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Original article

Use of a non-medicated plaster in chronic lumbar back pain: a randomized controlled trial

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Abstract. *Background and aim:* The latest technology on far infrared radiations reflects the radiations emitted by the human body and induces an antalgic and anti-inflammatory effect without active ingredients. Our primary aim was to assess pain level modifications throughout the treatment period with two different types of patches, compared to a placebo. As secondary aims, we focused on addressing patients' quality of life and range of motion changes with each patch. *Methods:* We assessed 54 patients with chronic lumbar back pain treated with FIT Therapy (far infrared technology) patch. Three different types of FIT Therapy patches (F4, F3, and placebo) were used according to the different power of action and patients allocated in a randomized fashion into the 3 arms of the study. Every single patient was assessed during the study using the VAS pain scale, the Roland Morris Disability Questionnaire for quality of life, and ROM for a total of 14 days. *Results:* Only the F4 patch group significantly reduced pain level at T14 compared to the placebo group ($p<0.05$). Meanwhile, F3 showed only a non-significant decrease compared to placebo ($p=0.254$). In terms of lifestyle improvements, both F3 and F4 recorded a decrease on the RMDQ of 4 and 6 points, respectively. *Conclusions*: Currently, we still need further studies with longer follow-up to consider the FIT Therapy patches F4 a valid alternative as a "non-medicated pain relief", but it proved to have a role in alleviating painful symptoms and improving function in chronic lumbar back pain without adverse events. (www.actabiomedica.it)

Key words: lumbar pain, non-medicated patches, FIR, conservative treatment

Introduction

Lower back pain is a common disorder due to musculoskeletal or peripheral nervous system issues, which affects a wide range of age groups. A large part of the population presents with intervertebral disc degeneration and osteophyte formation even in the younger age groups. For instance, 97% of the population at 47 years of age already exhibit osteoarthritic changes in the spine (1). Suppose most of them will never seek medical attention because asymptomatic the remaining group will ask professional help for this common condition. The intertwined relationship between disc degeneration and facet joint osteoarthritis (OA) is widely known since they affect one another. However, it is still debatable which one comes first and sets this vicious cycle in motion, despite studies finding more patients with degenerative disc disease who subsequently developed facet osteoarthritis. Meanwhile, some others exhibit only facet joint OA without disc degeneration (2,3). Unfortunately for many who present a pathomorphological correlate during their assessment, many others afflicted by lower back pain do not find any correlation due to a weak clinical and imaging correlation and fall under the diagnosis of non-specific lower back pain (2).

Medical treatment for the acute phases of lumbar back pain usually entails intramuscular steroid injections, non-steroid anti-inflammatory drugs (NSAIDs), skeletal muscle relaxants, and diet supplements such as multivitamins (especially from the B group). In order to resolve the underlying causes of the lower back pain,

clinicians can reiterate all the treatments mentioned above until there is a resolution of the symptoms in association with a physical therapy program (5).

The FIT Therapy patch (D. FENSTEC s.r.l. Altavilla Vicentina, Italy) is a medical device class 1 which mechanism of action is through the ability of biominerals to reflect the far-infrared radiation (FIR). Usually, the human body temperature would dissipate regular far infrared radiations, but, thanks to the FIT Therapy (Far Infrared Technology), these waves are reflected and allowed to reach deeper areas in the human body. Far infrared radiations have a wavelength spectrum of 4-21 μm with a denser concentration at 11 μm. Therefore, every FIT Therapy device acts as a mirror. Thanks to this biophysical process, they can induce an antalgic effect simply without releasing any active ingredient or creating a thermic shock. The plasters are made of 100% polypropylene non-woven fabric, an acrylic adhesive mass, and a mix of titanium dioxide adequately incorporated in the inks used for printing on the external surface of the patches therefore not directly in contact with the skin. Particle sizes above 100 nm characterize this particular mix in powder form. The intrinsic properties of the FIT Therapy technology are due to the blend of titanium dioxides that reflect the far-infrared radiations emitted by the human body, as stated by the manufacturer.

Recent studies have revealed that reflective (capacity to reflect radiant energy) technologies applied to the far-infrared radiation dissipated by the human body dramatically increase the superficial microcirculation, with possible clinical and metabolic-functional implications on muscular masses (3-5). Currently, far-infrared radiation-based therapies are mainly used as pain relief in musculoskeletal and articular pain cases (6,7). According to the published literature, FIR aids the functional recovery processes of the muscular tissues. It promotes the pain relief and myorelaxation of the affected area, especially in contractures, strength deficits, and over-use syndromes (4-6, 8-10). Since it is a reasonably new technology, few studies have been published on FIR based patches in cases of musculoskeletal pain so far. The lack of research about this treatment makes orthopedic surgeons overlook this therapeutic option. Hence the urgency to deepen our knowledge on the actual efficacy of this remedy (10,11). Patients showed functional and pain improvement in the case of shoulder tendinopathy and a statistically significant wellbeing improvement in general health, pain, and from an emotional standpoint in the case of different pathologies that affected other anatomic areas (10).

As already stated, this is a new technology, and we hypothesize that it can effectively reduce both pain and the duration of lumbar strain. Hence the primary goal of this study is to determine the effect of FIT Therapy patches, named for convenience “F3” and “F4” based on the different reflectance spectrum of the infrared radiations, in the treatment of lower back pain (measured on the VAS). First, we aimed to compare the results of the two different types of plasters (F3 vs F4) and compare the single patches' results with a placebo (F3 vs placebo and F4 vs placebo). Secondly, the different FIT Therapy patches' range of motion (ROM) improvements were compared between F3 and F4 and again with the placebo. The ROM was expressed in degrees of flexion-extension and lateral bending of the patient and was followed by the Roland Morris Disability Questionnaire (RMDQ).

Methods

Patients

The AOUI Verona ethical committee approved the study and its design (Protocol number: 2128CESC). Afterwards, 54 patients were enrolled from May 2019 to November 2019 at the AOUI (Azienda Ospedaliera Universitaria Integrata) Verona. The authors did not change any part of the trial design or chosen outcomes after the beginning of the study.

A population of otherwise healthy 26 females and 28 males spanned from office and labor workers, recreational and professional athletes from Verona and the surrounding area. The study design contemplated a prospective analysis in a 3-arm, randomized double-blind (patients and physicians in charge or enrolling and application of patches), and placebo-controlled study to assess the effect of FIT Therapy patches on the chronic lumbar spine pain, quality of life (with the RMDQ) and the ROM (Table 1).

Table 1. Demographics of the enrolled patients divided by treatment

RMDQ	Placebo	F3	F4
Age, yrs (SD)	49.1 (±11.1)	52.2 (±7.62)	48.6 (±11.8)
Female, number (%)	8 (44%)	10 (56%)	8 (44%)
Male, number (%)	10 (56%)	8 (44%)	10 (56%)
Total (%)	18 (100%)	18 (100%)	18 (100%)

Values are mean unless otherwise indicated
Standard deviation (SD)

Inclusion criteria of the study were: patients suffering from chronic lumbar spine pain (>6 months), over-use without neurological symptoms; a signed informed consent and patients between 30 and 60 years of age. All the enrolled patients were otherwise healthy without any concomitant disease that needed medications.

First of all, history taking focused on excluding any Red Flags, which could lead to a diagnosis of infection, neoplastic masses, neuropathies, and metabolic disorders triggering the lumbar pain. The patients recruited did not take any cortico-steroids or painkillers throughout the treatment. If this condition could not be followed, the patients were considered as dropouts from the study.

We excluded patients presenting signs of possible herniated disk or spinal stenosis leading to radiculopathy during the physical examination. In contrast, we included those who experienced pain focused on the lower back without irradiation, hypoesthesia, or hypoesthesia to the lower limbs. Both Lasegue and Wasserman had to test negative to enroll patients in our trial.

Every patient came to our attention, referred from their primary care physician, with an MRI of the lumbar spine that either demonstrated the presence of intervertebral disc degeneration, osteoarthritic changes in the spine, or was not able to identify a clear cause for their symptoms.

Design

We performed a data analysis about the placement of FIT (Far Infrared Technology) patches on the lumbar area. Based on the type of patch, 3 groups were defined, each consisting of 18 patients randomly assigned. The "Placebo" group was treated with placebo patches, and the "F3" and "F4" groups were treated with patches with different reflection and penetrating action of FIR. Patients were subdivided into 3 randomized groups with an allocation ratio of 1:1:1 generated by the Stata software 14.

Each group was evaluated for the primary and the secondary aims during the study: at the time of first application (T0), after 5 days (self-removal -T5-), after 8 days (application of the new patch -T8-) and at the end of treatment (T14). The patches' estimated effectiveness is 7 days according to the manufacturers; therefore, we decided to let the patients self-remove and re-apply it 3 days later to avoid any possible side effect. Side effects were assessed during every clinical encounter and by reading the daily journal provided to our patients at the beginning of the trial.

Different Scores Were Utilized To

Primary Aim

Evaluation of variations in pain level both within the same treatment group and between different groups. The Visual Analogic Scale (VAS) was administered to quantify the subjective pain level from 0 (no pain) to 10 (maximum pain ever experienced). Also available a daily monitoring of the pain.

Secondary Aim

Quality of life. The Roland Morris Disability Questionnaire (RMDQ) focuses on the disability caused by low back pain during ordinary daily activities. The score of the RMDQ varies from 0 (normal function) to 24 (inability to perform any ordinary daily activity due to back pain).

Range of Motion (ROM). We evaluated flexion and extension, lateral bending, and lumbar spine

rotation. Flexion and extension were calculated on the sagittal plane using a goniometer. Lateral bending was scored using the same method on the coronal plane, while rotation was calculated on the transversal plane.

We utilized the mean-between group effects defined by Chou et al. (12) and described in a systematic review about non-pharmacological treatments for low back pain. On a VAS scale from 0-10, numerical variations between 0.5-1 are considered as "slight", between 1-2 are "moderate", and finally "substantial" in case of modifications larger than 2 points. We applied the same grading system to our patients' function according to the RMDQ. Thus, between-group changes consisting of 1-2 points are "slight", 2-5 points are "moderate" and "substantial" for more than 5 points.

Fit therapy patches:

The plasters are made of 100% polypropylene non-woven fabric, an acrylic adhesive mass, and a mix of titanium dioxide adequately incorporated in the inks used for printing on the external surface of the patches therefore not directly in contact with the skin. Particle sizes above 100 nm characterize this particular mix in powder form. In this study, the examiners used three different plasters: a placebo (without any biomineral, therefore with no reflectance ability), an "F3" patch, and an "F4" one, characterized by different reflection and penetrating action of FIR. Specifically, according to the manufacturer, F3 has 0,8% of titanium dioxide incorporated in its fabric, compared to 1% of the F4. The 3 plasters presented no difference in size, color, and shape (**Figure 1**).

Intervention:

The trial consisted of a total of 14 days for each patient. On day 0, during the first clinical encounter, patients were enrolled by signing an informed consent. Still, during the clinical encounter, the lumbar spine ROM was measured, our patients took the VAS and the RMDQ. Only after all these necessary steps, the clinician applied the first patch. Patients were given an RMDQ and a journal, with requests of daily updates, always at the same time every day. The wanted information was the pain level experienced and any adverse effect to the FIT Therapy patch. On day 5 the patch was self-removed and the RMDQ given during the first encounter filled. The second clinical encounter was on day 8. The patients' ROM and VAS were tested for the second time, and they put on a new FIT Therapy patch. On day 13 the FIT Therapy patch was dismissed and a second RMDQ filled at home. Patients attended their last clinical encounter on day 14, and once again, all 54 patients' ROM and VAS were assessed. Finally, we collected the daily journal and asked the patients if any other pain medication was self-administered during the entirety of the tests.

Figure 1. Enrolled patient wearing the FIT patch

Statistical Analysis

The number of samples and the type of variables detected do not allow the use of parametric tests or synthesis indices typical of continuous and normally distributed distributions. The data are then expressed as medians and interquartile intervals in parentheses (IQR= 75°-25° centile).

Analysis of the single treatment groups

Evaluation of the efficacy was performed by measuring and comparing the baseline values (T0) versus the data after 5, 8, and 14 days (T5, T8, T14) separately for all the 3 treatment options (placebo, F 3, and F4). The Friedman test for one-way repeated measures analysis of variance was used and, when statistically significant, it was followed by a post hoc analysis for further comparisons.

Comparison between the different treatment groups

To evaluate the differences between treatments, the results of the Placebo group, F3 and F4, were compared at T0, T5, T8 and T14.

The differences among treatments were evaluated by calculating the baseline and short- and long-term pain levels (T5, T8, and T14). In such cases, the Krustal-Wallis (KW) test was used in every time frame taken into consideration (T0-T5, T0-T8, and T0-T14).

In all the previous tests, a statistically significant threshold of $p<0.05$ was used. All the data were elaborated with the SPSS v.25 software (IBM).

Results

Primary outcome: Variations in pain levels

Effectiveness of each treatment over time

The efficacy in pain reduction was evaluated on the median values of the VAS scale at T0, T5, T8 and T14 for each treatment.

- Placebo: there was a total reduction of 2 points on the VAS at T5 and T8 and 2.5 points at T14. The differences in pain level were significant between T0 vs T5 ($p<0.05$), T8 ($p<0.01$) and T14 ($p<0.001$, 99% CI).
- F3: there was a total reduction of 2 points on the VAS at T5, 1 point at T8 and 4 points at T14. T14 vs T0 ($p<0.001$, +95% CI) and T5 vs T0 ($p<0.001$, +95% CI) proved statistically significant. This study evidenced a further difference between T14 vs T8 ($p<0.01$, +95% CI). Minor and non-significant increases in the pain level was identified at T8.
- F4: the pain significantly reduced by 3 points at T5 and even more so at T14 with a total reduction of 5 VAS points, although a return to baseline values at T8 is noted. Statistically significant differences were detected T14 vs T0 ($p<0.001$, 99% CI) and T5 vs T0 ($p<0.001$). Even in this case, more differences were identified between T8 vs T5 ($p<0.01$, +95% CI) e T14 vs T8 ($p<0.001$, 99% CI).

Pain relief, measured on the VAS, resulted statistically significant, especially when the FIT Therapy patch was on (T5 and T14). There was a minimal increase in the pain level during the three days when the patch was removed before the second application (T8). This proved to be an unexpected post-hoc observation, present in all the studied patches

Effectiveness between treatments

To analyze contrasts among the 3 treatment options, we considered the difference between T0 and the following checkpoints in our study: T5, T8, and T14. The difference proved moderate at T14 between the placebo treatment and the F 4 group ($p<0.05$, +95% CI) (**Figure 2**). Instead, we detected only a slight pain decrease between the placebo vs F3 ($p=0.254$, +95% CI) and F3 vs F4 ($p=0.984$, +95% CI), which proved non-significant from a statistical standpoint. The median reduction value at T14 was 2.5 for the placebo group, 3.5 with an F3, and 4 points with an F4 plaster (table 3). No significance was also calculated in all the other cases: at T5 and T8, the different treatments had the same results ($p=0.06$ and $p=0.05$, respectively).

Secondary outcome

Quality of life: Roland Morris Disability Questionnaire (RMDQ)

Effectiveness of each treatment over time

The comparison of efficacy in lifestyle improvement was evaluated on the median values of RMDQ at times T0 and subsequent times (T5, T14) for each treatment.

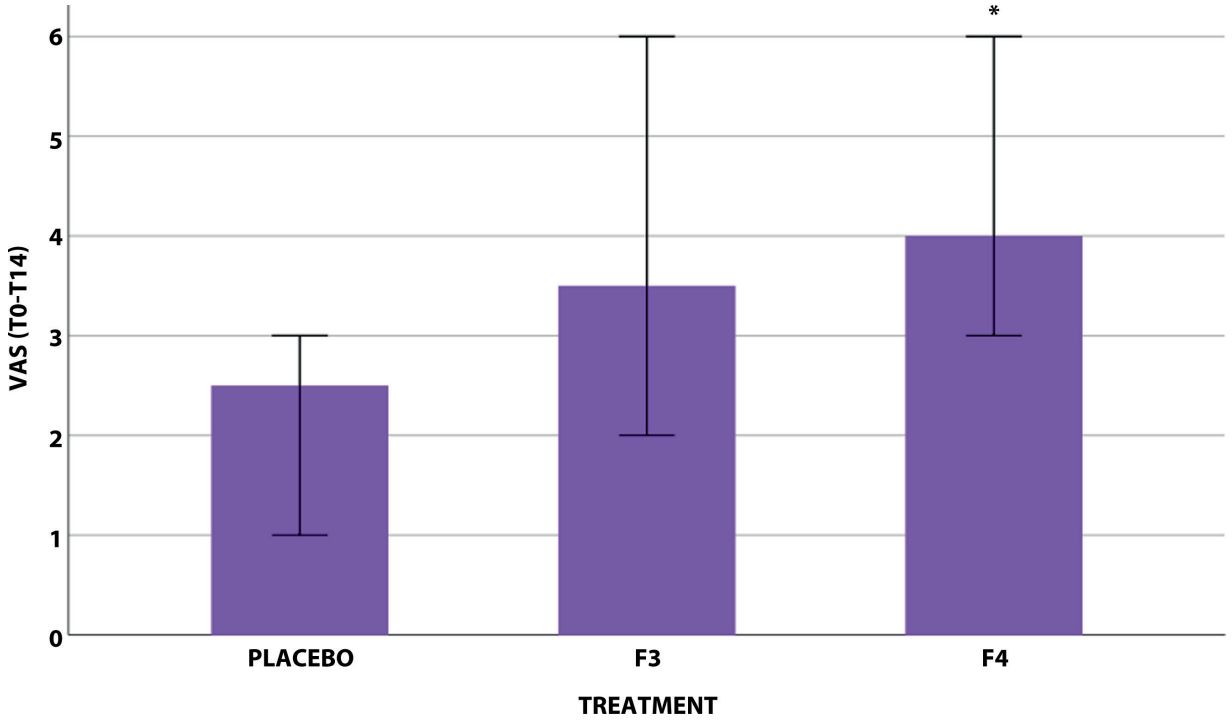

Figure 2. Efficacy, in terms of difference T0-T14, on the 3 treated groups. *p<0.05

Table 2. Comparison between different treatment groups

VAS at T14	Significance	
Placebo vs F3	2.5 vs 2	p = 0.254
Placebo vs F4	2 vs 1	p < 0.05
F3 vs F4	2 vs 1	p = 0.984

Table 3. Median of RMDQ at T0, T5, and T14 for each treatment

RMDQ	T0	T5	T14
Placebo	7.5 (4)	4.5 (4)	3.5 (3)***
F3	10.5 (11)	5.5 (10)**	4.5 (6)***
F4	10 (8)	5 (4)**	3 (2)***

,*: p<0.01, p<0.001 T vs T0

- Placebo: significant differences between T14 vs T0 (p<0.001) with a significant reduction of 4 RMDQ points at T14
- F3: Significant differences between T5 vs T0 (p<0.01), and T14 vs T0 (p<0.001). The improvement in the quality of life, by wearing the F3, is appreciated since day five of treatment with a reduction of 5 points at T5 and 6 points at T14;
- F4: significant differences between T0 vs T5 (p<0.01) and T0 vs T14 (p<0.001). The F4 patch improves the quality of life since the fifth day of treatment (5 points) and even more at T14 with a reduction of 7 points.

Effectiveness between treatments

Considering the differences between T0, T5 and T14 and comparing the treatments with each other, it appears that the differences among the groups are significant at both T5 (T5-T0) and T14 (T14-T0). Pointedly it is significant the difference between the placebo and F4 at T5 (p<0.05, +95% CI) and a T14 (p<0.05, +95% CI), while it is not significant between the placebo and F3 (T5 p=0.057, T14 p=0.308 both with +95% CI).

As demonstrated by the median values depicted in Table 3, every group presented an improvement in lifestyle (F: p<0.001, 99% CI). Again, the F4 plaster resulted as the most effective overall. At T14, the median reduction values on the RMDQ were 2.5 for the placebo, 4 points with the F3, and 6 with an F4. (Figure 3)

Range of motion (ROM)

Flexion

There was an increase of flexion within-group for all study arms which resulted significant differences between T8 vs T0 ($p<0.01$) and T14 vs T0 (Placebo $p<0.01$, F3 and 4 $p<0.001$).

In the comparison of treatments there is a significant difference at T8 between Placebo vs F3 ($p<0.01$) and Placebo vs F4 ($p<0.001$). At the end of treatment (T14) the difference between Placebo vs F 4 treatments is significant ($p<0.001$).

Extension

We found no significant difference for placebo treatment ($p=0.073$) at the different time points. Meanwhile, F3 and F4 resulted in improved extension at T8 (F3 $p<0.001$, F4 $p<0.01$) and T14 (F3 and F4 $p<0.001$).

Comparing the treatments, there is a significant difference at T8 between Placebo vs F3 ($p<0.01$) and Placebo vs F4 ($p<0.01$). At the end of treatment (T14) the difference between placebo vs F3 ($p<0.001$) and placebo vs F4 ($p<0.001$) is significant.

Rotation

Significant differences between T8 vs T0 (Placebo $p<0.001$, F3 $p<0.001$, F4 $p<0.05$) and T14 vs T0 (Placebo $p<0.01$, F3 and 4 $p<0.001$). Significant differences also between T8 vs T14 ($p<0.05$) for F4 treatment.

When comparing treatments, we noticed a significant difference at T8 between Placebo vs F3 ($p<0.05$) and Placebo vs F4 ($p<0.01$). And, at the end of treatment (T14), the difference between placebo vs F3 ($p<0.01$) and placebo vs F4 ($p<0.001$) treatments was even more so.

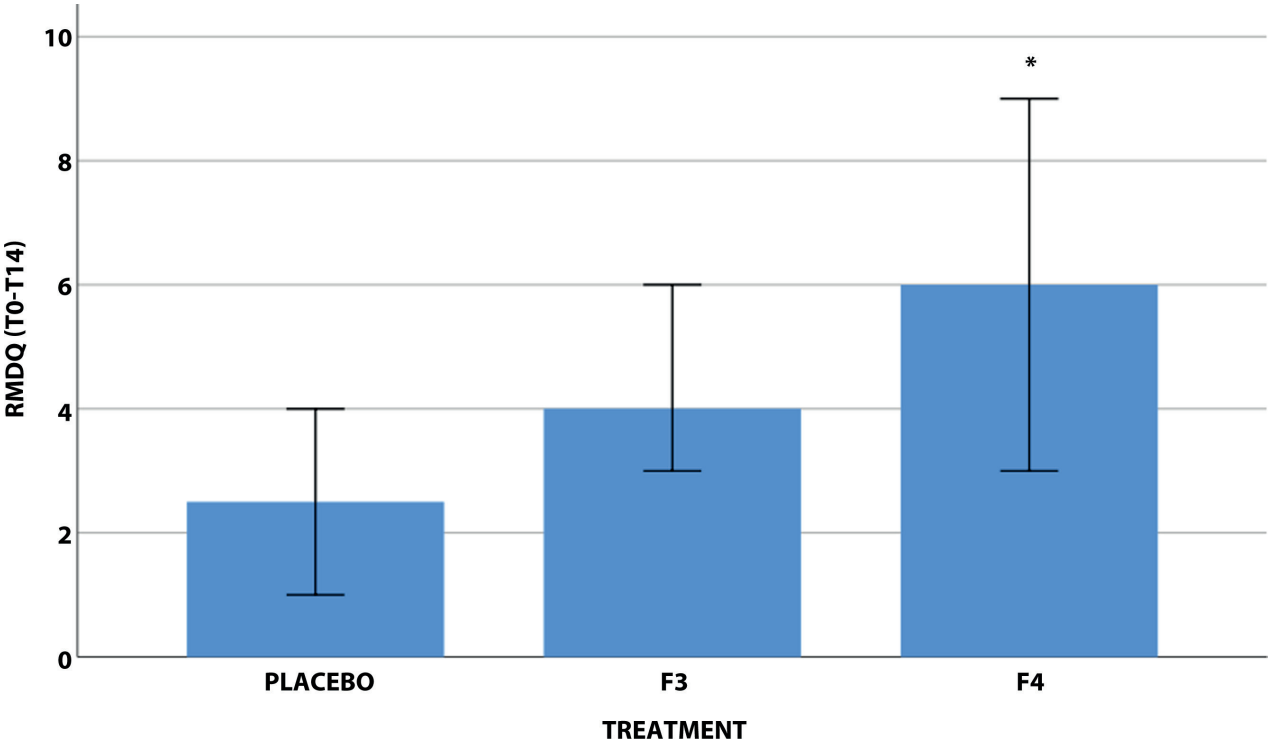

Figure 3. RMDQ, evaluated in terms of difference T0-T14, on the 3 treated groups. *$p<0.05$

Lateral bending

Significant differences between T8 vs T0 (Placebo $p<0.001$, F3 $p<0.001$, F4 $p<0.05$) and T14 vs T0 ($p<0.001$) for each treatment.

A significant difference at T8 between Placebo vs F4 ($p<0.05$) was outlined. At the end of treatment (T14) the difference between Placebo vs F4 treatments is significant ($p<0.001$).

The improvement of ROM with the F4 FIT Therapy patch was both noticeable and statistically significant compared to the remaining treatment options already at T8 between the placebo v the FIT F3 ($p<0.01$, +95% CI) and v the FIT F4 ($p<0.001$, 99% CI). Patients showed improvement in flexion, extension, rotation, and lateral bending. Also, the F3 improves patients' performance, but not to the same extent as the top-tier FIT Therapy patch compared to the placebo. In-depth at the end of our trial (T14), the comparisons were once again significant between the placebo and the plasters containing the titanium dioxides ($p<0.001$, 99% CI). The only exception is flexion, resulting in a non-significant difference between the placebo and the F3.

Discussion

The use of FIT Therapy has shown activation of the endogenous analgesic pathway, which reduces the inflammation and consequently the pain by decreasing the endogenous levels of IL-6 and TNF-α (13). Especially since lumbar pain is a widely common medical condition, it could be easy to misdiagnose or mistreat it. The estimated 1-year prevalence is 38% of the global population, according to Hoy et al., with a great 24-80% chance of recurrence over the following year (16).

Medicated plasters were developed over the centuries to improve the effectiveness of treatments in cases of low back pain. They promote a continuous intervention with the possibility of a retard release of the active ingredient with, at the same time, limited or completely ineffective systemic side-effects (14-17).

There has been a stretch in the recent years when the Far Infrared radiation technology was introduced. FIR are electromagnetic radiations produced by the human body, and they would dissipate in normal conditions. Still, the intrinsic properties of the FIT Therapy patches absorb the emissions amplifying and reverberating them on the body. According to recent studies, the biological action of FIR is to act on mitochondria and cells to modulate signaling pathways, production of Reactive Oxygen Species (ROS), adenosine triphosphate (ATP), Ca++, nitric oxide (NO). These effects lead to increased blood circulation and a decrease of the pro-inflammatory response through the regulation of cytokines (18-21). IR can improve multiple medical conditions according to several studies: pain and stiffness of rheumatoid arthritis, ankylosing spondylitis, neurological and psychiatric disorders, heart failure (11,22-25). FIR emitting clothing was also proposed as a post-exercise recovery method, especially for elite athletes since the perception of muscle pain was significantly reduced after 48 hours of treatment (19,26,27).

Our primary goal was to evaluate the efficacy of FIT Therapy patches on chronic lumbar pain precisely by assessing the VAS. A study conducted by Lai et al. (13) on myofascial neck pain supported our results since they reported a statistically significant difference of VAS in both the experimental and control group. The difference between the 2 groups lies in the decrement of pressure pain threshold and maximal pain tolerance measured in the treatment group after 1-day treatment courses.

The present study aims to evaluate the possibility of an alternative treatment based on a biophysical effect reached by the action of FIT Therapy technology. FIT Therapy patches act by reflecting the far-infrared waves emitted by human body. On this matter, the biomineral contained in the FIT Therapy patches underwent spectroscopic analysis. It was revealed that the technology involved reflects waves with a radiance wavelength between 2 and 24 μm, precisely in the range of the body infrared radiations (13).

All the treated patients showed a high tolerance for the device without any side effects, only a minimal skin temperature increase on the application site. However, this was also assessed in literature and did not prove to be significant (10,29,30).

The results of this double randomized clinical trial demonstrated a significant reduction of pain in all three

treated arms (F3, F4, placebo) with some differences. Patients treated with the FIT Therapy patches (F3 and F4) showed a substantial improvement in their pain level, followed by a slight rebound when the plaster was removed from T5 to T8. The increment of the values on the VAS scale when the FIT Therapy patches were removed can be seen as proof of their pain relief properties even in the first 5 days of application compared to the placebo group. Pain reduction has been effective since T5 and reached the best results at day 14 for F4. Most notably, the F4 results proved to be significantly better than the placebo (p-value <0.05, CI 95%). In contrast, F3, even with a within group improvement of the pain level, was not substantially better when compared to the placebo group (p-value=0.254). Probably, this is because of the chronic condition and requires prolonged treatment.

And finally, the placebo group experienced a minor and non-significant improvement in their symptoms throughout the entire treatment course.

The VAS is easy to read, and the difference between T0 and T14, notably for F4, had a substantial decline of 5 points. The study also underlined that F3 results were less effective than F4: at T14, the results showed that F3 treatment induced a non-significant reduction when compared to the placebo, instead of significant result of the F4 treatment. On the other hand, the placebo group itself demonstrated a reduction of 2.5 points on the VAS scale, which can be interpreted as a bias of the subjective evaluation methods chosen by the authors.

The reduction from baseline in the placebo group was also noticed by Bagnato et al. (9) when they compared far-infrared emitting plasters and placebo in a population with knee osteoarthritis. On a scale of 100-mm VAS, the placebo group experienced a reduction of 6.30 mm after 7 days but only an additional 0.45 mm decrease in the following 3 weeks. Most likely, the placebo effect was mitigated in the long run, whereas in a shorter treatment like ours, this result was not noticeable. Furthermore, the decrease of the pain level was associated with a significant functional recovery of the back mobility; consequently, patients improved their quality of life since day 5.

Only one study by Ervolino et al. (30) examined the disability or the physical wellbeing and quality of life (QOL) following a FIR treatment. The questionnaire of their choice was the SF-36v2 QOL, which is an 8-domain questionnaire aggregated to assess physical and mental wellbeing and over a 4-week course of treatment for low back pain, they noticed a steady weekly improvement in every category resulting in a statistically significant difference ($p<0.001$). Since the highest scores for vitality and physical function were at the end of their study, it was suggested that the therapeutic effect may not have peaked yet, especially in long-lasting low back pain. Our results from the RMDQ presented the same pattern. Both F3 and F4 patches reduced substantially ($p<0.01$) the scores from 10.5 and 10 at T0 to 5.5 and 4 respectively at T5. The scores dropped even more to 4.5 for F3 and 3 for F4 at T14 with a significance of $p<0.001$. In the future, it will be necessary to perform longer prospective studies to prove if the patches could alleviate the symptoms even more, as this can be seen as one limitation to our manuscript.

A possible limitation of this type of study is the use of a pain score, in this case, VAS, since the placebo effect could contribute to the pain relief stated by the patients. Thus, the treatment expectations, possibly caused by non-specific effects of the clinician-patient interaction, associated with high anxiety levels, may influence the patients' judgement (30-31). Secondly, the course of treatment does not consider the long-lasting effect after T14. Longer follow-ups can determine the reliability.

Conclusions

Lumbar spine pain is one of the most common issues that affects different age groups in the population. Even though further studies are needed to determine if the FIT has a long-lasting effect, it is undoubtedly true that it is an option to regular treatments since the patch is non-medicated and does not have side effects. Consequently, based on the safety of the FIT patches technology and promising results of our study, after a course of failed medical treatments in the acute phase, they can be utilized as support to alleviate painful symptoms, improve mobility in chronic lumbar pain (32-33), and represents a valid alternative as "non-medicated pain relief."

Declarations

Ethics approval and consent to participate: the design of the study was approved by the ethical committee of the Verona AOUI (Protocol number: 2128CESC); all the patients signed an informed consent before being enrolled in the study.

Consent to publish: all patients were enrolled before a full explanation of our trial and signed an informed consent.

Availability of data and materials: the dataset generated is not publicly available due to the risk of compromising patients' privacy but is available from the corresponding author on reasonable request.

Funding: the plasters were given for free by the D.Fensec srl to test them on selected patients. No funds for the study were provided, all the authors willingly extended their clinic hours to assess the enrolled patients.

Authors' contributions: R. M. is the designer of the work, M. A. oversaw data collection and interpretation, E. N. drafted and revised the manuscript, V. E. oversaw writing and revised the manuscript once completed, V. R. handled most of the data analysis, G. M. took part in the conception and designed the work to fit the ethical committee requests. All authors have read and approved the manuscript.

Conflict of Interest: Each author declares that he or she has no commercial associations (e.g. consultancies, stock ownership, equity interest, patent/licensing arrangement etc.) that might pose a conflict of interest in connection with the submitted article. Due to the large population of the surrounding area, our department was given the opportunity to test a limited number of patches on our patients, completely free of charge.

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