Effect of the combination of AREDS2 formulation and a polyphenol preparation on dry age-related macular degeneration: analysis of case studies

1Robert T. McHugh, O.D., 2Jack L. Hollins, M.D., 3Francis C. Lau, Ph.D. and 3Bruce P. Daggy, Ph.D.

1McHugh Optometry, Morehead, KY; 2Hollins Ophthalmology, Lexington, KY; 3Shaklee Research Center, Pleasanton, CA

BACKGROUND AND OBJECTIVES
Age-related macular degeneration (AMD) is a leading cause of blindness worldwide with limited pharmaceutical and surgical treatment options. In the United States, more than 50% of all blindness is caused by AMD. AMD is characterized by damage to the macula, a region of the retina. The etiology of AMD is largely unclear but it is associated with aging and other risk factors including genetics, hypertension, cardiovascular disease, obesity, and smoking. Nutrient-based preventive treatments for AMD have been evaluated in age-related eye disease study (AREDS) and AREDS2. AREDS2 formulation has been shown to significantly reduce the risk of developing advanced AMD. Case studies indicate that remission of AMD, though rare, does occur spontaneously. In this regard, retinal regeneration is possible. The purpose of the current study was to investigate the effects of combining AREDS2 treatment with a resveratrol/polyphenol-enriched supplement (RPS) on macular structure and visual function in dry AMD patients.

METHODS
Study design: clinical case studies.

Subjects: Patients (n=34, 8M/26F, mean age 73, range 56-85) with dry AMD.

Supplementation: AREDS2 plus RPS (5 mL/day) for at least four months.

Assessments: self-reported vision and Snellen acuity, OCT scan of maculae, and fundus photos before and after treatments.

RESULTS

Table 1. Summary of % improvement in vision and macular structure

<table>
<thead>
<tr>
<th>Assessments</th>
<th>Improvement (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Improved vision of at least one line, Snellen acuity</td>
<td>44.1</td>
</tr>
<tr>
<td>Improved vision and reduction in size and number of macular drusen</td>
<td>14.7</td>
</tr>
<tr>
<td>Decrease in size and number of drusen</td>
<td>26.5</td>
</tr>
<tr>
<td>Improved contour of macula</td>
<td>8.8</td>
</tr>
<tr>
<td>No change in vision or drusen</td>
<td>23.5</td>
</tr>
<tr>
<td>Reduction in visual acuity</td>
<td>0</td>
</tr>
</tbody>
</table>

The effects of AREDS2 + RPS combination on visual/structural improvements in AMD patients were including in Table 1:

- 15 patients experienced improved vision of at least one line of Snellen acuity test (44.1%).
- 5 patients showed improved vision and reduction in size and number of macular drusen (14.7%).
- 9 patients exhibited reduction in size and number of drusen (26.5%).
- None of the patients showed decreased visual acuity.
- 8 patients did not show any change in vision or drusen (23.5%).

SUMMARY
Supplementation with AREDS2 plus RPS improved vision by at least one line in Snellen acuity in 44% of the participants. Reduction in size and number of drusen was observed in 26.5% of the patients and improvement in contour of macula was seen in 8.8% of the patients. No reduction in visual acuity was recorded after supplementation. 23.5% of the patients had no change in vision or number of drusen.

CONCLUSIONS
Overall, supplementation with AREDS2 plus RPS for at least four months resulted in structural and/or visual improvements in approximately 70% of patients. The limitations of these case presentations are that the observations do not distinguish between the possibilities that the effects of the polyphenol preparation on retinal structure/function depend on synergistic interactions with AREDS2, or if the polyphenols alone are responsible. Future randomized, placebo-controlled clinical trials are warranted to confirm the beneficial effects of RPS alone and in combination with AREDS2 formulation in the treatment of dry AMD.