Comparative of Arthrex ACP® and Thrombinator™ System to Regen Lab RegenKit-BCT Plus Kit for the Preparation of PRP and Autologous Thrombin Serum

Arthrex Research and Development

Introduction

Platelet-rich plasma (PRP) is defined by an above-baseline concentration of platelets, with commercial systems achieving 2 to 6 times baseline depending on sequestration of additional blood cell components such as leukocytes.[1] Thrombin is a multifunctional enzyme that converts soluble fibrinogen in plasma to an insoluble fibrin clot and triggers degranulation of platelets, resulting in the release of growth factors, cytokines, and other bioactive molecules.[2,3] In practice, PRP and thrombin are mixed with autograft or allograft bone to improve handling characteristics prior to application to an orthopedic surgical site. The Arthrex ACP® system and Thrombinator™ system provide a rapid means of preparation of PRP and autologous serum. The purpose of this study was to compare the Arthrex system to the similarly marketed Regen Lab's RegenKit® BCT Plus kit for production of leukocyte-reduced PRP and autologous serum.

Methods

Seven healthy normal adult blood donors were used in this paired study. A licensed phlebotomist drew whole blood (WB) from donors after obtaining written informed consent. A small sample of blood was saved for baseline analysis, then blood was processed according to standard instructions for use provided with the kits. Briefly, a large volume of ACP was prepared as both the PRP and input fluid into the Thrombinator system. For the RegenLab system, 10 mL WB was collected into each of the two vacutainer tubes labeled "RegenBCT" and "RegenATS". The tubes were processed in a RegenLab centrifuge with preset centrifuge settings. The RegenBCT tube was removed from the centrifuge and inverted multiple times to resuspend platelets above the gel before harvesting the PRP. The RegenATS tube was centrifuged again for an additional 5 minutes prior to collection of the autologous serum.

After the PRP was harvested, a complete blood count (CBC) was performed on PRP and WB samples (Horiba Micro60). Thrombin activities were determined for both the Thrombinator and RegenLab sera when combined in a 1:1 ratio (100 µ thrombin serum to 100 µ pooled plasma) using time to clot on an automated coagulation analyzer as compared to a thrombin standard (Diagnostica Stago). Coagulation testing was performed 0 and 30 minutes after harvesting the thrombin sera from the devices.

Platelet gels of thrombin serum were made for each donor immediately post-production using a 1:1 ratio (v/v) of PRP to thrombin serum from each system. Gels were incubated for 0.5 or 2 hours at 37° C. After incubation, the supernatant was collected after centrifugation (2940 g for 5 minutes) and frozen at -70° C. Samples were sent to Eve Technologies (Calgary, Canada) for growth factor analysis using Luminex® multiplexing technology.

Results were compared in Sigmaplot 14 (Systat) using paired t-tests if normally distributed; otherwise, a Wilcoxon signed rank test was used.

Results

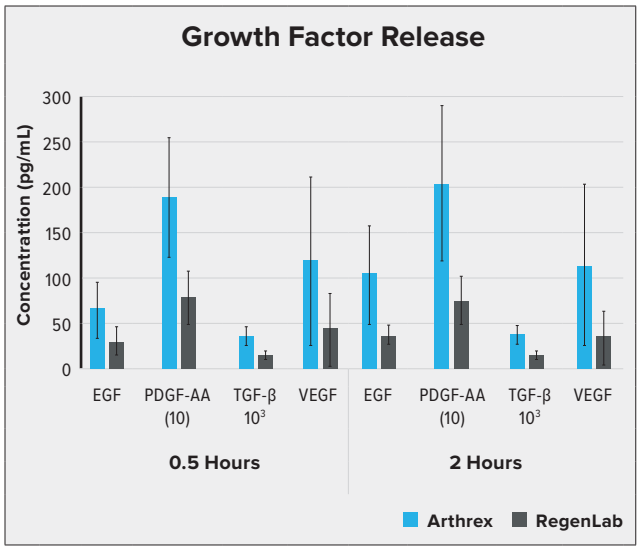
Comparison of the systems' autologous products are shown in Table 1. The Arthrex ACP PRP had a twofold increase in platelet concentration compared to baseline, in contrast to the RegenLab product that was not enriched for platelets ($p<0.01$). Both systems were similarly depleted of red blood cells and white blood cells. Serum prepared using the Thrombinator system had higher levels of thrombin activity immediately and after 30 minutes when compared to RegenLab thrombin activity ($p<0.01$).

Table 1. Comparison of Autologous Products

	PRP			Thrombin	
	PLT Fold X	**WBC Fold X**	**RBC Fold X**	**Immediate Thrombin Activity (U/mL)**	**30 min Thrombin Activity (U/mL)**
Arthrex	2.1 ± 0.2	0.02 ± 0.01	0.01 ± 0.01	29.1 ± 1.6	6.9 ± 1.3
RegenLab	0.4 ± 0.2	0.04 ± 0.01	0.00 ± 0.00	8.8 ± 2.7	0.8 ± 0.8
p value	p<0.01	p<0.01	p=0.50	p<0.01	p<0.01

Growth factors (EGF, PDGF-AA, TGF-β1, and VEGF) were released in higher concentrations from Arthrex-derived PRP gels compared to RegenLab-derived gels. This was maintained at 0.5 and 2 hours post gel creation.

Figure 1. Comparison of growth factors from combined PRP and thrombin gels. Concentrations in pg/mL for different growth factors are modified by an order of magnitude of 10 if indicated. All groups were significantly different (p<0.05).



Discussion and Conclusions

The RegenLab system employs centrifugation and relies on a thixotropic gel to separate platelets, whereas the Arthrex system employs rate-controlled centrifugation to isolate platelets. The results demonstrated that the Arthrex system generated PRP that was significantly richer in platelets than the RegenLab system. The Regen Lab PRP tube produced plasma with an insufficient concentration of platelets to meet the minimum definition of PRP.[2]

The two-step Thrombinator™ system with ACP produced a bolus of high thrombin activity serum that maintained usable levels out to 30 minutes, relative to the 2-spin RegenLab system. When these sera were mixed with the relative PRP systems, the Arthrex system had more than twice the concentration of platelet-derived cytokines and growth factors than the the RegenLab's platelet gel supernatants.

References

1. Alves R, Grimalt R. A review of platelet-rich plasma: history, biology, mechanism of action, and classification. *Skin Appendage Disord.* 2018;4(1):18-24. doi:10.1159/000477353
2. Sclafani AP, Saman M. Platelet-rich fibrin matrix for facial plastic surgery. *Facial Plast Surg Clin North Am.* 2012;20(2):177-vi. doi:10.1016/j.fsc.2012.02.004
3. Sang Y, Roest M, de Laat B, de Groot PG, Huskens D. Interplay between platelets and coagulation. *Blood Rev.* 2021;46:100733. doi:10.1016/j.blre.2020.100733

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