



## Analgesic Effect of Textile Supports with Static Field Magnets in Patients with Osteoarticular Pain Syndrome: Results of a Randomized, Placebo Controlled, Double Blind Clinical Trial

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### Abstract

In a randomized, placebo controlled, double blind, longitudinal, clinical trial we investigated the analgesic effect of static field magneto therapy on pain perception and sleep quality in 48 patients with osteoarticular pain syndrome (35% with osteoporosis). The evaluation of pain perception and sleep quality was assessed at baseline, 2 and 4 months. Twenty-four patients were randomized to the active arm (textile supports with magnets) and 24 patients to the control arm (textile supports without magnets). During the study period, pain perception (visual rating scale) reduced in the active arm (baseline: median 55; 2 months: 40; 4 months: 35,  $P < 0.001$ ) whereas it remained unchanged in the control arm (baseline: 58; 2 months: 58; 4 months: 60). Similarly, pain perception (verbal rating scale) decreased in the active group (baseline: 3; 2 months: 2; 4 months: 2,  $P < 0.001$ ) while it remained stable in the control group (baseline: 3; 2 months: 3; 4 months: 3). The analysis of sleep quality data provided similar results. No side effects were observed during the study. The use of textile supports incorporating static field's magnets is associated with a significant reduction in the pain perception and with an improvement of sleep quality in patients with osteoarticular pain syndrome.

**Keywords:** Osteoarticular disease; Randomized clinical trial; Static field magneto therapy

### Introduction

Osteoarticular diseases are the most common and disabling chronic condition in the general population and the pain associated with these complications negatively impacts upon the quality of life, particularly in the elderly [1]. In a systematic review published in 2005 and focused on the effect of magnetic therapy on pain perception in patients with osteoarticular pain of various origin, 13 studies out of 21 (i.e. 62%) reported an analgesic effect of stable magnetic fields [2]. Furthermore, in a small clinical trial performed in a series of patients with post-polio syndrome and bone pain, the local application of magnetic fields associated with a 60% reduction in pain perception [3,4]. However, to date the analgesic effect of stable magnetic fields in osteoarticular diseases remains matter of debate. With this background in mind, we designed a randomized, placebo controlled, double-blind, longitudinal, clinical trial examining the additional effect, beyond and above that provided by traditional drugs treatment, of textile supports with stable field magnets on pain perception (primary endpoint) and sleep quality (secondary end point) in a cohort of patients with osteoarticular pain prospectively followed at the Orthopedics Unit of the "Bianchi - Melacrino-Morelli" Hospital of Reggio Calabria, Italy. As inclusion criteria we considered patients of both sexes, aged between 35 and 90 years, all affected by osteoarticular pain syndrome for at least 2 months. Pregnant women, patients with ischemic heart disease, pacemaker, epileptic syndromes and cancer were excluded from the study. Only for precautionary reasons, we also excluded patients with active bleeding or deep venous thrombosis. All patients who met the inclusion/exclusion criteria were consecutively enrolled in the out patients clinic of the same Orthopedics Unit between May and June 2013.

### Methods

The study was approved by the ethical committee of "Bianchi - Melacrino-Morelli" Hospital of Reggio Calabria, Italy [Prot. N. 1356, December 27<sup>th</sup>, 2012] and informed consent was obtained from each participant. The study design was a randomized, placebo controlled, double blind, longitudinal, clinical trial. The textile supports with and

without stable field magnets were produced by INNOVA-TEX s.r.l. Via dei Tintori, 40 - 59013 Montemurlo (PO). Magnets had a power of 1500-2000 Gauss. Textile supports (with and without magnets) used in the study included jacket, lumbar band, knee band, mattress cover (Figure 1), wrist band, and cervical band. All textile supports were assembled by using a coating fabric 100% polyester, neodymium magnet (only in patients in the active arm), padding of hollow fiber wadding (100% polyester) and supporting belt for magnets (100% polyester). The evaluation of pain perception (by two validated visual analogue and verbal rating scales) and sleep quality (by a questionnaire) was assessed at baseline, 2 and 4 months. We used a 4 month follow-up duration on the basis of a pilot study conducted in the Unit and including a group of 4 volunteers enrolled among the staff. The visual analogue scale (VAS) is a measurement tool used to assess the pain level across a continuous range of values. The amount of pain perceived by a patient ranges across a continuum, from none (0) to an extreme (100) perception of pain. From the patient's perspective this spectrum appears continuous - the perceived pain does not take discrete jumps, as a categorization of none, mild, moderate and severe would suggest. Operationally, a VAS is a horizontal line, 100 mm in length, anchored by words descriptors at each end. The patient marks on the line the point that he/she feels represents his/her pain perception. The VAS score is determined by measuring in millimeters from the left hand end of the line to the point that the patient marks [5,6]. The verbal scale of pain ranges from 0 to 5 (0=no pain; 1=mild pain; 2=moderate pain; 3=severe pain; 4=very

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severe pain; 5=worst possible pain) [6]. The quality of sleep was assessed by a 0-100 scale using the valid and reliable Richards-Campbell Sleep Questionnaire [7].

The study sample included 48 patients (age:  $56 \pm 13$  years; M: n=18; F: n=30) with osteoarticular diseases (35% were affected by osteoporosis): 24 patients (8 with osteoporosis) were randomized to the active arm (i.e. using textile supports with magnets) and another group of 24 patients (9 with osteoporosis) to the control arm (i.e. textile

	Active group (n=24)	Control group (n=24)
Age (years)	$57 \pm 14$	$56 \pm 13$
Body mass index (kg/m <sup>2</sup> )	$26 \pm 4$	$24 \pm 4$
Males/Females	12/12	6/18
Quality of sleep score	$69 \pm 10$	$68 \pm 12$
Visual rating scale (score of pain)	$58 \pm 12$	$59 \pm 12$
Verbal rating scale (score of pain)	$3.4 \pm 0.9$	$3.5 \pm 0.8$
Physical activity		
Inactive	19	19
Mild/moderate	4	4
Vigorous	1	1

Data are expressed as mean  $\pm$  standard deviation.

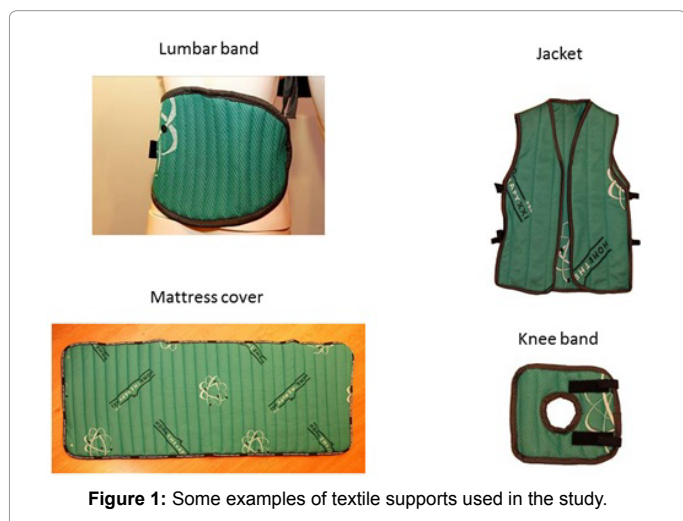
**Table 1:** Main clinical and demographic data in patients of the active and control arm.

	Active group (n=24)	Control group (n=24)	P
Cervical spine	16	16	0.59
Knee	4	3	
Lower back	1	0	
Wrist	0	1	
Shoulder	3	4	

**Table 2:** Anatomical location of pain.

	Active group (n=24)	Control group (n=24)
Jacket	6	4
Cervical band	2	1
Lumbar band	0	2
Knee band	4	3
Wrist band	0	1
Mattress cover	12	13

**Table 3:** Types of textile supports (with and without magnets) used in the study.



**Figure 1:** Some examples of textile supports used in the study.

supports without magnets). All enrolled patients were invited to wear textile supports for 2-8 hours/day for 4 months after enrollment. Textile supports with and without magnets were identical for manufacture and color and therefore indistinguishable between them. Patient recruitment took place in May 2013. The first analysis was carried out in July 2013 and the final analysis in the month of September 2013.

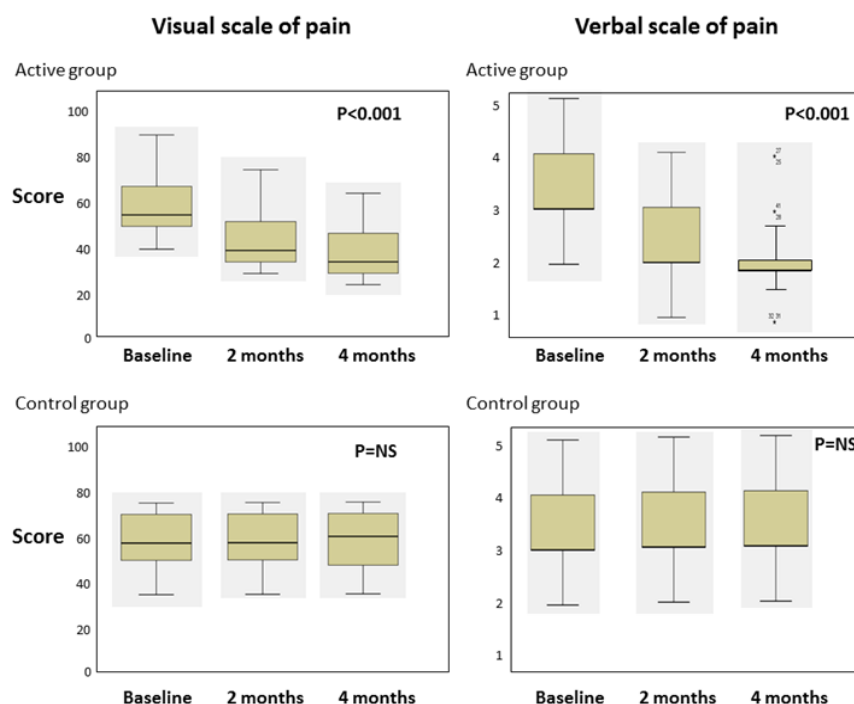
### Statistical analysis

Data are expressed as mean and standard deviation or as absolute frequency and percentage. Data are plotted by Box and Whisker plots reporting median, interquartile range, 2.5<sup>th</sup> and 97.5<sup>th</sup> percentile. The sample size was calculated by assuming a 25% reduction in pain perception in patients in the active group and a variation of 10 % in patients in the control group. With these assumptions and by considering an alpha error of 5% and a beta error of 20%, we calculated that by allocating 22 patients in the active group and 22 patients in the control group will achieve at least 80% power to detect as statistically significant ( $P < 0.05$ ) the expected difference between the two groups (25% versus 10%). To compensate for the loss of statistical power due to the potential drop out, the sample size was increased by 10%. Therefore a total of 48 patients (24 in the active group and 24 in the control group) were enrolled. Data analysis was performed by "intention to treat". Between groups comparisons were made by T-Test, Chi Square Test or ANOVA test. The potential confounding effect of gender on the study results was tested by multivariate linear regression analysis. All calculations were carried out by two commercially available software (NCSS 2004 and PASS. Statistical Systems, Kaysville, Utah, USA and SPSS for Windows, Version 9.01, Chicago, Illinois, USA).

### Results

At enrollment, patients in the active and the control groups did not differ as for demographic characteristics, perceived level of pain (visual and verbal rating scale) and quality of sleep (Table 1). One patient in the control group had a fracture in his medical history while none of enrolled patients had type II diabetes and severe cardiovascular disorders. At baseline, 19 patients in the active group (79%) occasionally were taking anti-inflammatory drugs, and a similar percentage (n =17, 71%) was observed in the control group. Seventeen patients (35%) were diagnosed to be affected by osteoporosis (8 allocated in the active group and 9 in the control group). The anatomical location of pain and the types of textile supports used in the study are listed in Tables 2 and 3.

During the study period, pain perception (visual analogue rating scale) reduced in the active arm (baseline: median 55; 2 months: median 40; 4 months: median 35,  $P < 0.001$ ) whereas it tended to increase in the control arm (baseline: 58; 2 months: 58; 4 months: 60) (Figure 2). Similarly, pain perception (verbal rating scale) decreased in the active group (baseline: 3; 2 months: 2; 4 months: 2,  $P < 0.001$ ) while it remained stable in the control group (baseline: 3; 2 months: 3; 4 months: 3) (Figure 2). We also compared the analgesic effect of static field magnets on pain perception between men and women (as assessed by visual and verbal rating scales) as well as on sleep quality and we found that such a beneficial effect did not differ between males and females indicating that the use of static field magnets is equally effective between genders. We also performed a multivariate linear regression analysis adjusting the study results for the potential confounding effect of gender and the difference in pain perception and sleep quality remained highly significant between patients in the active and the control arm (all  $P < 0.001$ ). In patients in the active arm, the pain reduction was paralleled by a marked improvement in the quality of sleep (baseline: 70; 2 months: 80; 4 months: 85,  $P < 0.001$ ) whereas



**Figure 2:** Pain perception in patients in the active and the control group across the follow-up period. Data are median, interquartile range, 2.5 and 97.5 percentiles. The P value in the figure represents the comparison of pain perception and quality of sleep throughout the three points in time, i.e. it compares the observed effect simultaneously among baseline, 2 months and 4 months assessments (ANOVA test). **NS**=Not significant.

such an effect was not observed in the control group (baseline: 70; 2 months: 70; 4 months: 70). At the study end, changes (4 months versus baseline) of performance indicators (pain perception and quality of sleep) were significantly better in patients in the active group than in those of the control group ( $P < 0.001$ ). No side effects related to the use of textile supports with magnets were observed during the study. No change in pharmacological treatment was scheduled throughout the trial. Between groups comparison at 4 months showed that the score of the pain perception reduced by 19 points ( $\Delta = -19$  points, 95% CI: from -16 to -12 points,  $P < 0.001$ ) according to visual scale and by 1.3 points according to the verbal scale ( $\Delta = -1.3$  points, 95% CI: from -1.8 to -0.8 points,  $P < 0.001$ ) in patients in the active group as compared to those in the control group. The quality of sleep increased in patients of the active group as compared to that of the control group ( $\Delta = +15$  points, 95% CI: from 10 to 20 points,  $P < 0.001$ ). In patients in the active group, the increase in sleep quality was directly related to the reduction of pain perception as evaluated by visual ( $r = 0.70$ ,  $P < 0.001$ ) and verbal ( $r = 0.71$ ,  $P < 0.001$ ) scales

## Discussion

The use of textile supports incorporating static field's magnets was associated with a significant reduction in pain perception and with an improvement in the quality of sleep in patients with osteoarticular pain syndrome. Our results are in keeping with those reported in a very recent double blind experimental study in mice [8] in which pain was elicited by intraperitoneal injection of 0.6% acetic acid. In this study [8], the authors investigated behavioral responses (such as writhing) of mice to pain with the help of a specially designed cage that partially protruded into static magnetic fields. Cognitive recognition of analgesia was evaluated by comparing writhing of mice when they were on the side of cage exposed to static magnetic fields and when they were on the

sham sides of the same cage. Comparison of writhing observed in the sham versus static magnetic fields side of the cage revealed that static magnetic fields exposure resulted in a significantly fewer writhing than sham (-73%,  $P < 0.03$ ) indicating an analgesic effect of static magnetic fields. These findings offer experimental support to our results in which pain perception importantly reduced in patients allocated to the active arm (i.e. in patients exposed to static magnetic fields). Indeed, in our study, the perception of pain (as assessed by visual scale) significantly reduced in the active group (from 55 to 35, -36%) and tended to increase in the control group (58 to 60, +3.4%) and this was also true when the perception of pain was quantified by the verbal scale (active group: -33%; control group: no change). The reduction in the intensity of pain perception in patients with textile supports with magnets could be explained by the anti-inflammatory action of magnets. This hypothesis is supported by the notion that in inflamed tissues (at interstitial fluid level), inflammation leads to tissue acidity with  $H^+$  ions prevailing on those  $OH^-$ . The use of magnets, energizing  $OH^-$  ions, could exert a buffering effect on acidity tissue and thus playing an analgesic and anti-edema effect. Unfortunately, the study protocol of our pragmatic trial did not contemplate the measurement of anti-inflammatory biomarkers and for this reason future studies are needed to fully clarify the biological basis of our findings. Another possible explanation of the analgesic effect we observed in our study could be explained by a direct action of the magnetic fields on the nerve fibers "C" which are known to be responsible for the transmission of pain, as suggested by an experimental study in vitro [9]. An interesting observation emerged in our study was that the reduction of pain perception in the active group was paralleled by a significant improvement in the sleep quality which increased in the active arm (from 70 to 85, +21%) and remained unchanged in the control arm. The beneficial effect of the magnetic fields on the quality of sleep may be due to the recovery, driven by

magnetic fields, of the communicability between the central nervous system and activities related to metabolism, resulting in a decreased peripheral responsiveness and excitability [10]. The results of our study contrast with those of a clinical trial of Mészáros S. et al. conducted in postmenopausal women with osteoporosis, osteoarticular pain and spinal deformity [11]. In this study [11], the authors did not observe any effect of the static field's magnets on pain perception. However, the absence of a significant effect of magneto therapy in the study of Mészáros S. et al. could be explained by the extremely small number of patients enrolled (only 10, including 5 in the active arm and 5 in the control arm) [11]. In another paper by Brown et al. [12,13], the treatment with static field's magnets significantly reduced the pain related to chronic pelvic pain in 32 women with this disorder.

Our study has strengths and limitations. Strengths are the rigorous study design (randomized, placebo controlled, double-blind, longitudinal, clinical trial) and the fact that it focuses on the pain perceived by the patient. The main limitations are 1) that the study protocol did not schedule a bio-bank creation; 2) the fact that we did not measure the circulating levels of inflammatory markers.

In conclusion, the use of textile supports incorporating static field's magnets was associated with a significant reduction in the pain perception and with an improvement of sleep quality in patients with osteoarticular pain syndrome. Further randomized clinical trials are needed to confirm the external validity of our findings.

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