

# Bio-Directed Joint Research Study

A recent research study was done on Nikken's Bio-Directed Joint formula by independent research groups outside of Nikken. It showed that the joint product is effective on over 96% of the people who take it. We now have clinical proof...

## CLINIAL TRIAL SUMMARY:

A randomized double blind Phase III placebo study was done on 93 sufferers of osteo-arthritis, who have been diagnosed with OA for an average of 6 years. 52 men and 41 women, aged 37-77 over a period of 60 day treatment period w/ Cetyl Meristolate (CMC) which s the major active in Nikken's joint product.

Half of the population got the CM complex (6 CMC capsules per day) Half got the placebo (6 vegetable oil capsules per day) (the capsules were indistinguishable)

Total of 153 affected joints in this population.  
139 had painful swelling.  
100 had stiffness associated with degrees of deformity.  
25 included some soft tissue involvement.

Clinical assessments were conducted in 3 visits over the 60 day period - Day 0, Day 30, and Day 60.

Three major areas of investigation:

Pain  
Range of motion  
Physical activity indicators

Range of motion (physician assessment):

Participants lay face down and flex leg to determine maximum angle of flexion using goniometers (sp?) Also questionnaires: completed at each visit - Lequesne Indices baseline)

## **Range of Motion Results:**

Day 0:  
CMC - 86 degrees  
Placebo - 82 degrees

Day 30:  
CMC - 93 degrees  
Placebo - 84 degrees

Day 60:  
CMC - 96 degrees  
Placebo - 83 degrees

Walking Capabilities:

Maximum distance you can walk in 15 minutes.

Day 0:  
CMC - 700 feet

Placebo - 700 feet

Day 60:

CMC - 2300 feet

Placebo - 700 feet

Walking Up and Down Stairs:

Walking Upstairs -

CMC - 35% improvement

Placebo - 12% improvement

Walking Downstairs -

CMC - 43% improvement

Placebo - 11% improvement

Knee Bending:

More than 2-fold improvement

Day 30 -

CMC - 17% improvement

Placebo - 7% improvement

Day 60 -

CMC - 23% improvement

Placebo - 12% improvement

## Rheumatism Research Studies

A double-blind controlled trial of 64 individuals with rheumatoid arthritis of the knee compared the effects of strong alternating polarity magnets (See How to Use Magnet Therapy for definition) with a deliberately weak unipolar magnet.<sup>36</sup> Researchers used the weakened magnet as a control group so that participants wouldn't find it easy to break the blind by testing the magnetism of their treatment.

Patients were assessed daily for one week. After one week of therapy, 68% of the participants using the strong magnets (the "treatment group") reported relief, as compared to 27% in the control group, and this difference was statistically significant. Four other measurements of symptom severity showed greater benefits in the treatment group than in the control group, but in only two of these were the differences statistically significant. Treatment did not alter results of blood tests for inflammation severity, nor did it change physician's assessment of joint tenderness, swelling or range of motion.

This study suggests that magnet therapy may reduce the pain of rheumatoid arthritis without altering actual inflammation. However, the mixture of statistically significant and insignificant results indicates that a larger trial is necessary to factor out "statistical noise."

From: <http://www.tnp.com/encyclopedia/therapy/1/5/>

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From: <http://www.cogreslab.demon.co.uk/Magnetsmed.htm>

The disease is believed to be caused by an infection that prompts the immune system to form damaging aggregates of antigen and antibody. Treatment is confined to control of inflammation and the relief of pain by bedrest, splintage, physiotherapy, and anti-inflammatory or pain killing drugs.

Several studies on this disorder report beneficial effects with pulsed magnetic fields in combination with conventional management (Kocian et al., 1985a, 1985b; Jezek, 1990). In a large study of cervical osteochondritis Detlavs (1987) applied static magnetic fields (100-400 gauss, 15-20 minutes duration, 10-20 treatments) to 425 patients, of whom 138 were male. The results were a significant improvement in arterial tonus and venous tonation as measured by rheography, in some patients after 3-6 exposures and in all by the end of treatment.

An earlier study on patients with rheumatoid arthritis (Aryshenskaya, 1977) used a static magnetic field (150-350 gauss, 10 minutes, 10-20 exposures) reported that patients in stages 1 and 2 responded well, not only clinically, but also as measured by laboratory parameters such as % albumin, gamma globulin and fibrinogen (gm/l). In gamma globulins a decrease of 24% was observed.

## **Sexual Disorders Research Studies**

[http://www.garynull.com/Documents/magnets.htm#PEER-REVIEWED SCIENTIFIC STUDIES](http://www.garynull.com/Documents/magnets.htm#PEER-REVIEWED%20SCIENTIFIC%20STUDIES)

Results of this placebo-controlled study showed that magnetotherapy exhibited beneficial effects with respect to cavernous blood flow in male patients suffering from sexual problems.<sup>280</sup>

This study examined the effects of a combination pulsing magnetic field (PMF)/vacuum therapy in the treatment of impotence. Vacuum therapy consisted of the penis being placed into a hermetic cylinder with a negative pressure of 180-260 mmHg for 10-12 minutes per exposure for a total of 12-15 exposures. PMF therapy consisted of the same length and number of exposures, with 6 Hz, 30 mT being applied to the penile area at the same time as vacuum therapy. Results showed that, following the combination therapy, sexual function was restored in about 71 percent of patients, was improved in 17 percent, and did not change in 17 percent. For those patients receiving vacuum therapy only, the numbers were 51, 24, and 24 percent, respectively.<sup>281</sup>

This double-blind, placebo-controlled study examined the effects of weak magnetic fields in men suffering from various sexual disorders, including decreased erection and premature ejaculation. The three different magnetic stimulators used included the "Biopotenzor," "Eros," and "Bioskan-1" devices. All patients wore one of the three devices for a 3-week period. Results showed full restoration of sexual function in 38 percent of patients in the Biopotenzor group, 31 percent in the Eros group, 36 percent in the Bioskan-1 group, and in just 15 percent of the controls. Improvements in sexual function were seen among 42 percent, 39 percent, 47 percent, and 18 percent, respectively.<sup>282</sup>

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## **Sleep Disorders Research Studies**

[http://www.garynull.com/Documents/magnets.htm#PEER-REVIEWED SCIENTIFIC STUDIES](http://www.garynull.com/Documents/magnets.htm#PEER-REVIEWED%20SCIENTIFIC%20STUDIES)

Results of this double-blind, placebo-controlled study indicated that low-energy-emission therapy significantly improved sleeping patterns among patients suffering from chronic psychophysiological insomnia. Therapy was administered 3 times per week, always in late afternoon and for 20 minutes, over a period of 4 weeks.<sup>284</sup>

This double-blind, placebo-controlled study examined the effects of low-energy emission therapy (27 MHz amplitude-modulated electromagnetic fields) in patients suffering from insomnia. Treatment consisted of 3 exposures per week over a 4-week period. Results showed significant increases in total sleep time among patients in the treatment group relative to controls.<sup>285</sup>

This review article notes that studies have found low-energy emission therapy to be effective in the treatment of chronic insomnia, and suggests that it may also be of value for patients suffering from generalized anxiety disorders.<sup>286</sup>

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# Static Magnetic Field Therapy for Symptomatic Diabetic Neuropathy: A Randomized, Double-Blind, Placebo-Controlled Trial

Michael I. Weintraub, MD, FACP, FAAN, Gil I. Wolfe, MD, Richard A. Barohn, MD, Steven P. Cole, PhD, Gareth J. Parry, MD, Ghazala Hayat, MD, Jeffrey A. Cohen, MD, Jeffrey C. Page, DPM, Mark B. Bromberg, MD, Sherwyn L. Schwartz, MD, and the Magnetic Research Group

**ABSTRACT.** Weintraub MI, Wolfe GI, Barohn RA, Cole SP, Parry GJ, Hayat G, Cohen JA, Page JC, Bromberg MB, Schwartz SL, and the Magnetic Research Group. Static magnetic field therapy for symptomatic diabetic neuropathy: a randomized, double-blind, placebo-controlled trial. *Arch Phys Med Rehabil* 2003;84:736-46.

**Objective:** To determine if constant wearing of multipolar, static magnetic (450G) shoe insoles can reduce neuropathic pain and quality of life (QOL) scores in symptomatic diabetic peripheral neuropathy (DPN).

**Design:** Randomized, placebo-control, parallel study.

**Setting:** Forty-eight centers in 27 states.

**Participants:** Three hundred seventy-five subjects with DPN stage II or III were randomly assigned to wear constantly magnetized insoles for 4 months; the placebo group wore similar, unmagnetized device.

**Intervention:** Nerve conduction and/or quantified sensory testing were performed serially.

**Main Outcome Measures:** Daily visual analog scale scores for numbness or tingling and burning and QOL issues were tabulated over 4 months. Secondary measures included nerve conduction changes, role of placebo, and safety issues. Analysis of variance (ANOVA), analysis of covariance (ANCOVA), and chi-square analysis were performed.

**Results:** There were statistically significant reductions during the third and fourth months in burning (mean change for magnet treatment,  $-12\%$ ; for sham,  $-3\%$ ;  $P_{.05}$ , ANCOVA), numbness and tingling (magnet,  $-10\%$ ; sham,  $-1\%$ ;  $P_{.05}$ , ANCOVA), and exercise-induced foot pain (magnet,  $-12\%$ ; sham,  $-4\%$ ;  $P_{.05}$ , ANCOVA). For a subset of patients with baseline severe pain, statistically significant reductions occurred from baseline through the fourth month in numbness and tingling (magnet,  $-32\%$ ; sham,  $-14\%$ ;  $P_{.01}$ , ANOVA) and foot pain (magnet,  $-41\%$ ; sham,  $-21\%$ ;  $P_{.01}$ , ANOVA).

**Conclusions:** Static magnetic fields can penetrate up to 20mm and appear to target the ectopic firing nociceptors in the epidermis and dermis. Analgesic benefits were achieved over time.

**Key Words:** Diabetic neuropathies; Magnetics; Rehabilitation.

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**D**IABETIC PERIPHERAL NEUROPATHY (DPN) is a common and often disabling complication of diabetes mellitus (DM). Depending on criteria, DPN is estimated to occur in 50% to 90% of individuals with diabetes for more than 10 years.<sup>1-4</sup> As many as half of the 16 million diabetics in the United States will experience neuropathic pain at some point in their lives.<sup>5-9</sup> DPN begins insidiously, presenting as a symmetrical sensory polyneuropathy that follows a stocking-glove pattern. Selective involvement of unmyelinated C fibers and small myelinated A delta fibers produces pain of the burning dysesthetic type and is often accompanied by hyperalgesia and

allodynia in the feet.<sup>7,10-12</sup> Neuropathic pain symptoms fluctuate and can be described as superficial, deep, aching, lancinating, constant, or episodic. Complaints are often worse at night.

Although initial symptoms and the course of DPN vary, once neuropathic pain is established, it is almost always progressive, leading to increased discomfort and disability.<sup>6,13-15</sup> Furthermore, individuals with DPN are at augmented risk for foot trauma and infections that may necessitate amputative procedures.

<sup>2,16</sup>

From a pathophysiologic standpoint, these symptoms are believed to be secondary to ectopic firing of nociceptive afferent axons that are undergoing degeneration.<sup>7,9-12</sup> This ectopic depolarization appears to be related to dysregulated expression of sodium and calcium channels<sup>17-19</sup> and a deficit in the potassium-internal rectifying channel.<sup>20-22</sup> Neurons at the level of the dorsal root ganglion (DRG) also become hyperexcitable after peripheral nerve injury, presumably because of loss of peripheral inhibitory influences.<sup>23</sup> Currently, there are no treatments that reverse or arrest progressive diabetic polyneuropathy.<sup>24</sup> A variety of standard oral therapies used for symptomatic neuropathic

pain include tricyclic antidepressants,<sup>25</sup> antiepileptic medications,<sup>26</sup> and narcotic analgesics.<sup>27,28</sup> Additionally, topical products such as capsaicin<sup>29,30</sup> have been applied and have produced incomplete pain relief and significant side effects. Overall, the results have been disappointing and associated with significant side effects.<sup>15,31,32</sup> The search for reliable, safe, and effective mainstream treatments for the neuropathic pain of DPN remains a major challenge,<sup>13,15,25-27,31-34</sup> and, not surprisingly, patients have explored a variety of alternative approaches, including homeopathy, acupuncture, and magnetic

From the Department of Neurology, New York Medical College, Valhalla, NY (Weintraub); University of Texas, Southwestern Medical Center, Dallas, TX (Wolfe, Barohn); Research Design Inc, Yorktown Heights, NY (Cole); University of Minnesota, Minneapolis, MN (Parry); St. Louis University, St. Louis, MO (Hayat); Kaiser-Permanente Medical Group, Denver, CO (Cohen); California College of Podiatric Medicine, San Francisco, CA (Page); University of Utah, Salt Lake City, UT (Bromberg);

and Diabetes and Glandular Disease Clinic, San Antonio, TX (Schwartz).

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Reprint requests to Michael I. Weintraub, MD, Dept of Neurology and Medicine, New York Medical College, 325 S Highland Ave, Briarcliff Manor, NY 10510, e-mail: [mivneuro@pol.net](mailto:mivneuro@pol.net).

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