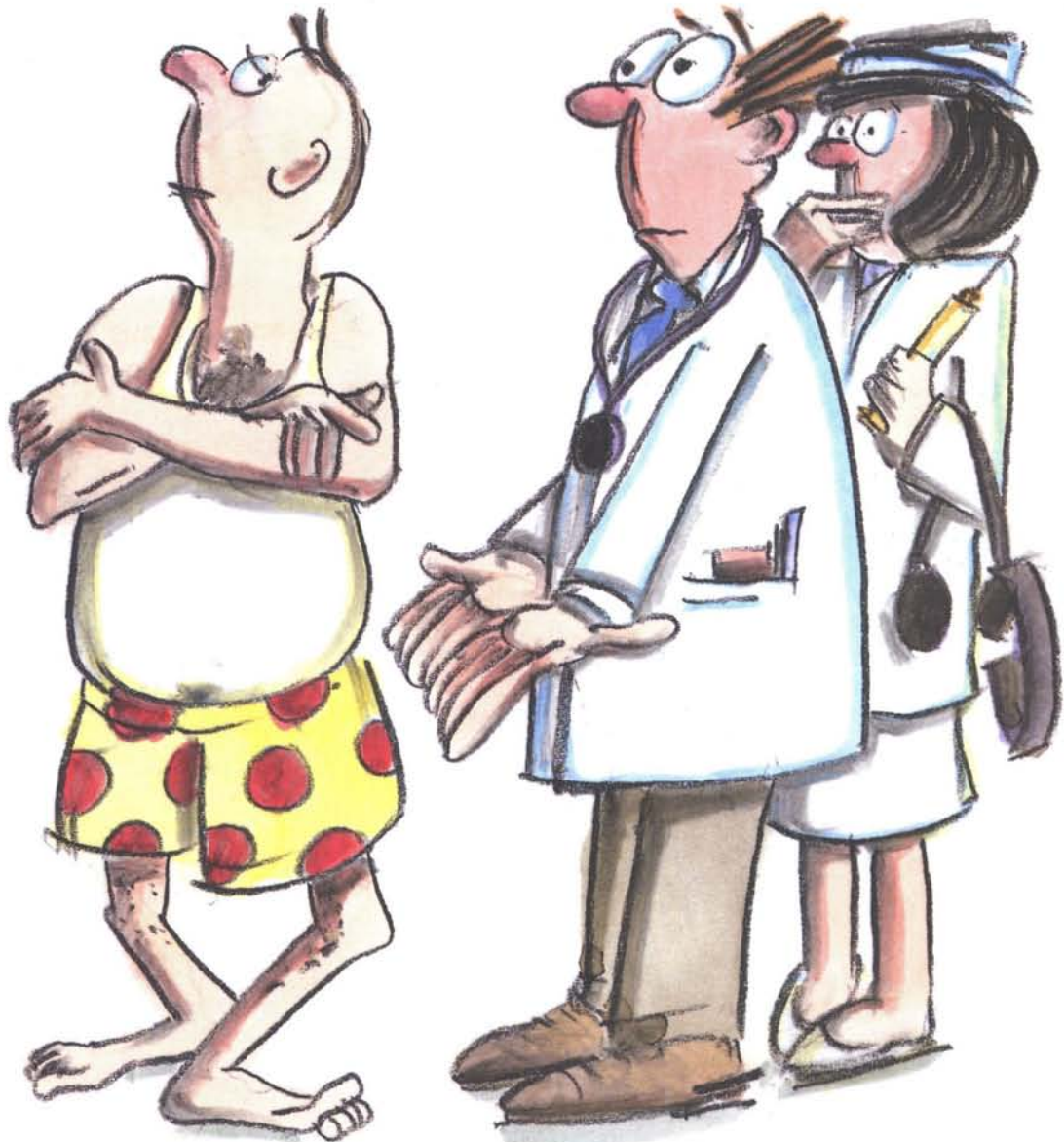


# DIABETES

## SELF-MANAGEMENT<sup>®</sup>

MARCH/APRIL 2004

\$4.00



### OVERCOMING THE MACHO MINDSET

NEW HOPE FOR NUMB FEET?  
RISKY DRUG COMBINATIONS

# MONOCHROMATIC INFRARED ENERGY

## New Hope for Painful, Numb Feet?

by J. Joseph Prendergast, M.D., Pamela Scarborough, P.T., M.S., C.D.E., C.W.S., and Thomas J. Burke, Ph.D.

**P**eripheral neuropathy, or nerve damage in the extremities, is one of the most common complications of diabetes. It is characterized by pain and numbness in the feet and legs and sometimes the hands and arms, and it is estimated to affect between 10% and 90% of people with diabetes, depending on the testing method and the population being tested. The risk of developing peripheral neuropathy rises the longer a person has diabetes. In addition to causing discomfort, peripheral neuropathy can cause problems with balance and mobility, and it is the primary cause of slow-healing foot wounds and amputations, in large part because a person who has lost sensation in his feet cannot feel when he has an injury to his foot.

While much research has been and continues to be devoted to the problem of diabetic neuropathy, it is still not known exactly what causes it, although high blood glucose levels seem to be involved. Indeed, maintaining near-normal blood glucose levels has been shown to lower the risk of developing peripheral neuropathy, to slow its progression, and to improve symptoms in those who have neuropathy. With no cure in sight, treatment of neuropathy focuses mainly on improving blood glucose control, reducing pain, maintaining mobility through exercise and balance training, and preventing further complications through frequent foot examinations and sometimes special footwear.

Current treatments for reducing neuropathy pain include tricyclic antidepressants, certain antiseizure drugs, opiates, capsaicin ointment, and transcutaneous electrical nerve stimulation (TENS). However, none of these works for everyone, and sometimes a treatment that initially helps stops working over time. In addition, little can be done to help with numbness or loss of sensation.



Given the number of people affected by neuropathy and the limited success of current therapies, it's always news when a new neuropathy treatment possibility enters the arena. One treatment that is receiving increasing attention in the medical community uses monochromatic infrared energy to increase blood circulation to the affected nerves and surrounding tissues.

### How it works

Infrared energy is invisible to the human eye, but its effects are experienced by people every day. So-called far-infrared energy is felt as heat—from the sun, fires, space heaters, and heat lamps, for example. Near-infrared energy, which does not normally feel hot, is what television remote control devices

use to communicate with the TV.

One of the monochromatic infrared energy therapy devices cleared by the U.S. Food and Drug Administration, the Anodyne Therapy System, uses a single wavelength of near-infrared energy, namely 890 nanometers. The energy is produced by light-emitting diodes that are embedded in flexible pads. The pads are placed in contact with the skin in the area of numbness or pain. The infrared energy is believed to relieve the pain of neuropathy and possibly improve nerve function by increasing blood flow to the affected area and, over time, spurring the growth of new capillaries in the area. It does this by causing red blood cells and the cells lining blood vessels to release nitric oxide.

Nitric oxide is a chemical produced by cells in the body and used for a number of important functions. One of those functions is to cause blood vessels to dilate, or widen, allowing blood to flow easily and ensuring adequate oxygen delivery to cells. Another is to inhibit blood platelets from clotting. Impaired nitric oxide production may contribute to constricted blood vessels, high blood pressure, and atherosclerosis. But too much is no good either: Overproduction of nitric oxide, which can be triggered by bloodborne infections and certain brain disorders, can contribute to severe medical problems.

For most people, one way to safely increase the amount of nitric oxide released by cells and to improve blood vessel health

Please ask your health care provider for full prescribing information.



#### Patient Information and Instructions

Patients should have detailed instructions regarding the use of PENLAC<sup>™</sup> NAIL LACQUER (ciclopirox) Topical Solution, 8%, as a component of a comprehensive management program for onychomycosis in order to achieve maximum benefit with the use of this product. Discuss your treatment plan with your health care professional for regular removal of the unattached, infected nail.

#### Who should not use Penlac<sup>™</sup>?

You should not use Penlac<sup>™</sup> if you are allergic to any of its ingredients. The active ingredient in Penlac<sup>™</sup> is ciclopirox. The inactive ingredients are ethyl acetate, isopropyl alcohol, and butyl monoester of poly-[methylvinyl ether/maleic acid] in isopropyl alcohol.

Before using this medication, tell your health care provider if you:

- Are pregnant or nursing
- Are an insulin dependent diabetic or have diabetic neuropathy
- Have a history of immunosuppression
- Are immunocompromised (e.g., received an organ transplant, etc.)
- Require medication to control epilepsy
- Are currently taking an oral antifungal medication for nail fungus
- Use or require topical corticosteroids on a repeated monthly basis
- Use steroid inhalers on a regular basis

#### Patient Information:

- Use PENLAC<sup>™</sup> NAIL LACQUER (ciclopirox) Topical Solution, 8%, as directed by your health care professional.
- PENLAC<sup>™</sup> NAIL LACQUER (ciclopirox) Topical Solution, 8%, is for external use only.
- Contact with skin other than skin immediately surrounding the treated nail(s) should be avoided.
- Avoid contact with the eyes and mucous membranes.
- Removal of the unattached, infected nail, as frequently as monthly, by your health care professional is needed with use of this medication to obtain maximal benefit with use of this product. If you have diabetes, or problems with numbness in your toes or fingers, talk to your health care provider before trimming your nails or removing any nail material.
- Inform your health care professional if the area of application shows signs of sensitivity or increased irritation (redness, itching, burning, blistering, swelling, oozing). The most common side effects are redness around the nails and nail disorders including shape change, irritation and discoloration.
- Up to 48 weeks of daily applications with PENLAC<sup>™</sup> NAIL LACQUER (ciclopirox) Topical Solution, 8%, with professional removal, as frequently as monthly, of the unattached, infected nail, is considered the full treatment time to achieve a clear or almost clear nail (defined as 10% or less residual nail involvement). Six months of therapy with professional removal of the unattached, infected nail may be required before initial improvement of symptoms is noticed.
- A completely clear nail may not be achieved with use of this medication. In clinical studies less than 12% of patients were able to achieve either a clear or almost clear toenail.
- Do not use nail polish or other nail cosmetic products on the treated nails.
- Avoid use near heat or open flame, because product is flammable.

#### Patient Instructions



1. Before starting treatment, remove any loose nail or nail material using nail clippers or nail files. If you have diabetes, or problems with numbness in your toes or fingers, talk to your health care provider before trimming your nails or removing any nail material.



2. Apply PENLAC<sup>™</sup> NAIL LACQUER (ciclopirox) Topical Solution, 8%, once daily (preferably at bedtime) to all affected nails with the applicator brush provided. Apply the lacquer evenly over the entire nail. Where possible, nail lacquer should also be applied to the underside of the nail and to the skin beneath it. Allow lacquer to dry (approximately 30 seconds) before putting on socks or stockings. After applying medication, wait 8 hours before taking a bath or shower.

3. Apply PENLAC<sup>™</sup> NAIL LACQUER (ciclopirox) Topical Solution, 8%, daily over the previous coat.



4. Once a week, remove the PENLAC<sup>™</sup> NAIL LACQUER (ciclopirox) Topical Solution, 8%, with alcohol. Remove as much as possible of the damaged nail using scissors, nail clippers, or nail files.

5. Repeat process (steps 2 through 4).

#### Please Note:



1. To prevent screw cap from sticking to the bottle, do not allow solution to get into the bottle threads.

2. To prevent the solution from drying out, bottle should be closed tightly after every use.

3. To protect from light, replace bottle into carton after each use.

Prescribing Information as of June 2003.

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DERMIK<sup>®</sup>

throughout the body is to perform regular aerobic exercise. In fact, the increased availability of nitric oxide may be one of the reasons regular exercise has been shown to reduce blood pressure. Aerobic exercise can sometimes help with symptoms of neuropathy, but it may not be enough. The use of the Anodyne Therapy System also appears to be a safe way to increase nitric oxide availability.

## Getting treated

While diabetes is a major cause of peripheral neuropathy, it is not the only one. The condition can also be caused by circulatory problems, certain drugs, chemotherapy, alcohol abuse, anemia, AIDS, back problems, surgery, and unknown causes. (When the cause is unknown, it's called *idiopathic* neuropathy.) In fact, while neuropathy in a person with diabetes is often assumed to be a complication of his diabetes, it may not be. That's why it's important to have a complete evaluation of any neuropathy symptoms by a doctor to ensure that the treatment is appropriate for the underlying problem.

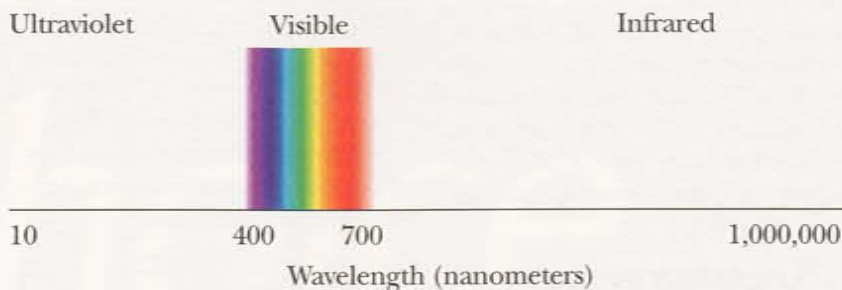
If the cause of neuropathy is diabetes, improving blood glucose control and maintaining good blood glucose control is the first line of therapy. Ensuring good blood circulation to the extremities is important too, since blood carries needed oxygen and nutrients to the nerves and skin. Poor blood circulation to the extremities contributes to the slow healing of wounds.

Pain control is also an important part of treatment, and while more doctors are familiar with drug treatment for neuropathy pain, the availability of monochromatic infrared energy therapy is growing, with about a thousand centers offering this treatment in the United States. (For more information on where this therapy is available, see "To Learn More" on page 56.)

Generally, monochromatic infrared energy therapy is administered by a doctor or physical therapist.

# THE ELECTROMAGNETIC SPECTRUM

## ULTRAVIOLET, VISIBLE, AND INFRARED RANGES



NOTE: Not drawn to scale.

pist. First, for the purpose of infection control, a clear plastic barrier is placed on the area to be treated, then the diode-containing pads are placed on the plastic. The pads may be lightly held in place with a cloth strap, paper tape, or an elastic bandage. The device is then turned on, and the pads are left in place for 20 to 45 minutes, depending on the condition of a person's skin. The pads warm up when in use and can cause burns if the energy level is set too high; therefore, the doctor or therapist checks the person's skin every 10 minutes during the first session to adjust the energy level as needed. The makers of the Anodyne Therapy System recommend daily treatment sessions initially (with a minimum of three per week) and a maintenance schedule of one to two treatments per week.

Most people say that monochromatic infrared energy treatments feel warm and soothing. Others say they feel some tingling and pulsing, which is normal as blood flow returns. Some forms of neuropathy respond very quickly, while others take longer. In studies, many participants have reported pain relief and improved sensation after about 12 sessions. But like other neuropathy treatments, monochromatic infrared energy treatments are not universally effective, and balance problems associated with neuropathy may require additional physical therapy. Most therapists will work with you as long as you are willing and they can continue to show that your neuropathy is improving.

People with diabetes who undergo monochromatic infrared energy therapy are advised to monitor their blood glucose levels regularly, especially during the first month of treatment. As their pain diminishes, their blood glucose levels may decrease as well. This is because stress, whether physical or psychological, can raise blood glucose levels, and reducing stress may lower blood glucose. Increases in physical activity—as a part of treat-

You may know more about the electromagnetic spectrum than you think. Every day you are affected by different kinds of electromagnetic waves, including ultraviolet waves, visible light waves, and infrared waves, which are constantly traveling through the air. Collectively, these waves, along with gamma rays, X-rays, microwaves, and radio waves, compose the electromagnetic spectrum.

What differentiates one category of wave from another is the wavelength, or the distance from one wave crest to the next. Waves can range in size from several miles, in the case of radio waves, to one-hundredth of a nanometer (which is already one-billionth of a meter), in the case of gamma rays.

Waves that are between 10 nanometers and 400 nanometers fall into the ultraviolet range. Ultraviolet-C light, which has the smallest wavelength in the ultraviolet spectrum, is emitted by the sun, but it is filtered out by the ozone layer before it ever gets to Earth. Ultraviolet-A and ultraviolet-B light, also emitted by the sun, have longer wavelengths, and can penetrate the ozone layer. Although humans cannot see ultraviolet light, many of us have been acquainted with its effects in the form of sunburn.

Visible light is the only form of electromagnetic radiation that can be detected by the human eye. This

portion of the spectrum has wavelengths that measure from 400 nanometers to 700 nanometers, and ranges in color from violet to red. The perception of color is created by the reflection of particular wavelengths of light off objects and into the eye. A blue sweater, for example, absorbs all of the wavelengths in the visible spectrum except that which corresponds to the color blue; this wavelength is reflected off the object to the eye and interpreted as the sweater's color. Because the sun emits wavelengths for all the colors in the visible spectrum, it appears to us as white.

Wavelengths just beyond the visible spectrum fall into the infrared range, which extends from approximately 700 nanometers to 1,000,000 nanometers (or 1 millimeter). Humans generally do not detect near-infrared energy, which has the shortest wavelengths in the infrared zone. Rather, we observe its effects only indirectly, such as when we use a remote control to operate a television set. The Anodyne Therapy System emits energy in the near-infrared zone. Far-infrared energy, on the other hand, is detected directly by the human body every day in the form of heat. In fact, when someone holds his hand over a hot stove or a space heater, his sensation of heat is actually caused by his body's absorption of far-infrared energy.

ment or as a result of improved neuropathy symptoms—can also lower blood glucose.

While monochromatic infrared energy therapy is considered safe for most people, the makers of the Anodyne Therapy System caution that the device should not be used over or near the womb of pregnant women or over an active malignancy (cancer).

## Reimbursement

Medicare and most private insurance carriers will cover monochromatic infrared energy therapy (after any deductibles and copayments) if you are being treated by a physical therapist. In some cases, doctors can also be reimbursed for treatments, but that varies from state to state. You will need a prescription from your doctor to be referred to a physical therapist if you want the treatments to be covered by your insurance or Medicare.

## Ongoing care

Because diabetes and most other causes of neuropathy are chronic conditions, your therapist or doctor will likely recommend home exercises to help you continue to improve your balance and ability to walk. They may also suggest continued use of monochromatic infrared energy at home for ongoing pain relief and to help you maintain your circulation. Medicare or your private insurance may cover a monochromatic infrared energy home treatment system with your doctor's prescription if you have shown improvement during your clinical treatment program.

No matter how your feet feel, regular foot exams are critical for people with diabetes. The American Diabetes Association (ADA) recommends that all people with diabetes receive an annual foot exam to assess the sense of feeling in their feet, foot structure, blood circulation to the feet, and skin

For a listing of Anodyne Neuropathy Care Centers, which offer monochromatic infrared energy therapy, call (800) 521-6664 or visit [www.anodynetherapy.com](http://www.anodynetherapy.com).

For more information on foot care and neuropathy, contact the following organizations:

### AMERICAN DIABETES ASSOCIATION

[www.diabetes.org](http://www.diabetes.org) (Click on "All About Diabetes," then "Type 1 Diabetes," then "Complications.") The ADA also publishes *The Uncomplicated Guide to Diabetes Complications, 2nd Edition*, which can be ordered by calling (800) 232-6733.

### AMERICAN PODIATRIC MEDICAL ASSOCIATION

(800) FOOTCARE (366-8227) (Call for information about foot health.)

[www.apma.org](http://www.apma.org) (Click on "Foot Health Information," then on "Diabetes.")

### DIABETES SELF-MANAGEMENT

[www.DiabetesSelfManagement.com](http://www.DiabetesSelfManagement.com) (Click on "Feature Articles," then "Diabetes Complications," then

health. The ADA says those with peripheral neuropathy should have a visual inspection of their feet at every scheduled visit to a health-care professional. In addition, you should check your feet for any blisters or irritation every day. If your feet have changed shape because of neuropathy, your doctor may refer you to a podiatrist, who can prescribe special shoes or shoe inserts to protect your feet from injuries and relieve pressure points.

Neuropathy does not inevitably worsen in everyone who has it. By controlling your blood glucose levels, blood pressure, and cholesterol, as well as by exercising regularly and staying abreast of new

## TO LEARN MORE

"Treating Neuropathy While Waiting for a Cure.")

### NATIONAL DIABETES INFORMATION CLEARINGHOUSE

[www.diabetes.niddk.nih.gov](http://www.diabetes.niddk.nih.gov) (Click on "Complications of Diabetes," then "Diabetic Neuropathies: The Nerve Damage of Diabetes.")

For a free paper copy of "Diabetic Neuropathies" or a copy of the booklet *Prevent Diabetes Problems: Keep Your Nervous System Healthy*, call (800) 860-8747.

### NATIONAL INSTITUTE OF NEUROLOGICAL DISORDERS AND STROKE

[www.ninds.nih.gov](http://www.ninds.nih.gov) (Click on "Disorders," then on "Diabetic Neuropathy.")

### THE NEUROPATHY ASSOCIATION

[www.neuropathy.org](http://www.neuropathy.org) (212) 692-0662

This nonprofit membership organization provides support and education and funds research on neuropathy. Membership is free but contributions are encouraged.

therapies, you may be able to slow this complication, avoid others, and make a real difference in your life. □

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*Dr. Prendergast has been a practicing diabetologist for over 30 years and is the founder of the Endocrine Metabolic Medical Center in Redwood City, California. Pamela Scarborough is currently the director of education for Educators 2000Plus, providing continuing education to medical professionals on wound care and diabetes management in Dallas, Texas. Dr. Burke is currently Director of Research and Clinical Affairs at Anodyne Therapy, LLC, in Tampa, Florida.*