# The Effect of Monochromatic Infrared Energy on Sensation in Subjects With Diabetic Peripheral Neuropathy: A Double-Blind, Placebo-Controlled Study

## Response to Clifft et al.

The recent paper by Clifft et al. (1) concludes that monochromatic infrared energy (MIRE) is no better than placebo MIRE in restoring sensation in the lower extremities of subjects with diabetes. We would like to suggest an alternative conclusion.

First, the subjects were treated with a MIRE device that delivered photo energy and therapeutic heat at a lower level than has been used in other clinical studies. Treatment times per session were also only 66% of those reported by Leonard et al. (2). As a result, each subject received ~50% less photo energy than used in the Leonard protocol. The clinical effect of phototherapy treatment is time dependent. In and of itself, this difference in treatment protocol may account for the authors' inability to obtain results similar to those reported by Leonard et al. (2).

Second, while many subjects who cannot sense the larger 6.65 Semmes-Weinstein monofilament (SWM) at any site are unlikely to obtain sensation to the 5.07 SWM during a course of 12 treatments, it is possible that sensation to an intervening monofilament (for example, a 5.65 monofilament) may actually occur (2,3). These data were omitted from the article.

Third, subjects were selected solely on ". . . self-diagnosed. . ." diabetes and their inability to detect the 5.07 SWM at one of four sites on either foot. It is likely that a number of the subjects did not have diabetic peripheral neuropathy, since many exhibited sensory loss in only one limb and/or at only one site. The selection and treatment of subjects was further confounded by the fact that while some subjects received active treatment on one extremity and placebo treatment on the other, some received active or placebo treatment on both extremities.

Finally, the authors neither used a forced-choice method of SWM testing nor required the patient to specify the location at which they sensed the SWM; these are preferred testing methodologies using the SWM as it was used in other studies (2,3). Since it is well known that subjects responding to a SWM may specify a location other than that which is actually being touched, the SWM data obtained may be less accurate than it could have been, possibly explaining the apparent improvement in the placebo-treated limbs.

We believe that the reported conclusion may be attributed to the variance of the treatment dosage (amount of photo energy delivered). Additionally, it is important that utmost care is required in properly administering an SWM test to maximize the reliability of the data obtained.

**THOMAS J. BURKE, PHD**

From Anodyne Therapy, Tampa, Florida.

Address correspondence to Thomas J. Burke, PhD, Director of Research and Clinical Affairs, Anodyne Therapy LLC, 13570 Wright Circle, Tampa, FL 33626. E-mail: tburke1@qwest.net.

T.J.B. is employed by Andoyne Therapy, manufacturer of the MIRE device mentioned in this letter.

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**References**

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## Response to Burke

We thank Dr. Burke (1) for his thoughtful comments and critical review of our research study (2). In responding to his comments, we have addressed each of his stated concerns in order.

First, regarding the level of photo energy delivered, the manufacturer preset our active monochromatic infrared energy (MIRE) units to deliver the recommended 6–8 bars of energy or 1.95 J · $cm^{-2}$ · $min^{-1}$ for 30 min (total energy of 58.5 J/$cm^2$), whereas the MIRE units used in the Leonard study (2) delivered 1.3 J · $cm^{-2}$ · $min^{-1}$ for 40 min (total energy of 52.0 J/$cm^2$). Therefore, our subjects received slightly more photo energy per treatment than subjects in Leonard's study, contrary to Dr. Burke's comments.

Second, we analyzed our data in the same manner as the only other placebo-controlled study (3) to have a more meaningful analysis. However, in our active MIRE group, sensation decreased at 46 of 139 test sites, improved at 54 of 139, and did not change at 39 of 139. In the placebo group, sensation decreased at 28 of 140 sites, improved at 74 of 140, and did not change at 38 of 140.

Third, all subjects in our study had received a diagnosis of diabetes and were being medically managed by their physicians. Peripheral neuropathy was confirmed by monofilament testing, which is standard practice and used by other researchers (3,4). A few subjects in each group were insensitive to the 5.07 monofilament at one of four test sites, but there was no significant difference between groups in mean number of sites sensitive to the 5.07 monofilament at baseline. In regard to Dr. Burke's comments about group assignment, it is not clear to us why he believes that our results were con-