

# **Cuba Study, P.E.M.F., in the treatment of lumbar disc herniation pain utilizing the Magna Wave Maxx device.**

**Borroto Vivian (1)**

**Rodriguez-Jimenez Tapia Antonio (2)**

**Cesar Morales Villalobos Martinez (1,3)**

**Aguilera Yolanda<sup>1</sup> (1,3)**

**Roosevelt (4)**

**Cámbara Peña González Yoandris (5)**

**1. Institute of Neurology and Neurosurgery,  
Calle 29 esq. D, Vedado. Havana Cuba.**

**2. Institute Hope4cancer, Tijuana, Mexico**

**3. Address Disability Qualification CCSS, Costa Rica.**

**4. University Polyclinic, Rampa, Vedado, Havana, Cuba.**

**5. Faculty of Physics of the University of Havana, Vedado,  
Havana, Cuba**

**Abstract:** In order to evaluate the effect of treatment with pulsed electromagnetic fields in the lumbar herniated disc pain, a randomized, prospective, longitudinal study was conducted in 160 patients; with clinical and radiological diagnosis of uncomplicated herniated disc in the lumbar spine at L4-L5 and L5-S1 with more than 6 weeks of evolution with radicular pain type; who attended the consultation of Natural and Traditional Medicine Department of Physical Medicine and Rehabilitation Institute of Neurology and Neurosurgery of Cuba, in the period from January to June 2015. The sample was divided into two groups of 80 patients each:

**Group 1 Control:** received treatment with analgesics, anti-inflammatories and muscle relaxants (Paracetamol. 500 mg 1 tablet every 6 hours for five days, Ibuprofen 400 mg 1 tablet every 8 hours for ten days and Metocarbamol.. 750 mg 2 tablets every 6 hours for ten days).

**Group 2:** 15 sessions of pulsed electromagnetic fields in the lower back level hernia injury on a daily basis were applied. Both groups were assessed before, after, and three months after completion of treatment in the following variables: the degree of improvement in pain by an analog scale of pain and functional capacity by administering the questionnaire OSWESTRY Index, which provides information as to how pain affects the ability to manage in everyday life. When applying an analysis of covariance to compare the means (ANOVA) it was found that there is no difference between the groups before treatment behaved evenly across the two groups.

It was obtained as a result that the group treated with electromagnetic fields group Pulsed was statistically superior to the Control Group treated with NSAIDs, analgesics and muscle relaxants regarding the capacity index ( $p = 0.000$ ) and pain intensity assessed with the scale EVA evaluation of pain ( $p = 0.000$ ). No adverse events were reported in the group treated with pulsed electromagnetic fields, the group treated with anti-inflammatory non-steroidal analgesics and muscle relaxants gastrointestinal adverse reactions occurred. We conclude that treatment with pulsed electromagnetic fields in the treatment of pain uncomplicated herniated lumbar disc with more than six weeks of evolution is a safe and effective method.

**Keywords:** disc herniation, lumbar pain, pulsed electromagnetic fields.

## **INTRODUCTION**

**Low back pain is one of the problems most common and important clinical, social, economic and public health that affect the global human population**

**1. About 70% of adults suffer from low back pain at some point in their life varying degrees of severity of the symptom. Also, from 1.6% to 43% of these patients, this pain is associated with sciatic symptoms.**

**2 In the United States, the incidence of this condition is pain ratings of 15% to 45%, with a prevalence of 30% in 1. 5% to 15% of cases, the source of the pain is related to degenerative lesions and intervertebral disc disease. The natural history of herniation of intervertebral disc is favorable; the improvement of symptoms is the norm, and most episodes have spontaneously improved after conservative therapy resolution. However, studies have shown that this pain does not resolve with drug treatment or rehabilitation and is maintained for long periods of time (at least 12 months) by 37% to 54% of patients. As need for surgery arises, 70% of operated patients have residual lumbar pain, of them 23% experienced not severe but constant pain, 45% with more severe pain, 35% will remain in permanent treatment, 14% will be disabled permanently and 17% will undergo a second surgery. (3,4)**

**Electromagnetic fields are most commonly used for diagnostics and treatments in medicine. The application of P.E.M.F. started in the late '40s in Japan, but not fully recognized until 1979 when the Food and Drug Administration (FDA) supported its use in the United States to stimulate bone repair in non-union fractures. A decade later, the FDA approved its use for the treatment of pain and edema in soft tissues superficial. (5)**

The National Institutes of Health (NIH) of the USA accept treatment with electromagnetic fields for the following indications: bone and chronic tendon injury repair, nerve stimulation, wound healing and varicose ulcers, osteoarthritis, electronic acupuncture, tissue regeneration stimulation system and immune modulations neuroendocrinology.(6) Other authors have expanded this list by adding: pain management, trauma, and injuries, reducing inflammation and improving blood circulation, fibromyalgia, infectious processes (antimicrobial effects), specific treatment of malaria, stress reduction, correction of neurological disorders, increased physical energy and athletic performance, etcétera.(7) Different studies reported that PEMF therapy reduced pain and disability in patients with back pain.(8) and beneficial effects in the treatment of patients with radiculopathy lumbar pain and lumbar discogenic pain.(9)

#### **ETHICAL CONSIDERATIONS GENERAL RESEARCH:**

The study was reviewed and approved by an ethics committee, complied with the provisions of the Helsinki Declaration, the latest version corresponding to the General Assembly in Edinburgh, Scotland, October 2000. For the study patients were asked in writing and orally by the researcher as prescribed in the Guidelines for Good Clinical Practice, after being informed about what will take place during the investigation, it was guaranteed not to disclose personal data of patients reporting or publishing the results consent this.

Medical personnel who participated in the study have clinical experience in the management of ozone therapy and were trained in the management and evaluation of patients and treatment application. Information regarding the identity of the study subjects was treated confidentially, using codes to identify them, this was handled only by trained personnel who participated in the research.

## **MATERIAL AND METHODS**

The study group consisted of patients diagnosed with lumbar disc herniation at L4-L5 and L5-S1 with clear clinical neurological correspondence with imaging study of high resolution (NMR lumbosacral spine) in chronic subacute stage or They attended the consultation of Natural and Traditional Medicine Department of Physical Medicine and Rehabilitation Institute of Neurology and Neurosurgery of Cuba, in the period from January to June 2015.

The sample was divided into two groups of 80 patients each:

**Group 1 Control:** Received treatment with analgesics, anti-inflammatories and muscle relaxants, Paracetamol: 500 mg. 1 tablet every 6 hours for five days, Ibuprofen 400 mg. 1 tablet every 8 hours for ten days, Methocarbamol: 750 mg. 2 tablets every 6 hours for ten days, then held maintenance dose one tablet every 8 or 12 hours for ten days.

**Group 2** received therapy with pulsed electromagnetic fields. They were administered 15 sessions of magneto-therapy in the lumbar region at the site of the herniated disc three times a week. With the patient sitting, the coil was oriented in the painful area and was stimulated for three minutes, rested for five minutes and repeated for three minutes at 1000 Gauss. PEMF-100 Magna Wave US equipment was utilized for the study. All groups were assessed before and after treatment and three months after the end of the same, the variables studied were: the degree of clinical improvement in pain assessed by visual analog scale and the degree of disability assessed with the questionnaire Oswestry.

Inclusion criteria were patients with a clinical and radiological diagnosis of uncomplicated lumbar disc herniation at L4-L5, L5-S1, aged 15 years, of any kind, with a pain intensity scale EVA 7 10 considered intense and very intense consenting to be included in the study.

Exclusion criteria considered were that patients were aged below 15 years, who did not give his consent to be included in the study, or those with mental or neurological deficits, as well as patients with a diagnosis of herniated discs complicated, extruded or migrated, narrow canal with spinal cord compression and those with electronic implants.

Exit criteria were defined as a voluntary departure of the study, no more than two consecutive sessions of treatment and those with irregular treatment.

In the interrogation and physical examination data of interest as age, sex, predisposing factors, duration, previous treatment and adverse reactions were obtained, among others.

As a measuring instrument visual analog pain scale (VAS) 10 was used as a subjective method of measuring pain. It consists of a line of values from 0 through 10. The leading 0 means no pain and ten on the far right, maximum tolerable pain between the two extremes there are intermediate values from 1 to 9 in increasing order. The patient once the procedure has scored in each session, the intensity of pain on the scale explained. 0 1 2 3 4 5 6 7 8 9 10, an evaluation was also performed considering the following categories 0: no pain; 1-2: Very mild; 3-4: Mild; 5-6: Moderate; 7-8: Intense; 9-10: Very intense.

The evaluation of the functionality was performed by administering the questionnaire Oswestry quoted by Shabbat, et al, (11) it is a recognized rating scale and internationally validated. It has ten areas to be evaluated with five items each, must take into account that each number is equal to the score, Example 1 = 1 point. Then you must add the results of each answer and multiply the result by 2, so the result is obtained as a percentage of disability, considering 0-20% Minimum disability, moderate disability 21 -40% 41 -60% severe disability, 61 -80% incapacitated patient and 81 -100% patient bedridden). The evaluation criteria to measure the effectiveness of treatment for pain as EVA scale in relation to the first

assessment were as follows: Good: If you went from intense pain to mild or severe to mild. Regular: if it went from very intense to moderate or severe to mild. Bad: if there was no change or passed to a higher intensity, also the initial and final averages were considered on this scale.

The evaluation criteria for functionality evaluated by administering the questionnaire of Oswestry in relation to the first evaluation were as follows, a minimum difference of 15 points between pre- and post-treatment assessments as an indication of clinical change was considered, it was considered very good if dropped more than 45 points, well yes it decreased between 31 and 45 points. Regular: if decreased between 15 and 30 points. Bad: if fell less than 15 points. The sample consisted of sciatica patients persistent after six weeks of evolution, in which a herniated disc magnetic resonance in the segments L4-L5, L5-S1 and present with severe and very severe pain, corresponding was identified values 7 to 10 according to the scale of EVA. Statistical processing.

A statistical analysis was performed on a scale of response of three values by ordinal logistic regression method, using Confidence Interval 95% for a proportion considering the improved and unimproved (binomial) in the two groups. An analysis of covariance to compare the means (ANOVA) between groups and before and after treatment was performed. The incidence of adverse events in the groups was also evaluated during the study, causality criteria were as rated by Uppsala Monitoring Center(12), and intensity according to the criteria of Claudio Naranjo. (13)

## **RESULTS**

In the population studied a sample of 160 patients, the age range was 39 years minimum and 70 years maximum and an average of 55 years, predominant age range between 51 and 60 years. (Table 1) Regarding gender 69 patients (43.1%) were female and 91 (56.9%) males. (Table 2). Regarding gender and age by treatment group, behaved evenly in the two groups, no

discrepancy was detected with the assumption of risk ratios ( $p > 0.05$ ), so it was considered appropriate any conclusion drawn from the fit of the regression Cox.

When making an assessment of pain intensity by visual analog scale and Disability Index applying the questionnaire, Oswestry found that before treatment there was no statistically significant difference between the two groups ( $p = 0.909$ ) and ( $p = 0.750$ ) respectively. The significant difference after treatment ( $p = 0.000$ ) and the three months ended the same ( $p = 0.000$ ) in favor of the PEMF group. (Tables 3 and 4)

Upon comparing the mean values of the scale of EVA it was found that in the PEMF treated group after treatment was reduced 5.7 scale values EVA and 7 within three months of completion of treatment, while in the control group was reached only decrease 2, 2 values after treatment and 2, 7 within three months of completion of treatment, was obtained at the end. (Table 5)

In the analysis performed related to capacity index Oswestry considering the amount of points that was reduced after treatment and three months ended the same as in the PEMF group was obtained that 82% of decreased between 31 and 45 points, and 17, 2% decreased between 15 and 30 points, while control 17 group, 2% decreased between 31 and 45 points, and 62% fell between 15 and 30 points, to repeat this analysis at three months treatment was found that in the PEMF group was reduced more than 45 points and 36.2% between 31 and 45 points on 63.7% much higher than what was achieved in the control group only decreased between 15 and 30 points and 70% decreased less than 15 points. (Table 6)



Table 7 lists adverse events that occurred in this study; the groups treated with PEMF no reported adverse event was shown. In the group treated with paracetamol, ibuprofen and Methocarbamol Group Five adverse events related to the digestive system were presented, two patients had nausea and three epigastric pain, all causality possible because it occurred at a plausible time in connection with the administration of drugs, being taking three drugs can not really identify which of them produced or undesirable effect or whether it was the combination thereof, but it may be for ibuprofen because clinical response was adequate transient suppression same with rapid recovery.

## **DISCUSSION**

The origin of root damage is not directly due to the physical compression exerted by disc herniation, but other collateral factors such as: the stenosis foramina by fibrosis, protrusion of joint covers, local irritation by fissures and fenestrations annulus fibrosus that allow constituents toxic components of the nucleus pulposus initiate an inflammatory process by chemical irritation, such situations could not be solved by surgical approaches with a display which can provide a microscope and even less likely with the simple display surgeon unassisted technique microscope, unable to visualize bends, breaks or foramina media. Thus, lumbar disc herniation, the term has evolved to lumbar disc disease or lumbar disc disease: that is broader and includes an additional number of pathological situations related medical herniation.(14)

It has been found that pulsed electromagnetic fields influence cell behavior by inducing changes in cell membrane potential and increased tissue oxygenation, activating cell regeneration, also because it increases the calcium transport stimulating repair and growth of cartilage and at the same time it reduces pain and increases matrix synthesis disk intervertebral.(8)

Every cell in the body functions as a transmitter and a receiver of electromagnetic information and are precisely those frequencies which correspond to precede or biochemical functions. Normal cells oscillate with different frequencies to diseased cells, therefore, the biological activity is the product of interaction energy. The cellular response to electromagnetic radiation is known as inductive coupling. Electromagnetic forces act intracellularly producing biochemical responses characterized by mobilization of electrolyte through the cell membrane, excretion of toxic products, protein synthesis, stimulation of cellular metabolism and high link generation energy.(15)

The magnetic fields produce biochemical, cellular, tissue and systemic effects, initially diversion of electrically charged particles in movement occurs, producing induced intra- and extracellular currents generating a stimulus of cellular metabolism, with normalization of membrane potential altered that favors a direct stimulation of cell tropism, manifested by stimulation in the synthesis of the energy required by the body for its function at the cellular level thus benefiting cell division, protein synthesis and the production of prostaglandins that confers it a ant-inflammation effect.(16)

If we consider that magnet therapy has different biological effects at the biochemical level, sub-cellular, cellular and tissue, as well as evaluating the therapeutic effects derived from these biological effects, then you can get an idea of all processes in the which can be influenced by magnetic fields. The good results obtained in this study correspond to those found in the literature reviewed which are reported to the application of PEMF therapy is effective in treating chronic back pain (9) and in patients with lumbar radiculopathy and Lumbar Discogenic Pain, (17) this may be to pulsed electromagnetic fields influence the behavior of the cell, inducing changes in cell membrane potential, increasing tissue oxygenation, activating cell regeneration, also because it increases the calcium transport stimulating repair and growth of cartilage and at the same time

reduces pain. Regarding the incidence of adverse events in this study were not reported in patients treated with PEMF, while patients in the control group in which within the drugs used were ibuprofen includes, digestive system disorders were presented, which coincides with the results of previous studies. (18)

## **CONCLUSIONS**

After all the above it can be concluded that the protocol used in this study treatment with PEMF applied to patients with a clinical and radiological diagnosis of herniated disc in the lumbar spine at L4-L5 and L5-S1con more than six weeks of evolution with radicular pain type, is safe and effective.

## **Citation**

1. Freynhagen R BR, Gockel U, Tölle TR.painDETECT: A new screening questionnaire to identify identity neuropathic components in Patients with back pain. Curr Med Res Opin 2006; 22: 1911-1920.
2. Kaki A M E-YAZ, neuropathic pain Youseif E. Identifying Patients With chronic Among low-back pain: use of the Leeds assessment of neuropathic symptoms and signs pain scale. Reg Anesth Pain Med 2005; 30: 422.e1-422.e9.
3. Rodríguez-García J, Sanchez-Gastaldo A, T. Campos Ibáñez-related factors botched surgery for lumbar disc herniation. Neurosurgery 2005; 16: 507-17.
4. Van Buyten JP, Linderth B. The failed back surgery syndrome: definition and therapeutic algorithms - anupdate.Eur J Pain 2010; (Suppl. 4): 273-86.
5. Appelt C. Pulsed Electromagnetic Field Therapy (PEMF): New Perspectives in Therapy. Anti-Aging Medical News. Winter 2006: 2-4
6. Rubik B, Becker RO, Flower RG, Hazlewood CF, Liboff AR, Walleczek bioelectromagnetics J. Applications in medicine. Study Panel of the National Institutes of Health (NIH). [www.sld.cu/galerias/pdf/sitios/rehabilitacion-fis/biomagnetismo.pdf](http://www.sld.cu/galerias/pdf/sitios/rehabilitacion-fis/biomagnetismo.pdf)

7. Markov MS. Expanding Use of Pulsed Electromagnetic Field Therapies. *ElecBioMed* 2007; 26: 257-274.
8. Okada M, Kim JH, Hutton WC, Yoon ST. Upregulation of intervertebral disc-cell matrix synthesis by pulsed electromagnetic field is mediated by bone morphogenetic proteins. *J Spinal Disord Tech* 2013 May; 26 (3):. 167-73
9. Lee PB, Kim YC, Lim YJ, CJ Lee, Choi SS, Park SH, Lee JG, Lee SC. Efficacy of pulsed electromagnetic therapy for chronic lower back pain: a randomized, double-blind, placebo-controlled study. *J Int Med Res* 2006 Mar-Apr; 34 (2):. 160-7.
10. Hjermstad M, et al. Review Article Studies Comparing Numerical Rating Scales, Verbal Rating Scales, and Visual Analogue Scales for Assessment of Pain Intensity in Adults: A Systematic Literature Review. *Journal of Pain and Symptom Management*. 2011; 41 (6): 1073-1094.
11. Shabbat SH, Miller, JE Block, R. Gepstein Minimally invasive lumbar spinal stenosis treatment of interspinous With novel spacer. *Clinical Interventions in Aging*. [Internet]. Sept 2011 [cited 16 November 2012]; 6: [approx. 6 p.]. Available in: <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3180519/pdf/cia-6-227.pdf>.
12. World Health Organization. The Uppsala Monitoring Centre. 2002. Safety monitoring of Medicinal products. Guidelines for Setting and Running to Pharmacovigilance Centre Uppsala. Sweden, 23 (3): 3.
13. Claudio Naranjo, Usoa EB. Adverse drug reactions. *Methods of clinical pharmacology. Development Programme PAHO health services*. WHO Regional Office; 1992.p.331.
14. Francisco N et al., Ozone Therapy as a Treatment for Low Back Pain Herniated Disc to  
Secondary: A Systematic Review and Meta-analysis of Randomized Controlled Trials *Pain Physician* 2012; 15: E115-E129
15. Raghunath J, Salacinski HJ, Sales KM, Butler PE, Seifalian

AM. Advancing cartilage tissue engineering: The application of stem cell technology. Curr Opin Biotechnol. 2005; 16: 503-9. 16. Krouham AO et al. Magnetism in Medicine: An Ondamed Med (Mex) 2011; 56 (2): 91-98 17. Omar AS, Awadalla MA, MA El-Latif. Evaluation of pulsed electromagnetic field therapy in the treatment of patients with lumbar radiculopathy discogenic. Int J Rheum Dis. 2012 October; 15 (5): e101-8. doi: 10.1111 / j.1756-185X.2012.01745.x.

18. Borroto, Vivian. (2016). Pulsed electromagnetic fields and ozone in the treatment of knee osteoarthritis in the elderly. Spanish Journal of Ozone Therapy. Vol. 6, No. 1, pp 27-39

## ATTACHMENTS

Table 1: Descriptive by age group and treatment group in the total sample.

Age range PEMF Group Group CONTROL entire sample

Patients% Patients% Patients%

30 to 40 years 3 3.7 3 3.7 6 3.7

41 to 50 years 20 25 21 26.3 41 25.7

51 to 60 years 44 55 44 55 88 55

61 to 70 years 13 16.3 12 15 25 15.6

Total 80 100% 80 100% 160 100%

160 n = 80 per group. Source: History

Table 2: Descriptions of the genus CONTROL GROUP

Frequency Percent

Valid F 35 43.75

M 46 57.5

Total 80 100.0

GROUP PEMF Frequency Percent

Valid F 34 42.5

M 45 56.25

Total 80 100.0

ALL SHOWS Frequency Percent

Valid F 69 43.125

M 91 56,875

Total 160 100.0

Legend: F = female M = male

Frequency = number of patients

160 n = 80 per group. Source: History

TABLE 3: Homogeneity of the groups before and after three months of treatment by administering the questionnaire EVA  
EVA ANOVAa

Before Sum of Squares df Mean Square F Sig.

Among groups .006 1 .006 .013 .909

75,338 groups in 158 .477

Total 75 344 159

After Sum of squares df Mean Square F Sig.

Among groups 286,225 1 286,225 457,381 .000

98,875 groups in 158 .626

Total 385 100 159

Three months Sum of Squares df Mean Square F Sig.

Among groups 286,225 1 286,225 457,381 .000

98,875 groups in 158 .626 Total 385 100 159 Legend:

Sign .: statistical significance p value.

F: the ratio between two different estimators of the population variance, variation Inter-groups, and intra-group variation df: degrees of freedom.

TABLE 4: Homogeneity of the groups before and after three months of treatment by administering the questionnaire OSWESTRY

See all the latest ANOVAa

Before Sum of Squares df Mean Square F Sig.

Among groups 5,625 1 5,625 .101 .750

8756.350 158 groups within 55,420

Total 8761.975 159

After Sum of Squares df Mean Square F Sig.

Between 1 34105.600 34105.600 groups .000 493 542

Within groups 10918.400 69 104 158

Total 45024.000 159

Three months Sum of Squares df Mean Square F Sig.

Between 1 55204.900 55204.900 groups .000 905 609  
 Within groups 9631.500 60 959 158 Total 64836.400 159 Legend:  
 Sign .: statistical significance p value.

F: the ratio between two different estimators of the population variance, variation Inter-groups, and intra-group variation df: degrees of freedom.

Table 5: Mean values on the scale of EVA  
 groups EVA

EVA before

Differences after before/after EVA

Differences three months

Before / three months

CONTROL 8.8 6.5 2.3 6.2 2.6

PEMF 8.8 3.8 5 3.5 5.3

Differences 0 2.7 2.7 2.7 2.7

Source: History of a primary n = 160 80 (per group)

EVA before: average value before treatment

EVA later: average value after treatment

EVA three months: average value at three months after treatment

0: no pain; 1-2: Very mild; 3-4: Mild; 5-6: Moderate; 7-8: Intense; 9-10: Very intense.

Table 6: Response according to the Oswestry disability index and after three months of treatment in both groups.

See all the latest response by

A group PEMF After three months

Patients% Patients% Very good 0 0 29 36.25 good 66 82.5 51 63.75

Regular 14 17.5 0 0 bad 0 0 0 0

See all the latest response by

A control group after three months

Patients% Patients% Very good 0 0 0 0 good 0 0 0 0 Regular 18 22.5 24 30

62 77.5 56 70 poor

Legend: very good if dropped more than 45 points in the

**Oswestry Disability Index (See all the latest), good yes decreased between 31 and 45 points. Regular: if decreased between 15 and 30 points. Poor: if fell less than 15 points n = 160 (80 per group)**

**Table 7: Incidence of adverse events per treatment group.**

**Adverse events CONTROL PEMF Group Group**

**Epigastralgia 3 0**

**Nausea 2 0**

**© Magna Wave 2016**