5 Much attention has focused on the use of PRP in AGA. At this point, clinical studies have found PRP to have beneficial effects on AGA6; however, there has been criticism of some trials mainly due to varying methodologies and the subjectivity of results. In response, a recent favorable clinical study<sup>7</sup> was designed to have the strengths of similar patient baseline characteristics (all participants had AGA III vertex pattern of hair loss on the Norwood-Hamilton scale) as well as the use of objective evaluation measurements to evaluate efficacy. In this study,7 26 patients were randomized to receive four subcutaneous injections of PRP or saline at 15-day intervals. The trial demonstrated a significant increase in hair count (P=.0016), hair density (P=.012), and percentage of anagen hairs (P=.007) in the PRP group compared with the control. Interestingly, the study was not found to have a correlation with actual platelet counts, and there was no attempt to quantify specific helpful growth factors. But the improvement seen in this study<sup>7</sup> is consistent with results seen in the literature, albeit of varying methodologies, over the past several years.8

Similar to these recent clinical studies, in our clinical experiences, we have seen patients who have demonstrated noticeable, and in many cases significant, improvement with PRP injections for AGA (and just like most procedures, some having more improvement on a spectrum than others). Aside from AGA, PRP injections for facial rejuvenation have been hyped in the media as "the vampire facial" for many years, but it was not until recently that Alam et al<sup>9</sup> at Northwestern University performed a trial that actually documented some efficacy. Their data showed masked participants found significant improvement in fine and course texture on the side of the face treated with PRP injections compared with the contralateral control side treated with saline.<sup>9</sup>

In our practices, we use PRP injections mainly as a treatment for AGA. The procedure entails drawing 22 mL of blood from the patient into a labelled test tube from a commercially available PRP preparation system. A centrifuge is then used to

separate the red and white blood cells, and a layer of plasma containing platelets remains at the top of the collection tube. Plasma at the most superficial part of the tube is discarded, leaving behind a plasma layer with a hyperconcentration of platelets (3-5 times higher than whole blood). This remaining PRP is drawn into syringes and injected in a grid pattern over the entire area of hair loss, depositing 0.2 to 0.3 mL at the superficial subcutis in approximately 1-cm increments. This procedure is repeated monthly for 3 to 4 months. If there is improvement in the treatment area at a follow-up appointment 3 months following the last monthly injection, the treatment is continued once every 4 to 6 months thereafter for maintenance (Figure). Good photography of the treated area and documentation are essential to monitor improvement.

In addition, we often utilize other modalities, such as minoxidil and/or finasteride, in between PRP treatment sessions. A recent study¹o on injected PRP plus topical minoxidil and/or oral finasteride showed the potential for enhanced efficacy in the treatment of AGA. In this study,¹o statistically significant positive effects of PRP associated with either medication vs baseline were observed at 6 months in both hair counts and hair density, with a greater improvement noted in the PRP/minoxidil combination. Some physicians also incorporate nutraceuticals into their combination treatment regimen for AGA, and one author, Dr Hooper, integrates red light therapy as well.

As for topical application of PRP after procedures, dermatologists have begun to use this approach in an attempt to expedite healing and/or potentially lead to a synergistic response. There is data<sup>11</sup> to support this type of approach for some of the procedures commonly performed in aesthetic dermatology offices. The theory behind this modality makes sense: if a treated area is exposed to an increase in the growth factors their body uses to heal after injury, then hyperconcentration of these factors could expedite recovery and also potentially have an enhanced or synergistic result from the procedure. We offer PRP to patients who express interest in trying to expedite recovery after significant downtime procedures such as ablative fractional and fullfield laser resurfacing. Some patients who undergo procedures with less downtime express a desire to incorporate topical post-procedure PRP to potentially help enhance results, such as with nonablative fractional laser procedures, bipolar fractional radiofrequency treatments, chemical peels, and microneedling. In a recent split-face study on facial laser resurfacing for texture and acne scars,12 the combination of ablative fractional carbon dioxide (CO<sub>2</sub>) plus topical post-laser PRP showed less redness, swelling, and pain than fractional CO alone.

There is undoubtedly much to be learned regarding PRP use in many fields of medicine. More rigorous study design features, including large samples, controlled preparation methods, objective efficacy measurements, and longer periods of follow-up are needed to consolidate the utility of PRP for treating patients with AGA and other conditions. We are excited about the future prospects of PRP in aesthetics and dermatology.





Figure. Patient at (A) baseline and (B) 23 weeks post treatment of platet-rich plasma (PRP) for the treatment of androgenetic alopecia. The patient received 4 sessions of PRP.

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