The following summary of the research on the use of microcurrent stimulation in the treatment of retinal disease is from the company ScyFIX, and was part of their submission to the FDA in an attempt to gain approval for a clinical trial that would allow them to market a unit for eye treatment. They refer to studies done as part of this submission to the FDA, but these were never published. ScyFIX became Acuity Medical, and was eventually sold to a company named "The Eye Machine". As of 2016, they have still not been able to gain FDA approval to proceed with any clinical trials.
ScyFIX did have a unit approved for use in Europe, but it seems to be currently out of production.

ScyFIX became the only company in the world to initiate FDA guidelines compliant Pilot trials using Neuromodulation for ophthalmic blindness-causing diseases in 2007. The company develops and intends to make available to patients medical devices based on the use of its proprietary MCN technology to address a range of degenerative ophthalmic conditions. MCN is a therapeutic form of neurostimulation (often referred to as neuromodulation) that involves the trans-corneal application of small, precise dosages of electrical current to the retina, via electrodes placed over the patient's closed eyelids. ScyFIX owns the intellectual property related to the delivery of electrical current to the eye. The initial target markets are Retinitis Pigmentosa (RETINITIS PIGMENTOSA) and the dry form of Age-Related Macular Degeneration (ARMD). ScyFIX believes that MCN could be effective in treating several other degenerative conditions such as Presbyopia, Open-Angle Glaucoma, Diabetic Retinopathy and Stargardt's Disease, among others.

Retinitis Pigmentosa affects approximately 75,000 people in the U.S. and 1.75 million worldwide. Retinitis Pigmentosa is a genetic eye condition causing a loss of function in retinal photoreceptor cells outside the macula. There is currently no medical treatment that can either slow the progression of disease or cure Retinitis Pigmentosa. The primary treatment to slow progression of the disease includes daily ingestion of up to 15,000 IU of Vitamin A palmitate. Other options currently being evaluated are very costly, investigative, highly invasive and may involve retinal transplants, prosthesis, and/or gene therapies. Recognizing the genetic cause and rarity of Retinitis Pigmentosa in the US, the FDA has granted the Humanitarian Use Device designation to ScyFIX for the treatment of Retinitis Pigmentosa.

Approximately 50 million people are affected by Age Related Macular Degeneration (ARMD) worldwide, making it a leading cause of blindness. The prevalence and severity of Age Related Macular Degeneration increases with age, accounting for 55% of blindness cases in adults over age 40 in the U.S. and the prevalence of Age Related Macular Degeneration is expected to grow significantly with the aging baby-boomer population. The current treatment for this condition is the long-term use of pharmaceuticals, which are costly and often involve regular physician visits in which the patient receives an injection into the eye. The alternative is complex, invasive surgery, typically reserved for late stage conditions as a treatment of last resort.
The FDA has approved treatments for the Wet form of Age Related Macular Degeneration only, which accounts for approximately 10% of all Age Related Macular Degeneration cases. There is no approved treatment for the much larger Dry Age Related Macular Degeneration population which accounts for 90% of all Age Related Macular Degeneration cases. Consequently, most of the Age Related Macular Degeneration population is not treated as their degenerative condition progresses.
The ScyFIX MCN device offers a non-invasive, patient-administered treatment option that eliminates the extended patient recovery of the alternative, invasive techniques and frequent physician visits for the limited pharmaceutical therapies available (for the Wet form of Age Related Macular Degeneration). The device consists of a portable controller, disposable patches and lead wires. The ScyFIX 700 MCN device is CE Mark approved and is the commercialized product version of the ScyFIX 650 MCN device which was used in the ScyFIX's FDA trials.

ScyFIX recently completed two FDA guidelines compliant Pilot studies with 24 months follow up to evaluate safety and potential efficacy in patients with Dry Age Related Macular Degeneration and Retinitis Pigmentosa. No serious device related adverse events have been reported to date. Additionally, data through twenty-four months suggests that MCN therapy is clinically effective. Observations from the Pilot Trial data, suggest that MCN therapy not only slowed down the progression of disease symptoms as intended in a majority of patients in the study, but has in many cases halted, and in some cases reversed the progression of the disease. Early data from these Pilot trials was presented at three major International ophthalmic conferences: the 2008 ISCEV Symposium (International Society of Clinicians in the Electrophysiology of Vision), American Society of Retina Specialists, and the American Academy of Ophthalmology (AAO) conferences.

In the US, ScyFIX intends to make the ScyFIX 700 MCN system available under an FDA HDE approval, when received, to patients suffering from Retinitis Pigmentosa. The Company received its Humanitarian Use Device (HUD) distinction in March 2008 from the FDA, and will be submiting the 24 months data and HDE application to the FDA for approval. In addition to its ISO 13485 medical quality system certification, ScyFIX has met the Canadian regulatory requirements, and received the CE MARK for European approval for the new ScyFIX 700 device during May 2009 which allows for making the device commercially available to patients with Retinitis Pigmentosa and Dry Age Related Macular Degeneration, in international (outside the USA) markets where approval is achieved.
Additional Pivotal Clinical studies are anticipated for Dry Age Related Macular Degeneration before the ScyFIX MCN therapy

will be available in the US. ScyFIX is working diligently on the requirements of the regulatory pathway to facilitate FDA approval in the US.

For a short introduction to MicroCurrent Neuromodulation (MCN), read this:
Mechanisms of Action

For information on previously published studies which indirectly support the results with ScyFIX technology, please follow the links below.

1. Treatment of Macular Degeneration Utilizing Micro-Current Stimulation
2. Treatment of Retinitis Pigmentosa Utilizing Micro-Current Stimulation
3. Nutritional Supplementation, Electrical Stimulation
   And Age Related Macular Degeneration
4. The Treatment of Retinal Diseases With Micro Current Stimulation And Nutritional Supplementation
5. Bioelectrical Stimulation In An Integrated Treatment for Macular Degeneration, Retinitis Pigmentosa, Glaucoma, CMV -Retinitis, & Diabetic Retinopathy
6. The Effects of Electric Currents on ATP Generation, Protein Synthesis, and Membrane Transport
7. Macular Degeneration Treatment with Nutrients and Micro Current Electricity

Treatmentfor Macular Degeneration Utilizing Micro-Current Stimulation

Larry B. Wallace, O.D. FCSO, Journal of Optometric Phototherapy, March, 1997

Abstract

Forty-three patients were treated, twenty two with both eyes, with direct Micro-current of 200 Micro-amps for 20 minutes, for 36 sessions. All were diagnosed with dry macular degeneration. Of those, 54% improved 1 to 4 lines of Snellen acuity and 31% improved 2 to 4 lines. Kinetic visual fields expanded horizontally for 85% and 70% vertically for all patients. Humphrey 30-2 threshold fields significantly improved for 55% of those treated. These field improvements imply changes in receptor and ganglion cell function, with implications for treating Retinitis Pigmentosa as well. Flourescein Angiography documented improved blood flow and scar reduction. These positive outcomes show the potential of Micro-current therapy in the treatment of Macular Degeneration and retinal disease.

Treatmentfor Retinitis Pigmentosa Utilizing Micro-Current Stimulation

Jeffrey Rapkin, M.D., Research Project for Advanced Medical TechnologiesInc., 1998, presented at ARVO 1999.

Abstract

A small sample of patients diagnosed with RetinitisPigmentosa were treated with direct current of 200 Micro-amps. Visual acuity ranged from 20/40 to 20/400. Of these patients, 66% hadsignificant improvement in visual acuity. All of the patients demonstratedimproved visual fields as measured by Humphrey Field testing. The resultsindicated improved RPE metabolism, ocular blood flow, and /or the release oftrophic factors that may reduce photoreceptor degeneration.

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NutritionalSupplementation, Electrical Stimulation And Age Related Macular Degeneration

Leland D. Michael, O.D. and Merrill J. Allen. O.D.,. Ph.D.

Abstract

This is a preliminary report of an ongoing study of the rate of developmentof age related macular degeneration in people using nutritional supplements andtreated with weak electrical currents. Twenty-five subjects, ages 48 to 79 yearshave been treated for periods from two to seven years. Fifteen subjects haveimproved their acuity. 10 have lost acuity. Two have had laser treatment, twohad to stop because of age and transportation problems and two have died. Thesubjects have lost an average of 0.30 letters of acuity over an average of 4.0years. By comparison, Newsome's2 test group lost 4.1 letters and his placebogroup lost 7.1 letters of acuity in 2 years using nutritional supplementswithout electrical treatment. It appears that

electrical stimulation of theeyelids can enhance the success rate of nutrients alone in controlling AMD.

Keywords

Age–related macular degeneration, nutrition, zinc, electrical stimulation,micro ampere

Introduction

Age-related macular degeneration (AMD) and cataract are the major causes ofvisual impairment and blindness in the United States in persons over 55 years ofage.1 AMD damages the retinal tissues in the macular area causing finepigmentary stippling, pigment epithelium changes and the development of drusen.Drusen usually occur in a mirror pattern in both eyes AMD is called "dry" or "wet". The dry type is characterized with either normal acuity or only amoderate acuity loss, while the wet type may progress to rapid and severe visionloss. The average rate of acuity reduction has not been clearly defined in theliterature. At the present time there is no recognized therapy for the dry typeof AMD. A study by Newsome et al2 showed that a slower progression of AMDoccurred over a two year period, for subjects receiving vitamin and mineralsupplements high in zinc compared to unsupplemented (control) subjects. Thetreatment for the "wet" type of AMD involves using a laser to seal off theleakage in the choriocapillaris layer up through Bruch's membrane. There isthe real possibility of further vision loss due to leakage in the area aroundwhere the laser burn was applied. This stage of AMD is a depressing time for thepatient. In 1983, one of us (LDM) upon recovering from retinal detachment,decided to try to help patients with early signs of macular degeneration. Hebegan a study of the effects of nutritional supplements and micro ampereelectrical treatments on the rate of progress of the "dry" type of AMD.Electrical treatment was incorporated because the eye has a electrical potentialthat may play a role in retinal health and that can be modified with an externalsource of electricity. (The first patient, age 74 has been in the study forseven years and has had no further acuity decline.)

Procedure

Each patient who was diagnosed as having AMD was referred to a localophthalmologist who confirmed the diagnosis. The patient was then offered threealternatives; a) evaluation every 6 months; b) use a nutritional supplement andbe evaluated every 6 months; or c) use a nutritional supplement and receivemicro ampere electrical treatments at least once every month. Most AMD patientschose alternative c) and became part of this study. The control for this studyis the data presented by Newsome2 because this study differs from Newsome's study only by the addition of electrical treatment to the area around the eyes.

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Figure 1. The formula for the nutritional supplement that we provided to allsubjects.(

Eight Tablets Contain		%RDA
Vitamin A (Fish Liver Oil)	25,000 IU	500
D (Fish Liver Oil)	800 IU	200
Vitamin E (d-alpha Tocopherol Acetate)	400 IU	1336
Vitamin C (Ascorbic Acid)	2,000 mg	333
Vitamin B1 (Thiamin HCL)	100 mg	6567
Vitamin B2 (Riboflavin)	150 mg	8838
Niacin	80 mg	400
Vitamin B6 (Pyridoxine)	150 mg	7500
Pantothenic Acid (dCalcium Pantothenate)	100 mg	550
Inositol	150 mg	*
Calcium (Phosphate)	500 mg	50
Magnesium (Oxide)	250 mg	62
Selenium	100 meg	*
Zinc (Gluconate)	75 mg	495
Bioflavinoids	300 mg	*
Glycine	200 mg	*
L-Glutamine	200 mg	*
L-Arginine	300 mg	*

L-Cysteine HCI	400 mg	*
Glutahione	40 mg	*

* RDA has not been established. + Vision-Eze Professional Products. 925 HalePlace, Suite A4. Chula Vista, CA 91914Suggested Use: four tablets two timesdaily

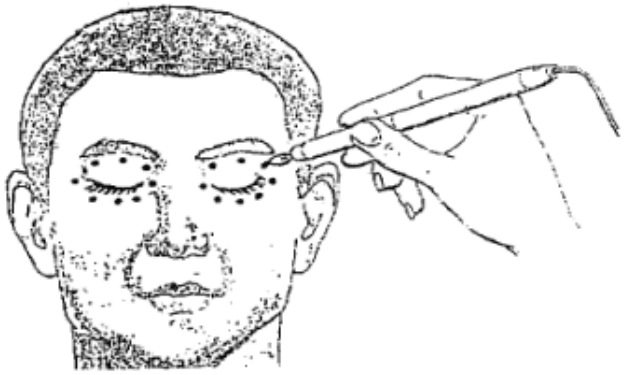

Figure 2: Each point on the eyelids was stimulated for about one minute with a sqare wave alternating electric current of 206 micro aperes at 10 cycles per second. The eyelid contact was via a wet cotton electrode and the ground was the palms of the subject's hands.

Figure 3. Summary of the data for 25 subjects treated with nutritionalsupplements and weak electrical stimulation during the period from July '85 to July '92. Subject 11 was dropped from the study when she received a cardiacdefibrillator because electrical stimulation might have adversely affected it.Subject 14 suffered severe vision losses after lasering because she had begun toshow signs of leakage. One line of acuity is 5 letters.

#	Age	Sex	Date Start	Date End	Beginning Acuity		End Acuity		Number of Letters change		REASON FOR LEAVING STUDY
					Right	Left	Right	Left	Right	Left	
1	74	F	7-18-85	7-92	30	20	30+2	15-2	+2	+3	
2	71	F	7-31-85	7-92	30	25	30+3	20+2	+3	-7	
3	74	M	9-10-85	11-91	100	30-2	100+1	30+2	+1	-4	Deceased
4	56	M	12-2-85	7-92	20	30	15	20+3	+5	+8	
5	77	M	5-28-86	7-92	20	15	20-2	20-2	-2	-7	
6	69	F	7-29-86	10-91	20	30	20+3	20	+3	+5	Poor health
7	76	F	10-14-86	9-91	20	25+1	20-1	400	-1	-66	Leakage, not lasered
8	48	M	1-19-87	7-92	40-3	20-2	30+1	20-1	+6	+1	
9	79	F	3-23-87	7-92	20-1	25-2	20	30+3	+1	-4	
10	65	F	8-17-87	7-92	30-2	15-3	40-2	15-2	-5	+1	
11	67	F	2-25-88	4-90	25	25	15	15	+10	+10	Cardiac defibrillator
12	79	F	6-28-88	7-92	25	40+3	20-3	25-1	+2	+6	
13	74	F	5-10-88	6-89	40-2	400	30+4	400	+7	0	Deceased
14	78	F	5-17-88	8-90	20-1	60-1	25-1	60-1	-5	0	Lasered OU = 20/400
15	74	F	9-16-88	4-92	400	25-1	400	70	0	-22	Poor health
16	66	F	5-30-89	7-92	25-1	40-1	30-1	40-1	-5	0	
17	73	F	11-15-89	4-92	20	25	25	50	-5	-15	Leakage, not lasered
18	76	F	1-03-90	6-92	25	30	25-2	25-2	-2	+3	Poor health
19	79	F	1-02-90	7-92	30	30	20-1	20-3	+9	+7	
20	65	M	1-09-90	09-91	25+2	100+1	100	100	-28	-1	OS Lasered
21	70	F	1-29-90	7-92	30	30-1	20-2	25	+8	+6	
22	70	M	3-05-90	7-92	400	40+3	400	40-3	0	-6	
23	66	F	4-09-90	7-92	50-2	25	25	20	+17	+5	
24	79	F	5-17-90	7-92	30-1	30-3	25-1	25-2	+5	+6	
25	66	F	8-13-90	7-92	70	20+4	50-2	10+3	+8	-1	
								SUM	+34.0	-50.0	
								AVG.	+1.4	- 2.0	
							AVG. Both Eyes		- 0.30		

Supplemental vitamins and minerals (see Figure 1) were assigned to be takentwice per day with meals. During the first 10 weeks the patient was seen 20times for fundus and acuity examination and for electrical treatments. Afterthis initial period the subject was examined and treated once a month. Theelectrical treatments of 200 micro amperes were applied to pints on the closedeyelids as shown in Figure 2

For a total of about 7 minutes for each eye using the ElectroAcuscope.

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Results

Figure 3 shows the initial age of the subjects who have been in the studyfrom two to seven years. It also shows the duration of involvement, the enteringacuity, the acuity at the end and the number of letters change in acuity duringthe study. For those who have received laser treatment, the final acuity wastaken just before lasering. Fifteen subjects improved acuity from 1 to 17letters and 10 lost 1 to 66 letters. On average a slight reduction of visionoccurred during this study amounting to 0.3 letters

where 5 equals one line oftest letters.

Discussion

To evaluate the results, Newsome's data were used for comparison. Thevisual acuity test letter sequence that Newsom used was as follows:

20/10	20/32	20/100
20/12.5	20/40	20/125
20/16	20/50	20/160
20/20	20/63	20/300
20/25	20/80	--

There were five letters in each line. Three lines totaling 15 letters doublesthe visual angle of the test letters.

Newsome found that for his 71 untreated control subjects, average age 68years (42 to 88). 18.3% lost 10 to 14 letters of acuity, 8.45% lost 15 to 18letters and 7% lost 20 or more letters over a period of 24 months using astandardized visual acuity test.4 Newsome's zine-treated experimental groupcontained 80 subjects of average age 67.6 (46 to 89) years, of whom 6.25% lost10 to 14 letters, 5% lost 15 to 19 letters and 2.5% lost 20 or more letters.

Newsome has shown a positive effect of selected nutrients on AMD. The averagerate of acuity reduction that Newsome found was 7.1 letters for the controlpopulation and 4.1 letters for the test population over a two year period. Ourstudy can be compared to Newsome's because our study uses similar visualacuity criteria, the same diagnostic procedures , and includes pharmacologicaldosages of supplemental zinc.

The possibility of a Hawthorn effect causing an improvement in visual acuitywas considered. In situations where the rewards are high as in a driver licensetest, the acuity test must be randomized to obtain accurate acuity measures.However, when the subject is concerned about permanent vision loss, we believethat learning the charts will have minimal effect on acuity measures.

According to Lane, "the dry type of AMD is different from the wet type andis related to inadequate amounts of zinc. If the wet type AMD subjects had beenomitted from this study the results would have shown a gain rather than a loss.We did not do this because Newsome did not do it.

There have been no reported adverse effects either from the nutritionalsupplements or the electrical stimulation. Subjects are protected byexaminations once a month. In the event of fondus leakage, these monthsexaminations assure early detection and immediate referral to the retinalspecialist and laser expert. These professionals and the subject then decidewhether to proceed with laser therapy.

Conclusion

This is a preliminary report of an ongoing study, and so far the results arevery encouraging. On average, the subjects have shown only a slight reduction invisual acuity. By comparing this study to Newsome's study, it appears thatadding electrical stimulation has improved the ability of nutritionalsupplements to slow the progression of AMD. To permit a proper statisticalevaluation more subjects are needed. Thus the experiment is continuing foranother four to five years.

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The Treatment of Retinal Diseases with Micro Current Stimulation and Nutritional Supplementation

Edward L. Paul, Jr., O.D., Ph.D., Visiting Professor of Ophthalmology, Chairman, Department of Continuing Medical Education, St. Luke's University School of Medicine

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 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. ATP Synthase (ATPase) 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 NIH at five 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 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, or the "indication." 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 is considered an *off-label* use.

The author was not the first research scientist to report on the effects of MCS therapy. 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*."

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(The above paper was presented to the "International Society for Low-Vision Research and Rehabilitation (ISLRR)", at the Low Vision Congress in Gothenburg, Sweden, 2002.)

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Bioelectrical Stimulation In An Integrated Treatment for Macular Degeneration, Retinitis Pigmentosa, Glaucoma, CMV -Retinitis, & Diabetic Retinopathy

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Abstract

From December 1995 to September 1997, thirty individuals diagnosed with typically untreatable eye diseases including retinitis pigmentosa, macular degeneration, CMV -retinitis, Stargaardt's and others attended an integrated treatment protocol employing bioelectrical stimulation, nutritional and herbal supplementation (including Ginkgo Biloba, Lutein, DHA) and other health care modalities. The study was monitored by a neuroophthalmologist, evaluating standard clinical visual function examinations, including objective field of vision tests obtained by the Humphrey FOV analyzer, visual acuity and color discrimination. Four controls were evaluated, with the monitors masked, and although the sample was small, the results were significant in their lack of change. Follow- up examinations of the graduates were provided, establishing efficacy of the rehabilitative progress made originally, including a review of two graduates who participated in a five- day course of treatment at the six month-post treatment period. Therapy protocol consisted mainly of bioelectrical stimulation with the Electro-Acuscope 80. Overall results showed remarkable increase in visual function in visual acuity in most, and clearly established the safety of the integrated treatment protocol. Long-term follow-up indicate maintenance and continued improvement when compliance of home program is continued. Participants of the five-day refresher demonstrated a marked increase in visual function, in visual acuity and field of vision.

Keywords

Bioelectrical, CMV -Retinitis, DHA, Electro-Acuscope, Ginkgo Biloba, Lutein, macular degeneration, nutrition, retinitis pigmentosa, Stargaardt's.

Discussion

For the past twenty-five years, both of us have dealt with significant visual impairment. Halloran as a practitioner and patient and Reader as a medical specialist Most of the diseases that we are dealing with have been designated as chronic. Progressive, untreatable and uncurablc. The majority of these patients are left on their own with no resources available to try to improve their situation. The numbers are staggering and increasing as our population ages. The National Institutes of Health estimates that there are nearly eighteen million Americans suffering from serious visual impairments, with nearly half being diagnosed with macular degeneration.

Halloran was diagnosed with a genetic eye disorder, retinitis pigmentosa, and Reader as a neuroophthalmologist, have individually and collectively been searching for methods and therapies that may be of some benefit We feel that we have been fortunate to rediscover some ancient and natural methods that definitely impact positively on visual function. Also, we have integrated the most technically advanced bioelectrical stimulation devices available to promote cellular healing. We believe that this marriage of western medical technology and eastern traditional healing practices provides the most effective treatment modality for those diagnosed with degenerative and progressive eye disorders.

From December 1995 to September 1997, thirty sight impaired individuals participated in a two-week course of an integrated treatment protocol for visual rehabilitation. The course is based on the Integrated Visual Healing program, developed by Halloran in the 1980's). This report is an extension of a pilot study conducted from 1983- 1985, documenting 114 participants4 with a similar treatment protocol and results as encompassed in this current two-year study. The 1983~85 study was monitored by independent optometrists. This study has more objective and medically monitored documentation. Although this study lacks the electrophysiological ERG's, the intent of this two-year study was to demonstrate safety and the need for further investigation.

Material and Methods

The 1995-97 group had an age range of 13 to 83. with the following diagnoses: twenty cases of retinitis pigmentosa (RP), seven macular degeneration (AMD - age related macular degeneration) including two cases of Stargaardt's, a juvenile form of macular degeneration, one diabetic retinopathy, one glaucoma (GL), and one CMV -retinitis (related to the AIDS virus).

Pre- and post-treatment visual testing was monitored by August L. Reader. M.D. F .A.C.S. Visual examinations consisted of field of vision (utilizing the Humphrey Field Analyzer Test, 30-2 Central, a computerized objective test of peripheral vision). standardized testing of best-corrected visual acuity (reading and fine recognition sight). Ishihara Color Plate identification. slit lamp examination and intraocular pressure.

A two-week intensive therapeutic session provided approximately thirty hours of primary treatments. An average of thirty treatments of bioelectrical stimulation of the Acu- Eye and Acuscope protocol With the Electro-Acuscope 80 were performed using 2.5 Micro Hertz and 25-50 micro amps intensity. These therapies were performed initially by the therapist and later taught to the individual patients for their self-application. The patients were encouraged to use the unit a minimum of three times per day, and up to six times per day. The

patients received other supportive therapies including eight sessions of applied kinesiology and neuro-lymphatic deep stimulation, eight treatments of deep tissue acupressure6 in the head/neck and shoulder region, twenty sessions of color-shape identification therapy (Tyro Instrument). Nutritional and herbal support was provided for one group of seven participants (September 1996), all others were instructed to incorporate the supplemental program for on-going long term use? Nutritional regime consisted of a broad based complete multiple vitamin and mineral supplement (Life Pat, IDN, Provo Utah), emphasizing specific nutrients known to impact the visual system which included: DHA 8, Omega 3 Fatty Acid. Lutein9, Ginkgo Biloba la, Pycnogenol11. and a combination of antioxidants such as carotenoids.

The integrated rehabilitative program included other disciplines such as stress rnanagemenr4, acupressure based on acupuncture points for improving eye health. And other exercises to keep circulation optimum for on-going overall health benefits.

Results

The following tables (fables 1 .4) illustrate the improvements noted in this two-year study. These tables depict the mean deviation on visual field testing from normal compared from the pre-treatment period to the post-treatment period. Also included are the visual acuities and the color vision testing performed before and after the treatment protocols. The mean improvement in visual field function for all patients was 3.16 decibels. The improvement in the RP patients was only 2.58 decibels, while Macular Degeneration improved 4.61 db. Average visual acuity improvements were 0.98 lines. Color vision improved on average of 1.71 out of 18 color plates per eye in patients with Macular Degeneration, but only 0.35 of 18 plates in the Retinitis Pigmentosa patients (Ishihara Color Plate test for color vision anomalies is not considered the most reliable method of color vision testing).

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Key Code Explanation

ID-Code = Diagnosis: First & Last Initials-Age -Right Eye MD=Macular Degeneration RP=Retinitis Pigmentosa GL=Glaucoma CMV=Retinitis MD-A=Mean Deviation on Humphrey Field of Vision Analyzer Pre-treatment MD-B=Post treatment Test Normal Mean Deviation Range: -6 to +4 VA-A=Visual Acuity (Distance) Pre-treatment VA-B=Visual Acuity Post-treatment CT-A=Ishihara Color Test (Ishihara) Pre-treatment (18 color plates total) CT-B=Ishihara Color Test at Post treatment

Controls	Pre--	Post-	Particip.	Pre--	Post-
JL ◆RE	-26.66	-27.35	MW-RE	-29.13	-7.86
JL-LE	-26.96	-27.84	MW-LE	-29.44	-15.47
RM-RE	-32.23	-32.58	RO-RE	-32.07	-18.89
RM-LE	-32.53	-32.75	RO-LE	-31.58	-13.07
TC-RE	-31.63	-31.63	IM-RE	-24.04	-23.11
TO-LE	-31.55	-31.11	IM-LE	-25.26	-21.82
MH-RE	-24.25	-22.97*	BF-RE	-28.23	-27.86
MH-LE	-25.64	-20.56*	BF-LE	-29.29	-28.85
*Individual took pain medication and muscle relaxant 90 minutes prior to test, VA dramatically decreased on post examination					

Table 1 depicts the most significant objective evidence demonstrated during the two-year period in the field of vision test, by the Humphrey FOV Analyzer (30-2 Central). The measurements outlined reflect the Mean Deviation, an analysis produced by the computerized testing device. Mean deviation is a comparison of the individual testing to a 'normal' population by sex and age. Normal range of mean deviation measurement for healthy population is -6 to +4. Table 1 demonstrates the difference between a control (masked to the monitor) groups of RP to RP participants. The control group was tested with the participant group on both pre~ and post-examination days, receiving the identical testing procedure in a two week period.

Control data for the most part was the same. Participants in the integrated treatment protocol showed significant improvement in post field of vision analysis with the Humphrey Fay device. Recovery of field of vision is not usually associated with Retinitis Pigmentosa or any of the other disorders involved in the study.

Table 2 - Macular Degeneration Results

ID -CODE	MD-A	MD-B	VA-A	VA-B	CT-A	CT-B
MD-AH-83-RE	-7.19	-5.19	20/400	20/200+2	12	12
Left	N/A	-18.89	CF@1'>	CF@1'	0	0
MD-EK-73-RE	-22.64	-20.26	20/60	20/40	0	2.5
Left	-18.51	-16.35	20/40	20/40+1	0	14
MD-SY-58-RE	-10.99	-8.19	20/300+1	20/200	14	15.5
Left	-11.84	-4.97	CF@5'	20/100+1	14	15
MD-JA-35-RE	-16.57	-15.38	CF@3'	CF@13'	6	6
Left	-15.08	-15.85	CF@3'	20/200	6.5	5
MD-RO-35-RE>	-32.07	-18.89	20/60	20/50+1	0	2
Left	-31.58	-13.07	20/60	20/50	0	1.5
MD-EL-35-RE	-12.75	-12.87	20/60+1-1	20/60	11	11
Left	-6.27	-3.73	20/50-1	20/50+1	15.5	15
N/A = not able to perform test due to poor visual function						

Table 3 - Glaucoma & CMV -Retinitis Results

ID-CODE	MD-A	MD-B	VA-A	VA-B	CT-A	CT-B
GL-PM-67-RE	-18.3	-10.86	20/40	20/20+1	N/A	11.5
Left	-6.04	-5.46	20/30-1	20/25+1	N/A	12.5
CMB-GW-41-RE	-10.46	-9.07	20/30	20/25-1	18	18
Left	-6.15	-2.29	20/25	20/20+	18	1
N/A = Unable to locate pre-testing data						

Table 4 - Retinitis Pigmentosa Results

ID-CODE	MD-A	MD-B	VA-A	VA-B	CT-A	CT-B
RP-MW-65-RE	-29.13	-7.86	20/70-2+1	20/70+1	0.5	0.5
Left	-29.44	-15.47	20/100-2	20/100+1	0	0.5
RP-JO-46-RE	N/A	-28.47	20/200-1	20/70+1	1.5	2.5
Left	-30.95	-27.75	20/400	20/200	1	1.5
RP-SD-13-RE	-27.55	-26.5	20/20	20/20+1	18	14
Left	-29.57	-29.99	20/60+2	20/25-1	12	12
RP-IM-16-RE	-24.04	-23.11	20/200+1	20/100	11	11.5
Left	-25.26	-27.82	20/200	20/100	11	13
RP-ES-59-RE	-30.24	2.17	HM@1'	HM@2'	0	0
Left	-19.36	-22.85	HM@0.5'	HM@ 0.5'	0	0
RP-RS-72-RE	-28.81	-28.92	CF@ 1FT	20/400	0	1.5
Left	-28.3	-28.1	CF@ 1FT	20/200	0	1
RP-GF-50-RE	-26.69	-25.79	20/20+3	20/15	17	17.5
Left	-28.41	-27.1	20/20	20/15-1	17	17.5
RP-TC-50-RE	-31.56	-31.42	CF@1'	CF@2-3'	0	0.5
Left	-31.02	-29.69	CF@1.5'	CF@1-1.5'	0	0
RP-KH-48-RE	-25.19	-25.77	20/30+1	20/30-1	17	16.5

Left	-24.64	-23.6	20/25-3	20/25	17.5	17
RP-BF-72-RE	-2e+1	-2e+1	20/40+2	20/30-2+1	14	1
Left	-2e+1	-2e+1	CF@ 3'	CF@6'	0	0.5
RP-KH-45-RE	-31.67	-31.53	20/200	20/200	0.5	0
Left	-32.06	-31.86	20/200	20/100	0	1.5
RP-HC-60-RE	-24.9	-25.42	20/15	20/15+2	17.5	17
Left	-24.1	-2e+1	20/15	20/15+2	18	17
RP-ME-32-RE	-28.69	-30.19	20/200	20/100+1	8	6
Left	-28.56	-28.99	20/200	20/100-2	8	7
RP-TT-37-RE	-29.41	-28.54	20/30+1	20/25-2	10.5	11
Left	-28.84	-29.61	20/30-1	20/30	11	12.5
RP-BT-32-RE	-31.03	-31.67	20/60+1	20/50+1	2	6
Left	-31.94	-31.88	20/50-1	20/40+1	1	6
N/A = Not available due to computer failure						

Conclusion

This two-year study clearly shows that bioelectrical stimulation to acupuncture points around the eyes and face have definite positive affects on visual functioning. These techniques. in conjunction with other complementary therapies, have clearly demonstrated that chronic progressive visual loss from several different sources can be reversed to some degree. More importantly, the improvements in activities of daily living and the quality of life of these patients has been dramatically impacted.

This small study in conjunction with the larger study performed in the mid 80's, emphasizes the need for more research into alternative methods. The information we have thus far obtained only corroborates our previous beliefs that these methods provide patients with some hope for cure.

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The Effects of Electric Currents on ATP Generation, Protein Synthesis, and Membrane Transport

Ngok Cheng, M.D., Harry Van Hoof, M.D., Emmanuel Bockx, M.D., Michel J. Hoogmartens, M.D.*, Joseph C. Muler, M.D.*, Frans J. De Ducker, Ph.D.*, Willy M. Sansen, Ph.D.*, and William De Loecker, M.D.

*University of Louvain, Belgium

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Abstract: The effects of electro stimulation on the ATP concentrations in rat skin as well as protein synthesis and membrane transport were evaluated. It was found that electro stimulation of the skin using direct current from 10 to 1000 micro amps increased ATP concentrations in the tissue by up to 500% and stimulated amino acid incorporation into the proteins by up to 123 %. The effects of electro stimulation on ATP production can be explained by proton movements on the basis of the chemiosmotic theory of Mitchell, while transport functions are controlled by modifications in the electrical gradients across the membranes. It was noted that electro stimulation exceeding 1000 micro amps has the potential of reducing ATP levels. DNA metabolism was not affected by electrical stimulation.

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Macular Degeneration Treatment with Nutrients and Micro Current Electricity

Merrill J. Allen, O.D., Ph.D, John B. Jarding, O.D.,Ralph Zehner, O.D.

Introduction

This is the second report of a study of age related macular degeneration (AMD). The first report covered from July 1985 to July 1992 and was published in the fall of 1993. The positive results to date in this and in the earlier report are the slowing or reversing of the progress of AMD for most subjects.

This is exciting because the dry type of AMD is considered to be untreatable and can progress to the wet type which rapidly destroys vision. ABC's television show "20/20" (Dc. 6 '96) explained that 13 million Americans now have AMD. By the time the baby boomers reach age 65. 25% of Americans, or 30 million people, will have AMD. Happily, we are becoming aware of tutritional and electrical factors that can retard or reverse macular degeneration.

Leland D. Michael, O.D. of Rapid City, South Dakota, began studying electricity on the eyes in 1985 following his successful experience with using electricity to treat his own retinal detachment. Merrill Allen became the research designer and coordinator. Ralph Zehner began studying his tweleve subjects in July 1991. When "Doc Mike" became terminally ill, he arranged for John Jarding to continue the study. Jarding had thirty-four new subjects from August 1992 to May 1998. The total number of subjects in this report is forty-six.

Procedure

Each subject was independently confirmed as having dry macular degeneration. The nutritional supplements used by Zehner's subjects were similar to those used in the earlier study. 1 Jarding's more recent nutrients are shown in Figure 1 (p. 212). The additional nutrients used are bilberry, rutin and taurine.

In addition to nutrients taken daily, all subjects received micro ampere electricity applied to each eye's closed lids. Zehner's subjects were treated once per week for six weeks, then once per month. Jarding's subjects were treated several times per week.

Results

Figure 2 (p. 212) shows Zehner's twelve subjects. Figure 3 (p. 213) shows Jarding's 34 subjects. For Figures 2 and 3, start date is the date the subject received the first treatment; DOB means date of birth; Acuity means the denominator of the Snellen Fraction; R means Right Eye, L means Left Eye. Change means the number of letters lost (-), or gained (+) from the initial acuity to the final acuity. There were five letters in each line of acuity. To go from 20/30-2 to 20/20 is a gain of 12 letters. (20/30-2 to 20/30 = +2 letters. 20/30 to 20/25 = +5 letters. 20/25 to 20/20 = +5 letters.) Comments provide unusual events.

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Discussion

The data are presented according to the starting date. Jarding's subjects showed improvement while Zehner's showed a small loss. The changes in nutrition and the increase in the number of electrical treatments explains the improved success of Jarding's procedure compared to the earlier procedure used by Zehner.

At each office visit the patient's acuity was checked. Because many subjects reported better-vision as they left the office. Jarding began checking acuity both at the start and at the end of the office visit. Visual acuity usually improved following the electrical stimulation of the eyes. This suggests that still more frequent treatments would be beneficial.

This study is divided into two parts: Figure 2 is data from Zehner; Figure 3 is data from Jarding. The Electro-Acuscope 80, which is no longer available, was used earlier by Michael and in this study by Zehner. Jarding used the Micro-Stim 4006 which has a different output wave form compared to the Electro-Acuscope 80. The Micro-Stim 400 may be superior to the older machine, but we can't be sure because the the Micro-Stim 400 was used more frequently. The basic electrical stimulus parameters are: 200 micro-amperes at +9 volts, alternating, square wave current.

For Zehner's subjects there was an average loss of 3 letters of visual acuity per eye over a 2 year period. For Jarding's subjects there was an average gain of 8.5 letters of acuity per eye.

Newsome's research2 tested the value of zinc in treating macular degeneration. He used the same nutrients in the test and congrol groups. He added zinc only to the test group. The result was a slowing of the loss of vision of the 80 subjects in the test group receiving zinc when compared to the 71 subjects in the control group who did not receive zinc. On average his control group lost 7.1 letters of acuity and his test group lost 4.1 lett4ers of acuity in two years. His (and our) acuity test chart had 5 letters per line.

Conclusions

The results of this study strongly indicate that nutrition and electrical stimulation are able to delay or reverse the progress of macular degeneration.

The fact that acuity usually improved within minutes of electrical stimulation shows that micro current electricity applied to the eyelids is beneficial. The fact that a change in nutrients to include taurine, rutin and bilberry extract improved the success of treatment agrees with the recent literature7-10 on the importance of nutrition to the retina

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Figure 1. Nutrients used in treatment for Macular Degeneration

Nutritional Supplement	Two Per Day
Beta Carotene	40,000 IU
Natural Vitamin E	400 IU
Vitamin C	1500 mg
Citrus Bioflavonoid Complex	250 mg
Quercetin	100 mg
Bilberry Extract	10 mg
Rutin	100 mg
Zinc	25 mg
Selenium	100 mcg
Taurine	200 mg
N-Acetyl-Cysteine	200 mg
L-Glutathione	10 mg
Vitaming B-2	50 mg

Figure 2. Changes in Zehners 12 subjects using nutrients and micro-current electricity

Z/ehner				**Start Accuity**			**End Accuity**		**Change**		
Name:	**Sex**	**D.O.B**	**Start Date**	**R20/**	**L20/**	**End Date**	**R20/**	**L20/**	**R**	**L**	**Comments**
M.D.	F	5/30/31	7/1/91	30-1	30	4/28/98	20	20	+11	+10	Cataract Surgery 10/94
M.H.	F	10/3/10	7/5/91	40-2	60-1	2/2/94	70-2	200-1	-14	-16	Deceased
J.E.	F	5/13/20	7/23/91	60	80-1	11/18/93	50+1	60-2	+6	+9	Subject Left India

C.S.	F	9/5/02	7/26/91	70+1	60+2	9/13/96	60	30-2	+3	+10	Cataract Surgery 7/96
M.R.	F	5/12/23	8/30/91	30-1	40-1	5/1/98	20-1	50	+10	-4	Cataract Surgery 2/92
D.G.	F	1/20/18	10/17/91	30-2	400	9/26/95	80-1	400	-24	0	
D.F.	M	2/6/35	12/20/95	30	20-1	4/23/98	30+2	20-2	+2	-1	
L.P.	F	12/1/11	10/17/96	70-1	80+1	4/30/98	100-1	100+1	-10	-5	Poor Health
P.B.	F	10/21/18	11/22/96	60-1	60-1	5/20/98	80	50-1	-7	+5	
I.C.	F	9/7/07	12/2/96	400	50-2	1/5/98	400	400	0	-35	
C.H.	F	7/18/23	12/12/96	40+1	40+2	4/27/98	50+2	50+1	-4	-4	
H.K.	F	8/11/15	4/27/97	80-1	20-2	12/15/97	60	20-3	+11	-1	Poor Health

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Figure 2. Changes in Zehners 12 subjects using nutrients and micro-current electricity

Jarding				**Start Accuity**			**End Accuity**		**Change**		
Name:	**Sex**	**D.O.B**	**Start Date**	**R20/**	**L20/**	**End Date**	**R20/**	**L20/**	**R**	**L**	**Comments**
F.T.	F	7/31/23	8/20/92	50-3	25	2/4/98	30	25+1	13	1	
J.B.	F	11/1/05	8/24/92	40-2	25-1	2/13/98	400	25-2	-33	1	Hemorrhage 12/95
Y.H.	F	3/30314	12/21/92	60+3	25+3	12/15/95	70	25+3	-8	0	
C.B.	M	9/10/24	2/9/93	400	40-1	2/12/98	200	200	0	2	
R.E.	F	7/9/19	4/1/93	60	40-2	2/18/98	200	40-2	-20	0	
A.P.	M	12/28/18	5/3/93	20-1	400	5/17/95	30-1	80-2	-10	18	Hemorrhage 2/95
M.C.	F	8/10/18	5/25/93	60-2	50-1	2/11/98	40-1	80+1	11	-28	
L.0.	M	8/23/09	8/19/93	25+3	400	12/11/96	40-1	CF3Ft	-14	-5	
B.B.	M	6/10/18	11/9/93	25	20+3	10/23/95	15-2	15	8	2	
G.S.	F	9/13/22	1/21/94	60	100	2/4/98	80-2	60-1	-12	14	
M.J.	F	10/25/31	1/26/94	25	40	12/12/97	20	30+2	5	7	
J.D.	M	7/23/26	9/30/94	70	400	10/27/95	100	400	-5	0	
W.K.	M	12/11/19	4/21/95	300	40+2	4/18/97	200+1	40	11	-2	
H.R.	F	12/25/10	8/7/95	60	400	10/14/97	40+1	200	11	10	
E.C.	F	12/30/16	11/13/96	400	60+2	2/5/98	400	30-2	0	10	
H.H.	F	2/2/28	12/6/96	50-2	60	2/9/98	15-3	15-2	19	23	

M.G.	F	12/12/34	1/3/97	40	50	2/18/98	15-1	50-2	15	-2	
N.S.	F	5/18/26	2/27/97	200	70	10/8/97	20	25-3	0	22	
B.P.	F	12/15/36	4/22/97	50+2	40	1/27/98	20	25-2	18	8	
V.N.	F	5/9/26	5/19/97	40	40	2/19/98	25+2	30-2	12	3	
L.S.	F	9/9/20	6/23/97	30-1	25-2	2/24/98	25+2	25-2	8	0	
M.S.	F	9/14/15	8/15/97	70	200	1/20/98	50-1	80-1	9	14	
D.T.	M	8/25/24	9/11/97	40-2	50+2	2/20/98	20-1	20	16	18	
R.S.	M	3/4/33	9/23/97	400	LP	9/29/97	400	400	0	1	
V.C.	F	11/6/24	9/26/97	80	60+2	1/20/98	50+2	40-2	17	6	
H.C.	F	4/27/23	10/10/97	50-2	30-1	2/19/98	80-2	25-1	-15	-5	Hemorrhage 1/98
R.C.	M	3/14/20	11/24/97	LP	300	1/30/98	LP	100+1	0	20	
E.L.	M	9/7/14	12/5/97	LP	70	2/17/98	LP	50-1	0	9	
L.T.	M	6/21/12	12/22/97	60+1	50-2	1/30/98	60+2	30-2	1	10	
A.D.	M	1/16/18	1/12/98	40	50-1	1/15/98	20-2	20-2	13	19	
R.P.	F	1/18/34	1/19/98	200	30-2	1/22/98	100	20-2	10	10	
D.W.	F	5/18/13	1/27/98	200	200	2/20/98	200	400	0	-10	
V.H.	M	13/12/20	2/2/98	CF8	CF6	2/13/98	200	200	?-+4	?+6	
L.E.	M	8/10/29	2/16/98	200	100	2/19/98	60+2	100	12	0	

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