Rev. Date: 01-Nov-2010

Pall Corporation

C-PET

C-PET Canine Platelet Enhancement Therapy

Description

A simpler, easier way to prepare a platelet therapy. No centrifuge, no additional equipment, just 15 minutes from blood draw to delivery.

- Non-surgical
- Non-pharmaceutical
- Outpatient procedure
- No additional equipment or outside lab processing required
- Can be done in the office, in the field, or even in a client's home
- Gentle gravity filtration is easy on platelets, creating a high quality platelet therapy rich in growth factors
- Once the blood is drawn, preparing the platelet therapy takes approximately 15 minutes. Including the blood draw and injection, a single treatment typically takes 30 minutes.
- Autologous preparation reduces the risk of immune mediated reactions

Applications

- For the treatment of tendon and ligament damage, and osteoarthritis.

Performance

- Requires 55ml blood draw
- Produces 6-8ml of platelet therapy
- 3-4x concentration of platelets and platelet derived growth factors
- 2x concentration of white blood cells

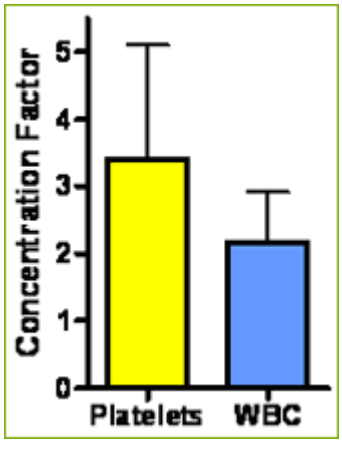


Figure: Platelet and WBC concentrations post C-PET processing. (n = 40 dogs, +/- standard deviation)

- As of July 26th 2010, 60 dogs have been treated in our pilot study for osteoarthritis and tendon and ligament damage. Dogs enrolled in the pilot study are evaluated before and 3 months after C-PET treatment using the Hudson Visual Analog Score questionnaire, an assessment tool correlated with force plate kinetics . As of this writing, 27 of the dogs have reached their 3-month evaluation, and their data are presented below. (Be sure to check back for periodic updates as our trial progresses)

Note: The C-PET pilot study is meant to provide a broad, multi-center, assessment of C-PET efficacy; encompassing 15 evaluation sites and counting. The primary limitation of this study is that it does not include a randomized control. While osteoarthritis is not a self-limiting disease, many acute tendon and ligament injuries are, and the evaluation of C-PET for their treatment is complex without matched controls. To address this, prospective randomized controlled studies of C-PET are currently under way at 3 prominent US university veterinary colleges.

[1]Hudson et al. Assessing repeatability and validity of a visual analogue scale questionnaire for use in assessing pain and lameness in dogs. Am J Vet Res. 2004 Dec;65(12):1634-43.

All inclusive data set: C-PET to treat lameness in dogs associated with osteoarthritis, or tendon or ligament injuries.

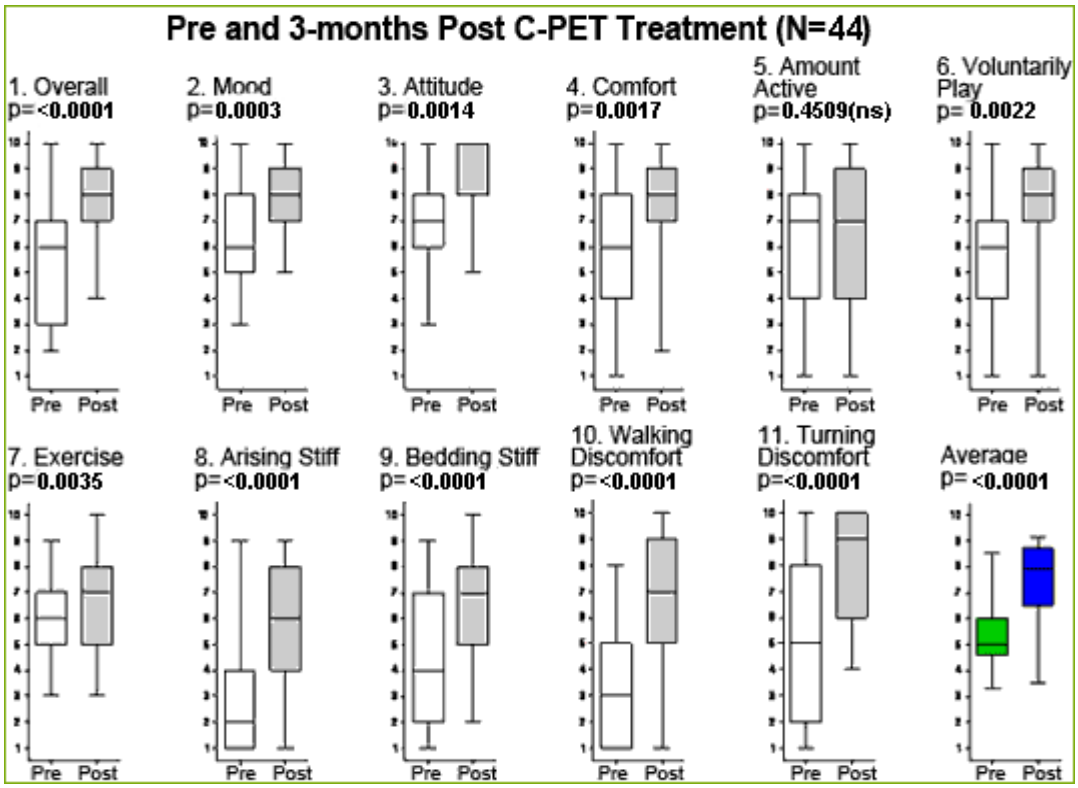


Figure: *Hudson Visual Analog Score (VAS) results measured pre and 3 months post C-PET treatment for osteoarthritis, or tendon or ligament injuries. Panels show results from individual VAS questions as well as the 11-question average (bottom right). P-values reported are for Wilcoxon matched-pairs signed rank test (a standard method of analyzing nonparametric, paired data). Significant changes were observed in 10 of the 11 questions (α=0.05), with no significant change in question 5, "amount active". Box plots represent the median, 25th and 75th quartiles, and range.*

Subset analysis of C-PET treatment by indication

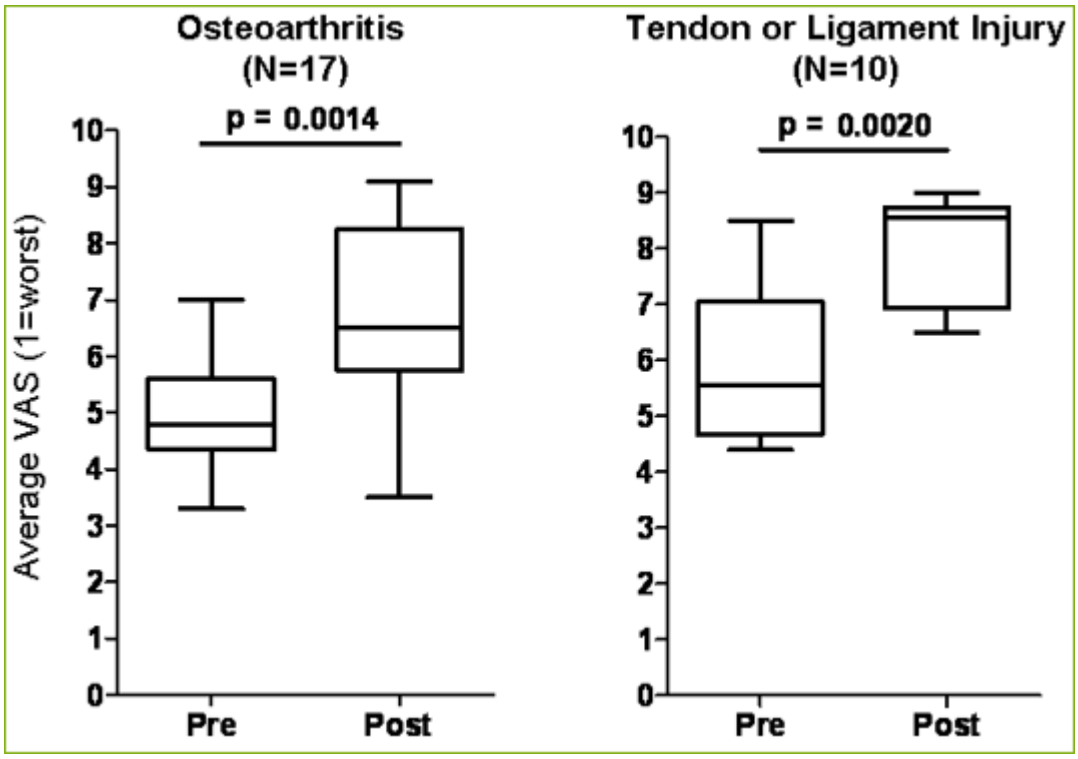


Figure: *11-question average of Hudson Visual Analog Score (VAS) results measured pre and 3 months post C-PET treatment for osteoarthritis (left panel), and tendon or ligament injuries (right panel). P-values reported are for Wilcoxon matched-pairs signed rank test (a standard method of analyzing nonparametric, paired data). Significant changes were observed in both the osteoarthritis and tendon-or-ligament injury sub populations (α=0.05) Box plots represent the median, 25th and 75th quartiles, and range.*

Early indications of age-mediated effectiveness of C-PET in treating canine osteoarthritis (note low sample size at this level of sub analysis; studies are ongoing)

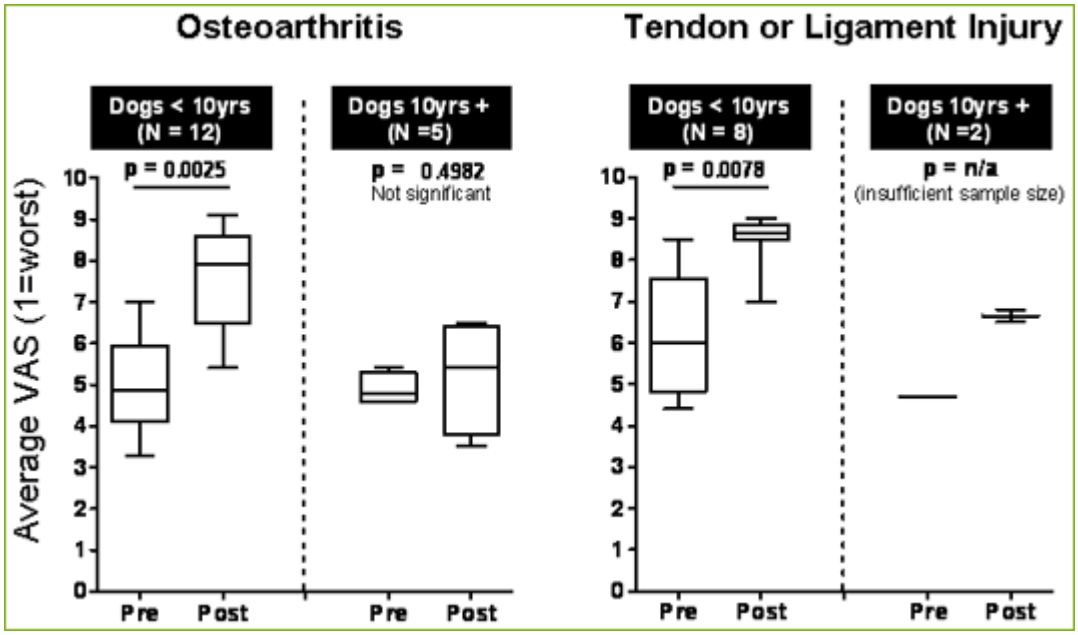


Figure: *11-question average of Hudson Visual Analog Score (VAS) results measured pre and 3 months post C-PET treatment for osteoarthritis (left panels), and tendon-or-ligament injuries (right panels). Sub panels are segmented by age, with results from dogs younger than 10 yrs on the left, and results from dogs 10 years and older on the right. P-values reported are for Wilcoxon matched-pairs signed rank test (a standard method of analyzing nonparametric, paired data). Significant changes were observed between age groups in dogs treated for osteoarthritis (α=0.05). There is an insufficient sample size to analyze age related effects in the tendon-or-ligament injury sub population. Box plots represent the median, 25th and 75th quartiles, and range.*

Additional Information

Canine Platelet Enhancement Therapy (C-PET)

This product is used to create a platelet therapy from autologous canine blood.

C-PET application is as easy as 1, 2, 3

1. Prepare

2. Filter

3. Recover

Filter the blood through the C-PET system. Recover the platelets and deliver the therapy to the site of injury or disease.

Equipment Provided

C-PET System comprising:

- 1 - C-PET set
- 1 - Anticoagulant solution (ACD-A)
- 1 - Capture solution
- (sterile water for injection)
- 1 - Harvest Solution
- 3 - 10 mL luer lock syringes
- 1 - 60 mL luer lock syringe
- 1 - Clean drape

Equipment Required

- 1 - Needle for aspiration of blood
- 3 - Needles for aspiration of anticoagulant, capture, and harvest solutions
- Equipment for clipping and surgical preparation of aspiration site
- Equipment for implantation/application

How to Recover Concentrated Platelets

Preparation

1. Place clean drape on a flat surface.

2. Remove C-PET set from box and lay it on the drape.
3. NOTE: Push the top and bottom clamps into the closed position.
4. Preload the 60 mL syringe with 5 mL anticoagulant solution.
5. Withdraw 9 mL of capture solution into one of the 10 mL syringes and then transfer the capture solution into the top bag via Port A.
6. Remove the syringe and replace the cap on Port A.
7. Hang the C-PET set so that the bag containing the capture solution is above the filter, the arrows on the filter point downward, and the bags hang freely. Check that both top and bottom clamps are closed.

Blood Collection

1. Collect 55 mL whole venous blood into the preloaded 60 mL syringe, giving a total volume of 60 mL.
2. Attach the syringe to Port A and transfer the anticoagulated whole blood to the top bag while gently mixing it with the capture solution by rocking the bag.
3. Remove the syringe and replace the cap on Port A.
4. Continue mixing the blood and capture solution by removing the C-PET set from its hanging position and inverting the bag set at least 10 times.
5. Good results require that the sample and capture solution are well mixed.

Filtration

1. Once the blood sample and capture solution are mixed well, re-hang the C-PET set in a vertical position with the top bag above the filter, the arrows on the filter pointing downward, and the bag hanging freely.
2. Open the bottom clamp and then the top clamp to allow the whole blood to flow through the filter into the lower bag. Filtration should take between 5 and 14 minutes.
3. Once the filtration is complete (when the unprinted side of the filter is free of fluid and flow has stopped) push the bottom and top clamps into the closed position.

Recovery of Platelets

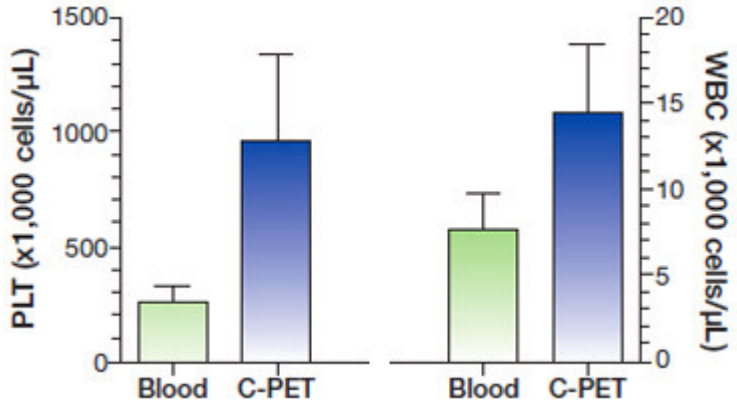
1. Withdraw 8 mL Harvest Solution into one of the 10 mL syringes.
2. Attach this syringe to Port C. The platelets will be collected in the remaining empty 10 mL syringe. This syringe should be handled in a sterile fashion if full sterility is required for the application/implantation procedure.
3. Remove any residual air from the remaining empty 10 mL syringe by depressing the plunger.
4. Attach this empty syringe to Port B.
5. Holding the filter with one hand, inject the Harvest Solution through the filter with constant pressure. This will take only a few seconds.
6. If the plunger does not depress easily, remove syringe(s) and then reattach.
7. The platelet concentrate will be back-flushed into the empty 10 mL syringe attached to Port B.
8. Remove the syringe containing the platelet concentrate from Port B.
9. The platelet concentrate is now ready for use and should be applied/implanted within 60 minutes of recovery.

NOTE: The C-PET set is for single use only.

Additional training and consultation available at Pall by calling, 516-801-9727 or emailing Jeffrey_Schaffer@pall.com

Always dispose of blood-contaminated products and 'sharps' in a manner consistent with established biohazard safety procedures.

Filter performance of C-PET (n=9)



Ordering Information

To place an order for C-PET, call (516) 801-9738 and press 1 for the order menu.

Contact Information

Visit us on the Web at www.pall.com

This information is accurate as of the revision date indicated.