The Treatment of Retinal Diseases With Micro Current Stimulation And Nutritional Supplementation

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Abstract

From May 2001 to November 2002, 94 eyes diagnosed with typically untreatable retinal diseases including age-related macular degeneration, retinitis pigmentosa and Stargardt's were treated with an integrated treatment protocol employing micro current electrical stimulation and nutritional supplementation. Overall, 68% showed a marked increase in vision function and visual acuity following therapy. The success rate in age-related macular degeneration was 72% (26 out of 36 eyes), in retinitis pigmentosa 53% (18 out of 34 eyes), and in Stargardt's 83% (20 out of 24 eyes). The average level of improvement was 2-3 lines as measured using the Snellen eye chart.

Keywords

Micro Current Stimulation, Macular Degeneration, Retinitis Pigmentosa, Stargardt's, AREDS, Nutrition, Lutein, DHA, Taurine, Micro Amp, ATP, RPE

Discussion

Micro Current Stimulation (MCS) therapy is a noninvasive procedure which involves stimulating the retina and nerve fibers with very low intensity electrical current using a FDA and CE Mark approved electrical stimulation device. The current is delivered in the micro Amp range at different electrical frequencies through electrodes applied over closed eyelids. The treatment causes no discomfort or pain and is administered for 12 minutes, twice each day. While a very effective form of treatment, MCS therapy is not a cure for retinal diseases and must be continued for the life of the patient. Overall, no side effects or adverse reactions related to this procedure have been observed.

It is theorized that MCS therapy works by increasing intracellular ATP (adenosine triphosphate) concentrations, enhancing protein synthesis, and stimulating the cells' ability to absorb nutrients. Through these mechanisms, MCS therapy improves RPE (retinal pigment epithelium) efficiency and thereby may restore and/or improve retinal function.

ATP is synthesized in the mitochondria process known as the Kreb's Cycle, the sequence of reactions in the mitochondria that complete the oxidation of glucose in respiration. Kroll and Guerrieri have shown that there are age related changes in mitochondrial metabolism resulting in a decrease of the ATP synthase activity in the retina with age. Guerrieri has gone further to show functional and structural differences of the mitochondria F0F1 ATP synthase complex in aging rats. It is theorized that many retinal diseases, at least in part, are due to a decrease in mitochondria function and the subsequent decrease in intracellular ATP. This decrease in mitochondria function results from free radical damage and the mutation of mtDNA (mitochondria DNA). It is interesting to note the genetic link between ATP and retinal disease. ATPase (ATP Synthase) is an enzyme which catalyzes the synthesis of ATP. A genetic defect in the ATPase 6 Gene has now been implicated in retinitis pigmentosa.

In October 2001 the National Eye Institute, a division of the National Institutes of Health, published the *Age-Related Eye Disease Study* which stated unequivocally that nutritional supplementation is an effective therapy against macular degeneration. This study was based on a seven-year double-blind study conducted by the NEI at eleven medical centers across the United States. It is clear that proper nutritional support can help protect us from diminishing eyesight and degenerative ocular complications as we grow older.

In evaluating MCS therapy in the treatment of retinal disease, clinical testing has shown that nutritional supplementation serves as a synergistic catalyst in boosting the effectiveness of MCS therapy. Subsequently, nutritional supplementation is a critical part of the MCS therapy program. The formula used on the test subjects was identical to that used in the *Age-Related Eye Disease Study* with the addition of Lutein, Taurine, and DHA (DocosaHexanoic Acid).

In respect to the legal status of MCS therapy, the Food and Drug Administration does not regulate the practice of medicine, however they do regulate the sale of medical devices. Before a medical device can be legally sold or used in the U.S., the person or company that wants to sell or use the device must seek approval from the FDA. To gain approval, they must present evidence that the device is reasonably safe and effective for a particular use. The devices used in MCS therapy are approved, however they were originally developed and approved for *the symptomatic relief of chronic intractable pain and as an adjunctive treatment in the management of post-surgical traumatic pain problems.* Once the FDA has approved a medical device, a doctor may decide to use that device for other indications if the doctor feels it is in the best interest of a patient. Subsequently, the use of an approved device for anything other than its FDA approved indication is called *off-label*. MCS therapy for the treatment of retinal disease is considered an *off-label* use.

At least twenty other studies have been published regarding electrical current's effectiveness in dealing with degenerative disease, tissue repair, and cell regeneration. Four other studies have been published specifically addressing MCS therapy's effect on retinal disease.

The American Academy of Ophthalmology issued a position statement regarding micro current stimulation which states … *the overall rate of adverse effects from electrical stimulation appears to be low. In the study of AMD and micro current stimulation, there were no reported adverse side effects from the electrical stimulation … long-term studies with larger samples of patients, and adequate control groups compared to micro current stimulation are critical to establishing a base of evidence regarding effectiveness*.

The author agrees with the Academy's position and two double-masked, randomized, and multi-site clinical trials are planned. The first will be coordinated by the University of California, San Francisco Medical Center on the treatment of dry (non-exudative) age-related macular degeneration (AMD). A second study will evaluate the effect of MCS therapy on a variety of retinal pathologies including Stargardt's, retinitis pigmentosa, and the wet (exudative) form of AMD. However, since there is no harmful aspect to the treatment as it currently exists and there is no viable alternative to this treatment, the author feels that eye care professionals should not withhold this option from patients pending the results of the long-term studies.

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