World Journal of Preventive Medicine, 2015, Vol. 3, No. 3, 61-72
Available online at http://pubs.sciepub.com/jpm/3/3/3

DOI:10.12691/jpm-3-3-3

Continuous Low Level Heat Wraps; Faster Healing and Pain Relief during Rehabilitation for Back, Knee and Neck Injuries

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Received June 18, 2015; Revised July 18, 2015; Accepted July 20, 2015

Abstract Back, knee and neck pain are the 3 most common disabilities found in outpatient physical therapy. In-clinic therapy is accomplished 2-3 times per week, which is far less than optimal in providing pain relief and healing. Home therapy and self-range of motion is limited by pain. Continuous low level heat wraps are sold over the counter and used to reduce pain. In this study, they were used to reduce pain before home exercise programs to see if this would increase compliance and healing during a 2 week therapy intervention. Two hundred and forty eight subjects participated. There were 3 control groups and 3 investigational groups. Two groups had diagnosed back pain, 2 with knee pain and 2 with neck pain. Subjects were followed for 2 weeks with 2 therapy sessions per week. Progress was measured by analog visual pain scales, range of motion, strength measurements and mobility questionnaires. The groups receiving 6 hours of continuous low level heat wraps per day had less pain each day, participated in significantly more home exercise and increased significantly more range of motion and strength than the control groups. Conclusion- Continuous heat wraps are an important adjunct to rehabilitation outpatient therapy, reducing pain and increasing recovery.

Keywords: *heat, pain, outpatient rehabilitation, physical therapy*

Cite This Article: Jerrold Petrofsky, Michael Laymon, Faris Alshammari, Iman Akef Khowailed, and Haneul Lee, "Continuous Low Level Heat Wraps; Faster Healing and Pain Relief during Rehabilitation for Back, Knee and Neck Injuries." *World Journal of Preventive Medicine*, vol. 3, no. 3 (2015): 61-72. doi: 10.12691/jpm-3-3-3.

1. Introduction

Heat has been used for pain management and healing for over 2000 years [1,2]. It has been well established that heat provided by clinical modalities such as hydrocollator heat packs reduce pain [3]. This is mediated by inhibiting purine receptors in the peripheral pain nociceptor pathways through voltage gaited calcium channels sensitive to temperature [4,5]. These channels, the TRPV1 and TPRV4 receptors on sensory neurons, are sensitive to hot and warm temperatures respectively [4,6,7,8]. An often overlooked value of heat in increased healing of damaged tissue.

When heat is applied to wounds, even wounds in people with diabetes that showed no healing for 2 years, there was rapid healing [9,10,11,12]. Part of this was attributed to an increase in blood flow due to heat but blood flow remained elevated for over 24 hours after a 30 minute heat session showing a carryover that kept the tissue warm. The same was seen for pain relief if a continuous low level heat wrap was applied. Here 8 hours of continuous heat resulted in 16 hours of pain relief [13,14].

A problem with heat is the depth of penetration. Hydrocollator heat wraps are usually left on for 15 minutes. While this warms the skin, deep heat penetration is poor [15]. Further, the use of warm temperature modalities such as whirlpool and other forms of clinical thermal therapy have caused infections of the skin [16] and burns in susceptible populations [16]. For wounds, heat penetration is not an issue since the wound is superficial. But for deep tissues such as the shoulder, knee or back, due to the influence of subcutaneous fat, heat penetration is very poor to none at all in 15 minutes of heat exposure [15]. A key to increased healing is temperature penetration both to increase tissue blood flow and increase metabolism. Generally, for every 3 degrees increase in tissue temperature, metabolism doubles, promoting faster repair of tissue [17]. Without good tissue penetration, there is pain relief but little effect on healing. For this reason, a recent Cochran review and other reviews of low back pain, state that while there was some evidence that heat would help alleviate back pain, there was no solid evidence that healing occurred with low back pain with heat modalities [14,18,19,20].

Recently, a number of studies have examined the effect of continuous low level heat wraps on back pain [13,21], wrist pain [22] and delayed onset muscle soreness

[23,24,25,26]. It has been shown that when continuous heat wraps are applied to the lower back for 8 hours a day there is rapid pain relief and good heat penetration. It would make sense, then, to use continuous heat wraps between therapy sessions. This should reduce pain so that home exercise compliance is better and increase healing. Studies show that with continuous heat, there is increased elasticity of tissues [27-32] which should reduce further injury.

In the present investigation, we used continuous low level heat wraps as an adjunct to physical therapy for back, knee and neck pain (the most common reported injuries that are treated [18]) to see if the use of continuous low level heat wraps(ThermaCare) would reduce pain and increase recovery over 2 weeks of therapy.

2. Subjects

Two hundred and forty eight subjects participated. There were 3 control groups and 3 investigational groups. The demographics and numbers of each subjects in the back injury, neck injury and knee injury groups is shown in Table 1. All subjects were treated at an outpatient physical therapy center in Southern California. All subjects attended therapy twice a week for 2 weeks using the same protocols for either the back, neck or knee pain. Those with knee pain caused by fractures or full tears, those who have undergone knee surgery within the last year, or those with diagnosed diabetes were excluded from this study. Those taking oral analgesics including opioids and muscle relaxants were excluded. For the neck injury patients, those with neck pain caused by fractures or spinal damage, those who have undergone neck surgery within the last year, those with radiculopathy or those with diagnosed diabetes were excluded from this study. Neck pain was assessed by the classification of pain for ICF (International Classification of Functional Disability [33,34]). The average of the classification for pain with mobility impairments (1), neck pain with headaches (2), and neck pain with coordination impairments (3) was seen in about half of the population for each classification. ICF4, radiating pain, was not seen since it was an exclusion criteria. The average duration of neck pain was about 2 years. There was no statistical difference between the groups on any duration or classification ($p>0.05$). For the back injury group, people with low back pain caused by recent (in the last year) fractures or spinal damage, who have had low back surgery within the last year, or diabetes were excluded from this study. Subjects were excluded with any history of radiculopathy and neurological deficits (tested with low leg raises patellar reflexes or lack of bowel and bladder function). They could not have back pain for more than 3 months continuously. They could have no history of peripheral vascular disease, renal disease, or sensitivity to heat. Subjects were randomly assigned to either control of heat groups and all subjects were from Southern California.

All procedures were approved by the Solutions IRB and all subjects signed a statement of informed consent.

Table 1. The demographics of the subjects in each of the heat and control groups for the 3 different types of injury +/- the SD

Group	Age(years)	Height (cm)	Weight (Kg)	BMI	N
heat knee injury	54.1+/-11.0	169.5+/-11.9	90.4+/-30.7	30.7+/-8.3	23
control knee injury	54.5+/-14.1	171.7+/-9.7	97.5+/-20.1	33.1+/-6.3	21
heat neck injury	166.4+/-9.1	52.1+/-13.7	80.1+/-18.8	29.1+/-7.2	29
control neck injury	167.5+/-6.4	50.5+/-17.5	87.9+/-30.1	31.2+/-10.9	30
heat back injury	166.4+/-9.4	44.8+/-14.9	79.4+/-22.7	32.8+/-11.2	71
control back injury	171.5+/-9.4	48.8+/-13.4	82.82+/-18.7	27.5+/-6.1	74

3. Methods

3.1. Analog Visual Pain Scale

The visual analog pain scale that was used in this study was 10 cm long. Subjects placed a vertical mark across a 10 cm horizontal line such that the closer they marked near the 10 cm point, the greater was their pain. The first step in calculating the combined pain scale was to multiply the visual analog score by 10. Thus, the score would go from 0 to 100. One hundred on this scale was extremely painful whereas zero indicated no pain. This scale has been extensively validate for pain measures [35].

3.2. Application of Heat

Heat was applied with a continuous dry heat wrap (ThermaCare, Pfizer Consumer Healthcare, Richmond, VA). The wrap was applied as per manufacturer's instructions. A knee wrap was used for the knee, a neck wrap for the neck studies and a lower back wrap for the back. For the back large size wraps were used. The wraps were kept on for 6 hours or, if less, was self-reported by the subject.

3.3. Range of Motion

Range of motion was determined as shown by Kendall et al for the 3 different groups of subjects [36]. In all cases a digital goniometer was used to measure the joint angles(Baseline 12-1027 Absolute Axis 360 Degree Digital Goniometer, Dedham, Massachusetts). For the knee, the subjects were in the sitting position with the lower leg dependent. Trunk range of motion was determined with the patient in the standing position and asked to bend forward, backward, left side, right side, rotate left, rotate right as far as comfortable without pain, discomfort, or loss of balance. For the neck, range of motion was determined with the patient in the sitting position. They were asked to move their neck in flexion and extension, left and right rotation and left and right bending.

Questionnaires for disability –

There were different questionnaires used for self-assessment of the neck, back and knee as described below.

Roland-Morris back disability index

For the back group, the Quality of Life Outcomes was used to assess chronic pain in each subject involved a well-established index, the Roland Morris Disability Questionnaire (RMDQ) [37,38].

Oswestry back disability index

The Oswestry is a common disability index used in the interpretation of disability level due to back pain. It examines 10 categories of activities of daily living and looks for limitations due to pain. If participant's limitations fall in-between two questions, they were instructed to pick the higher point value for the question. The total number of points possible is 50. After they have finished the test, the points are added and divided by 50, and multiplied by 100 to get the percent disability [39,40,41].

Neck Disability Index

The NDI is a modification of the Oswestry Low Back Pain Disability Index. It is a patient-completed, condition-specific functional status questionnaire with 10 items including pain, personal care, lifting, reading, headaches, concentration, work, driving, sleeping and recreation. The NDI has sufficient support and usefulness to retain its current status as the most commonly used self-report measure for neck pain [42]. The minimal clinically important difference or change (MCID / MCIC) is described as the smallest difference or change that patients perceive as beneficial [43]. In patients with musculoskeletal related complaints MCID can be said to occur when the changes are over 5 points of change (10%).

Knee pain questionnaire-

A knee outcome survey was used before and at the end of the study. The survey evaluated the effect of knee pain on activities of daily living. If the score was 60, there was no impairment. A score of zero was maximum impairment[44]. The score was normalized to a 100% scale.

3.4. Home Exercise Log

Subjects kept a home exercise log. They scored, the total time they exercised each day. This was then scored as a percent of completed exercise by the investigators. For example, if they exercised for 30 minutes and were to exercise 60 minutes, they would score 50% for that day.

3.5. Measurement of Strength

Strength was assessed by the same physical therapist so that the measures would have better reliability. Measures of strength was on a 5 point scale with plus and minus for 2, 3, 4 and 5 [36]. However, for purpose of data entry, this scale was converted to a 12 point numeric scale so that statistics could be used to analyze differences. The new 12 point scale on the recorded data was as follows

0 = 0
1 = 1
2- = 2
2 = 3
2+ = 4
3- = 5
3 = 6
3+ = 7
4- = 8
4 = 9
4+ = 10
5- = 11
5 = 12

3.6. Clinic Therapy

Therapy: stretching, mobilization, hot packs, and postural exercises were used. The session length was 45min to 1 hour per treatment day and was the same for all subjects in each subgroup. Obviously the exercises were different depending on each muscle group. How packs were sued for 15 minutes with a hydrocollator.

3.7. Home Therapy

The home therapy program was 1 hour in duration and included 15 minutes stretching exercises and 45 minutes of strengthening exercises.

3.8. Procedures

Pain patients were randomly assigned to either a heat or control group. An initial evaluation and rehabilitation program was established which included a home exercise program. The heat group was given a commercially available, over the counter, heat pack (ThermaCare) which they would apply to their sore area six hours before they performed their home exercise each day they were not in therapy. The control group only participated in the clinic and home therapy. This was done since placebo heat is impossible to use since subjects would notice that the wraps were cold.

All groups were evaluated each week. They were given home exercise and heat compliance logs and analog visual pain scales to be filled out each night before exercise and, if they used heat, before and after heat were applied.

3.9. Statistical Analysis

Statistical analysis involved the calculation of means and standard deviation and t tests and ANOVA on Excel. The level of significance was $p<0.05$.

4. Results

4.1. Neck groups

The change in strength in the neck muscles is shown in Figure 1. For the heat group, the average increase in strength after 2 weeks of therapy was significant ($p<0.01$) and was about 1 unit on the 12 point strength scale. The control group had significantly less of an increase in strength for all 6 strength measurements compared to the home heat group ($p<0.01$).

The range of motion of the neck (Figure 2) increased in all 6 planes by about 13 degrees in the heat at home group (Figure 2). The increase in range of motion was significant from the beginning to the end of the 2 week test period ($p<0.01$). For the control group, the change over the 2 weeks was small averaging just a few degrees but was a significant gain ($p<0.05$) and was significantly less than that see for the heat group ($p<0.01$).

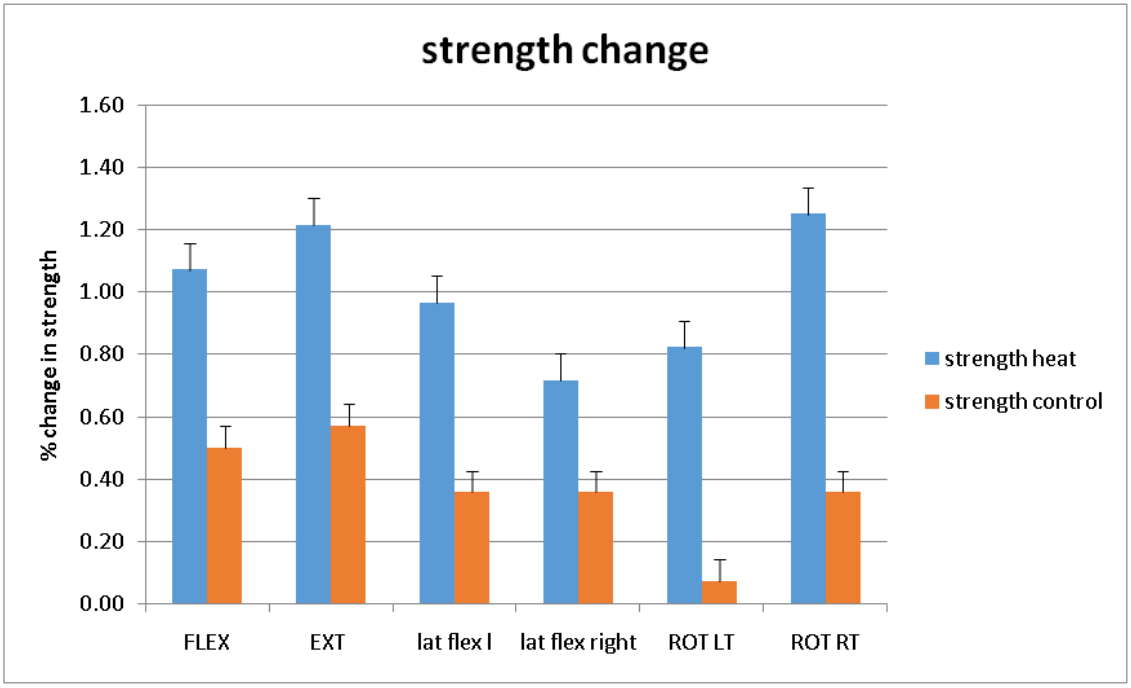

Figure 1. The strength difference in neck flexion, extension, lateral left and right rotation and left and right flexion

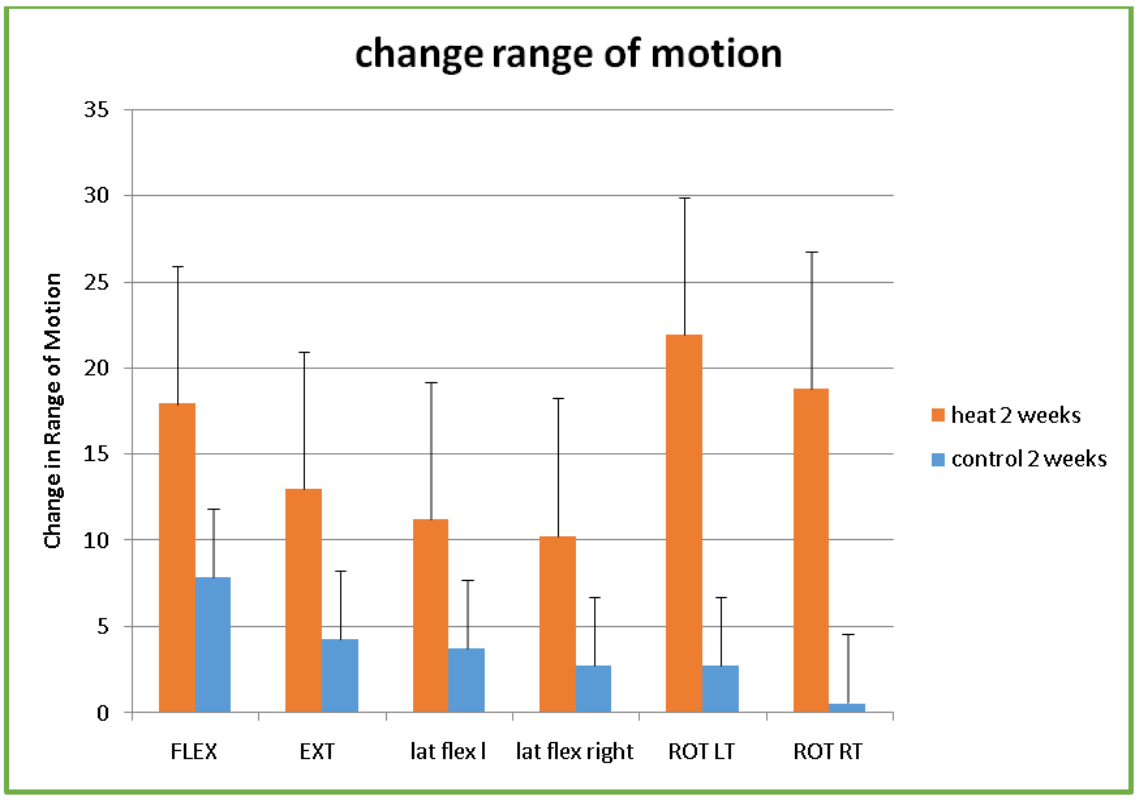

Figure 2. The change in range of motion in neck flexion, extension, lateral left and right rotation and left and right

The disability score in Figure 3 for the neck was reduced significantly more in the heat than in the control group ($p<0.05$). This would show better healing in the heat group in that functional activities were significantly better after the 2 weeks.

For the group using ThermaCare heat wraps, there was a significant reduction in pain after using the heat wraps each day as shown in Figure 4. This reduction in pain each day was significant ($p<0.01$ ANOVA). The reduction in pain in the heat group was 14.0+/-19.9 units. For the control group (Figure 5), pain was reduced with 2 weeks of therapy but the reduction in pain here was significantly less than that of the heat group ($p<0.05$). Thus using heat each day when therapy was not conducted, resulted in a reduction in pain that was additive each succeeding day.

Compliance

For the heat group, home exercise compliance averaged 74.18+'-6.83% while the control group averaged 52.1+/-6.1% of home exercise completed. This difference was significant ($p<0.01$).

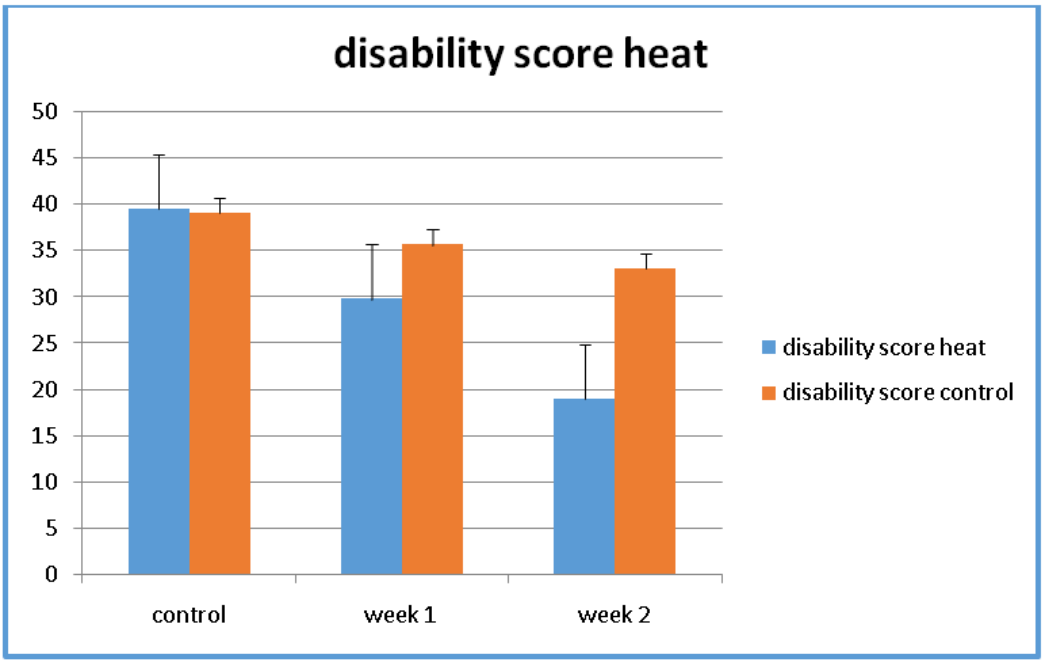

Figure 3. The disability score each week in the 2 groups of subjects

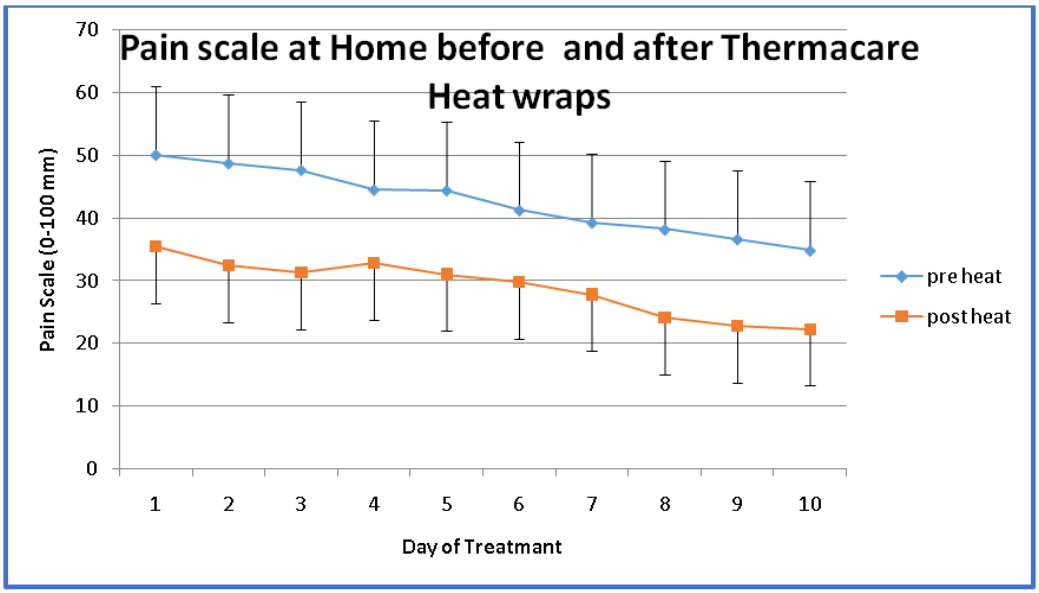

Figure 4. The analog visual pain scale before and after heat in the heat wrap group

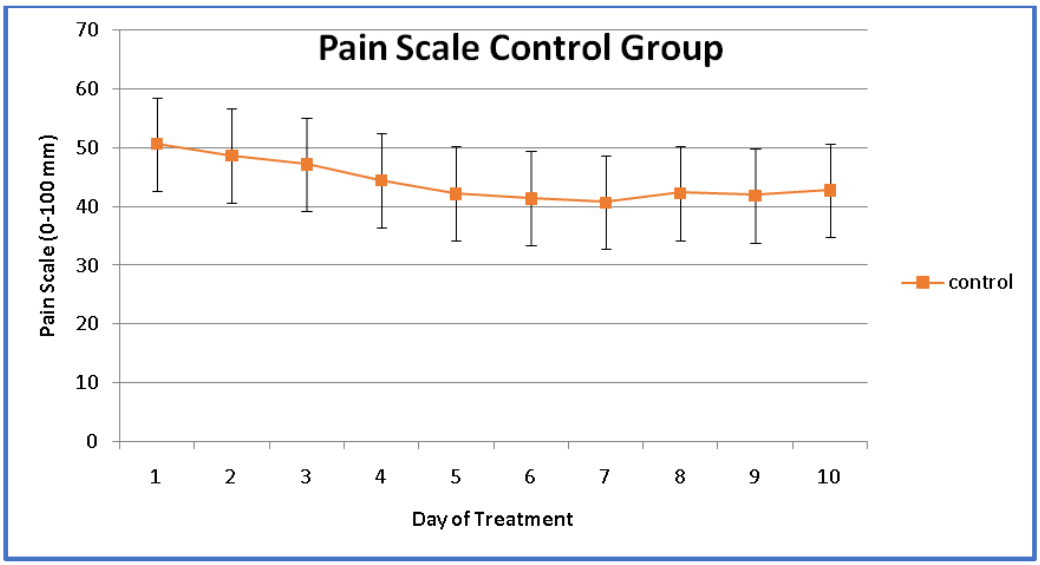

Figure 5. The analog visual pain scale before exercise in the control group. Each point is the mean +/_ the standard deviation for all subjects

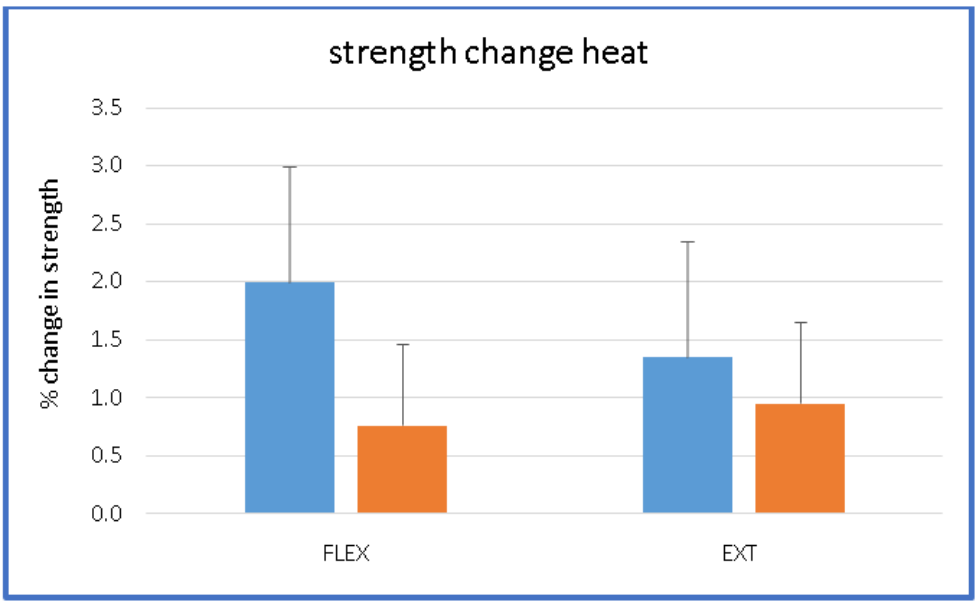

Figure 6. The change in strength from the beginning to the end of the study for knee flexion and extension in the heat and control group

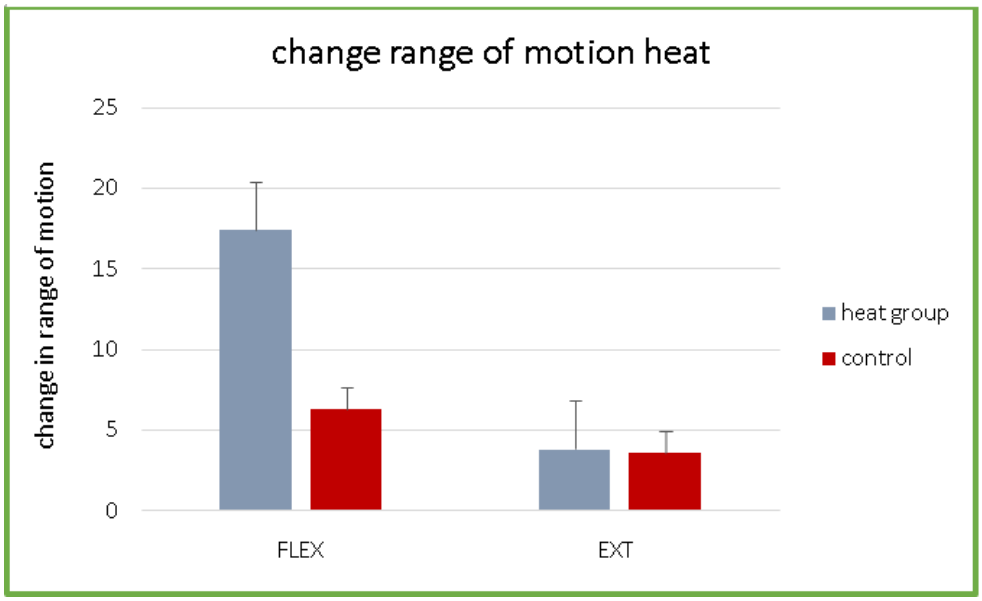

Figure 7. The change in range of motion from the beginning to the end of the study for knee flexion and extension in the heat and control groups

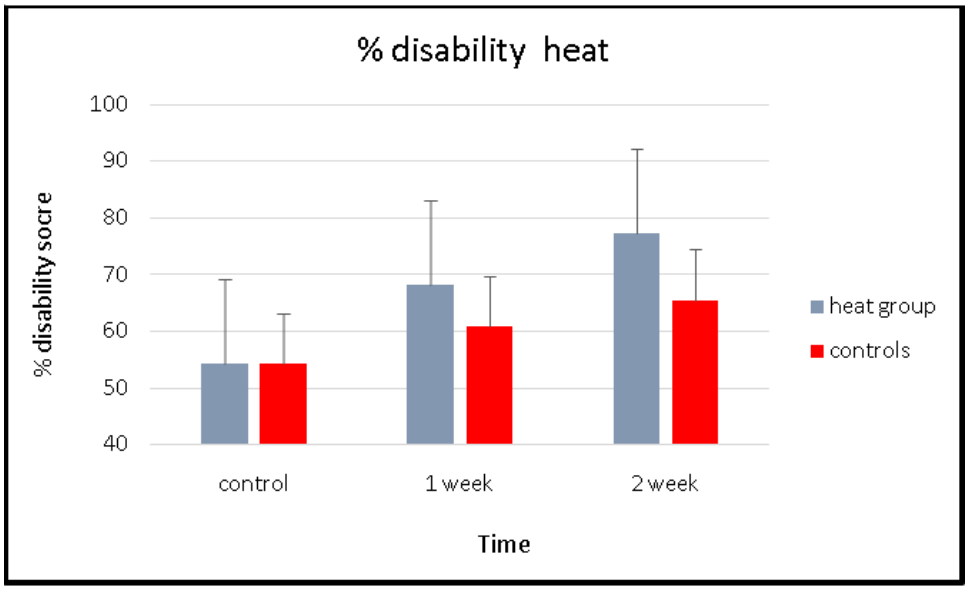

Figure 8. Disability score in the heat and control groups

4.2. Knee Groups

The change in strength for flexion and extension before and after the 2 weeks of clinical and home therapy for the knee is shown in Figure 6. The increase in strength in the heat group was more than double that of the control group over the 2 weeks and was significantly greater ($p<0.01$) for flexion but not significant for extension.

Figure 7 shows the change in range of motion of the heat and control groups over the 2 week periods respectively. As shown in this figure, there was a significant increase in range of motion at the knee without pain in both groups of subjects. However, the increase in range of motion was significantly greater in the heat group than that measured in the control group over the 2 weeks of therapy and home exercise ($p<0.05$).

The results of the disability score measurement are shown in Figure 8. Both groups had a significant decrease in disability (increase in the score) associated with the 2 weeks of therapy ($p<0.01$). However, the reduction in the disability score was greater ($p<0.05$) at 1 and 2 weeks in the heat at home group. While there was no significant difference in the score in the 2 groups pre therapy ($p>0.05$), post therapy (2 weeks) the heat group showed an improvement of 23 points, the increase in the control group was 11.28 points.

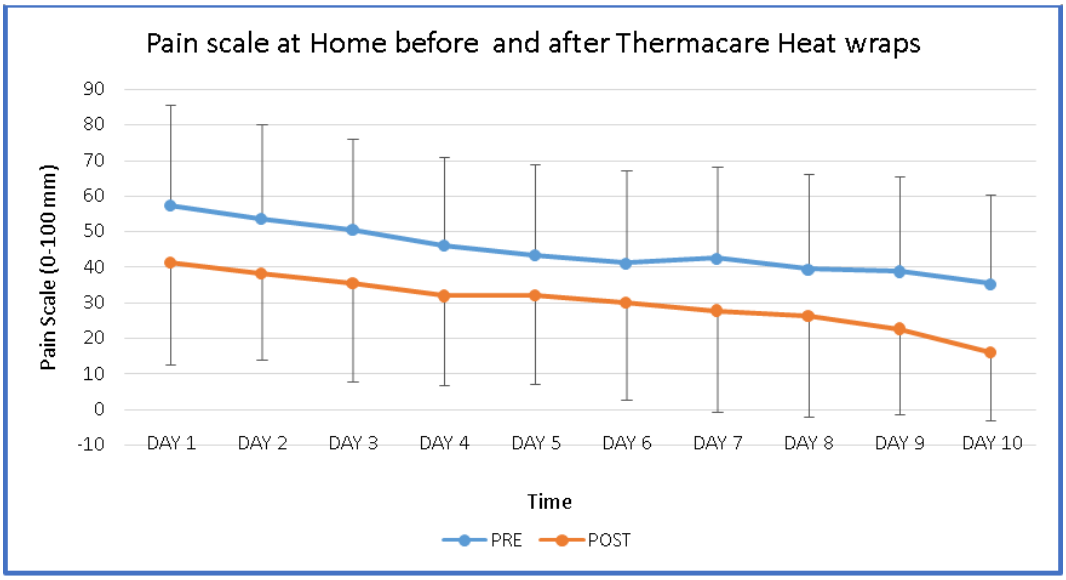

Figure 9. The pain recorded before and after heat use at home before home exercise

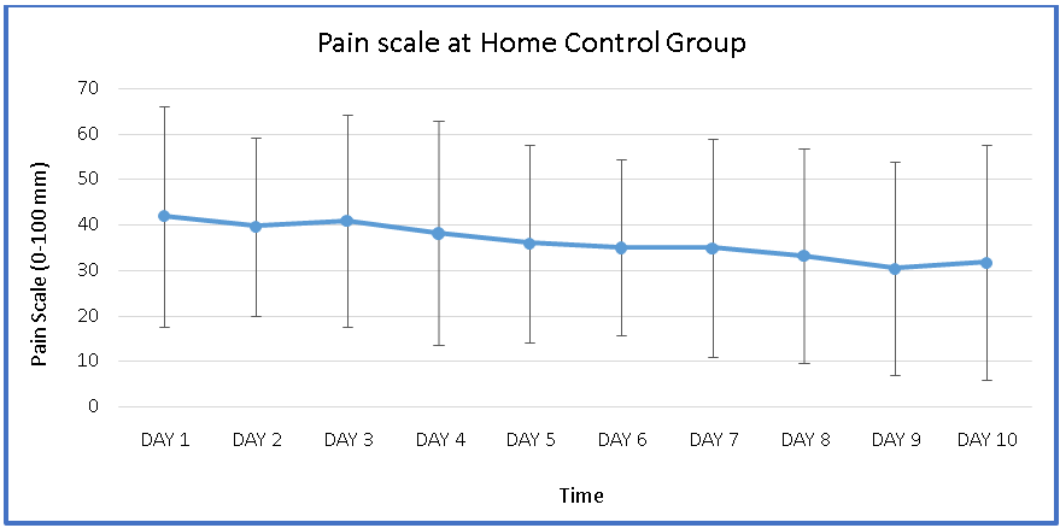

Figure 10. The pain recorded before home exercise in the control group

The pain scale as self-reported by the subjects is shown in Figure 9 and Figure 10 for the heat at home and control groups with knee pain respectively. As can be seen in Figure 9, for the heat group, pain was less each day for the 10 days of home measures (ANOVA $p<0.05$). In addition, heat always caused a significant reduction in knee pain each day before home exercise therapy. Comparing Figure 9 and Figure 10 (control subjects), there was a greater reduction in pain over the 10 sessions before heat in the Heat group (Figure 9) compared to the control (Figure 10) group. The reduction in pain before heat was significantly greater after the 2nd day of heat in the heat group compared to the control group ($p<0.01$). Each day heat was applied, there was a reduction in pain that was significant ($p<0.01$).

Compliance

The compliance for home exercise averaged 79.3+/-7.2% in the heat at home group and 61.2+/-7.2% for the

control group. The increased compliance in the heat at home group was significant ($p<0.05$).

4.3. Back Injury Groups

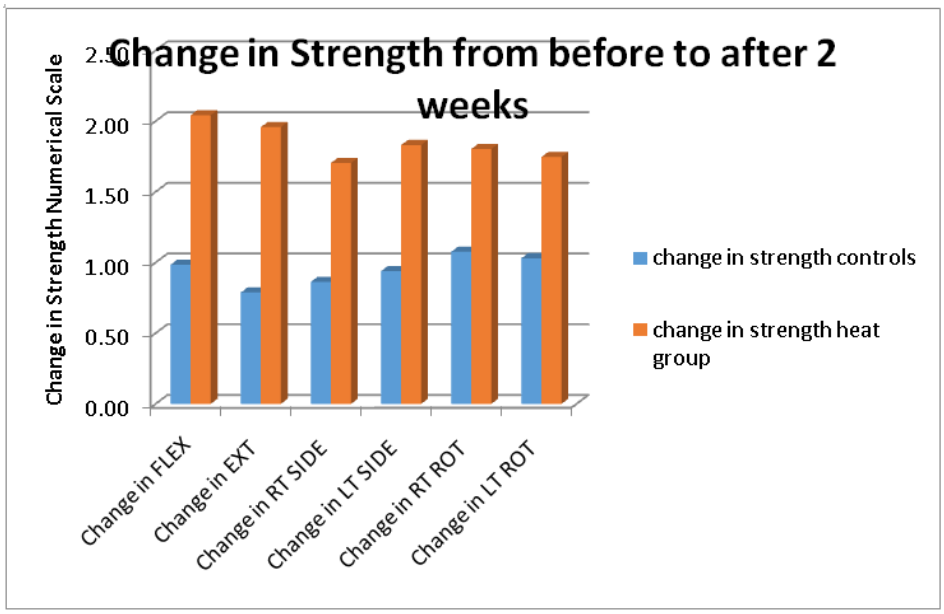

Figure 11. The change in strength on a 0 to 12 scale for the control and heat groups comparing pre to 2 week post measures. Each point is the mean of the group +/- the SD

The strength, as assessed on a 0-12 scale, was not different in the 2 groups of participants at the beginning of the 2 week period. The increase in strength was significant for the groups comparing pre to post data ($p<0.01$) and the greater increase in strength in the heat group was significantly greater than that seen in the control group ($p<0.01$). (Figure 11) In terms of muscle strength gains on the standard 5 point scale, a 2 point increase in this scale would equal a gain, for example, from 4- to 4+. For the 2 groups of participants, the average strength was in fact about 3+ at the beginning of the study and for the heat group 4 to 4+ on a 5 point scale at the end of the therapy.

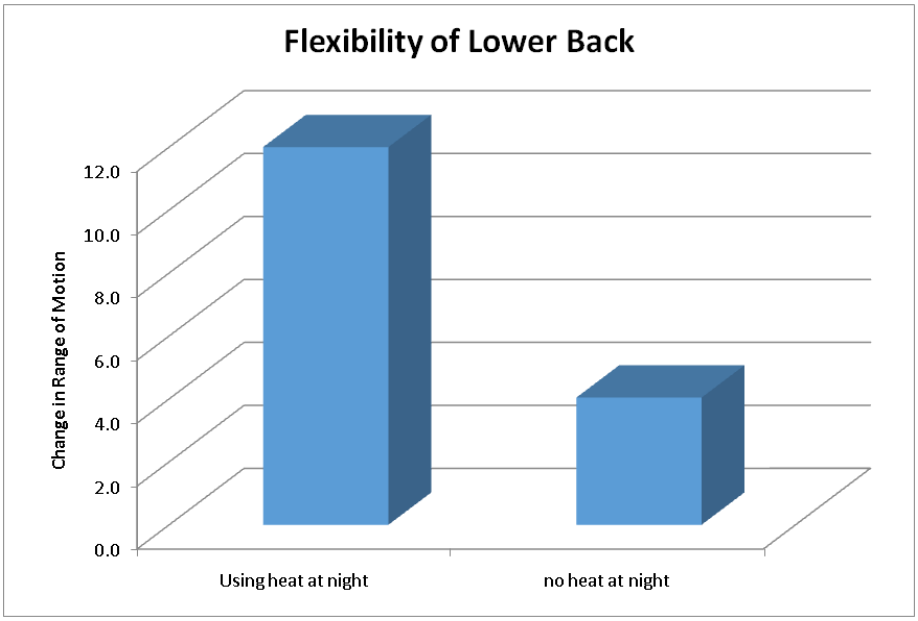

Figure 12. Change in Range of motion in the control and heat groups over the 2 week period. Each point is the mean for the group +/- the Standard Deviation

4.4. Back Range of Motion

The range of motion of the back is shown for the control and heat groups as a difference pre to post the 2 week therapy period in Figure 12. The range of motion of the back for flexion, extension right and left side bending and rotation was not significantly different between the groups ($p>0.05$) when the participants began the 2 week period. As shown in Figure 12, the heat group had significantly greater improvement in range of motion at the back after 2 weeks than did the control participants when comparing the pre to post gains in range of motion ($p<0.01$). For the control group the improvement across all measures was only 4.0 +/- 6.0 degrees whereas for the heat group it was 13.5 +/- 12.0 degrees, over 3 times greater.

4.5. Roland Morris

The initial scores on the Roland-Morris disability index were 15.2+/-8 for the control group and 12.7+/-12.6 for the heat group; the 2 groups were not significantly different from each other at baseline (p>0.05). The heat group and control groups both showed a decrease after the 2 weeks of therapy but the heat group had over 2 times the loss of disability score compared to the control group as shown in Figure 13. This difference in loss in the Roland Morris between the groups was significant (p<0.01) while the loss shown by both groups comparing the pre therapy data to the post 2 week data was also significant (p<0.01).

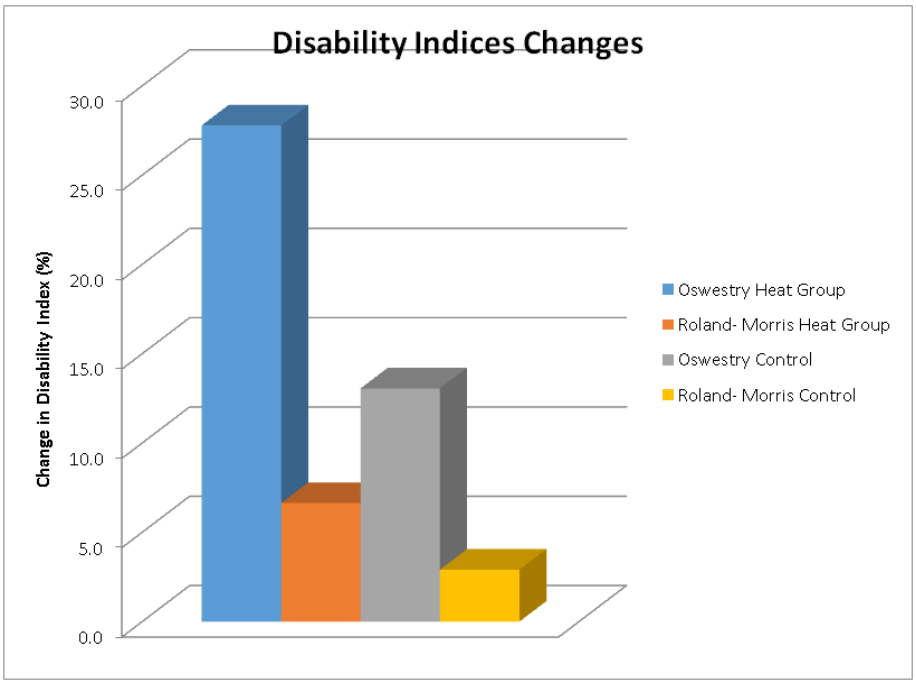

Figure 13. Change in disability index as assessed in the Roland-Morris and Oswestry tests in the control and heat subject groups. Each point is the mean for the group +/- the Standard Deviation

4.6. Oswestry

For the Oswestry back disability index, the average disability index was 52.0+/-25.1%. For the heat group at the start, the Oswestry disability index of 50.6+/-24 %. The difference in the % disability was not significant comparing the heat and control groups at the start of the study (p>0.05). After 2 weeks of therapy, the control group had a reduction in the Oswestry disability index which was significant (p<0.01). The decrease in disability index comparing the measurements at the beginning and end of the study was 10.7+/-11.2%. For the heat group, there was also a significant drop in the disability index from baseline which were also significant (p<0.01) (Figure 13). Here the reduction was 27.3+/-24.6 % disability. This greater loss in disability in the heat group was significantly greater than that seen in the control group comparing the data at the start to at the end of week 2 (p<0.01).

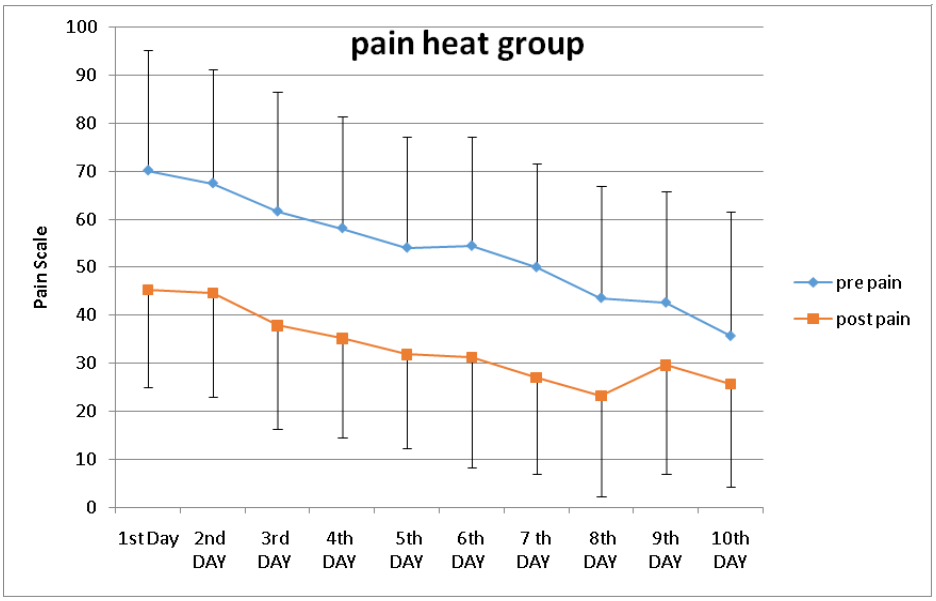

Figure 14. The analog visual pain scale as recorded by the participants at home each day before heat (blue) and after heat but just before exercise (red). Each point is the mean of the group +/- the SD for the Heat group

4.7. Pain

Pain was lower each day at home as the therapy progressed. Pain was only measured at night on days when therapy was not accomplished. For the control participants, the analog visual pain scale was recorded just before (within a few minutes) of the home exercise program. For the heat group, the analog visual pain scale was measured twice, once before heat was applied and then when heat was removed just before the home exercise program.

As shown in Figure 15 for the controls and Figure 14 for the heat group, there was a steady reduction in pain at home which was significant ($p<0.01$) in both groups of participants. The back pain was no different in the 2 groups at the beginning of the study, ($p>0.05$). For the control group, there was a small but significant reduction in pain each exercise day before the home exercise was accomplished. For the heat group, the 2 lines in Figure 14 represent the pain measured before heat and after heat (before exercise). As shown here, heat, each exercise day, was associated with a reduction in pain. At the end of the 2 week period, both the pain before and after heat were significantly lower than the pain at the end of the 2 weeks in the control participants. This significant reduction in the heat group ($p<0.01$) amounted to a 50% reduction in pain compared to an 18% reduction in pain in the control group. After heat in the heat group, pain was significantly less each day as shown in Figure 14 (ANOVA $p<0.01$).

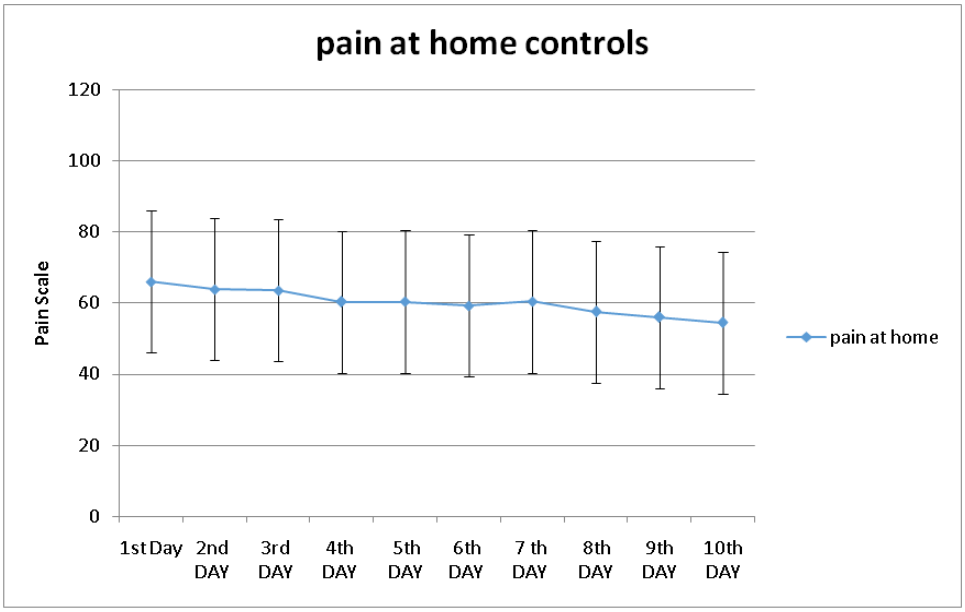

Figure 15. The analog visual pain scale as recorded by the participants at home each evening before their home exercise program. Each point is the mean of the group +/- the SD for the control group

Compliance

For the control group, the participants self-reported that they completed 42.0 +/- 28.6 percent of the exercise that was prescribed to them. For the heat group, after heat, patients self-reported they completed 73.8+/23.1 percent of their exercise, a significant improvement over the control group ($p<0.01$).

5. Discussion

One of the most common work related injuries is an injury to the lower back associated with twisting or lifting improperly [45]. Many other causes can also cause lower back injuries. Over half of the American male population has had such an injury in their lifetime [46]. These injuries have a life time prevalence of 60-90% [47,48]. Neck pain is a common form of pain and only second to back pain in everyday life. It is often seen in athletes due to sports as well as in the casual weekend warrior [49,50,51]. On the job, neck injuries are also common. For example, of health care workers, 45% of all upper body daily pain was neck pain [52]. Next to lower back injuries, knee injuries are one of the most common types of injuries in physical therapy [53,54]. Anterior and posterior cruciate ligament tears are common and many require surgery [55,56]. But lesser injuries such as knee collateral ligament tears and meniscus tears are also common [57].

Because of rising medical costs and budget limitations [58], it becomes more important than ever to increase the effectiveness of physical therapy in people with pain so that costs can be minimized and people can return to work faster; both of these impacting society's health care costs in a positive way [46,59]. It has been established that most people do not see a professional to treat pain, especially lower back [60]. By not treating pain, neurons become hypersensitive and acute pain is converted to chronic pain [61]. Treatment usually includes either singly NSAIDS, steroids, muscle relaxants, and antidepressants [62]. Non pharmacological intervention includes treatments such as hot and cold and was evaluated in a 2006 Cochrane Review [19,20]. Here heat was found to be supported for relief of pain while many of the pharmacological interventions had no clear benefit.

A common problem encountered in physical therapy is the limitation on duration of clinical treatment sessions. For example, after a work related injury to the back, the most common injury treated in this category, only 2-3 weeks of therapy are allowed by most insurance companies in the United States [63,64]. This is due to the

fact that back pain generally resolves in a few weeks unless there is significant pathology [64]. But pain at home limits how much exercise patients will do delaying healing even further. In this investigation, home continuous heat wraps were used each night a home exercise program was to be used. Previous studies have shown that heat reduces pain and increases range of motion and tissue flexibility [32,65]. This is confirmed in the present investigation. Range of motion was increased with heat. Heat also reduced pain for the neck, knee and back each day such that there was less pain before home exercise was accomplished. With less pain, patients accomplished more of their home exercise program and, as assessed by strength increases and reduced pain and increased range of motion of the 2 weeks, healing was increased significantly compared to the control group. Thus, in this study, heat was a good adjunct to normal therapy. Heat has not been used in any study we are aware of with physical therapy. However, in the Cochrane review cited above, 9 studies using heat therapy were examined in combination with NSAIDS or alone. Heat provided a small but significant reduction in back pain[20]. Here, compared to the control group, there was a dramatic reduction in pain, reduction in disability and increase in strength for all 3 impairments studies here much greater than that seen. For example, the reduction in the Roland Morris for back pain was 7.6, here it was 21.2. Similar findings were seen in studies by Kettenmann et al [66] and Mayer et al. [67]. In both, heat reduced pain and increased flexibility but not to a fraction of the extent seen here. Nadler et al. [21] used heat at night for 8 hours and after 5 days of continuous low level heat wrap treatment, the Roland Morris disability score was reduced by just about 2%. Here, it was reduced by 14% after 1 week and 23% after 2 weeks. While many of the measures in these 3 studies were hard to directly compare, the measures that were the same were dramatically better when physical therapy was alternated with night heat therapy.

One of the limitations of this study is the 2 weeks that subjects were examined. There was no follow-up months later to see if these benefits were extended past the 2 week period; this would be a good thing to study in the future.

Acknowledgements

This work was supported by a contract from Pfizer Pharmaceuticals.

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