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COMPOSITION AND METHODS FOR IMPROVING RETINAL HEALTH

FIELD OF THE INVENTION

The present invention relates to a nutritional dietary supplement composition and related methods of administration for the treatment and/or prevention of retinal diseases, and their concomitant impairment of vision. In particular, the invention relates to a nutritional supplement comprising a combination of ingredients useful for treating and/or preventing macular degeneration.

BACKGROUND OF THE INVENTION

Age-related macular degeneration (AMD) is an eye disease that affects the central part of the retina and is the leading cause of vision loss and blindness in people over the age of 50 in the U.S. AMD affects an estimated 15 million people in North America alone, and causes severe vision impairment in about 1.2 million of these patients. About 30% of US patients over the age of 75 have some form of AMD, and 23% of the remainder will develop it within five years. Generally, the prevalence of AMD increases with age from 16.8% in patients ages 55-64 to 25.6% in patients ages 65-74 and up to 42% in patients over age 75 in some societies.

Macular degeneration is a disorder which is often characterized as one of two types: (a) non-exudative (the dry form); or (b) exudative (the wet form). Although many theories abound, there is no known cause of AMD, neither is there currently any known cure for the dry or atrophic form of AMD. Dry AMD is characterized by hard or soft drusen (deposits of cellular debris), changes in the retinal pigment epithelium (RPE), or atrophy of photoreceptors and RPE. The dry form accounts for approximately 90% of all AMD cases; the remainder being diagnosed with the "wet" form of AMD. Wet AMD is characterized by neovascularization and exudative changes in the retina. Although both types are bilateral and progressive, each type may reflect different pathological processes. With few exceptions however, non-exudative AMD almost always precedes the development of exudative AMD.

Both exudative (wet form) and non-exudative (dry form) macular degeneration are typically accompanied by the formation of drusen. Drusen are characterized by irregular, discrete, round yellow-white deposits which accumulate in the retina (back of the eye) between the basement membrane of the RPE and the rest of Bruch's membrane. The presence of drusen most likely reflects abnormalities in retinal pigment epithelial function. Drusen deposits can be further characterized into hard drusen or soft drusen. Hard or nodular drusen derive from debris accumulation from retinal pigment epithelial cells in Bruch's membrane. Soft drusen are usually larger than hard drusen and have soft, indistinct margins. Soft drusen are small detachments of the retinal pigment epithelium and presumably derive from diffuse retinal pigment epithelial dysfunction. Soft drusen can also derive from diffuse or confluent drusen, which further derive from a thickening of the inner portion of Bruch's membrane. Calcified drusen are characterized by a glistening appearance and are the consequence of calcification of nodular and diffuse drusen formations.

The non-exudative (dry form) macular degeneration ("D-AMD") involves atrophy and degeneration of the outer retina, retinal pigment epithelium, Bruch's membrane, and choriocapillaris. The resultant effects of non-exudative

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macular degeneration are formation of drusen, pigmentary changes, and atrophy. Dysfunction of the retinal pigment epithelium, in particular, leads to the loss of photoreceptors, which are metabolically dependent on the retinal pigment epithelium. Vision loss in dry AMD is typically slowly progressive.

Exudative (wet form) macular degeneration is characterized by serous or hemorrhagic separation of the retinal pigment epithelium or neurosensory layer. Patients may develop choroidal neovascularization, which is manifested as fluid accumulation, hemorrhage, and/or lipid exudation. Vision loss can be rapid. These defects typically cause metamorphopsia (distortion) which is detected clinically by Amsler grid testing. An Amsler grid consists of a chart with lines forming small squares. When choroidal neovascularization is manifested as fluid accumulation, hemorrhage, and/or lipid exudation the vision is distorted and the lines making up the squares of the grid become blurred and/or wavy.

Choroidal neovascularization occurs by vessels from the choroidal membrane growing through Bruch's membrane into the subretinal pigment epithelial or subretinal space. This in itself can lead to severe visual loss, however, the retinal pigment epithelium or the neurosensory retina may also detach. Patients with pigment epithelial detachments may develop associated choroidal neovascular membranes. Even with no choroidal neovascular membranes present, 40% of patients with pigment epithelial detachments may continue to experience further loss of vision. Affected patients may exhibit metamorphopsia by Amsler grid testing. Further consequences of exudative macular degeneration can include tearing of the retinal pigment epithelium and often development of a disciform scar with associated photoreceptor degeneration.

Both of the above-described forms of macular degeneration (non-exudative and exudative) usually proceed continuously toward irreversible loss of central vision. Ultimately, the retina is damaged by long-standing edema, underlying hemorrhage, and/or detachment. Following detachment, the retina may undergo fibrosis, metaplasia, elevation and scarring.

A number of therapies have recently been introduced for the treatment of wet AMD which target the inhibition of certain underlying angiogenesis processes, but at present there is no effective treatment for non-exudative macular degeneration that has been proven in its ability to enhance vision in a large clinical trial. Management of non-exudative macular degeneration is limited to early diagnosis and careful follow-up to determine if the patient develops choroidal neovascularization. In addition, intervention with diet, exercise and dietary supplement programs are frequently instituted.

However, the dietary supplements in use today have not demonstrated an ability to reliably slow the rate of progression in the vision loss or prevent AMD. Also, none of the supplements in use today have undergone the rigorous testing and demanding controls encountered within the context of an FDA-regulated clinical trial. Therefore, there exists a currently unmet need in the art for a proven effective dietary supplement composition and method to treat and/or prevent AMD, in particular D-AMD, which afflicts 90% of patients with AMD. Thus, a treatment means that can effectively stabilize and/or enhance the visual function of patients diagnosed with the dry form of AMD would be of considerable benefit; especially if patients and physicians could point to the results of such a treatment that occurred within the context of a rigorous randomized prospective