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Initial results of Microcurrent Stimulation in the treatment of Age related Macular Degeneration

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Macular degeneration - an epidemic

Macular Degeneration is an epidemic affecting over 13 million Americans and is the leading cause of blindness in developed countries. The Senate Appropriations Committee of the United States Congress has recognized ARMD with the following statement: "Age related macular degeneration is the leading cause of severe visual impairment and blindness in the United States. Most cases develop over the age of 65, but certain hereditary conditions may cause it to develop in younger individuals. Persons over the age of 75 have a 30% chance of developing ARMD; it rarely affects anyone younger than 55 years old. Caucasians develop it more than persons of darker colored skin because they have less pigment in the retina, especially if they have blue, gray, or green eyes. It affects men and women equally. People who are nearsighted (myopic) have a greater chance of developing the condition as do people who work or spend a lot of time out of doors and are exposed to ultraviolet radiation from sunlight.

Two Types of ARMD

There are two types of macular degeneration the wet and the dry type. The wet type, which is less common, 10-20% of patients, consists of neovascularization with

hemorrhages and accumulation of fluid under the retina. A small percentage of cases, early in the disease, can benefit from laser photocoagulation. The dry type is much more common , 80 to 90% of patients with ARMD, consisting of drusen, pigment clumping and atrophy in the macular.

Early Warning Signs of ARMD

Early signs of deteriorating retinal health include blurred vision with close work, seeing straight lines as wavy, and diminishing color vision. The first change is a lessening of sight as they look straight at things, like print or faces or clocks. This may be a dimming, a blurring, or actual 'holes' or black spots in the vision. Extreme light sensitivity and poor night vision also precede ARMD in many cases. Light-to-dark adaptation, the ability to find a seat in a movie theatre is also apt to be very slow. ARMD rarely leads to total blindness. Instead, worsening symptoms include a loss of central vision and a diminished ability to see things straight ahead. Looking at a clock or a face becomes more and more difficult. People with ARMD come to rely more and more on peripheral vision. Sometimes, in the early stages, there are holes in vision, called scotoma. These are areas where you cannot see anything. Most people with ARMD become unable to drive and are eventually declared legally blind. Unfortunately there is no effective treatment is available and most of current research is in the fields of molecular biology, genetics, photobiology and transplantation. This paper will look at a new approach to the treatment of ARMD- using electrical energy in the form of microcurrent stimulation.

The History of Microcurrent Stimulation

The history of MCS is a long and interesting one. The first report of the use of an electrical current to treat disease is from the Roman physician Scribonius Largus in 46AD. He described using the black torpedo fish to treat gout. This fish would produce an electrical shock when frightened, and Largus advised persons with gout to stand in the surf and step on the fish. The electrical current produced by the fish was reputed to eliminate the terrible pain of gout.

There is some evidence that the ancient Egyptians (2500 BC) also knew of this treatment. Stone carvings of a species of catfish called Malapterurus electrus are found in hieroglyphics. These historical reliefs may be the first 'written' records of electricity being used to treat painful conditions. Like in Rome, using the shock of an electrical fish.

It wasn't until 1745 that a device was developed that could actually store and supply electricity for the treatment of pain. This was first called the Leyden jar. Later, this device became the "Electreat". The Electreat device received a US patent in 1919 and sold for $12.50. Electreat was the precursor of the modern day Transcutaneous Electrical Nerve Stimulation or TENS unit. This device is the prototype of the Microcurrent Stimulation unit.

In 1965, two researchers named Melzack and Wall published a book on the gate control theory and dorsal column nerve stimulation. The gate control theory is an explanation of the transmission and treatment of pain. It suggests that there is a gate on the spinal cord which acts as an on or off switch for the transmission of pain. This

gate then allows the pain impulse to proceed to the brain or it has the ability to stop the pain.

Melzak and Wall discovered that an electrical stimulus at the dorsal column would prevent the sensation of pain. The dorsal column of the spinal cord is an area on the back of the spinal cord where nerves that conduct pain to the brain are located. This research made possible the development of and medical use of the first generation of Transcutaneous Electrical Nerve Stimulators (TENS units) that have helped hundreds of thousands of patients control pain.

It took nearly sixty years before the next big breakthrough in electrical stimulation surfaced. Although no one can really say for sure at this time, it seems that Dr. Thomas Wing may have been the father of the next generation of electrical stimulator, the MicroCurrent Stimulator. Somewhere around the end of the 1970s, Dr. Wing introduced his Acu-O-Matic device.

Although TENS devices are primarily used for the treatment of pain, a number of other effects have been reported. Several studies have found that using the TENS unit increases blood flow and stimulates wound healing. Kjartansson and Lundeberg in 1990 did a study on 20 patients who had poor skin circulation due to plastic surgery. After using the TENS treatment the skin showed a significant increase in blood flow.

Debreceni in 1995 reported the results in using the TENS unit for circulatory problems. Twenty-four patents were studied who had blockage of the arteries to their lower leg, which resulted in poor circulation and pain. After the TENS treatment,

twenty patients showed marked improvement. There was decrease in pain, reduction in pain on walking and healing of persistent ulcers after the TENS treatment.

Kaada in 1982 studies the effects of TENS in four patients with Raynauds disease and two with diabetic polyneuropathy. Both of these conditions produce narrowing and spasm of the small blood vessels, resulting in symptoms of coldness, numbness, pain, and loss of movement. Results of his study showed that treatment with the TENS unit increased the skin temperature and gave the patients relief from their pain.

The following year in 1983, Kaada studied the effect of TENS in the treatment of chronic leg ulcers. There were 10 patients who were treated. These patients had leg ulcers which had resisted the standard medical approaches. After the TENS treatment 8 of the 10 patients had successful healing of their leg ulcers!

Ngok Cheng in 1982 studied the effects of TENS on the skin of the rat. He applied different levels of current on the surface of the rat skin and then studied the changes in the cells using electron microscopy. This technique enabled him to observe the changes in the cellular mechanics. His results indicated that between 50 and 500 microamperes will cause an increase in mitochondria and an increase of 300 to 500 percent in ATP levels. He also noted that at this level there was an increase in protein synthesis and gluco-neogenesis. This study is exciting because it gives us a model on how MCS might work inside the eye. The MCS applied to the eye will stimulate the diseased retinal cells, increasing cellular functions and stimulating the diseased cells to recover.

Microcurrent Stimulation and Retinal Disease

Grace Halloran was a pioneer in designing and conducting the first studies on the efficacy of Microcurrent Stimulation in reversing retinal damage. In 1983, one of her life dreams was realized, when with a grant from Dr. Joel Rossen's MicroStim Corp, she opened The Center for Eye Health Education in Sonoma County. The Center operated from 1983 to 1985. Here the first study to evaluate the effects of MCS on degenerative retinal disease was undertaken. Dr. Joel Rossen donated the equipment used in this first study on the effectiveness of Microcurrent Stimulation in treating serious eye disorders.

In her first study, one hundred fourteen patients were treated and independently monitored at the center for various retinal conditions. Dr. Halloran's clinic provided a number of therapies, and all patients received the MCS therapy that she had developed with Dr. Rossen. The results: Of the 114 patients that were treated, 18 patients had macular degeneration, and16 showed improvement. Seventy-eight patients had Retinitis Pigmentosa, and 62 showed improvement. The other 18 patients had various retinopathies and 16 improved. Of the ones who did not demonstrate any improvement, 14 stayed the same, and 2 continued to lose visual acuity, although only slightly. An interesting point about the 14 patients who stayed the same is that all fourteen of those patients had been diagnosed with early retinopathies. None of them presented with any loss of visual acuity at the beginning

of the study. Hence, they also showed normal visual acuity at the end of the two-year study at a time when many of them would be expected to lose vision.

In 1985, two optometrists, Drs. Leland Michael and Merrill Allen of Rapid City, South Dakota and Purdue University in Indiana, heard about the work being done in California for pain and retinopathies. They attended a three- day MCS pain management seminar presented in San Francisco by Dr. Rossen. It was there that they met with Dr. Halloran. Following the Rossen seminar, the doctors visited the Center in Santa Rosa and spent several days studying Dr. Halloran's techniques.

Soon after, they returned to the Midwest and, together, began a ten-year clinical study of the treatment of age-related macular degeneration (ARMD) using MCS. In this early study they found that MCS stabilized the degenerative process.. When Dr. Michael died of cancer in 1995, his work was taken over by another optometrist, Dr. John Jarding, who has done a considerable amount of additional research himself.

Dr. John Jarding continued the work of Dr. Michaels. He began to study a variety of Microcurrent frequencies and waveforms to determine which parameters would work best in regenerating the diseased macula. He presented data on 400 eyes treated with MCS. Seventy-eight percent of the eyes showed from one to nine lines improvement on the visual acuity chart, and over 50 percent improved from two to nine lines. In his study there were two patients with a vein occlusion and swelling of the macula. Both patients had a dramatic improvement in their vision. One patient improved from 20/50 vision to 20/15. The second patient, who could only see

fingers at a distance of one foot, was able to read the 20/200 line. There was one patient in the study with a macular hemorrhage who showed a significant improvement of vision from being able only to count fingers to a vision of 20/100. Damon Miller, MD who is also a naturopath and acupucturist has reviewed his results using Microcurrent Stimulation in the treatment of Stargardt's Disease, retinitis pigmentosa and other degenerative retinal disease. His results indicate that of 120 patients treated, 83% showed improvement of greater then or equal to two lines of visual acuity in one or both eyes.

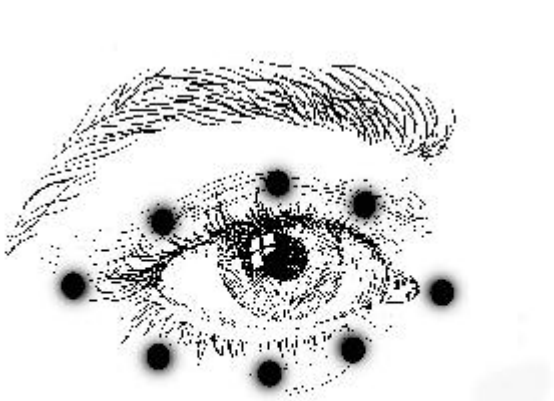
Purpose of this study

To evaluate the safety and efficacy of using the Microstim 400 and the Microstim 100 in the treatment of dry macular degeneration patients

Technique

The Microstim 400 unit was used for the initial 8 treatments. One treatment was conducted on each eye using 4 frequency settings of 292 HZ, 30 Hz, 9.1 Hz and 0.3 Hz. 8 points were treated with each frequency for 12 seconds located along the

periorbital area. 4 points above the eye and 4 points



below.

Patients were instructed to carefully monitor the current at each treatment point. The current was slowly turned up until a sensation was produced and then it was turned down until all sensation of electricity subsided. All treatments were conducted at this sub-threshold level.

After the initial 8 treatments using the Microstim 400, patients were instructed on the use of the Microstim 100. Patients then used the Microstim 100 twice a day for 5/7 days a week. Follow-up examinations were conducted every 3 months unless a patient experienced a side effect or a loss of vision.

Method

Pilot study of Ten Patients. Ten patients were selected with dry macular degeneration. The nature of the pilot study was discussed in detail with all patients and an informed

consent was signed. Each Patient received 2 treatments a day for four consecutive days. Before each treatment snellen acuity and amsler grid were measured. A detailed examination was conducted on each patient, including external examination, intraocular tensions and fundus examination. All patients received vitamin and nutritional supplementation consisting of Pure Focus sublingual spray (Biomax) and the Macular Degeneration Formula (Nutritional Research) after each treatment visual acuity; amsler grid and intraocular tensions were measured. This study was conducted from September 1998 - November 2000.

Post pilot study protocol

No loss of vision, change in amsler grid or change in intraocular pressure was noted in the first group of 10 patients. The protocol was then changed to record visual acuity, amsler grid, intraocular tension at day 4, and every three months for one year.

Results

28 patients/ 56 eyes

All patients with dry macular degeneration

Patients with glaucoma and previous retinal laser surgery were eliminated from this study. Minimum 3 month follow up

Analysis of Data (See attached data sheet)

Pre-MCS, Range - 20/25 to 1/400

Post- MCS, Range - 20/20 to 3/800

1) Percent of eyes with improvement of acuity- 66%

2) Range of improvement- 0 to 2.5 lines of vision

3) Average number of lines improvement- 0.48 lines

4) Patient RE with visual improvement with corresponding changes in retinal photography

RE vision improved from 20/100 to 20/50 OU after 3 months of treatment and he had a corresponding change in his fundus photos. (See attached photos)

5) One patient HS had a loss of vision in on eye and a gain of vision in the other eye. The loss of vision was attributed to the natural progression of the dry macular degeneration

Discussion

This initial study indicates that Microcurrent stimulation has a beneficial effect on the level of visual acuity in patients with dry macular degeneration. This initial study did not show any adverse affects after three months of treatment. It is very exciting that this fairly non-evasive technique improved the visual acuity in this group of dry macular degeneration. This study should encourage other Ophthalomologist's to begin to investigate this method of treating macular degeneration. In addition other studies need to be conducted to look at the beneficial effects of Microcurrrent with the wet form of macular degneration, Stargardt's Disease and Retinitis Pigmentosa. A double blind study needs to be designed to address the possible placebo effect. Currently a proposed study of using MCS to treat dry macular degeneration is being submitted to the Food and Drug Administration.

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