

The Weintraub Report: Historic Research Focuses on Magsteps

Text of the Nikken Press Release

Following is a portion of the text of a press release issued by Nikken after Dr. Michael Weintraub published his landmark research study:

“Diabetic peripheral neuropathy (DPN) is a common and often disabling complication of diabetes mellitus (DM) ... As many as 8 million diabetics in the United States will experience neuropathic pain at some point in their lives.”

So begins a report in the May 5, 2003, issue of the Archives of Physical Medicine and Rehabilitation that concludes:

“the present study provides convincing data confirming that the constant wearing of static, permanent, magnetic insoles produces statistically significant reduction of neuropathic pain.”

The insoles used in the study (which were developed and are marketed by Nikken) were described by the researchers as a non-invasive, non-prescription product/treatment that affords both “safety and minimal cost” for more than 80 million sufferers world-wide.

When the Weintraub study was published, all three networks reported the news:

ABC News: “Magnets may provide effective relief ... Dr. Michael Weintraub says it’s only a certain kind of bipolar magnetic insole that seems to help enough to make a difference.”

NBC News: “...a simple device may be able to help. ... A non-traditional treatment is getting results.”

CBS News: “If you think all those... claims about magnets are a bunch of hoey, think again. A new study shows wearing magnetic shoe insoles may help.”

The researchers are quick to point out that “studies are needed ... to confirm and extend these results.” And Dr. Michael Weintraub (New York

Medical College Department of Neurology and Medicine, and lead academic in the study) warns:

“Not all magnets are created equal! As important to the results of our tests as any of the other control features – the randomization, the double blinding, the placebo control – was the consistency of the product technology.”



The consumer product used in Dr. Weintraub’s test are “commercially sold under the brand name of Magsteps® by Nikken Inc.”

Dr. Weintraub’s study included 48 investigative sites in 27 states. There were 11 university-based centers and 37 private practices involving nearly 400 persons. The historical significance of this study, Dr. Weintraub says, is:

“This is the first randomized, double-blind, placebo-controlled trial to scientifically demonstrate the merits and clinical benefits utilizing static magnets. The same protocol used in drug studies was used for this trial.”

Dr. Weintraub concludes that not only is magnetic therapy “comparable or

superior to that observed with various conventional drugs,” it has the advantage of being non-invasive and is also less expensive and has no side effects.

Many professionals believe Dr. Weintraub’s study will become an important scientific event in the growing field of “energy medicine,” of which Dr. Weintraub says: “we must keep an open mind.”

“If you think all those... claims about magnets are a bunch of hoey, think again.”

— CBS News

The Magsteps® used in this study are developed and marketed by Nikken, Inc.

Nikken President and COO Kendall Cho says of the study:

“We are very encouraged by the growing scientific interest in our consumer products. For decades we have appreciated the anecdotes received from our customers on the benefits they believe are associated with the use of our products. However, even such dramatic conclusions by such a prestigious group of medical professionals will not affect the way we market our products. We have many products that incorporate magnets, such as our Sleep Systems, the revolutionary new PalmMag™, the Elastomag® wrist wraps (reported in a previous scientific study), and other wearable products. However, we do not sell our products as therapeutic devices, and we prohibit our Independent Wellness Consultants from making therapeutic claims. Nevertheless, this study may indicate a broader range of benefits for magnetic products than we permit to be claimed.”

Dr. Weintraub came to similar conclusions in a prior study of carpal tunnel syndrome (published in the Journal of Back and Musculoskeletal Rehabilitation). Once again, the constant wearing of a static magnet (in that case, the Elastomag™) was effective.

The Question Heard from Prospects: What Can Magnets Do for You? ... Just Point Them Toward the Scientific Research

A challenge faced by many Wellness Consultants who market magnetic products starts something like this:

You: I'd like you to take a look at these magnetic insoles. This is the product that started Nikken back in 1975.

Prospect: What will they do for me?

You: The pebbly surface of these insoles is based on an idea from Japanese public baths. Isamu Masuda, the man who founded Nikken, noticed that walking on the pebbly floor of public baths was relaxing, like getting a foot massage. So he decided to incorporate that surface into his insoles.

Prospect: And they have magnets in them?

You: Better than just magnets. The entire insole uses Advanced EQL

Magnetic Technology. It gives your soles 100% magnetic coverage.

Prospect: And what will that do?

Ah, the big question. What do magnets DO?

Wellness Consultants have an agreement with Nikken that includes the following statement:

"Wellness Consultant understands that products are not considered and are never offered or intended as medicines or medical treatments for any disease or disorder, either physical or mental."

You can, however, encourage your prospects to do their own research. You can point out that scientific studies have been conducted using magnets, including two significant ones led by Dr. Michael Weintraub, an independent

physician based in New York.

The most recent study led by Dr. Weintraub was published in the May 5, 2003, issue of the *Archives of Physical Medicine and Rehabilitation*, part of the respected family of American Medical Association publications.

"This is the first randomized, double-blind, placebo-controlled trial to scientifically demonstrate the merits and clinical benefits utilizing static magnets," Dr. Weintraub said. "The same protocol used in drug studies was used for this trial."

For those prospects who like to see detailed scientific literature, we offer below an abstract from the Weintraub study, which is also available online at the Web site of the Archives of Physical Medicine and Rehabilitation. You may find a link to the abstract atop the Nikken corporate Web site, nikken.com.

The only magnetic insoles used during Dr. Weintraub's research were Nikken Magsteps.

Static Magnetic Field Therapy For Symptomatic Diabetic Neuropathy:

A Randomized, Double-Blind, Placebo-Controlled Trial

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ABSTRACT

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

Design: Randomized, placebo-control, parallel study.

Setting: Forty-eight centers in 27 states.

Participants: Three hundred seventy-five subjects with diabetic peripheral neuropathy stage II or III were randomly assigned to wear constantly magnetized insoles for four months; the placebo group wore a 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 quality of life issues were tabulated over four months. Secondary measures included nerve conduction changes, role of placebo, and safety issues. Analysis of variance, analysis of covariance, 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%; $P < .05$, analysis of covariance), numbness and tingling (magnet, -10%; sham, +1%; $P < .05$, analysis of covariance), and exercise-induced foot pain (magnet, -12%; sham, -4%; $P < .05$, analysis of covariance). 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%; $P < .01$, analysis of variance) and foot pain (magnet, -41%; sham, -21%; $p < .01$, analysis of variance).

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.