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Pulsed Signal Therapy® (PST™) for the treatment of Osteoarthritis in canines – Pooled Data -

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INTRODUCTION

Over 150 disorders and syndromes, which are usually progressive and associated with pain, may be classified as musculoskeletal conditions (1). They are generally broadly categorized as joint diseases, physical disability, spinal disorders and conditions resulting from trauma (1). Arthritis is one of them. It is one of the world's most common health problems characterized by inflammation of the cartilage and the lining of the body's joints, (1). It ails both humans and canines alike, with an estimated 70-80% of dogs of certain breeds being afflicted, the incidence of which increases with age (2). According to Karyl Hurley, a specialist in small animal internal medicine and a researcher at the Waltham Centre for Pet Nutrition, in Leicestershire, England, one in five of Britain's 4.8 million dogs, suffers from inflammation of the joints, (3). In the US alone, an estimated 10 million dogs have been reported to suffer from this debilitating disease (4).

Arthritis comprises over 100 different diseases and conditions, the most common being osteoarthritis (OA), rheumatoid arthritis (RA), fibromyalgia, and gout. Osteoarthritis is one of the most common form of degenerative joint diseases, that progresses over time and affects approximately 20% of the canine population over 1 year of age (5). It is primarily a non-inflammatory joint disorder characterized by an imbalance between the synthesis and degradation of

articular cartilage (6). It may also involve changes in the underlying bone and other tissues of the joint. As the disease progresses the cartilage protecting the bone wears down and new bone forms at the joint surfaces and margins (osteophytes). In severe OA, calcification (calcium crystal deposition) often occurs resulting in increased pain, loss of mobility (lameless), and in some cases, disability (5, 7).

In general, there is no cure for OA. In addition to encouraging low-impact exercise and weight loss, nonsteroidal anti-inflammatory drugs (NSAIDs) and slow-acting disease modifying OA agents (SADMOAs) are the two most commonly prescribed group of drugs for the long-term treatment of canine OA. These are generally prescribed because they are said to allow for better control of chronic pain, improvement of general mobility, slower progression of the disease, and therefore improvement in the quality of life, to a greater extent than other "suitable" drugs (8-12). There is a consensus that long-term use of a drug can produce side effects or alter the functions of different body systems (13). In a study on 21 dogs, carprofen (Rimadyl), the prescribed NSAID for the long-term treatment of OA, was shown to significantly decrease both serum thyroxine levels and endogenous thyroxine stimulating hormone (14). Although another study by Sauvé and colleagues, demonstrated that carprofen (Rimadyl) had no affect on thyroid function, the well-known, undesirable, untoward effects, and short duration of "therapeutic" effects, attributed to NSAIDs, including gastrointestinal, cardiovascular and renal effects, can not be excluded.

While the quality and amount of information available regarding OA in humans and treatment options is reasonable, the quality and amount available on OA in canines is questionable. In fact, a study conducted by Jehn and colleagues in 2003, reported that while some sites conveyed conventional information with reasonable accuracy, the information therein was "incomplete, of minimal use,

and often considered counterproductive" (15). As canines continue to be afflicted by OA and statistics continue escalating, efforts to develop improved therapeutic modalities to preserve function, and reduce arthritis related disabilities, pain as well as adverse effects, have emanated. Initiatives to raise money and encourage canine arthritis research, for example, the "Just Ask" advocacy program, have even been instigated. Amidst conventional treatment options available and demands for alternative therapies, arises "the Pulse of Life" - an innovative paradigm in modern medicine – a certified, medical technology known as **PULSED SIGNAL THERAPY® (PST™)...**

Pulsed Signal Therapy® was developed over 20 years of intense scientific research for the treatment of humans with musculoskeletal conditions, most notably OA. It is currently available in over 800 clinics and/or medical institutes worldwide. In contrast to the pharmacological agents currently prescribed for OA, no known adverse effects have been reported with PST™. Furthermore, it is non-invasive, non-pharmacological, painless, with long-term follow-up and sustained efficacy (16). It is based on PEMF (Pulsed Electromagnetic Fields), known to promote bone healing and provide pain relief in OA and traumatic joint damage, with a consistent success rate of 70-80% (17, 18). However, since most of the results obtained with PEMF were based on non-randomized studies using numerous PEMF devices, a superior technology, was developed that produced pulsed electromagnetic fields with more consistent results (19). More than 25 clinical studies, supported by 5 *in vitro* studies have demonstrated PST™

therapeutic success and long-term benefits (19-26). PST™ is characterized by an energy pulse employing a direct current, low biological frequencies of 10 to 30 Hertz in a quasi-rectangular waveform and field strengths between 0.5 and 1.5 milliTesla (5-15 Gauss). PST™ therefore delivers modulated, pulsed electromagnetic signals in an alternating fashion through the injured tissue, targeting the affected area via direct induction (27). Through inductive coupling, PST™ induces the repair and regeneration of damaged or injured connective tissue, by promoting the biosynthesis of important extracellular matrix (ECM) components, most likely through upregulation of associated genes, to restore innate processes and accelerate healing.

In these studies, canines befitting the selection criteria were subjected to PST™. Pain and physical function, including stiffness were assessed, using validated instruments of measurement applicable to canines, pre-PST™ treatment, post-PST™ treatment and at follow-ups (2-, 4-, 8-, and 12-weeks post-PST™ treatment).

STUDY DESIGN

Patients and Methods

Patient Selection

Canines of all ages and breed, befitting the selection criteria, were recruited, after owners formally signed a consent form.

Inclusion Criteria

- Clinical diagnosis of idiopathic OA fulfilling preliminary ACR criteria

- Significant OA symptoms, at least during the last 6-months,
- Pain Score of at least 10 on the WOMAC pain section (Likert scale)
- A Global Assessment at baseline of either very poor, poor or fair
- A Physician Global Assessment at baseline of either very poor, poor or fair
- Full compliance
- No alteration of medication in the 2 weeks before commencing the study

Exclusion Criteria

- Patients with OA secondary to other conditions (septic arthritis, inflammatory joint disease, gout, Paget's disease of bone, recurrent pseudogout, articular fracture, major chondrodysplasias, congenital abnormalities, ochronosis, acromegaly, hemachromatosis, Wilson's disease, and primary osteochondromatosis)
- Rheumatoid arthritis
- Intra-articular hyaluronate treatment in the last 90 days
- Intra-articular glucocorticoid treatment in the last 30 days
- Arthroscopic or open surgery on the symptomatic knee in the past 6 months
- Disease of the spine or of other lower extremity joints sufficient to interfere with assessment of the treated knee
- Use of assistive devices
- Any implanted device containing iron
- Metallic implant within 10 cm of the knee joint to be treated
- Pregnancy at onset and during the treatment period

Methodology

Canines were subjected to nine, 30-minute daily treatments, over nine consecutive days, with allowed interruption over the weekend. Pain and

functional activity were assessed before PST™ treatment (baseline), after the 9-day treatment course, and at 2-, 4-, 8- and 12-weeks post-PST™ treatment.

Treatment

The PST™ treatment device consists of a magnetic field generator and air coil system, connected by an electronic interface. It employs direct current with low frequencies, in the range 10 to 30 Hertz, to deliver modulated, changing pulsed electromagnetic signals, through the injured tissue via direct induction (19). The treatment protocol consists of nine consecutive 30-minute therapy sessions with interruption not exceeding 2 days.

Assessment of Pain and Physical Function, including Stiffness

The outcome measures for pain and physical function were recorded as assessed by canine owners. Global treatment effectiveness was assessed as reported by both owners and physicians.
The specific primary outcome measures assessed were:

- **Pain** using the WOMAC Pain Scale (modified to canine application)

[Pain parameters were assessed on walking, climbing stairs, running, sitting/lying and standing]

- **Physical function** using the WOMAC Function Scale (Likert format modified to canine application),

[Parameters evaluating physical function were assessed upon descending and ascending stairs, rising, standing on all fours, standing on the hind legs only, walking, climbing in/out of the car, playing, and going to the bathroom. Stiffness was assessed on awakening and in the later day].

- **Physician Global Assessment**

- **Owner Global Assessment of Disease Severity** (owner's assessment of the canine's response in considering all the ways that the OA affects the canine)

The secondary outcome measure evaluated was the use of analgesics/NSAIDs (measured with a daily diary).

RESULTS

Evaluation of the pooled data obtained for pain and physical function, including stiffness, demonstrated an overall (total) decrease in scores assessing pain, stiffness and difficulty with performing physical functions, post-PST™ treatment (Table 1 and Figure 1). This decreasing trend continued in the long-term, post-PST™ treatment. The overall improvement in physical function, pain and stiffness in 22 canines was 79,89%, 86,31% and 73,91% respectively, 12 weeks post-PST™ treatment (Table 2 and Figure 2).

Table 1: Total scores for Physical Function, Pain and Stiffness, as assessed using appropriate WOMAC scales modified to canine application pre- and post-PST™ and at follow-ups

	Baseline (57 canines)	End of Treatment (49 canines)	2- Weeks Post Treatment (45 canines)	4-Weeks Post Treatment (39 canines)	8-Weeks Post Treatment (31 canines)	12-Weeks Post Treatment (22 canines)
Total Physical Function	1.114	1.120	923	624	417	224
Total Pain	526	322	307	212	132	72
Total Stiffness	230	228	188	134	109	60

Table 2: % improvement from baseline in Physical Function, Pain and Stiffness, pre- and post-PST™ and at follow-ups.

	End of Treatment (49 canines)	2- Weeks Post Treatment (45 canines)	4-Weeks Post Treatment (39 canines)	8-Weeks Post Treatment (31 canines)	12-Weeks Post Treatment (22 canines)
Total Physical Function	1,00	17,15	43,99	62,57	79,89
Total Pain	38,78	41,63	59,70	74,90	86,31
Total Stiffness	0,87	18,26	41,74	52,61	73,91

DISCUSSION

There is only one health, and a myriad of diseases. There appears to be one fundamental force that heals, and a myriad of medical professionals denying its existence. In western medicine, our prevailing mythology has left us to somewhat deny the existence of any natural (healing) force(s). Instead, we remain fixated in the chemical-mechanistic dogma of old, integrated with the technology of new, even though we gradually experience its increasing failure to heal. One need only consider the family of NSAIDs, now under surveillance following Vioxx's withdrawal from the market, in September 30, 2004. In fact, Pfizer was reprimanded by the US FDA in a letter dated 12 January 2005 and requested to cease promotional activities featuring Celebrex and Bextra, because they contained misleading claims of safety, as well as unsubstantiated claims of superiority and effectiveness.

Electromagnetism in medicine is not a new concept. In the era before Christ, the words "magnetism" and "electrical" were already synonymous with modalities used for the treatment of (daily) ailments, including wound healing. By 1950, the chemical-mechanistic concept of life was in play, breaching the interdisciplinary gap between physics and medicine, as foreseen by Bassett, Becker, Liboff and others. Today, many scientists still foster the classical chemical-mechanistic orthodoxy, failing to recognize how fundamental electromagnetic energy

parameters relate to biology and life. However, many are growing dissatisfied with the doctrines of old and many physicians and veterinarians are reexamining and applying "therapeutic techniques formerly considered "unscientific", including acupuncture, and herbal preparations. Understanding how specific biological signals carried on electromagnetic fields (EMFs), specifically affect life processes, how EMFs and electrical stimuli interact with cells to elicit trillions of interrelated and carefully balanced biochemical enzymatic processes, requires a new paradigm in the understanding of the forces that regulate life itself – a scientific revolution in the 21st century...

Pulsed Signal Therapy® (PST™), is a paradigm in modern medicine. It has been successfully used for the treatment of musculoskeletal conditions in humans since 1992, and in animals since 1994, with establishment of the first veterinary treatment centre in Boca Raton, Florida, USA. In total, there are over 50 veterinary clinics worldwide, offering PST™ as an alternative treatment for canines with OA. It has proven to be an effective treatment alternative, with no known side-effects, requiring only one course of treatment, to provide sustained pain relief and restoration of normal mobility. Long-term follow-up studies in humans have constantly demonstrated its therapeutic benefits in musculoskeletal conditions (19-24). These have been supported by *in vitro* and imaging studies, conducted worldwide (25, 26).

In these studies evaluating PST™ for the treatment of canines with OA, pooled data results verified PST™ established therapeutic success for the treatment of OA. As evident in Tables 1 and 2, and corresponding Figures 1 and 2, a vast improvement in physical mobility and stiffness was observed, post-PST™ treatment, with a concomitant decrease in pain. A greater than 50% improvement in all parameters was evident, 8 weeks post-PST™ treatment. By 12 weeks post-PST™ treatment, improvement was greater than 75%, with continued increase in the long-term.

Canine physiology essentially parallels that of humans, therefore, it is not surprising that the response and successful results obtained following PST™ treatment of canines with OA are comparable to, and confirm, those obtained for the treatment of humans with OA. When connective tissue is injured and physiological signaling is disturbed, PST™, as the external biological "electromagnetic stimulus" (field) acts in harmony with the body, to restore its own, natural biophysical-biochemical signaling network(s). Unlike the diverse "therapeutic" electromagnetic devices currently available on the market, PST™ constitutes a *unique* biological signal of specific energy parameters, characteristic of connective tissue. Biophysically, it acts as the external signal (stimulus), of physiological energy parameters and waveform, inducing an electromagnetic field in the targeted area (tissue), with concomitant passive induction of "fluid flow" and creation of "streaming potentials". Through subsequent coupling to biochemical processes, diverse intra- and intercellular signal transduction pathways are activated, genes upregulated and transcribed, thereby eliciting and restoring innate repair and regenerative mechanisms.

PST™ veterinary application for the treatment of OA, is not only limited to canines. In retrospect, horses have also benefited from PST™. Equine weight-bearing joints, most commonly affected include the hocks (ankles), fetlocks, pastern and coffin joints (referred to as ringbone in severe cases); with stifle (knee) joints and the spine (neck and back) less commonly affected. The PST VET™ device is either available as a stationary unit (for treatment in the practice) or as a mobile device, to allow treatment of canines at home and horses in a PST VET™ equipped stable.

PST™ documented success has received worldwide recognition through documented rigorously controlled clinical and *in vitro* studies in humans, its numerous publications in well-respected international journals, and its presentation at world congresses, including the 8th and 9th OARSI (OsteoArthritis Research Society International) World Congresses and the IOF (International

Osteoporosis Foundation) World Congress on Osteoporosis. In July 24-28, 2004, PST™ was welcomed as an alternative treatment option for canines with OA, at the AVMA (American Veterinary Medical Association) Convention in Philadelphia, USA. In fact, a journalist from the well known "AAHA (American Animal Hospital Association) NEWStat" attending the convention was highly intrigued, prompting her to publish an entire article in the August 11, 2004, volume 2, issue 16 edition.

With continued studies in both humans and animals, it is envisioned that PST™ fundamental role in both medicine and veterinary science, for the treatment of musculoskeletal conditions, will challenge and revolutionize modern therapeutic beliefs, and reintroduce electromagnetism into medical and veterinary science...

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PST VET®
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Figure 1: Canine Extremity Osteoarthritis Study Interim Evaluation

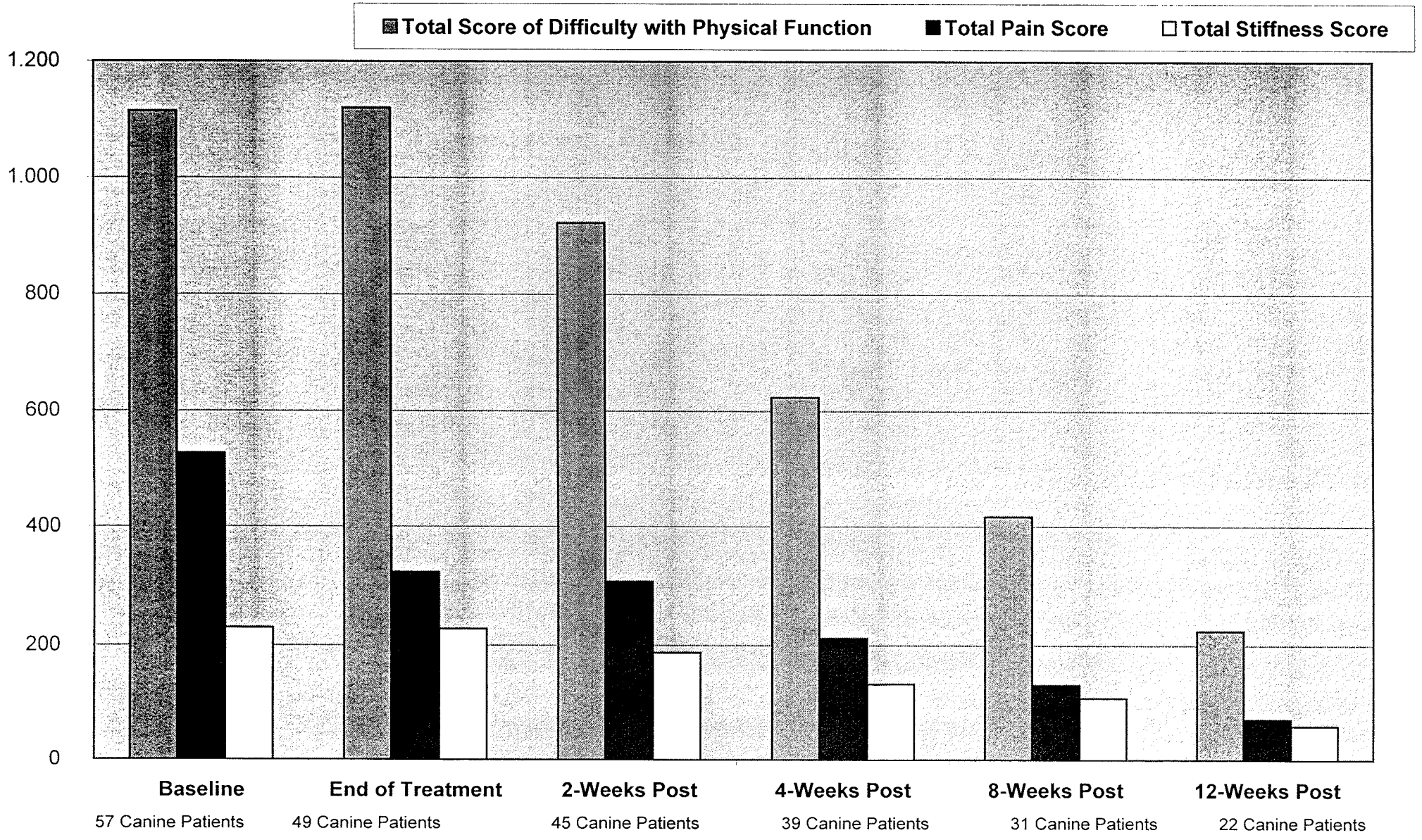

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Figure 2: Canine Extremity Osteoarthritis Study Interim Evaluation

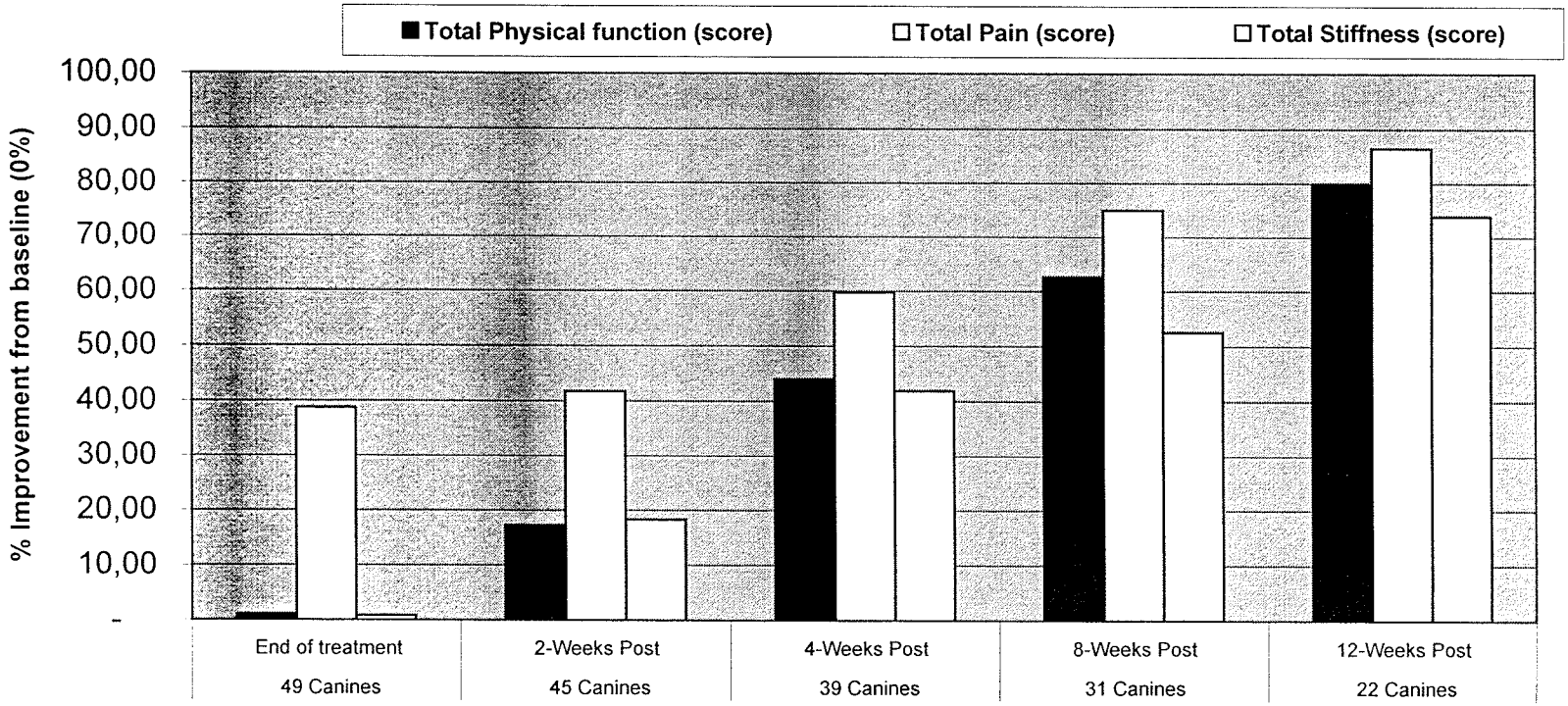

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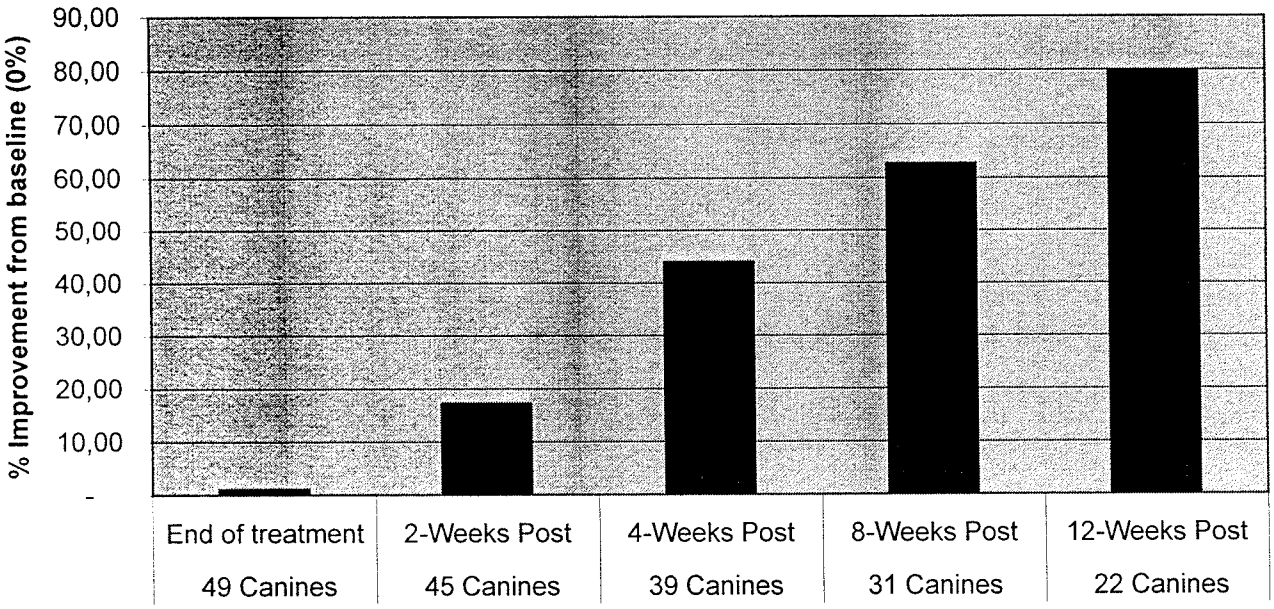
Figure 2a: Canine Extremity Osteoarthritis Study
Interim Evaluation
Total Physical Function Improvement



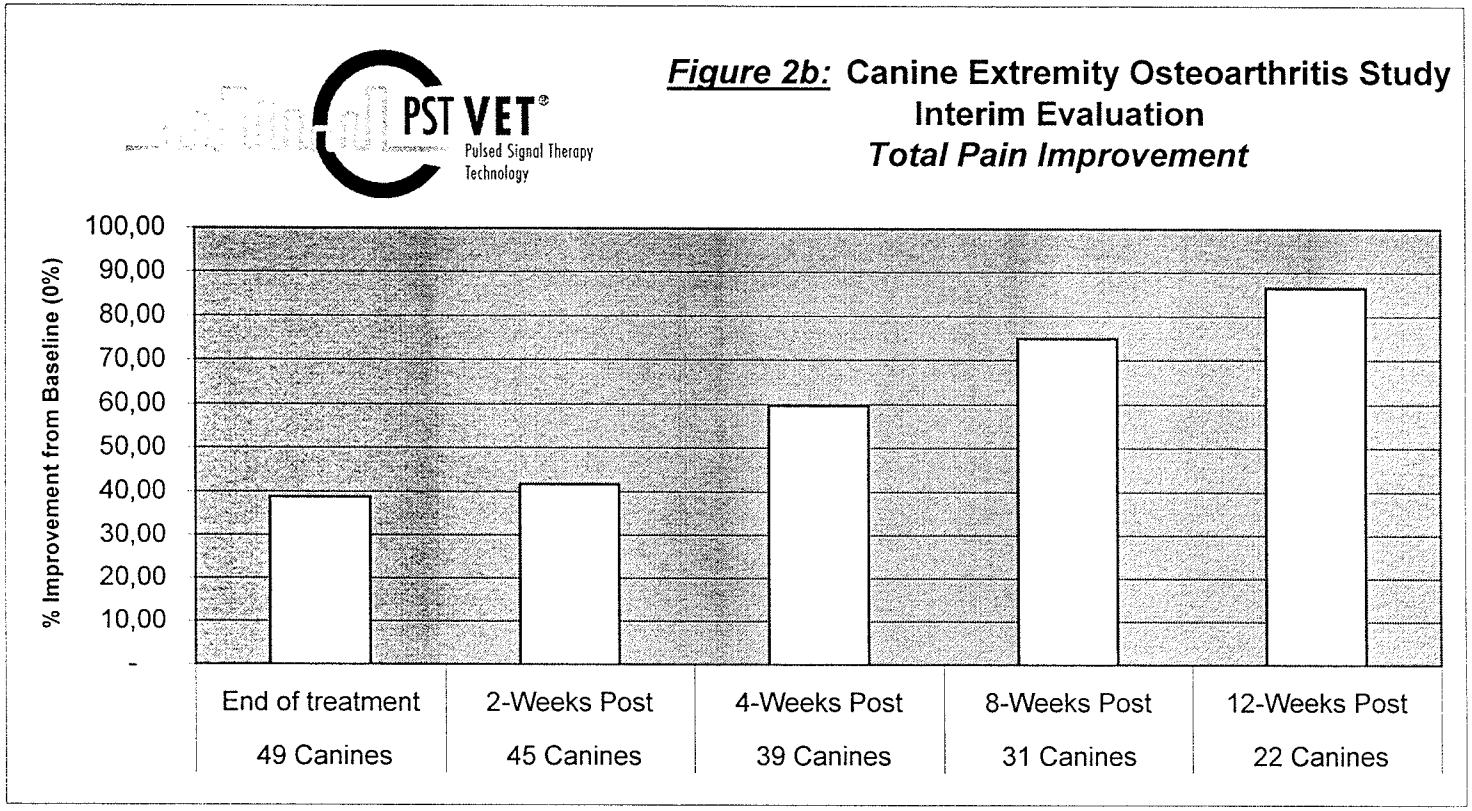

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Figure 2b: Canine Extremity Osteoarthritis Study
Interim Evaluation
Total Pain Improvement
% Improvement from Baseline (0%)
100,00
90,00
80,00
70,00
60,00
50,00
40,00
30,00
20,00
10,00
-
End of treatment
49 Canines
2-Weeks Post
45 Canines
4-Weeks Post
39 Canines
8-Weeks Post
31 Canines
12-Weeks Post
22 Canines

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***Figure 2c*: Canine Extremity Osteoarthritis Study**
Interim Evaluation
Total Stiffness Improvement