EVALUATION OF NON-SURGICAL TREATMENT OPTIONS FOR TYPE 2C ACHILLES TENDINOPATHY

Purpose: The purpose of this study is to investigate the effectiveness of non-surgical management of Type 2 common calcanean (Achilles) tendinopathy.

Study Design: The study will objectively evaluate the outcome of non-surgical treatment via tarsal orthosis, rehabilitation and pain management of Achilles tendinopathy in (n=12) dogs. Efficacy of the treatment will be evaluated by owner questionnaires, objective gait analysis, ultrasound, x-rays, activity counts and veterinary assessment. The study spans over one year and involves approximately 10 visits to the VTH.

Inclusion Criteria*:

- Body weight ≥15kg
- Irregular gait/visually identifiable unilateral lameness that is due to Type-2c Achilles Tendinopathy
- Palpable presence of swelling of Achilles tendon insertion and visible “crab-claw” appearance
- No palpable abnormalities of the other Achilles tendon
- At home assessment by owner (owner questionnaires) showing impairments that can be defined (such as not jumping into truck, less active etc.)
- Generally healthy with no other indication of systemic disease (confirmed through bloodwork)

Owner agrees to:

- Adhere to recheck schedule as outlined below
- Adhere to current treatment regime unless a change is recommended by us or primary DVM (in which case owner agrees to notify us)
- Allow canine tracking device on CSU issued collar to be worn 24/7 for duration of the study
- Fill out DAILY activity/medication log for duration of the study
- Fill out owner questionnaires at several rechecks

Please contact Kelsie Condon at Kelsie.Condon@colostate.edu or by calling (970) 297- 5000 with any questions
Exclusion Criteria*:

- Previous surgery of affected tendon/tarsus
- Animals not suitable for functional orthosis fittings due to anatomy/build
- Animal not suitable for repeated appointments, gait analysis etc. (such as stressed animals or due to behavioral issues)
- Tendinopathy of the other Achilles tendon
- Owner wanting to pursue regenerative medicine or surgical treatment in addition to device
- Concurrent CCLD of affected stifle (based on palpation, no radiographs necessary to r/o stifle disease unless clinically indicated)
- Other orthopedic or neurological conditions that affect or are suspected to affect the gait significantly
- Owner unwilling/incapable to return to CSU for follow-up visits for a 1 year duration
- Owner unwilling to allow sedation for the ultrasound evaluations

Benefits of Participation:

- Tarsal orthosis free of charge
  - Please note that fulfillment of the recheck schedule at CSU is required to receive the orthosis free of charge
- Rechecks, device adjustments for the duration of the study (1 year)
- Radiographs of the tendon at 0 and 52 weeks
- Ultrasound of the tendon at 0, 12, 24 and 52 weeks to assess progression of healing
- Owner expense:
  - Initial enrollment visit and bloodwork required to ensure enrollment is feasible
  - Physical therapy visits

Required Visits:

The study requires owner compliance of pain assessment questionnaires, sedated procedures for radiology/ultrasound, gait analysis, physical therapy (during the first 3 months or until your dog returns to normal gait) and a canine activity monitor to be worn by your dog. A total of approximately 10 visits are required over the course of 12 months:

Date: __________(Week 0) – Enrollment visit**:

- Orthopedic and general physical exam at owner expense
- Baseline bloodwork at owner expense

Please contact Kelsie Condon at Kelsie.Condon@colostate.edu or by calling (970) 297-5000 with any questions
☐ Gait analysis to quantify degree of lameness
☐ Subjective Outcome Scoring (SOS) to quantify degree of physical limitations
☐ CBPI to quantify daily limitations
☐ CSOM to quantify daily limitations – define current limitations with owner****
☐ Tarsal angles (NOTE: should be 165° or greater) ****
  ☐ Tarsal standing angle measured during square stance
  ☐ Tarsal standing angle measured during square stance when lifting up contralateral limb (if allowable per vet assessment)
  ☐ Gastrocnemius flexibility measured in lateral recumbence (stifle in extension, hip in standing angle -> measure the flexion angle of the tarsus)
  ☐ Thickness of Achilles tendon just proximal to the calcaneus (in mm)
☐ Sedated radiographs of tibia (if not performed within the last 4weeks)
☐ Sedated ultrasound of affected tendon – assign tendon score*****
☐ Orthosis molding with GlideWear and activity monitor placeholder (NOTE: notify Orthopets that this is study participant)
☐ Rehabilitation visit #1: Phase I (pain management and inflammation treatment)
☐ Attach Actical activity monitor to pet
☐ Provide owner with activity log

Date: __________ (~Week 2 – delivery of device)
☐ General physical and orthopedic exam****
☐ Tarsal angles (NOTE: should be 165° or greater) ****
  ☐ Tarsal standing angle measured during square stance
  ☐ Tarsal standing angle measured during square stance when lifting up contralateral limb (if allowable per vet assessment)
  ☐ Gastrocnemius flexibility measured in lateral recumbence (stifle in extension, hip in standing angle -> measure the flexion angle of the tarsus)
  ☐ Thickness of Achilles tendon just proximal to the calcaneus (in mm)
☐ Gait analysis to quantify degree of lameness
☐ Subjective Outcome Scoring (SOS) to quantify degree of physical limitations
☐ Collect owner activity log/discuss any changes in activity/lameness/systemic health****
☐ Delivery of orthosis (device fitting with tibiotarsal joint at 165° and the metatarsophalangeal joint at 75° with external component if SDF-injury present based on clinical indication)
☐ Rehabilitation visit #2: Phase II (weight bearing with device and prescription of home program to promote strengthening of co-joint muscles)
☐ Attach Actical activity monitor to device
☐ Retrieve data from Actical attached to collar to verify it is working (do not reset)
☐ Owner to start phase 1 of the rehabilitation protocol (weight bearing exercises)
Date: __________ (~Week 3 – 1 week after delivery)

☐ General physical and orthopedic exam****

☐ Tarsal angles (NOTE: should be 165° or greater) ****
  ☐ Tarsal standing angle measured during square stance
  ☐ Tarsal standing angle measured during square stance when lifting up contralateral limb (if allowable per vet assessment)
  ☐ Gastrocnemius flexibility measured in lateral recumbence (stifle in extension, hip in standing angle -> measure the flexion angle of the tarsus)
  ☐ Thickness of Achilles tendon just proximal to the calcaneus (in mm)

☐ Device recheck

☐ PRN Rehabilitation visit only if not weight bearing with device

☐ Subjective Outcome Scoring (SOS) to quantify degree of physical limitations

☐ Collect owner activity log/discuss any changes in activity/lameness/systemic health****

☐ Retrieve data from Actical attached to device to verify it is working (do not reset)

Date: __________ (~Week 4 – 2 weeks after delivery)

☐ General physical and orthopedic exam****

☐ Tarsal angles (NOTE: should be 165° or greater) ****
  ☐ Tarsal standing angle measured during square stance
  ☐ Tarsal standing angle measured during square stance when lifting up contralateral limb (if allowable per vet assessment)
  ☐ Gastrocnemius flexibility measured in lateral recumbence (stifle in extension, hip in standing angle -> measure the flexion angle of the tarsus)
  ☐ Thickness of Achilles tendon just proximal to the calcaneus (in mm)

☐ Device recheck

☐ PRN Rehabilitation visit only if not weight bearing with device

☐ Subjective Outcome Scoring (SOS) to quantify degree of physical limitations

☐ Collect owner activity log/discuss any changes in activity/lameness/systemic health****

☐ Gait analysis to quantify degree of lameness

Date: __________ (~Week 10 – 8 weeks after delivery)

☐ General physical and orthopedic exam****

☐ Tarsal angles (NOTE: should be 165° or greater) ****
  ☐ Tarsal standing angle measured during square stance
  ☐ Tarsal standing angle measured during square stance when lifting up contralateral limb (if allowable per vet assessment)
  ☐ Gastrocnemius flexibility measured in lateral recumbence (stifle in extension, hip in standing angle -> measure the flexion angle of the tarsus)
  ☐ Thickness of Achilles tendon just proximal to the calcaneus (in mm)

Please contact Kelsie Condon at Kelsie.Condon@colostate.edu or by calling (970) 297-5000 with any questions
Device recheck
Increase tarsal flexion angle by 10° (NOTE: only if equal standing angle to unaffected side is documented – if not delay as clinically indicated)
Rehabilitation visit #3: Phase III graded return to activity schedule
Subjective Outcome Scoring (SOS)
Collect owner activity log/discuss any changes in activity/lameness/systemic health
Gait analysis to quantify degree of lameness

----------------------- IF STANDING ANGLE DIFFERENT THAN UNAFFECTED SIDE-----------------------

⇒ RECHECK q 2 WEEKS UNTIL EQUAL STANDING ANGLE ACCOMPLISHED

Date: __________ (Week _____)

General physical and orthopedic exam
Tarsal angles (NOTE: should be 165° or greater)
Tarsal standing angle measured during square stance
Tarsal standing angle measured during square stance when lifting up contralateral limb (if allowable per vet assessment)
Gastrocnemius flexibility measured in lateral recumbence (stifle in extension, hip in standing angle -> measure the flexion angle of the tarsus)
Thickness of Achilles tendon just proximal to the calcaneus (in mm)
Device recheck
Continue with rehabilitation phase 2
Subjective Outcome Scoring (SOS)
Collect owner activity log/discuss any changes in activity/lameness/systemic health
Gait analysis to quantify degree of lameness

----------------------- ONCE EQUAL STANDING ANGLE AS UNAFFECTED SIDE-----------------------

Date: __________ (~Week 13 – if equal standing angle at 8 weeks)
General physical and orthopedic exam
Tarsal angles (NOTE: should be 165° or greater)
Tarsal standing angle measured during square stance
Tarsal standing angle measured during square stance when lifting up contralateral limb (if allowable per vet assessment)
Gastrocnemius flexibility measured in lateral recumbence (stifle in extension, hip in standing angle -> measure the flexion angle of the tarsus)
Thickness of Achilles tendon just proximal to the calcaneus (in mm)
☐ Device recheck
☐ Increase tarsal flexion angle by 10° (NOTE: only if no deterioration)
☐ Collect owner activity log/discuss any changes in activity/lameness/systemic health****
☐ Gait analysis to quantify degree of lameness
☐ Subjective Outcome Scoring (SOS) to quantify degree of physical limitations
☐ CBPI to quantify daily limitations
☐ CSOM to quantify daily limitations
☐ Actical data download of both devices (do not reset)

Date: __________ (~Week 16 – if no set-back in standing angle)
☐ General physical and orthopedic exam****
☐ Tarsal angles (NOTE: should be 165° or greater) ****
   ☐ Tarsal standing angle measured during square stance
   ☐ Tarsal standing angle measured during square stance when lifting up contralateral limb (if allowable per vet assessment)
   ☐ Gastrocnemius flexibility measured in lateral recumbence (stifle in extension, hip in standing angle -> measure the flexion angle of the tarsus)
   ☐ Thickness of Achilles tendon just proximal to the calcaneus (in mm)
☐ Device recheck
☐ Increase tarsal flexion angle by 10°
☐ Collect owner activity log/discuss any changes in activity/lameness/systemic health****
☐ Gait analysis to quantify degree of lameness
☐ Subjective Outcome Scoring (SOS) to quantify degree of physical limitations
☐ CBPI to quantify daily limitations
☐ CSOM to quantify daily limitations

Date: __________ (~Week 19 – if no set-back in standing angle)
☐ General physical and orthopedic exam****
☐ Tarsal angles (NOTE: should be 165° or greater) ****
   ☐ Tarsal standing angle measured during square stance
   ☐ Tarsal standing angle measured during square stance when lifting up contralateral limb (if allowable per vet assessment)
   ☐ Gastrocnemius flexibility measured in lateral recumbence (stifle in extension, hip in standing angle -> measure the flexion angle of the tarsus)
   ☐ Thickness of Achilles tendon just proximal to the calcaneus (in mm)
☐ Device recheck
☐ Sedated ultrasound of affected tendon – assign tendon score*****
☐ Increase tarsal flexion angle by 10°, removal of paw segment, switch to Dacron strap
Rehabilitation visit #4: Phase 4 (concentric and eccentric in the device, initiate fast
twitch muscle contractions, continue controlled walking)
☐ Collect owner activity log/discuss any changes in activity/lameness/systemic
health****
☐ Gait analysis to quantify degree of lameness
☐ Subjective Outcome Scoring (SOS) to quantify degree of physical limitations
☐ CBPI to quantify daily limitations
☐ CSOM to quantify daily limitations
☐ Actical data download on both devices (do not reset)

Date: __________ (Week 24)
☐ General physical and orthopedic exam****
☐ Tarsal angles (NOTE: should be 165° or greater) ****
   ☐ Tarsal standing angle measured during square stance
   ☐ Tarsal standing angle measured during square stance when lifting up
contralateral limb (if allowable per vet assessment)
   ☐ Gastrocnemius flexibility measured in lateral recumbence (stifle in extension,
       hip in standing angle -> measure the flexion angle of the tarsus)
   ☐ Thickness of Achilles tendon just proximal to the calcaneus (in mm)
☐ Device recheck
☐ If clinically indicated and confirmed via diagnostics (tendon US) and OGA data,
   consider transition to ‘as needed’ sports brace (to be used during high impact
   activity), otherwise continue to use of orthosis in current status.
☐ Collect owner activity log/discuss any changes in activity/lameness/systemic
   health****
☐ Gait analysis to quantify degree of lameness
☐ Subjective Outcome Scoring (SOS) to quantify degree of physical limitations
☐ CBPI to quantify daily limitations
☐ CSOM to quantify daily limitations
☐ Actical data download on both devices (replace battery-do not reset)
☐ Check/Replace battery in both Actical devices

Date: __________ (Week 36)
☐ General physical and orthopedic exam****
☐ Tarsal angles (NOTE: should be 165° or greater) ****
   ☐ Tarsal standing angle measured during square stance
   ☐ Tarsal standing angle measured during square stance when lifting up
   contralateral limb (if allowable per vet assessment)
   ☐ Gastrocnemius flexibility measured in lateral recumbence (stifle in extension,
       hip in standing angle -> measure the flexion angle of the tarsus)
   ☐ Thickness of Achilles tendon just proximal to the calcaneus (in mm)
Device recheck
Rehabilitation visit #5 for prescription of graded return to activity schedule
Collect owner activity log/discuss any changes in activity/lameness/systemic health****
Gait analysis to quantify degree of lameness
Subjective Outcome Scoring (SOS) to quantify degree of physical limitations
CBPI to quantify daily limitations
CSOM to quantify daily limitations

Date: __________ (Week 52)

General physical and orthopedic exam****
Device recheck
Tarsal angles (NOTE: should be 165° or greater) ****
- Tarsal standing angle measured during square stance
- Tarsal standing angle measured during square stance when lifting up contralateral limb (if allowable per vet assessment)
- Gastrocnemius flexibility measured in lateral recumbence (stifle in extension, hip in standing angle -> measure the flexion angle of the tarsus)
- Thickness of Achilles tendon just proximal to the calcaneus (in mm)
Collect owner activity log/discuss any changes in activity/lameness/systemic health****
Gait analysis to quantify degree of lameness
Subjective Outcome Scoring (SOS) to quantify degree of physical limitations
CBPI to quantify daily limitations
CSOM to quantify daily limitations
Sedated radiographs of the tibia
Sedated ultrasound of affected tendon – assign tendon score*****
Actical data download (both devices)
NOTE: This is internal information – do NOT print this page for owners

–– Note: we do have funding available to cover parts of the rehab if it’s a good candidate and client that will follow through on the recheck appointments – ask Felix or Sasha

* Note – not all inclusion criteria details are provided to owners so they do not adjust their scoring (for example for CBPI) – here are the details:

**Inclusion Criteria***:

- Body weight ≥ 15 kg
- Irregular gait/visually identifiable unilateral lameness that is due to Type-2c Achilles Tendinopathy
  - Subjective lameness scoring: SOS-grading ≥ 3
  - Objective lameness scoring (gait mat): %BWD outside reference range (NOTE: if this is not the case and the dog is otherwise a great candidate let’s look at ASI instead)
- Palpable presence of swelling of Achilles tendon insertion and visible “crab-claw” appearance
- No palpable abnormalities of the other Achilles tendon (ultrasound of the other side is not required – if it is performed an abnormal this is NOT an exclusion criteria)
- At home assessment by owner (owner questionnaires) showing impairments that can be defined (such as not jumping into truck, less active etc.)
  - CBPI-scoring: Pain severity score (PSS) ≥ 2
  - CBPI-scoring: Pain interference score (PIS) ≥ 2
- Generally healthy with no other indication of systemic disease (confirmed through bloodwork)

**Owner agrees to:**

- Adhere to recheck schedule as outlined below
- Adhere to current treatment regime unless a change is recommended by us or primary DVM (in which case owner agrees to notify us)
- Allow canine tracking device on CSU issued collar to be worn 24/7 for duration of the study
- Fill out DAILY activity/medication log for duration of the study
- Fill out owner questionnaires at (some) rechecks

**Exclusion Criteria***:

- Previous surgery of affected tendon/tarsus
- Animals not suitable for functional orthosis fittings due to anatomy/build
- Tendinopathy of the other Achilles tendon

Please contact Kelsie Condon at Kelsie.Condon@colostate.edu or by calling (970) 297-5000 with any questions
Owner wanting to pursue regenerative medicine or surgical treatment in addition to device

- Concurrent CCLD of affected stifle (based on palpation, no radiographs necessary to r/o stifle disease unless clinically indicated based)
- Other orthopedic or neurological conditions that affect or are suspected to affect the gait significantly
- Owner unwilling/incapable to return to CSU for follow-up visits for a 1 year duration

** Proceed with evaluation in this order to avoid enrolment cost if not a candidate for study

*** If owners elect to change pain regime they are not eligible for enrolment until consistent treatment stage is accomplished. This is includes weight loss (i.e. most dogs with BCS of 6 or greater should not be included unless we don’t expect that the owners will work on it. Discuss the limitations of these treatments but advise that this is our standard of care and they can elect to try these things first. Our current standard of care for medical management of OA includes:

- Weight loss (if overweight)
- Physical therapy/exercise modification
- NSAIDs (=Rimadyl if the patient has not received any NSAIDs. If the patients has received NSAIDs, the owner may opt to switch to Rimadyl [i.e. covered by study] or continue with the current NSAID. Rimadyl will be prescribed @ 2.2mg/kg BID for the time of the study, however, owners are advised about the potential side effects (however, these side effects don’t appear to be more common with long-term administration – see paper attached) and are informed that they may elect to taper the dose to ½ the dose (i.e. SID dosing; which is safer for liver/kidney since these side effects are dose-dependent) if they feel that their pet’s lameness has improved. Recheck CBC/Chem will be performed at 2 weeks after initiation of drug and 3 months after initiation of drug (covered by study).
- Gabapentin (=@ 5-10mg/kg TID (start with lower dose, if no sedation move up to higher dose after 2 weeks)
- Welactin (EPA/DHA in mg) (=@ 310mg X BW 0.75 for dogs with BCS 4-5/9, and 100mg/kg for dogs with higher BCS – start with ¼ dose of the max dose and increase weekly to the max tolerated dose)
- Dasuquin (= as recommended on the package label: start with BID for a month, then SID only – if the owners prefer to use a different product containing GCS they don’t need to switch)
- Adequan injections (=@ 4.4mg/kg SQ inj. X 2/week for 4 weeks, then once/week for 4 weeks, then once/month (off label)

**** Note findings in Xcel enrolment sheet on T-drive – this needs to include sores, thickness of Achilles tendon etc.
**** Tendon scoring system (to be assigned by the radiologist – please provide this sheet to the ultrasonographer)

Scores will be assigned to the echotexture and architecture of the tendon based on a previously described scoring system.40,41 Score 1 will be assigned when the majority of the area (>80%) is anechoic. Score 2 will be assigned when approximately 30-50% of the area is anechoic and approximately 30-50% of the area is hypo-echoic. Score 3 will be assigned when the majority of the area (>80%) is hypo-echoic. Score 4 will be assigned when the majority of the area (>80%) is displaying normal echotexture.40,41 Additional parameters recorded will include homogeneity and diameter of the tendon, as well as reappearance of typical fibrillar structure.41,42

Sebastian – can you outline this clearly and make a nice scoring sheet please?

Gait analysis protocol

All gait analysis should be performed without the devices if this is allowable per vet assessment (and what the owner is currently doing at home). If the dog is not allowed to walk without the device gait analysis will be performed with the device in place but this needs to be clearly noted in the excel sheet and gait data.

Rehabilitation treatment protocol

Sebastian – I believe you have this? This is at home mostly, right?