Owl Manor Veterinary®

Bringing New Life to Animal Health™



Point-of-Care Regenerative Medicine • Tendons - Ligaments - Joints - Wounds



Point-of-Care Convenience • Prepared Under 30 Minutes • Natural - Drug-Free



Platelet - Buffy Coat Concentrate



Autologous Protein Solution w/ IL-1ra



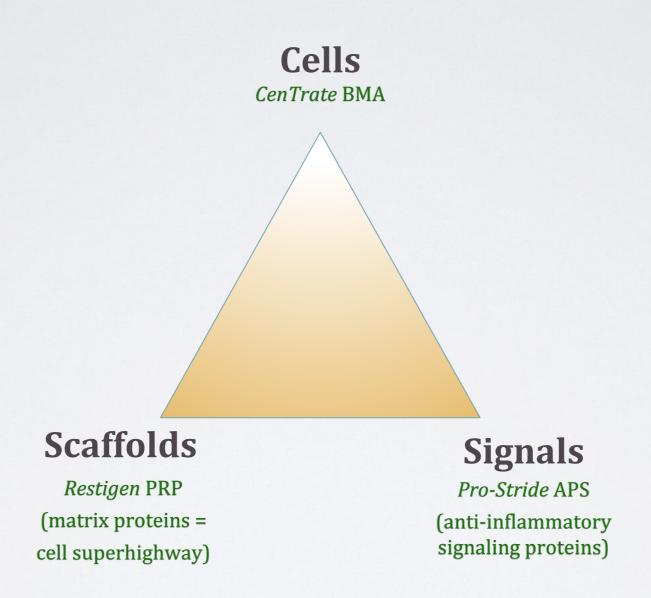
Bone Marrow Aspirate
Concentrate







Regenerative Medicine



Promote natural healing, restore normal tissue function, regrow normal structures



About Owl Manor Veterinary

- US operations based in Warsaw, IN (Worldwide Orthopedic Capital)
- Products have nearly 20 year development history (human and animal) in conjunction with leading biomedical companies
 - Ongoing clinical / data collaboration (15+ year commercial history)
 - Patented designs
- Manufactured in ISO 13485 Certified Facility (Huntington, IN)
- Products available throughout US and Internationally









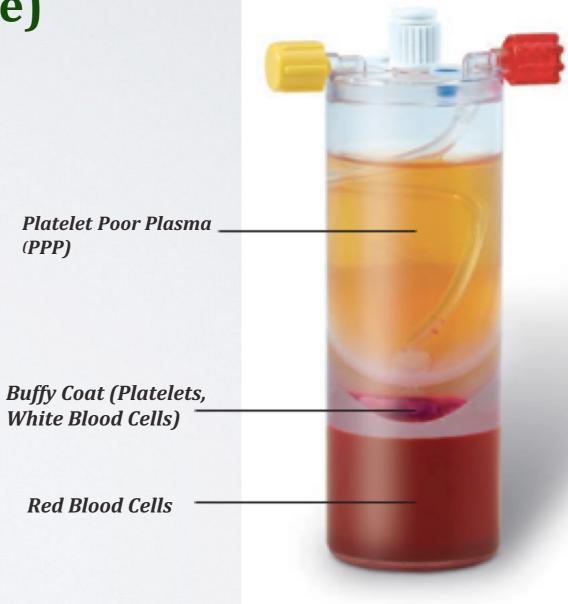
Restigen.

(Platelet - Buffy Coat Concentrate)

Restigen is a proprietary platelet isolation device that maximizes platelet recovery / capture and concentration.

- 90% platelet recovery / capture
- 9X platelet concentration
- 15 minute blood processing
- Natural Drug-Free

- Floating buoy adjusts to Hct
- Platelets and white cells are kept in tact





Restigen

Restigen

Equine autologous platelet concentrates: A comparative study between different available systems

L. N. HESSEL, G. BOSCH, P. R. VAN WEEREN and J.-C. IONITA*†

Department of Equine Sciences, Faculty of Veterinary Medicine, Utrecht University, The Netherlands †Large Animal Clinic for Surgery, Faculty of Veterinary Medicine, University of Leipzig, Germany.

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Summary

Reasons for performing study: Autologous platelet concentrates (APCs) are being used increasingly in horses to enhance regeneration in tissues that have poor natural healing capabilities. Numerous APC systems, which are based on different preparation techniques and were originally developed for human patients, are now routinely used in equine cases. However, preliminary process validation and adequate *in vitro* biochemical characterisation of most of these systems do not exist for horses.

Objectives: To compare haematological findings and growth factor concentrations of equine APCs obtained with 4 commercially available systems and a noncommercial double-centrifugation technique.

Study design: Nonrandomised in vitro experiment.

Methods: Blood samples from 6 horses were processed to produce APCs using one equine-specific filtration-based and 4 different centrifugation-based techniques. Platelet, leucocyte, platelet-derived growth factor-BB and transforming growth factor- β_1 concentrations were measured in all APCs, and their respective enrichment factors were compared.

Results: Mean platelet concentration increased in all systems in comparison to baseline; however, the mean enrichment factor, which ranged from 130% to 527% depending on the APC, was statistically significant in only 2 products. One method reduced total leucocyte counts to 9% of the baseline value, while the others had a mean fold increase varying from 116 to 663% of the baseline. Differential leucocyte count also differed between the products. Moreover, the various systems had significantly different mean growth factor enrichments (184–1255% for platelet-derived growth factor-BB and 93–560% for transforming growth factor-B₁).

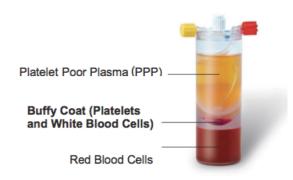
Conclusions: Haematological and biochemical characteristics varied markedly among 5 techniques used in the field to produce APCs in horses. These discrepancies could have an impact on clinical outcomes, and further studies are needed to determine their influence on the quality of tissue regeneration. Clinicians should not rely on the manufacturers' data relating to human patients to select the most appropriate method for horses.

Keywords: horse; platelet concentrates; growth factors; platelet-rich plasma; tissue regeneration; comparison

Equine Veterinary Journal 47 (2015) 319–325

Restigen™ PRP (Platelet-Buffy Coat Concentrate) Restigen is a proprietary platelet isolation device that maximizes platelet recovery / capture and concentration.

- 9X platelet recovery / capture
- 90% platelet concentration
- 15 minute blood processing

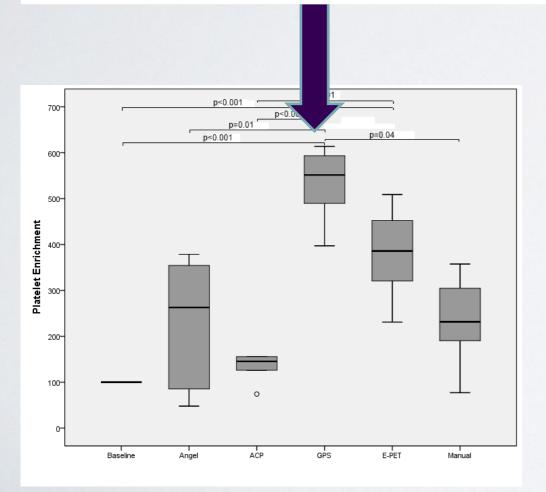




Restigen

Equine autologous platelet concentrates: A comparative study between different available systems

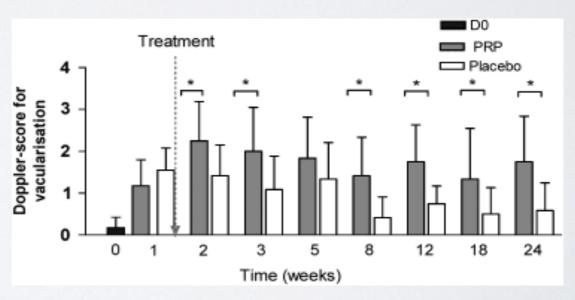
L. N. HESSEL, G. BOSCH, P. R. VAN WEEREN and J.-C. IONITA* †



Injection of platelet- and leukocyte-rich plasma at the junction of the proximal sesamoid bone and the suspensory ligament branch for treatment of yearling Thoroughbreds with proximal sesamoid bone inflammation and associated suspensory ligament branch desmitis

Katherine S. Garrett, DVM, DACVS; Lawrence R. Bramlage, DVM, MS, DACVS; Deborah L. Spike-Pierce, DVM; Noah D. Cohen, VMD, PhD, DACVIM

Horses treated with Restigen were significantly more likely to start at least 1 race during the 2 year old racing year



Horse tendons treated with Restigen had sustained greater vascularization- a mark of tissue healing



Restigen Comparison

	RESTIGEN	VARIOUS SYSTEMS*	
Processing Time	15 minutes	15 minutes	
Platelet Yield	90%	~60%	
Platelet Concentration	<u>9X</u>	2X	
White Blood Cells	<u>High yield</u>	variable	



PRO-STRIDE MAPS

(Autologous Protein Solution w/ IL-1ra)

Pro-Stride is a proprietary dual-device system whose output produces a concentrated solution of cells, platelets, growth factors, and anti-inflammatory proteins (including IL-1ra and other anabolic proteins).

- < 20 minute blood processing (no incubation)
- *Clinically demonstrated pain relief at 52 weeks
- Natural Drug-Free
- Ambulatory convenience

*A. Bertone, Am J Vet Res 2014; 75:141-151

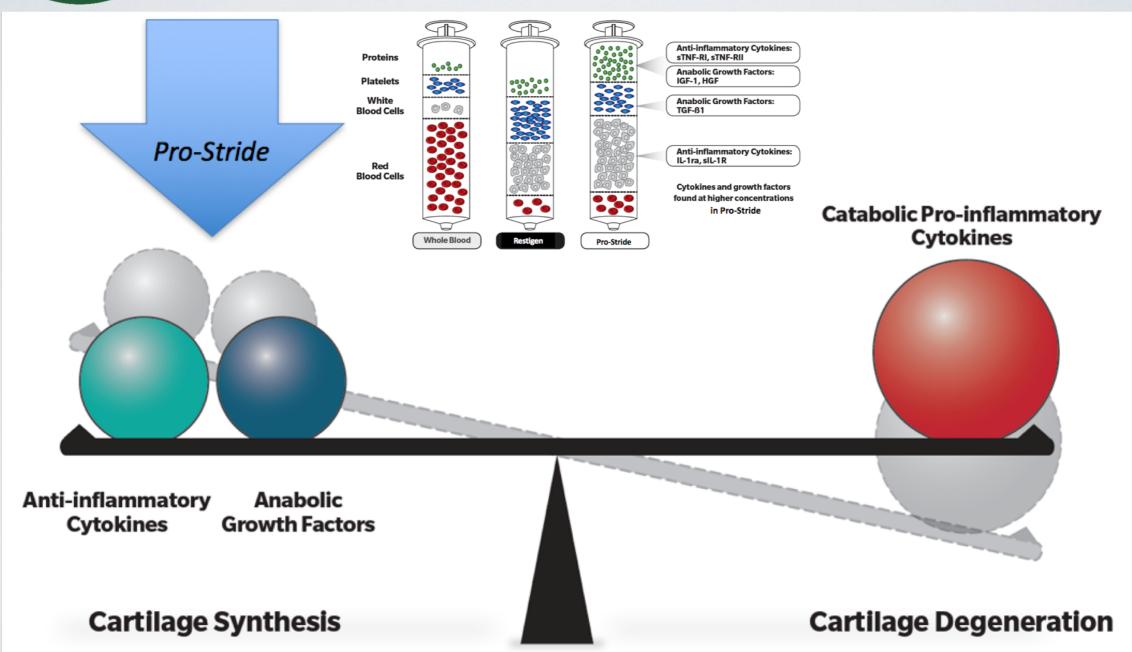






PRO-STRIDE MAPS

(Autologous Protein Solution w/ IL-1ra)



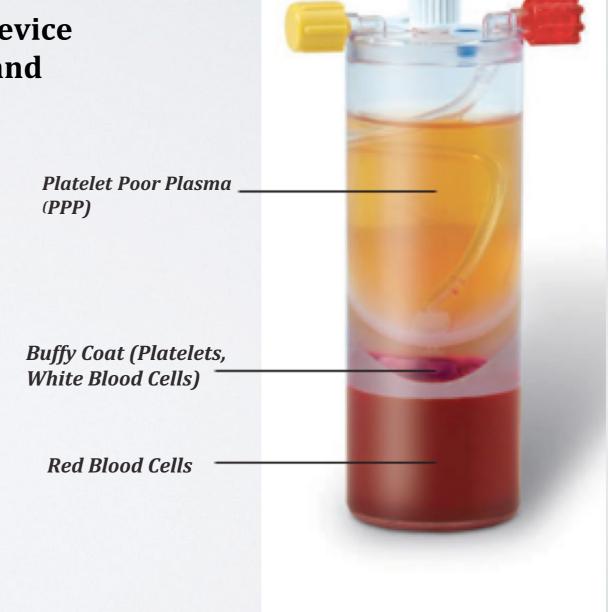


Step 1

Platelet - Buffy Coat Separation / Concentration Device

Device 1 is a proprietary platelet isolation device that maximizes platelet recovery / capture and concentration.

- 90% platelet recovery / capture
- 9X platelet concentration
- 15 minute blood processing
- Natural Drug-Free
- Floating buoy adjusts to Hct
- Platelets and white cells are kept in tact



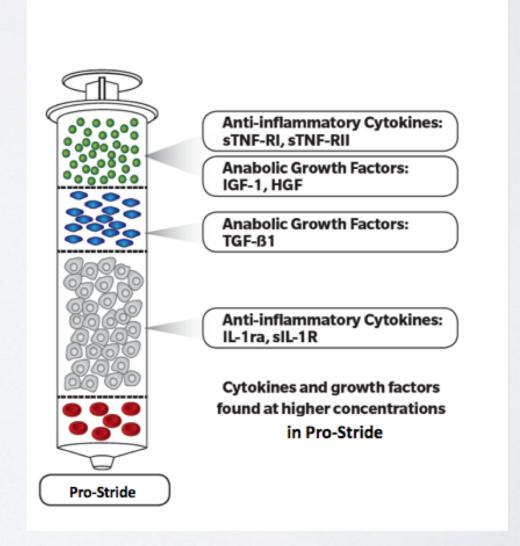


Step 2

APS Concentration Device

Device 2 is a proprietary device that produces a concentrated solution of cells, platelets, growth factors, and anti-inflammatory proteins (including IL-1ra and other anabolic proteins).

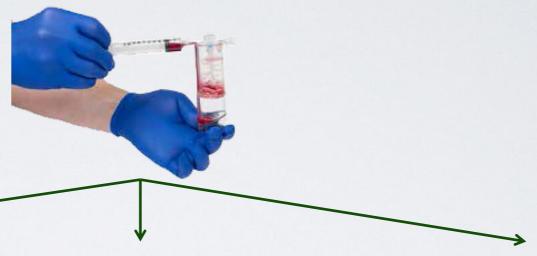






PRO-STRIDE MAPS

Composition of Pro-Stride



White Blood Cells



IL-1ra sTNF-RI sTNF-RII **Platelets**



TGF-β VEGF
PDGF EGF
FGF-2

Concentrated Plasma



sIL-1R IGF-1 sTNF-RI HGF sTNF-RII A2M



PRO-STRIDE





Load Device 1 (60 ml anti-coagulated blood)



Centrifuge (15 min @ 3200 RPM)





Prepare PRP (90% Recovery/9x **Concentration**)



Load Device 2



Centrifuge (2 min @ 2000 RPM)



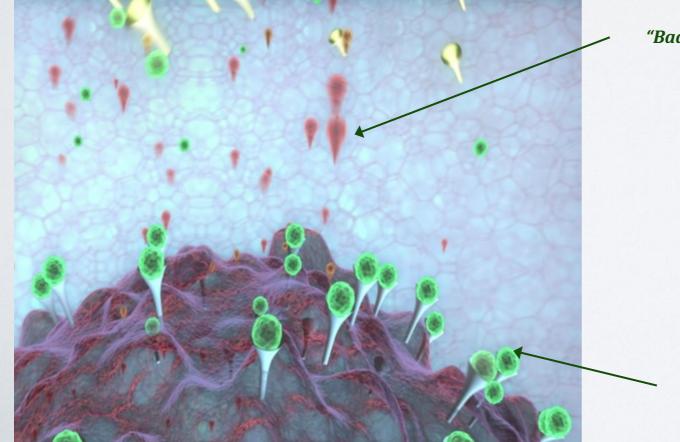
Pro-Stride APS



PRO-STRIDETM APS

Why is *Pro-Stride* Different?

- No incubation required
- Autologous Platelet Solution (not an Autologous Conditioned Serum ACS)
- No freezing / subsequent injections
- Pro-Stride is a supercharged PRP + anti-inflammatory (including IL-1ra) concentrate



"Bad" Proteins (IL-1b)

These high concentrations of "good" (IL-1ra) proteins have shown to block inflammation and prevent cartilage degradation.

"Good" (IL-1ra) proteins attach to cells and balance is restored.

"Good" Proteins (IL-1ra)



PRO-STRIDE MAPS

PRO-STRIDE"

APS

Evaluation of a single intra-articular injection of autologous protein solution for treatment of osteoarthritis in horses

Alicia L. Bertone, DVM, PhD; Akikazu Ishihara, BVSc, PhD; Lisa J. Zekas, DVM;
Maxey L. Wellman, DVM, PhD; Katharine B. Lewis, BS; Rebecca A. Schwarze, BS;
Andrea R. Barnaba, BS; Michael L. Schmall, DVM, MS; Peter M. Kanter, DVM, PhD; Ron L. Genovese, VMD

Objective—To evaluate intra-articular autologous protein solution (APS) for the treatment of osteoarthritis in horses.

Animals—40 client-owned horses with naturally occurring osteoarthritis.

Procedures—APS was generated from a dual-device system that concentrated plasma and WBC proteins and enriched platelet growth factors. Horses were randomly assigned to receive an intra-articular injection of 5 mL of saline (0.9% NaCl) solution (n = 20) or APS (20), exercised on a treadmill, and evaluated on the basis of lameness grades, kinetic gaint analysis, joint circumference, and range of motion for 14 days. Horses that received saline solution were administered APS at termination of the study, and clients scored horses for lameness and discoppleratioenter, textweeks after, and 52 weeks after the APS injection.

Results—The APS group had significant improvements in lameness grade, asymmetry indices of vertical peak force, and range of joint motion by 14 days, compared with baseline or control group values. No adverse effects associated with APS treatment were evident. Clients assessed lameness and comfort as improved at 12 and 52 weeks. The APS had greater likelihood (OR, 4.3 to 30.0) of a therapeutic response in horses with a lameness score < 4, < 10% vertical force asymmetry, or absence of marked osteophyte formation, subchondral sclerosis, or joint space narrowing. Concentration of interleukin-1 receptor antagonist in APS was 5.8 times that in blood.

Conclusions and Clinical Relevance—Intra-articular administration of APS can be considered an effective treatment option for equine osteoarthritis, with the potential for disease-modifying effects. (Am J Vet Res 2014;75:141–151)





Pro-Stride™ APS

(Autologous Protein Solution w/ IL-1ra)

Pro-Stride APS is a proprietary dual-device system
whose output produces a concentrated solution of
cells, platelets, growth factors, and anti-inflammatory
proteins (including IL-1ra and other anabolic

- <20 minute blood processing (no incubation)
- Clinically demonstrated pain relief at 52 weeks following a single injection. (A. Bertone, Am J Vet Res 2014; 75: 141-151)
- Natural Drug Free
- Ambulatory convenience



Evaluation of a Single Intra-Articular Injection of Autologous Protein Solution for Treatment of Osteoarthritis in a Canine Population

Audrey W. Wanstrath, Bianca F. Hettlich, Lillian Su, Ashley Smith, Lisa J. Zekas, Matthew J. Allen, and Alicia L. Bertone

Department of Veterinary Clinical Sciences, College of Veterinary Medicine, The Ohio State University, Columbus, Ohio

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DOI:10.1111/vsu.12512



Pro-Stride™ APS

Objective: To evaluate the safety and efficacy of an intra-articular injection of autologous protein solution (APS) for treatment of canine osteoarthritis (OA).

Study Design: Prospective, randomized, blinded, placebo-controlled pilot clinical trial.

Animals: Client-owned dogs with single limb lameness because of OA in a stifle or elbow joint (n=21).

Methods: Lame dogs, confirmed with OA by physical and lameness examination and imaging, were randomly assigned to control or treatment groups. Owners, blinded to treatment, scored pain (University of Pennsylvania Canine Brief Pain Inventory) and lameness severity (Hudson Visual Analogue Scale [HVAS]). Weight-bearing was assessed by kinetic gait analysis. Dogs were injected intra-articularly with APS (treatment group) or saline solution (control group). Evaluations were performed before injection, and 2 and 12 weeks post-injection.

Results: Compared to pretreatment values, APS treatment data showed a significant improvement in week 12 pain scores (improved 25.6% over baseline), lameness scores (improved 15% over baseline) and peak vertical force (PVF; N/kg; increased 14.9% of baseline), as well as vertical impulse (Ns/kg) and PVF normalized to stance time (N/kg/s). Control group dogs improved at week 2 in owner assigned indices, but not force plate values and had no significant improvement in scores or force plate values from pretreatment values at 12 weeks.

Conclusion: APS injection reduced pain and lameness scores and increased weight-bearing associated with the OA-affected joint in dogs at 12 weeks providing preliminary evidence that APS therapy may be beneficial in the treatment of OA in dogs and supporting pursuit of additional studies.

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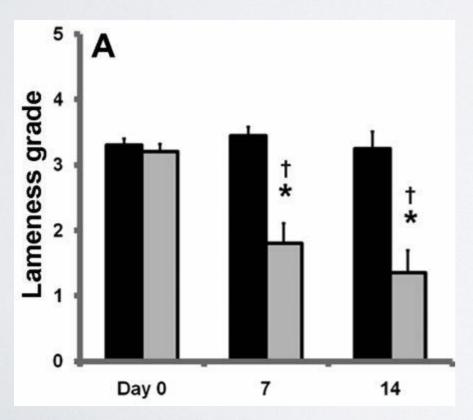


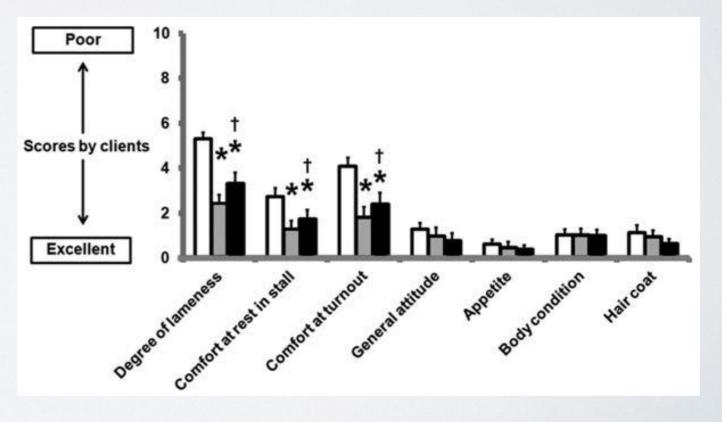
PRO-STRIDE MAPS

Evaluation of a single intra-articular injection of autologous protein solution for treatment of osteoarthritis in horses

Alicia L. Bertone, DVM, PhD; Akikazu Ishihara, BVSc, PhD; Lisa J. Zekas, DVM; Maxey L. Wellman, DVM, PhD; Katharine B. Lewis, BS; Rebecca A. Schwarze, BS; Andrea R. Barnaba, BS; Michael L. Schmall, DVM, MS; Peter M. Kanter, DVM, PhD; Ron L. Genovese, VMD

Clinical studies have demonstrated improved scores on lameness for over a year following a single application of Pro-Stride





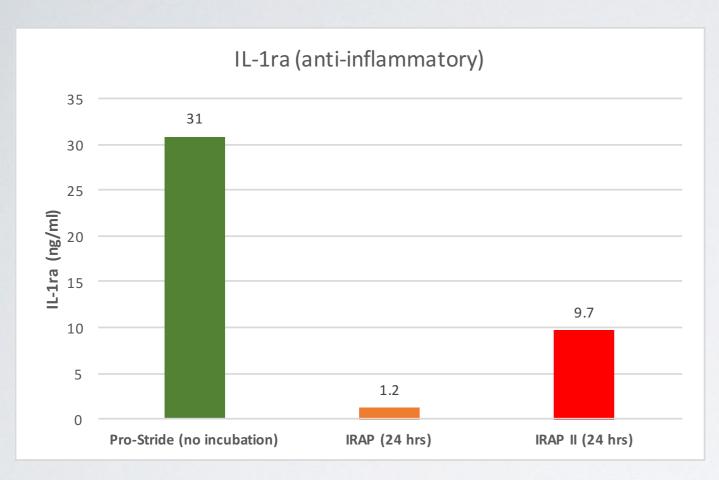
Pro-Stride (APS) to IRAP (ACS) Comparison

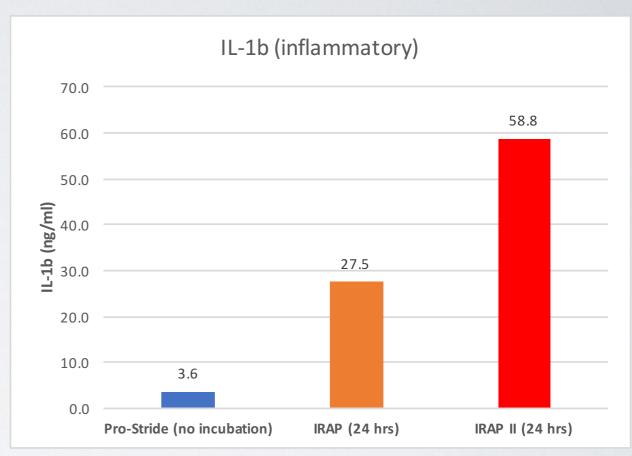
	IRAP I & II	
Processing Time (from blood draw)	<20 MINUTES	24 HOURS
Visits	1	2 to 6
Anti-inflammatory factor IL-1ra (ng/ml)	30+	1.2 (IRAP 1) 9.7 (IRAP II)
IL-1ra/IL-1b Ratio	8500: 1	45:1 (IRAP I) 165:1 (IRAP II)
Typical Duration (months post injection)	9-12	1-3

Owl Manor Veterinary Data "Effect of Prepara9on Technique on An9-inflammatory Properties of Autologous Therapies - APS 2015 Poster Data from Arthrex IRAP II System study (Arthrex Vet Systems - Arthrex Research and Development)

Pro-Stride compared to IRAP I and II

(independent data)





	IL-1ra (ng/ml)	IL-1b (ng/ml)	IL-1ra/IL-1b
Pro-Stride (no incubation)	31	0.0036	<i>8535</i>
IRAP (24 hrs)	1.2	0.028	44.8
IRAP II (24 hrs)	9.7	0.059	164.8

Owl Manor Veterinary Data "Effect of Preparation Technique on An9-inflammatory Properties of Autologous Therapies - APS 2015 Poster Data from Arthrex IRAP II System study (Arthrex Vet Systems - Arthrex Research and Development)



CenTrate

(Bone Marrow Aspirate Concentrate)

CenTrate is a proprietary bone marrow aspirate concentration device that allows efficient delivery in a natural suspension of plasma proteins.

- Dual buoy design eliminates need to filter bone marrow prior to processing
- 5-19x increase in MSCs (compared to original bone marrow
- Natural fibrin matrix
- 15 minute processing



Available in 30 ml and 60 ml





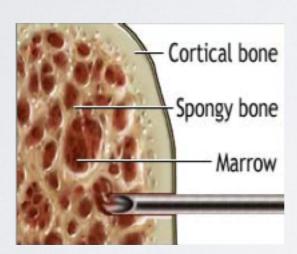
CenTrate

Anticoagulated Bone Marrow Aspirate

CenTrate BMA Concentration

Separation
Aided by
Centrifugation

Concentrated
Bone Marrow
Aspirate (cBMA)







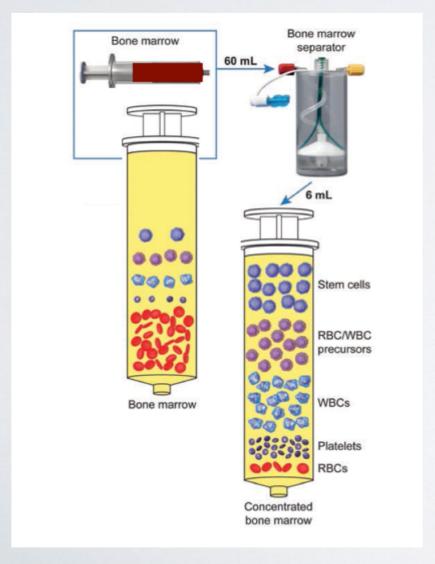


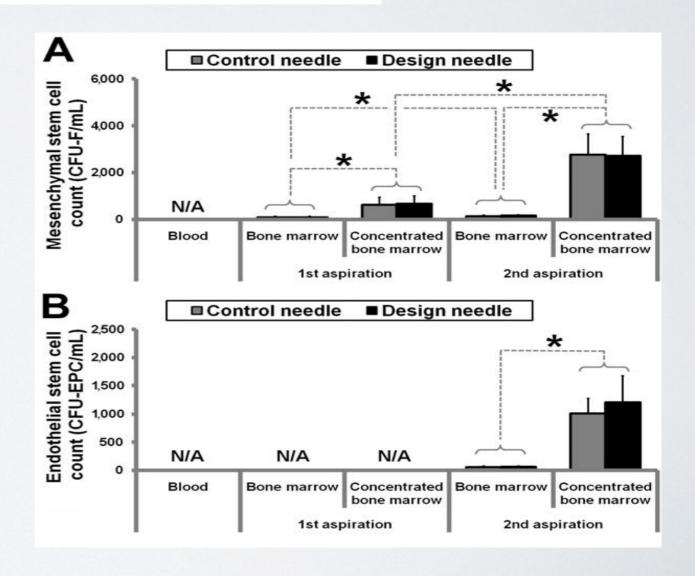


CenTrate

Performance of a gravitational marrow separator, multidirectional bone marrow aspiration needle, and repeated bone marrow collections on the production of concentrated bone marrow and separation of mesenchymal stem cells in horses

Akikazu Ishihara, BVSc, PhD; Holly J. Helbig, BS; Rebekah B. Sanchez-Hodge, BS; Maxey L. Wellman, DVM, PhD; Matthew D. Landrigan, PhD; Alicia L. Bertone, DVM, PhD







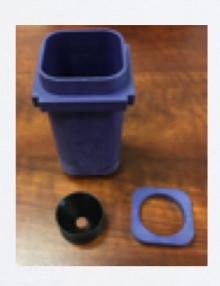
Owl Manor Veterinary Centrifuge



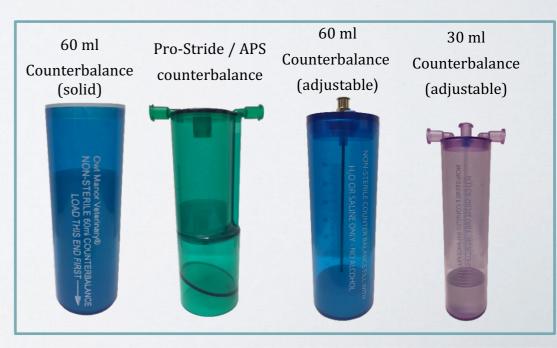
All Owl Manor Veterinary products are designed specifically to work with the Owl Manor Veterinary Centrifuge.

- Swinging bucket design
- Precise tolerance / clearance for Owl Manor Veterinary products
- Multi-use centrifuge (optional buckets and inserts available)









Centrifuge

- •15 years history with our products and this centrifuge.
- •There are specific tolerances critical for allowing the devices to function properly (expansion of the tube, separation, concentration, etc). It is more than just a looking at the devices and confirming they fit both diameter and depth in another centrifuge.
- •The swinging bucket design is critical (a fixed rotor centrifuge will not work).
- •If the clearance is not sufficient, the ports could be subject to breakage or even cracking of the device).
- •Even if you could try to replicate tolerances through a custom bucket or insert, the speed and rpm settings are a factor of measurements of the center of the rotor to the distance of the bottom of the buckets when swung out. This varies from centrifuge, rotors, buckets, etc. and introduces the risk of further error and inconsistencies.

Education and Awareness











Point-of-Care Regenerative Medicine



Restigen™ PRP
Platelet-Buffy Coat
Concentrate



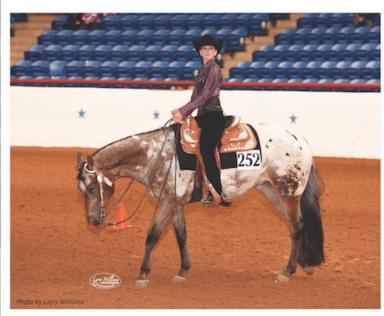
ProStride™APS (Autologous Protein Solution w/IL-1ra)



CenTrate™ BMA Bone Marrow Aspirate Concentrate





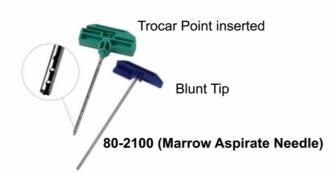


POINT-OF-CARE CONVENIENCE • PREPARED UNDER 30 MINUTES • NATURAL - DRUG-FREE WWW.OMVETERINARY.COM

CenTrate™ BMA (Bone Marrow Aspirate Concentrator) Instructions

Part # 903002VET-6PK (60ml) and 903001VET-6PK (30ml)









1. Bone Marrow Aspirate (BMA) Harvest Preparation

For 903002VET device, use (2*) sterile 30ml syringes to collect the combined total of 60ml (following BMA Draw). Prepare syringes with anticoagulant using either Heparin (concentration of 1000 U/ml) or ACD-A.

If using Heparin:1st Syringe: Draw 3ml heparin solution (1000 U/ml) into 30ml syringe; ensure the heparin coats the entire inner surface of the syringe.

2nd Syringe: Draw 10ml heparin solution into a 2nd 30ml syringe; ensure the heparin coats the entire inner surface of the syringe. Attach the 2nd 30ml syringe to the BMA needle (Part # 80-2100) and prime with heparin, ensuring 3ml heparin remains in the 30ml syringe. Remove BMA needle and replace the trocar point.

For 903001VET (30 ml) CenTrate device, use only (1) 30ml syringe, follow the 2nd Syringe instructions above.

*Use of (2) syringes helps to manage the risk of coagulation during the BMA draw.

If using ACD-A: 1st Syringe: Draw 5ml ACD-A into 30ml syringe; ensure the ACD-A coats the entire inner surface of the syringe.

2nd Syringe: Draw 10ml ACD-A into a 2nd sterile 30ml syringe; ensure the ACD-A coats the entire inner surface of the syringe. Attach the 2nd 30ml syringe to the BMA needle and prime with ACD-A, ensuring 5ml ACD-A remains in the 30ml syringe. Remove BMA needle and replace the trocar point.

2. Draw BMA / Load BMA into Concentrator

With the (2) 30ml syringes prepared with anticoagulant, follow the BMA needle manufacturer instructions to draw the combined mixture:

For 60ml CenTrate device:

- · 6ml of Heparin with 54ml of BMA
- · 10ml of ACD-A with 50ml of BMA

For 30ml CenTrate device:

- 3ml of Heparin with 27ml of BMA
- 5ml of ACD-A with 25ml of BMA

Unscrew cap on center top port (No.1), remove and discard packaging post. Slowly load BMA mixture into center port being careful to keep the blue vent on top clear. Remove syringe after loading. Remove sterile plug from the tethered cap and attach the cap to the top port. The CenTrate device is now ready to be loaded into the certrifuge.



3. Centrifugation (755VES-VET Required)





Push Open/Stop button on control panel. The "unlocked" indicator will illuminate. Turn latch counterclockwise to open lid. Place CenTrate Device into centrifuge. Be sure the centrifuge is balanced with counterbalance (Part # 904001VET-60ML or #904003VET-60ML Solid) or second full CenTrate Device placed directly across. For 903001VET (30 ml device), use counterbalance Part # 904000VET-30ML.

Close lid by rotating the lid latch clockwise. "Latched" indicator will illuminate. Set speed to 3200 RPM and time to 15 minutes. Press Start button. Once spin is complete, press Open/Stop button. Twist latch counterclockwise to open lid.

4. Plasma Discard



Remove tube and unscrew yellow cap. Withdraw the plasma for discard (port No. 2) with a 30 ml syringe. When removing the plasma, tilt at an angle, but avoid inverting, keeping the flid below the top blue vent. Replace yellow cap.

5. BMA Concentration Extraction



Shake the CenTrate Device vigorously for 30 seconds to resuspend BMA concentration. Unscrew red cap and withdraw BMA concentration (3 ml for 30 ml device; 6ml for 60 ml device) with a 10 ml syringe from port No. 3.

www.omveterinary.com 122 E. Center Street Suite A Warsaw, IN 46580





Pro-Stride™ APS Instructions (APS Separator & APS Concentrator Devices)

Part # 903000VET-6PK

1. Blood Draw



Attach 18 gauge needle to 60 ml syringe. Withdraw 5-8 ml of ACD-A (citrate anticoagulant). Prime apheresis needle with anticoagulant. Slowly draw 52-55 ml of blood (for a total of 60 ml) into the syringe. Gently mix anticoagulant with blood in syringe.

2. Load Blood



Unscrew cap on center top port (No.1) of the APS Separator and discard green packaging post. Slowly load blood into center port. Remove syringe and attach tethered cap to the top port.

3. Balance Centrifuge (755VES-VET Required)



Push Open/Stop button on control panel. The "unlocked" indicator will illuminate. Turn latch counterclockwise to open lid. Place APS Separator into centrifuge. Be sure the centrifuge is balanced with counterbalance (Part # 904003VET-60ML Solid or 904001VET-60ML) or second full APS Separator.

PRO STRIDE

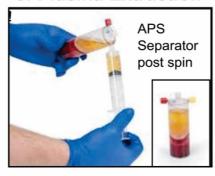
4. Spin in Centrifuge



6: PRP Suspension and Extraction

Close lid by rotating the lid latch clockwise. "Latched" indicator will illuminate. Set speed to 3200 RPM and time to 15 minutes. Press Start button. Once spin is complete, press Open/Stop button. Twist latch counterclockwise to open lid.

5: Plasma Extraction



Extract remaining PRP

attached 10 ml syringe.

suspension into the

Remove yellow cap on side port (No. 2) and connect 30 ml syringe. When removing the plasma, tilt at an angle, but avoid inverting, keeping the flid below the top blue vent. Replace yellow cap.

7: Load APS Concentrator Device



Gently shake device to ensure beads are evenly distributed across bottom of top chamber. Unscrew yellow cap (port No. 1) on APS concentration device and fil with cell suspension from 10 ml syringe. Remove 10 ml syringe and attach tethered cap on port 1.

cell solution is fully





Spin paddle until mixed with beads.

8: Spin in Centrifuge

syringe. Withdraw 2 ml of PRP.

Remove red cap on side port

(No. 3) and connect 10 ml

Leave syringe attached.



Place concentrator into centrifuge. Balance centrifuge with Pro-Stride/ APS counterbalance (904002VET-APSCB) or second full APS Concentrator. Spin for 2 minutes at 2000 RPM.

With 10 ml syringe attached,

suspend PRP by shaking

tube for 30 seconds.

9: Extract Pro-Stride Solution



Gently resuspend Autologous Protein Solution in bottom of APS Concentrator. Unscrew red cap (port No. 2) and connect sterile 10 ml syringe. Extract Autologous Protein Solution.

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Restigen™ PRP (Platelet Concentrator) Instructions

Part # 903004VET-6PK (60 ml) and # 903003VET-6PK (30 ml)

1. Blood Draw



For 903004VET device, attach ☐ 18 gauge needle to 60 ml syringe. Withdraw 5-8 ml of ACD-A (citrate anticoagulant). Prime apheresis needle with anticoagulant. Slowly draw 52-55 ml of blood (for a total of 60 ml) into the syringe. Gently mix anticoagulant with blood in syringe.

For 903003VET (30 ml) device, use 4ml ACD-A and 26ml whole blood.

2. Load Blood



Unscrew cap on center top port (No.1) of the Restigen Device and discard green packaging post. Slowly load blood into center port. Remove syringe and attach tethered cap to the top port.

3. Balance Centrifuge (755VES-VET Required)



Push Open/Stop button on control panel. The "unlocked" indicator will illuminate. Turn latch counterclockwise to open lid. Place Restigen Device into centrifuge. Be sure the centrifuge is balanced with counterbalance (Part # 904003VET-60ML Solid (shown) or 904001VET-60ML) or second full Restigen Device. For 903003VET (30 ml device), use counterbalance Part # 904000VET-30ML.

4. Spin in Centrifuge



Close lid by rotating the lid latch clockwise. "Latched" indicator will illuminate. Set speed to 3200 RPM and time to 15 minutes. Press Start button. Once spin is complete, press Open/Stop button. Twist latch counterclockwise to open lid.

5: Plasma Extraction

Restigen



Remove yellow cap on side port (No. 2) and connect 30 ml syringe. When removing the plasma (PPP), tilt at an angle, but avoid inverting, keeping the flid below the top blue vent. Replace yellow cap.

6: PRP Suspension and Extraction



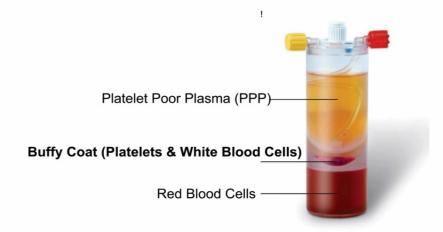
Remove red cap on side port (No. 3) and connect 10 ml syringe. Withdraw 2 ml of PRP. Leave syringe attached.



With 10 ml syringe attached, suspend PRP by gently shaking tube for 30 seconds.



Extract remaining PRP suspension into the attached 10 ml syringe.



Buffy Coat (Platelets and White Blood Cells) = PRP

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