

# Use of a non-medicated plaster in shoulder tendinopathies

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**Summary.** We assessed 20 shoulders with rotator cuff tendinopathy and partial tendon tears treated with FIT<sup>®</sup> plasters (far infrared technology). The criteria for inclusion were pain at night and during active shoulder movement. Patients with restricted passive movement (adhesive capsulitis) and complete tendon tears were excluded. Two different types of FIT<sup>®</sup> plasters were used according to the different power of action. Plasters were replaced after 7 days and dismissed after 15 days. The patients were assessed using the VAS pain scale and the Constant Murley score for function. The use of FIT<sup>®</sup> plasters have shown a certain effectiveness in activation of the endogenous analgesic action, with a role in alleviate painful symptoms and improve function in rotator cuff tendinopathies, without adverse events. On the base of the safety of this technology and promising results of our study, further studies should be encouraged to confirm its effectiveness, increasing the sample number and follow up so as to demonstrate definitely that the use of technologies, on which FIT<sup>®</sup> plasters is based, may be a valid alternative as “non-medicated pain relief”. ([www.actabiomedica.it](http://www.actabiomedica.it))

**Key words:** shoulder tendinopathies, non-medicated plaster, topic treatment, FIT<sup>®</sup> plaster

## Introduction

Rotator cuff pathology is a common cause of shoulder pain. The differential diagnosis includes tendinitis, tendinopathy, subacromial impingement, complete and partial tendon tear and calcific tendinopathy. There is a high incidence of degenerative tendinopathy, which can lead to tendon rupture. Torn tendons are due to continual injuries as well as work that involves repetitive movements. Excessive mechanical loads are considered the main causes in these degenerative processes.

The aim of conservative treatment, based on physical therapy, is to reinforce the shoulder muscles such as the scapula elevators and the humeral head depressors. To avoid physiotherapy in the initial stages, infrared radiation is used in a wavelength that matches the body's own. This technology has already been widely studied and used to support the therapy of various pathologies or to help improve conditions, also as an

alternative to pharmacological therapy, which is not always effective. Although there is no evidence in literature on the topical treatment in this type of pathology, encouraging results have been reported on the use of plasters with nitric oxide derivatives, even though the mechanism of action is still be studied (1).

The purpose of our study is to assess the effectiveness of the FIT<sup>®</sup> (Far Infrared Technology) plaster, which reflects the “far” infrared radiation (4-21 micron) emitted by the human body, in the treatment of rotator cuff tendinopathy.

## Materials and methods

Our study assessed 18 patients (20 shoulders), 10 males and 8 females, with rotator cuff tendinopathy and partial tendon tears treated with FIT<sup>®</sup> plasters.

The criteria for inclusion were pain at night and during active shoulder movement. Patients with re-

stricted passive movement (adhesive capsulitis) and complete tendon tears were excluded.

Two different types of FIT® plasters were used according to the different power of action: the most potent plasters (conventionally coloured white) were used in 10 shoulders and less potent plasters (conventionally coloured black) in other 10 shoulders. In each shoulder two plasters of the same type (random choice) were applied, 1 in the anterolateral region and 1 in the posterolateral region under the acromion.

Two pairs of plasters, black on the one and white on the other side, were applied to two patients suffering from bilateral tendinopathies.

The patients were assessed using the VAS pain scale and the Constant Murley score for function.

Plasters were replaced after 7 days and dismissed after 15 days.

Clinical assessment was conducted before the positioning of plasters and at the end of the topical therapy.

## Results

All the patients treated with FIT® plasters had an increase in Constant Murley score values except for one patient with bilateral tendinopathy whose shoulder treated with black plasters recorded the same score pre and post application of the plasters. Regarding to the VAS pain scale, 4 patients had no improvement (3 treated with black plasters and 1 treated with white plasters) while all the others reported an improvement in pain symptoms.

Analysing all 20 shoulders treated, the Constant Murley score average prior to application was 67.05 points (42-82) and at the end of the therapy it was 72.85 points (61-85), showing an average increase of 5.8 points. The average VAS score prior to application was 3.95 (2-7) and at removal it was 2.5 (1-3), with an average reduction of 1.45.

As far as the 10 patients treated with the black plaster were concerned, the Constant Murley score average prior to application was 73 points (56-82) and at the end of the therapy was 76.7 points (62-85), showing an average increase of 3.7 points. The average VAS score prior to application was 3.7 (2-6) and at removal

it was 2.6 (1-3), with an average reduction of 1.1.

As far as the 10 patients treated with the white plaster were concerned, the Constant Murley score average prior to application was 61.1 points (42-73) and at the end of the therapy was 69 points (61-78), showing an average increase of 7.9 points. The average VAS score prior to application was 4.2 (3-7) and at removal it was 2.4 (2-3), with an average reduction of 1.8 (Tab. 1).

FIT plaster was well tolerated by all patients without cases of intolerance.

## Discussion

FITs are plasters consisting of 100% non-woven polypropylene and an acrylic adhesive mass containing a composition of biominerals, in particular metal dioxides (including titanium and excluding aluminium), which have the property of reflecting the furthest part of the light spectrum within the infrared range (between 4 and 21 mm, with a particular concentration around 11 mm). This composition is in powder form and is called AT5.05.

FIT® plasters are recommended for relieving situations of muscular-skeletal discomfort caused by the excessive build up of tissue acidosis, from overloading the muscular fibres through quicker disposal of lactic acid. They are also recommended in functional recovery processes of the muscle tissues affected by contraction due to overload, antalgic contraction and strength deficit from over-stress syndromes as they promote relief of the painful symptoms and bring about a myorelaxing action on the muscle area in question.

According to recent scientific hypotheses, the technology of FIT® plasters can be applied to the human body by taking advantage of reflected infrared radiation, normally emitted by the dispersion of body heat, lead to an increase in the skin's surface microcirculation.

There are several studies in literature related to the use of infrared radiation in the "organic" wavelength range for pathologies and conditions such as dysmenorrhea (2, 3), fibromyalgia (4), chronic pain of psychosomatic origin (5), or even simply for obtaining a better degree of general wellbeing (6). In the research

**Table 1**

Name		Side	Pre CMS	Post CMS	Delta	VAS pre	VAS post	Delta	Colour
BA	68	right	72	72	0	3	3	0	black
		left	58	73	15	5	3	-2	white
BR	63	right	69	71	2	2	1	-1	black
		left	42	68	26	7	2	-5	white
CA	52	right	71	74	3	3	2	-1	black
ML	57	right	54	62	8	4	2	-2	white
MM	60	right	57	62	5	4	3	-1	white
RP	62	left	82	85	3	3	3	0	black
ZE	57	right	63	65	2	3	2	-1	white
LL	70	right	76	80	4	4	3	-1	black
RF	66	left	70	77	7	4	2	-2	white
CM	61	left	80	84	4	3	3	0	black
MM	63	left	68	80	12	6	3	-3	black
ML	62	right	60	61	1	5	3	-2	white
DF	58	left	64	68	4	3	2	-1	white
RG	50	left	73	76	3	3	3	0	white
TS	58	right	56	62	6	4	3	-1	black
AF	61	right	82	85	3	5	2	-3	black
BG	64	right	70	78	8	4	2	-2	white
BG	69	left	74	74	0	4	3	-1	black

carried out, only the works related to the applications of the far infrared in the therapy of muscular-skeletal pain due to causes were selected for the purpose of this report.

Although the properties and pathway of infrared radiation within the range of organic wavelengths has been widely studied, there are, however, very few evidence regarding the use of this technology for the above-mentioned applications, in support of the innovative nature of these products.

A recent single blind randomized study was carried out on patients with osteoarthritis of the knee (7) to evaluate the effectiveness of a plaster containing substances with far-infrared emission on the pain and on the ultrasound measurement of any joint effusion. The patients were randomized into 2 groups, with a plaster containing substances with far-infrared emission applied to the first group and a placebo plaster to the second. The primary endpoint of the study was to assess improvement in pain after one month of treatment, using the Visual Analogue Scale (VAS); the secondary endpoints were the evaluation of the pain after one week of treatment and analysis of ultrasound results after one month of treatment. While the VAS scores both after one week and after one month of

treatment were comparable (although significantly decreased) between the group being treated with plaster with far-infrared emission and the placebo group, in terms of the ultrasound results in the FIR group there was a 40% reduction in the number of patients with joint effusions. This reduction was not evident in the placebo group, showing that FIR technology may be effectively applied as a non-pharmacological alternative in treating pathologies such as osteoarthritis of the knee.

In another double blind randomized study with placebo control (8), the effectiveness of FIR radiation on patients with chronic myofascial pain in the neck was evaluated. Patients in the treatment group wore a collar device containing ceramic powder with far-infrared emission (cFIR), while patients in the control group wore an inert collar device, both for one week. Measurements were taken of the pain intensity (through VAS), the quality of sleep, the pressure pain threshold (PPT), muscular tone and skin temperature. After one week of treatment the intensity of the pain was noticeably less in both groups without statistically significant differences between the groups. A significant difference was, however, recorded in the decrease in muscular rigidity, which was better in the treat-

ment with collar with cFIR powder than in the control group, leading to the supposition that long-term treatment could be an effective solution for the problem of muscular rigidity, which is typical of these disorders.

Wang et al (9) evaluated the analgesic effect of FIR radiation on patients during post-operative care following complete arthroplasty of the knee. The 41 patients taking part in the study were randomly assigned to the treatment or to the control group. The pads of material with FIR technology were positioned in various specific therapeutic points on each patient in the experimental group from the third to the fifth day after the operation. The effectiveness of the analgesia was evaluated using the Numeric Rating Scale (NRS) for pain and measuring the serum level of interleukin-6 (IL-6) and endothelin-1 (ET-1). At the end of the treatment both the pain and the levels of IL-6 and ET-1 were reduced in the group of patients treated with FIR.

For all these reasons it is obvious that the use of infrared radiation in the body's infrared wavelength is a technology widely studied and used to assist and support the therapy of various pathologies or to help improve conditions, also as an alternative to pharmacological therapy, which is not always effective.

Regarding the technology contained in the FIT® plasters, a number of studies have conducted also on the powder AT5.05 firstly to assess its properties and then with application to human beings to check its effectiveness in relation to the directions for use declared by the manufacturer.

First of all a spectroscopic analysis was carried out on the powder at the base of the FIT® plaster technology in order to assess its radiance value in the precise wavelength range between 2 and 24 mm, which includes the range of the body's infrared radiation (16). The radiance of the powder within this wavelength range was also measured in temperature range between 25°C and 50°C. These preliminary tests show that the radiance of the powder AT5.05 is not only higher than the radiance of an infrared opaque medium, but also that it increases with the temperature increases and the maximum difference in emission is obtained within the wavelength range of approximately 9-12 mm (11 mm are considered the emission wavelength of the body's infrared radiation).

We completed this pilot study, whose objective was to study the application of FIT® plasters in the treatment of degenerative rotator cuff tendinopathy, on the basis of all that has been stated above.

Despite the very small sample of population, results are very encouraging. There was functional improvement (Constant Murley score) in 95% of the treated shoulders, while 80% reported a benefit in terms of pain relief. As could be expected, the best results in terms of increased functionality and less pain were obtained with the white plasters, the more potent type called "AT5.06".

Moreover patients showed satisfaction to use a device that is easy to position, water-resistant and in no way hinders shoulder joint movement, only needing replacement by medical staff after 7 days.

## Conclusions

In conclusion the use of FIT® plasters, as support to alleviate painful symptoms and improve function in rotator cuff tendinopathies, has so far been studied little in literature, but there are preliminary studies on devices with these properties that have shown a certain effectiveness, in stimulating activation of the endogenous analgesic action and in particular the absence of adverse events. On the base of the safety of this technology and promising results of our study, further studies should be encouraged to confirm its effectiveness, increasing the sample number and follow up so as to demonstrate definitely that the use of technologies, on which FIT® plasters is based, may be a valid alternative as "non-medicated pain relief".

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