Clinical Research Project
Client Consent Form

Study Title: Minimally invasive, integrated endoscopic hemilaminectomy for Hansen Type I intervertebral disc herniation in chondrodystrophic 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:
The purpose of this study is to evaluate a minimally invasive surgical approach to the spinal cord to address intervertebral disc herniation. Muscle and soft tissue dissection is thought to be associated with the majority of postoperative discomfort. Traditionally, the standard approach to the spinal cord in dogs with intervertebral disc herniations involves a significant amount of soft tissue dissection and retraction. Many studies in people have shown that patients that have minimally invasive spinal surgery are more comfortable after surgery in comparison to patients undergoing open approaches. Studies also show that there are shorter hospital stays, fewer complications like blood loss and infection and faster recovery times associated with minimally invasive spinal surgery. In addition, the skin incision is significantly smaller with the minimally invasive approach. Our goal is to establish a minimally invasive technique to be used in dogs that will result in less pain, quicker recovery, fewer complications, smaller skin incisions and less time in the hospital.

Study Design/Procedures
This is a prospective clinical trial in which eligible canine patients will be treated using a minimally invasive approach to remove spinal cord compression secondary to intervertebral disc herniation. To be included in the study, a patient must be diagnosed with an acute, intervertebral disc herniation causing compression of the spinal cord. The area of disc herniation as seen on MRI must also fall within the parameters as defined by a previous study. Pre-anesthetic bloodwork must be within normal limits to be enrolled. Eligible patients will undergo a minimally invasive integrated endoscopic hemilaminectomy. Patients will have a second MRI performed immediately postoperatively to evaluate for resolution of spinal cord compression. If a significant amount of spinal cord compression remains (>10%), then the patient will immediately return to surgery under the same anesthesia to undergo a traditional approach to remove remaining disc material and ensure that they will have the best possible outcome. Patients must return in 2 weeks for a full neurologic exam and staple removal.

Risks and Benefits:
The risks associated with participation in this study are consistent with those for any neurologic surgery, including but not limited to anesthesia, infection, blood loss, worsening of neurologic signs, failure to improve or death. These will be discussed in detail on an individual basis. The minimally invasive approach does not represent increased surgical risk compared to an traditional, open hemilaminectomy. The benefit is the potential for a surgical option at decreased cost with less pain and potentially decreased complication rate overall. If at any point during the minimally invasive procedure there is concern for adequate removal of the disc material or any questions about the safety or stability of the patient, the minimally invasive technique will be abandoned and the surgery will be converted to a traditional, open approach.

Study Costs and Compensation:
The estimated cost for a traditional, non emergent hemilaminectomy is $4,500-$5,500. Clients that elect to pursue the minimally invasive approach and the disc herniation evaluated on MRI falls within the parameters for use in this study will be compensated by having a $500 credit applied to their bill. There will also be no additional cost for the postoperative MRI, a conversion to a traditional, open approach (if necessary) or the 2-week recheck. Clients will be responsible for the remainder of the cost for the surgery and recovery in the ICU, any after hours emergency fees, preoperative blood work,
preoperative MRI and any other costs that may occur normally depending on the specific patient and are not specifically addressed as part of the study as listed above.

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: __________

Attending Clinician Signature: ___________________________ Date: __________

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.