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Comparing Veterinary Diagnosis and A Novel Non-invasive Device (PainTrace®) to Quantify Acute and Chronic Pain in Dogs and Horses

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Introduction

Currently, persistent pain is principally measured by self-report in humans or validated pain scales in veterinary medicine based on physical exam and activity. There has been an increase in the number of pain-related fMRi & EEG studies, and complementary human experimental techniques including quantitative sensory testing but a direct objective biosignal has not yet been elucidated. In this study PainTrace®, a novel pain monitor employing skin-mounted sensors, was compared to veterinary diagnosis for both acute and chronic pain. The use of this novel pain biosignal holds promise for quantitative correlation to both animal and human pain diagnosis.

Goals

Animals cannot verbalize their pain levels directly. The following data analyzes veterinary diagnosis compared to PainTrace® biosignal to establish the capacity to differentiate pain and non-pain with a high degree of confidence building on previous work establishing the statistical significance of PainTrace® to differentiate pain levels.

For illustration purposes, we show the correlation of self-reported VAS (Visual Analog Scale), commonly employed in human studies in comparison to PainTrace® biosignal (Figure 1). VAS Self-report is graphed in blue and PainTrace® (PT) values are graphed in red. Note the inverse relationship.

- More Pain Equals a Greater Negative Peak Deflection
- A Positive Deflection or Trend Equates to No Pain, Recovery, or Level of Vigor.

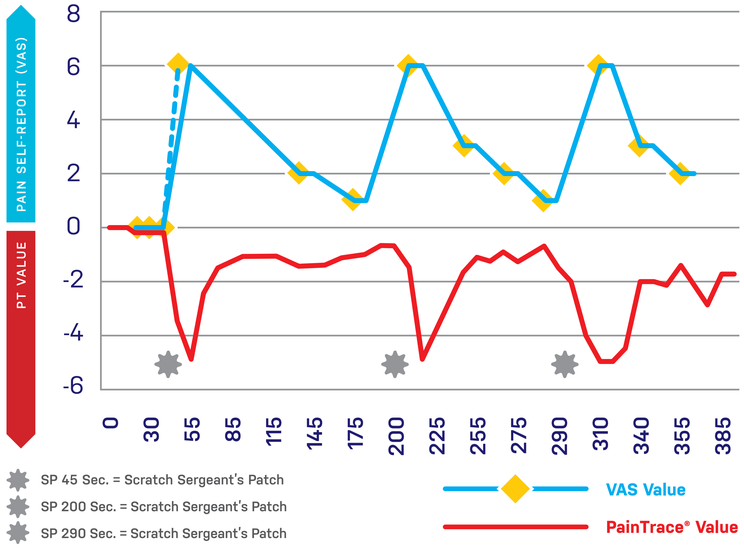

FIGURE 1. SELF-REPORTED PAIN (BLUE) VS. PAINTRACE® BIOSIGNAL (RED) IN AXILLARY NERVE INJURY.

During this visit pain was produced by scratching the area of the skin associated with the Axillary Nerve Injury/Sergeant's Patch at 45, 200, and 290 seconds. Pain levels recorded with the BioTraceIT™ device appear to correspond with self-report of pain. Note: The VAS (Visual Analog Scale) equal to 6 at 45 seconds was not recorded and was added for graphing purposes. All recorded VAS scores are denoted by the yellow diamond markers.

Materials and Methods

In two separate observational studies, involving 24 dogs and 71 horses, pain was assigned via veterinary diagnosis and monitored using PainTrace® (Figure 2) from BioTraceIT™. All study participants were submitted to a thorough exam by the respective Veterinarian to assign a painful or non-painful diagnosis. That determination was then associated with the PainTrace® measurements taken at the time of the exam.

FIGURE 2. PAINTRACE® A PATENTED, WEARABLE MONITOR THAT UTILIZES DISPOSABLE ECG-LIKE SKIN MOUNTED SENSORS TO OBTAIN REAL-TIME NUMERICAL PAIN INFORMATION.

Results

Based on veterinary diagnosis using palpation of anatomy during examination, the dogs were categorized into pain and non-pain groups (Figure 3). Pain, as defined in this study, was an acute reaction to manipulation or movement that includes strong reactions of withdrawal or aggression. A total of 207 acute events, from the 24 dogs in the study, were chronicled and statistically analyzed resulting in a 97% specificity for no pain diagnosis with sensitivity of 90% for pain at a 95% CI.

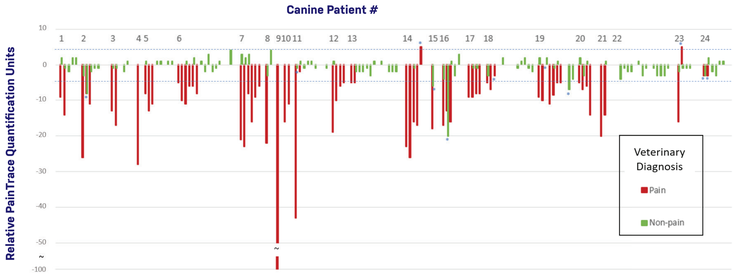

FIGURE 3. ASSOCIATING PAINTRACE® ABSOLUTE PEAK VALUES WITH CANINE VETERINARY DIAGNOSIS FOR ACUTE PAIN.

Summary of acute pain responses of **24 dogs** during veterinary examination. Red bars represent PainTrace® absolute biosignal values associated with pain. Green bars represent a non-painful response. All data was normalized to a scale of 100 and the cutoff indicated by the dotted line was used to differentiate non-painful events during examination. The data points indicated by an asterisk (*) are those points that differ from the veterinary diagnosis of the presence of pain.

In a separate equine study, chronic pain was ascertained by veterinary evaluation. Diagnosis included: exams, lameness at a walk, dietary and behavior changes, patient history, coffin bone movement, and radiology dependent of pain source. Pain was evaluated over days or weeks utilizing the PainTrace® baseline value, with positive values corresponding with no pain and negative values related to pain rather than the acute peak deflection at time of palpation during a single exam as in the dog study. The horses were also categorized as pain /non-pain illustrated in Figure 4. The resultant statistics showed the 71 horses evaluated for pain had a 93% specificity for no pain diagnosis and 100% sensitivity for pain at a 95% CI as compared to veterinary diagnosis.

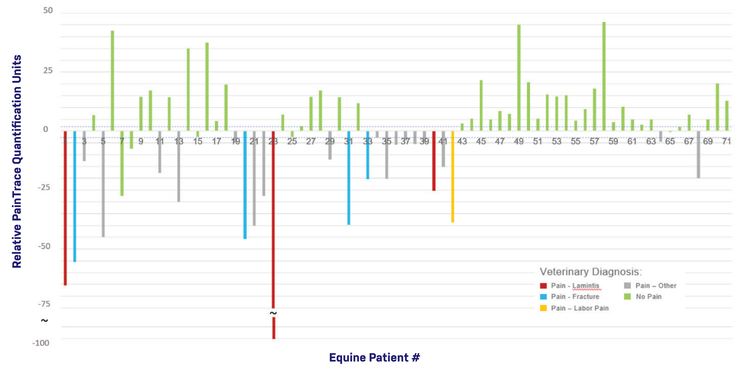

FIGURE 4. ASSOCIATING PAINTRACE® PEAK VALUES WITH EQUINE VETERINARY DIFFERENTIAL DIAGNOSIS FOR CHRONIC PAIN.

Summary of chronic pain baseline values normalized to a scale of 100 for the **71 horses** and their correlation with pain diagnosis based on veterinary exam. Green bars represent positive valued PainTrace® baseline values which agree with non-pain diagnosis. Patients 7 and 8, are the two out of 46 non-pain PainTrace® values, beyond the cut-off threshold indicated by the dotted lines, that do not agree with the veterinary diagnosis resulting in 93% specificity. 100% sensitivity reflects complete agreement of the negative PainTrace® peaks that agree with the veterinary diagnosis of pain.

Discussion

In these observational studies, we have established that the novel pain monitoring device, PainTrace®, quantifies pain correlating with veterinary diagnosis achieving specificities & sensitivities of > 90%, at a 95% Confidence Interval, for both acute and chronic pain in either canine or equine studies. The utility of the device, as a wearable monitor for extended periods of data collection and multi-activity pain monitoring – e.g. exam, rehabilitation, and pre/post-surgery, supports long-term follow-up care to determine the effectiveness of treatment(s). Additional human studies in both the rotator cuff and lower back pain have been completed and produced p values < 0.001 to demonstrate the versatility of the device in other species. In human studies PainTrace® correlates with self-reported pain and differentiates pain levels on a one-point scale using VAS 0-10. Orthopedic protocols in both canine and equine patients and further animal studies are in progress and warranted based on outcomes in IRB approved human studies employing PainTrace®. These results, along with data in other studies, indicate that investigations with less than twenty participants can achieve a power of 80%.

Based on these positive outcomes, we plan to further the potential of quantitative pain measurement to improve pain studies and increase efficiencies through statistically significant outcome measures that support translational medicine.

Acknowledgement

Thank you for access to our canine patients and for clinical diagnosis to Nigel Gumley, DVM, MSc, Diplomate American Board of Veterinary Practitioners (Canine/Feline), Certified Canine Rehabilitation Practitioner, Cedarview Animal Hospital, Ottawa, Ontario. BioTraceIT™ provided the pain monitoring device and performed statistical analysis.