

# A New-Wave Therapy for Diabetic Neuropathy

By **Norra MacReady**

**S**haron Wade has seen firsthand the dreadful toll of severe diabetes. Her mother developed diabetic neuropathy in her feet that progressed to gangrene. Finally it became so advanced that she required an amputation — and died on the day she was to undergo surgery. She was 67 years old.

Sharon Wade, now 48, herself was diagnosed with diabetes eight years ago and developed neuropathy about five years later. So when she learned of a study involving magnetic energy as a treatment for diabetic neuropathy, she took notice.

Neuropathy, or nerve damage, afflicts 50 percent to 70 percent of the 21 million Americans with diabetes. The causes haven't been completely identified, but they are thought to include prolonged exposure to the high blood sugar levels characteristic of diabetes, genetic factors, and damage to the blood vessels that carry oxygen and nutrients to the nerves.

Whatever the cause, neuropathy is a serious complication. Its symptoms include numbness, tingling and pain that patients describe as shooting, burning or stabbing. Neuropathy may also cause muscle weakness and loss of reflexes, especially at the ankle, leading to changes in gait. Foot deformities, such as hammertoes and the collapse of the midfoot, may occur. Blisters and sores may appear on numb areas of the foot and become infected because the injury goes unnoticed. Without prompt treatment,

the infection may spread to the bone, and the foot may then have to be amputated. Some experts estimate that half of all such amputations are preventable if minor problems are caught and treated in time.

So far, there are no good remedies for diabetic neuropathy, but the nationwide study

plates for the feet. Under each footplate are three magnets, which rotate continuously and deliver 1,800 gauss of magnetic energy that penetrate three inches into each foot.

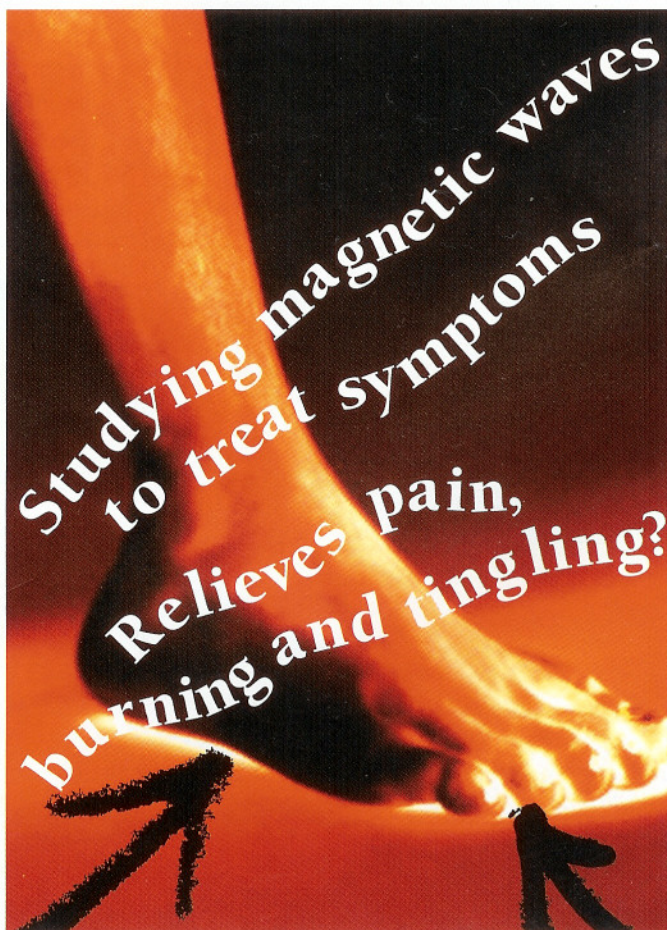
"These are powerful magnets — refrigerator magnets won't work," says Michael Weintraub, M.D., the clinical trial's principal investigator.

Study participants must use the device for a total of two hours a day, for 90 days. Some say the energizer feels like a foot massager. It has no side effects and is painless; most users say they feel only a mild vibration. However, because of its magnetic field, pregnant women and people with heart pacemakers are excluded from the study.

Dr. Weintraub, clinical professor of neurology at New York Medical College in Valhalla, N.Y., became interested in the power of magnets after a few of his patients claimed they relieved pain. He's been studying them formally since 1996, when he asked 14 patients with severe diabetic neuropathy to wear magnetized insoles in their shoes or socks 24 hours a day, even while asleep. After four months, nerve conduction improved by an average of 75 percent, with a corresponding decrease in feelings of numb-

ness, pain, tingling and especially burning. He repeated the study in another small group of patients, with similarly encouraging results.

Next, Dr. Weintraub studied magnetized insoles for patients with moderate to



that Sharon Wade joined is evaluating a promising new approach involving pulsed magnetic energy.

The energy is provided through a device called the Biaxial Body Energizer. The energizer resembles a bathroom scale, with two

severe neuropathy. He randomly assigned patients to wear either the magnetized insole or a sham device. This trial was double-blind, meaning that neither he nor the participants knew which group they were in until the study was over. Patients who wore the real device experienced a statistically significant decrease in pain, burning and tingling, as well as a significant improvement in walking, over the individuals in the comparison group.

"The analgesic effects were equal to or better than those achieved with painkilling drugs, and there were no side effects, with a device that costs about \$100 apiece," Dr. Weintraub reports.

For the current trial, Dr. Weintraub and his associates want to recruit 250 volunteers with moderate to severe neuropathy at 12 to 15 university diabetes centers and 10 private medical groups nationwide. This study also is double-blind, so the par-



**Three magnets in each of the energizer's footplates are designed to deliver therapeutic waves.**

ticipants are randomly assigned either to a working energizer or a sham device that feels as if it's working but is not actually delivering any magnetic energy. Neither they nor any of the investigators will know which type of device they've received until the study is completed.

The participants undergo an objective assessment of nerve function just before they start using the device and again when the 90-day study period is up. They are also required to keep a daily log in which they rate their pain on a scale ranging from 0 (nonexistent) to 10 (most severe). In addition, the researchers will compare biopsies taken from 40 randomly selected patients

with foot ulcers before and after their participation in the study.

The participants may not know if they have a real or sham energizer, but some volunteers — including Sharon Wade — are already reporting benefits.

"I've seen a remarkable improvement," says Wade. "My feet used to become crampy and swollen, and I had trouble walking, but no longer."

It took a little over a month for Wade to see any effects. But relief came faster for another study participant, Carol Thom.

"My feet stopped burning and tingling within a day or two," Thom says.

Thom was diagnosed with diabetes about 15 years ago, when she was 50. She finished her official three-month stint with the device just before last Christmas. She still doesn't know if her unit was a sham or the real thing, but she found it so helpful nevertheless that she kept it and continues to use it. Volunteers are allowed to keep the device, which is manufactured and provided by the Nikken Corp. of Irvine, Calif.

The energizer weighs three pounds. It's light and convenient enough for Wade, who lives in the Bronx, to take to her job as a social worker so she can use it for the requisite two hours a day while sitting at her desk. Thom, who lives in Fishkill, N.Y., took hers on her Christmas vacation: She simply packed it in her suitcase and checked it on the airplane.

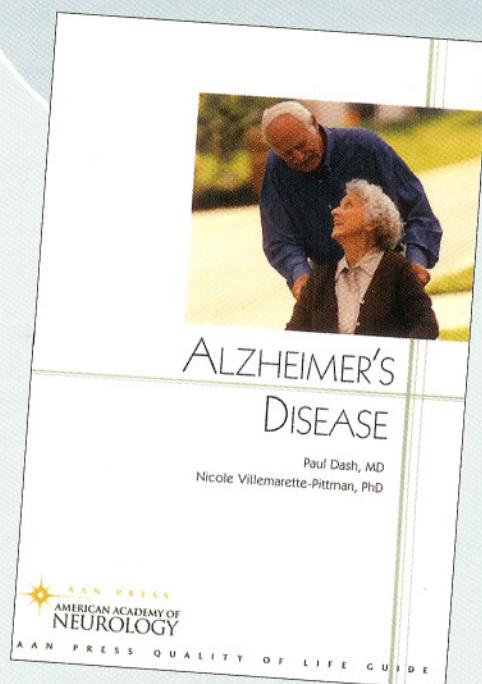
"We want to offer the diabetic population a truly effective treatment for neuropathy," Dr. Weintraub says. "We're hoping that this study will provide the objective evidence we need to demonstrate that the device relieves neuropathic symptoms."

Carol Thom, for one, is convinced. "The machine is great," she declares. "I don't want to let it go." NN

**For more information on this trial, contact Dr. Weintraub at 914-941-0788 or miwneuro@pol.net.**

**For clinical trials listed in the AAN's journal *Neurology*, visit [www.neurology.org/clinicaltrials](http://www.neurology.org/clinicaltrials).**

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