

Clinical Efficacy of Noninvasive Cryolipolysis and Its Effects on Peripheral Nerves

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Abstract

Background Cryolipolysis provides a method for noninvasive fat reduction that significantly reduces subcutaneous fat in a pig model without apparent damage to skin and surrounding structures. This study aimed to determine whether fat reduction in humans caused by cold exposure is associated with alteration in local sensory function or nerve fibers.

Methods In this study, 10 subjects were treated with a prototype cooling device. Fat reduction was assessed in 9 of the 10 subjects via ultrasound before treatment and at the follow-up visit. Sensory function was assessed by neurologic evaluation ($n = 9$), and biopsies ($n = 1$) were collected for nerve staining.

Results Treatment resulted in a normalized fat layer reduction of 20.4% at 2 months and 25.5% at 6 months after treatment. Transient reduction in sensation occurred in six of nine subjects assessed by neurologic evaluation. However, all sensation returned by a mean of 3.6 weeks after treatment. Biopsies showed no long-term change in

nerve fiber structure. There were no lasting sensory alterations or observations of skin damage in any of the subjects evaluated.

Conclusion Noninvasive cryolipolysis results in substantial fat reduction within 2 months of treatment without damage to skin. The procedure is associated with modest reversible short-term changes in the function of peripheral sensory nerves.

Keywords Cryolipolysis · Efficacy · Fat reduction · Neurologic effects · Noninvasive

A new method of noninvasive fat layer reduction called cryolipolysis has been shown to reduce fat layer thickness significantly in a Yucatan pig model. A cold-induced inflammatory mechanism gradually reduces fat thickness in 90 days after a 30- to 60-min cold plate exposure to the skin surface (data on file) [1]. *In vitro* examination of the adipocyte response to cold showed that cooling of adipocytes to temperatures above freezing but below normal body temperature results in apoptosis-mediated cell death [2], which suggests that cryolipolysis produces an apoptotic injury in the adipose tissue. Furthermore, the subsequent inflammatory response may cause additional damage to those adipocytes not immediately affected by the cold exposure.

The results from the aforementioned animal study indicated that cryolipolysis caused a 30% to 50% reduction in fat layer thickness, with no damage to skin or associated structures and without causing changes in lipid profiles, including total cholesterol, low- and high-density lipoprotein cholesterol, and triglycerides (data on file) [1, 3]. There was no histologic evidence of necrotic or inflammatory damage to nerves.

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