

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

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Received 16 October 2013

Accepted 2 May 2014

Abstract.

BACKGROUND: Low back pain is a significant cause of lost workplace productivity. Identification of simple, safe, and effective treatment strategies that can be used in the workplace are needed.

OBJECTIVE: To assess whether far-infrared therapy (FIR) can ameliorate chronic back pain in office workers with the hypothesis that back pain could be effectively treated while at work with minimal interruption to the normal working day.

METHODS: In a cohort study, 50 subjects with low back pain of at least six months duration were recruited from a Florida corporation. The subjects were instructed to use a FIR pad placed in their chairs in contact with the affected area while on the job over a 4 week period for at least 45 minutes a day during workdays. The FIR device used for the study was the Thermotex TTS Platinum Pad, a widely available FDA-registered medical device with preclinical data on its deep heating effects. The outcomes were assessed using subscales of the SF-36v2.

RESULTS: Results showed statistically significant changes in 9 of 10 SF-36 subscales including both physical and mental components with a near significant improvement to General Health. There was progressive improvement each week in physical component and bodily pain scales. There were no reported adverse events.

CONCLUSIONS: Use of site-specific FIR therapy over a four-week period in the workplace was associated with significant clinical improvements in pain and quality of life for office workers with previously refractory low back pain.

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

1. Introduction

Low back pain (LBP) is a major cause of disability and health care utilization with concomitant loss of productivity due to both disability and time away from work for treatment. In addition, most people who experience activity-limiting low back pain go on to have recurrent episodes. Estimates of recurrence at 1 year range from 24% to 80% [1]. The indirect costs of chronic LBP in the U.S. are estimated to be around \$16,000 annually per patient. Cumulatively, this totals approximately \$50 billion in productivity losses

annually [2]. Current guidelines for the management of low-back pain emphasize the importance of using non-pharmacologic approaches as first line therapy [3, 4]. Despite this, millions of Americans do not receive such recommendations and either continue to be in pain or are referred for pharmacological or surgical interventions despite a lack of evidence. In fact, trends demonstrate increased use of opioid analgesics (up 108% since the 1990 s), spinal injections (up 231 %) and surgeries (up 220%) without significant increases in benefits [5]. These trends are also associated with a 65% increase in health expenditures [6]. There is an urgent need for effective treatments for LBP. If an effective self-treatment of LBP that does not interfere with productivity could be identified, it would be an important and an efficient strategy to improve care and

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

2. Methods and materials

2.1. Population

Employees with low back pain were recruited from a U.S. corporation in Palm Beach County, Florida. All par-

ticipants were office workers in the company's voluntary employee wellness program and remained anonymous to their employer. Participants were recruited through flyers and emails, were screened for inclusion criteria. Participants that qualified and provided informed consent were enrolled in the cohort study. Screening was completed through an online confidential survey. Ninety nine employees were screened; 55 were enrolled, and 50 completed the observation period.

2.2. Inclusion criteria

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

2.3. Intervention

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

radiation formula which describes how radiation is affected by the medium in which it is traveling in. The closer the FIR signal (the emitting medium) is to the body (the absorbing medium, then the loss of emitting signal due to absorption and scattering there is allowing the FIR signal to penetrate deeper into the body. The key feature of the TPP used in this study was its ability to maintain a low temperature, which determines the peak emission wavelength. Many commercial infrared devices do not have the ability to maintain the temperature needed to maintain this peak emission wavelength. This is because they rely on higher temperature focally generated FIR signals in devices such as LED lights, tungsten wire or a single wire copper wire to generate the FIR signal. By doing this they increase the amount of absorption and scattering of the FIR signal reducing its penetration. By utilizing Planck's Law of radiation one can tailor the FIR signal to obtain the maximum penetration into the body allowing the FIR signal to reach a depth which would surround the vertebral bodies and their associated structures providing maximum benefit (5–7.5 cm). The TPP measures 17" x 15" and is made with 3 carbon radiators incorporated into a fabric pad and is powered by 120 volt AC. The peak emission wavelength of the pad is 9.37 nanometers, and radiant energy is $11.5 \text{ MJ s}^{-1} \text{ m}^{-2} \text{ Hz}^{-1}$. Devices were supplied to each participant at no cost by the manufacturer for use over the four-week duration of the study. Directions on daily use of the pad were given in a 45 minute orientation at the workplace. The subjects were asked to use the pad in their chairs over their clothing at their workstations for a minimum of two 35 minute sessions per day at the setting of their choice (either 'low' or 'high') for at least 5 days a week for 4 weeks. They were allowed to use the pad multiple times during the day and were allowed to bring the pad home for use on the low back or other areas at will. There was no maximum specified treatment duration or frequency. Outcomes were measured with the Quality-Metric (QualityMetric, Inc., Lincoln, RI) online version of the SF-36v2 Quality of Life (QOL) questionnaire. The SF-36v2 is well-validated [18] and widely used and measures eight domains of health-related QOL: physical functioning (PF), role limitation due to physical functioning (RF), bodily pain and limitations (BP), general health (GH), vitality and well-being (VT), social functioning (SF), mental health (MH) and role limitations due to mental health (RE). Items from the 8 domain scales are aggregated to provide summary scales for physical (PCS) and mental health components (MCS) from weighted scores of the 8 individual scales.

The PCS – designed to summarize the SF-36v2 health domain scores weighted so as to yield a single value indicating overall physical health – was selected as the primary measure. Test subjects provided their data via a secure web-based data entry portal from work or home, at baseline and weekly. Instructions for online access to the questionnaire were provided to participants at the orientation. Participants completed a baseline form no later than the first Monday morning before using the TPP and repeated the evaluation each Friday for the subsequent four weeks. Any participant who had not filled out their survey each week of the study by Friday afternoon at 4 p.m. was sent a reminder e-mail. If the survey was not filled out by mid-afternoon on the following Monday, they received a reminder phone call. Any participant who did not fill out the survey by Tuesday morning was dropped from the study.

2.4. Analysis

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

3. Results

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

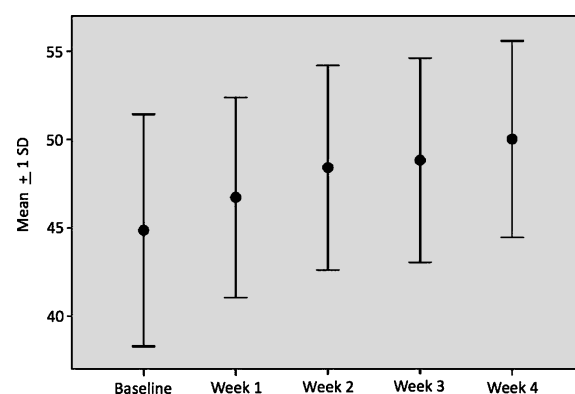


Fig. 1. Physical components summary means and standard deviations over 4 weeks.

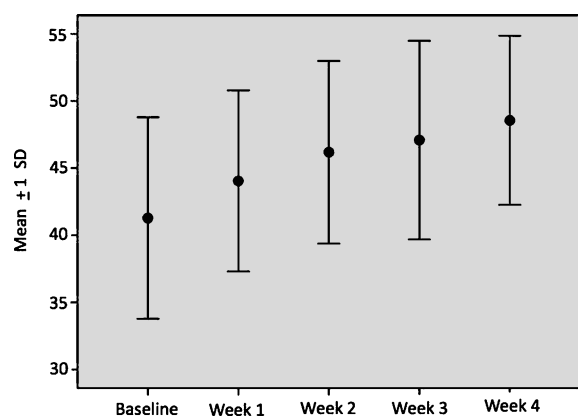


Fig. 2. Bodily pain means and standard deviations over 4 weeks.

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

toward significance ($p = 0.052$). The greatest change was noted in Bodily Pain (7.29, $p < 0.001$) with Vitality at close second (7.19, $p < 0.001$). No adverse events were reported by any participant.

4. Discussion

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

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

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

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

5. Conclusion

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

Acknowledgments

Appreciation to the Naturopathic Physicians Research Institute for assistance with manuscript preparation.

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