

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

Response to Clift et al.

**T**he recent paper by Clift 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.

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T.J.B. is employed by Andoyne Therapy, manufacturer of the MIRE device mentioned in this letter. DOI: 10.237/dc06-0040

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

Response to Burke

**W**e 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  $1.95 \text{ J} \cdot \text{cm}^{-2} \cdot \text{min}^{-1}$  for 30 min (total energy of  $58.5 \text{ J/cm}^2$ ), whereas the MIRE units used in the Leonard study (2) delivered  $1.3 \text{ J} \cdot \text{cm}^{-2} \cdot \text{min}^{-1}$  for 40 min (total energy of  $52.0 \text{ J/cm}^2$ ). 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-

founded by the fact that some patients had one leg randomized to receive active MIRE and the other leg randomized to receive placebo MIRE. In the majority of subjects, both legs received the same treatment, but, in any case, we have no reason to question the value of random assignment. In addition, all subjects in the Leonard study (3) had one leg in the active group and the other leg in the placebo group.

Finally, when performing monofilament testing, we used the "yes-no" method of testing, which is equally accurate and faster than the "forced-choice" method (4). We concur with Dr. Burke that only valid and reliable testing methods should be used.

While it is disappointing to discover that a promising new treatment may not be effective, patient treatment should be based on credible evidence. We hope that more randomized, placebo-controlled studies are conducted to either support or refute the results of our study and to help determine the rightful place of MIRE in the treatment of patients with peripheral neuropathy.

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## Ischemia Imaging and Plaque Imaging in Diabetes: Complementary Tools to Improve Cardiovascular Risk Management

Response to Raggi et al.

**H**ere we respond to the review by Raggi et al. (1). We are concerned that the stated aims have not been fulfilled.

The American Heart Association (2) and the U.S. Preventative Task Force (3) have strongly discouraged coronary heart disease (CHD) screening in asymptomatic subjects with diabetes. Only one small randomized study has shown benefit from revascularization in asymptomatic subjects with diabetes screened for CHD (4). This study needs to be replicated in larger groups with rigorous analysis of the psychological and physical benefits and cost effectiveness. Screening guidelines should remain conservative until further studies show clear evidence of clinical benefit. Raggi et al. present no data to validate the algorithm presented in Fig. 1 in their review; this is based on opinion only.

Although subjects with diabetes may be at high CHD risk even when myocardial imaging for ischemia is negative, we would disagree with the statement that this lends support to the concept of refining risk stratification in diabetes using plaque imaging techniques. For instance, using carotid intima-media thickness in asymptomatic diabetic patients to identify candidates for angiography will lead to many invasive tests in which the likelihood of finding significant CHD is low. Some of these patients will have luminal atherosclerosis, but current CHD prevention guidelines in diabetes mandate aggressive medical therapy regardless of the results of additional investigation. A lower threshold for angiography based on

carotid intima-media thickness for instance could result in angioplasty for lesions that are not producing symptoms, that are moderate in stenosis severity, and for which there is no known survival benefit of angioplasty over medical therapy alone. More information on this debate will be available when the Bypass Angioplasty Revascularization Investigation 2 Diabetes (BARI-2D) study reports.

Finally, the authors fail to make a clear distinction between subjects with and without CHD symptoms. Revascularization may be justified at low thresholds in symptomatic patients, whereas screening of asymptomatic subjects should be reserved for limited situations (2,3). We share the authors' desire to develop a better strategy to manage asymptomatic patients with diabetes and CHD, but how to do this remains unclear.

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