Clinicians often see adult patients where underlying conditions or lifestyle behaviors such as diabetes, vascular disease, or alcoholism have caused microvascular impairment and poor circulation. These patients pose important clinical dilemmas directly related to a number of problems including impaired circulation, increased frequency of falls, poor wound healing, increased amputation rates, and increased healthcare costs. Additionally, the peripheral pain often experienced by these patients has shown to impact a patient's mood, level of daily activity and their quality of life.

Recent medical research has established that diabetes impairs vascular endothelial function. As discussed in Petrokfky et al, “In people with Diabetes, a reduction in principally nitric oxide release or the sensitivity of nitric oxide receptors in smooth muscle reduces the ability of the smooth muscle to vasodilate.”

The Anodyne® Therapy System provides a way for clinicians to treat patients with poor circulation because the use of infrared light therapy has been shown to temporarily increase blood flow, and trigger the local release of nitric oxide. Treatment with Anodyne® Therapy is non-invasive, drug free, and has the potential for both therapeutic and prophylactic utility, with positive results becoming evident after several treatments of 30-40 minutes duration. Efficacy of Anodyne® Therapy is proven in 18 published, peer-reviewed clinical studies.

Treatment with Anodyne® Therapy may be an alternative for patients with underlying poor circulation and subsequent extremity pain, especially those who have obtained an unsatisfactory level of relief while using various oral medications. This treatment might also be an alternative first line treatment in some patients with significant extremity pain who have not yet begun drug therapy.

Like the administration of pharmaceutical interventions for the management of chronic pain, treatment with Anodyne® Infrared Therapy is not a cure. Once a patient responds to an initial clinical treatment program - they can easily move to a home treatment regimen for ongoing symptomatic relief.

Anodyne® Therapy is FDA cleared to temporarily increase local blood circulation and reduce pain stiffness and muscle spasm. It should not be used over an active cancer, or directly over the womb in pregnancy. The use of Anodyne® Therapy carries a slight risk for a superficial burn, which is further minimized when recommended protocols are followed. For full prescribing information please visit www.anodynetherapy.com or call 800-521-6664.

Your Local Anodyne® Therapy Provider

www.anodynetherapy.com
CLINICAL STUDY KEY POINTS

Many of the studies published on Anodyne® Therapy Systems involve medical conditions for which there is no known cure, which do not spontaneously reverse, or for which conventional care has failed to help the patient over many months or years. 18 studies published in peer reviewed journals demonstrate positive outcomes in response to Anodyne® Therapy Treatments. Some key endpoints with respect to pain reduction are discussed below.

In a double-blind, randomized and placebo controlled study published in Diabetes Care, subjects (N=27) experienced a 45% reduction in pain levels over the course of 12 treatments.10

In a retrospective analysis and questionnaire published in Practical Pain Management, 51% of subjects (N=493) noted that they were able to decrease use of pain medications by using Anodyne Therapy.11

64% mean decrease in pain was reported by both diabetic and non diabetic subjects.

In a repeated measures analysis published in Physical and Occupational Therapy in Geriatrics (N=272), a 38% reduction in pain as measured using the 11 point VAS was noted for all subjects.12

Subjects noting horrible to excruciating pain (VAS 8.5-10) experienced a 49% reduction in pain.

Subjects noting distressing pain (VAS 6.5 to 8) experienced a 36% reduction in pain.

Subjects noting discomforting pain (VAS 4-6) experienced 34% reduction in pain.

In a retrospective analysis published in Age and Ageing (N=252) 87% of subjects obtained a substantial reduction in pain. All 252 subjects were diabetic.13

In a repeated measures analysis published in the Journal of Diabetes and Its Complications, subjects (N=2239) averaged a 67% reduction in pain on the 11 point VAS and 98% of subjects experienced

MORE INFORMATION AVAILABLE UPON REQUEST

4. Tseng CL; Sambamoorthi U; Helmer D; Tiwari A; Rosen AK; Rajan M; Pogach L. The association between mental health functioning and nontraumatic lower extremity amputations in veterans with diabetes. Gen Hosp Psychiatry - 01-NOV-2007; 29(6): 537-46.

The FDA has not reviewed, evaluated or approved the data in the above referenced published studies.