

The Emperor Has No Platelets: Minimal Effects in an Alopecia Split-Scalp Study Unsurprising as Platelet-Rich Plasma Was Actually Platelet-Poor

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A recent paper by Dr Gordon Sasaki looked at the effect on alopecia of 2 different platelet concentrations of platelet-rich plasma (PRP) compared to placebo.¹ Although improvement was associated with the higher concentration, statistical significance was not reached. As the main variable, and the basis of this study, platelet concentration deserves a closer look. This concentration may be expressed as the platelet increase factor (PIF): $PIF = (PRP \text{ platelet concentration}) / (\text{whole blood platelet concentration})$.

The PIF was reported as 4.5× in this study, obtained from the datasheet provided by the manufacturer of the PRP kits used in Dr Sasaki's study, Eclipse (The Colony, TX), who also sponsored the study. This value is foundational to any conclusions reached. A PIF of 4.5× would equal 1 to 1.5 million platelets/μL, which Dr Sasaki notes is widely believed to be the optimal concentration for favorable results. Indeed, the classic definition of PRP is a minimum of 1 million platelets/μL; conversely, concentrations below whole blood (~200,000 platelets/μL) are termed platelet-poor plasma (PPP).²

Presumably to verify the PRP platelet concentration, Dr Sasaki sent 1 mL from each PRP sample to a local hospital laboratory for Coulter Counter analysis (CCA). He writes, "quantification of platelets ... by Coulter Counter in Batches A and B were calculated as 4.5-fold increases over baseline values." However, a check of this calculation, ie the ratio of CCA PRP platelet concentration to baseline platelet concentrations, shows the PIF was actually only 0.1× to 0.2×, far lower than 4.5× (Table 1). In other words, PPP was used as treatment instead of PRP.

For example, according to Table 5 in Dr Sasaki's paper, CCA showed that the mean number of platelets for males,

Batch A PRP (5 mL) was 136,991,250, which equates to 27,398/μL, or only 10% of the baseline platelet concentration of 276,750/μL. Therefore, the PIF is only 0.1× and 27,398/μL is 36.5× lower than the optimal value of 1 million/μL. This level of concentration would not qualify as PRP and it would not be surprising to see poor clinical results.

Looking more closely at the study, 2 batches of PRP were used, A and B, representing low and high concentrations, respectively. However, both Batch A and B are described as "4.5 times the baseline platelet concentration of a patient's whole blood." Also, 1-mL aliquots of each batch were sent for CCA. Table 5 shows a very precise relationship between the batches; for both mean and standard deviations, the values for Batch B are exactly double the values for Batch A. This would not be expected if separate samples were measured by CCA. A PIF value of 4.5× still appears on Eclipse's current website, based on "An average of several independent, verified tests" and "Whole Blood Platelets counts of 209 (10⁶/mL)" (Table 2).

Important questions arise from the manufacturer's claims. How does the PIF improve from 3.5× to 4.5× simply by using 2 identical tubes, with no other change in protocol? How can the total number of platelets claimed be more than the starting number in whole blood multiplied by the claimed yield (~85%). For the 44-mL kit (2 × 22 mL): total

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Table 1. Platelet Increase Factor based on Coulter Counter Analysis

	Male	Female
Baseline number of platelets/ μL (whole blood) ^a	276,750	245,000
Calculated platelets in 5mL whole blood	1,383,750,000	1,225,000,000
Batch A, CCA, mean total platelets in 5mL PRP ^a	136,991,250 [56 206 022]	121,275,000 [49,475,242]
Batch B, CCA, mean total platelets in 5mL PRP (note = 2 \times Batch A) ^a	273,982,500 [112,412,046]	242,550,000 [98,950,486]
Batch A, number of platelets/ μL	27,398	24,255
Batch B, number of platelets/ μL	54,796	48,510
Batch A, PIF, per CCA ^b	0.1	0.1
Batch B, PIF, per CCA ^b	0.2	0.2

Values are mean [standard deviation] or number. CCA, Coulter Counter analysis; PIF, platelet increase factor; PRP, platelet-rich plasma. ^aValues from Table 5 in Sasaki.¹
^bPIF = (platelet concentration PRP)/(whole blood platelet concentration).

Table 2. Eclipse HC PRP³

Description	Eclipse HC 22-mL tube	Eclipse HC 44-mL tube
Platelet concentration (PIF)	3.4 \times	4.5 \times
Total number of platelets (billion)	5	10
PRP volume (mL)	6	12
Platelet yield	>80%	>80%

PIF, platelet increase factor; PRP, platelet-rich plasma. The 44-mL kit consists of two 22-mL tubes.⁴

platelets = $0.85 \times (44 \text{ mL} \times 209 \text{ million/mL}) = 7.8 \text{ billion} < 10 \text{ billion}$ claimed; for the 22-mL kit: total platelets = $0.85 \times (22 \text{ mL} \times 209 \text{ million/mL}) = 3.9 \text{ billion} < 5 \text{ billion}$ claimed. To obtain 5 and 10 billion platelets from the 22- and 44-mL kits would require yields of 93% and 123%, respectively. Where do the extra platelets come from?

There is an extremely wide variety of PRP being produced by different systems available today. A recent comprehensive review of 34 different systems showed a 28 \times difference between the lowest and highest PIF, with platelet concentrations ranging from 79,000/ μL (Eclipse) to 2.3 million/ μL (Arthrex).⁵ The same review showed single-spin systems had an average PIF of 1.25 \times .

Eclipse HC PRP consists of a single-spin system using a setting of 10 minutes \times 1500g. Other researchers studying the effects of force and time on PRP preparation have concluded that maximum platelet yield is obtained at much lower settings,⁶⁻⁸ eg, 900g \times 5 minutes⁷ or 160g \times 10 minutes.⁷ As time and force increase, yield decreases, leading to a more "platelet pure" sample with fewer erythrocytes and leukocytes, but also lower platelet yield. These studies have demonstrated that a relatively high setting of

1500g \times 10 minutes would lead to maximum volumes of plasma, but lower concentrations of all cell lines, including platelets, similar to the results of other independent studies of the Eclipse PRP system.⁹

Taking such a high value of 4.5 \times for PIF on a single-spin system, at face value, without independent verification, and contrary to other known research, can lead to unfounded conclusions. The only independent testing of concentration in this study, CCA, showed very low PIFs and platelet concentrations. It seems this study looked at the effects of PPP rather than PRP.

Disclosures

Dr Yam has used PRP for regenerative and aesthetic purposes and has been an invited speaker on the preparation and use of PRP in clinical practice for international organizations (eg, IMCAS, FATS). The speaking engagements were unpaid, although one organization offered an honorarium after the fact that has not yet been received. Dr Yam has also used a hematology analyzer to test PRP and blood samples in clinical practice. The author has no financial relationships with any company related to PRP.

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Safety and Performance of POLYTECH Mesmo Breast Implants: A 5-Year Post-Market Surveillance Study on 919 Patients

Objectives

Provide an update on safety and performance outcomes at 5 years for Mesmo breast implants.



Methods

Breast augmentation patients completed questionnaires to assess complications and satisfaction.



Conclusions

With low complication rate, Mesmo implants are a safe choice for both surgeons and patients.



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