THERMOTEX

FAR INFRARED WAVELENGTH TREATMENT FOR LOW BACK PAIN

THERMOTEX THERAPY SYSTEM INFRARED HEATING PAD VERSUS CONVENTIONAL HEATING PAD AND HOT TOWEL

THE EFFICACY OF THE THERMOTEX INFRARED HEATING BLANKET UPON THE STANDARDBRED RACEHORSE

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Far infrared wavelength treatment for low back pain: Evaluation of a non-invasive device

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Abstract.
BACKGROUND: Low back pain is a significant cause of lost workplace productivity. Identification of simple, safe, and effective treatment strategies that can be used in the workplace are needed.
OBJECTIVE: To assess whether far-infrared therapy (FIR) can ameliorate chronic back pain in office workers with the hypothesis that back pain could be effectively treated while at work with minimal interruption to the normal working day.
METHODS: In a cohort study, 50 subjects with low back pain of at least six months duration were recruited from a Florida corporation. The subjects were instructed to use a FIR pad placed in their chairs in contact with the affected area while on the job over a 4 week period for at least 45 minutes a day during workdays. The FIR device used for the study was the Thermotex TTS Platinum Pad, a widely available FDA-registered medical device with preclinical data on its deep heating effects. The outcomes were assessed using subscales of the SF-36v2.
RESULTS: Results showed statistically significant changes in 9 of 10 SF-36 subscales including both physical and mental components with a near significant improvement to General Health. There was progressive improvement each week in physical component and bodily pain scales. There were no reported adverse events.
CONCLUSIONS: Use of site-specific FIR therapy over a four-week period in the workplace was associated with significant clinical improvements in pain and quality of life for office workers with previously refractory low back pain.

Keywords: Workers, chronic back pain, alternative back pain treatment, device, workplace wellness

1. Introduction

Low back pain (LBP) is a major cause of disability and health care utilization with concomitant loss of productivity due to both disability and time away from work for treatment. In addition, most people who experience activity-limiting low back pain go on to have recurrent episodes. Estimates of recurrence at 1 year range from 24% to 80% [1]. The indirect costs of chronic LBP in the U.S. are estimated to be around $16,000 annually per patient. Cumulatively, this totals approximately $50 billion in productivity losses annually [2]. Current guidelines for the management of low-back pain emphasize the importance of using non-pharmacologic approaches as first line therapy [3, 4]. Despite this, millions of Americans do not receive such recommendations and either continue to be in pain or are referred for pharmacological or surgical interventions despite a lack of evidence. In fact, trends demonstrate increased use of opioid analgesics (up 108% since the 1990 s), spinal injections (up 231 %) and surgeries (up 220%) without significant increases in benefits [5]. These trends are also associated with a 65% increase in health expenditures [6]. There is an urgent need for effective treatments for LBP. If an effective self-treatment of LBP that does not interfere with productivity could be identified, it would be an important and an efficient strategy to improve care and

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rehabilitation. One common and effective modality for the treatment of chronic pain is heat [7]. Tissue heating by infrared radiation (IR) provides for deeper heating than conventional heating pads and could potentially be implemented in a manner that does not interfere in a workflow. IR is commonly applied in mid-range wavelengths of 1.5 to 5.6 microns, however far infrared radiation (FIR) in the range of 5.6 to 1000 microns provides heating in deeper tissues where injuries to muscles commonly occur and thus may be more effective. The Thermotex FIR pad used for the study was tested in horses for tissue heating in comparison to more usual equine hot packs of an electric heating pad on a hot towel covered by a stabilizing blanket [8]. A thermocouple probe measuring temperature in the *gluteus medius* showed the FIR pad to induce a therapeutic rise (5°F) in temperature to the maximum depth of the probe (6 cm) compared to heat packs where a 5°F rise occurred to a mean depth of 3.75 cm penetration within 5 minutes with the difference sustained over 20 minutes. Effective therapeutic heating in the thick musculature of the low back may call for such penetrance. FIR increases blood flow by multiple mechanisms [9–11] and has shown benefit in several relevant models and conditions including wound healing [12], contractures [13] and post-operative pain [14]. At a cellular level, FIR has been shown to stimulate the production of collagen and elastin from fibroblasts [15]. One of the limitations of heat therapy is adherence. Typical protocols call for people to apply heat and other therapies for extended periods multiple times per day at home or in a rehabilitation facility [7, 16] with specific exercise therapies 3–5 time per day as a first line therapy and returning to work as soon as pain is reduced [17]. However, if the pain persists, one would expect workers to be less than efficient in their duties. If treatment could be administered in the workplace, where people with LBP spend a substantial portion of the day, adherence may be improved and interference with the normal daily work routine would be minimized. The objective of this study was to evaluate the effectiveness of a novel treatment approach to LBP using a Far Infra-Red therapeutic device delivered through a workplace-based treatment protocol.

2. Methods and materials

2.1. Population

Employees with low back pain were recruited from a U.S. corporation in Palm Beach County, Florida. All participants were office workers in the company's voluntary employee wellness program and remained anonymous to their employer. Participants were recruited through flyers and emails, were screened for inclusion criteria. Participants that qualified and provided informed consent were enrolled in the cohort study. Screening was completed through an online confidential survey. Ninety nine employees were screened; 55 were enrolled, and 50 completed the observation period.

2.2. Inclusion criteria

To be eligible for participation, employees must have been experiencing chronic back pain of at least six months duration, had sought out a previous medical opinion on their pain and were not candidates for imminent surgery, were able to use the pad as directed, and were not anticipating absences from their usual workplace. The intervention was designed to satisfy management's requirement that there be minimal disruption of their daily work routine. The observation period was 4 weeks. At the request of the corporation which provided access to their employees as subjects for this study, there was no control group. The Chief Medical Officer and the internal review board felt that they would be misleading their employees if a control group was established. The company's goal was to provide a benefit or not provide a benefit to their employees. If a control group was used then that group would have been denied access to the potential benefit Effort was made to include an equal gender distribution.

2.3. Intervention

The protocol included use of an FIR pad, the Thermotex TTS Platinum Pad (TPP, Thermotex Ltd., Calgary, Alberta, Canada) applied locally to the lower back. The TPP is a registered medical device with the U.S. Food and Drug Administration and Health Canada. The TPP provides a reliable FIR signal, is reasonably-priced and in wide distribution and has been used for several years in the U.S. with a good safety history. The Thermotex corporation which manufactures the TPP has sold roughly 100,000 pads in the U.S. since 1989 with 2 reported incidents of adverse effects. Both incidents were due to misuse. A reliable FIR signal is one whose wavelength is close to the peak emission wavelength (frequency) of the body which has been determined in research to be close to 10 microns. This is the wavelength of infrared light the human body emits because of the body's temperature. This is done using the Planck

radiation formula which describes how radiation is affected by the medium in which it is traveling in. The closer the FIR signal (the emitting medium) is to the body (the absorbing medium, then the loss of emitting signal due to absorption and scattering there is allowing the FIR signal to penetrate deeper into the body. The key feature of the TPP used in this study was its ability to maintain a low temperature, which determines the peak emission wavelength. Many commercial infrared devices do not have the ability to maintain the temperature needed to maintain this peak emission wavelength. This is because they rely on higher temperature focally generated FIR signals in devices such as LED lights, tungsten wire or a single wire copper wire to generate the FIR signal. By doing this they increase the amount of absorption and scattering of the FIR signal reducing its penetration. By utilizing Planck's Law of radiation one can tailor the FIR signal to obtain the maximum penetration into the body allowing the FIR signal to reach a depth which would surround the vertebral bodies and their associated structures providing maximum benefit (5–7.5 cm). The TPP measures 17"x15" and is made with 3 carbon radiators incorporated into a fabric pad and is powered by 120 volt AC. The peak emission wavelength of the pad is 9.37 nanometers, and radiant energy is 11.5 $MJs^{-1}m^{-2}Hz^{-1}$. Devices were supplied to each participant at no cost by the manufacturer for use over the four-week duration of the study. Directions on daily use of the pad were given in a 45 minute orientation at the workplace. The subjects were asked to use the pad in their chairs over their clothing at their workstations for a minimum of two 35 minute sessions per day at the setting of their choice (either 'low' or 'high') for at least 5 days a week for 4 weeks. They were allowed to use the pad multiple times during the day and were allowed to bring the pad home for use on the low back or other areas at will. There was no maximum specified treatment duration or frequency. Outcomes were measured with the QualityMetric (QualityMetric, Inc., Lincoln, RI) online version of the SF-36v2 Quality of Life (QOL) questionnaire. The SF-36v2 is well-validated [18] and widely used and measures eight domains of health-related QOL: physical functioning (PF), role limitation due to physical functioning (RF), bodily pain and limitations (BP), general health (GH), vitality and well-being (VT), social functioning (SF), mental health (MH) and role limitations due to mental health (RE). Items from the 8 domain scales are aggregated to provide summary scales for physical (PCS) and mental health components (MCS) from weighted scores of the 8 individual scales. The PCS – designed to summarize the SF-36v2 health domain scores weighted so as to yield a single value indicating overall physical health – was selected as the primary measure. Test subjects provided their data via a secure web-based data entry portal from work or home, at baseline and weekly. Instructions for online access to the questionnaire were provided to participants at the orientation. Participants completed a baseline form no later than the first Monday morning before using the TPP and repeated the evaluation each Friday for the subsequent four weeks. Any participant who had not filled out their survey each week of the study by Friday afternoon at 4 p.m. was sent a reminder e-mail. If the survey was not filled out by mid-afternoon on the following Monday, they received a reminder phone call. Any participant who did not fill out the survey by Tuesday morning was dropped from the study.

2.4. Analysis

All data were stored in a database on Quality Metric's server and were accessible only to the study team. For this report, the raw SF-36 scale scores was converted to a 0–100 scores which were then converted to a Z-score and subsequently to a T-score with a US population mean of 50 and a standard deviation of 10. These methods enabled a reference comparator despite lack of a control group. Mean differences were tested with *T*-test statistics.

3. Results

Fifty-five employees meeting qualifications were enrolled to take part in the study including 27 females

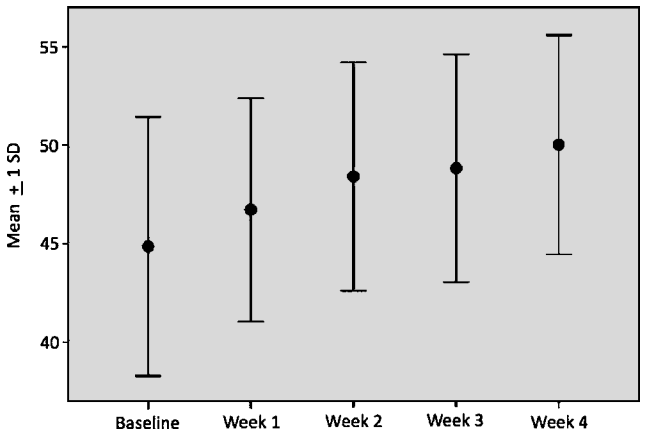

Fig. 1. Physical components summary means and standard deviations over 4 weeks.

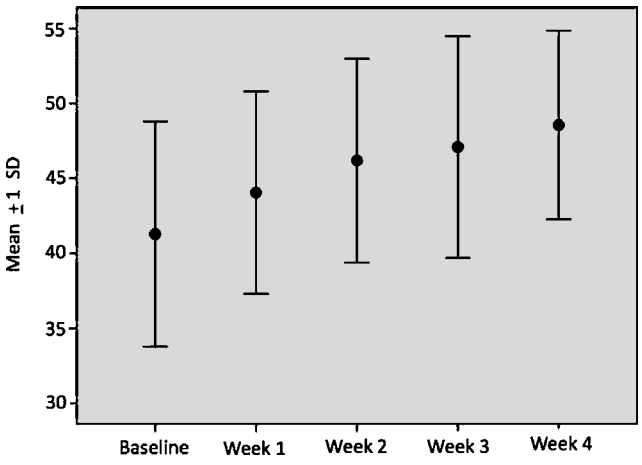

Fig. 2. Bodily pain means and standard deviations over 4 weeks.

and 28 males. Five participants were dropped because they failed to complete their initial or second survey. At the conclusion of the four weeks, a total of 50 with no missing data were included in this analysis, 24 males and 26 females. Changes over time were calculated for both the composite patient-reported health function, and the relevant sub-domains. The scales of particular interest in this study given the target condition were: physical health (PCS) and bodily pain. Longitudinal graphs for each of these scales are presented at Figs. 1 and 2. Each of the scales shows progressive improvement over four weeks, with statistically significant improvements ($p < 0.001$) from baseline to 4 weeks in each. Significantly, the bodily pain results improved from mean of 41.27 score to 48.56 within 4 weeks ($p < 0.001$. Table 1). The Physical Function scale also showed improvements progressively at each assessment over the 4 weeks as did the Vitality scale (VT). The data showed improvements in all of the 10 scales of the SF-36 (see Table 1) with statistically significant improvement in all (all $p < 0.001$) except for one scale, General Health, which demonstrated a strong trend toward significance ($p = 0.052$). The greatest change was noted in Bodily Pain (7.29, $p < 0.001$) with Vitality at close second (7.19, $p < 0.001$). No adverse events were reported by any participant.

4. Discussion

The population studied were office workers with chronic (>6 months standing) low back pain. Despite this complaint, participants at baseline were generally healthy (reflecting the "healthy worker" effect). Their health status, as measured by serial responses to the SF-36, improved during the study. There were statistically significant improvements across all scales. The improvement of all scales may be indicative of the large impact of pain in this population as chronic pain has adverse effects on general and mental health parameters and on self-care activities [19]. The steady week-by-week improvements in the physical function, pain and vitality scales with highest scores at the end of the study suggest the possibility that the effect may not have peaked and that continued use of the pad might have a positive impact beyond the four-week test period; future studies should investigate a longer duration period. Beyond statistical significance, the results also showed clinical significance. The magnitude of improvement was substantial, especially in Bodily Pain, which, at the commencement of the study, was nearly a standard deviation below the U.S.mean and by the end of the study approached the U.S. mean. The mean reduction in back pain, as measured by the primary outcome metric the Physical Component Summary, improved from a baseline score –0.5 standard deviations from the U.S. mean to a 4 week mean score of 50.02 equivalent to the U.S. mean. Thus, in effect improving the participants' health status sufficiently to categorically report them as healthy again. No adverse events were reported by this study's participants. The manufacturer reports the TPP has had no reported adverse side

Table 1
Changes in domains of quality of life and functioning over the 4 week study period

SF-36v2 scales	Baseline	1 wk	2 wks	3 wks	4 wks	*p* value BL-4wks
Bodily Pain (BP)	41.27	44.06	46.07	46.96	48.56	<0.001
Physical Functioning (PF)	45.78	47.45	49.01	49.87	50.69	<0.001
Physical Role Limitation (RP)	46.84	49.94	49.01	49.87	50.69	<0.001
General Health (GH)	51.59	52.63	52.57	52.50	52.85	0.052
Vitality (VT)	47.58	51.71	53.03	54.65	54.77	<0.001
Social Functioning (SF)	48.12	50.92	51.67	52.53	52.42	<0.001
Mental Health (MH)	49.86	52.74	54.40	54.73	55.01	<0.001
Mental Health Role Limitation (RE)	49.24	52.12	52.42	52.97	52.73	<0.001
Physical Component Summary (PCS)	44.84	46.70	48.30	48.70	50.02	<0.001
Mental Component Summary (MCS)	50.71	54.03	54.68	55.43	54.94	<0.001

effects from current or former users since data collection began in 1994. Perhaps contributing to lack of reported adverse events is that the FIR TPP operating temperature is around 111ºF versus conventional heating pads that may be in excess of 131ºF. While a limitation of the study is its lack of controls, the chronicity of pain that persists for at least six months might reasonably be expected not to resolve spontaneously during the study's 4 week observation period. Comparison to population-derived Z scores provides a point of comparison by which the results experienced by this cohort can be interpreted. This magnitude of improvement with such a benign intervention is somewhat surprising. Yet, this study corroborates prior research that shows infrared therapy to be useful in the reduction of low back pain [20]. An explanatory cause for improvements specific to the use of FIR is ascribed to heating deeper tissues than ordinary heating methods. The TPP was easily and unobtrusively integrated into a work environment without interfering with job duties or work activities for these office workers. Modest cost and little intrusion to work flow while getting relief comparable to or better than other perhaps more expensive treatments with more side effects [21] suggests high utility in the work setting. Though productivity was not directly measured, improved physical capacities and better mental outlook and subsequent increased productivity would be appropriate directions for future study. Cost-effectiveness studies are also warranted; direct savings by cost-effective treatment without lost work time and indirect gains of increased productivity together make further study of this intervention of potentially great interest to employers.

5. Conclusion

FIR TTP self-care in the workplace demonstrates clinically and statistically significant reductions in LBP over 4 weeks. The FIR TTP also demonstrated benefits in subdomains of vitality, and mental and social functioning. Workplace implementation of the FIR TTP intervention had minimal impact on the everyday work routine. FIR TPP appears to be a safe, low-tech, low-cost, non-invasive approach to treating chronic back pain.

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THERMOTEX™ THERAPY SYSTEM INFRARED HEATING PAD VERSUS A CONVENTIONAL HEATING PAD AND A HOT TOWEL

RONALD J. RIEGEL D.V.M.

HYPOTHESIS:

Many consider the hindquarters and especially the gluteal muscles the "engine" of the horse. Intense, high level training places great physical demands upon these muscles. Standardbred racehorses not only have to have speed but also endurance and stamina. This breed of horses, because of the training regimes utilized, places an incredible amount of stress upon these muscle tissues.

Traditionally, placing a hot towel then an electric heating pad and then a stable blanket, to hold all of this in place, is the standard treatment for muscle soreness in this area. This system, although cumbersome, does have some degree of success but how deep does the heat really go? Does the Thermotex™ Therapy System Heating pad provide an easier and deeper penetrating heat to this anatomical area?

GOALS:

These are the questions that will be answered by this endeavor:

1. How deep within the tissue will the heat from the traditional hot towel/electric heating pad penetrate?

2. How deep within the tissue will the Thermotex™ Therapy System Infrared heating pad penetrate?

3. Will there be any side effects such as skin soreness, pain or dehydration with the traditional treatment?

4. Will there be any side effects such as skin soreness, pain or dehydration using the Thermotex™ Therapy System Infrared heating pad?

PROCEDURE AND METHODOLOGY:

Two four-year-old standardbred racehorses were chosen at random. Each animal had to meet the following criteria:

1) Both animals were in good health and free of any visible signs of lameness.
2) No medications either systemic, intraarticular or topical had been administered to these animals within the past three weeks.
3) The level of training was similar for each animal.
4) Over the past two weeks, no other physical therapy modalities were administered to them.

Each of the equine subjects will serve as their own control. A thermocouple probe will be placed at varying depths within the musculature. On the right side of the gluteal area a Thermotex™ Therapy System heating pad will be used to treat the musculature whereas on the left side the traditional treatment of a warm moist towel covered by a heating pad will be used.

Thermocouples will be placed at 1/2 centimeter intervals to a depth of six centimeters. The first will be placed just beneath the skin. The remainder will be placed centrally within the *gluteus medius* muscle at the stated depths.

Therapy will last twenty minutes with both the electric heating pad and the Thermotex™ Therapy System infrared heating pad set at their highest settings. Temperatures will be recorded at five minute intervals at each depth.

RESULTS AND DISCUSSION:

The literature states that the muscle tissue must rise at least five degrees to increase the metabolic rate of the muscle cells. There is a "therapeutic window," with the application of heat, where it is beneficial and not at a level that is causing pain.

The normal skin temperature of the horse is approximately 90° Fahreheit. Therefore, the source of heat to the tissues must be greater than this level to increase the underlying tissue temperatures. Application of temperatures greater than 133° Fahreheit, for a prolonged period of time, will cause skin sensitivity and eventually damage to the dermis. Gentle deep penetrating heat is ideal therapy for this muscle tissue.

Data was collected and revealed the following results:
(See table)

1) The Thermotex™ Therapy System infrared heating pad achieved both a higher level of temperature within the tissues and a greater depth of penetration within the musculature.
2) The temperature of the musculature rose faster and stayed at a therapeutic level longer with the Thermotex™ Therapy System infrared heating pad than using the conventional heating pad and a hot towel.
3) Upon digital palpation there wasn't any soreness or pain elicited by either treatment.
4) If there was any dehydration by either treatment, it was minimal.

SUMMARY AND CONCLUSSIONS:

The scientific evidence provided by this study allows the following conclusions:

- ❖ The Thermotex™ Therapy System infrared heating pads provide a very therapeutic, deep penetrating form of heat to the musculature.

- ❖ The temperature within the muscle tissue rises faster and is maintained at a therapeutic level longer when compared to the conventional therapy.

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ANIMAL ONE: TEMPERATURE MEASUREMENTS AT INCREASING DEPTHS OVER TIME

DEPTH	INITIAL		FIVE MINUTES		TEN MINUTES		FIFTEEN MINUTES		TWENTY MINUTES	
(CM)	RIGHT	LEFT	RIGHT	LEFT	RIGHT	LEFT	RIGHT	LEFT	RIGHT	LEFT
1	98.6	98.8	102.2	102	105.8	104	105.5	103.8	106.2	104.4
1.5	98.4	98.5	102.4	102.4	105.5	104.2	105.5	104	106	104
2	98.4	98.4	102.4	102.4	105.6	103.8	105.5	103.8	106.2	104
2.5	98.4	98.6	102.6	102	105.5	103	105.2	102.8	105.8	102.5
3	98.8	98.6	102.6	101.2	105.2	101	105.2	101.2	105.6	101
3.5	98.6	98.4	102.2	100.4	104.6	100.2	104.8	99.8	105.2	100.2
4	98.4	98.4	101.8	98.8	102.4	98.6	104.2	98.8	104.8	98.6
4.5	98.6	98.5	101.6	98.6	102.6	98.5	103.8	98.4	105.2	98.4
5	98.5	98.4	101.8	98.5	102.5	98.4	103.8	98.6	104.8	98.5
5.5	98.5	98.5	102	98.4	102.6	98.4	103.8	98.6	104.5	98.4
6	98.2	98.4	102.2	98.4	102.5	98.4	103.6	98.5	104.4	98.5

ANIMAL TWO: TEMPERATURE MEASUREMENTS AT INCREASING DEPTHS OVER TIME

DEPTH	INITIAL		FIVE MINUTES		TEN MINUTES		FIFTEEN MINUTES		TWENTY MINUTES	
(CM)	RIGHT	LEFT	RIGHT	LEFT	RIGHT	LEFT	RIGHT	LEFT	RIGHT	LEFT
1	99.8	99.6	103.6	101.5	106.8	103.4	106.6	103	106.8	103.2
1.5	99.5	99.4	103.4	101.4	106.6	103.4	106.6	102.8	106.8	103
2	99.8	99.5	103.4	101.2	106.2	102.8	106.6	102.8	106.6	103.2
2.5	99.8	99.6	103.6	101.2	106.2	102	106.4	102.4	106.6	102.8
3	99.6	99.6	103.5	101.2	106.5	101.6	106.4	101.2	106.5	101
3.5	99.5	99.5	103.2	100.8	106.4	101.5	106.2	100.5	106.5	100.2
4	99.4	99.6	102.8	100.5	105.6	101.4	106.4	100.6	106.4	100.2
4.5	99.2	99.8	102.5	99.6	105.4	99.8	105.8	99.6	106.2	99.8
5	99.4	99.8	102.6	99.5	103.8	99.6	104.8	99.4	105.6	99.6
5.5	99.6	99.5	102.5	99.5	103.8	99.5	104.8	99.5	105	99.5
6	99.4	99.4	102.2	99.5	103.6	99.5	104.5	99.5	105.2	99.5

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THE EFFICACY OF THE THERMOTEX INFRARED HEATING BLANKET UPON THE STANDARDBRED RACEHORSE

RONALD J. RIEGEL D.V.M.

SEPTEMBER, 2001

THE EFFICACY OF THE THERMOTEX INFRARED HEATING BLANKET UPON THE STANDARDBRED RACEHORSE

HYPOTHESIS:

Harness racing is one of the most demanding of all of the equine athletic endeavors. Months of foundation miles are accomplished before this athlete is even close to race condition and speed. After this long period of training, the animal must then drop in time, over the mile distance, to be competitive. This hard training regime is extremely taxing upon the equine athlete and all methods must be considered to alleviate the pain and inflammation within the musculature to ensure the success of this equine athlete.

The Thermotex ™ Infrared heating blanket has been scientifically proven to be effective in providing deep heat to the musculature of the equine athlete. Infrared thermographs correlated with blood chemistry analysis will provide proof that this physical therapy modality is effective in relieving both pain and inflammation within the muscle tissues of these equine athletes.

INFRARED HEAT AS A PHYSICAL THERAPY MODALITY:

The application of heat to the animal in itself possesses many benefits. Application to the muscle tissues provides vasodilatation of the blood vessels, an increased circulation of blood and lymph, an increased metabolism within the tissues, a reduction in swelling and some degree of analgesia. These therapeutic benefits aid in the restoration of these tissues, promote healing within these tissues, allow for an increase in athletic ability and speed the recovery of the athlete from an arduous training schedule.

GOALS:

These are the questions that will be answered by this research endeavor.

- Will the infrared thermal gradients within the musculature of the lumbar and sacral spinal anatomical areas be reduced when treatment with the Thermotex ™ infrared heating equipment is applied?

- What are the clinical pathological changes within the blood chemistry levels as an animal receives treatment with the Thermotex ™ Therapy blanket?

- Will there be a correlation between the thermographic findings and the blood serum chemistry findings?

INFRARED THERMOGRAPHY:

An infrared thermograph is a pictorial photograph of the surface temperature of the anatomical area it is measuring. The circulatory system, inflammation, environmental

changes, the metabolic rate of the animal and other individual thermographic characteristics influences its measurements.

The use of infrared thermography as a measurement of the efficacy of different therapeutic modalities is easily accomplished. Changes within thermal gradients can depict a decrease or increase in circulation, a decrease or increase in inflammation and even nerve irritation somewhere along the neuron pathway. Therapeutic results can be visualized by a series of infrared thermographs taken over a period of time and then compared.

BLOOD CHEMISTRY ANALYSIS:

AST is an abbreviation for Aspartate aminotransferase which is the synonym for the old term SGOT (serum glutamic oxaloacetic transaminase). This enzyme occurs in almost all cells within the body but it is used to primarily diagnose liver and muscle disease. The liver and muscle cells have the highest activity of this enzyme. In itself it is not specific for a liver disorder but is more diagnostic for the muscle tissues.

Aspartate aminotransferase is present in the mitochondria and the cytoplasmic fluid within the cells. The serum levels of this enzyme are increased following hard exercise or skeletal muscle injury. Circulating concentrations of this enzyme will peak approximately 24 hours after an inciting incident and return to normal within 7-10 days.

CPK (CK) is an abbreviation for Creatine phosphokinase (or Creatine kinase). This is the most organ specific of all of the clinical enzymes. Most serum CPK activity is from a muscular origin. The plasma half-life of this enzyme is short and will peak as early as six hours. This enzyme will then only take 2-3 days to return to normal.

PROCEDURE AND METHODOLOGY:

Two groups of ten three and four-year-old standardbred racehorses that are in full training were utilized as the test subjects. These twenty animals will have to meet the following criteria:

1. These animals will be healthy upon physical examination.
2. The animals will be serviceably sound and not had any or be giving any systematic or intraarticular medications. This includes all steroidal and nonsteroidal anti-inflammatory medications such as phenylbutazone, flunixin meglumine and corticosteroids.
3. Training schedules and racing times are all similar and nearly in the same class of races.
4. All other physical therapy modalities and topical applications of counter-irritants discontinued at least seven days before the initiation of this project.

The study will last six weeks, have a two-week break to all equine subjects and then resume with the control group becoming the treatment group and the treatment group becoming the control group for another six weeks.

All twenty animals will be thermographed initially, and then at weekly intervals during the duration of the study. Blood samples will be taken initially from all of the animals and then repeated weekly until the conclusion of the study. These blood samples will be evaluated for a complete blood count and total serum chemistry analysis.

The complete blood count will have the following parameters tested:

1. RBC count
2. WBC count
3. Packed cell volume
4. The types of WBCs
5. In addition to all the normal tests

Serum chemistry analysis included:

- Albumin levels – 35 – 50% of the serum protein
- Alkaline Phosphatase levels – hepatic function
- BUN – renal function
- Calcium – calcium metabolism
- Creatinine – renal function
- Glucose – measured to monitor other diseases
- Magnesium – magnesium metabolism
- Phosphorus – phosphorus metabolism
- **AST(SGOT)**
- Serum protein –nutritive function
- Total bilirubin – hepatic function
- Sodium – electrolyte balance
- Potassium – electrolyte balance
- Chloride – electrolyte balance
- GGT – renal function
- **CPK(CK)**
- A/G ratio – albumin/globulin ratio: total protein values
- Globulin – calculated by subtracting the albumin conc. from the total Protein concentration
- Lipemic index – hepatic function
- Hemolytic index – a value that may affect other tests
- Icteric Index – hepatic function

The animals will be randomly placed into two groups: a treatment group and a control group.

Those animals within the control group will not receive any treatments with the Thermotex ™ therapy blanket during that portion of the study. The animals within the treatment group will receive treatment for thirty minutes each day just before exercise. The temperature control was placed on the high setting for ten minutes and then on low for the remaining twenty minute duration of the treatment.

Infrared thermographs and blood samples were taken every seven days for a total of fourteen weeks.

RESULTS AND DISCUSSION:

Thermographic Results:

The initial infrared thermograph (**See initial thermograph – animal #5**) revealed an increased thermal gradient over the thoracic, lumbar and lumbosacral spine. This thermograph was taken at a setting of 0.5 degrees centigrade per isothermic level. White is the highest reading and purple is the coldest or lowest level with a five-degree difference between them. These areas depicted by the color white were fairly symmetrical except within the lumbosacral area. In this anatomical area, there is an increased thermal gradient predominantly on the left side. These areas of white, gold and yellow reveal an increased thermal gradient within the tissues that is indicative of an inflammatory response within.

This particular animal (#5) was chosen as an example of the entire study since the response within this animal was close to the average of animals within the entire study. This animal also palpated digitally with a slight tenderness throughout the areas that are depicted by the color white.

After eight weeks of training without any treatment, the infrared thermograph of animal number five revealed the following comparisons to the initial thermograph. (**See infrared thermograph – animal #5 - week 8**) There is an increase within all of the thermal gradients as compared to the initial findings. The increased thermal gradients throughout the thoracic spine now continue into the right shoulder region. Those increased thermal gradients within the lumbar and lumbosacral areas have increased in intensity and are now more predominant on the left side continuing into the gluteal areas. These increases are due to a rigorous training schedule and are normal for an animal that is receiving no therapeutic help for this inflammation.

All ten of the animals that were in the control group depicted these types of thermographs for the first eight weeks of the study. They were all becoming increasingly sore and their thermographs all revealed increases along the lumbar and sacral spine.

Immediately after treatment with the Thermotex ™ therapy blanket, there was a huge increase within the thermal gradients within the tissues. This increase lasted an average of four to five hours after the treatment was concluded. These thermographs were done before the initiation of the study just to establish a baseline of data. During the study, the

animals were always exercised after their treatment, which also increased the thermal gradients found within the individual making the duration of effect impossible to measure.

The infrared thermograph taken of animal #5 at the conclusion of the study revealed large decreases within the thermal gradients along all of the anatomical areas examined. **(See infrared thermograph – week 14)** Within the lumbosacral spine area there is a remarkable **95%** reduction within the thermal gradients. Clinically, this also corresponds to insensitivity upon digital palpation. The thoracic and thoracolumbar spinal areas also experienced a reduction within the thermal gradients to an extent of a **68%** reduction. This area was also no longer sensitive to digital palpation.

Serum Chemistry Results:

The AST levels for the ten animals that served in the control group were consistently high during the first eight weeks of the study and then gradually dropped to lower levels during the last six weeks of the study.

(See table one data, graph and chart of averages) Pages 12, 13, 14

Initially, seven of the ten animals tested with higher than normal AST levels within the serum. By week eight, eight of the ten animals depicted AST levels higher than normal. After the initiation of treatment at week eight, these levels gradually fell, in all but those animals testing normally, to a level lower than that found at the eight week tests. By week fourteen, six of the ten animals were now testing within normal limits. The results seen within chart one summarize this data.

Those animals that initially received treatment for six weeks and then were left untreated revealed quite different results within their AST levels.

(See table two data, graph and chart of averages) Pages 15, 16, 17

Five of these ten animals depicted higher than normal AST levels at the initiation of treatment. Nine of the ten animals experienced an immediate drop within the first week of treatment. By week six, seven of the ten animals were testing within normal AST ranges. After the cessation of treatments, seven of the ten animals within this group immediately experienced a rise within the AST levels during week seven. At fourteen weeks, eight of the ten animals revealed higher AST levels than those measured initially. The data graphed on chart two reveals this decline in AST levels through week six and then a gradual increase when the use of Thermotex ™ blanket was stopped.

The CK levels followed the same pattern as the AST levels within the group of ten animals that was used as a control for eight weeks and then provided treatment.

(See table three data, graph and chart) Pages 18 ,19, 20

Initially, five of the ten animals tested within the normal limits for CK levels in the horse. By week eight, six of the animals tested with an increase in CK levels over those initial levels. Over the next six weeks, during treatment with the Thermotex ™ therapy blanket, **all ten** of the animals experienced a decline in CK levels. Eight of the ten animals are now testing within normal limits. The other two animals could even be considered in the high normal range.

Chart three is a summary of all of the averages on a weekly basis. During the control part of the study, the group maintained an even level throughout the first 6-8 weeks. After the initiation of treatment, the CK levels gradually fell.

When the animals initially received treatment and then became the control group, the results mimicked those of the same AST group.

(See table four data, graph and chart) Pages 21 ,22, 23

Initially, only four of the ten animals tested within normal limits for CK. After six weeks of treatment with the Thermotex ™ therapy blanket, six of the ten animals were within normal limits. By the time fourteen weeks had passed, Seven of the ten animals exhibited higher than normal levels with seven of the ten animals also showing increased levels from the initial testing. Chart four exhibits the gradual decline in CK levels and then the gradual increase after treatment protocols have ceased.

The summary of the blood chemistry analysis revealed that the AST and CK levels were lower during treatment with the Thermotex ™ therapy blanket.

(See table five data and graph) Pages 24, 25

As depicted on the data table and corresponding graph, the AST and CK levels increased while the animals were in training and not receiving treatment with the Thermotex ™ therapy blanket and decreased when receiving treatment.

SUMMARY AND CONCLUSSIONS:

The evidence provided by this study allows the following conclusions:

- There is thermographic and serum chemistry evidence that the therapy provided by the Thermotex ™ therapy blanket is efficacious.
- The lowering of both the AST and CK levels indicates that treatment with the Thermotex ™ therapy blanket alleviates the inflammatory response within the muscles of the standardbred racehorses that are in training.
- Thermographic evidence provides evidence of a decrease within the inflammatory response and some analgesia when the Thermotex ™ therapy blanket is used on a daily basis on the standardbred racehorse.
- This evidence concludes that the Thermotex ™ therapy blanket is an ideal drug free modality to use before competition, as a therapy program in itself, as an adjunct to

massage therapy, as a preventive program for athletic injuries and as a tool to help improve the quality of life for the equine athlete.

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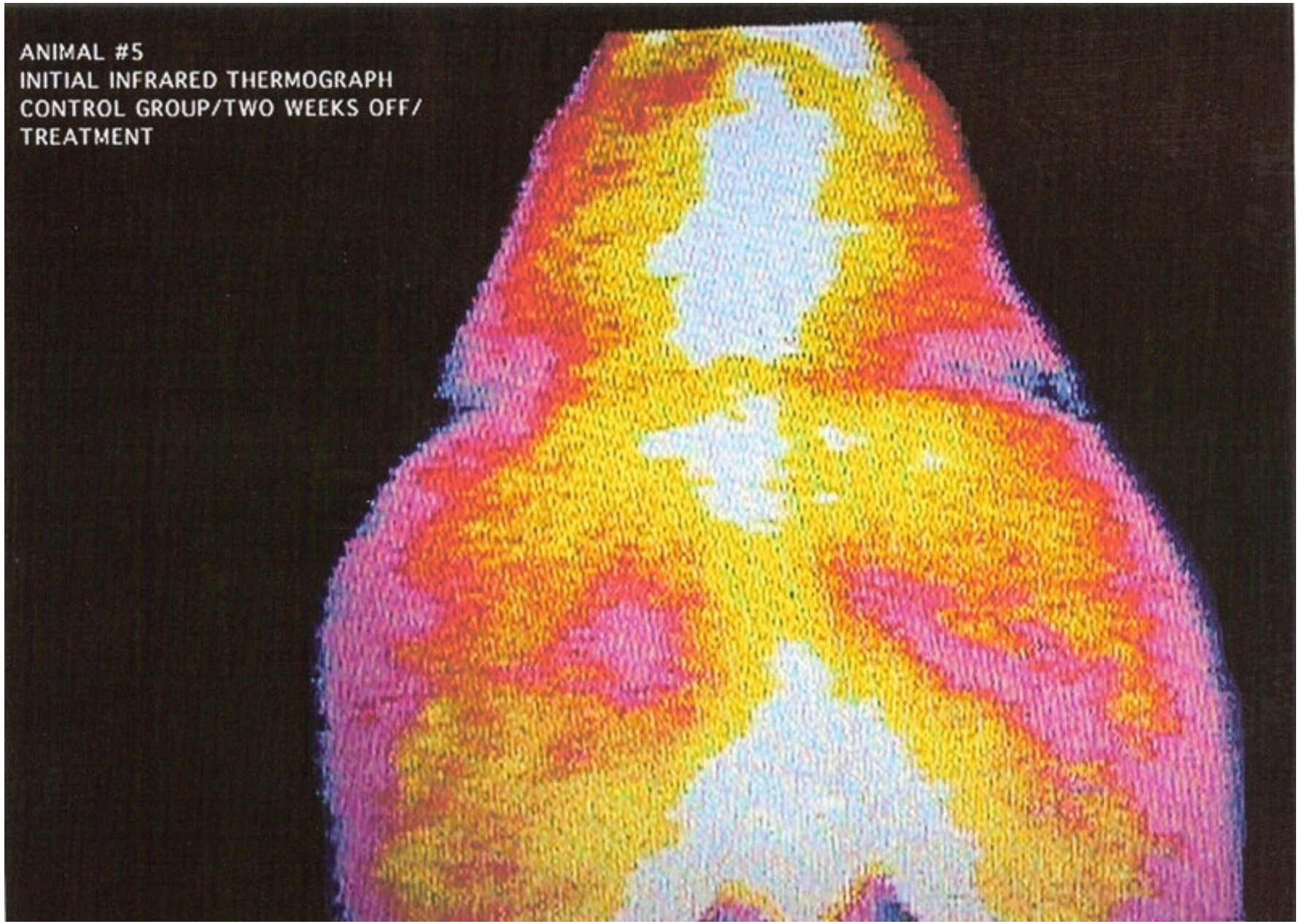
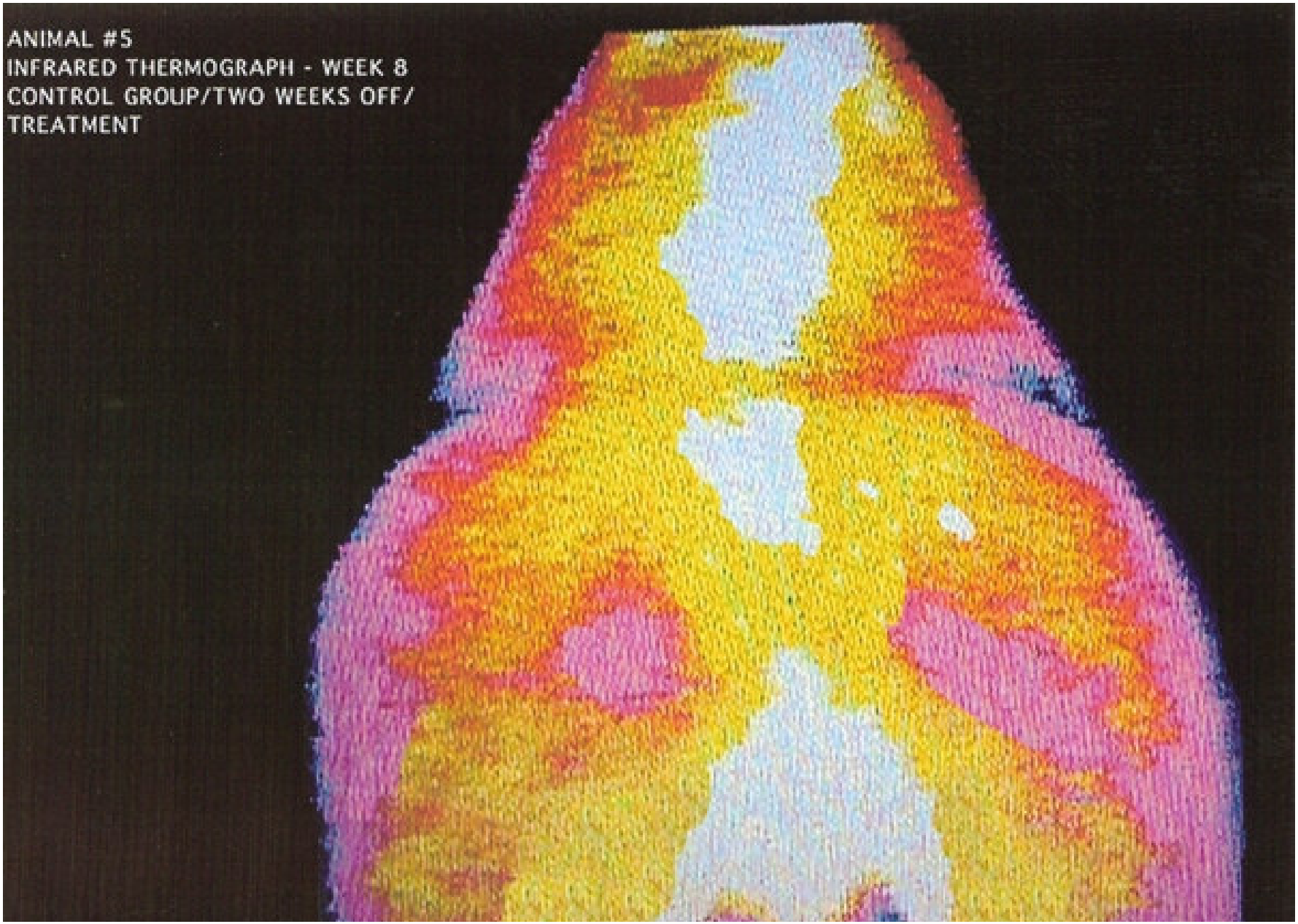
4. Stashak, S. Ted. *Adam's Lameness in Horses.* Fourth Edition. Lea and Febiger. 1987. Philadelphia. 1962.


ANIMAL #5
INITIAL INFRARED THERMOGRAPH
CONTROL GROUP/TWO WEEKS OFF/
TREATMENT


ANIMAL #5
INFRARED THERMOGRAPH - WEEK 8
CONTROL GROUP/TWO WEEKS OFF/
TREATMENT

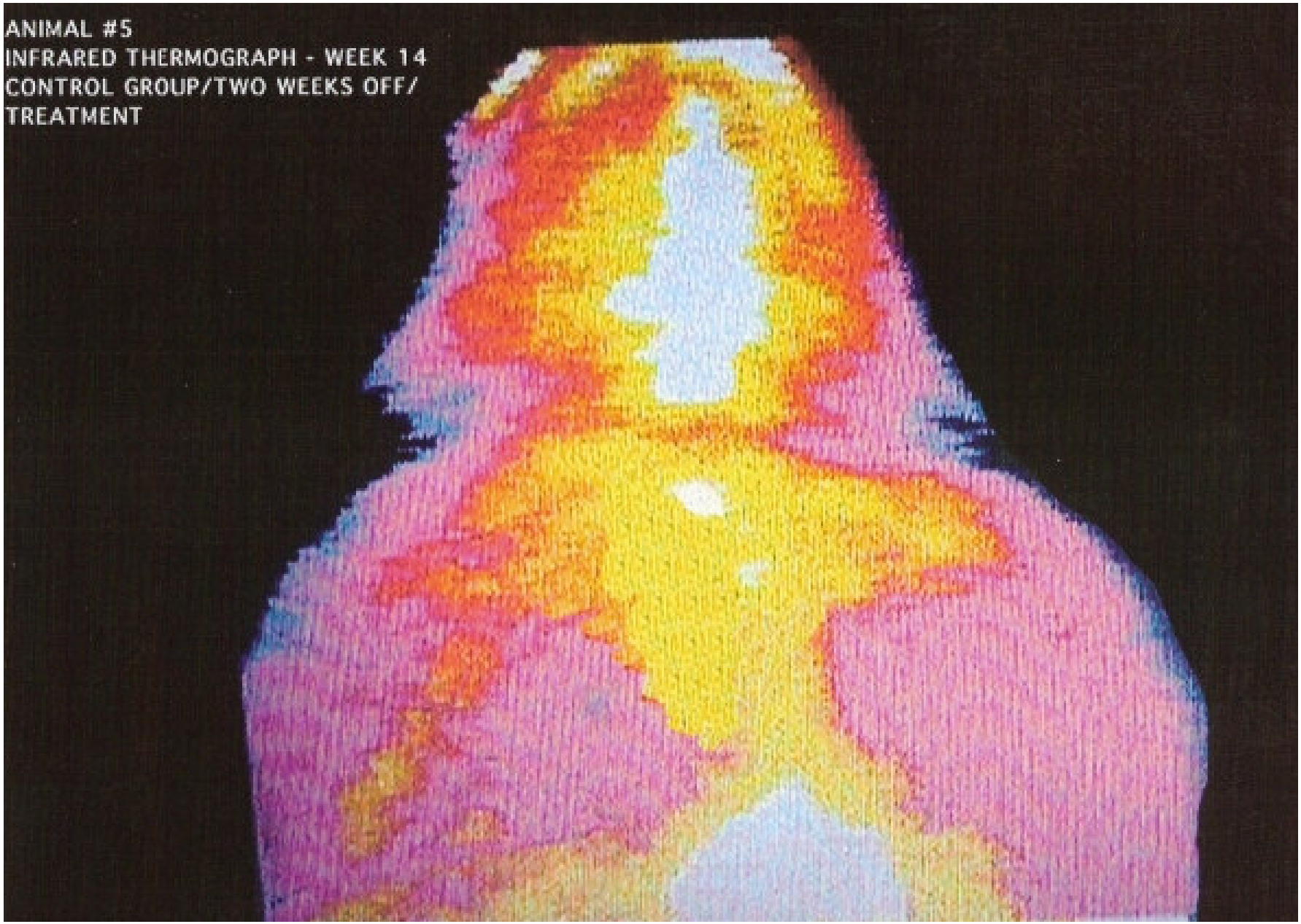

ANIMAL #5
INFRARED THERMOGRAPH - WEEK 14
CONTROL GROUP/TWO WEEKS OFF/
TREATMENT

TABLE ONE - AST LEVELS (U/L) FIRST SIX WEEKS CONTROL, TWO WEEKS OFF, THEN TREATMENT

AN.	INITIAL	WK. 1	WK. 2	WK. 3	WK. 4	WK.5	WK.6	WK.7	WK.8	WK.9	WK.10	WK.11	WK.12	WK.13	WK.14
1	420	485	465	510	546	518	512	524	502	465	437	422	348	342	328
2	366	350	356	388	420	458	464	485	490	426	372	348	240	242	218
3	645	624	594	626	593	628	588	614	594	528	536	492	474	443	428
4	474	498	476	524	515	488	513	532	538	482	449	387	362	354	341
5	524	534	562	624	547	528	554	588	564	532	480	448	427	388	376
6	486	485	474	502	468	523	534	546	568	544	538	524	547	526	504
7	708	724	685	691	710	674	688	668	697	635	624	610	526	488	485
8	354	342	364	334	386	344	335	328	354	364	302	322	318	304	286
9	266	284	278	264	274	268	276	284	294	264	254	258	262	234	228
10	672	648	638	645	590	607	625	615	632	624	604	584	586	532	482
AVER.	491.5	497.4	489.2	510.8	504.9	503.6	508.9	518.4	523.3	486.4	459.6	439.5	409	385.3	367.6

NORMAL AST LEVELS ARE 160-412 U/L
STANDARD DEVIATION FOR THIS DATA IS +/- 50

TABLE ONE-AST LEVELS FIRST SIX WEEKS CONTROL, TWO WEEKS REST, SIX WEEKS TREATMENT

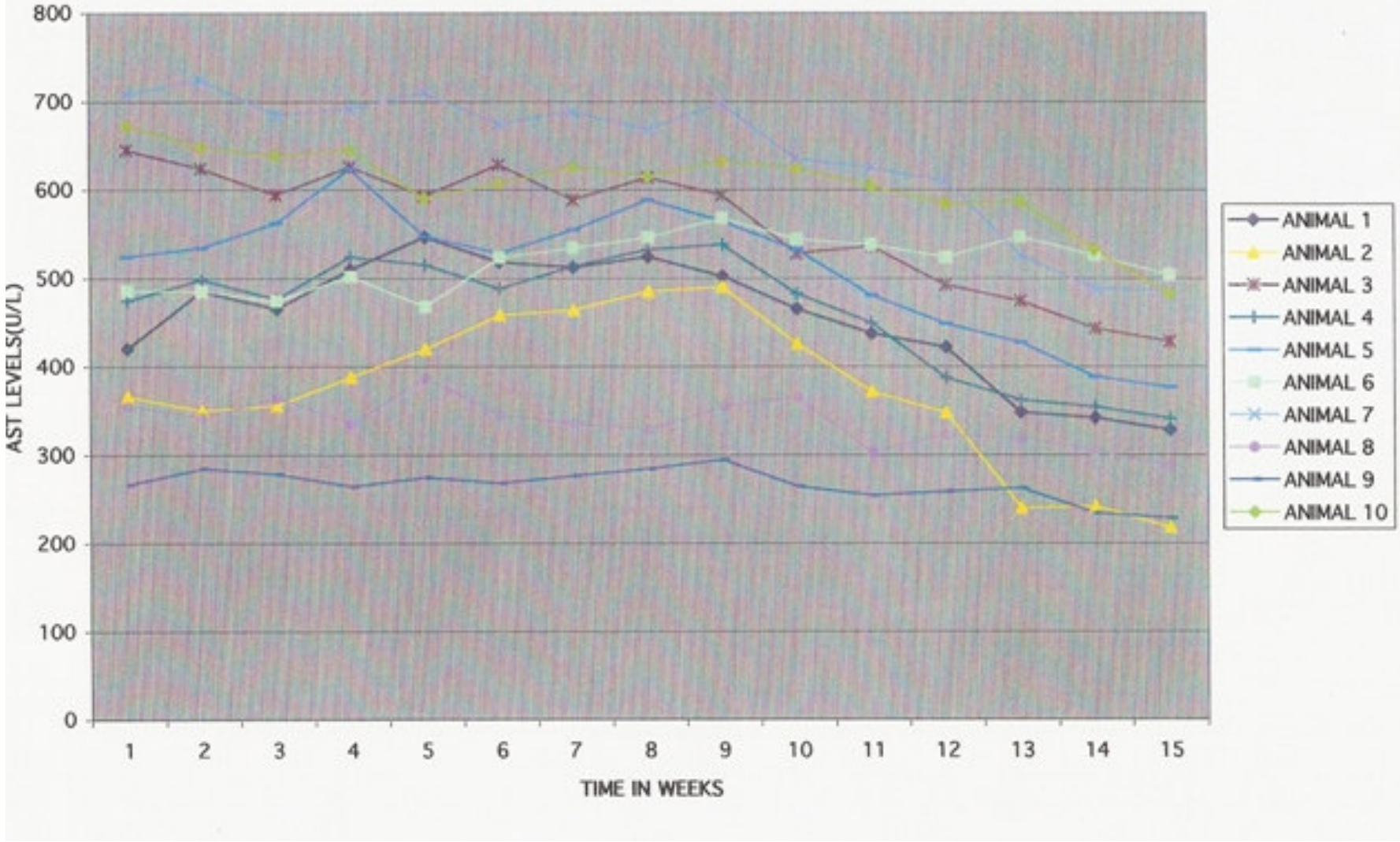


CHART ONE-AST LEVELS WITH THE FIRST SIX WEEKS CONTROL, TWO WEEKS REST, SIX WEEKS TREATMENT

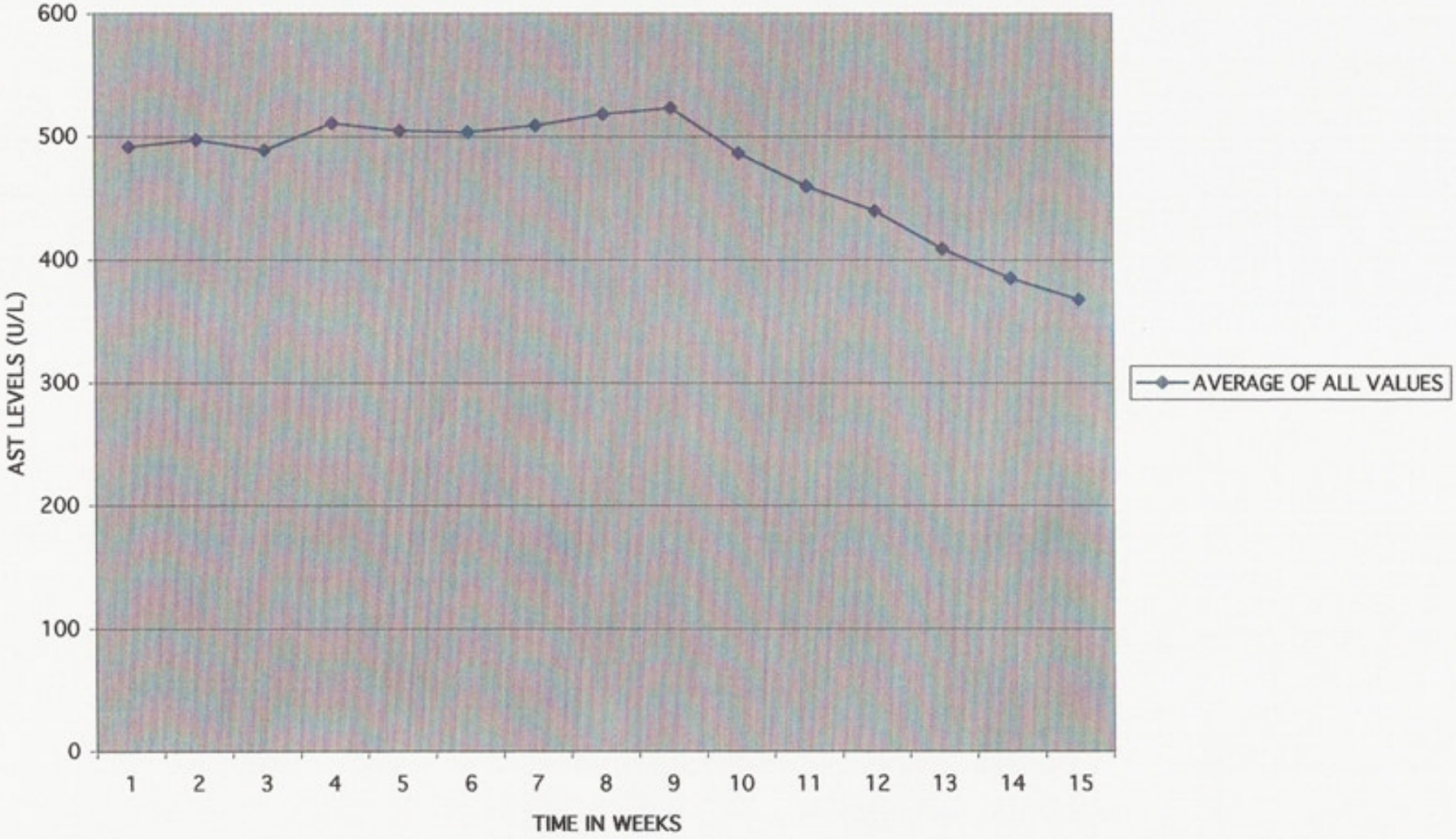


TABLE TWO - AST LEVELS (U/L) FIRST SIX WEEKS TREATMENT, TWO WEEKS OFF, THEN CONTROL

AN.	INITIAL	WK. 1	WK. 2	WK. 3	WK. 4	WK.5	WK.6	WK.7	WK.8	WK.9	WK.10	WK.11	WK.12	WK.13	WK.14
1	285	274	288	254	265	245	240	256	268	323	342	422	348	385	368
2	627	632	582	585	546	534	537	485	524	564	558	526	585	594	610
3	406	394	367	341	310	286	318	345	364	468	436	492	474	443	438
4	364	344	326	324	311	287	262	274	268	324	348	395	412	438	445
5	532	485	472	492	468	424	415	426	446	445	487	467	495	523	558
6	724	684	678	656	520	486	474	468	564	558	532	526	512	564	588
7	643	632	624	584	524	482	456	487	514	542	568	562	588	575	584
8	278	286	245	268	236	212	224	235	248	258	268	326	316	364	397
9	482	454	467	424	386	374	354	326	364	387	374	394	442	467	512
10	344	362	358	264	246	232	196	212	238	226	247	258	282	342	368
AVER.	468.5	454.7	440.7	419.2	381.2	356.2	347.6	351.4	379.8	409.5	416	436.8	445.4	469.5	486.8

NORMAL AST LEVELS ARE 160-412 U/L
STANDARD DEVIATION FOR THIS DATA IS +/- 50

TABLE TWO-AST LEVELS TREATMENT FOR SIX WEEKS, TWO WEEKS OFF, THEN CONTROL

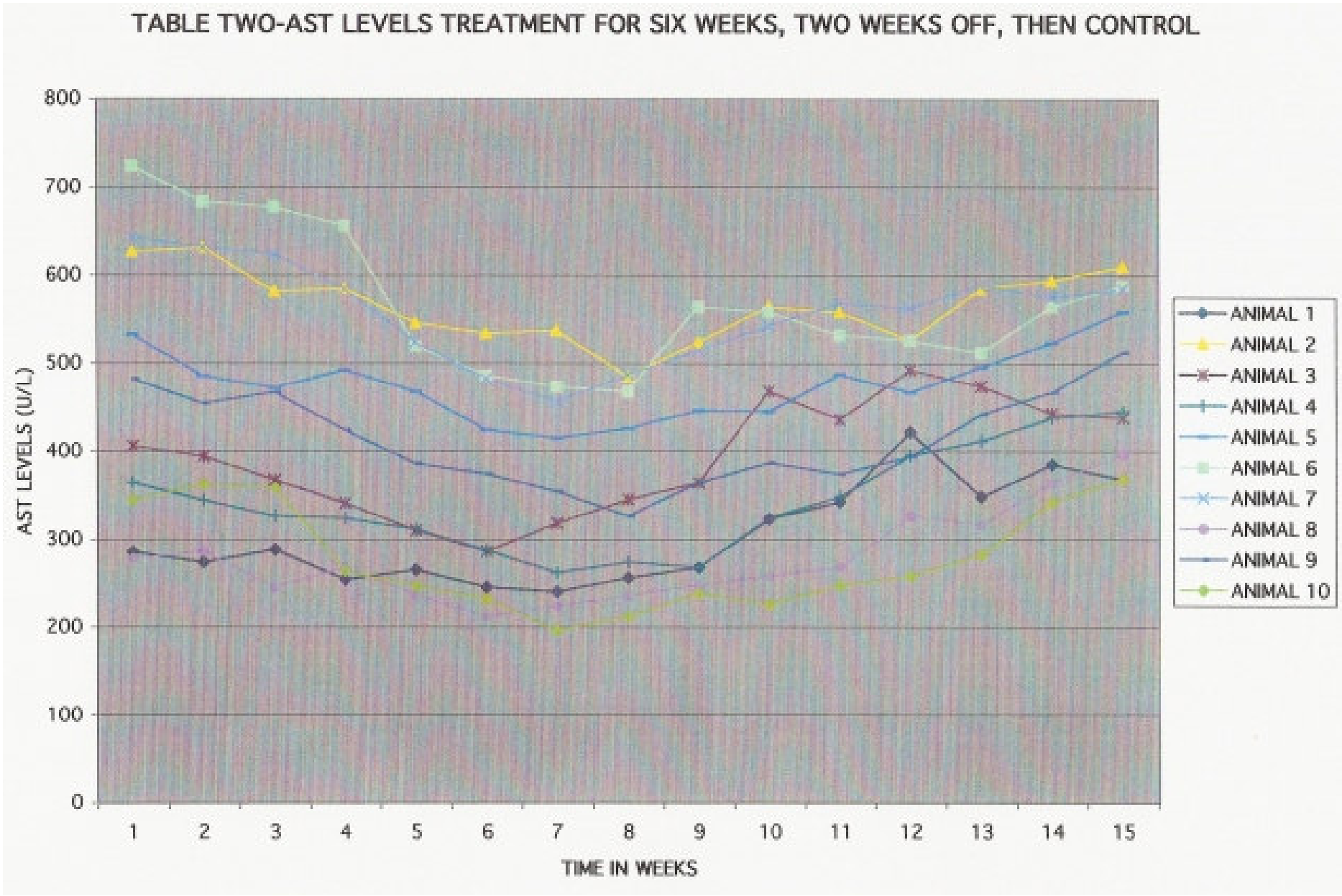


CHART TWO-AST LEVEL AVERAGES FOR ANIMALS RECEIVING TREATMENT FOR SIX WEEKS, TWO WEEKS OFF, THEN CONTROL

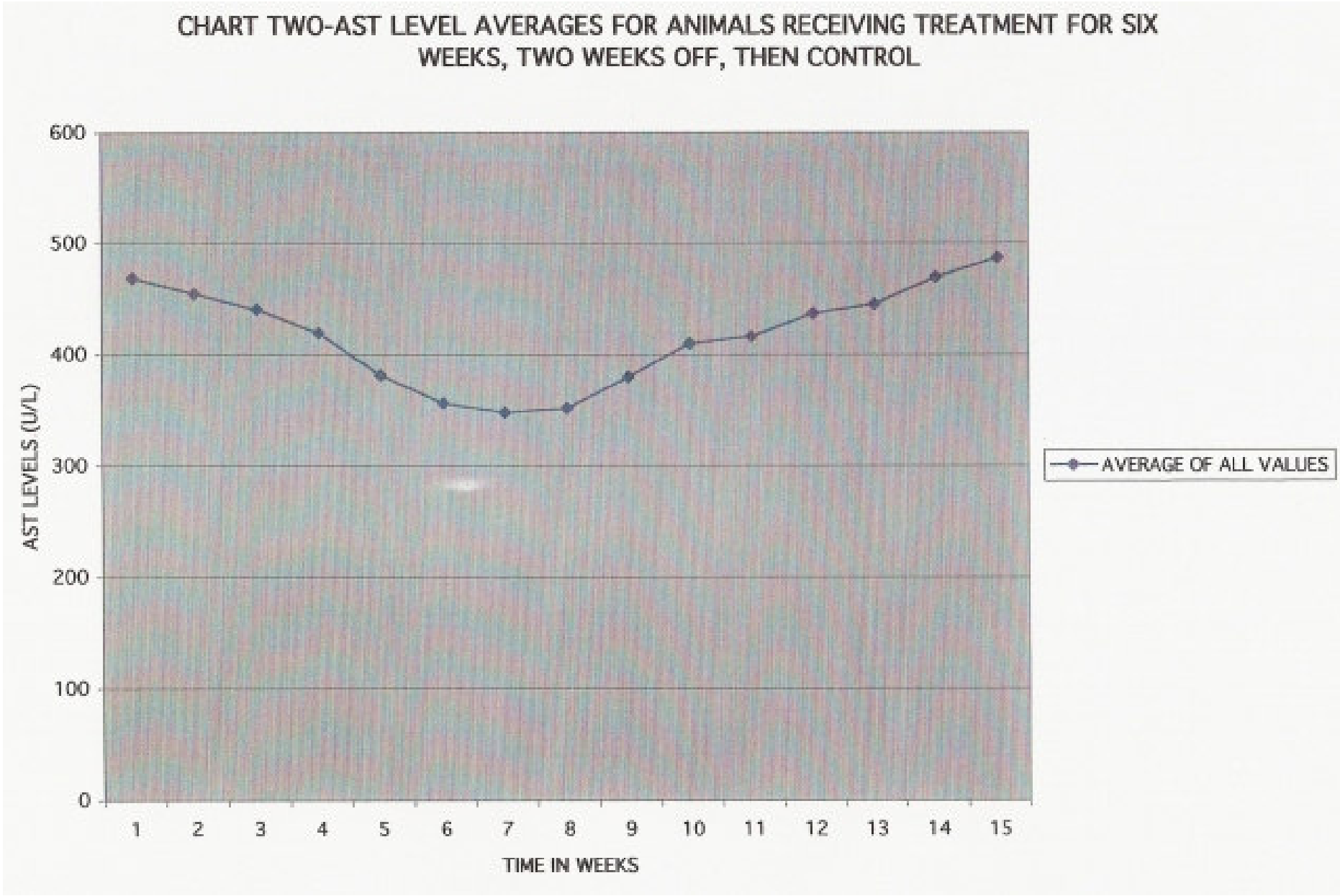


TABLE THREE - CK LEVELS (U/L) FIRST SIX WEEKS CONTROL, TWO WEEKS OFF, THEN TREATMENT

AN.	INITIAL	WK. 1	WK. 2	WK. 3	WK. 4	WK.5	WK.6	WK.7	WK.8	WK.9	WK.10	WK.11	WK.12	WK.13	WK.14
1	346	354	348	356	362	374	370	354	360	312	304	274	268	244	226
2	242	246	238	248	256	254	247	244	234	220	168	174	188	165	154
3	426	432	418	412	402	396	390	412	387	354	324	312	264	248	262
4	472	468	478	484	488	490	498	512	486	454	438	396	374	362	374
5	118	126	132	128	136	124	136	142	148	138	116	112	102	94	88
6	286	298	292	284	273	278	282	294	274	276	245	212	228	197	194
7	512	514	496	506	500	496	494	514	523	486	435	424	368	345	328
8	174	178	168	170	166	164	160	172	164	148	152	137	124	132	112
9	482	492	496	542	538	546	526	538	542	492	484	428	378	364	345
10	224	218	220	212	206	200	198	226	234	214	194	168	172	145	154
AVER.	328.2	332.6	328.6	334.2	332.7	332.2	330.1	340.8	335.2	309.4	286	263.7	246.6	229.6	223.7

NORMAL CK LEVELS ARE 60-330 U/L.
STANDARD DEVIATION FOR THIS DATA IS +/- 30

TABLE THREE - CK LEVELS FIRST SIX WEEK WEEKS CONTROL, TWO WEEKS OFF, SIX WEEKS TREATMENT

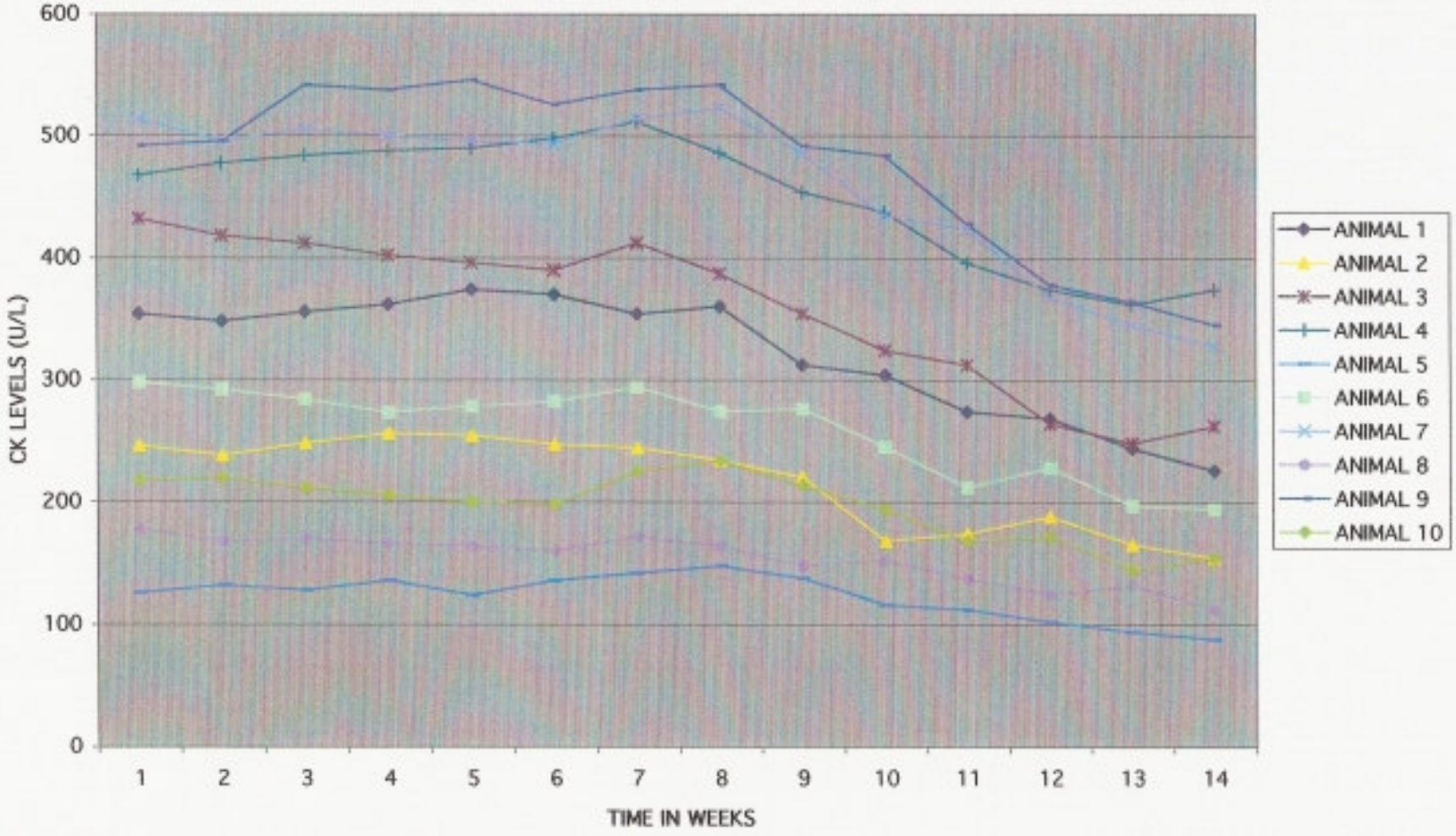


CHART THREE - CK LEVELS FIRST SIX WEEK CONTROL, TWO WEEKS OFF, SIX WEEKS TREATMENT

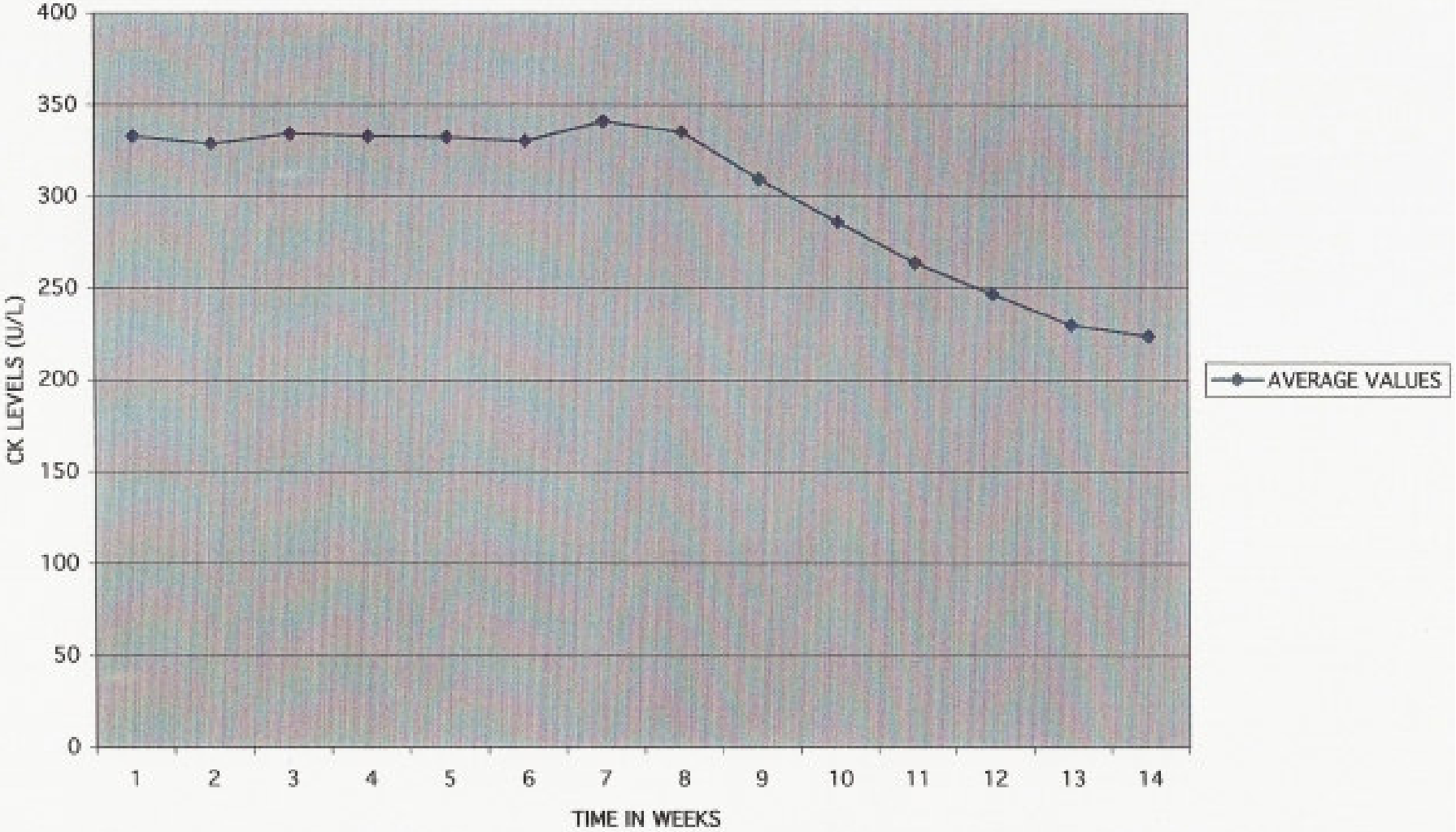


TABLE FOUR - CK LEVELS (U/L) FIRST SIX WEEKS TREATMENT, TWO WEEKS OFF, THEN CONTROL

AN.	INITIAL	WK. 1	WK. 2	WK. 3	WK. 4	WK.5	WK.6	WK.7	WK.8	WK.9	WK.10	WK.11	WK.12	WK.13	WK.14
1	228	204	216	194	178	164	138	142	158	194	212	238	243	254	246
2	526	488	462	442	418	398	386	244	294	322	356	345	380	412	426
3	298	284	258	244	232	226	218	228	262	274	268	312	326	334	346
4	342	338	333	328	324	284	244	254	238	294	326	358	377	402	394
5	412	405	402	395	384	378	347	352	348	368	397	412	434	428	457
6	584	554	518	498	472	424	398	294	318	347	367	394	426	428	474
7	492	482	478	471	456	442	436	451	462	458	488	515	487	524	498
8	194	196	178	168	145	148	126	134	158	179	188	176	194	212	246
9	388	274	264	268	200	214	206	224	238	267	284	258	278	345	336
10	206	198	168	154	146	132	116	124	145	164	184	178	194	198	234
AVER.	367	342.3	327.7	316.2	295.5	281	261.5	244.7	262.1	286.7	307	318.6	333.9	353.7	365.7

NORMAL CK LEVELS ARE 60-330 U/L.
STANDARD DEVIATION FOR THIS DATA IS +/- 30

TABLE FOUR - CK LEVELS FIRST SIX WEEKS TREATMENT, TWO WEEKS OFF, THEN CONTROL

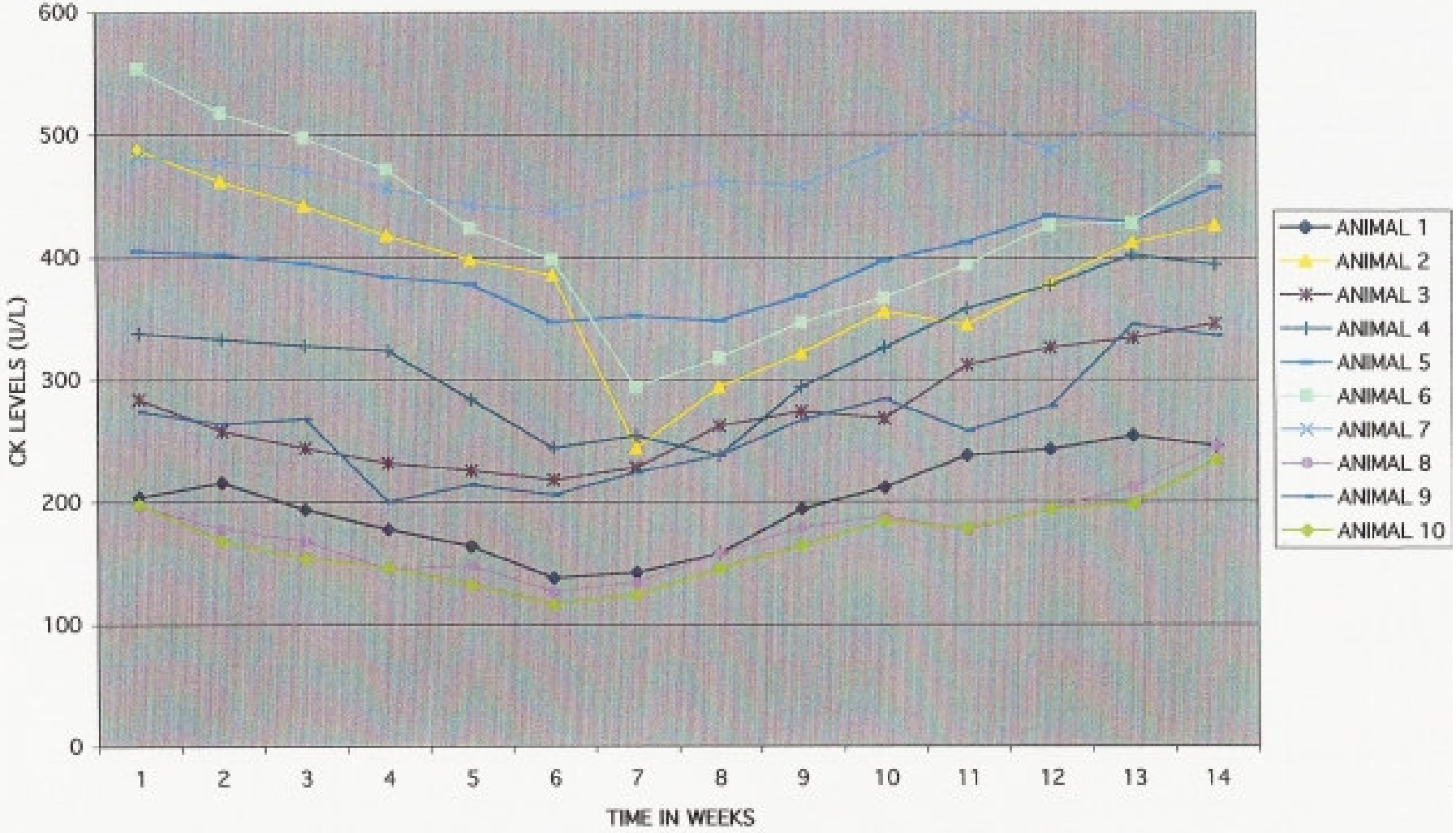


CHART FOUR CK LEVEL AVERAGES: FIRST SIX WEEKS TREATMENT,TWO WEEKS OFF; THEN CONTROL

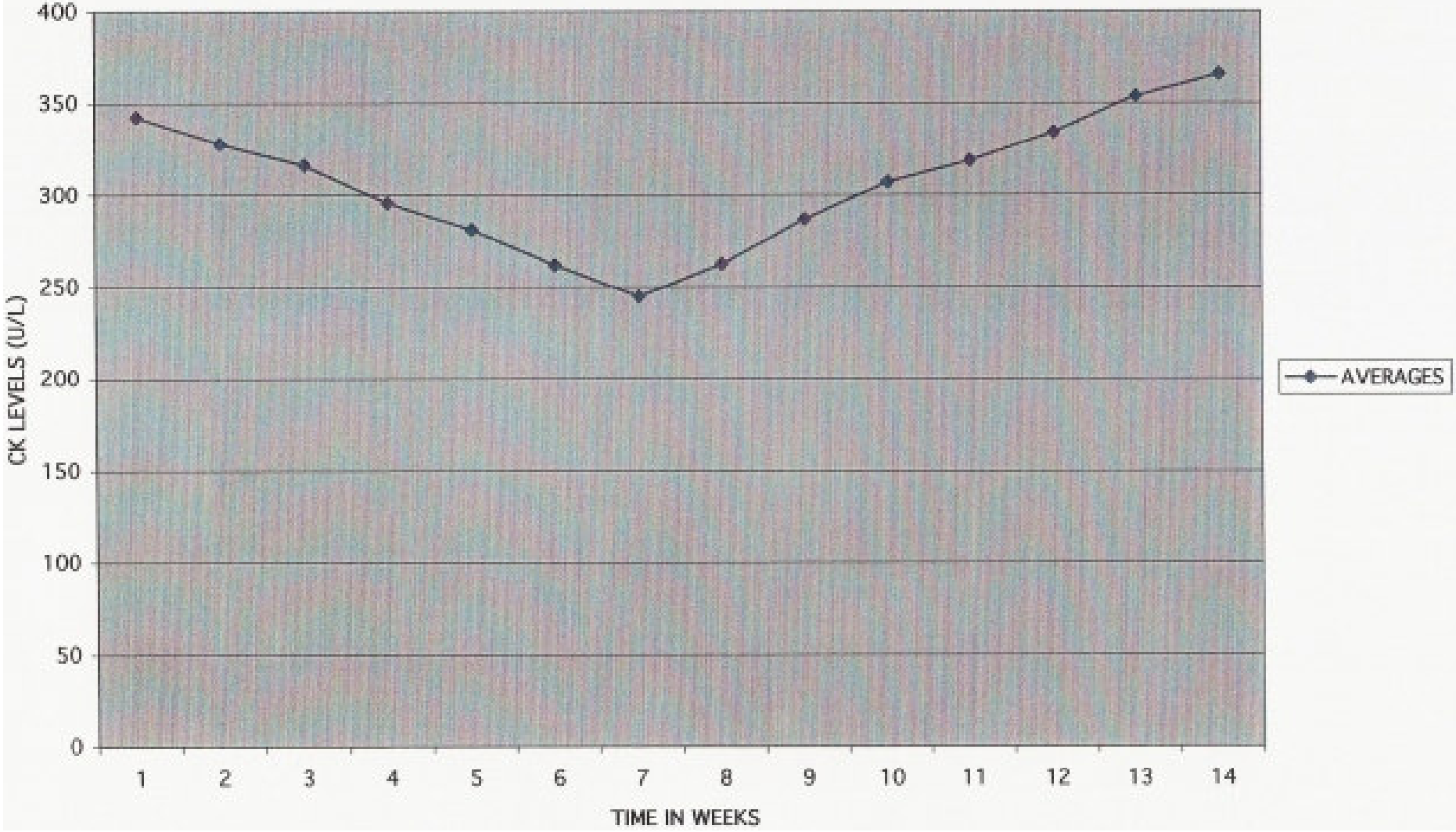


TABLE FIVE - AST LEVELS AND CK LEVEL (U/L) AVERAGES

LEVEL	INITIAL	WK. 1	WK. 2	WK. 3	WK. 4	WK.5	WK.6	WK.7	WK.8	WK.9	WK.10	WK.11	WK.12	WK.13	WK.14
ST CON	491.5	497.4	489.2	510.8	504.9	503.6	508.9	518.4	523.3	486.4	459.6	439.5	409	385.3	367.6
AST RX.	468.5	454.7	440.7	419.2	381.2	356.2	347.6	351.4	379.8	409.5	416	436.8	445.4	469.5	486.8
CK CONT	328.2	332.6	328.6	334.2	332.7	332.2	330.1	340.8	335.2	309.4	286	263.7	246.6	229.6	223.7
CK RX.	367	342.3	327.7	316.2	295.5	281	261.5	244.7	262.1	286.7	307	318.6	333.9	353.7	365.7

NORMAL AST LEVELS ARE 160-412 U/L
STANDARD DEVIATION FOR THIS DATA IS +/- 50

NORMAL CK LEVELS ARE 60-330 U/L.
STANDARD DEVIATION FOR THIS DATA IS +/- 30

TABLE FIVE - AST AND CK LEVEL AVERAGES