Rapid Preparation of Low-Leukocyte and Leukocyte-Enriched Platelet-Rich Plasma with

XCELL PRP

Richard Rosenthal, MD, Medical Director-APEX Biologix, Murray, UT, USA; Aaron Calodney, MD, Baylor Scott & White, Tyler, TX, USA; George Chang Chien, MD, GCC Institute, Arcadia, CA, USA; Sudhir Diwan, MD, Manhattan Spine & Pain Medicine, Manhattan, NY, USA; Matthew Murphy, PhD, Murphy Technology Consulting, Austin, TX, USA

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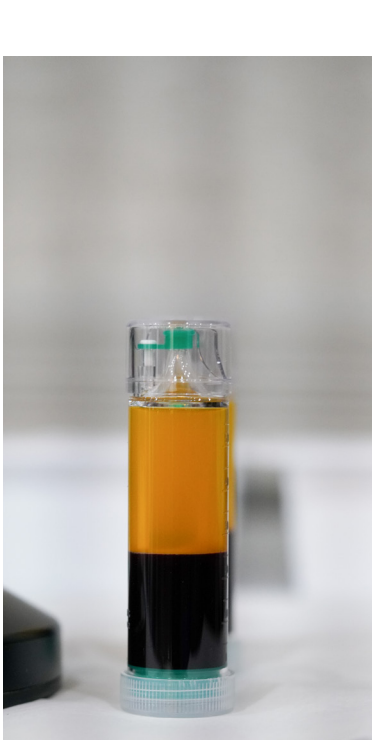
Introduction to Platelet-rich Plasma

Platelet-rich plasma (PRP) is an autologous blood product defined as a volume of plasma that has a supra-physiologic platelet count. These platelets contain over 30 biologically-active growth factors stored in alpha granules. Thus, increased platelet count is an ad hoc measurement of growth factor concentration, which can be utilized for many indications. Widespread use of PRP has been demonstrated to have efficacy to treat pathologic conditions involving orthopedic and spine pathology, as well as dermatologic conditions such as rhytids, commonly referred to as "wrinkles," and acne scarring.

Outcomes from Regenerative Medicine (RM) treatment are multifactorial and depend upon patient selection, pre-/post-procedural protocols, and accurate deposition of product. One key factor in the success of these interventions is the ability to consistently and precisely separate the blood component fractions, including the platelet-poor plasma (PPP), the buffy coat (BC), and the red blood cells (RBC). Additionally, the ability to concentrate the platelets with or without the white blood cells (WBC) allows the user to fine-tune their sample for the unique needs of each individual patient and indication.

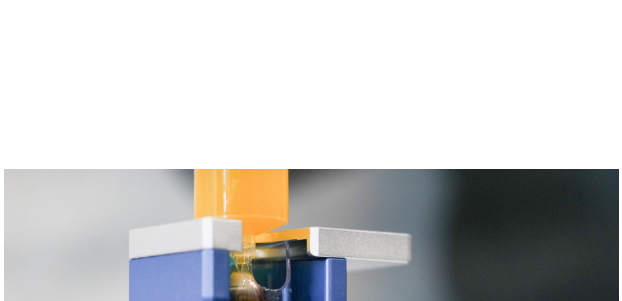
One method to separate the cell fractions is via centrifugation. Published concentration extraction for commercial PRP systems demonstrate a 3-9 fold increase in the concentration of platelets above baseline. Secondary mechanisms in many commercialized systems include gel separators that separate by density. A common drawback of these systems is their low capacity for blood draw volume. Concentration of platelets is simply not enough, for example, in cases where the initial volume is not large enough (e.g. systems that start with <10mL whole blood). The goal of this study was to evaluate the XCELL PRP platelet concentrating system (APEX Biologix, USA), a new device approved by the United States Food and Drug Administration (FDA) for point-of-care PRP separation.



XCELL PRP Concentration Device after centrifuge separation of blood fraction

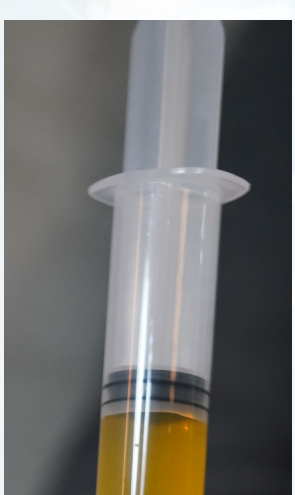
Methods

The XCELL PRP platelet concentration system is a proprietary product approved by the FDA for the point-of-care preparation of PRP (see BK180252/01). This system utilizes a 60mL syringe to draw up a mixture of anti-coagulated blood (51mL blood combined with 9mL anticoagulant citrate dextrose solution (ACDA) (Image 1). It is transferred to the PRP concentration device and centrifuged at 3800 rpm (2300rcf) for 10 minutes to separate blood components that may be collected as separate fractions. This device can tailor PRP to Low-Leukocyte (LL-PRP) and Leukocyte-Enriched PRP (LE-PRP). To evaluate these claims, two PRP separation protocols were followed.



ABBP allows precise separation of the blood fractions.

Low-Leukocyte PRP Methods



Low Leukocyte PRP

Eighty-three donor blood samples were centrifuged using a single-spin technique for 10 minutes at 3800 rpm (2300rcf). PPP was collected in a 60mL syringe using the proprietary XCELL Concentrating Device. Once this was completed, the blood products were separated into 3 general fractions: the PPP, the BC, and the RBCs. The XCELL Concentration Device was then placed into the APEX Biologix Benchtop Press (ABBP) (image 2). This system allows precise control of blood fraction separation. A piston is advanced through the ABBP which makes contact with the base of the XCELL Concentration Device. This base is driven upward through the device, propelling the fractions into a collecting syringe which has been attached to the top of the XCELL device. The user can choose the volume of PPP to remove, and subsequently the volume of enriched plasma, buffy coat and/or RBC appropriate for the desired concentrate. In this study, the PPP syringe was replaced with a 10mL syringe, and a total volume of 6-7mL was collected including the first ~100ul of RBC observed entering the tip of the syringe (image 3). All PRP samples were sent to an independent laboratory (Intermountain Health Care, Central Laboratory, Murray, UT, USA) for characterization of RBC, WBC, and platelets. The average composition of Low-Leukocyte PRP (LL-PRP) is provided in Table 1.

Table 1. Average volume, Platelet (PLT) and WBC concentration in blood and Low-Leukocyte PRP (LL-PRP), percent recovery and enrichment, total PLTs delivered to the patient, and average hematocrit concentration.

n=83 Samples	Avg. Vol (mL)	PLT/mL (millions/mL)	PLT Recovery %	PLT Enrichment over Blood	Total PLT's (billion)	WBC Conc. (millions/mL)	RBC (billion/ mL)
Blood	60.0	182	n/a	n/a	10.9	5.8	4.4
LL-PRP	6.5	1,068	63%	6.0x	6.9	17.0	0.3

Leukocyte-Enriched PRP Methods

To evaluate this system's ability to produce LE-PRP, 44 donor blood samples were centrifuged using a single-spin technique for 10 minutes at 3800 rpm (2300rcf). Platelet-poor plasma (PPP) was collected in a 60mL syringe using the proprietary XCELL Concentrating Device and process. The methodology used is similar to the process for producing LL-PRP except that a total volume of 6-7mL of PRP + BC was collected, including 2mL of RBC (Image 4). PRP samples were sent to an independent laboratory (Intermountain Health Care, Central Laboratory, Murray, UT, USA) for characterization of RBC, WBC, and platelets. The average composition of Leukocyte-Enriched PRP (LE-PRP) is provided in Table 2.

Leukocyte-Enriched Platelet Rich Plasma. Highly concentrated, low volume was selected for this sample.

Table 2. Average volume, Platelet (PLT) and WBC concentration in blood and Leukocyte-Enriched PRP (LE-PRP), percent recovery and enrichment, total PLTs delivered to the patient, and average hematocrit concentration.

n=44 Samples	Avg. Vol (mL)	PLT/mL (millions/mL)	PLT Recovery %	PLT Enrichment over Blood	Total PLT's (billion)	WBC Conc. (millions/mL)	RBC (billion/ mL)
Blood	60.0	177	n/a	n/a	10.6	6.6	4.4
LE-PRP	6.5	936	58%	5.3x	6.1	30.3	2.3

RESULTS

Low-Leukocyte Platelet Rich Plasma Protocol

The XCELL Concentration Device LL-PRP protocol was able to concentrate the platelets on average approximately 6-fold over baseline (1,068 million/mL; 182 million/mL). This same protocol was able to remove over 90% of the RBC from the final product (4.4 billion/mL to 0.3 billion/mL). Leukocyte concentration increased just below 3-fold over baseline (17.0 million/mL; 5.8 million/mL).

Leukocyte-Enriched Platelet Rich Plasma Protocol

The XCELL Concentration Device LE-PRP protocol was able to concentrate the platelets on average approximately 5.3-fold over baseline (936 million/mL; 177 million/mL). This same protocol was able to remove over 52% of the RBC from the final product (4.4 billion/mL to 2.3 billion/mL). Leukocyte concentration increased nearly 5-fold over baseline (30.3 million/mL; 6.6 million/mL).

Conclusions

The XCELL PRP device is a user-friendly blood-fraction-separation system that can efficiently prepare PRP with high concentrations of platelets at customizable product volume with or without enrichment of leukocytes. The device can deliver consistent blood separation to obtain LL-PRP or LE-PRP in a single-spin process quickly and efficiently. It is important to note that LL-PRP or LE-PRP may be prepared as desired by the physician, based on preference and application, without significantly changing XCELL PRP's platelet recovery efficiency, all while dramatically increasing WBC for the LE-PRP concentrate.

References:

The XCELL PRP system is designed and manufactured in the United States. Link to FDA Device Database here:
https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=BK180252