

Top-selling eye vitamins found not to match scientific evidence

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With Americans spending billions of dollars each year on nutritional supplements, researchers have analyzed popular eye vitamins to determine whether their formulations and claims are consistent with scientific findings. They determined that some of the top-selling products do not contain identical ingredient dosages to eye vitamin formulas proven effective in clinical trials. In addition, the study found that claims made on the products' promotional materials lack scientific evidence. The results of their study were published online in *Ophthalmology*, the journal of the American Academy of Ophthalmology.

The leading cause of blindness among older adults in the United States is



age-related macular degeneration (AMD). This is the deterioration of the eye 's macula, which is the central part of the retina that enables the eye to see fine details clearly. Recommended treatment for AMD at certain stages of the disease includes <u>nutritional supplements</u>. The landmark Age-Related Eye Disease Study (AREDS) found in 2001 that a specific formula of nutritional supplements containing high doses of antioxidants and zinc could slow the worsening of AMD in those who have intermediate AMD and those with advanced AMD in only one eye. A follow-up study that concluded in 2011, AREDS2, determined that the formula was still effective if one ingredient, beta-carotene (a form of vitamin A), was replaced with related nutrients, lutein and zeaxanthin. Beta-carotene was substituted in AREDS2 due to its link to increased risk of lung cancer in smokers. The two studies prompted a surge in sales of eye supplements which are marketed as containing the AREDS or AREDS2 formulas.

To test whether the <u>products</u> are consistent with the studies' findings, researchers compared the ingredients in top-selling brands to the exact formulas proven effective by AREDS and AREDS2. The researchers - based at Yale-New Haven Hospital-Waterbury Hospital, Penn State College of Medicine, Providence VA Medical Center and Warren Alpert Medical School of Brown University - identified the five top-selling brands based on market research collected from June 2011 to June 2012, and analyzed the brands' 11 products.

They found that, while all of the products studied contained the ingredients from the AREDS or AREDS2 formulas:

- Only four of the products had equivalent doses of AREDS or AREDS2 ingredients
- Another four of the products contained lower doses of all the AREDS or AREDS2 ingredients
- Four of the products also included additional vitamins, minerals



and herbal extracts that are not part of the AREDS or AREDS2 formulas

In addition, while all 11 of the products' promotional materials contained claims that the supplements "support," "protect," "help" or "promote" vision and eye health, none had statements specifying that nutritional supplements have only been proven effective in people with specific stages of AMD. There were also no statements clarifying that currently there is not sufficient evidence to support the routine use of nutritional supplements for primary prevention of eye diseases such as AMD and cataracts..

"With so many vitamins out there claiming to support eye health, it's very easy for patients to be misled into buying supplements that may not bring about the desired results," said first author Jennifer J. Yong, M.D. "Our findings underscore the importance of ophthalmologists educating patients that they should only take the proven combination of nutrients and doses for AMD according to guidelines established by AREDS and AREDS2. It's also crucial that physicians remind patients that, at this time, vitamins have yet to be proven clinically effective in preventing the onset of eye diseases such as cataracts and AMD."

A results table of the analyzed products can be found at <u>http://www.aao.org/newsroom/release/upload/Table-1-OcularNutritional</u> <u>Supplements-InPress.pdf</u> (PDF file).

The American Academy of Ophthalmology recommends ophthalmologists consider antioxidant vitamin and mineral supplementation, per the AREDS and AREDS2 trials, for patients with intermediate or advanced AMD. It also maintains that, based on the sixyear timeframe of the AREDS trial, there is no evidence to support the use of these supplements for patients who have less than intermediate AMD. Ophthalmologists can read the Academy's AMD Preferred



Practice Pattern guidelines at <u>http://bit.ly/aaoamdppp</u>. The public can learn more information about AMD and AREDS supplements at <u>http://bit.ly/eyesmartamd</u>.

Dietary <u>supplements</u> are neither evaluated nor regulated for efficacy or safety under the Dietary Supplement Health and Education Act (DSHEA) of 1994. In addition, FDA approval is not required for <u>dietary</u> <u>supplements</u> to be marketed.

Provided by American Academy of Ophthalmology

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