

Monochromatic Infrared Photo Energy in Patients with Knee Osteoarthritis

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ABSTRACT

Knee osteoarthritis is a frequent physical condition worldwide for which there is no optimal treatment. Monochromatic infrared photo energy is a relatively new modality used in the United States for reducing pain and increasing circulation. This study investigated the effects of the monochromatic infrared photo energy on reducing pain and increasing physical function in patients with knee osteoarthritis. Forty participants with knee osteoarthritis completed the program and were randomly assigned into two groups. Group 1 (experimental, n=20) received monochromatic infrared photo energy and therapeutic exercises. Group 2 (control, n=20) received hot packs, ultrasound and therapeutic exercises. Both groups received three visits per week for four weeks. Outcome included pain intensity measured on a visual analogue scale and physical function measured with the distance walked in 6 minutes and the lower extremity functional scale, before and after the 12 therapy sessions (1 month after the start of the intervention). Analysis of covariance tests revealed statistically significant improvement, specifically, $P = .004$, $.0001$, and $.0001$, for pain, distance walked in 6 minutes, and lower extremity functional scale, respectively, in the experimental group. Therefore, it can be concluded that the monochromatic infrared photo energy may play a role in treating knee osteoarthritis by reducing pain and increasing physical function.

Keywords: Light energy, osteoarthritis, knee, nitric oxide, pain.

INTRODUCTION

Osteoarthritis is an epidemic physical disorder for which there is no known cure¹. Osteoarthritis is the most common cause of pain and physical disability in the United States². It is characterized by pain and functional limitations³. Treatment of knee osteoarthritis focuses on reducing pain and improving physical function. Treatment approaches include drug therapy, hyaluronic acid injection, glucosamine and chondroitin

sulphate, aerobic, muscle strengthening and water-based exercises, weight reduction, orthosis, thermal modalities, low level laser therapy, biomagnetic therapy, transcutaneous electrical nerve stimulation and acupuncture^{4,5,6,7,8}. Despite the wide variety of intervention options, the management of knee osteoarthritis is still far from optimal.

The Monochromatic infrared photo energy represents a relatively new approach for treating knee osteoarthritis. It has been recently utilized and cleared by the United States Food and Drug Administration in 1994 for increasing circulation and reducing pain⁹. The monochromatic infrared photo energy device is a non-invasive drug-free that delivers monochromatic infrared photo energy with a wavelength of 890nm⁹. The light is emitted by an array of 60 superluminous Gallium Aluminum Arsinide diodes located on flexible pads⁹. The diode array must be placed in direct contact with the target skin, as the monochromatic infrared photo energy energizes cells in the epidermis and the most superficial portion of the dermis, thereby warming the skin⁹. The 890-nm photo energy penetrates the skin enough to be absorbed by hemoglobin in the rete capillary loops in the papillary dermis, rather than just water in the more superficial layers⁹.

The benefits of the monochromatic infrared photo energy rely on skin contact, pulsation, wavelength, radiant power, and energy density¹⁰. The monochromatic infrared photo energy delivers pulsed adjustable radiant power of up to 10 milliwatts per diode, a power density per diode array of up to 10 milliwatts per cm², and an energy density of up to 1.6 joules/cm²/minute¹⁰. Therefore, treatment duration of 20-30 minutes of monochromatic infrared photo energy can deliver up to 48 joules/cm² when the diodes are in direct contact with the epidermis¹⁰. The mechanism of action is a combination of topical heat and a transient increase of local release of nitric oxide for pain relief¹¹.

There is no research that investigated the use of the monochromatic infrared photo energy in patients with knee osteoarthritis. The purpose of this study was to evaluate the effect of the monochromatic infrared photo energy on reducing pain and increasing physical function in patients with knee osteoarthritis.

MATERIAL AND METHODS

Design

This was a randomized controlled trial with participants randomly assigned to one of two treatment groups: (1) group 1 that received the monochromatic infrared photo energy and therapeutic exercises or (2) group 2 that received hot packs, ultrasound and therapeutic exercises. Neither the participants nor the investigating tester were aware of the treatment group. The tester made group comparisons at the initial visit (before initiation of treatment) and four weeks. The duration of intervention was 4 weeks per participant, and each participant was scheduled to undergo 3 therapy sessions per week.

Participants

Forty seven participants who met the inclusion criteria were recruited from an outpatient physical therapy clinic in Houston, Texas (July 2009 to November 2009). The inclusion criteria was a diagnosis of unilateral knee osteoarthritis based on fulfillment of one of the following clinical criteria developed by Altman and colleagues¹² 1) the knee pain, age 38 years or younger, and bony enlargement; 2) knee pain, age 39 years or older, morning stiffness for more than 30 minutes, and bony enlargement; 3) knee pain, crepitus on active motion, morning stiffness for crepitus on active motion, morning stiffness for more than 30 minutes, and age 38 years or older. Altman found these criteria to be 89% sensitive and 88% specific¹³.

Participants who did not experience surgery for the lower limbs, malignancy, or receive intra-articular glucocorticoid injection within one month of study entry were also eligible for enrollment into the trial. All potential subjects signed a consent form permitting the use of their data for research purposes, and confidentiality was assured by

the use of an anonymous coding system. The consent form also included a clear explanation of the benefits and expected possible risks of the study, and the rights of human subjects were protected at all times.

Instrumentation

The monochromatic infrared photo energy intervention was administered using the Anodyne® Therapy System, model 480 (Anodyne Therapy, LLC, Tampa, FL). The device consists of a base power unit and 8 therapy pads, each containing 60 gallium aluminum arsenide diodes. The area of Anodyne LEDs per therapy pads is 22.5 cm², yielding a total treatment area of 180 cm². The device delivers monochromatic infrared photo energy pulsed at 292 Hz with a wavelength of 890 nm through the diodes⁹. The active unit provides 62.4 Joules/cm² of energy density⁹.

The 10-cm visual analog pain scale was used to measure pain because it is reliable and provides a valid assessment of pain intensity¹⁵. Physical function was measured by a physical test and a questionnaire (distance walked in 6 minutes and lower extremity functional scale). Distance walked in 6 minutes is a self administered tool that has been found valid and reliable in evaluating functional capacity in different patient populations such as healthy older adults, people with knee or hip arthroplasty, fibromyalgia, and scleroderma¹⁶⁻¹⁸. Distance walked in 6 minutes has also been used as a measure of physical function in osteoarthritis studies¹⁹. Each patient was instructed to walk as far as possible in six minutes and was allowed to rest if needed during the test. This test measures the total distance a patient can walk over six minutes on a hard, flat surface. The lower extremity functional scale is a valid, reliable and responsive measure in patients with lower extremity dysfunction²⁰. Benkley et al.²⁰ found high correlations between the lower extremity functional scale and SF-36 (physical function subscale, $r=0.80$ and physical component score, $r=0.64$). The scale has an Italian version which is valid and reliable in assessing function for patients with lower extremity dysfunction²¹. Moreover, it is an appropriate alternative to the Western Ontario and McMaster Universities Osteoarthritis Index

physical function subscale. It is also valid and reliable in assessing group and individual change among orthopedic inpatients²². These outcome measurements were obtained a baseline, prior to intervention, and again at 4 weeks following the intervention.

Procedure

Participants who met the inclusion criteria were randomly assigned to one of two groups. Blank folders were numbered from 1 to 100 and were given concealed codes for the group assignment, determined by a random-number generator. When a patient was eligible and gave consent to participate, the investigator drew the next folder from the file, which determined the group of assignment. Then each patient was tested using the visual analogue scale, distance walked in 6 minutes and lower extremity function scale. Only one independent investigator, blinded to group allocation, conducted the testing procedures at both the initial and final sessions. After initial testing, participants began the treatment on the same day. Another licensed physical therapist performed all interventions with participants in both groups. All participants received three sessions per week for four weeks.

Group 1 received the monochromatic infrared photo energy for 30 minutes and therapeutic exercises for 30 minutes. Each subject sat comfortably in a quiet room at 21°C. The skin of the treatment area was covered with plastic wrap as a barrier between the skin and the diodes to ensure compliance with infection control procedures. The therapy pads were put on either side of the knee. The energy setting on the device was preset at 10 bars for every patient, in accordance with the manufacturer's recommendations. The diodes and plastic wrap were removed at the end of the treatment session.

Intervention with the monochromatic infrared photo energy was followed by therapeutic exercises for 30 minutes. The exercises included active range of motion exercises of the knee (knee mid-flexion to end-range extension in the long sitting position, knee mid-flexion to end-range flexion in the long sitting position and a stationary bicycle). The exercises also included stretching exercises for the hamstring in supine and calf

muscles in standing position, if tight. Furthermore, participants also received strengthening exercises for the quadriceps, hip extensors, hip abductors, and ankle dorsiflexors, if weak.

Participants in Group 2 received hot packs for 15 minutes, ultrasound (1.5w/cm²) for five minutes at the start of each session. Participants in group 2 underwent the therapeutic exercises which were the same regimens undertaken by the participants in group 1.

Participants in both groups were educated as to the rationale for the therapy, and they received verbal and written instructions related to the proper method of exercise, and they demonstrated to the treating physical therapist their ability to properly perform the prescribed exercises. All participants were instructed to exercise at home on the days that they did not go to the clinic for supervised intervention, and the home program was monitored by asking the participants to record exercise using weekly self-reported exercise logs.

Statistical Analysis

Data analysis was performed by using SPSS for Windows. Descriptive data analysis and tests for the assumptions of normality and homogeneity of variance were done. Separate univariate analyses of covariance with the pretest scores as the covariates, were performed to determine whether there is a difference between the two groups on the posttest scores of pain, distance walked in 6 minutes, and lower extremity functional scale. A Bonferroni approach was used to maintain the alpha level at $P < 0.05$.

RESULTS

Participants with knee osteoarthritis were randomly assigned into two groups. Group 1 (n=24; 15 men and 9 women). Group 2 (n= 23; 11 men and 12 women). One patient in each group withdrew for difficult transportation reasons. Two participants in the first group withdrew for taking care of a sick relative and developing stroke. Another patient in the first group withdrew for being too busy with work. Two participants in the second

group withdrew due to time constraints. Therefore, 20 participants completed the study in each group.

Baseline characteristics of the 40 participants who completed the study are given in Table 1. As expected with random allocation of the intervention, there were no statistically significant differences between the

treatment groups in regard to age, height, body weight, and body mass index ($P > .05$). Mean values, standard deviations and 95% confidence intervals of pain intensity, distance walked in 6 minutes, and the lower extremity functional scale score at baseline and at 4 weeks are presented in Table 2.

Table (1): Physical characteristics of the participants (mean \pm SD).

	Group 1 (n=20)	Group 2 (n=20)	t	P value
Age (years)	40.23 \pm 8.05	38.2 \pm 6.71	-1.93	0.074
Height (cm)	158.50 \pm 5.31	155.63 \pm 4.95	-0.65	0.57
Body weight (kg)	67.59 \pm 13.19	72.03 \pm 11.61	-1.94	0.25
Body mass index kg/m ²	26.45 \pm 6.33	27.8 \pm 3.14	-0.70	0.51

Independent sample t test

Table (2): Pain intensity, distance walked in 6 minutes (DW6m) and lower extremity functional scale (LEFS) at baseline and at four weeks.

Test	Baseline		4 weeks	
Mean pain score\pm SD (95% CI)				
Group 1	6.8 \pm 1.1	(6.3-7.4)	2.9 \pm 1.8	(2.0-4.7)
Group 2	7.3 \pm 1.5	(6.6-8.1)	4.1 \pm 2.3	(3.3-5.6)
Mean DW6m \pm SD (95% CI)				
Group 1	475.7 \pm 120.5	(419.3-532.1)	645.8 \pm 133.3	(583.5-708.2)
Group 2	488.4 \pm 132.1	(426.5-550.1)	521.6 \pm 140.7	(455.7-587.4)
LEFS \pm SD (95% CI)				
Group 1	42.8 \pm 9.5	(38.3-47.3)	64.7 \pm 9.4	(60.4-69.1)
Group 2	47.1 \pm 9.3	(42.7-51.5)	55.5 \pm 10.3	(50.6-60.3)

The assumptions of normality and homogeneity of variance were met. Therefore, it was appropriate to use the analyses of covariance. The analyses of covariance revealed significant differences between the two groups on reduction of pain ($F_{1, 37}=9.2$, $P=0.004$), increase of the distance walked in 6 minutes ($F_{1,37}=41.3$, $P=0.0001$) and increase of the lower extremity functional scale ($F_{1, 37}=43.7$, $P=0.0001$). The monochromatic infrared photo energy group displayed lower mean post-test pain scores, higher mean post-test distances walked in 6 minutes scores, and higher mean lower extremity functional scale scores.

The change in values of participants in group 1 was observed to be statistically more significant compared with participants in the second group. The mean plots are shown in the three graphs outlined below for visual displays of groups showing that the mean of pain scores for group 1 were lower compared with group 2 as shown in Fig. 1a and the means of distance walked in 6 minutes and lower extremity functional scale were higher for group 1 compared with group 2 as shown in Fig. 1B and C.

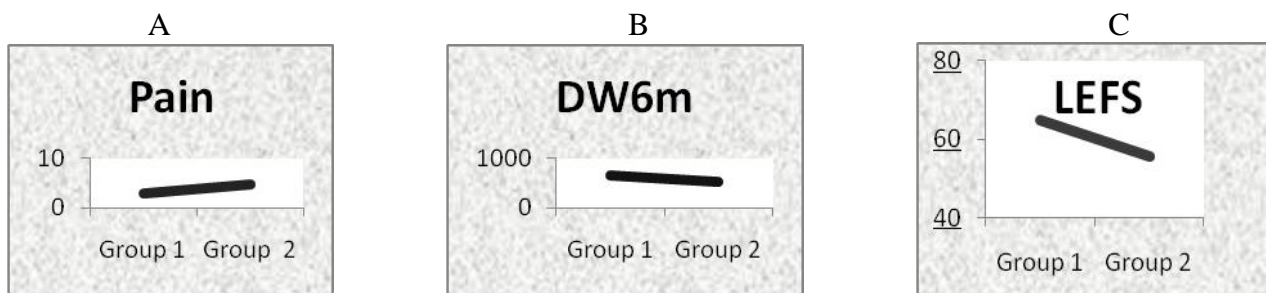


Fig. (1): (a) Plot of pain mean scores in both groups (b) Plot of distance walked in 6 minutes (DW6m) scores in both groups (c) Plot of lower extremity functional scale (LEFS) scores in both groups.

DISCUSSION

The results of the study demonstrate the effectiveness of the monochromatic infrared photo energy in decreasing pain and improving physical function in participants with knee osteoarthritis. The observed improvements in the monochromatic infrared photo energy group were most likely attributable to the monochromatic infrared photo energy. Given the design of the study (which included random assignment to study groups, relatively homogenous groups at the outset, and a blinder tester to group assignment); it is unlikely that the desirable outcomes were caused by the passage of time or by tester bias.

The dropout rate was slightly higher in group 1 than in group 2. If the treatment itself had led to negative results, causing the participants to withdraw, this dropout rate might affect the interpretation of the results of the trial. However, the reasons given for withdrawal were unrelated to the intervention.

The author measured pain perception and measures of physical function to get a thorough picture of the outcome of the intervention. Pain intensity was measured by the visual analogue scale that has been effectively used in pain studies. Physical function was measured by the distance walked in 6 minutes and the lower extremity functional scale that have been shown to be valid and reliable methods of measuring physical function, better than physiological studies.

Monochromatic infrared photo energy may reduce pain by promoting release of nitric oxide in the endothelium^{23,24}. Exposure to various wavelengths of energy enhances release of nitric oxide from the hemoglobin and the surrounding tissues^{23,24}. Nitric oxide relaxes smooth muscle cells in the arteries,

veins, capillaries and lymph vessels and results in vasodilatation of the blood vessels and thus increasing circulation^{23,24}. Monochromatic infrared photo energy treatment increases local blood flow by 400% after a 20-30 minute treatment. This was shown by use of a scanning laser Doppler (SLD; Moor Instruments Ltd, UK)⁹. Phototherapy, which includes monochromatic infrared photo energy, elicits changes in cell membrane permeability, resulting in enhanced synthesis of endorphins, increases nerve cell potential and the resulting pain relief^{25,26}. Thus, release of transiently produced nitric oxide reduces pain and increases functional ability of the knee joint^{25,26}. However, research in this field is still ongoing^{25,26}.

This is the first study that investigated the effects of the monochromatic infrared photo energy in patients with knee osteoarthritis. Monochromatic infrared photo energy has been shown to significantly decrease pain in diabetic and non-diabetic peripheral neuropathy²⁷⁻²⁹. It has also been shown to improve sensation and/or balance and reduce pain or risk of fall in participants with diabetic peripheral neuropathy³⁰⁻³³. Furthermore, it has been shown to effectively manage participants with restless leg syndrome³⁴. Also, it has been shown to improve wound healing of diabetic feet³⁵⁻³⁶. No authors investigated use of the monochromatic infrared photo energy in participants with musculoskeletal dysfunction.

There are a number of potential biases that could threaten the validity or the conclusions and for these reasons future investigation remains necessary in order to better understand the clinical value of the monochromatic infrared photo energy in the management of knee osteoarthritis. Perhaps the biggest limitation of this study relates to

the fact that the author did not employ sham monochromatic infrared photo energy, and the improvements in the dependent variables could have been due, in part, to the placebo effect. Still further, additional research is needed to more precisely identify the role that nitric oxide plays in these outcomes and whether or not the improvement in sensation that was observed in this 1-month follow-up study is sustained long-term. It is also recommend comparing monochromatic infrared photo energy to other photo energy modalities such as laser to establish its superiority over these modalities. Based on the results of this randomized, controlled clinical trial, the monochromatic infrared photo energy can be effective in decreasing pain and increasing physical function in patients with knee osteoarthritis.

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الملخص العربي

الأشعة تحت الحمراء أحادية اللون لمرضى خشونة مفصل الركبة

خشونة مفصل الركبة هو مرض بدني واسع الانتشار في جميع أنحاء العالم، أجريت هذه التجربة لبيان أثر استخدام الأشعة تحت الحمراء أحادية اللون في تخفيف الألم ورفع الكفاءة الوظيفية لمرضى خشونة مفصل الركبة. اشترك في هذه التجربة 40 مريضاً، تم تقسيم المرضى لمجموعتين متساويتين بطريقة عشوائية، تلقت المجموعة الأولى الأشعة تحت الحمراء أحادية اللون وتمارين علاجية، بينما تلقت المجموعة الثانية وسادات ساخنة وموجات فوق صوتية وتمارين علاجية. تم عمل القياسات اللازمة قبل التجربة وبعدها من قياس الألم والكفاءة الوظيفية. وقد أسفرت النتائج عن قدرة الأشعة تحت الحمراء أحادية اللون على تخفيف الألم ورفع الكفاءة الوظيفية لمرضى خشونة مفصل الركبة.