It is well-established that the heterodiatomic free radical, nitric oxide (NO), is a crucial component in many biological repair processes, although the exact mechanism of action has not yet been elucidated. When delivered directly to a particular site, blood flow can be enhanced and the healing process accelerated. Conditions that can benefit from topical nitric oxide therapy include: diabetic ulcers, peripheral neuropathy or other disease states resulting from vascular insufficiencies, cold hand and feet syndromes, and transdermal drug delivery where the diffusion rate is slow.

Researchers have sought various ways to deliver NO therapeutically to damaged tissue. Diazeniumdilolates (NONOates) exhibit the ability to deliver NO spontaneously. Previous work by Smith, et al. has shown that polymeric NONOates have been used for controlled release of NO to a specific site (USP 5,519,020; 6,737,447; 6,855,366). Thus, therapeutic levels of nitric oxide could be delivered in a controlled manner to tissues and organs to benefit the healing process and to prevent injury to tissues at risk.

The present invention is directed to nitric oxide releasing systems (dressings and compositions), and their use for mitigating or remediating diseases including peripheral neuropathy. In addition, the invention is directed to the use of transdermal patches containing agents for nitric oxide delivery, and a variety of NO transdermal drug delivery methods. A variety of transdermal drug delivery systems (TDDS) are envisioned, however a common topical NO delivery device may contain a patch comprising a diazeniumdilolate material; a nitric oxide derivatized polymer like linear polyethylene imine; a fibrous or nonwoven material; and an activating agent.

Specifically, a four-layer transdermal patch containing the above components was produced, and placed on a diabetic patient having a persistent open sore on his foot and suffering from neuropathy induced by poor circulation. As a result of the treatment, the sore healed and the patient regained sensation in his foot as well, in effect, the patient experienced a reversal of his circulation-induced neuropathy.

**About the Inventor**

Dr. Dan Smith is a Professor of Chemistry and Biomedical Engineering at The University of Akron. He also serves as a Research Professor for the Northeast Ohio Universities College of Medicine (NEOUCOM). His research involves novel polymers that are designed for controlled release of NO, as well as the development of genetically engineered biological bandages capable of drug delivery functionality. He is actively engaged in technology transfer and licensing to commercialize these valuable discoveries.

**Invention Information**

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