Virginia-Maryland College of Veterinary Medicine

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Clinical Research Project
Client Consent Form

Study Title: The Effect of a Modified Approach on Early Weight Bearing Following Tibial Plateau Leveling Osteotomy in Dogs

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One of the missions of the Virginia-Maryland College of Veterinary Medicine is to create, disseminate and apply medical knowledge through discovery, learning, and engagement. You are invited to participate in this mission by enrolling your animal in a clinical research study. Your participation is entirely voluntary, and you may withdraw your animal from the study at any time by notifying the Principal Investigator. There is no penalty if you choose not to participate.

Study Purpose:
Tibial Plateau Leveling Osteotomy (TPLO) is a common procedure to address cranial cruciate ligament rupture in dogs. In order to reach the top of the tibia (shin bone) to perform the surgery, the attachments of three muscles need to be transected. These muscles have a role in flexing the stifle (knee) and may help with stability of the stifle. The purpose of this study is to see if a modified approach, which allows improved preservation of the muscle attachments, will lead to earlier weight bearing and faster resolution of lameness following TPLO surgery.

Study Design/Procedures:
This is a prospective clinical trial in which eligible canine patients will be treated for cranial cruciate ligament rupture using the Kyon TPLO system. To be included in the study, a patient must be diagnosed with unilateral cranial cruciate ligament rupture without clinical lameness caused by other concurrent orthopedic disease based on orthopedic examination and radiographs of the stifle. Patients must have normal pre-anesthetic blood work and be able to receive non-steroidal anti-inflammatory pain medications following surgery to be enrolled. Patients will have stifle radiographs taken pre-operatively and immediately post-operatively. Gait analysis will be performed prior to surgery and patients must return in 2, 6 and 12 weeks for an orthopedic exam and gait analysis. Additionally, sedated radiographs to confirm healing will be performed at 12 weeks. Clients will be asked to complete a short survey at each recheck visit. If any complications are suspected between these times, patients should be evaluated sooner as necessary and any complications recorded.

Risks and Benefits:
The risks associated with participation in this study are consistent with those for any orthopedic surgery, including but not limited to anesthesia, infection, and fracture. These will be discussed in detail on an individual basis. The modified approach does not represent increased surgical risk compared to dogs undergoing a TPLO with a standard approach. The benefit is the potential to preserve the attachments of some of the muscles to the inside of the shin bone. This may lead to earlier weight bearing and a faster resolution of lameness following surgery.

Study Costs and Compensation:
The estimated cost for a TPLO is $3300-4200 per side, which includes bloodwork, hospitalization, anesthesia, surgery, implants, and immediate post-operative radiographs. This estimate does not include unforeseen complications. A more precise estimate based on your dog's weight will be provided at the time of your appointment.

If the patient returns for all recheck time points, the cost of the normal 12-week recheck including sedation and associated radiographs ($250-350 estimated value) will be covered by the study. If further radiographs are required following the 12-week recheck, or radiographs due to suspected complications are required prior to the 12- week recheck, these will not be covered by the study. Additionally, if the patient fails to return for the 2- and 6-week study time points, the owner will be responsible for the cost of the 12- week recheck radiographs.

Confidentiality:

The data collected in the course of this study is confidential. In any publication or presentation of the study data, we will not include information that would make it possible to identify a research participant. Research records will be kept in a secure location; only researchers will have access to the records.

Statement of Consent:
In giving my consent by signing this form, I acknowledge that I have been informed of the purpose and nature of this study and its associated procedures, as well as any possible side effects.

I have read and understood the above information. I have been given the opportunity to ask questions and receive answers, and I consent to participate in the study. I further certify that I am the owner (or duly authorized agent of the owner) of _____ .
(Animal's name)

Owner or Agent Signature: _____ Date: _____

Owner or Agent Printed Name: _____

Attending Clinician Signature: _____ Date: _____

Attending Clinician Printed Name: _____

Please don't hesitate to contact us if you have any questions or concerns about this study.
The research and procedures have been reviewed and approved by the Virginia Tech Institutional Animal Care and Use Committee and the Virginia-Maryland College of Veterinary Medicine Veterinary Teaching Hospital Board.

If you have any questions or concerns regarding the study and would like to talk to someone other than the researchers, please contact:

Hospital Director,
Veterinary Teaching Hospital
Virginia-Maryland College of Veterinary Medicine
Address: 245 Duck Pond Dr., Blacksburg, Virginia 24061-0443
Phone: 540-231-4621

You will be given a copy of this form to keep for your records.