



Project 1719 Report

<b>Title: Performance evaluation of Healeon 15 and 30mL PRP tubes</b>	
Principal Investigator(s): Dr. Robert Mandle, BioSciences Research Associates, Cambridge, MA Dr. Natalie Stephens, BioSciences Research Associates, Cambridge, MA	
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Type of Study: Performance Assessment

**Objective of Study:** Evaluate the performances of Healeon Platelet Rich Plasma (PRP) tubes.

**Introduction:**

The performances of the Healeon PRP 15 and 30mL tubes were evaluated. Testing was performed to assess blood fill volume, gel performance, PRP volume, platelet concentration and platelet yield.

**Experimental design:**

For each of fourteen (14) donors, 15mL and 30mL tubes were drawn. An EDTA tube was also drawn for baseline measurements.

Four centrifuge speeds were used: 1) 4500g, 10 min; 2) 1020g, 5 – 6 min; 3) 1020g, 10min; 4) 1600g, 10min.

A Drucker centrifuge, Model # 755VES with a swing bucket rotor was used. The centrifuge parameters were as shown in Table I.

**Table I: Centrifuge settings**

Nominal force (xg)	Time (min)
450	10
1020	5 – 6,
1020	10
1200	10
1600	10

Tubes from each donor were processed to produce a PRP concentrate by removing Platelet Poor Plasma (PPP) prior to re-suspending platelets. The goal was to produce a reduced volume PRP with a higher platelet concentration factor. For 15mL tubes, all ~5.8-6.5mL of the plasma phase was removed during PRP harvest. For 30mL tubes all but ~5.5mL of the plasma phase was removed prior to PRP harvest. Tubes were inverted 7x according to manufacturer's instructions to re-suspend platelets prior to PRP harvest.

Reported parameters:

*Percent Platelet recovery:* calculated from CBC data, using K<sub>2</sub>EDTA tube from each subject as baseline; adjusted for dilution with anticoagulant.

*Concentration factor:* calculated from CBC data, using K<sub>2</sub>EDTA tube from each subject as baseline and adjusted for dilution with anticoagulant. Values reported are for 4.0mL volumes, for 15 and 30mL tubes, respectively.

*Draw volume:* calculated from weight and blood hematocrit. 15mL tubes were filled by vacuum. 30mL tubes were opened and filled with ~30mL of blood.

*Product volume:* measured in graduated pipets.

*Gel performance:* visual inspection, note if gel formed and was positioned at the plasma interface

## Results:

Table II: **Fill volume, Product volume, and Gel performance.**

<b>Tube Type</b>	<b>Fill Volume</b>	<b>Product Volume</b>	<b>Gel performance</b>
<b>15mL</b>	12.3 (0.95)	6.4 (0.43)	Good
<b>30mL</b>	32.8 (0.46)	5.8 (2.16)	Good

Mean (Standard deviation); n = 14

Table III: **Mean Platelet Recoveries and Concentration Factor at t = 0 and t = 1hr**

For the 15mL and 30mL tubes, platelet recovery and concentration factor was 2.5 – 3.8-fold immediately after PRP harvest.

To determine whether platelets were trapped in the gel, tubes were rocked gently for a minimum of 1hr to allow platelet release, then platelet counts were repeated.

	<b>PRP (%)</b>		<b>Conc. Factor (x baseline)</b>	
	<b>15mL</b>	<b>30mL</b>	<b>15mL</b>	<b>30mL</b>
<b>0hr</b>	40% (11)	55% (8)	2.5 (0.7)	3.8 (0.7)
<b>1hr</b>	44% (16)	56% (16)	2.8 (1.1)	3.8 (1.4)

Mean (Standard deviation)

Platelet recovery and concentration factor increased for both tubes after 1 hr.

Table IV: **Effect of Speed on Platelet Recovery (%) and Concentration Factor in 15mL Tubes, t = 0**

Several centrifuge speeds (450g – 1600g) were tested to minimize loss of platelets in the plasma fraction.

	<b>% Platelet Recovery</b>		<b>Conc. Factor</b>
	<b>PRP</b>	<b>PPP</b>	
<b>450g</b>	35%	45%	2.2
<b>1020g</b>	43%	43%	2.5
<b>1200g</b>	37%	23%	2.7
<b>1600g</b>	24%	33%	2.4

**Table V: Effect of Speed on Platelet Recovery (%) and Concentration Factor in 30mL Tubes, t = 0**

	% Platelet Recovery		Conc. Factor
	PRP	PPP	
<b>450g</b>	35%	45%	3.7 - 4.3
<b>1020g</b>	53%	22%	3.6 – 4.1
<b>1200g</b>	34%	21%	3.0
<b>1600g</b>	24%	35%	2.2

While, platelet loss in the plasma fraction was minimal at 1600g, platelet recovery in the PRP concentrate was also lowest at this speed. The highest platelet recoveries were measured at lower speeds.

At all speeds tested, average platelet recoveries were >70% for 15mL and 30mL tubes.

**Table VI: Platelet Recovery (%) in PRP and PPP fractions and Concentration Factor By Donor in 15mL Tubes, t = 0**

	PRP (%)	PPP (%)	Total Yield (%)	Conc. Factor (x baseline)
<b>D1001</b>	32%	60%	92%	2.6
<b>D1002</b>	44%	39%	83%	2.1
<b>D1003</b>	41%	31%	72%	2.2
<b>D1004</b>	36%	31%	67%	2.1
<b>D1005</b>	50%	31%	81%	2.7
<b>D1006</b>	52%	35%	87%	2.6
<b>D1007</b>	44%	44%	88%	2.7
<b>D1008</b>	47%	26%	73%	2.7
<b>D1009</b>	42%	27%	69%	2.4
<b>D1010</b>	49%	29%	78%	2.5

Table VII: Platelet Recovery (%) and Concentration Factor By Donor in 30mL Tubes, t = 0

	PRP (%)	PPP (%)	Total Yield (%)	Conc. Factor (x baseline)
<b>D1001</b>	45%	31%	76%	4.1
<b>D1002</b>	37%	35%	72%	3.6
<b>D1003</b>	45%	32%	77%	4.0
<b>D1004</b>	46%	28%	74%	3.7
<b>D1005</b>	38%	34%	72%	3.8
<b>D1006</b>	52%	31%	83%	4.3

**Discussion:**

The gel separator moved and reformed at the plasma interface in all tubes at all centrifuge speeds (450g – 1600g). The average fill volume and product volume were 12.3mL and 6.4mL respectively, in the 15mL tube. The average product volume was 5.8 mL in the 30mL tube. Since the 30mL tubes were opened and the vacuum disrupted to fill each tube, the fill volume of 32.8mL may not be representative of a vacuum-driven draw volume.

The average platelet recoveries were > 70% for the 15mL tube and 30mL tube immediately following PRP harvest for all centrifuge speeds tested.

At 1600g, platelet loss in the PPP was minimal, however PRP yields were also the lowest.

Platelet concentration factor was increased by removal of the plasma phase to 2.5 fold (15mL) and 3.8 fold (30mL). An hour of gentle rocking resulted in a minimal increase in platelet recovery of <5% for both tubes, and increased concentration factors to 2.8 fold (15mL) and 4.2 fold (30ml)