



CapsiClearTM

An optical evolution

Ocular Nutrition's New Powerful Carotenoid
Capsanthin's Holistic Approach to Vision Health





The Need for Holistic Eye Health Solutions

With a steady increase of baby boomers and the rise of e-gamers, eye health is top-of-mind among consumers. CapsiClear™ is a patent pending clinically studied ingredient that provides complete eye health solution for all ages.

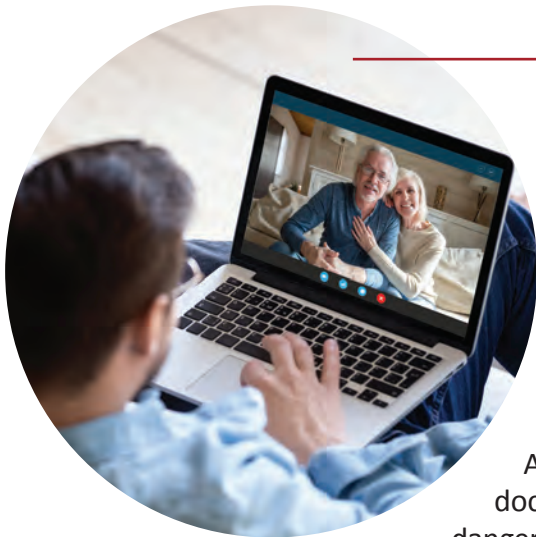


As technology continues to advance, the world becomes more digitized and people are relying even more on the devices that help run our lives. Despite all the advantages, one large concern is the effect that all this tech is having on our vision health. Constant digital screen time and a lack of proper eye care puts society at increased risk of multiple health conditions that affect vision. Combine this with the potential increase of persons aged 65 and older worldwide from **9%** to **16%** by 2050¹, age-and tech-related vision impairments will also experience a rise in numbers.

Recent research has revealed that the xanthophyllic carotenoid capsanthin delivers a new and efficacious way to support eye health. Unibar Corporation has developed patent-pending CapsiClear™ to serve the needs of a digital-focused world, helping to deliver holistic eye health support that:

- Increases macular pigment optical density
- Improves photostress recovery for reduced eye strain
- Helps to reduce intraocular pressure via an oral application
- Increases reading speeds under blue light

This whitepaper seeks to take an in-depth look at current eye health challenges and two recent clinical studies that detail how capsanthin is a novel solution that provides safe and efficacious eye health benefits that go beyond the benefits provided by other carotenoid ingredients such as lutein and zeaxanthin.



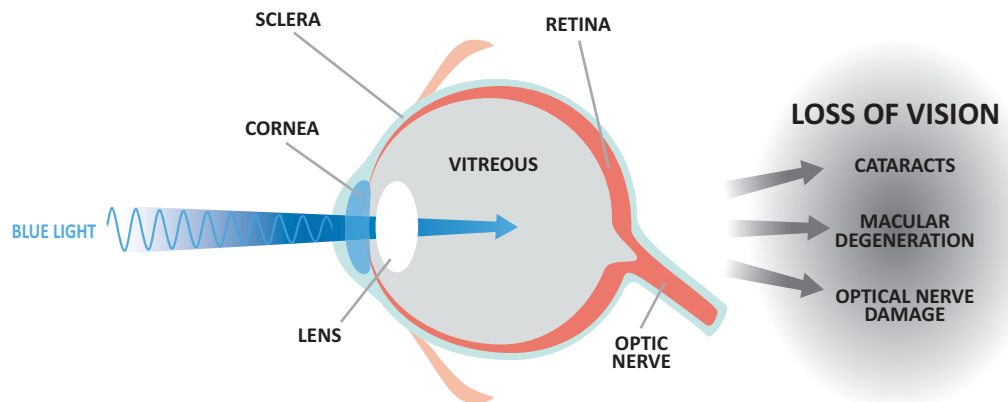
Increased Dependency on Digital Devices

It is common to kick off the day by perusing emails, the news or social media before heading off to work for eight hours of sitting in front of a computer screen. Even our evenings are spent in front of gadgets big and small. Before bedtime we often watch more TV, play games or read e-books. Screen usage has increasingly become dominant in our everyday lives.

Are these screens safe? According to The Huffington Post, many eye doctors claim that electronic gadgets emit blue light, which can be dangerous not only for the eyes but for the entire body.

When looking at digital screens, the eyes tend to focus solely on the device being used. Consequently, the eye blinking rate (BR) can reduce from a resting BR of 15 per minute to about 5 per minute. Gadgets that employ digital screens often produce blue light rays, which have the shortest wavelength but the highest energy in the visible light spectrum. Although our cornea and lens are very effective at blocking UV rays from reaching the sensitive retina at the back of the eyeball, virtually all visible blue light passes through the cornea and lens and reaches the retina. Laboratory studies have shown that too much exposure to blue light can damage light-sensitive cells in the retina. This causes changes that resemble those of macular degeneration, which can lead to permanent vision loss.

Some chronic problems have been linked to overexposure of high-energy light



Age-Related Macular Degeneration²

Age-related macular degeneration (AMD) is an eye disease that often occurs in older persons and affects the part of the eye called the macula that is especially important for seeing clearly. It can blur the sharp, central vision you need for activities like reading and driving.

AMD is a common condition and is a leading cause of vision loss for people age 50 and older. AMD doesn't cause complete blindness, but losing your central vision can make it harder to see faces, drive, or do close-up work like cooking or fixing things around the house.

AMD happens very slowly in some people. Even if you have early AMD, you may not experience vision loss for a long time. For other people, AMD progresses faster and can lead to central vision loss in one eye or both eyes.

AMD is a chronic condition that usually affects both eyes and is brought about by a metabolic disorder. But vision loss usually only occurs in more advanced stages of AMD. AMD is divided into two types: “dry” and “wet.” Wet AMD causes vision loss more quickly, but neither can be cured. The treatment for wet AMD can help to maintain and sometimes even improve vision, or at least slow down the progression of the disease.



Early-Onset Glaucoma³

Glaucoma is a group of eye disorders in which the optic nerves connecting the eyes and the brain are progressively damaged. This damage can lead to reduction in peripheral vision and eventual blindness. Other signs and symptoms may include bulging eyes, excessive tearing, and abnormal sensitivity to light (photophobia). The term “early-onset glaucoma” may be used when the disorder appears before the age of 40.

In most people with glaucoma, the damage to the optic nerves is caused by increased pressure within the eyes (intraocular pressure). Intraocular pressure depends on a balance between fluid entering and leaving the eyes.

Usually glaucoma develops in older adults, in whom the risk of developing the disorder may be affected by a variety of medical conditions including high blood pressure (hypertension) and diabetes mellitus, as well as family history. The risk of early-onset glaucoma depends mainly on heredity.

Structural abnormalities that impede fluid drainage in the eye may be present at birth and usually become apparent during the first year of life. Such abnormalities may be part of a genetic disorder associated with a group of symptoms called a syndrome. If glaucoma appears before the age of 5 without other associated abnormalities, it is called primary congenital glaucoma.

Other individuals experience early onset of primary open-angle glaucoma, the most common adult form of glaucoma. If primary open-angle glaucoma develops during childhood or early adulthood, it is called juvenile open-angle glaucoma.



1 in 10,000

Primary congenital glaucoma affects approximately 1 in 10,000 people



1 in 50,000

Juvenile open-angle glaucoma affects about 1 in 50,000 people



One Percent

Primary open-angle glaucoma affects about 1 percent of the population

Primary congenital glaucoma affects approximately 1 in 10,000 people. Its frequency is higher in the Middle East. Juvenile open-angle glaucoma affects about 1 in 50,000 people. Primary open-angle glaucoma is much more common after the age of 40, affecting about 1 percent of the population worldwide.



Carotenoids and Eye Health⁴

Numerous studies have identified lutein and zeaxanthin to be essential components for eye health. Lutein and zeaxanthin are carotenoid pigments that impart yellow or orange color to various common foods such as cantaloupe, pasta, corn, carrots, orange/yellow peppers, fish, salmon and eggs. Their role in human health, in particular the health of the eye, is well established from epidemiological, clinical and interventional studies. They constitute the main pigments found in the yellow spot of the human retina which protect the macula from damage by blue light, improve visual acuity and scavenge harmful reactive oxygen species. They have also been linked with reduced risk of age-related macular degeneration (AMD) and cataracts. But lutein and zeaxanthin only address part of the puzzle that eye health presents while research is beginning to position other carotenoids as playing an even more holistic role.

Carotenoids, which are synthesized *de novo* by microorganisms and plants, accumulate in various biological tissues throughout the food chain. More than 700 carotenoids, including the metabolites in animals, are present in nature. Most of the carotenoids contain oxygen functions in their molecules, and these carotenoids are referred to as xanthophylls. In recent years, a great deal of attention has been focused on biological activities of dietary xanthophylls such as lutein, zeaxanthin, β -cryptoxanthin, capsanthin, astaxanthin, and fucoxanthin. Paprika oleoresin, obtained from the fruits of *Capsicum annuum*, is commonly used as a natural colorant in food products. The major coloring compound capsanthin is a carotenoid that is exclusively synthesized in capsicum species and has shown promising results as a holistic solution to eye health challenges. Various other carotenoids are also present, including β -carotene, zeaxanthin, and β -cryptoxanthin⁵. *Recent research has shown capsanthin to be highly potent among all currently known carotenoids.*

The First-Ever Highly Enriched & Stabilized Capsanthin Extract

The unique, patent-pending composition of CapsiClear™ contains capsanthin: 50% to 80%, zeaxanthin: 5% to 15%, cryptoxanthin: 1 to 5%, and trace amounts of other carotenoids in a stable form. CapsiClear™, a clinically researched capsanthin, is ideal for everyday vision issues such as eyestrain. Original clinical research suggests CapsiClear™ helps the eyes recover more quickly after exposure to bright light and helps increase reading performance in both white and blue light — actions that may help reduce eye strain.* It has also displayed the unique ability to help manage intraocular pressure via oral administration.*

Clinical Studies in Focus

Study 1: CapsiClear™ (Capsanthin 50%) for Lowering of Carbomer Induced Intraocular Pressure in Sprague Dawley Rats⁶.

Objective

The objective of this study was to evaluate CapsiClear™ (Capsanthin 50%) for lowering of intraocular pressure induced by Carbomer SD rats. In this study, animals were treated with CapsiClear™ (capsanthin 50%) at low, mid, and high doses and intraocular pressure (IOP) levels were compared with control and disease groups. The high intraocular pressure originated from an increased resistance to drainage of aqueous humor through the trabecular meshwork. A sustained increase in aqueous humor may be due to an increase in the formation of aqueous humor, a difficulty in its exits, or a raised pressure in the episcleral vein. Studies showed that introduction of Carbomer into the anterior chamber of eye produced best chronic glaucoma.

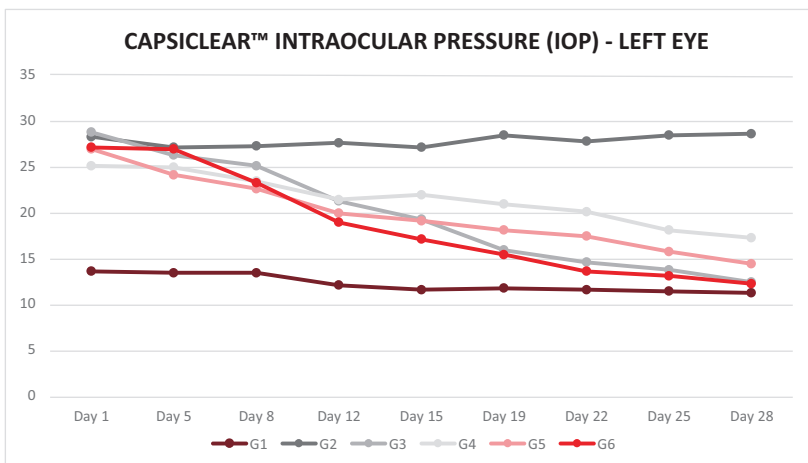
In this current study, IOP was induced by intravitreal injection of Carbomer, which elevated levels. IOP was confirmed before grouping and the vehicle/test item/reference item was administered for 28 days and IOP was recorded weekly.

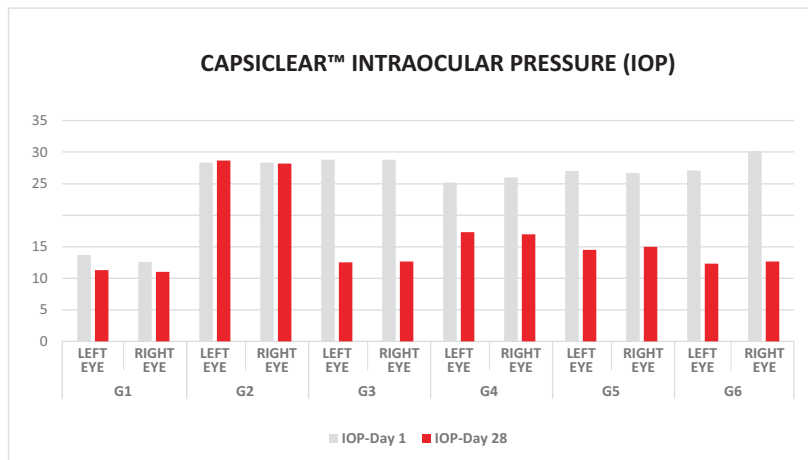
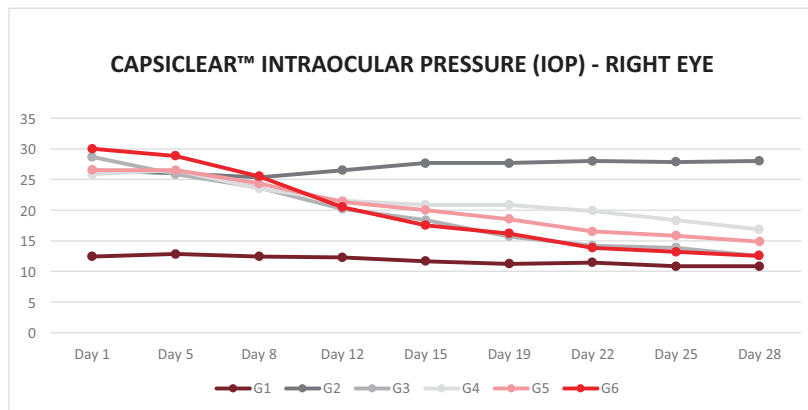
Outcome

The results showed that 28-day repeated administration of CapsiClear™ at dose levels of 20, 40 and 80 mg/kg reduced IOP from day 8 onwards. The IOP returned to a level almost equal to the untreated groups.

CapsiClear™ did not result in clinical signs of toxicity, mortality, changes in body weight and feed consumption. There was no treatment related changes in hematology and clinical chemistry parameters.

Based on the available results, it is concluded that daily oral administration of CapsiClear™ up to 80 mg/kg reduced the intraocular pressure in male Wistar rats.





- G1 Normal control
- G2 Disease control
- G3 Positive control
- G4 CapsiClear™ (Capsanthin 50%) low dose
- G5 CapsiClear™ (Capsanthin 50%) mid dose
- G6 CapsiClear™ (Capsanthin 50%) high dose

Study 2: Supplementation of CapsiClear™ for Improved Macular Health⁷

Objective

Unibar Corporation completed a 12-week human clinical study on CapsiClear™ at the University of North Texas with the objective to determine the effect of 12-weeks of capsanthin supplementation on biological and functional changes in a broad set of measures of eye/macular health.

Outcome

Cumulative Macular Pigment Optical Density (Higher # is Better):

For cumulative macular pigment optical density (MPOD), the 40mg/d dose resulted in improvement at 4-weeks and also the 40 mg/d group had additional increases at 8 and 12-weeks when compared to the placebo.

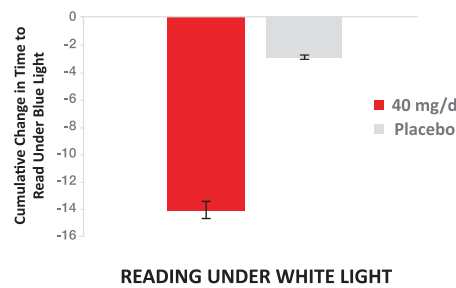
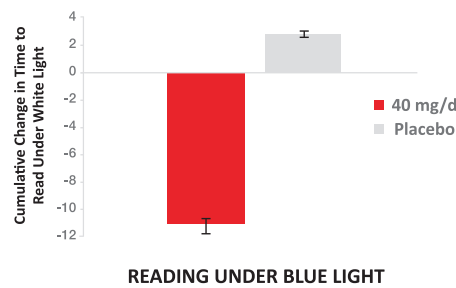
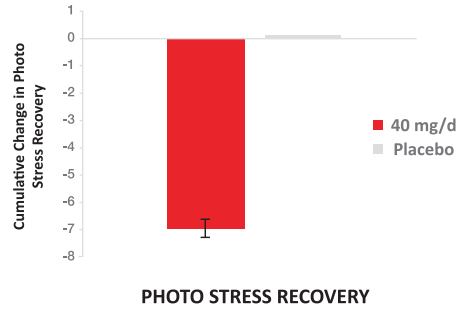
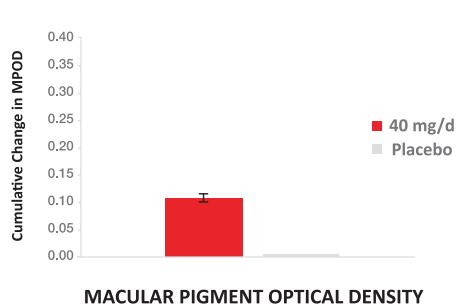
Cumulative Photo Stress (Lower # is Better):

Cumulative photo stress recovery is a measure of how long it takes for visual acuity to be restored after the retina is overloaded with a pen light (imitating the response from looking at the sun). A lower number in this case is better because a faster photostress recovery signifies that the eye is able to readjust quickly to bright light, decreasing the

risks that accompany temporary vision impairment, such as when driving a vehicle. The ability to recover from photo stress is directly related to MPOD. Also, just like MPOD, 40 mg/d response is more effective than placebo.

Cumulative Reading Under Blue and White light (Lower # is Better):

The ability to read under different cases of light exposure was tested. In this case a more negative number means a faster reading time. The subjects were given a random passage of words that was matched to their measured visual acuity and asked to read the words as quickly as possible. The test was conducted with one random passage under blue light and a second random passage under white light. In both cases the 40 mg/d condition outperformed the placebo conditions. These are direct measures of reading performance under different light conditions.



Why CapsiClear™

1. The first-ever highly enriched capsanthin for greater biological effect
2. The unique patent-pending and stable composition of capsanthin, zeaxanthin and cryptoxanthin
3. The first oral carotenoid for maintaining optimum intraocular pressure
4. Clinically tested for macular health benefits by increased MPOD and decreased the photo stress recovery time
5. Safe to use as the oral dose LD50 is greater than 2000mg/kg/b. wt.
6. Self-Affirmed GRAS

Safety⁸

Single oral administration of capsanthin at levels of 2000 mg/kg of body weight to two groups of three female Sprague Dawley rats each caused:

- No mortality in female rats, at 2000 mg/kg b.wt.
- No abnormal clinical signs, at 2000 mg/kg b.wt.
- No treatment related change in body weight was observed
- No abnormality detected at necropsy

Treatment with CapsiClear™ from Unibar Corporation to Sprague Dawley rats at the dose level of 2000 mg/kg body weight had no noteworthy effects on the general health of the animals nor the body weight and macroscopic lesions in females.

In view of the results observed, the median lethal dose of CapsiClear™ after oral administration to female rats with two fractions of dosage, observed over a period of 14 days, is more than 2000 mg/kg body weight.

Conclusion

CapsiClear™ – a ground breaking new capsanthin carotenoid extract geared toward overall eye health* – is the first ingredient to provide at least 50% Capsanthin. The resulting effects of CapsiClear's unique composition far surpass other carotenoids, and singularly positions the product to fight the mounting strain placed on our eyes.

People around the world are increasingly dependent on screens and all types of devices at an earlier age. Research has proven that the blue light emitted from these devices harms our vision by potentially causing macular degeneration and increasing eye strain. The net result—sore eyes, blurred vision, increased internal eye pressure, optical nerve damage and headaches—can be combatted with products offering a holistic approach. Capsanthin, a red pigment found in chili peppers and the key ingredient in CapsiClear™, is a carotenoid molecule specifically studied for its benefits on total eye health*.

Reference

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7. Determining the Effect of 12-weeks of Oral Capsanthin Supplementation on Body Weight, Lipid Profile, Liver Health, and Eye/Macular Health in Overweight Subjects. Study conducted by Dr. Brian et al at University of North Texas and sponsored by Unibar Corporation, USA.
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**The data presented here is not evaluated by the U.S. Food and Drug Administration (FDA). This product is not intended to diagnose, treat, cure or prevent any disease.*

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