The effect of Ocuvite supplementation on the density of macular lutein and zeaxanthin

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The effect of Ocuvite supplementation on the density of macular lutein and zeaxanthin

Abstract
A major disease of the retina is age related macular degeneration, or ARMD. In this disease, the photoreceptor cells die and blindness results. Lutein and zeaxanthin, two carotenoids highly concentrated in the macular area, are thought to help protect against ARMD. Supplementation has been shown to raise macular pigment levels of lutein. It is proposed that Ocuvite (Bausch & Lomb) supplementation, which is a preparation of lutein plus other antioxidant molecules, will increase the macular pigment density of lutein and zeaxanthin. This study had forty-eight optometry students, twenty-four male and twenty-four female, who were divided into two groups. Group one, the control group, received no intervention. Group two, the experimental group, received one tablet of lutein daily for six months. Heterochromic flicker photometry, a psychophysical technique, was used to measure the macular pigment density level over a seven-month period. The macular pigment density level was assessed at baseline before any intervention, and then approximately every month for six months. Lutein did not significantly increase macular pigment density levels over a six-month period in the experimental group versus the control group.

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Thesis

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Brian Miller
Tanya Sadler
JulieAnn Wick

Pacific University
College of Optometry
Forest Grove, OR
For the degree of
Doctor of Optometry
May 2003

Advisor

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Abstract

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significantly increase macular pigment density levels over a six-month period in the
experimental group versus the control group.
Introduction

The leading cause of visual impairment and blindness of people over 60 years of age in Western countries is age-related macular degeneration (AMD). Incidence of AMD is expected to increase due to the increase in the population of those over 65 years of age. There are two forms of AMD: dry (atrophic) and wet (neovascular). Dry AMD is the precursor of the more serious wet form. Oxidative damage due to free radical formation is thought to cause AMD. Blue light entering the eye causes free radical formation in the photoreceptor outer segments. The free radicals damage the disc membranes here; this damage prevents the digestion of the discs after they are phagocytized by the RPE. Disc membranes accumulate in the RPE forming lipofuscin and are also deposited in in Bruch’s membrane as drusen. With increasing damage, RPE cells, and subsequently photoreceptors, die.

Several significant risk factors for AMD have been identified. Persons with light irides (9), those with family history of AMD, and smokers (11) are known to be at a higher risk of AMD than the general population. Other contributing factors include age, diabetes, hypertension, and atherosclerosis.

While the progression of wet AMD can be slowed or halted with laser photocoagulation and photodynamic therapy, the dry form currently has no accepted treatment. Because of this, recent efforts have concentrated on preventing the damage that causes AMD. Much research has focused on nutrition, especially antioxidants and carotenoids (1, 4, 7, 8, 10, 12, 16, 19, 20, 23, 27, 28, 29, 31). Lutein and zeaxanthin are
two fat-soluble xanthophyll pigments that are classified as carotenoids (14). They are found selectively in the retina, with the highest concentrations in the macular area, and are classified as macular pigments. Both lutein and zeaxanthin appear to have a critical role in macular health, and have been shown to reduce the risk of developing AMD (3, 27, 28). In the retina, lutein can be converted to zeaxanthin. Because these molecules lie between the incoming light and the macular cones and because they are yellow, they act as a filter to reduce oxidizing blue light from reaching the cones (and rods) in the macular area. These two molecules also have antioxidant properties. They can quench free radicals by donating electrons without themselves becoming free radicals. Through this antioxidant and/or filter effect, lutein and zeaxanthin are thought to protect macular cones from oxidation and thus protect the retina from age-related macular degeneration.

Lutein and zeaxanthin are not produced in the body. They must be obtained from the diet. Foods rich in these carotenoids include dark green leafy vegetables, yellow vegetables, egg yolks, and fruits such as grapes and kiwi fruit (27, 30). Supplementation with lutein and/or increased dietary intake of lutein and zeaxanthin have been shown to raise these macular pigment levels (4, 7, 10, 13, 16).

Macular pigment density can be measured by heterochromic flicker photometry (HFP) (16). In this technique, blue and green lights flicker in counter-phase, and the subject is asked to match the brightness of two lights. Brightness match is determined when the lights are presented to the macula and again when they are presented in the retinal periphery where the concentration of lutein and zeaxanthin is low. The match value for the peripheral retina provides an indication of relative absorbencies of blue and green lights by the media of the eye exclusive of the macular pigment, and the match for
macular stimulation indicates the absorbance of the media plus the macular pigment. The difference in the macular and peripheral match values indicates the macular pigment density.

Though it has been shown that diets rich in foods containing lutein and zeaxanthin increase macular pigment levels and thus reduce risk of macular degeneration, results of various studies are inconsistent. It is generally accepted that there is an associative relationship between lutein and zeaxanthin intake and AMD, but a preventative link is still in question (20). Further research is necessary to prove this.

This study evaluated macular pigment density in young healthy participants. Macular pigment density was measured, using HFP, monthly for six months in two randomized groups of participants: one group taking Ocuvite with Lutein (Bausch & Lomb) daily, and one group taking no supplement.

Method

Participants

Forty-eight participants, all optometry students, were involved in this study. Twenty-four were females and twenty-four were males ranging from 21 to 30 years in age. All participants were screened (Appendix A) and had good ocular and systemic health. Participants were randomly divided into 2 groups: a control group who received no intervention, and an experimental group who took one lutein supplement (6 mg) a day for 6 months.

Supplementation

The lutein supplements that we used were Bausch and Lomb Ocuvite tablets containing 6 mg of lutein. Participants in this group took one capsule per day. Before
the onset of the experiment, intake of lutein was gathered from all participants using a questionnaire. Participants were asked if they were currently taking vitamins and if they were taking vitamins, if they contained lutein.

Measurement of Macular Pigment Density

Macular pigment density was measured using heterochromic flicker photometry. The optical system for this technique is illustrated in Appendix B. A xenon arc source was divided into three beams by a beam splitter and front surface mirror. Neutral density filters control the amount of light passing through the system. Interference filters produce the desired wavelength of 460 nm for the measuring field and background field, and 550 nm for the reference field. Apertures were used to concentrate both the reference field and measuring field to subtend one degree, and the background field to subtend ten degrees. A rotating sectored wheel produces the flickering test stimulus by alternating the transmission of the measuring field and reference field. The three fields were combined into one field through the use of beam splitters and a front surface mirror, and the combined image of all three apertures was placed at the subject’s pupil by an achromatizing lens.

Minimal flicker was achieved at 5.5 degrees from the macula, where macular pigment is optically undetectable, by adjusting the luminance of the measuring field. The target was then presented at the macula and participants readjusted the luminance of the measuring field with a variable density beam splitter to achieve minimum flicker. Macular pigment measures were based on the difference in neutral density filter used in the periphery to the neutral density filter used at the macula when minimal flicker was achieved. Multiple measures were taken on each eye for both macular and perimacular
positions. Macular pigment measures are expressed in equivalent terms of neutral density filters.

Two baseline measurements were taken during week one of the study before participants began taking the supplement. After the baseline measurement, one measurement was taken approximately one month apart for the next six months.

**Results**

Macular pigment density (MPD) at baseline, is shown in Table 1. Repeated-measures analysis of variance (ANOVA) was used to compare the control and supplement groups. There is a significant difference in MPD between the two groups throughout the study, $F(1, 43) = 8.37, p = 0.006$.

ANOVA was also used as a comparison across trials (seven measurements per group). There is no significant change in MPD across the seven-month measurement period, without regard to the study group, $F(6, 258) = 1.01, p = 0.422$.

ANOVA was used to look at the interaction effect of groups and trials. There is no significant rate of change in MPD between the two groups, $F(6, 258) = 1.05, p = 0.396$. 
Table 1. Macular Pigment Density at Baseline

<table>
<thead>
<tr>
<th>Study Group</th>
<th>Number of participants</th>
<th>Mean</th>
<th>Standard Deviation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Control Group</td>
<td>24</td>
<td>0.78</td>
<td>0.390</td>
</tr>
<tr>
<td>Supplement Group</td>
<td>21</td>
<td>0.99</td>
<td>0.454</td>
</tr>
</tbody>
</table>
Discussion

This study showed no significant differences in macular pigment density over time between a group of young subjects using lutein supplementation versus a similar group using no supplementation. There are studies, however, that do show a correlation between lutein supplementation and macular pigment density.

Previous studies have found that people with greater concentrations of the carotenoids, lutein and zeaxanthin, have lower rates of AMD (3,27,28). Since lutein can be converted into zeaxanthin in the retina, it is an essential carotenoid that must somehow be obtained through the diet.

Literature shows that macular pigment density decreases with age. It is particularly important then for elderly patients to take supplements or increase dietary intake of these carotenoids. A similar study using elderly participants should be considered. Another consideration should be the amount of lutein supplemented. While 6 mg a day might produce a change in an elderly patient, if younger people are going to participate, an increased amount of lutein should be considered.

Macular pigment density determination is a difficult process. Participants consistently reported having a very hard time distinguishing flicker. This may be attributed to the age of participants or to the procedure of HFP. Another method of measurement may be more reliable.

This study showed no significant results in changes of macular pigment density. There are studies, however, that do show a correlation between supplementation and macular pigment density. At this time it is recommended that all people with risk factors for AMD use supplements containing lutein and zeaxanthin.
Participant Name: ____________________________
Address: ___________________________________
Phone number: ________________________________
Email: _______________________________________
Age: ________

**Case History:**
Do you have any history of ocular disease?  ____ Yes  ____ No
If yes, what kind? _______________________________

Do any of your parents or relatives have any history of age related macular degeneration?

Do you or any of your relatives have any history of cataracts? ________________________________

Do you smoke?  ____ Yes  ____ No
Do you take any vitamin supplements?  ____ Yes  ____ No
If so, do they contain Lutein?  ____ Yes  ____ No

**Visual Acuities:**

Distance: 
OD  ___
OS  ___
OU  ___

Near: 
OD  ___
OS  ___
OU  ___

**Slit Lamp Exam:**

Lids/Lashes  ____ Clear
Conjunctiva  ____ Clear
Cornea  ____ Clear
Iris  ____ Clear
Ant. Chamber  ____ D/Q
Lens  ____ Clear

**Undilated High Plus Exam:**

ONH  ____ Normal
Macula  ____ + FLR, Flat and Dry
Other  ________________________________
Figure 1.
Optical system for measuring macular pigment density
References


