AcuLife Patches Produce Pain Relief in Horses

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Abstract

Veterinarians working with performance and pet horses on a daily basis have tremendous interest in drug-free pain relief and management of the very common musculoskeletal problems that these horses may experience. In an initial study carried out in 142 horses in 2005, it was demonstrated that horses responded dramatically to LifeWave Energy Patches. In this study, 137 out of 138 horses with mild to severe back pain, responded favorably and showed consistent pain relief manifesting more energy and power. In a second investigation carried out in 38 horses in 2010, we showed that IceWave Patches produce a highly significant pain reduction (cooling effect) in the areas affected by pain in these animals as measured by infrared thermal imaging and acupuncture palpation evaluation. We also showed that these nanoscale wearable devices exert a warming effect due to increased perfusion in hypothermic (cold) areas affected by abnormal circulation. Other published double-blind placebo-controlled studies in humans have demonstrated a skin cooling effect or parasympathetic response elicited by these Patches.

In 2012, LifeWave launched AcuLife, an acupressure device based on the LifeWave patch technology, specifically for equine use. Therefore, the main objective of the present study was to follow up on our previous investigations in horses and use the combined capabilities of infrared thermal imaging and acupuncture palpation evaluation methods to show the efficacy of AcuLife patches in pain relief and further pain management in these animals. The hypothesis to be tested was that: AcuLife Patches produce pain relief in painful areas in horses.

Fifty three horses: 1 Stallion, 32 Geldings and 20 Mares of varying ages (4 to 31 years old) and disciplines were included in this study. Informed consents were acquired from the owners of qualified candidates. Study subjects with pain symptoms were first evaluated by the Veterinarian to assess their pain severity based on acupuncture palpations (on a scale of 1-10). Then they had their area of pain scanned with an infrared thermal imaging system. The ease of normal activities of the animals was also considered as one of the measurement outcomes.

Statistical analysis of the acupuncture palpation data revealed a very highly significant (p<0.0001) reduction in pain level due to wearing the AcuLife Patches in the affected (painful) areas in horses compared to Placebo. Statistical analysis of thermal imaging data also revealed a highly significant (p<0.004) pain relief in the left side of the body due to wearing the AcuLife Patches in the affected (painful) areas in these animals. No significant differences were observed between Active and Placebo treatments on the right side of the body! This was mainly attributed to missing data that considerably reduced the sample size in this case - from 53 to 23 - for comparing Active to Placebo. When the average of the right and left sides data were used, the comparison between Active and Placebo in this case was nearly significant (p=0.062 by the paired t-test).

The overall data demonstrated that in *every* case there was a change in the sensitivity of the palpated points after application of the AcuLife Patches to painful points. In each case the sensitivity and pain observed were considerably lower compared to pre-patch application. The infrared thermal imaging data showed related changes as noted in palpation data sheets. In some cases, there was not just a cooling effect, but sometimes there was a warming effect: an obvious attempt of the body to *balance* the system. (This was quite exciting to the researchers and was indicative of the efficacy of the AcuLife Patches. In the veterinarian's expert opinion, this is a dramatic effect. (It should be

noted that as we learned from our previous study last year with the horse Munoso, who's very cold area warmed, as, at the same time, the inflamed areas cooled.) *Based upon these findings the hypothesis that:* AcuLife *Patches produce pain relief in painful areas in horses was accepted as generally true.*

Introduction

Chronic musculoskeletal pain could consist of categories such as chronic low back pain, non-inflammatory arthritis (e.g., osteoarthritis), inflammatory arthritis (e.g., rheumatoid arthritis), fibromyalgia, myofacial pain syndrome and others. Chronic pain treatments include Transcutaneous Electrical Nerve Stimulation (TENS), acupuncture, ultrasounds, thermal therapies, lasers, and drugs such as antidepressants, Non-Steroidal Anti-inflammatory Drugs (NSAIDs), opioids, and other medications [1]. *Drug-free pain relief and management offer tremendous advantages over drug-based approaches mainly due to lack of side effect complications and as such are of considerable interest in the treatment of humans and in veterinary medicine.*

Infrared thermal imaging, also known in the literature as infrared thermal imaging, or medical thermography is a non-invasive diagnostic imaging procedure, which detects and records surface skin temperatures by measuring the variations in heat that is spontaneously emitted from body surfaces. Since heat dissipation through the surface skin is mainly in the form of infrared radiation, *infrared thermal imaging* offers an effective way to study the physiology of thermoregulation and the thermal dysfunction associated with *pain [2, 3].* It is well established that patterns of surface skin temperature distribution in a healthy body shows a contralateral symmetry [4]. Asymmetrical patterns in skin temperature distribution may be strong indication of pathology [5-7]. It is also established that changes of temperature distribution in the skin are related to some nociceptive and most neuropathic pain pathologies, which manifest as hyperthermic or hypothermic regions [8]. Thermal measurements reflecting surface skin temperature distribution are converted into live images visualizing the autonomic nervous system activity. Therefore, changes in the neurological and musculoskeletal system influenced by *trauma* or dysfunction could then be detected, monitored and *quantified [3].* It is a useful approach in detecting the origin and extent of chronic and acute pain.

As the autonomic nervous system of the body controls the thermal response, the external skin temperature creates a thermal map that is an *objective* measure of normal as well as abnormal physiologic function. The infrared evaluation as a diagnostic procedure in evaluating normal physiologic function can be an accurate and objective evaluation of pain. In thermal skin readings, a 0.05 °C difference is considered significant [9].

As infrared thermal imaging does not use ionizing radiation (no energy is used to excite the body and it only involves measuring the infrared radiation emanating from the surface skin) it is considered as 100% safe and does not suffer from any side effects like other imaging modalities do. Whereas X-rays demonstrate *anatomy*, thermal imaging is unique in its capability to show *physiological change and metabolic processes*. It has also been proven to be a very useful complementary procedure [10, 11] to standard investigations based on X-rays and other 3-dimensional diagnostic scanning techniques such as Computerized Tomography (CT) and Magnetic Resonance Imaging (MRI). With recent advancements in infrared technology, intelligent image processing and enhancement algorithms as well as pathophysiological-based understanding, this imaging modality has emerged as a non-destructive, cost-effective and patient-friendly approach to health monitoring, examination and diagnosis.

The first surge of application of infrared thermal imaging in diagnostic medicine occurred in 1960's with breast cancer detection as the primary practice [12, 13]. Since then, it has been applied to a variety of

conditions including nerve root impairment [7] back and neck injuries [8] peripheral neuropathy [14] migraines [15], inflammation [16], complex pain syndromes [17], cervical sprains [18], shoulder impingement syndrome [19], and fibromyalgia [20] to name a few. Also a number of investigations have shown that infrared thermal imaging is *a sensitive, accurate, and practical* aid in the clinical evaluation of a variety of conditions in the equine patient [21-31].

In a recent clinical study the efficacy of infrared thermal imaging in distinguishing response to true acupuncture treatment was investigated. It was demonstrated that infrared thermal imaging is a reliable and easy to use tool to distinguish between true *acupuncture points* and non-acupuncture points [32].

AcuLife Patches are referred to by their manufacturer as a product for mild stimulation of *acupuncture points* using mild pressure exerted by the beads used in these Patches. These are currently marketed in the United States as a medical device for temporary pain relief and inflammation for horses. They are acupressure-based patches and work by placement on acupuncture points recommended by veterinarian and substantiated by research study data. As was mentioned above, stimulation of acupuncture points is achieved by beads applying pressure on these well-established points, which have lower electrical conductivity. Evidence obtained from clinical trials in both acupuncture studies with needles and acupressure studies has determined that the exact point of application if very important.

LifeWave Patches are a safe and effective (non-transdermal) new technology capable of gently stimulating acupuncture points without using needles *[33, 34]*. LifeWave Patches utilize this innovative technology to stimulate acupuncture points on the body for improving the flow of energy in the acupuncture meridians. These patches are designed to stimulate acupuncture points by several mechanisms that involve both *acupressure* and *energetic* principles.

In 2005, an initial study was carried out in 142 horses. It was demonstrated that horses responded dramatically to LifeWave Energy Patches. In that study, 137 out of 138 horses with mild to severe back pain, responded favorably and showed consistent pain relief manifesting more energy and power. That study proved that alternate (drug-free) treatment benefits were possible without harmful effects. It was further evident that these Patches might well be causing a measurable physiological effect to reduce pain and inflammation and therefore enable the body to heal itself more quickly [35].

Infrared thermal imaging is proving to be an accurate and sensitive method to identify the above mentioned issues even more precisely and was incorporated into this study to further validate the findings based on acupuncture theory and *palpation*. The standard approach for pain relief in horses can involve anti-inflammatory drugs and chemical pain relievers. These can of course, be effective. Drugs, however, cannot be used in most horse events, racing, or in shows, and if pain relief can be accomplished in a more natural way, that involves no harmful effects in the short or long term, we are far ahead. The current study was then designed to explore these possibilities further. Other published double-blind placebo-controlled studies in humans have also demonstrated a skin cooling effect or *parasympathetic response* elicited by these Patches [36-38].

Since animals cannot communicate in words, it is sometimes difficult for caretakers to identify painful areas in the body. Acupuncture evaluation and *palpation* of anatomical areas has been a great tool to help identify problems in the horse for further examination and treatment [39].

In 2010, *in a second investigation carried out in 38 horses, we showed that IceWave Patches produce a highly significant pain reduction (cooling effect) in the areas affected by pain in these animals and that the*

Patches exert a warming effect due to increased perfusion in hypothermic (cold) areas affected by abnormal circulation [40].

The main objective of the present study was to follow up on the two previous investigations carried out in horses and use palpation and infrared thermal imaging to further explore the efficacy of AcuLife Patches in pain relief and management. Acupuncture palpation evaluations complemented with infrared thermal measurements and imaging were performed. It was of interest to explore the effects of these Patches on painful and inflamed areas in horses and demonstrate their physiological impact and further cross-validate with the Veterinarian expert evaluations. The hypothesis to be tested was that: *AcuLife Patches produce pain relief in painful areas in horses.*

Methods and Materials

A total of 53 horses: 1 Stallion, 32 Geldings and 20 Mares, of varying ages (4 to 31 years old) and disciplines, were examined and owners were consulted about study suitability. Any obvious problems that the owner was aware of were noted. All horses that had chronic conditions, were on medication or had on-going physical problems were excluded from the study.

The study was carried out at the Vet's facility at Coffman Ranch in Clovis California in April 2011. Several horses participating in the study resided at this facility and the rest were brought in by their owners. The horses were taken right from their trailers and placed in holding stalls or held by the owner. Precautions were taken to ensure all horses enrolled in the study were kept calm and were maximally comfortable with the barn area where the study was conducted. None of the horses were upset, distressed or required special restraints. All the animals were palpated by the Veterinarian or one of her helpers, using the chart below:

10 Point Chart for Horses:
1. No detectable discomfort.
2. Marginal discomfort, skin may twitch in one or two areas.
3. Slight or localized muscle, skin may twitch in one or two areas.
4. Marginal sensitivity; twitching of skin in three or more areas or slight tendency of horse to move away from pressure.
5. Noticeable discomfort and generalized muscle tightness, moves away from pressure but is not terribly distressed.
6. Mild distress; skin twitches and horse moves away; may turn to look at tester and lay ears back.
7. Obvious distress may have muscle spasms, turn to look at tester, lay ears back, stomp foot, move away.
8. Frank pain, may grind teeth, lay ears back, threaten tester, try to get away, muscle spasms along the back common.
9. May not tolerate even a light touch. May drop and stumble from the palpation, lay ears back, etc.
10. May try to kick or bite as well as other signs of distress.

Palpation for painful responses in horses is not a diagnostic tool in itself, but must be supported by other methods of detection such as radiographs, sonograms, infrared thermal imaging, and conventional lameness exams. However, veterinarians use acupuncture palpation in their practice as an indicator for further investigation. Because of variations in breeds of horses, individual disposition and sensitivity, palpatory findings can be quite variable. Acupuncture palpation served as a useful

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complimentary method in evaluation of the results of the application of AcuLife Patches on acupuncture points, before and after patching in this study. Figure 1 shows the manufacturer's instructions (steps1-4) for patch placement and the details of an AcuLife Patch with the bead placed at its core.

Figure 1. Steps for patch placement and the detailed drawing for an AcuLife Patch.

Each horse was palpated and imaged before placing the patch (Baseline), after placement of the Placebo patch, then again after application of the Active patch. Ten minutes were allowed between each phase, imaging and palpation. The Patches with beads were placed on the acupressure points in the final patch event.

The 10-point palpation scales were subjective, of course, but certain acupressure points were used which gave consistent results in the neck, base of neck, back, mid-back and hips. These were Bladder 10, Bladder 13, Large Intestine 16, Bladder 23, and Bladder 28. Consistency was our achieved goal even though we acknowledge that the palpation was subjective.

Bladder 10 (Figure 2) - Located in the depression immediately caudal to the occipital bone and lateral to the m.trapezius. This is a good point to benefit the Qi and clear Interior and Exterior Wind from the head (headaches, convulsions, stiff neck, stimulate memory and concentration). It is the point at which the Bladder Meridian divides. They join in the popliteal fossa behind the stifle at Bladder 40. The outer branch relates to the parasympathetic system while the inner branch relates to the sympathetic system.

Bladder 13 (Figure 3) - is the Back-Shu (Association point) for the Lung Meridian. It is located 3 cuns lateral to the lower border of the spinous process of the eighth thoracic vertebra in the horse at the caudal edge of the scapular cartilage in the eighth intercostals space. This may be used to diagnose and or treat condition, at the caudal edge of the scapular cartilage of the lung or conditions on the Lung Meridian.

Large Intestine 16 (Figure 4) – This is located in the upper aspect of the shoulder, in the depression between the acromium extremity of the clavicle and the scapular spine. Stimulation of this point improves blood flow locally, opens the chest, and removes obstructions acupuncturally from the channel. It also benefits the joints and their overall function. This point has a powerful effect similar to LI 4 in humans affecting the sympathetic ganglion producing endorphine like effects and clocking the sympathetic system. Tenderness at this point may be caused by pain in the shoulder, elbow, knee, ankle, shin, and pastern.

Bladder 23 (Figure 5) - is the Association point for the Kidney Meridian and is found 3 cuns lateral to the lower border of the spinous process of the lumbar vertebra between the second and third lumbar vertebrae above the end of the last rib in the horse. It may be used to diagnose and/or treat conditions of the kidney or pathology on the Kidney Meridian. Use is generally in all immune related problems, in urinary problems, adrenal imbalances and fertility disorders.

Bladder 28 (Figure 6) – is the Association point for the Bladder Meridian and is located 3 cuns lateral to the lower border of the sacral spinous process between the foramen of the second and third sacral vertebrae. The Bladder Meridian is the most important of all the meridians diagnostically and therapeutically.

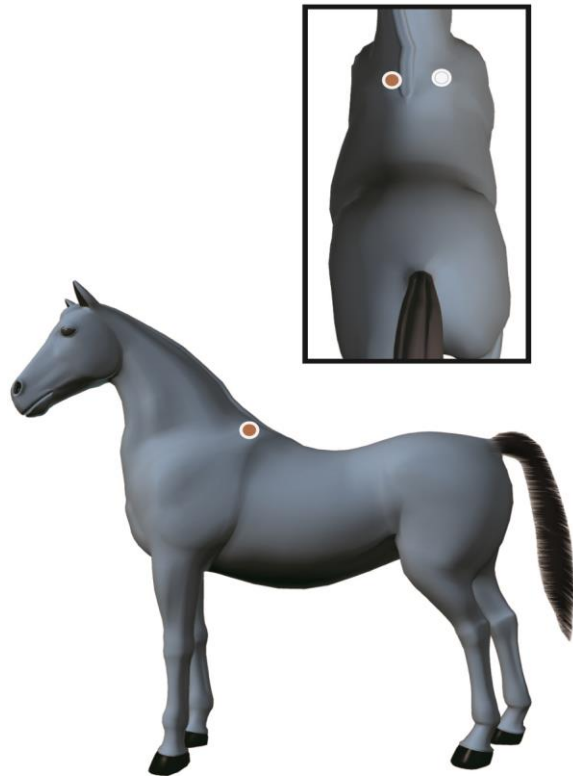Figure 2. AcuLife Patches placed on Bladder 10 acupressure point (Placement of Tan Patch is shown.)

Figure 3. AcuLife Patches placed on Bladder 13 acupressure point.

Figure 4. AcuLife Patches placed on Large Intestine 16 acupressure point (Placement of Tan Patch is shown.)
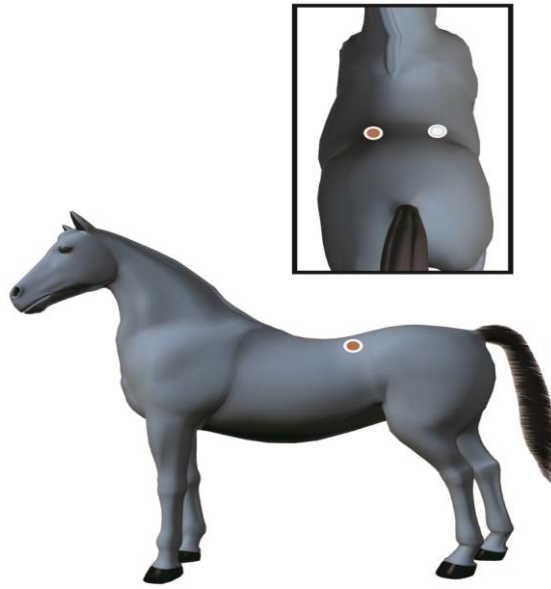
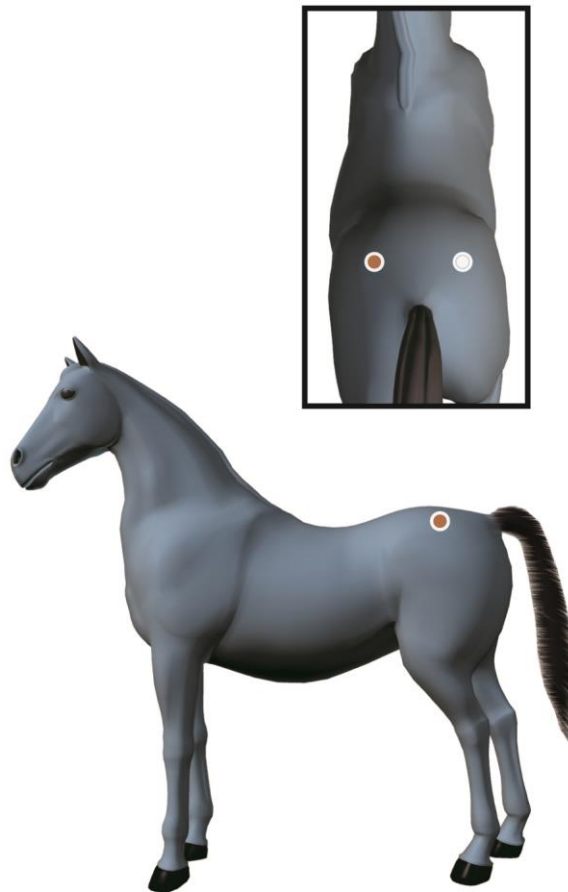Figure 5. AcuLife Patches placed on bladder 23 acupressure point.

Figure 6. AcuLife Patches placed on bladder 28 acupressure point.

The acupressure points were limited to those that have proven to have the best overall response in previous studies. Owners were asked to help visualize and palpate the areas on the neck, shoulders, back and hindquarters of their horse. If the horse had chronic problems with various other conditions, such as pain in the feet or legs, those were also noted. We did not concentrate on those abnormalities. This method of palpation aided in determining what region of the horse's body to image first, in order to determine the greatest source of pain. The resolution of the infrared imaging system used in this study was 0.01 degree centigrade (C).

Infrared thermal imaging data as well as acupuncture palpation data from 53 horses were acquired by the Veterinarian and the Chiropractor member of the team who is board certified in infrared thermal imaging and has been using infrared imaging as a diagnostic tool for chiropractic pain applications for years. Infrared thermal imaging measurements were repeated between 4 to 10 times in each horse.

Infrared thermal imaging was conducted in a temperature-controlled draft-free environment where the ambient air temperature averaged 48 degrees F° (~ 8.9°C using the following conversion formula: F = 32 + 1.8 C). Great care was taken to position the horses the same distance from the camera in each image sequence, especially when imaged the second time. All the horses were patched by the Veterinarian and Chiropractor member of the research team with the tan Patch on the left side and the white Patch on the right side. The Patches were applied in pairs based upon the most obvious thermal changes observed on the images. Several acupuncture points were found, which based on the observed thermal changes were not limited to the immediate local area, but with respect to the rest of the horse as well, created a holistic thermal effect. These points were as described above. The horses were imaged before patching and, utilizing the most affected areas on the images, the patches were placed for each case. Each horse was treated as an individual.

The Veterinarian palpated specific areas of the horses that were most commonly painful in performance and in older pet horses. The neck, base of neck, shoulders, back and croup were examined and palpated with about 3 pounds of pressure. A 10-point pain scale also used in the initial study was adopted for the current study [34]. The Veterinarian trained the owners to identify and gauge the painful areas. Owners were helped to visualize and palpate the areas on the neck, shoulders, back and hindquarters.

RESULTS

The data collected and analyzed in this report are summarized in Tables 1-4. Table 1 displays the palpation data. Columns 2-4 display the scores from Baseline and following Placebo and Active treatment. For Placebo, columns 5-6 display the reduction and percent reduction from Baseline. Similarly, columns 7-8 display the reduction and percent reduction from Baseline to Active. Column 9 displays the difference between Active and Placebo (computed as the Placebo score minus the Active score).

Table 2 displays the infrared (IR) data for right pre-, right Placebo, right Active, left pre-, left Placebo, and left Active acquired from each horse. These data were then used to compute the additional IR variables displayed in Tables 3 and 4.

Table 3 displays the changes from Baseline and the percent changes from Baseline for the right side, left side, and average of the right and left sides for both Placebo and Active Patches. Note that all changes and percent changes are computed by subtracting the Baseline score from the corresponding score. Also note that, if data from either the left side or the right side are missing, the average values are taken to be the values from the nonmissing side. (Due to space limitations, only one decimal place is displayed for the

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percent changes from Baseline and only two decimal places are displayed for the changes from Baseline. However, the full precision is used in all subsequent computations.)

Finally, Table 4 displays the differences between Active and Placebo for the right side, the left side, and the average of the two sides. These differences are computed by subtracting the Placebo value from the Active value.

Table 1. Listing of Palpations Data.

				Placebo		Active		Placebo-
Horse	Baseline	Placebo	Active	Reduct.	%Reduct.	%Reduct.	Reduct.	Active
1	5	5	0	0	0.0	5	100.0	5
2	2	2	0	0	0.0	2	100.0	2
3	5	5	0	0	0.0	5	100.0	5
4	4	4	1	0	0.0	3	75.0	3
5	2	2	0	0	0.0	2	100.0	2
6	8	8	2	0	0.0	6	75.0	6
7	4	4	0	0	0.0	4	100.0	4
8	8	8	0	0	0.0	8	100.0	8
9	9	9	0	0	0.0	9	100.0	9
10	6	6	0	0	0.0	6	100.0	6
11	3	3	0	0	0.0	3	100.0	3
12	5	6	0	-1	-20.0	5	100.0	6
13	7	7	0	0	0.0	7	100.0	7
14	7	7	0	0	0.0	7	100.0	7
15	4	4	0	0	0.0	4	100.0	4
16	5	5	0	0	0.0	5	100.0	5
17	2	2	0	0	0.0	2	100.0	2
18	5	5	0	0	0.0	5	100.0	5
19	6	6	0	0	0.0	6	100.0	6
20	7	7	1	0	0.0	6	85.7	6
21	6	6	0	0	0.0	6	100.0	6
22	8	8	1	0	0.0	7	87.5	7
23	3	3	0	0	0.0	3	100.0	3
24	3	3	0	0	0.0	3	100.0	3
25	9	9	1	0	0.0	8	88.9	8
26	5	5	0	0	0.0	5	100.0	5
27	4	4	1	0	0.0	3	75.0	3
28	3	3	0	0	0.0	3	100.0	3
29	6	6	2	0	0.0	4	66.7	4
30	8	8	0	0	0.0	8	100.0	8
31	5	5	0	0	0.0	5	100.0	5
32	6	6	0	0	0.0	6	100.0	6
33	4	4	0	0	0.0	4	100.0	4
34	9	9	0	0	0.0	9	100.0	9
35	8	8	0	0	0.0	8	100.0	8
36	8	8	2	0	0.0	6	75.0	6
37	9	9	1	0	0.0	8	88.9	8
38	8	8	0	0	0.0	8	100.0	8
39	6	6	0	0	0.0	6	100.0	6
40	8	8	0	0	0.0	8	100.0	8
41	9	9	2	0	0.0	7	77.8	7
42	4	4	0	0	0.0	4	100.0	4
43	7	7	0	0	0.0	7	100.0	7
44	7	7	1	0	0.0	6	85.7	6

45	7	7	0	0	0.0	7	100.0	7
46	9	9	0	0	0.0	9	100.0	9
47	8	8	1	0	0.0	7	87.5	7
48	8	8	2	0	0.0	6	75.0	6
49	3	3	0	0	0.0	3	100.0	3
50	6	6	1	0	0.0	5	83.3	5
51	7	7	1	0	0.0	6	85.7	6
52	8	8	1	0	0.0	7	87.5	7

Table 2: Listing of IR Data

Horse	Right Pre	Right Placebo	Right Active	Left Pre	Left Placebo	Left Active
1	30.450	30.400	31.260	30.080		30.630
2	30.950	31.013	30.613	31.563	31.563	30.863
3	29.900	30.500	30.810	29.063	31.100	30.770
4	29.880	30.888	30.230	30.063	30.460	30.513
5	30.290	30.960	30.460	29.700	29.410	29.310
6	30.988	30.950	30.675	29.725	29.400	29.225
7	31.163	31.850	29.688	30.863	30.712	30.100
8	30.462	30.688	31.025	30.462	30.900	30.450
9	30.325		29.650	31.425		32.138
10	30.050	30.200	31.913	30.850	31.688	31.600
11	31.800	32.100	31.430	31.875	31.900	31.087
12	30.110	30.300	30.350	30.100	30.150	30.520
13	26.450		27.310	31.690		27.380
14	28.775	28.525	30.450	29.087	30.038	31.000
16	31.480	30.500	31.010	31.340	31.190	29.390
17	22.160	24.110	22.960	24.790	23.000	22.140
18	31.050	31.140	30.990	30.880	31.040	30.440
19	31.840	31.810	32.440	31.540	31.590	31.440
20	31.830		32.160	31.990		31.560
21	30.520		30.240	30.510		30.380
22	30.730		30.700	30.290		29.960
23	29.550	30.110	30.050	30.360	30.400	29.310
24	30.540		29.900	32.210		30.270
25	32.390	32.090	32.150	32.210	32.500	32.730
26	30.540	30.680	29.660	30.770	30.080	29.210
28	26.460	26.430	25.110	26.460	26.350	25.570
29	25.690	26.180	26.270	26.850	26.390	26.300
30	25.140	26.580	24.890	25.700		24.600
31	25.520		26.440	25.640		26.510
32	27.930	27.350	27.190	27.830	28.150	26.710
34	26.690		25.600	26.500		25.700
35	28.600		27.680	28.300		27.250
36	27.500		25.925	26.875		25.700
37	22.860		23.490	24.150		22.400
38	27.060		25.330	27.240		
39	27.580		27.240	27.890		27.090
40	25.830		27.090	24.770		26.770
41	26.790		26.600	27.680		26.790
42	24.840		25.400	25.610		24.830
43	26.450		26.590	25.880		25.590
44	28.340		28.080	28.750		28.200
45	30.010		30.740	30.260		29.380
46	30.480		30.650	31.330		31.330
47	29.580		29.110	29.710		28.600
48	30.740		29.400	30.760		28.860
49	30.910		30.110	29.680		28.550
50	28.050		29.020	29.630		29.460
51	30.130		29.600	31.060		30.250
52	31.310		32.230	31.890		32.730
53	31.460		30.680	31.040		30.750

Table 3: Listing of IR Changes and Percentage Changes from Baseline

Horse	Right Plac. Chng	Right Plac. %Chng	Left Plac. Chnge	Left Plac. %Chng	Ave. Plac. Chng	Ave. Plac. %Chng	Right Act. Chng	Right Act. %Chng	Left Act. Chng	Left Act. %Chng	Ave. Act. Chng	Ave. Act. %Chng
1	-0.05	-0.2			-0.05	-0.2	0.81	2.7	0.55	1.8	0.68	2.2
2	0.06	0.2	0.00	0.0	0.03	0.1	-0.34	-1.1	-0.70	-2.2	-0.52	-1.7
3	0.60	2.0	2.04	7.0	1.32	2.0	0.91	3.0	1.71	5.9	1.31	4.5
4	1.01	3.4	0.40	1.3	0.70	1.9	0.35	1.2	0.45	1.5	0.40	1.3
5	0.67	2.2	-0.29	-1.0	0.19	1.0	0.17	0.6	-0.39	-1.3	-0.11	-0.4
6	-0.04	-0.1	-0.33	-1.1	-0.18	-0.2	-0.31	-1.0	-0.50	-1.7	-0.41	-1.3
7	0.69	2.2	-0.15	-0.5	0.27	1.0	-1.48	-4.7	-0.76	-2.5	-1.12	-3.6
8	0.23	0.7	0.44	1.4	0.33	0.6	0.56	1.8	-0.01	-0.0	0.28	0.9
9							-0.68	-2.2	0.71	2.3	0.02	0.0
10	0.15	0.5	0.84	2.7	0.49	0.7	1.86	6.2	0.75	2.4	1.31	4.3
11	0.30	0.9	0.02	0.1	0.16	0.5	-0.37	-1.2	-0.79	-2.5	-0.58	-1.8
12	0.19	0.6	0.05	0.2	0.12	0.3	0.24	0.8	0.42	1.4	0.33	1.1
13							0.86	3.3	-4.31	-13.6	-1.73	-5.2
14	-0.25	-0.9	0.95	3.3	0.35	0.0	1.68	5.8	1.91	6.6	1.79	6.2
16	-0.98	-3.1	-0.15	-0.5	-0.56	-1.6	-0.47	-1.5	-1.95	-6.2	-1.21	-3.9
17	1.95	8.8	-1.79	-7.2	0.08	3.5	0.80	3.6	-2.65	-10.7	-0.92	-3.5
18	0.09	0.3	0.16	0.5	0.13	0.2	-0.06	-0.2	-0.44	-1.4	-0.25	-0.8
19	-0.03	-0.1	0.05	0.2	0.01	-0.0	0.60	1.9	-0.10	-0.3	0.25	0.8
20							0.33	1.0	-0.43	-1.3	-0.05	-0.2
21							-0.28	-0.9	-0.13	-0.4	-0.21	-0.7
22							-0.03	-0.1	-0.33	-1.1	-0.18	-0.6
23	0.56	1.9	0.04	0.1	0.30	1.0	0.50	1.7	-1.05	-3.5	-0.28	-0.9
24							-0.64	-2.1	-1.94	-6.0	-1.29	-4.1
25	-0.30	-0.9	0.29	0.9	-0.00	-0.3	-0.24	-0.7	0.52	1.6	0.14	0.4
26	0.14	0.5	-0.69	-2.2	-0.28	-0.1	-0.88	-2.9	-1.56	-5.1	-1.22	-4.0
28	-0.03	-0.1	-0.11	-0.4	-0.07	-0.1	-1.35	-5.1	-0.89	-3.4	-1.12	-4.2
29	0.49	1.9	-0.46	-1.7	0.01	0.7	0.58	2.3	-0.55	-2.0	0.01	0.1
30	1.44	5.7			1.44	5.7	-0.25	-1.0	-1.10	-4.3	-0.67	-2.6
31							0.92	3.6	0.87	3.4	0.90	3.5
32	-0.58	-2.1	0.32	1.1	-0.13	-0.9	-0.74	-2.6	-1.12	-4.0	-0.93	-3.3
34							-1.09	-4.1	-0.80	-3.0	-0.95	-3.6
35							-0.92	-3.2	-1.05	-3.7	-0.99	-3.5
36							-1.57	-5.7	-1.18	-4.4	-1.38	-5.0
37							0.63	2.8	-1.75	-7.2	-0.56	-2.2
38							-1.73	-6.4			-1.73	-6.4
39							-0.34	-1.2	-0.80	-2.9	-0.57	-2.1
40							1.26	4.9	2.00	8.1	1.63	6.5
41							-0.19	-0.7	-0.89	-3.2	-0.54	-2.0
42							0.56	2.3	-0.78	-3.0	-0.11	-0.4
43							0.14	0.5	-0.29	-1.1	-0.07	-0.3
44							-0.26	-0.9	-0.55	-1.9	-0.41	-1.4
45							0.73	2.4	-0.88	-2.9	-0.08	-0.2
46							0.17	0.6	0.00	0.0	0.08	0.3
47							-0.47	-1.6	-1.11	-3.7	-0.79	-2.7
48							-1.34	-4.4	-1.90	-6.2	-1.62	-5.3
49							-0.80	-2.6	-1.13	-3.8	-0.97	-3.2
50							0.97	3.5	-0.17	-0.6	0.40	1.4
51							-0.53	-1.8	-0.81	-2.6	-0.67	-2.2
52							0.92	2.9	0.84	2.6	0.88	2.8
53							-0.78	-2.5	-0.29	-0.9	-0.54	-1.7

Table 4. Listing of Differences Between Active and Placebo

Horse	Active-Placebo (right)	Active-Placebo (left)	Active-Placebo (average)
1	0.860		0.8600
2	-0.400	-0.700	-0.5500
3	0.310	-0.330	-0.0100
4	-0.658	0.053	-0.3025
5	-0.500	-0.100	-0.3000
6	-0.275	-0.175	-0.2250
7	-2.162	-0.612	-1.3870
8	0.337	-0.450	-0.0565
9			
10	1.713	-0.088	0.8125
11	-0.670	-0.813	-0.7415
12	0.050	0.370	0.2100
13			
14	1.925	0.962	1.4435
16	0.510	-1.800	-0.6450
17	-1.150	-0.860	-1.0050
18	-0.150	-0.600	-0.3750
19	0.630	-0.150	0.2400
20			
21			
22			
23	-0.060	-1.090	-0.5750
24			
25	0.060	0.230	0.1450
26	-1.020	-0.870	-0.9450
28	-1.320	-0.780	-1.0500
29	0.090	-0.090	0.0000
30	-1.690		-1.6900
31			
32	-0.160	-1.440	-0.8000
34			
35			
36			
37			
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Table 5. Summary of Differences between Active and Placebo for the IR Data

| | | | | | | ----- p-value ----- | |
Endpoint	n	Mean	SD	Median	Sign	Sign Rank	Paired t test
Active-Placebo: IR Right	23	-0.16	0.97	-0.15	0.678	0.381	0.431
IR Left	21	-0.44	0.63	-0.45	0.007	0.003	0.004
IR Average	23	-0.30	0.74	-0.30	0.052	0.043	0.062

Table 6. Summary of Changes and Percent Changes from Baseline for Palpations and IR Endpoints

| | | | | | | ----- p-value ----- | |
Endpoint	n	Mean	SD	Median	Sign	Sign Rank	Paired t test
Placebo: Palpations Reduction	52	-0.02	0.14	0.00	1.000	1.000	0.322
Palpations % Reduct.	52	-0.38	2.77	0.00	1.000	1.000	0.322
Active: Palpations Reduction	52	5.62	1.95	6.00	<.001	<.001	<.001
Palpations % Reduct.	52	94.23	9.50	100.00	<.001	<.001	<.001
Placebo: IR Right Change	23	0.27	0.63	0.15	0.210	0.034	0.048
IR Right % Change	23	1.06	2.48	0.50	0.210	0.035	0.052
IR Left Change	21	0.08	0.72	0.04	0.503	0.577	0.626
IR Left % Change	21	0.20	2.60	0.13	0.503	0.596	0.727
IR Average Change	23	0.20	0.45	0.12	0.093	0.032	0.044
IR Average % Change	23	0.69	1.51	0.34	0.210	0.025	0.040
Active: IR Right Change	50	-0.03	0.84	-0.13	0.672	0.842	0.790
IR Right % Change	50	-0.06	2.96	-0.45	0.672	0.951	0.879
IR Left Change	49	-0.52	1.12	-0.55	<.001	<.001	0.002
IR Left % Change	49	-1.78	3.89	-2.05	<.001	<.001	0.002
IR Average Change	50	-0.29	0.83	-0.34	0.015	0.009	0.018
IR Average % Change	50	-0.97	2.89	-1.11	0.015	0.010	0.022

Table 7. Associations Between Active vs Placebo Differences for Palpations and IR Endpoints

| | ----- Pearson ----- | | ----- Spearman ----- | |
Side	Correlation Coefficient	p-value	Correlation Coefficient	p-value
Right	0.369	0.083	0.462	0.026
Left	0.343	0.128	0.389	0.081
Average	0.313	0.146	0.387	0.068

Discussion

D1. Comparisons Between Active and Placebo

The initial analysis was carried out to compare the Active and Placebo treatments. These comparisons are based on the data from the last column of Table 1 and on the data from Table 4.

For palpations (Table 1), the Placebo scores range from 2-9 with a mean (and median) of 6.0. In contrast, the Active scores range from 0 to 2 with a mean of 0.4 and a median of 0.0. There are no animals for which the Placebo score is lower than the Active score. The reductions range from 2 to 9 with a mean (median) reduction of 5.63 (6.0) and a standard deviation (SD) of 1.95.

It may be reasonable to assume that the reductions are normally distributed. In this case, one would use the paired t-test (two-sided) to assess whether there is a *significant* difference between Active and Placebo. Nonparametric alternatives would be the Wilcoxon signed rank test or the sign test. However, it does not matter which test is used in this case, since all three indicate that there is a *very highly significant* difference between Active and Placebo ($p<0.0001$).

Table 5 displays the results of these same comparisons for the IR data displayed in Table 4. For each endpoint, the sample size, mean, SD, and median are displayed. The final three columns display the p-values from the sign test, Wilcoxon signed rank test, and the paired t-test.

The results of these analyses *are less conclusive.* One issue is that, due to missing values, the effective sample size for comparing Active to Placebo is considerably reduced. For the right side, only 23 of the 50 animals provide both Active and Placebo data. The corresponding sample size for the left side is only 21.

The mean difference (Active-Placebo) for the right side is -0.16, but the corresponding mean difference for the left side is nearly three times larger (-0.44). The medians are similar to the means (-0.15 for right side, -0.45 for left side). As a result, the two-sided p-value from the paired t-test comparing Active to Placebo for the right side is 0.43, indicating that there is no evidence of a difference between Active and Placebo. In contrast, the paired t-test p-value for the left side is 0.004, indicating a *highly significant difference*.

When the average of the right and left sides is used, the mean (and median) difference is equal to -0.30. As expected, this is intermediate to the right and left side results. The comparison between Active and Placebo in this case is nearly significant (p=0.062 by the paired t-test).

D2. Analysis of Change and Percent Change from Baseline for Each Treatment

Based on the results summarized in Section *D1*, a subsequent task was to analyze the changes and percentage changes from Baseline for each treatment separately. These comparisons are based on the reduction and percent reduction data from Table 1 and on the data from Table 3.

These results are provided in Table 6, using the same format as described in Section 2. The first set of results summarizes the palpations data (reduction and percent reduction) for the Placebo treatment. This is followed by the same results for the Active treatment. The remaining two sets of results similarly summarize the IR changes and percent changes from Baseline for the Placebo and Active Patch treatments.

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For palpations, the reduction and percent reduction for Placebo *is not statistically significant*. However, both endpoints are *highly statistically significant for Active*. The mean reduction is 5.62 and the mean percent reduction is 94.2%.

For IR, there are *significant or nearly significant increases* from Baseline for Placebo treatment with respect to the right side change, the right side percent change, the average change, and the average percent change.

For Active treatment, there *are significant decreases* from Baseline for the left side change and percent change, and for the average change and percent change.

D3. Associations between Palpation and IR Data

The sample size is considerably reduced for these comparisons. First, there are three animals that are included in the palpations data set but not in the IR data set (15, 27, and 33), and one animal (53) is included in the IR data set but not in the palpations data set. In addition, the correlation can only be assessed using the animals that provide Active-Placebo differences for both types of endpoints.

The sample sizes for assessing the association between the reduction in palpations (Placebo-Active) and the Active-Placebo IR differences for right, left, and average are 21, 21, and 23, respectively. Table 7 displays the Pearson (parametric) and Spearman (nonparametric) correlation coefficients, as well as the p-value from the test of the null hypothesis that there is no association between palpations and IR.

The magnitudes of the Pearson and Spearman correlations are similar for right, left, and average. Using the Spearman correlation, the association is *statistically significant* (p=0.026) for the right side and nearly significant for the left side and the average of the two sides.

D4. General Observations

The overall data demonstrated that in *every case there was a change in the sensitivity of the palpated points after the AcuLife Patches were applied to acupressure points. In each case the sensitivity and pain observed was considerably lower from the start.*

The infrared thermal imaging also showed changes as noted in palpation data sheets. In some cases, there was not just a cooling effect, but sometimes a warming effect, and an obvious attempt of the body to *balance* the system. This was quite exciting to the observers and doctors and was indicative of the real efficacy of the AcuLife Patches. In the Veterinarians expert opinion, *this is a dramatic effect.* It should be noted that as we learned from our study last year with the horse Munoso, who's very cold area warmed, as, at the same time, the inflamed areas cooled.

While we understand that this is a subjective measurement, the important measure was before the Placebo patching, after the Placebo patching and then again after the Active AcuLife Patch System was applied. The results were noted. The images were taken before the horses had any patches placed, after the placebo patches, and after the placement.

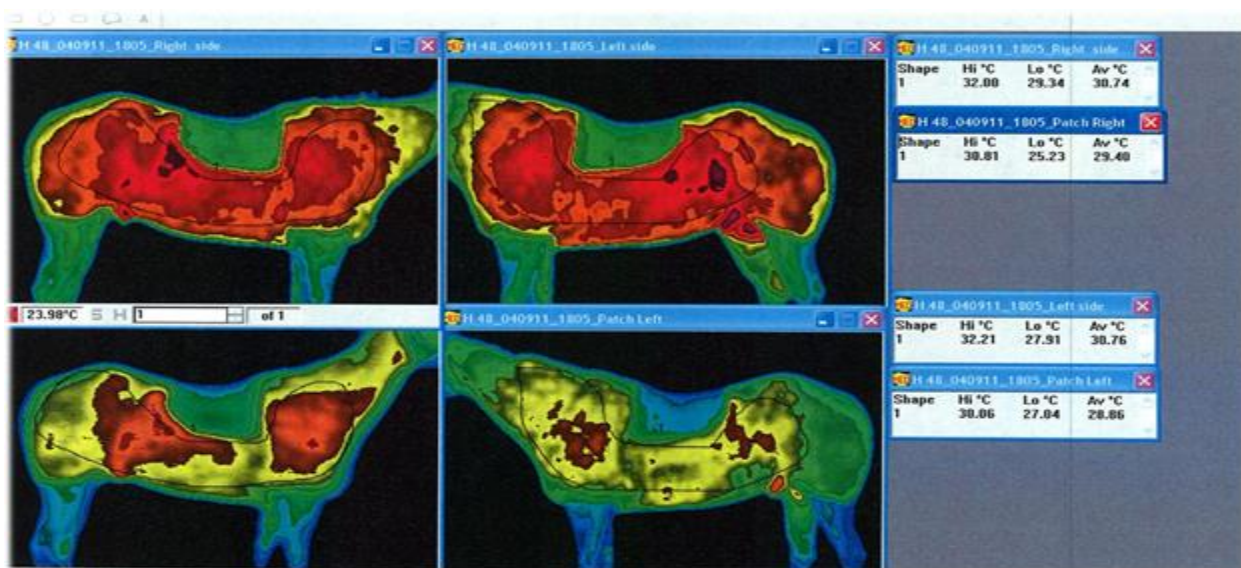Figure 7 shows a thermal image of an event horse, Horse 48, Mazone.

Figure 7. Thermal image of Horse 48, Mazone.

This is a 17 year old "eventing" horse which showed anxiety, was uncooperative and showed severe pain at an 8 level in his entire body especially in the back and hips. After the Placebo patches were applied he showed no difference. After application of the Active Patch System on Bladder 13, Bladder 23 and 28, his demeanor completely changed. He became calm and cooperative and his scale value went down to 1.5 (0-10 scale).

The following observations were also made: 11 horses had 2 sides that warmed; 26 horses had 2 sides that cooled; 8 horses had one side that cooled and one side that warmed; 2 horses had one side that cooled; 4 horses had one side that warmed. It is clear from such observations that the patches in this study offered a re-balance of the nervous system.

Based upon follow up measures extracted from subjective owner satisfaction questionnaires, the following observations were made: 14 owners were pleased and noticed a difference; 4 were very pleased and impressed; 11 owners were ecstatic about the good results with comments such as:

- "I am thrilled with the changes, my horse is moving better, not limping on old shoulder injury and much more relaxed."
- "AWESOME improvement, posture is much better, he has never looked like this"
- "Feels like a million bucks, was excluded from the herd before, but now is being accepted, moving better, active and calm."
- "No pain, calm, my student got a first and second place in show."
- "I rode Missy for the first time this year. It was the best ride we EVER had. Usually she is bucking, rearing back, has a stiff neck. She didn't show any of this behavior. She was holding herself neck and shoulders in place, best ride ever. I'm going to use the patches before showing in future."
- "Rosie is way less crabby, more relaxed in general and seems more alive. She usually rushes, especially on the way home, and wants to be away from all the other horses. The patches have made a major change for Rosie. She is getting along with the other horses and happy to walk slowly behind.

We also carefully observed our Hawkeye from last year. Hawkeye was a remarkable example. He has been much better since last year, and his owners patch him "now and then" (he was leaning against his stall to prop himself up last year at the first thermal imaging study – he has never had to do that since.)

Conclusion

The main objective of the present study was to follow up on our two previous investigations carried out in horses and use palpation as well as infrared thermal imaging to explore the efficacy of the AcuLife Patches in pain relief and management. Acupuncture palpation evaluations complemented with infrared thermal measurements and imaging were performed. It was of interest to explore the effects of these Patches on painful and inflamed areas in horses and demonstrate their physiological impact and further cross-validate with the Veterinarians expert evaluations. The hypothesis to be tested was that: *AcuLife Patches produce pain relief in painful areas in horses.*

Fifty three horses: 1 Stallion, 32 Geldings and 20 Mares of varying ages (4 to 31 years old) and disciplines were included in this study. Informed consents were acquired from the owners of qualified candidates. Study subjects with pain symptoms were first evaluated by the Veterinarian to assess their pain severity based on acupuncture palpations (on a scale of 1-10). Then they had their area of pain scanned with an infrared thermal imaging system. The ease of normal activities of the animals was also considered as one of the measurement outcomes.

Statistical analysis of the acupuncture palpation data revealed a very highly significant (p<0.0001) reduction in pain level due to wearing the AcuLife Patches in the affected (painful) areas in horses compared to Placebo. Statistical analysis of thermal imaging data also revealed a highly significant (p<0.004) pain relief in the left side of the body due to wearing the AcuLife Patches in the affected (painful) areas in these animals. (However, no significant differences were observed between Active and Placebo treatments on the right side of the body! This was mainly attributed to missing data that considerably reduced the sample size in this case - from 53 to 23 - for comparing Active to Placebo.) When the average of the right and left sides data were used, the comparison between Active and Placebo in this case was *nearly significant* (p=0.062 by the paired t-test).

The overall data demonstrated that in *every* case there was a change in the sensitivity of the palpated points after application of the AcuLife Patches to painful points. In each case the sensitivity and pain observed were considerably lower compared to pre-patch application. The infrared thermal imaging data showed related changes as noted in palpation data sheets. In some cases, there was not just a cooling effect, but sometimes there was a warming effect: an obvious attempt of the body to *balance* the system. (This was quite exciting to the researchers and was indicative of the efficacy of the AcuLife Patches. In the Veterinarian's expert opinion, this is a dramatic effect. It should be noted that as we learned from our previous study last year with the horse Munoso, who's very cold area warmed, as, at the same time, the inflamed areas cooled.) *Based upon these findings the hypothesis that:* AcuLife *Patches produce pain relief in painful areas in horses was accepted as generally true. (It was also observed that the Patches exert a warming effect due to increased perfusion in hypothermic –cold- areas affected by abnormal circulation.)*

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