

# **Impact of photobiomodulation therapy in dogs with CCLR after TPLO surgery**

## **A double-blind, randomized, placebo-controlled prospective study of the impact of laser photobiomodulation therapy in dogs with cranial cruciate ligament rupture after TPLO surgery**

### **Purpose and Brief Study Description:**

The purpose of this trial is to demonstrate if using photobiomodulation (PBMT) as an adjuvant therapy in patients with cranial cruciate ligament rupture (CCLR) after receiving tibial plateau leveling osteotomy (TPLO) surgery will be able to improve pain score, gait stance analysis, surgical site infection, along with reduction of C-reactive protein in blood, which is a marker of inflammation.

Cranial cruciate ligament rupture in dogs is one of the most common condition in dogs. Left untreated, this condition can lead to lameness and progressive osteoarthritis. Therefore, tibial plateau leveling osteotomy (TPLO) is one of the most common surgeries preferred from small animal surgery surgeons to treat this condition due to high owner satisfaction rates and good limb function. However, despite surgical correction and medical management with pain and anti-inflammatory medications, muscle atrophy and poor limb function may persist. Photobiomodulation therapy (also referred to as “low-level laser” or “cold laser” therapy) has been shown to decrease inflammation, and increase analgesia, vascularization, and tissue healing after musculoskeletal injury or surgery. However, the use of PBMT in dogs with CCLR after receiving TPLO surgery is still investigational, meaning it has not yet been FDA approved for this purpose.

This is a double-blind, randomized, placebo-controlled prospective study. Dogs who are eligible to participate in this study will be randomized (like flipping a coin) to either receive the investigational PBMT therapy or they will serve as a control. Therefore, the owner will not be able to choose in which group their dogs will be placed. Dogs in the control group will receive standard-of-care; similar to if you were to have the surgery performed and not participate in this trial. They will receive all of the same treatments otherwise, except they will not receive the investigational photobiomodulation therapy. Additionally, the study is double-blinded, meaning that neither your study doctor nor you will not know which study arm your dog was randomized to. This is to ensure the study doctor is not biased one way or another when assessing all patients on study. The individuals performing the laser photobiomodulation therapy will not be blinded during the study.

### **What does enrollment into this trial involve?**

The study will be conducted during 48 hours in hospital after TPLO surgery in combination of 8 weeks in owner's home after TPLO surgery. A first orthopedic assessment will be performed in your dog confirming cranial cruciate ligament rupture disease (CCLR) to ensure that your dog is an eligible candidate for the study. During the study time several gait analysis stances, PBMT, C-reactive protein tests and pain surveys will be performed.

**Procedures:** If your dog is enrolled preoperative bloodwork, additional diagnostics, anesthesia and TPLO surgery will be performed.

Gait stance analysis will be performed at the day of first orthopedic assessment before TPLO surgery, 24 hours, 48 hours and 8 weeks after TPLO surgery.

Blood drawn to perform a C reactive protein test (about ¼ teaspoon) the day before surgery, 24 hours, 48 hours and 8 weeks after surgery.

PBMT therapy will be performed, if applicable, for 5 minutes each at 30 minutes before surgery and 6 hours, 24 hours, 48 hours and 8 weeks after TPLO surgery for 5 total sessions. The individuals performing the therapy will not be blinded to the study.

A CMPS-SF pain questionnaire will be completed by the study doctor the day before surgery, 24 hours, 48 hours, and at 8 weeks after surgery. In addition, the client in charge of the patient will receive instructions covering how to use the Short form (CMPS-SF) pain scoring survey. These will be completed by the client every week for 8 weeks after surgery. To be consistent, the same person (client) should complete the survey.

Owner will receive a phone call at day 15 after TPLO surgery to collect information about the status of the surgical site.

Follow-up 8 Week Visit at KSU VHC: Owner will receive instructions to come back to the VHC at KSU for recheck. During the recheck a complete physical exam and orthopedic examination will be performed by the clinician in charge, in addition to the procedures indicated above. Additionally, recheck radiographs (with sedation, if required) on the stifle surgically repaired will be performed. This is standard following TPLO surgery. This will conclude your dog's participation in the trial.

#### **Eligibility:**

##### **Inclusion Criteria:**

- Owner pet dogs of any breed or sex, greater than one year of age.
- Orthopedic examination by one of the clinical investigators consistent with diagnosis of cranial cruciate ligament rupture.
- Sedate standard lateral and craniocaudal stifle radiographs taken at the VHC before TPLO surgery.
- Treatment by TPLO surgery with any of the following variations: arthrotomy, arthroscopy, partial meniscectomy, meniscal release.
- Preoperative complete blood count and serum chemistry results do not raise concern for disease that would prohibit patient for receiving carprofen.

##### **Exclusion criteria:**

- Aggressive or anxious temperament that might interfere with stance analysis and subjective pain scoring.
- Neurologic disease, confirmed by neurological examination by one of the clinical investigators.

##### **Client Compensation:**

The cost for surgery, preoperative radiographs, complete blood count, serum chemistry and, anesthesia incurring by your pet during this visit will not be covered by the study. Complications from anesthesia or surgery will not be covered by the study. The photobiomodulation therapy, C-reactive protein test and gait stance analysis during the project, as well as 24 hours of hospitalization in wards will be covered by the study funds. For dogs eligible to complete the study (not excluded) the 8 week recheck radiographs on the stifle surgically repaired, and sedation if required, will be covered by the study funds.

##### **Contact Information:**

Please contact Kris Richardson, Clinical Trials Coordinator at the Veterinary Health Center, for more information about this study. Phone: (785)-532-3046; email: [ClinicalTrials@vet.k-state.edu](mailto:ClinicalTrials@vet.k-state.edu)