BIOSCIENCES RESEARCH ASSOCIATES, INC.

Analysis of Improved GenesisCS Concentrating Systems with the Pilot Automated Aspirator:

Platelet Recovery of greater than 80%

September 15, 2009

Robert J. Mandle, Ph.D.
Investigator
Program in Cellular and Molecular Medicine
Children's Hospital Boston, MA
Immune Disease Institute
Harvard Medical School Affiliate
President
BioSciences Research Associates, Inc.
Cambridge, MA

Prepared by: Robert J. Mandle, Ph.D.

IN VITRO TESTING

1.1 TEST OBJECTIVE:

Studies were conducted at BioSciences Research Associates, Inc. (Cambridge, MA) to evaluate the use of the GenesisCS Component Concentrating System and the GenesisCS Mini Concentrating System for the preparation of a Buffy Coat Platelet concentrate (BCPC) and platelet rich plasma (PRP). Testing was performed using the Pilot Automated Aspirating Machine according to the manufacturer's protocol.

1.2 EXPERIMENTAL DESIGN:

Blood was collected from two donors into blood bags each containing 40ml of acid-citrate-dextrose formula A (ACD-A) (Baxter Health Care), and maintaining an anticoagulant ratio of 55ml of whole blood to 5ml of ACD-A anticoagulant. The blood draw was performed using 16g needle, and all samples were kept at room temperature from time of draw through processing and analysis. All donors signed IRB approved research donation consent forms.

Three GenesisCS Component Concentrating System process disposables, with 60 ml of sample, and three GenesisCS MINI Component Concentrating System process disposables with 30 ml of sample were tested. Two different centrifuges, Drucker model 755VES and IEC model HN-SII as well as purposeful changes in relative centrifugal force, 710 and 570 x g were used to test process robustness. All centrifuge run time was 15 min with zero breaking.

1.2.1 Calculations:

Platelet recovery was calculated as follows:

Where: Plt = BCPC or PRP platelet count
Vol = Volume of CPP or PRP
Plt_0 = Whole blood platelet count
Vol_0 = Total Whole blood processed

Platelet yield = (Plt x Vol) / (Plt0 x Vol0) x 100

Total percent platelet recovery = Σ (BCPC platelet yield + PRP platelet yield).

1.3 RESULTS GENESISCS:

The summary of calculated platelet recovery for the GenesisCS Component Concentrating System and the GenesisCS Mini Concentrating System disposables are shown in Tables I and II respectively.

Table I: GenesisCS Component Concentrating System Platelet Recovery.

	BCPC	PRP	Total PLT Recovery (%)
Yield (%)	66.4	17.4	84

55ml whole blood 5ml ACD-A. Post-Process Platelet Yields Data on file

Table II: GenesisCS Mini Concentrating System Platelet Recovery.

	BCPC	PRP	Total PLT Recovery (%)
Yield (%)	65.3	18.9	84

55ml whole blood 5ml ACD-A. Post-Process Platelet Yields Data on file

The platelet concentration expressed relative to the whole blood baseline platelet concentration is shown in Table III.

Table III: Average Platelet concentration relative to baseline platelet counts for the GenesisCS Component Concentrating System and the GenesisCS Mini Concentrating System disposables

Disposable	GenesisCS	GenesisCS Mini
Yield (%)	*5.7*	*5.3*

27ml whole blood 3ml ACD-A. Post-Process Platelet Yields Data on file

1.4 DISCUSSION

The GenesisCS Component Concentrating System was developed to provide a reproducible method for the preparation of autologous platelet concentrate from a small volume of patient's blood. The data from this study support that the GenesisCS and GenesisCS Mini disposables, used with the Pilot automated controller, utilizing detection sensors and controlled aspiration, produce concentrations of platelets greater than 5 times the concentration of platelets in the patient blood sample in a 7ml (GenesisCS) or 4ml (GenesisCS Mini) volume. High platelet recovery in the BCPC and PRP products provide clinicians with options to use one or both products for the clinical indication and the ability to deliver over 80% of the total platelets in the original blood sample. The yields and platelet concentrations achieved with both GenesisCS systems compare favorably with those achieved with other commercial CPC systems[1, 2.] .

Previous studies have demonstrated that the Dynamic Displacement Disc technology provides consist product in samples with varying hematocrits. Platelets produced with the GenesisCS disposables have been shown to be functional with respect to growth factor release, activation with platelet agonists, and collagen induced aggregation. {link or reference FDA study}

REFERENCES

1. Leitner GC, Gruber R, Neumüller J, et al. Platelet content and growth factor release in platelet-rich plasma: a comparison of four different systems. Vox Sang . 2006 Aug;91(2):135-9.

2. Kevy SV, Jacobson MS. Comparison of methods for point of care preparation of autologous platelet gel. J Extra Corpor Technol . 2004 Mar;36(1):28-35.