

Reversal of Vision Loss in Age-Related Macular Degeneration Using Medical Acupuncture – A Proof-of-Concept Report

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Abstract

Age-related macular degeneration (AMD) is the major cause of vision loss in the over age 50 population in USA. The AREDS Study has demonstrated the benefits of high-dose antioxidant supplements in slowing the progression of AMD. Intravitreal injections of anti-VEGF antibodies (ranaibizumab) have been shown to stabilize vision in exudative AMD, but vision improvement was found in only 34% of these patients. The efficacy and the safety of medical acupuncture were evaluated in an analysis of AMD patients (both dry and wet form with non-active and disciform lesions.) Patients underwent conventional therapy as well as receiving a standardized protocol of medical acupuncture treatments combining a number of different techniques. These techniques include Canadian Neuroanatomic Acupuncture, German Ear Acupuncture, Chinese and Japanese Scalp Acupuncture and French Energetics. The primary efficacy endpoint was mean change from baseline visual acuity using both distant and near ETDRS eye charts.

150 individual patients (268 eyes) with dry AMD and 68 individual patients (97 eyes) with wet AMD were treated between November 2007 and August 2008. Mean intake distant visual acuity was 26 letters for those with dry AMD (25 letters equals Snellen 20/80) and 15 letters for those with wet AMD (15 letters equals Snellen 20/125.) Mean intake near acuity was 32 letters (Snellen 20/115) for dry and 20 letters (Snellen 20/200) for wet AMD. 88.1% of dry eyes improved while 9.6% lost visual acuity. 84.5% of wet eyes improved while 13.4% lost vision. When visual acuities for near and distant tests for both eyes were combined, 93% of individuals had gains in vision for both wet and dry varieties of AMD.

The mean number of treatments per patient for both dry and wet AMD eyes was 4. The net overall improvement in visual acuity for patients with dry AMD was 5.8 letters for distant vision and 4.5 letters for near vision. Patients with wet AMD improved 5.5 letters for distant vision and 4.3 letters for near vision.

Additionally, there were consistent improvements in contrast sensitivity as measured by Pelli-Robson charts, color discrimination as measured by isochromatic charts and subjective vision as measured by VF-14 questionnaires. The only side effects were periorbital ecchymoses which always self-resolved.

Medical acupuncture administered in addition to conventional therapy provided significant visual acuity benefit to patients with both dry and wet AMD and was well tolerated. No serious ocular or non-ocular side effects were observed.

Introduction

Age-Related Macular Degeneration (AMD) is the most common cause of central vision loss in people older than 50 years. ¹ Current treatments do not restore visual acuity (except for antioxidant and lutein supplementation which increases vision especially in nutritionally deficient individuals ^{2,3}) A number of methods stop bleeding (thermal laser^{4,5}, photodynamic therapy with verteporfin ⁶, and anti-VEGF medications ⁷). Antioxidant vitamins slow progress but do not reverse the process. The expectation is that persons with AMD will lose visual acuity.

Since 2001 the author has been developing the Santa Fe Eye Protocol,^{8,9} a medical acupuncture treatment that increases visual acuity in persons with both dry and wet AMD. The Santa Fe Eye Protocol is used in addition to current conventional treatment and does not replace or change the patient's ophthalmologist recommendations. All patients were already taking antioxidant vitamin and lutein supplements.

This report covers 182 consecutive patients treated with the same version of the Santa Fe Eye Protocol between November 2007 and August 2008. All results reported are net results where losses are offset from gains .

Methods

Patient Selection

All patients had an ophthalmologist diagnosis of AMD and also an ophthalmologist determination that they were not leaking. If they had dry AMD, they were required to have had a professional eye exam in the last year. If they had wet AMD, they were required to not have leaked for at least 3 months and to have had an ophthalmologist eye exam within 3 months. Any patient with a significant loss of vision since their last exam was required to have another eye exam before being treated to ensure that no bleeding was occurring.

Virtually all patients were Caucasian. Many patients came from considerable distances and lower altitudes (Santa Fe is at 2,000 m/7,000 feet.).

Excluded were patients with dementia. It is hard to measure their visual acuity and they have not responded well in the past.

Table 1

Population Characteristics			
	Dry AMD	Wet AMD	Total

# Individuals	150	68	182
# Eyes Treated	268	97	368
Male/Female	76/66	36/26	
Average Age	76.6 years	77.5 years	
Range Age	52-98 years	56-90 years	

Totals do not agree with subtotals because some individuals either did not have an AMD diagnosis in both eyes, had one wet and one dry eye or were treated on only one side because the other side was leaking.

Vision Measurements

Baseline visual acuity was checked with both near and distant standard ETDRS charts (Precision Vision, La Salle, IL, USA), Pelli-Robson Contrast Sensitivity Charts (Clement Clarke, Harlow, Essex, UK), and H.R.R. (Hardy, Rand, and Ritter) Pseudoisochromatic Plates (Richmond Products, Boca Raton, FL, USA). Visual Function 14 questionnaires were used to evaluate subjective findings. Patients were each issued an Amsler grid for self-monitoring of distortions and scotomas.

Before treatment, patients had a wide range of intake characteristics. Some had advanced disease whereas others were asymptomatic and had only recently been diagnosed as having AMD.

Table II

Dry AMD Patients Before Treatment		
	Near Vision	Far Vision
Median Initial Acuity ETDRS	32 letters	26 letters
Median Initial Acuity Snellen	20/115	20/77
Range ETDRS	0 – 69 letters	0 - 55 letters
Range Snellen	0 – 20/21	0 – 20/20

Table III

Wet AMD Patients Before Treatment		
	Near Vision	Far Vision

Median Initial Acuity ETDRS	20 letters	15 letters
Median Initial Acuity Snellen	20/200	20/125
Range ETDRS	0 – 65 letters	0 – 69 letters
Range Snellen	0 - 20/25	0 – 20/12.5

After every 2nd treatment, patients were measured with near and distant ETDRS charts and VF-14 questionnaires, and after every 4th treatment, they repeated all the initial tests. Each patient was tested by the same technician. Light intensity was controlled and standardized. The ETDRS charts were changed daily. The eye with lesser vision was always tested first to prevent patients from recalling letters they really could not see.

Acupuncture Treatment

Five types of acupuncture were combined:

- 1) German Ear Acupuncture to indirectly stimulate the optic nerve, the retina, and production of cortisol.^{10, 11, 12, 13} (David Alimi, MD, Professor of Neurology and Ear Acupuncture at the University of Paris Medical School has demonstrated the one-to-one correspondence between points on the ear and areas of the brain.)
- 2) Canadian Neuroanatomic Acupuncture with needle/electrodes surrounding the orbit which may increase blood circulation or directly affect the retina itself when electrically stimulated.¹⁴
- 3) Chinese scalp acupuncture – electrical stimulation over the visual cortex of the brain, hence reversing the damage of a stroke there.¹⁵
- 4) Japanese scalp acupuncture at points identified as stimulating the optic nerve and probably other areas of the brain involved in vision.¹⁶
- 5) French Energetics acupuncture to stimulate classic Chinese points affecting the eye, increase parasympathetic stimulus, and add energy to the patient for self-healing.¹⁷

Electrical Stimulation

Except for the ear studs, the acupuncture needles were electrically stimulated using custom-made Pantheon Electric Stimulators (Pantheon Research, Venice, CA, USA) which had been adjusted to precisely produce Nogier frequencies. For this trial, Nogier Frequency A (1.14 HZ) was used and treatment time was 40 minutes. The stimulator output was adjusted to each patient such that a gentle tapping was felt at onset of treatment.

Followup

All patients are required to fill out consent forms to allow their optometrists, ophthalmologists and retinologists to supply further information about their vision and any changes to the retina that could be traced to the treatment. Such reports are solicited

annually from the treating physicians. Even after achieving miraculous (to them) results, patients are advised to continue with their regular treatment plan.

Results

Out-of-state patients typically come for a week and are treated daily. Thus it is convenient to report results after 4 treatments for all subjects. Tables IV and V report the net vision changes (gains minus losses) after 4 treatments. 5 letters = 1 line.

Table IV

Average Vision Gain after 4 Treatments Dry AMD			
	Near ETDRS	Distant ETDRS	Combined Near + Distant
Net Gain	4.5 letters	5.8 letters	5.1 letters
Range	(16) - 38	(8) - 41	
% gaining	75.9%	80.7%	88.1%
% no change	10.0%	8.9%	2.2%
% losing	14.1%	10.4%	9.6%

Table V

Average Vision Gain After 4 Treatments Wet AMD

	Near ETDRS	Distant ETDRS	Combined Near + Distant
Net gain	4.3 letters	5.5 letters	4.9 letters
Range	(8) - 24	(7) - 40	
% gaining	67.0%	79.4%	84.5%
% No change	12.4%	10.3%	2.1%
% losing	20.6%	10.3%	13.4%

Figures I and II report the net average response for persons with different visual acuity at intake. It appears that persons having lost more visual acuity respond more.

Figure I

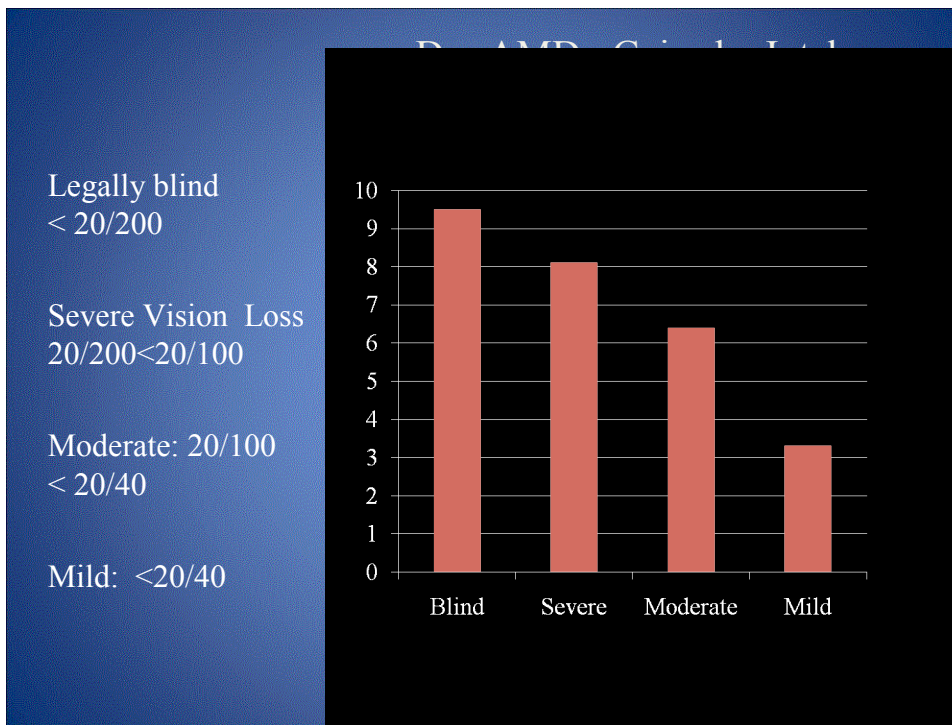
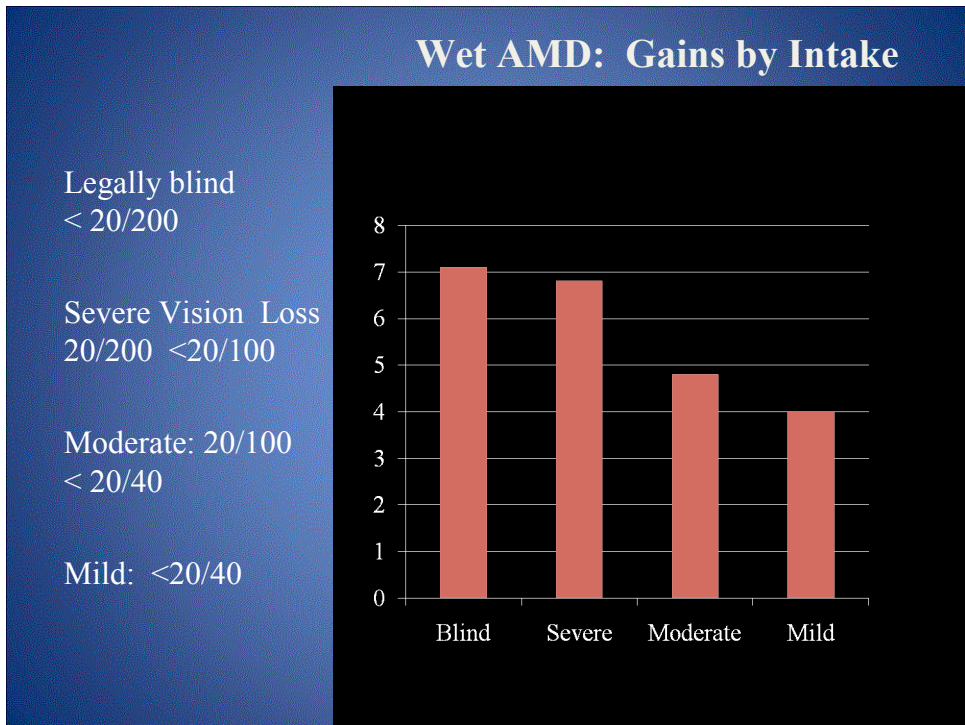


Figure II



Improvements in other tested parameters are summarized in Table VI.

Table VI

Average Gain in Other Tested Parameters After 4 Treatments

	Dry AMD	Wet AMD
Isochromic Color Screen	3.2 items	3.8 items
Pelli-Robson Contrast Sensitivity	1 cluster	1 cluster
VF-14 Questionnaire	1.4 points	1.8 points

Other Findings

Anecdotally, many patients report that scotomas get smaller or more translucent. They also report reduced distortions (on Amsler grid and in general) and reduced overall haze.

Complications and Vision Losses

The only complications noted were periorbital ecchymoses, which always resolved without treatment.

3 patients showed > 2 line vision loss in one eye. The worry was that there might have been a new bleed. Each was referred to a retinologist who performed an evaluation including angiograms. None exhibited signs of retinal hemorrhage. In none could a cause for the vision loss be determined.

21 eyes had a vision loss of more than one line. For those patients, when visual acuity for both left and right eyes were combined, only 3 actually lost overall vision.

Discussion

Mechanism

The acupuncture mechanism of action is not known at this time, but there are several hypotheses.

- 1) Blood supply to the retina may be increased, increasing the ability of the photoreceptors to convert light to electrical signals to the brain.
- 2) The function of the Retinal Pigment Epithelium, which is responsible for providing nourishment and removing wastes from the retina, may be improved.
- 3) Electric stimulation of the scalp may improve brain function in the visual cortex and other areas important to vision, allowing better interpretation of the signals received from the retina.
- 4) Stimulating precise ear points has been demonstrated to stimulate corresponding parts of the brain.¹³ The Santa Fe Eye Protocol specifically attempts to stimulate cranial nerve II, the retina, and the production of cortisol.

Clearly this is an area where imaginative investigations can help. As a start, pre and post treatment angiograms, OCT, and retinal photographs might help elucidate mechanisms.

Durability and Late Improvements

This report does not cover sufficient time to determine how long these improvements will last. Among patients treated before this study began, vision gains are still persisting as much as 4 years later. An ongoing Institutional Review Board-approved study should answer these questions.

Anecdotally, a number of patients have communicated that their vision improved both in the 2 weeks after treatment and some months later. The above mentioned study will help

evaluate those results as well as anecdotal reports that the rate of decline in vision is significantly retarded or halted.

Statistical Significance

Patients sometimes test better and sometimes test worse on eye charts on different days. Literature supports an individual having test-to-test variation as being $\pm 1 \frac{1}{2}$ lines in either direction with a 95% confidence level.^{18,19} That implies that $1 \frac{1}{2}$ lines equals 2 standard deviations. Thus one standard deviation is 0.75 lines on a logMAR chart like the ETDRS ones.

The Central Limit Theorem addresses the standard deviation of a group. The standard deviation of a group comprising N individuals each having a standard deviation of d is equal to d divided by the square root of N.²⁰

For groups of the sizes reported, the standard deviation is on the order of $1/10^{\text{th}}$ line. The probability of the measured improvements occurring by chance is $p < .001$. That makes the reported results extremely significant.

Discussion

Many questions remain. Determining before treatment who will have exceptional gains, who will have ordinary gains and particularly who will lose vision is high on that list. It appears that persons who have had multiple interventions, especially with thermal laser or photodynamic therapy respond slower than others. However, from patients treated prior to this study, it appears that there is a threshold after which even the extensively treated patients respond even if they did not initially. Amongst patients with dry AMD, the initial thought was that patients with long-standing disease would respond slower than those with recent onset disease. At least anecdotally that is not the case. Against logic, at least a few current heavy cigarette smokers have had exceptionally good responses.

Treatment was discontinued in those very few patients with a 2-line vision loss and they were referred to a local retinologist for evaluation. Bleeding was the major concern but none was found to be hemorrhaging. Conceivably some of them may have had a stroke in the visual cortex. Unless brain imaging were done before treatment and after vision loss, that would be hard to prove.

Conclusion

Medical acupuncture treatment appears to improve visual acuity in patients with both dry and wet varieties of AMD. Improvements averaged approximately 1 line in both near and distant ETDRS charts for 182 patients with both wet and dry varieties of AMD. That is a net number where losses in some patients were subtracted from gains in the others. Additional improvements were noted in color perception and contrast sensitivity. Subjectively patients reported improvements in distortions, scotoma size and density, overall haziness and improved VF-14 test scores.

A study is ongoing to quantify delayed improvements and also the durability of these gains. Further investigation is needed to delineate the mechanism of action and also to optimize the treatment itself.

The Santa Fe Eye Protocol may contribute to the improvement of vision in AMD patients who already are undertaking conventional treatment. The alternative of no such adjunct treatment is not appealing.

References

- 1) The Eye Diseases Prevalence Research Group. Prevalence of age-related macular degeneration in the United States. *Arch Ophthalmol* 2004;122:564-72.
- 2) Richer S, et al. Veterans Lutein Antioxidant Supplementation Trial (LAST). *Optometry* April 2004;75:216-30.
- 3) Richer S, et al. LAST II. *Optometry* May 2007;78:213-19.
- 4) Macular Photocoagulation Study Group. Laser photocoagulation of subfoveal neovascular lesions in age-related macular degeneration: Results from randomized clinical trials. *Arch Ophthalmol* 1991;109:1220-31.
- 5) Macular Photocoagulation Study Group. Laser photocoagulation for juxtafoveal choroidal neovascularization: Five-year results from randomized clinical trials. *Arch Ophthalmol* 1994;112:500-9
- 6) Verteporfin therapy for subfoveal choroidal neovascularization in age-related macular degeneration: Three-year results of an open-label extension of 2 randomized clinical trials – TAP Report No. 5. *Arch Ophthalmol* 2002;120:1307-14.
- 7) Gragoudas ES, Adamis AP, Cunningham ET Jr, et al. The VEGF inhibition study in ocular neovascularization: Clinical trial group for neovascular age-related macular degeneration. *N Engl J Med* 2004;351:2805-16.
- 8) Lundgren AC. Medical acupuncture for age-related macular degeneration: A preliminary report. *Medical Acupuncture* 2003;14(2):37-9.
- 9) Lundgren AC. An acupuncture protocol for treatment of age-related macular degeneration: A second report. *Medical Acupuncture* 2005;16 (3):33-5.
- 10) Nogier PFM. *Treatise of Auriculotherapy*. France: Moulins-les-Metz: Maisonneuve; 1972.
- 11) Bourdiol RJ. *Elements of Auriculotherapy*. Paris, France: Maisonneuve; 1982.
- 12) Stittmatter B. *Ear Acupuncture: A Precise Pocket Atlas Based on the Works of Nogier/Bahr*. Stuttgart, Germany: Thieme; 2003.
- 13) Alimi D, Geissmann A, Gardeur D. Auricular acupuncture stimulation measured on functional magnetic resonance imaging. *Medical Acupuncture* 2002;13(2):18-21.
- 14) Wong JY. *A Manual of Neuro-Anatomical Acupuncture, Vol II: Neurologic Disorders*. Toronto, Canada: Toronto Pain and Stress Clinic; 2001.
- 15) Solinas H, Maineville L, Auteroche B. *Atlas of Chinese Acupuncture*. Sillery, Qc, Canada: 3-8-3 Publishing Canada; 1998.
- 16) Yamamoto T. *Yamamoto New Scalp Acupuncture*. Tokyo, Japan: Axel Springer Japan; 1998.
- 17) Helms J. *Acupuncture Energetics: A Clinical Approach for Physicians*. Berkley, CA: Medical Acupuncture Publishers; 1995.
- 18) Siderov J, Tiu AL. Variability of measurements of visual acuity in a large eye clinic. *Acta Ophthalmol Scand* Dec 1999;77(6):673-6.
- 19) Rosser DA, Murdoch IE, Cousens SN; The effect of optical defocus on the test-retest variability of visual acuity measurements. *Invest Ophthalmol Vis Sci*. Apr 2004;45(4):1076-9.
- 20) Devore JL. *Probability and Statistics for Engineers and Basic Sciences*, 7th Edition, Chap 5, Section 5.4

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