The Arthrex Autologous Conditioned Plasma Double Syringe System®

Arthrex, Inc. Research and Development

Introduction

The Arthrex Autologous Conditioned Plasma (ACP) Double Syringe System is designed to concentrate platelets from a patient's own peripheral blood. The system features the patented double syringe technology which eliminates a second centrifugation step. The ACP System is fast, efficient and unique to the market.

Production of ACP

Figure 1 illustrates the ACP process. In step 1, 1.5 mL of anticoagulant citrate dextrose solution A (ACD-A) is drawn into the larger 15.5 mL syringe. ACD-A is a mixture of citric acid, sodium citrate and dextrose which acts as an anticoagulant by binding free calcium in the blood. If ACP is going to be used within thirty minutes of blood withdrawal, the use of ACD-A is not required. In step 2, 14 mL of the patient's peripheral blood is drawn into the larger syringe. In step 3, the entire syringe containing the whole blood is centrifuged at 1500 rpm for 5 minutes. This separates red blood cells (RBCs) from the platelet-containing plasma solution, but does not separate what is within the plasma further. In step 4, up to 6 mL of the platelet concentrate solution is carefully drawn into the smaller syringe, with care taken to not draw up any RBCs into the smaller syringe. In step 5, the smaller syringe is unscrewed from within the larger syringe. Finally in step 6, the ACP is ready to use at the point of care. What makes this system so attractive is the lack of a second centrifugation step, while still having a platelet concentrate solution in an easily removable syringe for application.

Cellular Concentrations in ACP

A study compared cellular concentrations in ACP vs. whole blood.[1] As seen in Table 1, ACP concentrated platelets while keeping WBC and NE concentrations well below baseline whole blood values. Also, in Table 2, ACP kept the hematocrit percentage (HCT %), or volume percentage of red blood cells, very minimal. An important aspect of ACP is the elimination of leukocytes, specifically neutrophils, as proteases and hydrolases within white blood cells can have catabolic effects.[2]

Comparison to Other PRP Products

Table 3. shows a comparison of various platelet concentrate products on the market. ACP contained 2.4x more platelets than whole blood, while WBC and NE concentrations were below baseline at 0.54x and 0.06x, respectively. In comparison to the competitive systems, ACP was very effective at concentrating platelets while removing the unnecessary and potentially harmful neutrophils.

Since the formation of platelet concentrate can depend on patient and processing variables that could interact with each other, there is no real range for platelet concentration over baseline. Therefore, each individual patient may require a different concentration for treatment to be effective.[3]

It has been described that a concentration of $3x10^5$ platelets/μL and 2-3x platelet concentration over baseline may help in the normal healing process.[3, 4]

A 2-3x platelet concentration can lead to an increase in proliferation of human osteoblasts and gingival fibroblasts *in vitro*.[5] There is sufficient evidence that a 2-3x platelet concentration over baseline may help in the normal healing process [3, 4].

References

1. Unpublished data

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4. Anitua E, Andia I, Ardanza B, Nurden P, Nurden AT. Autologous platelets as a source of proteins for healing and tissue regeneration. *Thromb Haemost*. 2004;91(1):4-15.

5. Graziani F, Ivanovski S, Cei S, Ducci F, Tonetti M, Gabriele M. The in vitro effect of different PRP concentrations on osteoblasts and fibroblasts. *Clin Oral Implants Res.* 2006;17(2):212-219.

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Figure 1: Steps in production of ACP using double syringe system

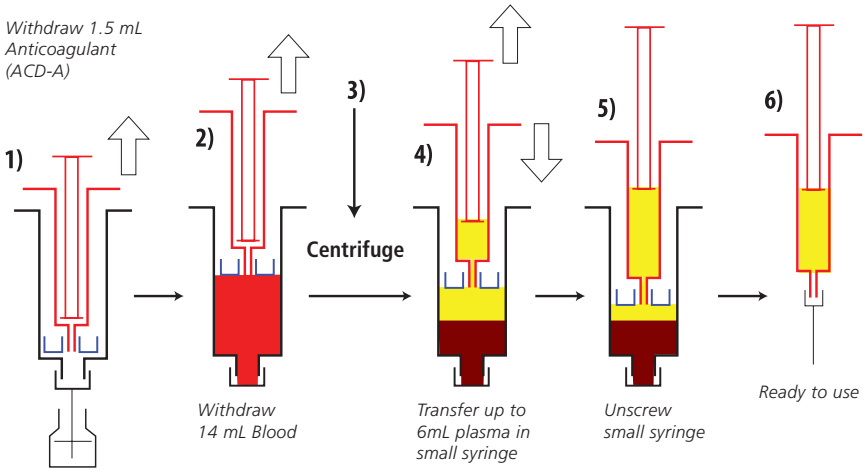

Table 1 – Straight output cellular concentrations of PRP systems

System, Company	PLT (k/uL)	WBC (k/uL)	NE (k/uL)
[1]ACP®, Arthrex®	545 ± 124	2.65 ± 1.97	0.11 ± 0.07
[1]GPS III, Biomet®	1343 ± 670	27.30 ± 7.14	9.44 ± 6.99
[1]Magellan®, Arteriocyte	1988 ± 1224	19.85 ± 17.65	4.11 ± 6.62
[1]GenesisCS, EmCyte	1129 ± 263	20.58 ± 3.90	7.42 ± 3.14
[1]SmartPReP, Harvest®	1507 ± 405	22.85 ± 4.34	4.21 ± 2.04
[2]Regen, Stryker®	360 ± N/A	6.28 ± N/A	N/A

Table 2 – Straight output PRP volumes and HCT%

System, Company	mL	HCT (%)*
[1]ACP®, Arthrex®	4.6 ± 1.4	0.3 ± 0.1
[1]GPS III, Biomet®	6.1 ± 0.2	9.1 ± 8.0
[1]Magellan®, Arteriocyte	5.3 ± 1.6	9.8 ± 12.1
[1]GenesisCS, EmCyte	6.0 ± 0.0	27.4 ± 14.1
[1]SmartPReP, Harvest®	7.0 ± 0.0	28.9 ± 4.4
[2]Regen, Stryker®	4.9 ± N/A	N/A

Table 3 – Straight output cellular ratios compared to whole blood of PRP systems

System, Company	PLT Increase	WBC Increase	NE Increase
[1]ACP®, Arthrex®	2.40x	0.54x	0.06x
[1]GPS III, Biomet®	6.41x	5.40x	3.58x
[1]Magellan®, Arteriocyte	9.29x	3.85x	1.99x
[1]GenesisCS, EmCyte	5.53x	4.10x	2.86x
[1]SmartPReP, Harvest®	7.25x	4.30x	1.57x
[2]Regen, Stryker®	1.70x	0.95x	N/A

Notes:
[1]In-house data
[2]Published data, where N/A = not reported
*Normal human circulating levels of HCT%=35.50%

The Double Syringe (ACP) System is used to facilitate the safe and rapid preparation of autologous platelet-rich plasma (PRP) from a small sample of blood at the patient's point of care. The PRP can be mixed with autograft and allograft bone prior to application to an orthopaedic surgical site as deemed necessary by the clinical US requirements.