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COMPARATIVE ANALYSIS OF A FIRST AND SECOND-GENERATION COMMERCIALLY AVAILABLE PLATELET-RICH PLASMA CONCENTRATION SYSTEM

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Abstract

Background: The use of orthobiologics, particularly platelet-rich plasma (PRP), has become increasingly prevalent for the treatment of musculoskeletal pathologies. However, there is limited research comparing the PRP yields from different commercially available systems. In 2024, the second-generation EmCyte PurePRP® TWO GenesisCS 120 mL Concentrating System was released, and the GS120-PurePRP® II 120 mL Concentrating System was retired.

Methods: This study evaluates the platelet concentrate products from these two PRP systems. A retrospective review of registry data from 20 consecutive patients treated with intra-articular PRP injections for knee osteoarthritis (OA) was conducted. Platelet recovery rate, deliverable platelet dose, and white (WBC) and red blood cell (RBC) counts were analyzed.

Results: There were no statistically significant differences in platelet recovery ($P = 0.4094$) or deliverable platelet dose ($P = 0.4104$) between the two systems.

Conclusion: Platelet recovery rate and dose, WBC and RBC counts were similar between the newly released and legacy systems.

Keywords: *platelet rich plasma; Knee Osteoarthritis; PRP*

INTRODUCTION

Platelet-rich plasma (PRP) is an autologous blood product derived from whole blood, containing high levels of platelets, growth factors, and cytokines.[1] While the precise biological mechanism by which PRP treats knee osteoarthritis (OA) remains uncertain, it is hypothesized that when platelets degranulate, they release growth factors that recruit and activate immune cells, reduce cartilage catabolism, and stimulate chondrocyte synthesis of the cartilage matrix.[2,3] PRP has also been shown to enhance cartilage synthesis, stimulate endogenous hyaluronic acid production, and suppress inflammatory mediators, contributing to pain relief and reduced joint inflammation.[4]

Platelet-rich plasma is typically obtained through centrifugation, separating anticoagulated whole blood to form three layers separated based on cell density: (1) platelet-poor plasma (top layer); (2) a buffy coat containing platelets and WBCs (middle layer); and (3) erythrocytes (lower layer). The EmCyte PurePRP® Concentrating systems utilize a double-spin method to optimize platelet concentration. After the first centrifugation, the top

platelet-poor plasma layer and buffy coat are subjected to a second spin. This concentrates the platelets, which are then resuspended in a predetermined volume of plasma based on the intended target.

Several studies have demonstrated superior outcomes with PRP compared to corticosteroid and hyaluronic acid (HA) injections for knee OA.[5,6] However, consensus on its efficacy remains inconclusive, and current management guidelines do not universally recommend PRP due to heterogeneous evidence in the literature.[7] One key limitation is the lack of standardization in PRP preparation, which affects platelet concentration, platelet dose, leukocyte differential, and injection volume. Despite calls for standardization, no universally accepted PRP injection regimen exists for knee OA.[8–11]

Platelet-rich plasma is typically characterized by its absolute platelet count after centrifugation. However, a major weakness in the literature is inconsistent reporting on PRP composition.[12,13] Multiple commercially available systems exist for PRP preparation, each following different protocols that yield varying final bioformulations.[14–21] Given these discrepancies, a detailed characterization and comparison of commercially available concentrating systems is necessary to accurately quantify platelet concentrations and growth factors. Automated hematology analyzers provide point-of-care analysis, but in many cases, they can be cost-prohibitive, leaving clinicians reliant on white papers and comparative literature to estimate platelet doses.

In 2024, the second-generation EmCyte PurePRP® TWO GenesisCS Concentrating System (EmCyte Corporation, Ft. Myers, FL, USA) was released, replacing the GS120-PurePRP® II Concentrating System. While the legacy PurePRP II system has been independently analyzed,[15,20] no analysis of the new EmCyte PurePRP® TWO GenesisCS System currently exists. This study compares the legacy and second-generation EmCyte system in routine clinical use for patients with knee OA.

METHODS

After Institutional Review Board approval, a retrospective review was performed of consecutive patients who received intra-articular PRP injection for knee OA. Data were obtained from registry records (Databiologics LLC, Gilbert, AZ) from 2024 and included 10 patients treated with PRP from the legacy EmCyte GS120-PurePRP® II Concentrating System, and 10 patients received PRP from the EmCyte PurePRP® TWO 120 mL GenesisCS Concentrating System. No exclusion criteria were applied.

All subjects donated blood on the same day as the procedure. A single technician collected 100 mL of whole blood from each patient using a 21-gauge butterfly needle (Becton Dickson and Company, Franklin Lakes, NJ) with 20 mL of sodium citrate anticoagulant. Immediately after collection, approximately 0.25 mL of whole blood was used for baseline analysis. Each whole blood sample was processed using the manufacturer's protocol to produce PRP,[22,23] and 0.25 mL of PRP was analyzed for platelet, WBC, and RBC count using the Horiba Micros 60 (Horiba ABX Micros Series Hematology Analyzer, Montpellier, France). The provider chose the injectate volume for the specific clinical indication (i.e., unilateral versus bilateral knee injections). Due to variability in injectate volume, the platelet recovery rate and deliverable platelet dose were calculated, along with platelet concentration (Table 1).[24] Statistical analysis was performed to determine the significance using independent two-sample t-tests with significance set at 0.05.

RESULTS

Twenty healthy adult subjects were included (Table 2). Baseline platelet levels and PRP concentrate yields were recorded for both systems (Table 3). The platelet capture rate was 74.1% ± 11.95 for the legacy PurePRP II and 78.3% ± 10.22 for the PurePRP TWO, with no statistically significant difference (P = 0.4094). Deliverable platelet doses were 15.5 billion ± 5.13 for Legacy system and 17.4 billion ± 4.73 for the second-generation system (P = 0.4104). No significant differences were found in WBC (P = 0.4379) or RBC (P = 0.1596) counts between the two systems (Table 4).

Table 1. PRP Output Data – Calculation Formulas

Platelet capture rate %	=	$\frac{\text{(PRP volume) x (PRP platelet concentration)}}{\text{(whole blood volume) x (whole blood platelet concentration)}}$
Platelet Dose ($x10^3/mm^3$)	=	(PRP volume) x (PRP platelet concentration)
WBC Count Final ($x10^3/mm^3$)	=	(PRP volume) x (WBC in platelet concentration)
RBC Count Final ($x10^3/mm^3$)	=	(PRP volume) x (RBC in platelet concentration)

Table 2. Patient Demographics

	LEGACY PurePRP II	PurePRP TWO	*P*
Gender			0.1769
Male	5	2	
Female	5	8	
Age (years)	57.2 (± 9.39)	68.1 (± 5.7)	0.0057

Table 3. Mean Baseline Whole Blood Analysis

	PRP Preparation System		
	LEGACY PurePRP II	PurePRP TWO	*P*
Whole Blood Platelet Baseline ($x10^3/mm^3$)	206.7 ± 45.31	221 ± 43.26	0.4907
WBC Count ($x10^3/mm^3$)	4.98 ± 1.47	5.5 ± 1.16	0.0215
RBC Count ($x10^9$)	3.96 ± 0.56	3.77 ± 0.39	0.3801

Table 4. Mean PRP Analysis

	PRP Preparation System		
	LEGACY PurePRP II	PurePRP TWO	*P*
Volume of PRP obtained (mL)	9.3 ± 2.71	6.1 ± 2.08	0.0083
Platelet Capture Rate (%)	74.1 ± 11.95	78.3 ± 10.22	0.4094
Total Platelet Dose in PRP ($x10^3/mm^3$)	15.52 ± 5.13	17.38 ± 4.73	0.4104
Platelet Concentration Final ($x10^3/mm^3$)	1723.4 ± 453.78	2912.1 ± 455.26	0.00001
WBC Count Final ($x10^3/mm^3$)	135.08 ± 57.36	121.31 ± 48.87	0.4379
RBC Count Final ($x10^3/mm^3$)	1.20 ± 0.22	0.94 ± 0.28	0.1596

The mean PRP volume produced was 6.1 mL ± 2.08 for PurePRP TWO, ranging between 5 and 10 mL, and 9.3 mL ± 2.71 for PurePRP II, ranging between 5 and 14 mL, with higher volume used for bilateral injections compared to unilateral.

DISCUSSION

This study provides a detailed comparison of the legacy and second-generation EmCyte PurePRP® TWO Concentrating Systems. PRP processing methods vary widely, leading to inconsistent reporting of PRP composition and dose.[12,13] Growth factors and cytokines released by the alpha granules within the platelets are thought to influence treatment efficacy,[25] and recent studies indicate a dose-dependent response to PRP with higher platelet doses appearing to provide better clinical outcomes and chondroprotection in knee OA.[26–31] Since PRP's clinical effects may be dose-dependent with specific

"doses" required to achieve a clinical efficacy, validation studies are crucial to comparing PRP processing kits.

Both systems used in this study produce similar PRP preparations, with no significant difference in platelet, WBC, or RBC counts. PRP cell yields and composition are strongly associated with both the kit design, geometry, and the centrifuge parameters.[32–34] Studies have reported high variability across PRP preparation methods.[14–21] There was a statistically significant age difference between groups (P = 0.0057), whereas gender distribution was not significantly different (P = 0.1769).

Baseline platelet count and WBC composition in whole blood were found to decrease with age, resulting in lower concentrations of these cells in the final PRP product, even when using standardized preparation systems.[35–37] PRP derived from younger individuals consistently demonstrates higher concentrations of key growth factors such as platelet-derived growth factor (PDGF), transforming growth factor-beta (TGF-β), vascular endothelial growth factor (VEGF), and insulin-like growth factor-1 (IGF-1), as well as anti-aging proteins such as GDF11 and clusterin, compared to PRP from older donors.[35,38–40] The average age of the Legacy PurePRP II group was younger (57.2, ± 9.39) compared to the PurePRP TWO group (68.1 ± 5.7). Despite the differences in average age, there was no difference in baseline whole blood characteristics, and both systems used in this study produced similar PRP preparations, with no significant difference in PRP bioformulations.

Prior research suggests that gender does not significantly affect total platelet or WBC counts in PRP preparations,[40–42] but can influence leukocyte composition. For example, younger men have a significantly higher neutrophil count when compared to women who are aged 50 years or more.[37] Lymphocyte composition may also vary based on age and gender, though age appears to be the more influential factor.[37] While gender may not greatly impact total cell counts, it can affect cytokine and growth factor profiles. Men tend to have higher levels of interleukin-1 beta (IL-1β), tumor necrosis factor-alpha (TNF-α), fibroblast growth factor-basic (FGF-basic), platelet-derived growth factor (PDGF-BB), and transforming growth factor-beta 1 (TGF-β1).[41] Younger individuals (≤ 25 years) have also been reported to exhibit higher levels of epidermal growth factor (EGF), insulin-like growth factor-1 (IGF-1), and PDGF-BB when compared to those over 25 years.[40]

In this study, the Micros 60 Horiba Hematology Analyzer was used to analyze baseline whole blood and PRP samples. Automated hematology analyzers are routinely employed for complete blood counts (CBCs) and have been validated for whole blood, demonstrating satisfactory accuracy and precision for platelet counting.[43–45] Various hematology analyzers on the market utilize different technologies for platelet counting, including impedance, optical methods, and immunofluorescence techniques.[46] While specific hematology analyzers have been validated for evaluating PRP products,[47–49] some reports and theoretical concerns highlight potential issues such as platelet clumping and machine errors due to the optically lighter color of PRP, which results from reduced RBC content in the PRP.[48,50] The Micros 60 system used in this study calculates CBC through impedance and selective lysing. This Horiba system has been validated for quantifying whole blood samples, as well as PRP.[47]

The primary finding of this study is that the second-generation system provided similar platelet capture rates and bioformulations as the legacy system. For clinicians using the EmCyte system, the transition from the legacy system to a new system without published white paper data to benchmark the device performance can create unknowns. This paper offers guidance on system selection based on yield predictability and dose consistency. The volume of PRP injected differed between groups. The data were collected from outside of a clinical trial, and the volume of PRP injected was based on clinician preference and treatment goals. Due to these differences in the volume of PRP produced, significant differences were observed between systems in platelet concentration. Platelet concentration is dependent on the volume of the injectate, and variability in individual provider protocols resulted in a statistically significant difference in platelet

concentration due to the dilution of the total platelet dose across a larger volume. Despite this, there was no significant difference in platelet dose (0.4104).

The authors attempted to account for this difference in volume by reporting total platelet count and platelet capture rate rather than platelet concentration to assess differences in kit efficiency.

Limitations included the smaller sample size, lack of power analysis, and potential variability in processing. While this study aimed to isolate variability attributable to device characteristics, some variability in processing technique is inevitable due to multiple technicians performing the procedures and the predicted inter-sample variability.[51] This study evaluates variance in the legacy EmCyte GS120-PurePRP® II Concentrating System and the new EmCyte PurePRP® TWO 120 mL GenesisCS Concentrating System, but differences in patient characteristics were not controlled for. Side-by-side testing of the two devices using the same patient would eliminate confounding variances among patients, but this was a retrospective study and reflects the real-world application of these concentration systems. The study could have been strengthened if clinical outcomes were reported. Nonetheless, this provides physicians with comparative data on the new commercially available EmCyte PurePRP® TWO Concentrating Systems to the legacy system to guide decisions about dosing and treatment protocols.

CONCLUSION

Simply defining PRP as an autologous blood product with platelets above baseline values is no longer sufficient.[52,53] To ensure consistency in orthobiologic research, guidelines have been developed for reporting key PRP characteristics, allowing for adequate assessment and reproducibility.[9] However, point-of-care devices for measuring PRP content can be cost-prohibitive and are not widely available in clinics, highlighting the need for white papers or independent publications to evaluate commercially available PRP processing systems. This study found no statistically significant differences in platelet capture rates or deliverable platelet doses between the EmCyte PurePRP® TWO GenesisCS 120 mL Concentrating System and the GS120-PurePRP® II 120 mL systems. These findings should help clinicians choose a PRP concentrating system that best meets their specific needs for a given indication.

CONFLICT OF INTEREST

Dr. Sussman is a consultant for Apex Biologics and teaching faculty for Gulf Coast Biologics.

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FINANCIAL DISCLOSURE

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