

A Discussion Between
Eye Care Professionals
And Members of RPList and MDList
December 30, 2002
Topic: Microcurrent Stimulation

GIRISH: This following article may not be new, but it is interesting for a few believers on this list. Although Grace [Holloran] has been discredited in the past, I believe that there is some truth in microcurrent therapy. Because improved vision was observed when computer chips were introduced into the eyes of retinitis pigmentosa (RP) patients. [Editor's note: see "Microchip Implantation."] These chips were generating microcurrent and stimulating the retina. How different is this from the microcurrent therapy? From the outside, it looks quite similar, but skeptics and pharmaceutical companies have no interest in promoting this idea, so we will not see any research in this area for a long time.

Quoted from wNBC.com:

Electricity Slows Macular Degeneration, Blindness
About 12 Million Americans Suffer From Condition
New York, November 26, 2002

Macular Degeneration Treatment

Macular degeneration is one of the most common forms of vision loss in this country. About 12 million Americans have it, and that number is expected to escalate to 30 million within the next few years. Lasers are the usual treatment for macular degeneration, but some experts say electricity is a better, non-invasive, alternative.

Grace Halloran was declared legally blind 30 years ago. She has macular degeneration, and she's tried everything to restore her vision.

"I was on nutrition, color therapy, exercises for the eye and upper body, acupressure and stress management ..." she said.

Patients with macular degeneration don't see the world like most people do. Their view's obscured by a large black spot that usually gets worse over time.

But Halloran came up with an idea during her son's rehabilitation from an elbow fracture.

"[The doctors] were using microcurrent technology to improve, speed up the process in sprains or back injuries and I found it to be useful in sports medicine, so I said, 'Why not the eyes?'" she said. "So I started using it."

The procedure Halloran used is called microcurrent stimulation. It involves applying an electrical current to acupuncture spots around your eyes, twice a day, three to four days a week.

"I've seen fields improve, color vision improve, and acuity -- coming down more than two lines on the eye charts," she said.

Dr. Damon Miller says microcurrent stimulation can help most patients with macular degeneration.

"I've had people who are legally blind who are driving again," Miller said. "I've had people who couldn't see the face on their grandchildren who can do that again. People who couldn't read do that again."

So why would the electric current help people see? No one is sure, but Miller believes it allows the eye to heal itself. But the problem is, there's no scientific proof.

Miller says that's the fault of the medical establishment.

"Medical studies in this country have been funded by drug companies -- and this is not a drug," he said.

The eye doctors NewsChannel 4 spoke to said they didn't know enough about microcurrent stimulation to comment about it. They did say they doubt it's a cure for macular degeneration. Miller also believes that microcurrent stimulation isn't a cure, but he says it can slow down the disease in most patients.

(End of article)

GISLIN DAGNELIE, Ph.D.: Grace Halloran has advocated a number of unconventional therapies for retinal degenerations over the years, and received some criticism for her wholesale embrace of most of those. But that doesn't mean there isn't some truth in there somewhere.

In particular, the idea that the same principles may underlie the reports that: 1. Dr. Chow's multiphotodiode array may give improved sight, even in retinal areas away from the device, and 2. patients receiving extraocular microcurrent stimulation have (temporarily) improved vision, suggests that small electrical currents may be good for sick rods and cones.

I wouldn't be surprised at all if some labs are going to pick up on this idea in the near future, even if there isn't big money in it, and even if the chances are slim that there will be a long-term benefit. As long as not much else is available, it seems worthwhile to explore any avenue that may bring even modest slowing of the degeneration process. The National Center for Complementary and Alternative Medicine (or even the National Eye Institute or the Foundation Fighting Blindness) might fund a small study, if the information gets a little less anecdotal than it has been thus far.

GIRISH: The following article surprised me to find that FDA has approved this form of therapy for retina. I thought it was still experimental. I don't think anyone should rush and get treated, but I would like to see more research funding in this area. I believe it has promise.

Microcurrent Stimulation (MicroStim or MCS)
(from the web site of visionworks.com)

MCS is novel, non-invasive and inexpensive treatment adapted from a FDA approved therapy used to treat other disorders. Preliminary studies have shown the MCS can be effective in treating retinal diseases ranging from Macular Degeneration (both wet and dry), Retinitis Pigmentosa, Stargardt's Disease, retinal vein occlusion and swelling, and other retinopathies.

The following 3 studies were summarized from the October, 2002 issue of the Townsend Newsletter:

The first study on MCS was a 2-year study done from 1983-1985 on 114 patients by Grace Halloran, Ph.D. The results of the study were as follows:

18 patients had Macular Degeneration, 16 improved.
78 had Retinitis Pigmentosa, 62 showed improvement.
18 patients had other various retinopathies, 16 improved.

Of the ones that did not demonstrate any improvement, 14 stayed the same (although they otherwise would have been expected to lose vision), 2 continued to lose vision, although only slightly.

A ten-year clinical study was done by Drs. Jarding and Michael on the use of MCS to treat Macular Degeneration. Of the 400 eyes studied, the results were as follows:

78% of the eyes showed from 1-9 lines of improvement in reading of the visual acuity chart.
Over 50% improved from 2-9 lines.

In the study, 2 patients suffered from retinal vein occlusion and swelling of the macula. Both had dramatic improvement in vision.

Damon Miller, MD, reviewed the results of using Microcurrent Stimulation in the treatment of Stargardt's Disease, Retinitis Pigmentosa and other degenerative retinal diseases. His results indicated that, of the 120 patients treated, 83% showed improvement of greater than or equal to 2 lines of visual acuity in one or both eyes.

There are several metabolic processes that are enhanced through the use of Microcurrent Stimulation. The first to boost the cells' ability to rid themselves of waste products. A cell with "stuck" waste products becomes a dead cell and interferes with cellular communication throughout the area where it is located. Cells need to take in nutrients and eliminate waste like all other living organisms. The energy supplied by Microcurrent Stimulation slows cells to become vital and less sluggish.

The second way Microcurrent Stimulation works is by increasing blood supply to

the area stimulated. By increasing blood flow to the area cells and tissues are nourished, refreshed and oxygenation is increased.

In general, the electrical current gently wakes up the cells from sleep and stimulates the healing process.

Individuals reporting a significant improvement in visual acuity after this therapy include legendary golfing great Sam Snead. [Editor's note: This claim was later denied privately by Mr. Snead.]

As its premier research project, the Macular Degeneration Foundation plans to conduct a nationwide controlled clinical trial to define the vision-enhancing value of administering what it terms Microcurrent Stimulation (MCS).

The Foundation's two-year preliminary MCS trial involving 120 patients resulted in an average of:

68 percent improvement over pre-treatment vision for patients with the dry macular degeneration.

58 percent improvement over pre-treatment vision for those with the wet form of macular degeneration.

Among certain subsets of patients with dry disease the results were even more dramatic, with a third gaining 100 percent or more improvement and a sixth gaining 150 percent or more improvement.

Patients were able to sustain these vision improvements over time by periodic self-administration of booster treatments and many report that this therapy has made a remarkable difference to their lives.

Is Microcurrent Stimulation Safe?

No side effects or adverse outcomes related to this treatment have been seen so far. No increase in the conversion to the wet form of ARMD has been seen to those who have been treated.

In a consensus statement by the NIH reports that, "One of the advantages...is that the incidence of adverse affects is substantially lower than that of many drugs or

other accepted medical procedures used for the same conditions."

(End quote)

DR. DAGNELIE: Well, I guess there were more studies than I had realized. Unfortunately, they have not been published in peer-reviewed journals, or at least not in any that are listed on Medline. So I think we should look at these reports with some healthy skepticism.

By the way, the fact that the equipment has been approved by the FDA just means that it is safe for human use if used as directed. The normal use is for the treatment of motor nerve and muscle problems, and even for that application it is not widely used. There are only about a dozen Medline publications over the last 10 years, less than half of which present solid data. The equipment was never tested for FDA approval for sensory nerve stimulation, nor for applications with the electrodes on the eyelids. It is, therefore, not at all clear whether this is a safe procedure in untrained hands, or whether it can cause long-term damage.

For now, I would not go out and spend \$800 on something for which the safety and efficacy have not been demonstrated. But I still think more and better research is justified.

EARL: I've read about microcurrent therapy, and I think that it is worth further research in the field. From my knowledge, correct me if I'm wrong, that the ganglion cells talk to each other via tiny electric currents but how to control the message sending through those cells is still up to this point unknown is it not?? So isn't this equipment kind of risky? It might not do anything, but also wouldn't it make things worse?

DR. DAGNELIE: Ganglion cells use electrical impulses to send signals to the brain. Cells in the retina do not really talk to each other through electrical impulses (they use chemical messengers instead), though in the outer retina voltage levels probably play some role in cell to cell communication between horizontal cells. The microcurrent stimulation takes place through the eyelids, pretty far from the retina. You are correct, however, that safety is a concern. If the currents are too large, they would damage, rather than help, the remaining retinal cells.

GARY: I read with interest the articles regarding the use of electrical stimulation to assist with retinal disorders. My viewpoint is that if there is no side effect, it may be worth giving it a try. Psychologically, it is amazing what happens when a given area is concentrated on. I feel that in the cold light of day, things would very soon return to the original status when the "buzz" has worn off.

My way of dealing with RP is getting on with life being positive. Look back over the years, and find out how many people have been greatly helped by "miracle cures" for RP. It is far better to deal with reality.

Any medical research into retinal disorders is important, and I can well understand a doctor wanting to stake a claim for treatments that can help. But when they then follow by marketing devices, it spells out commercial and material gain for them. They would probably argue that it is a way of bringing attention to their cause. I understand the use of electrical stimulus on muscle tissue producing contraction and regenerating tissue, but I cannot find any truth in how it can trigger dead or diseased cells to function when a disease like RP is in your DNA blue print. You have what you have, and no amount of treatment can effect it, unless you can influence the original blue print at the source (i.e. the genes).

I think I'll carry on as I am with my RP, since I've gotten used to it now for 44 years. I don't accept it, don't like it, but have learned to cope with it.

PHILIP: Five or six years ago when people were talking about going to Cuba to have eye surgeries for RP, I suggested on this list that we be patient, not damage our eyes any further, and wait for breakthroughs that have more of a potential for success. I hoped we wouldn't have to be this patient. There still is no accepted cure, but we do seem to be closer, with several potential avenues for success.

So, let's be patient. Maybe some of the loss we experience everyday can be reversed. Let's not muck up the what capacities we may still have left and save our money for procedures that we have some assurance will work.

JOHN: Gary brought and interesting point out when he alluded to the idea that a cure or product that is marketed is a clue to financial gain rather than an actual cure.

I believe that, just like counterfeiters try to get close to the real thing in order to

gain. So, shysters market products and services to get gain. However, the marketing itself is not the issue, nor is the money that is being counterfeited. What matters is when the shyster who knows what he is peddling is worthless.

I have experienced some things in my life, both with my RP and other things that I was told were just a placebo affect. That is great as far as I am concerned. I welcome the placebo affect for any area in my life it improves. Especially, those parts of my life where I received improvements that doctors could not do a thing with.

Dr. Dagnelie, can you prove, or has it ever been proven, that "Cells in the retina do not really talk to each other through electrical impulses (they use chemical messengers instead)?" I would like to read scientific proof that they do not speak electronically. I am curious how science can actually prove that, as they can't actually prove how electricity works.

DR. DAGNELIE: I can't possibly summarize the literature on the physiology of the retina, which has accumulated over at least 40 years and is growing by leaps and bounds daily. There are excellent books on the subject (such as John Dowling's "The Retina: An Approachable Part of the Brain") that will give you a good overview. One of the things you will learn there is that cells in the retina communicate via synapses, small contact areas where information is exchanged in the form of neurotransmitters (special molecules).

Within cells, electrical currents are very important, and charged ions flow in and out through cell membranes continuously to allow the signal transmission at synapses to occur.

Only in the last few years has there been solid evidence that some cell-to-cell communications in the retina are purely electrical, and only for a very limited class of cells and limited types of information.

Dr. Frank Werblin at UC Berkeley has a series of wonderful animation videos to show how information is processed in the retina. You can reach those through his lab web page at <http://mcb.berkeley.edu/labs/werblin>.

BARBARA: I always copy and print information about treatments to show my eye specialist. If he feels suspect about it, then he will warn me not to go ahead. I

haven't presented anything to him about this treatment, but I will show it to him and find out.

WENDY STROUSE WATT, O.D. (Member, Professional Advisory Board, Macular Degeneration Support): I agree with Dr. Dagnelie's thoughts about microcurrent stimulation. I am bothered by the misquote in the article about the NIH consensus statement on Acupuncture. As to the safety of the instrument, they purposely misquote the Acupuncture NIH consensus Statement 1997 Nov 3-5; 15(5):1-34, by substituting MCS Therapy for Acupuncture.

They quote, "In a consensus statement by the National Institutes of Health, they report that, "One of the advantages of MCS Therapy is that the incidence of adverse affects is substantially lower than that of many drugs or other accepted medical procedures used for the same conditions."

They also state, "The procedure is safe, noninvasive and painless and no side effects or adverse reactions have been observed. The deliberate misquoting and representing an instrument as safe to use because it is an off label use of an instrument approved by the FDA. The instrument is approved by the FDA for pain and not for use around the eyes or the head and neck and the FDA has not established that the instrument is safe and effective for the new use."

People with macular degeneration are desperate to improve their vision. When a treatment is presented as safe and with no side effects, they are willing to pay anything, are easily mislead, and are put at risk. ScyFIX and Dr. Edward Paul are promoting, distributing, and selling Micro 400 for a new use, the treatment of macular degeneration and other ocular diseases. Grace Halloran, Damon Miller, George Khouri, and Edward Kondrot are all promoting, distributing, and selling the Microstim in the same manner.

The claims they all have made for the treatment of macular degeneration are anecdotal, and they rely on testimonials and not controlled clinical trials. The clinical studies that they list on their sites quote the statistics of others and were not controlled studies, and the instruments used were entirely different instruments. (The first two articles used the ElectroAcuscope and the third the Microstim). They are all in the business to make money and have no interest in going through the proper steps to get the instrument approved and to do the scientific research needed to gain credibility. In fact, Dr. Kondrot says he is doing

a NIH study, and this claim is false according to the NIH.

The following information is from the FDA warning letter sent to Damon Miller on November 5, 2001:

"Both the MicroStim 100-2C and the MicroStim 100i were cleared through the 510(k) premarket notification process as Transcutaneous Electrical Nerve Stimulation (TENS) devices. The MicroStim 100-2C and the MicroStim 100i are intended for the symptomatic relief of chronic (long-term) intractable pain and as an adjunctive treatment in the management of post-surgical traumatic pain problems. The beginning of your web site (<http://www.acupunctureworks.com/micro.htm>) includes a broad discussion of Microcurrent Stimulation. There you discuss how Microcurrent Stimulation is used for treating problems in the muscles, joints, tendons, and bones; the reduction of scar formation following plastic surgery; treating acute sports injuries, non-healing bone fractures, retinal disease, and other eye diseases such as the wet and dry forms of macular degeneration and the treatment of Stargardt's disease.

"Other sections of your web site specifically mention the use of the MicroStim 100-2C and the MicroStim 100i, manufactured by Microcurrent Technology, for the treatment of age-related macular degeneration. In these sections, you discuss your use of the Microstim devices in the treatment of age-related macular degeneration. You state that your patient's vision improved by becoming clearer and brighter. Additionally, you indicate that of 120 patients treated in your office, 101 (83%) of those patients showed improvement greater than or equal to two lines of visual acuity in one or both eyes. You further state that if you were to include those patients who had at least one line of improvement in visual acuity, your success rate jumps to 93%.

"We advise you that claims for the treatment of age-related macular degeneration or any other disease conditions (not specifically cleared) represent a major modification in the intended use of these devices as described at 21 CFR 807.81 (a)(3)(ii) and require the submission of a new 510(k).

"Promoting the MicroStim 100-2C and/or the MicroStim 100i for claims of age-related macular degeneration is a violation of the law..."

The following information is from the FDA warning letter sent to George Khouri on January 3, 2002:

"During an inspection of your firm located in West Palm Beach, Florida August 30, 2001, FDA Investigator Michelle S. Dunaway collected information revealing serious regulatory problems involving MicroStim Model 100 TENS units. The inspection revealed that you promote, distribute and sell Model 100 TENS units, manufactured by MicroStim Technology, Tamarac, Florida, for therapeutic treatment of age related macular degeneration (AMD). AMD is a new use for these device(s), for which neither premarket approval or premarket clearance has been obtained.

"Under section 201 (h) of the Federal Food, Drug, and Cosmetic Act, these products are devices, because they are used in the cure, mitigation, treatment, or prevention of disease, or to affect the structure or function of the body. During the inspection the investigator documented violations of the Act resulting in the devices being adulterated within the meaning of section 501 (f)(1)(B) and misbranded within the meaning of section 502(0) of the Act."

On the surface, these people seem to be out for the patient's best interest, but it appears that money is their main motivation. I don't doubt that they are helping some patients, but without instrumentation that is specific for the eye, works consistently, and proven to be safe, patients could be misled and could receive little to no benefit. Those who are treating patients should be trained to look into the eye and be able to see if there are any adverse reactions. Several of those treating patients are not eye care specialists. To have the patients best interest in mind and to improve their vision must be the ultimate goal. Those treating seem to not want to take the time and to make the commitment to gain proper approval of the treatment and instrumentation.

EDWARD L. PAUL, JR., O.D., Ph.D.: [Here is] a study [which I] presented to the Swedish Academy of Ophthalmology regarding microcurrent stimulation therapy: The Treatment of Retinal Diseases With Micro Current Stimulation and Nutritional Supplementation. [Editor's note: This file is in PDF format, requiring Acrobat Reader to open.]

DAMON P. MILLER II, M.D., N.D.: As to the costs, we do our best to keep the costs as low as possible. The cost of the unit may seem high, but included in that

cost is all of the contact time with us. These are all therapies that people learn to do for themselves, for they must be done on an almost daily basis to work. The cost of our entire program is less than one some people are paying as their out-of-pocket portion for a single treatment with photodynamic laser therapy. Why are you not writing about the most recent papers presented at the ophthalmology conferences showing the dismal results from PDT (NO improvement of vision, still at high risk of bleeding). Why have you never mentioned on your discussion board that the centers (Johns Hopkins, UCLA, etc.) that were doing the long term follow-up of patients treated with conventional coagulating laser have stopped the studies because people treated with conventional laser were MORE prone to bleed than those who were never treated -- yet many eye doctors continue to treat people with coagulating laser. I see and talk with them everyday.

Retinal tissue is capable of healing, even regeneration, but the conditions for this to occur need to be optimal. We are working to define and provide those optimal conditions. If you want a better understanding of Microcurrent Stimulation, I suggest you read the book by Robert Becker, MD called "The Body Electric".

DAN ROBERTS, Director, MD Support: I would like very much to communicate with anyone who can provide proof that microcurrent stimulation has either significantly improved or even stabilized their retinal condition. For years, I have requested that patients write to me, either with such proof or at least a positive report following treatment, but I have yet to hear from anyone. Their comments would be well-received and published in our Treatment Archives for others to read.

You may remember that your reply to me of a few years ago was published in the MD Support Library. I also moderated a discussion a while back with Dr. Edward Kondrot, in which he was invited to present his views about both chelation therapy and microcurrent stimulation. That transcript may be read in our Clinic section.

In other words, I am doing all that I can to present both sides of this issue. If my personal opinion seems biased, it is because, in addition to not having heard from patients themselves, I have not seen any results from a peer-reviewed double-blind study published in a major journal after carefully-controlled trials. If I am to speak positively of any treatment, this is my standard. Until such convincing evidence is forthcoming, the best I can do is to present opportunities for people to

learn as much as possible about the issue so that they can make their own educated decisions. The open discussion now taking place is part of that approach, and I appreciate your taking part in it.

In response to your other comments:

I don't have an argument with the costs of the treatment or the equipment. My concern (which is also the principal concern of most doctors with whom I have spoken) is that money is being charged for a yet-unproven therapy.

You wrote: "Why are you not writing about the most recent papers presented at the ophthalmology conferences showing the dismal results from PDT (NO improvement of vision, still at high risk of bleeding)." PDT (photodynamic therapy) is intended to neither improve vision nor stop future neovascularization. I read the reports, but I have seen nothing that would cause me to stop recommending PDT as an option. If there were such misrepresentation going on, you know the FDA would rescind its approval as fast as they did recently when Novartis could not provide enough evidence to satisfy them that the therapy would be effective in cases of occult choroidal neovascularization.

Regarding your concern about the problems with laser photocoagulation, my standard recommendation since the advent of both PDT and transpupillary thermotherapy is that patients undergo laser photocoagulation only as a final resort. I'm sorry you misunderstood my position on this.

EDWARD C. KONDROT, MD (H), CCH, DHT: Patients with chronic eye disorders are investigating alternative therapies especially when traditional medicine offers very little hope. It is frustrating when patients are told, "Nothing can be done." It is more frustrating when the medical establishment refuses to investigate new therapies that might have a possible role in the treatment and reversal of these problems. When dealing with controversial treatments it is important to keep an open mind and investigate both sides thoroughly.

As a Board Certified Ophthalmologist and licensed Homeopathic doctor I have been interested in alternative therapies for the treatment of retinal problems. My approach is to look at the whole person evaluating both the physical and emotional components of the disease. Therapies that I utilize include nutrition, homeopathy, chelation and microcurrent therapy. Like many new therapies microcurrent has

been met with extreme skepticism.

My initial results of Microcurrent Stimulation were published in the Townscend Letter a peer review journal for both lay and professionals. (If you are interested in a copy of this article please email me a request or call the office below) I also published the book, *Microcurrent Therapy: Miracle Eye Cure?* To educate the public on this new treatment and to encourage patients to consider this therapy to slow and in many cases reverse the effects of this degeneration.

It is a false statement that Sam Snead retracted the benefits of MCS. Mr. Snead's dramatic improvement in his eye sight was reported by Tim Franklin Publisher of the Hot Springs Star on March 17, 1998. Sam was quoted as saying, "I am going to get a drivers license next year. This is exciting." In fact this information was on the MDF web page in 1999 and the MDF was advising patients on how to obtain treatment.

I had the pleasure of performing micro current on Sam Snead at his home in Palm Springs, Florida Feb 11-14. 2000. This was done under the supervision of his family doctor Ramesh Khurana, MD. At this time we recorded over a two line improvement in both eyes. Mr. Snead was extremely delighted and he volunteered to give the microcurrent therapy a testimonial.

There are two proposed mechanisms to explain the reversal of macular degeneration and improvement of visual acuity in patients who undergo microcurrent stimulation. The first is that the microcurrent stimulates the blood flow to the macula. This is substantiated by 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.

Debrececi 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.

The second proposed mechanism is the effect of microcurrent on the cellular level. 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.

References:

- 1- Kjartansson J, Lundberg T 1990 Effects Of Electrical Nerve Stimulation (ENS) In Ischemic Tissue. *Scandinavian Journal of Plastic and Reconstructive Surgery and Hand Surgery* 24: 129-134.
- 2-Debrececi L, Gyulai M, Debrececi A, Szabo K 1995 Results Of Transcutaneous Electrical Stimulation (TES) In Cure Of Lower Extremity Arterial Disease. *Angiology* 46: 613-618.
- 3- Kaada B 1982 Vasodilation Induced By Transcutaneous Nerve Stimulation In Peripheral Ischemia (Raynauds Phenomenon And Diabetic Polyneuropathy). *European Heart Journal* 3:303-314
- 4-Kaada B 1983 Promoted Healing Of Chronic Ulceration By Transcutaneous Nerve Stimulation. (TNS) *VASA* 12: 262-269
- 5-Cheng, Ngok, The Effects Of Electrical Current On ATP Generation, Protein Synthesis And Membrane Transport In Rat Skin, *Clinical Orthopedics and Related Research*, 171 (Nov.-Dec. 1982) 264-271

MARY: I realize that some may benefit from microcurrent stimulation therapy, and I am glad if you know some who have REALLY been helped. I had no success with it, however, and I have never found anyone who has. It angers me that some doctors may be taking advantage of desperate people. If it is possible to improve vision, there should be a way it doesn't cost hundreds of dollars to find out. I feel the same about the alternative medicines. I just can't help feeling that this may be snake oil. But of course, we must try it and test it out.

BRYAN GERRITSEN (Certified Low Vision Therapist): About last March this was a hot topic following a news piece on CNN. Like many professionals in the field, I received numerous calls from persons with a vision loss or their families, wanting to know about the efficacy of microcurrent stimulation. My colleague at Johns Hopkins Medical Center in Baltimore called me and asked me if I knew of the source of this information, and any relevant studies or data. I began calling, and had some revealing conversations. I learned that CNN's story came from an interview with an ophthalmologist in the Portland, OR area. A person doing microcurrent stimulation in Oregon had earlier approached the doctor, asking for his opinion on the subject. (I have since discarded my notes on this, so I apologize that I can't recall names of the ophthalmologist or the man doing microcurrent stimulation who made the inquiry). The doctor informed me that he basically told the man that he knew of no research to support the practice of microcurrent stimulation, or that it had any value to slow or reverse visual loss. However, he said that without such research, he could not entirely rule out any possible benefit. With that latter statement, the man doing the microcurrent therapy evidently contacted CNN, and got them to do a story, who unfortunately got things turned around, and the ophthalmologist was quoted inappropriately. He received calls on this almost non-stop from across the country, and had to repeat many times a day that he does not support microcurrent stimulation therapy, and was misquoted in the story.

To better understand research that would support or not support a specific practice or product that in fact may be efficacious, one needs to know more of the background and rigors of research practice. Research is usually classified as "Phase 1, Phase 2, or Phase 3 research." Each phase becomes progressively more constrictive, with more arduous stipulations. Before the AREDS (Age Related Eye Disease Study) was released to the public in October, 2001 by the National Eye Institute (NEI), regarding implications of nutrition on visual impairment, it had undergone years of scrutiny in all three phases of research. Such is the case with

most other funded research. As far as I know, microcurrent stimulation has only been in the proposal stage for Phase 1 trials of research until now. Rosie Janiszewski at NEI could comment more conclusively about whether they are now actually into Phase 1 trials. Regardless, it is likely far too early to comment about the effectiveness of microcurrent stimulation therapy on macular degeneration or related eye disease at this time.

One of the five ophthalmology practices I work for in Utah includes a retinal specialist who is currently doing funded research on acupuncture for macular degeneration. He is speaking to the staff at lunch today about some of his research and studies. However, until any research gets into the late Phase 2 stage or completes the Phase 3 trial stage, it is usually very premature to comment on almost any such research.

Persons with a visual impairment and those of us who serve as professionals in the field are extremely anxious to find something new that offers hope for a solution to macular degeneration and related diseases. But we must be cautious to not offer false hope, which can mislead and perhaps be very destructive.

DAN ROBERTS: Dr. Kondrot, in reply to my comment that Sam Snead had rescinded his much-advertised testimonial for microstimulation therapy, you responded, "It is a false statement that Sam Snead retracted the benefits of MCS."

Since Mr. Snead is now deceased and not able to confirm my statement, I contacted his son and daughter-in-law, Jack and Ann Snead, for verification. Here is a link to a resulting article which I have published with Jack and Ann's permission in the MD Support Library:

"Microcurrent Stimulation Testimonial 'Blown Out Of Proportion'"

As you see, Sam's son and daughter-in-law confirm that he was not helped by MCS, and that his name is being used without license. Further, Ann Snead made the following comment in her recent email to me:

"It is not right for Sam's name to be used as a marketing tool for something that did not help his eyesight. I hope your article will put a stop to such usage. It is sad to think that people desperate to find a 'cure' are spending money on a treatment that may not help them at all."

Finally, Dr. Kondrot, please comment on the following references to your above remarks, about which there are several inconsistencies:

1. According to Jack Snead, Sam did not live in Palm Springs, Florida (he says there is no such town), rather, he was raised in Hot Springs, Virginia, and lived for a while in Fort Pierce, Florida.
2. If Ramesh Khurana, M.D., is the neurologist who practices at Johns Hopkins and Union Memorial Hospital, he denies knowing Sam Snead personally, and Jack Snead says that no doctor by that name was ever their family physician. I could find no other Dr. Ramesh Khurana to ask about this, so I hope you can clear up the mystery.
3. Jack Snead does not recognize your name, and he says that his father had no further microstimulation therapy after his 1998 appointment with Dr. John Jarding in South Dakota. Another mystery about which I would appreciate your clarification.

Thank you for your time, and I hope to hear from you soon, either personally or through this open forum.

DR. KONDROT: I would like to supply you and the readers some additional information regarding Sam Snead. I examined and treated Sam Snead at his home in Panther Wood Golf Course which is located in Fort Pierce which is I believe North of West Palm Beach (Not Palm Springs as I mentioned in error). Dan I am going to send you a few pictures that were taken during Sam Snead's 4-day treatment of Microcurrent in February 2000, along with a shot of Sam giving me some golf lessons.

The medical doctor who observed the treatment was Dr. Ramesh Khurana, who has an office in Pittsburgh, PA, but who also has a home in Fort Pierce. He had become Sam's friend and medical advisor when Sam stayed at his home in Panther Wood. It was Dr. Khurana who arranged the treatments and who observed his improvement of vision. I will be sending you his office address and phone number for you to confirm these facts.

Another interesting note: I had several meeting with Sam's manager, Joe

Bachman, who was planning to develop Sam Snead Macular Degeneration Clinics. These clinics would utilize Microcurrent, Nutrition and vitamin therapy for people with ARMD. Joe Bachman had produced a prospectus for these clinics and was in the process of raising money for this project. I am going to see if I can find a copy of his prospectus for you to review. Sam Snead was happy with his treatments in Florida and was interested in writing a forward for my book *Microcurrent Stimulation: Miracle Eye Cure?* Joe Bachman advised him against this, because he wanted Sam to be focused on the macular degeneration clinics.

There have been several independent studies of Microcurrent Therapy by medical investigators. Dr. David Williams in his Newsletter Alternatives and recently, Robert Rowan in his popular Newsletter 2nd Opinion, devoted an issue on microcurrent in August 2002. His conclusion is, "I recommend MCS along with nutritional therapies for all of my MD patients. This is a wonderful breakthrough to avoid crippling visual loss."

Dan, I will email the phone number of the medical writer Dr. Robert Rowen.

DAN: Thank you for clarifying the discrepancies regarding the location of Sam Snead's therapy and the status of Dr. Khurana as a personal advisor, rather than as a family doctor. That would explain why the family had not heard of him.

It appears that Mr. Snead's manager, Joe Bachman, was planning to capitalize on the publicity that was gained from the therapy, and Jack and Ann Snead were not aware of it. Such ventures are a manager's job, and I'm sure he was within his rights. Jack, however, intimated to me that his father was easy to take advantage of, due to his amiable nature, so I wonder how much input he actually had in the project. In any case, it is a moot point since Sam's passing, and the license to use the Snead name has reverted to the family.

On another point, I have noticed that nutritional supplements are part of the microcurrent stimulation therapy program. Is it possible that the observed improvement in visual acuity is due to this variable? Also, as I looked at the photos of you and Sam Snead playing golf during the 4-day treatment period (thank you for sending them), I wonder if there is a psychological effect that may be influencing the results, i.e. 4 days in a relatively stress-free environment with an increased amount of personal attention.

Such variables will be eliminated when MCS is put through the rigors of clinical testing, so those questions will surely be answered in the process. Drs. John Jarding and Ed Paul are both making separate efforts to begin FDA-approved studies, and I am very interested in following their progress. If MCS proves to be beneficial, even in combination with supplements and stress therapy, that would be good news for all of us. On the other hand, if the trials show no significant improvement, then by proving the hypothesis in reverse, it will still have been time and money well-spent.

DR. PAUL: [Regarding the letters of warning sent by the FDA to Drs. Miller and Khouri. See Dr. Watt's comments, page 1.]

The FDA issued warning letters to these doctors for various marketing and promotion methods that were questionable. The treatment of retinal disease with microcurrent stimulation machines is perfectly legal as an "off-label use." Microcurrent stimulation machines are currently FDA 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. The use of an approved device for other than its FDA approved indication is called "off-label use."

Here is an excerpt from the FDA's website at www.fda.gov/oc/ohrt/irbs/devices.html:

"Does FDA require IRB review of the off-label use of a marketed device?"

YES, if the off-label use is part of a research project involving human subjects.
NO, if the off-label use is intended to be solely the practice of medicine, i.e., for a physician treating a patient and no research is being done. The FDA recognizes that off-label use by prescribers is often appropriate and may represent the standard of practice.

We are currently preparing documentation for IRB review so that we can conduct FDA-approved research, however as stated above, it is perfectly legal for physician's not engaged in research to treat patients with the device as a part of the practice of medicine.

DR. WATT: Dr. Paul, you wrote, "The FDA issued warning letters to these doctors for various marketing and promotion methods that were questionable."

The FDA said in the warning letter to Damon Miller, "We advise you that claims for the treatment of age-related macular degeneration or any other disease conditions (not specifically cleared) represent a major modification in the intended use of these devices and require the submission of a new 510(k)." This refers to the treatment of MD, etc., not marketing and promotion. Saying that it is a "major modification in the intended use" doesn't sound like they condone this "off-label" use.

Promoting the MicroStim 100-2C and/or the MicroStim 100i for claims of age-related macular degeneration is a violation of the law. On their web site, the FDA says, "There is a provision in the Federal Food, Drug, and Cosmetic Act that allows a practitioner to use a cleared device for an unapproved or 'off label' use." There are a number of restrictions that do apply in this case. The practitioner can only use the device "off label" in a legitimate practitioner-patient relationship. They may not advertise or promote the "off label" use of the device in their practice, and the manufacturer may not promote, advertise, or label the device for the "off label" use.

It is questionable whether the people who promote MCS always have a legitimate practitioner-patient relationship when they sell the instruments over the phone or over the Internet. They often do this without ever seeing the patient or consulting with a referring doctor who is trained as an eye care specialist: someone who has physically examined the patient and who is referring the patient to the practitioner for treatment.

A while back, you were discussed on the RPList email group. To quote one of the posts:

"I live in the UK, so I inquired as to how I would be able to try it. [Dr. Paul] told me that it cost \$2400 for the treatment and equipment and 4 days in-house treatment and checkup which I thought fair enough. However, I was sceptical, because he offered an alternative, whereby he would send me the treatment and equipment for a charge of \$1000, which he was willing to do without even physically seeing me, not knowing my history my RP status. So does anyone

know how a doctor would be able to administer treatment like this without knowing anything about me or seeing me for tests etc.?"

You and others who treat with microcurrent stimulation are advertising and promoting the "off-label" use of the device you are using. This is counter to the FDA restriction mentioned above. Aren't you doing just what you interpreted that the FDA was warning the others about by advertising and promoting the instrument's "off-label" use?

To quote from your web site, "MicroCurrent Stimulation (MCS) is an enhanced adaptation of a FDA-approved therapy." But is the "enhanced adaptation" FDA-approved? In their letter to Dr. Khouri, the FDA states, "The MicroStim 100-2C and the MicroStim 100i [machines]...do not have approved applications for premarket approval [or] investigational device exemptions." The FDA also states that Model 100 TENS units have not been approved or cleared for therapeutic treatment of ARMD.

In your remarks above, you wrote that the FDA requires Institutional Review Board (IRB) review of the off-label use of a marketed device if that use is part of a research project involving human subjects, but not if that use is solely for the practice of medicine where no research is being done. The study you posted shows that you are doing research involving human subjects, as are the others treating patients with MCS. It is clear that none of you are using the MCS machines solely for the practice of medicine.

You also quoted from the FDA's website about the need for IRB review of the off-label use of a marketed device: "YES, if the off-label use is part of a research project involving human subjects. NO, if the off-label use is intended to be solely the practice of medicine, i.e., for a physician treating a patient and no research is being done." It also states, "The investigational use of approved, marketed products differs from the situation described above." This refers to off-label use as part of a research study involving human subjects. Aren't the patients you have treated in your office with MCS the ones listed in your study?

In your response, you also wrote that you are currently preparing for IRB review so that you can conduct FDA-approved research, and that "it is perfectly legal for physicians not engaged in research to treat patients with the device as a part of the practice of medicine."

More is needed than just an IRB review. You need to submit for an Individual Device Exemption (IDE). You are engaged in research, as are Khouri, Miller, Kondrot, and Halloran. In Dr. Khouri's warning letter, the FDA wrote that the Microstim (and other instruments similar to it) are Class III and require premarket approval. According to them, "Class III is the most stringent regulatory category for devices [requiring] scientific review to ensure...safety and effectiveness." The Micro 400, which you use, is virtually identical to the Microstim in its electronic specifications. That device, therefore, must be proved to be safe and effective in the new intended use. The bottom line is that the FDA and the FTC regulate devices, and they do not permit a new or modified Class III (the highest risk class) medical device to be tested in humans for safety or effectiveness without an IDE.

In their warning letter to Dr. Miller, the FDA stated, that "promoting the MicroStim 100-2C and/or the MicroStim 100i for claims of age-related macular degeneration is a violation of the law." They did not say, "Since you are doing research, or since you are not doing research, it is perfectly legal for physicians to treat patients with the device as a part of the practice of medicine."

The following links lead to examples of how the FDA views off-label use:

Manufacturers and Users of Lasers for Refractive Surgery

Primer on Medical Device Regulation Part III. Regulatory Mechanisms and Import/Export Regulation

Townsend Letter: Robert Sinaiko, MD, Placed on Probation

Clinical Trial Issues Result in Criminal Prosecution - U.S. v. Prigmore, 243 F.3d 1 (1st Cir. 2001)

Medical Research Issues

Legal Status of Off-label Drug Use (contained in letter written by Robert J. Sinaiko, M.D.)

The bottom line is that the FDA and the FTC regulate devices, and they do not permit a new or modified Class III (the highest risk class) medical device to be tested in humans for safety or effectiveness without an IDE.

The legal requirements for medical devices are detailed by the Food, Drug and Cosmetic (FD&C) Act of 1938, which prohibits the movement of adulterated or misbranded products in interstate commerce. Performing a "prohibited act" is a

violation of the law, which is subject to FDA action, including monetary and other penalties. The FDA ensures compliance with legal requirements. They meant business when they sent the warning letters. The patients who are purchasing the instruments don't realize that the instrument can be recalled, seized, and destroyed, with no refunds or other financial considerations.

Also, according to the court case in California, "A doctor can lose the license to practice medicine by using a new treatment learned at a medical conference or in a medical journal. A doctor can lose the license to practice medicine by an off-label use of a safe drug even when such use is supported by the medical or research literature, and even when the patients get better."

In the information about lasers, the FDA admitted that they do not seek to regulate the practice of medicine. The practice of medicine, however, does not allow the advertising of the device for off-label uses. The FDA believes that "the best data and protection of patients are achieved when these unapproved uses are studied under an FDA approved investigational device exemption," and that, "practitioners who use these lasers [lasers not approved by the FDA for this new use] are not operating within the legal requirements of the Federal Food, Drug, and Cosmetic Act, unless they have an IDE that has been submitted to and approved by the agency." So, according to this view, wouldn't those treating with microcurrent stimulation without an IRB and/or an IDE, and who are advertising the unapproved off-label uses, be challenging the law?

Sorry that this has been so lengthy, but all of it is important.

CAROL: Human research requires an enormous amount of "paperwork," planning, investigation, and approval. Then, there are vast differences between the terms "Study" and "Research." The scientific methods of research must follow strict guidelines by any and all participating in investigations. Research is as a multi-faceted gem. It is critically important that ALL of the facets be examined, measured, and determinations be finalized before any conclusions may be presented in ANY way. Those conclusions must be replicated by other teams of investigators at other institutions. At that point, the FDA phases may be applied for, and possibly, a Phase I granted.

That being said, we cannot overlook how individuals perceive a practice, mores, a benefit, a response, utilize tradition, communication, etc. It's important to bear in

mind reality, and it is a reality that people who can afford to try alternatives that have no given scientific proof, are just going to do it. Yes, they could be out enjoying life in a special way during such treatments, and realize that there's no objective, clinical analysis that can prove they are being benefited . . . but they won't and/or cannot accept they are not either cured or being helped.

It is difficult enough in the U.S. to be a prepared health care consumer in such a fragmented medical system. It is beneficial, however, to pick our fights and protect our time carefully.

A Discussion Between
Eye Care Professionals
And Members of RPList and MDList
Beginning December 30, 2002
Topic: Microcurrent Stimulation

(Page 3)

JOHN JARDIN, O.D., FAAO: I want to take this opportunity to inform you of a Feasibility Study now underway by Acuity Medical, Inc. This study is being conducted under the auspices of the Food and Drug Administration (FDA). Acuity Medical holds the license for new, patented technology using biocurrent to treat Age-Related Macular Degeneration. The new instrument, the TheraMac, uses low microcurrent with a very specific range of frequencies. Because any medical device used above the neck is considered a class 3 device by the FDA, it must pass the rigors of FDA double-masked, randomized, placebo-controlled studies. The instrument must have been granted an Investigational Device Exemption (IDE), which has been granted. By being granted an IDE, the FDA is satisfied with safety and the instrument may now be used in FDA trials. The feasibility study is overseen by an Institutional Review Board (IRB) and is now being conducted at two sites, one in South Carolina and one in North Carolina. The clinical research organization monitoring the study is Discovery Alliance, Inc.

I am fully aware of all of the controversy on treating macular degeneration patients with microcurrent. I have been involved with this research since 1985. I have felt that it was only appropriate to follow FDA protocol when treating patients. Until we prove the benefits of BioCurrent Therapy to the FDA, it is not appropriate to sell instruments or advertise the benefits of BioCurrent for the

treatment of macular degeneration. These are FDA rules. These are things we plan to prove or disprove to the FDA through the trials.

Because there are significant differences in microcurrent instruments, none of which are FDA approved for the treatment of macular degeneration, appropriate research in current amounts, current frequencies, and frequency of use must be studied. Through my work with electrical engineers and a cell biologist, The TheraMac instrument has passed these items to the FDA's satisfaction, allowing it to be used in clinical trials. I have had a continued fear that uncontrolled use of microcurrent and unapproved instruments would shed unfair and negative light on my work. My open clinical studies have shown very positive results using the appropriate current, frequency levels and frequency of use with TheraMac and BioCurrent. Sixty two percent of the eyes treated have gained 2 or more lines of best-corrected visual acuity.

We hope to conclude our feasibility study within the next 2 to 3 months. We plan to publish the results in a juried journal of our peers. I look forward to presenting you this information. Immediately following the feasibility study, the approval phase of research will begin.

DAN: It is good to hear that approved trials will soon be underway. A number of years have passed since you helped to pioneer this therapy under Dr. Michaels, and I hope that some scientifically-based positive results will finally be forthcoming. Thank you for contributing this important information to our discussion.