Research Study Comparison of

Angel Whole Blood Separation System and EmCyte PurePRP®

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1. Introduction

The objective of this study was to compare the platelet rich plasma product produced by the EmCyte Pure PRP® device and the platelet rich plasma product produced by the Arthrex Angel Whole Blood Separation System (Angel PRP System).

2. Study Design

This is a single center study of whole blood collected from five healthy human donors, for processing into a platelet rich plasma product according to the manufacturer's instructions for use. The study data was collected by BioSciences Research Associates, Inc. (BSR). BSR provides custom contract research and laboratory services for product development, medical device testing and clinical trials support to Pharmaceutical and Biotechnology companies. All studies were conducted within BSR's Quality Systems and were cGMP compliant. BSR has extensive experience with development, testing and product evaluation for platelet or bone marrow concentration devices, including support for FDA CBER and CDRH filings. Donors met the requirements of the American Association of Blood Banks (AABB). There were no specific exclusion specifications other than the donor be healthy. There was no selection for age, sex or ethnicity. Donors are referenced only by assigned code numbers.

3. Experimental Design

Approximately 150mL of anticoagulated whole blood was obtained from each of 5 donors. The whole blood used for the EmCyte PurePRP® product was collected in Anticoagulant Sodium Citrate Solution, U.S.P. (Fenwal) in a ratio of 1:5 of anticoagulant to whole blood. The whole blood used for the Angel PRP product was collected in Anticoagulant Citrate Dextrose Solution, USP Formula A (Citra Labs) in a ratio of 1:7 of anticoagulant to whole blood. After obtaining a 1mL baseline sample from each sample, the products were prepared according to the manufacturers protocols.

Angel PRP System

The Angel PRP disposable was processed using a program for 70mL whole blood volume with a 7% Hct product. The processing centrifugal time was just over 17 minutes. The system is automated and produced approximately 3mL of PRP. The PRP was diluted with plasma to obtain a 7mL sample according to manufacturer's instructions.

EmCyte PurePRP® System

The PurePRP® concentrating device processed 75mL of whole blood using the PurePRP® Double Spin protocol. The first spin was 3800 RPM for 1.5 minutes in the Executive Series Centrifuge II. After the centrifugation, the plasma containing the platelets was aspirated into a 60mL syringe and transferred to the second concentrating device. The second spin was 3800 RPM for 5 minutes. After this centrifugation the platelets were separated from the plasma forming a clear platelet buffycoat at the bottom of the concentrating device. The platelet poor plasma was aspirated until the concave collection piston arrived at the bottom of the device, trapping approximately 7.5mL of concentrated PRP. The PRP was re-suspended by gentle inversion of the device and then collected into a 12mL syringe.

Comparison of the Angel PRP and the EmCyte PurePRP® product was performed using the following parameter metrics:

Platelet Concentration Factor

Platelet concentrations were measured using a hematology analyzer for baseline whole blood and PRP samples. The platelet concentration factor, which is the ratio of the concentration of platelets in the PRP product to the concentration of platelets in baseline anticoagulated whole blood sample, was determined for each test.

Platelet Yield

Complete blood counts (CBCs) were performed using a hematology analyzer to quantify the platelets contained within the PRP samples. The platelet yield, which is the ratio of the number of platelets in the PRP product to the number of platelets in the baseline anticoagulated whole blood sample, was determined for each device.

Total Deliverable Platelets (Most Significant for Clinical Efficacy)

This is the total amount of platelets in the PRP product that's available for delivery to the patient. It is a reflection of the platelet concentration relative to the PRP volume.

Mononuclear Cell Yield

The mononuclear leukocytes fraction contains the less dense white cells and contains the circulation CD34 positive stem/progenitor cells. The mononuclear yield, which is the ratio of the number of

lymphocytes and monocytes in the PRP product to the number of lymphocytes and monocytes in the baseline anticoagulated whole blood sample, was determined for each device.

Granulocyte Recovery

The granulocytic series of leukocytes are a first line of defense against pathogens. They contain granular enzymes which can degrade extracellular matrix proteins and cause inflammation. The granulocyte yield, which is the ratio of the number granulocytes in the PRP product to the number of granulocytes in the baseline anticoagulated whole blood sample, was determined for each device.

4. Results

A summary of platform protocols is shown in Table 1.

Table 1. Preparation Protocols

System	Whole Blood Baseline (mL)	PRP Product (mL)	Centrifugal Spin Protocol
PurePRP®	**75**	**7.4mL**	**1st Spin: 3800 RPM, 2.5 min 2nd Spin: 3800 RPM, 5 min**
Angel PRP	**70**	**6.9mL**	**7% HCT Standard Protocol**

Platelet recovery, concentration factor and total deliverable platelets for the products from both Angel and EmCyte PurePRP® platforms are summarized in Table 2.

Table 2. PRP Platelet Recovery (average and standard deviation with 5 donors per system)

System	Whole Blood Baseline (PLT x 10^6/mL)	PRP (PLT x 10^6/mL)	Concentration Factor (times baseline)	Yields	Total Deliverable Platelets x 10^6
PurePRP®	**154.8 ± 35**	**1067.6 ± 253**	**6.9 ± 0.7**	**68%± 10**	**7,955± 2230**
Angel PRP	**162.6 ± 51**	**774.2 ± 324**	**4.8 ± 0.7**	**47%± 6**	**5,292± 2027**

Table 3. Leukocyte Yields (average and standard deviation with 5 donors per system)

System	Mononuclear Cell Yield	Granulocyte Cell Yield
PurePRP®	**57% ±17**	**18 % ± 7**
Angel PRP	**46% ± 10**	**7 % ± 7**

5. Discussion

Platelet concentration and platelet yield are the primary hematologic parameters that define the efficiency of a platelet concentrating system. The total number of deliverable platelets is likely to be of significance in determining clinical efficacy. In this report we evaluated the platelet rich plasma product produced with two PRP systems: The EmCyte PurePRP® System and the Angel PRP System. The EmCyte platform had superior platelet recovery with a yield of 68% of starting platelets at a concentration averaging almost 7 times the whole blood baseline. The Angel platform had a poor platelet recovery (average 47% yield) resulting in a significant lower platelet concentration in a 7 ml PRP product. Both systems enriched mononuclear cells and reduced granulocytes in the product. The improved platelet recovery of the EmCyte PurePRP® System resulted in 48% more deliverable platelets than the Angel PRP System, with both systems starting with the same whole blood sample of 61ml whole blood.