# Pulsed Shortwave Electromagnetic Field Therapy Increases Quality of Life in Canines with Symptoms of Osteoarthritis

Running Title: Increasing Quality of Life in Canines with OA

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## Abstract

Background: Joint stiffness, lameness, and reduced activity levels are commonly attributed to canine osteoarthritis (OA) and are generally treated with systemic anti-inflammatories.

Objectives: Investigate the efficacy of a FDA-cleared pulsed-shortwave-therapy (PSWT) device to modulate vagus nerve activity and initiate a systemic anti-inflammatory response to improve functionality of canines diagnosed with OA.

Methods: A randomized, blinded, placebo-controlled 14-day study of 60 dogs having prior veterinary-diagnosis OA in at least one limb joint. Two outcomes measuring the dog's quality of life were assessed: subjectively determined changes in eight behaviors associated with discomfort, and objectively determined changes in passive range of motion (PROM). The device was secured near the cervical region of the dog's spine. PROM measures were taken at baseline and end of study. Behavioral measures were taken daily.

Results: Forty-nine animals completed the study. No negative side effects were reported. Average subjective discomfort scores for the treatment group (N=26) were reduced from 4.26 to 2.31 (45%) compared to no improvement in the placebo group (N=23) over the study period. Average PROM scores increased by 5.51 (4.59--6.23) degrees relative to the placebo group. Ninety-six percent of the treatment group showed either increased PROM or improved behavioral changes or both compared to 4% for the placebo group. Most changes occurred within the first 8 days of treatment.

Conclusions: PSWT applied at the cervical spine level, in order to expose the vagus nerve, may have the potential to significantly improve quality of life for dogs and other small domestic animals with OA.

## 1. Introduction

Lameness, joint stiffness, and declines in physical activity levels are commonly observed in older canines, resulting in significantly decreased quality of life for the animal. These symptoms are often attributed to osteoarthritis (OA), a painful, non-curable, progressive disease of the joints. The most prevalent interventions for canine OA are pharmacologic, often in the form of non-specific, systemic, non-steroidal anti-inflammatory drugs (NSAIDs). While well established, a pharmacologic treatment regimen often needs veterinary prescription, can be expensive, and can have both short and long-term side effects (1).

Although NSAID appear to be effective in improving quality of life for animals with symptoms of OA, alternative approaches which have similar systemic anti-inflammatory effects may be equally effective. One such approach is biophysical intervention, specifically tissue exposure to electromagnetic fields. Biophysical therapies date back as long as modern pharmacologic therapies, though they tend not to be as well accepted (2). More recently, electric stimulation of the vagus nerve has been receiving substantial interest as a therapeutic intervention as it has been shown to produce anti-inflammatory effects in a number of animal models (3, 4).

While vagus nerve stimulation commonly relies upon the introduction of low frequency (10-1000 Hz) electrical currents into the tissue through either surface or implanted electrodes (5), these approaches introduce a number of potential complications. Alternatively, non-invasive electromagnetic stimulation has also been shown to be capable of modulating nerve activity. This approach utilizes much higher frequency stimuli (megaHertz) at very low magnetic field intensities (microTesla). Devices using this approach are referred to as pulsed shortwave therapy (PSWT) devices. This therapeutic approach appears to rely on quantum magneto-biology effects (6). A number of studies have shown that PSWT devices can provide relief for acute postoperative (7, 8) as well as chronic pain (9-15) in humans and has received clearance for both conditions from the Food and Drug Administration (FDA). Two recently completed human clinical studies specifically looked at osteoarthritis and showed PSWT improved physical functionality, reduced pain, and reduced the need for pharmacotherapy (9, 15). In addition, one prospective six-month study showed these effects were long lasting for subjects who reported initial pain reduction within the first 7 days of use and continued to use the device in a “as needed basis” (16). We propose that these positive results and the lack of adverse effects makes PSWT attractive as a modality for vagus nerve stimulation in order to produce a systemic anti-inflammatory response.

The goal of this randomized, placebo controlled, double-blind study was to investigate the effectiveness of one specific, commercially available, PSWT device to improve the quality of life in canines demonstrating behavioral symptoms consistent with OA.

## 2. Methods and Materials

### 2.1 Study Design

The experimental protocol was designed according to the guidelines of the current European and UK laws on the protection of animals used for scientific purposes (Directive 2010/63/EU,) and was approved by the Research Ethical Committee of Plumpton College. Prior

to enrolment, each owner was briefed about the aims of the study. This briefing included answering questions to assess suitability for enrolment and ensuring that safety measures were explicitly communicated to the owner. Owners and the supervising veterinarian were then asked to sign a consent form. In addition, owners completed both a pre-assessment and post assessment form detailing information about the dog's demographics, medication use prior to the trial and any changes in medication during the trial, as well as any planned hydrotherapy and/or unusual activities during the trial.

The selected treatment duration was 14 days, consistent with previous studies on humans which found that those who reported relief indicated it occurred within 7 days. Treatment duration of 24 hours per day for each dog was selected. Following the recommendations of the 2017 Pain in Animal Workshop (17), both subjective behavioral and objective outcome measures were obtained. The start of the trial for dogs on bedinvetmab were timed two weeks after injection so the end of the trial preceded the next injection.

### 2.2 Animal recruitment

Dogs were recruited from established hydrotherapy, veterinary physiotherapy, and veterinarian facilities as well as local dog walking groups via posters deployed at various dog walking parks across the UK.

The inclusion criterion was the owner's primary veterinarian asserting that in his/her professional opinion the [subject] dog has "arthritis in one or more joints", although diagnosis did not typically include imaging evaluation. Exclusion criteria included pregnancy, cancer, infections and the dog's medication use being altered during the trial.

### 2.3 Treatment Device

The PSWT device used in this study was Biolectronics' model 088 (Bioelectronics Corporation, Frederick, MD, USA), an over-the-counter (OTC) product cleared by the United States FDA for human use (Figure 1). This device uses a loop antenna (magnetic dipole) covering about 110 $cm^2$ in area. The device produces a pulsed, radio frequency magnetic field at 27.1 MegaHertz, with a pulse width of 100 microseconds and a pulse repetition frequency of 1 KiloHertz. This device produces a peak incident spatial power density of 73 microwatts/$cm^2$ which translates into a specific absorption rate (SAR) of approximately 0.35 microwatts/$cm^3$. This SAR is roughly three orders of magnitude lower than the FDA approved exposure levels for cell phones, but the peak flux density of about 2.25 microTesla is more than two orders of magnitude above levels shown to influence quantum biological phenomenon. Thus, although the magnetic flux density levels are too low to be felt, these flux density levels are adequate to produce magneto-biological effects that probably arise through quantum mechanical processes (18). Additionally, the low intensity exposure suggests that any effects of the device will be slow to develop which is in line with the manufacturer's suggestion that the device be utilized at least 12 hours/day with the expected time until the subject experiences results being up to 4 days or more.

BioElectronics Corporation, upon request from the lead researcher, supplied 60 medical devices, 30 of which were placebo and 30 were active. The placebo devices were identical to the

active units in appearance. However, when the device was turned on, no current flowed through the antenna of the placebo device and thus there was no magnetic field generated. However, since the active device is sensation-free, it was not possible for the user (owner) to determine if the device was active or non-active. The codes to the device identity were released to the lead researcher after the conclusion of the study and recording of the data, blinding the lead researcher and owners to treatment assignment.

**2.4 Placement of the Device**

The most accessible site for vagus nerve stimulation is the neck region where the vagus nerve descends posterior to the carotid sheath. Unlike stimulation using electric fields, which can be blocked by bone and fatty tissue, magnetic fields readily pass through all biological tissues. The depth of penetration of a 27MHz electromagnetic field in biological tissues is approximately 0.3 meters. Correspondingly, in order to ensure exposure of the vagus nerve and to limit the ability of the dogs to damage the device, we positioned the PSWT device over the cervical region of the spine by tapping the device to the dog's collar and positioned it on the back of the dog's neck (Figure 2).

**2.4 Subjective Behavioral Assessment**

The primary outcome measure was a subjective behavioral assessment associated with levels of the dog's quality of life (QOL). We refer to this QOL assessment as "discomfort associated behavior" (DAB) and derive it from the BEAP measurement scale developed by Dr. Shea Cox and found at https://pethospice.bluepearlvet.com/wp-content/uploads/2021/09/BEAP-Pain-Scale-Dog-Handout.pdf). Designed for use in the home or hospice settings, it is primarily a quality of life assessment tool. This assessment utilizes a set of eight behavioral indicators thought to be associated with discomfort; specifically, these involve Breathing, Eyes, Ambulation, Activity, Appetite, Attitude, Posture, and Palpation. Although not validated as a pain assessment tool, this measurement tool taps into many of the same behaviors found in the Helsinki Chronic Pain Index, Liverpool Osteoarthritis in Dogs measure, and the functionality part of the Canine Brief Pain Inventory (CBPI) instrument. It is easily understood, uses pictures, and relies extensively on easily observable animal behaviors, thereby allowing owners to reliably assess their animal's quality of life. These behaviors include such activities as walking, playing, getting up from a sitting position, postures, and interacting with others. The BEAP instrument results in a dog being classified into one of six levels of discomfort, anchored by the terms no discomfort/pain and worse possible discomfort/pain. These six levels are assigned with scores that range from 0 to 10, values that correspond to the often used 0 to 10 Virtual Analog Scale (VAS) found in human and many canine pain studies. We followed the recommended scoring convention to form our DAB measure, where 0 is assigned to the lowest level and reflects behaviors associated with no discomfort/pain and the remaining scores are incremented by two for each higher level, so the sixth level reflects behaviors associated with highest level of discomfort and is scored a 10.

This subjective QOL assessment was completed by the dog's owner just prior to the start of the trial period and used a baseline measure. Specifically, the lead researcher went through the form in detail with the owner, the intent being to insure consistency across the different owners.

Then she asked the owners how they would grade their dog right at this moment in time highlighting things they should be looking for. Subsequently, the owners filled out daily BEAP assessment sheets. At the conclusion of the trial the lead researcher collected these daily evaluations and tabulated the individual measures to form our DAB measure. In a few instances the owner checked some behaviors in one category and the remaining behaviors in another category. In these instances, the score assigned was the average of two categories.

Change in DAB level was calculated relative to the dog's baseline. Successful intervention was defined as a decrease of at least 2 units on the DAB scale. This success measure is analogous to the definition of success of a two-point reduction in the pain-related measure studying the effectiveness of bedinvetmab found in (21). Success determination was done for day 7 and day 14.

**2.5 Objective Behavioral Assessment**

Joint stiffness is associated with reduced QOL. In order to capture this aspect of dog's quality of life we measured the passive range of motion (PROM) in any affected joint in the animal. Our expectation for this objective measure was that increased PROM would indicate increased functionality and thus increased QOL. PROM angles were measured in degrees using a digital *EasyAngle* Goniometer, following the manufacturer's guidelines (Gait and Motion Technology Ltd, Bury St. Edmunds, UK, 2021). This device has been shown to yield reliable measurements with an Inter-rater Correlation Coefficient (ICC) between assessors of .994 and a Standard Error of Mean (SEM) of differences within an individual over a short time period of between 1.15 and 1.48 degrees (19).

Measurements were obtained either in lateral recumbence or in a standing position where both the initial and the 14-day follow-up appointment used the same procedure and were taken by the lead researcher. Only restricted joint movement (along with the contralateral side of that limb, whether restricted or not) was measured. Carpus, elbow and tarsus were measured in flexion, while shoulder, stifle and hip were measured in extension.

Change in PROM over the trial period were measured at the joint level by first averaging the two readings for a given joint for a given point in time and then subtracting these two joint averages, i.e., one for baseline and the other for the final measure. For extension, the baseline was subtracted from the final reading, while for flexion, the final reading was subtracted from the baseline so that a positive value always implies improvement. These differences were also averaged over all of the measured joints to obtain a measure of average change (in degrees) for the dog. Successful intervention was defined as an increase in the PROM measure greater than three SEM's of the measurement instrument as determined in (19), i.e., 4.5 degrees or more.

**2.6 Statistical Analysis Plan**

A statistical power calculation was performed using the G* Power program (20) assuming an effective effect size of .25 (based on human trials) and repeated measures. The needed sample size was determined to be 36. We therefore planned on a sample size of 60 to allow for a 30% drop-out rate. The programming language Python was used to obtain Wilcoxon

ranked sum tests to non-parametrically test for differences, if any, between the two group's distributions of starting conditions, e.g., demographics, the DAB and PROM scores, both at the joint level and the aggregate level.

Excel was used to obtain the measures of daily percent change in baseline DAB score and the percent of subjects successfully showing a decrease of at least one category (two DAB points) from baseline within 7 and 14 days. Similarly, a change in the 14-day PROM measures from the initial PROM measures was calculated, both with respect to a specific joint and also the patient's average improvement in degrees over the focal joints. Changes over time, in distribution, but within a group, for a given measure were analyzed using Wilcoxon signed rank tests and determined using Python.

In addition, the overall effect of the device on the difference in the response time paths of DAB for each group was investigated by a regression model using a SAS PROC MIXED (SAS Institute, Inc. Cary, NC, USA), which uses iterative optimization methods that maximize the likelihood function. Individual time dummies were interacted with treatment and the effect was measured via these interaction terms. Subjects were included in the time path model as a random effect to allow consideration of both within and between group variances. The effects of intervention on the aggregate PROM measure was also investigated using a regression model and the SAS PROC MIXED procedure. Significance levels for all tests were set to be a two-tailed test at 0.05. When presenting estimates we also provide the standard deviation in parenthesis.

## 3. Results

Sixty client-owned dogs, ranging in age between one and 18 years (average 9.9±3.2) were enrolled into the study from five locations around the UK. This intent-to-treat sample size of 60 was evenly divided between treatment and placebo. During the 14-day period, 11 dogs chewed and destroyed the PSWT device, seven in the placebo group and four in the treatment group, leaving a per-protocol sample size of 49, 26 in the treatment group (15M; 11F) and 23 (15M; 8F) in the placebo group, well above the previously derived needed group size of 18. All but seven of the animals had been neutered. Twenty-five dogs in this sample were on OA related medications at the start of the study, twelve of which were in the treatment group and an additional five where using just hydrotherapy, three of which were in the treatment group. None were disqualified due to changes in medication or special activities. Consequently, all analyses that look at changes over time control for any medication effect.

The 49 dogs completing the study represented 35 breeds including purebred and crosses and came from five different parts of the UK. Each dog was either visited at their home address or a familiar clinic (hydrotherapy center or physiotherapy clinic). The nine-point body condition score (BCS) was scored by the lead researcher and the average over the sample was 3.21 (median 3) ranging from 2.5 to 4.75. Thirty-nine dogs had two joint locations with apparent OA (and thus 4 readings per time period, since measures were taken for both sides), five had only one joint location with apparent OA, while five had 3 or 4 joints which were assessed for PROM.

Table 1 shows the group assignment in terms of means, medians and S.D.s in age, BCS and gender, the initial average DAB score, the percent using medications, and average measured degrees of motion by joint along with the standard deviations. The last column provides the average PROM by joint for a dog without any restrictive range of motion, as reported in (23), and thus can be used to assess the possible improvement in degrees of range of motion. Over the five joints considered, the average possible improvement was approximately 50 degrees for both groups.

Individual Wilcoxon tests on differences in group distributions across all the measures shown in Table 1 yielded null results, i.e., there were no significant initial group distribution differences in age, BCS, gender, DAB scores, medication use or the five individual joint PROM measures.

Initial DAB levels ranged from 2 to 8 for both the active and placebo groups. The initial DAB level for the active group was 4.23 with a median of 4 and a standard deviation of 2.48. The respective figures for the placebo group were 4.26, 4 and 2.38. Compatible with the veterinary's diagnosis, approximately one half of each group was using OA related medications. These DAB numbers imply the median (and average) dog in each group was panting intermittently, having eyes slightly more dull in appearance and/or slightly furrowed brow, be noticeably slower to lie down or rise up, possibly exhibiting lameness when walking, possibly being slightly unsettled and more restless, have difficulty getting comfortable, be a finicky eater, subdued, less engaged in play, have difficulty squatting or lifting leg to urinate, have subtle changes in posture, tail more tucked and ears more flat, and minding being touched on specific areas of the body.

Daily average DAB scores are shown in Figure 3. The scores for the placebo group remained essentially constant at 4.2 (only one placebo dog was recorded as having any change in DAB levels over the course of the study, although variation in behavior was observed for a few dogs across the 14 days). In contrast the average DAB scores for the treatment group decreased over time from 4.26 to 2.31, representing an average reduction of 45% from initial levels. The Generalize Linear Model (GLM) regression results show that the time*treatment effect was highly significant ($p<.001$) and the individual contrasts between the treatment and placebo were significant after day 8. This difference in the time path of DAB levels was also found when comparing the percent of subjects who showed at least two DAB points calculated at day 7 and 14. For the treatment group the figures were 27% and 65% respectively, compared to 9% and 4% respectively for the placebo group. Both differences are significant at the .05 level.

Table 2 provides more detail on the reduction DAB scores over the 14 days for the treatment dogs by displaying the amount of reduction conditional on the dog's initial DAB level. For example, there were five treated dogs that initially were scored to have behaviors associated with moderate discomfort. Of that group, three were reported as having behaviors associated with no discomfort by the end of the trial, one was reported to have mild discomfort and one was reported to experience no change in discomfort level. In total, seventeen treatment dogs (65%) showed a decrease in DAB and thus an increase in quality of life. Eleven (42%) of the treatment dogs were reported to have experienced a two-point decrease, and 6 (23%) were reported to have four or more point improvements. In comparison, no only one placebo dog (4%) was found to have reduced behaviors associated with discomfort levels over the trial. In addition, forty-two percent

of the treatment dogs by the end of the study were reported showing behaviors associated with no discomfort compared to zero percent for the placebo dogs.

The objective PROM assessments were evaluated by individual Wilcoxon tests on the before and after distributions for all 5 of the OA joints. The treatment group was found to significantly increase over the trial period for all joints except the tarsal where the sample size was only three. One significant increase in PROM over time was observed in the placebo group, this being for shoulder extension. Tests comparing the distribution of average changes in PROM for the focal joints between the two groups was highly significant ($p < .001$) with the treatment group averaging a 5.66 (1.80) degree increase compared to .050 (1.56) degree increase for the placebo group. The GLM regression results, where the dependent value was the average PROM improvement in degrees, yielded the treatment effect significant at the .001 level. The coefficient for the treatment variable was 5.51(.46), indicating that the treatment group experienced an increase of 5.51 degrees relative to the placebo group. GLM regressions that also included demographics yielded similar results.

We conducted two post-hoc analyses. The first was to compare the improvements for the front and hind limb joints separately. The average improvement for the front joints was 6.84 (3.40) degrees for the treatment group and .02 (1.77) degrees for the placebo group. The figures for the hind limb joints were 3.56 (2.65) and .22 (1.37) respectively. The second analysis recognized that our subjective and objective assessments may be tapping different aspects of QOL. Thus, we calculated the percent of subjects who experienced success in either PROM or DAB after 14 days. For the treatment group this percentage was 96% compared to 4% for the placebo group.

## 4. Discussion

The study findings are encouraging in that we observe a robust effect of PSWT intervention on animal behavior, as well as a significant increase in range of motion in the affected limbs, for canines diagnosed with OA, when the PSWT therapy was applied at the cervical spine region of the treated dogs. This is particularly impressive since 58% were concurrently receiving OA related medication and/or hydrotherapy. Nonetheless, the results raise a number of interesting questions.

The highly significant improvement in quality of life behaviors and the increase in flexibility as measured by PROM compare favorably to those found in the recent clinical trial for Bedinvetmab, an anti-inflammatory medication intended to treat canine OA. In that trial 45% of the treatment group reported having at least a 2 scale-point reduction on the used 11-point pain scale within 14 days (21). The current study shows a two-point reduction in our 11-point DAB scale for 65% for the treatment group over the same period of time. Also encouraging was the finding that 96% of the treatment group experienced success in reducing DAB scores or improvement in PROM or both and all of this occurred within 14 days.

In contrast to these results, a recent human study of cervical spine pain utilizing the same therapeutic technology (15), showed relatively small effect sizes (0.6-0.8; using Cohen's d test) where self-reported pain was the measured outcome. In the current study, we observe a Cohen's d effect size of 1.64 (utilizing the average standard deviation of change in DAB scores for two groups). This difference may be due to the fact that the human clinical study involved the use of

prescription strength level NSAIDs in the control group, whereas in the current study the placebo group received no additional intervention. Alternatively, these results may indicate that pain and QOL behaviors are, physiologically, only weakly associated.

We also observed a remarkably robust effect of PSWT therapy on range of motion measures for both the front and hind limb joints. These results, therefore, are consistent with the effect of stimulation being systemic, rather than localized, and similar to that observed with pharmacologic interventions. These responses are also consistent with reports going back more than 20 years that vagus nerve stimulation attenuates inflammatory responses (24), although the pathway by which vagus nerve stimulation influences inflammation remains unknown.

Prior studies of this PSWT device on humans found that the vast majority of users reported relief within 4 to 5 days. We found in the GLM analysis that it took about 8 days for the results to show statistically significant differences between the two canine groups. The slower response observed may be due to the placement of the device and therefore the nerves being modulated. In this study, we were targeting the vagus nerve to achieve a systemic response, whereas in prior human studies the focus was on obtaining a localized response by modulating nerve activity near an injury site. Other explanations are that the behavioral changes occur more slowly than changes in pain perception, the owner not being able to quickly determine behavioral changes or our measure is less sensitive to changes than the VAS pain scale.

An interesting observation was the lack of any placebo response, both in terms of improvement in PROM and DAB reduction. While one might not expect the dogs to be aware they were being treated, the owners were well aware that their pets might have been given an active device and this knowledge might be expected to influence their BEAP assessments. Therefore, we expected a significant placebo effect in our study, but none was observed. It remains unclear why the DAB data do not exhibit some placebo effect.

Closely related to the question of lack of placebo response was the lack of variability in the placebo data. In subjective assessment studies it is not uncommon to see both random recovery or worsening of the condition over the course of an experiment. One explanation might be the coarseness of our BEAP measurement instrument. Dog owners were asked to score their dogs daily on eight behavioral measures that could vary from hour to hour depending on the dog's activities. Owners, very possibly just integrated over the day to come up with average assessments which are less likely to change. In this way our measure is similar to the average severity of pain measure used in the CBPI index. If true, this explanation also implies the observed reduction in DAB for the treatment group wasn't just a momentary improvement, but instead an enduring change.

The drop-out rate was somewhat lower than anticipated, which was encouraging. The fact that 18% of the units "failed" due to the dog removing and/or destroying the device, should be an easy issue to address for future trials. One could envision a small pouch into which the device could be placed and then attached to the collar, better protecting it from the dog removing it.

A final interesting observation is the lack of association between our subjective measure of discomfort and objective range of motion measures. Similar findings were reported in (22)

where the changes in the objective gait force measures and the subjective pain interference score were found to be not significantly correlated. One possible explanation has the increased flexibility leading the dogs to be more active thereby increasing the noxious stimulation and thus negating any discomfort reduction. Another is that our two measures were tapping different aspects of the dog's behavior. In any case the vast majority of the treated dogs showed improvement in one or both measures by the end of the trial.

A limitation of this study is the short length of the trial. However, a six-month prospective study in humans found that users who reported getting relief within the first 7 day, reported sustained relief with continued use of the device on a "as needed basis", over the remainder of the six-month trial (16). Thus, there is some supporting evidence that continued use of the device should keep or even increase both types of observed behavioral improvements. This possibility could be readily tested as the device utilized in this study has a 30-day life with 24 hour/day use.

With these caveats and questions noted, we believe that this initial (admittedly small and short duration) study promotes the intriguing possibility that PSWT applied at the cervical spine level to modulate vagus nerve activity may have the potential to significantly improve the quality of life in dogs and possibly for other small domestic animals with symptoms of OA.

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Table 1. Average baseline group means, medians and standard deviations (in parentheses) along with typical normal PROM in degrees. No significant differences were found between the distributions of any of the two groups' measures.

| | Placebo | Treatment | Normal PROM (23) |
|---|---|---|---|
| Sample size | 23 | 26 | |
| Age in years | 8.91, 9, (3.23) | 10.7,10.5, (3.40) | |
| BCS | 3.12, 3, (.58) | 3.29, 3, (.75) | |
| Percent Male | 62% | 65% | |
| Percent Female | 38% | 35% | |
| Average DAB score | 4.26, 4, (2.38) | 4.23, 4, (2.49) | |
| Medication and/or Hydrotherapy | 65% | 58% | |
| PROM Carpus (flexion) in degrees | 82.6, 79.5 (29.5) | 87.6, 101.5 (40.9) | 29 |
| PROM Elbow (flexion) in degrees | 49.1, 50.5, (14.4) | 53.7, 61, (16.3) | 30 |
| PROM Shoulder (extension) in degrees | 101.4, 85 (31.5) | 110.7, 118.5 (27.2) | 163 |
| PROM Tarsus (flexion) in degrees | 72.1, 73 (10.3) | 81.5, 81.5 (13.8) | 34 |
| PROM Hip (extension) in degrees | 85.9, 69.75 (29.3) | 91.8, 96.5 (28.3) | 158 |

Table 2 Discomfort category at the end of the trial, conditional on baseline discomfort category for the 26 dogs in the treatment group. For example, 12 treatment dogs initially were scored as having mild comfort. By the end of the study seven (7) of these 12 dogs were scored as having no discomfort. Dogs along the diagonal (shown in red) were reported to show no discomfort reduction. All others were reported to reduce DAB at least by one level.

| | | | | | | |
|---|---|---|---|---|---|---|
| **End of study** / **Start of Study** | No | Mild | Moderate | Moderate to Severe | Severe | Row Totals |
| No Discomfort | | | | | | |
| Mild Discomfort | 7 | 5 | | | | 12 |
| Moderate Discomfort | 3 | 1 | 1 | | | 5 |
| Moderate. To Severe Discomfort | 0 | 1 | 2 | 0 | | 3 |
| Severe Discomfort | 1 | | 1 | 1 | 3 | 6 |
| Total end of trial | 11 | 7 | 4 | 1 | 3 | 26 |

1. Figure 1. Medical device showing the location of the battery and the field of therapeutic area within the antenna.

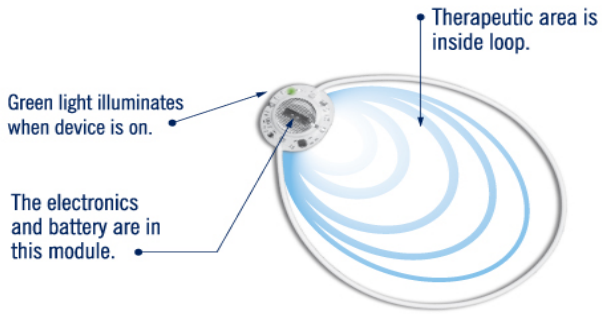


Figure 2 – Typical attachment of PSWT device to the dog's collar in order to expose the cervical region of the spine to the magnetic field therapy. The device was turned on and worn continuously for 14 days.

Figure 3. Average DAB scores over time for placebo (blue) and treatment (black) along with lines for one standard deviation