CapsiClear™

An optical evolution

White Paper

Managing eye health never been simple but now it is possible with CapsiClear® Capsanthin – an optical evolution

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Managing eye health has never been simple but now it is possible with CapsiClear® Capsanthin – *An optical evolution*

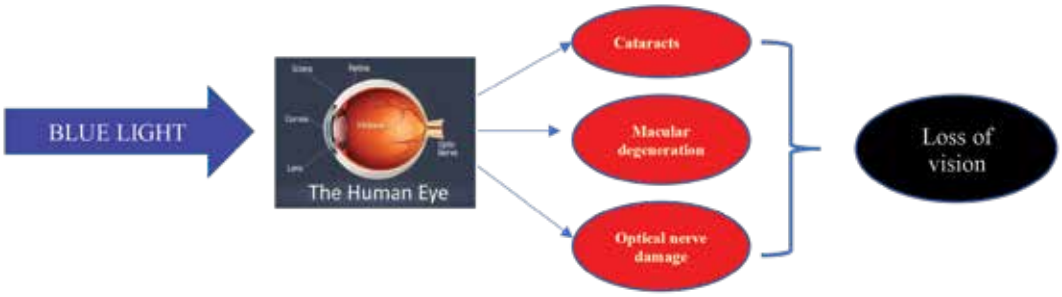
Humans are increasingly dependent on gadgets of all sorts

It is common to kick start the day by reading emails in bed before heading to work for eight hours sitting in front of a computer screen. Even the evenings are spent in front of electronic devices big and small. Before bedtime we often read books, with e-books now replacing the traditional paper versions. In other words, using and watching screens has become increasingly dominant in our everyday lives.

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

When using gadgets and looking at digital screens, the eyes will focus to this near range object. As such, the eye blinking rate (BR) can reduce from resting BR of 15 per minute to about 5 per minute. Gadgets employ digital screens which produce blue light rays which in the visible light spectrum has the shortest wavelength but the highest energy. 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



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Age related Macular Degeneration (AMD)1

Age-related macular degeneration (AMD) is an eye disease that can blur the sharp, central vision you need for activities like reading and driving. “Age-related” means that it often happens in older people. “Macular” means it affects a part of your eye called the macula. AMD is a common condition — it is a leading cause of vision loss for people age 50 and older. AMD does not 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. It develops in the macula, the part of the eye that is especially important for seeing sharp images. But vision loss usually only occurs in more advanced stages of AMD. There are two types of AMD: “dry” and “wet.” Wet AMD causes vision loss more quickly. Neither can be cured. But treatment for wet AMD can help to keep and sometimes even improve vision, or at least slow down the progression of the disease.

Early-onset Glaucoma2

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 side (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 that affects many body systems, 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.

Frequency

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 Health3

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, corn, carrots, orange and 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.

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 the 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 is obtained from the fruits of *Capsicum annuum* and is commonly used as a natural colorant in several food products. The major coloring compound Capsanthin is a carotenoid that is exclusively synthesized in capsicum species. Various other carotenoids are also present, including β-carotene, zeaxanthin, and β-cryptoxanthin[4].

Capsanthin is one of the most potent, double bonded among known carotenoids.

Unibar offers the first-ever highly enriched and stabilized patent pending CapsiClear™ Capsanthin. The unique patent pending composition of CapsiClear™ contains Capsanthin, Zeaxanthin, Cryptoxanthin and trace amounts of other carotenoids in a stable form. CapsiClear™ is a novel capsanthin supplement 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.*

CapsiClear™ Capsanthin 50% for lowering of Carbomer Induced Intraocular Pressure in Sprague Dawley Rats5.

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Study Objective

The objective of this study was to evaluate the CapsiClear™ (Capsanthin 50%) for lowering of Intraocular Pressure (IOP) induced by Carbomer SD Rats. In this study, animals were treated with CapsiClear™ (Capsanthin 50%) at low, mid, and high doses and Intraocular pressure was 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 and elevated levels. IOP was confirmed before grouping and vehicle/Test item/reference item was administered for 28 days and weekly IOP was recorded.

Animal Welfare

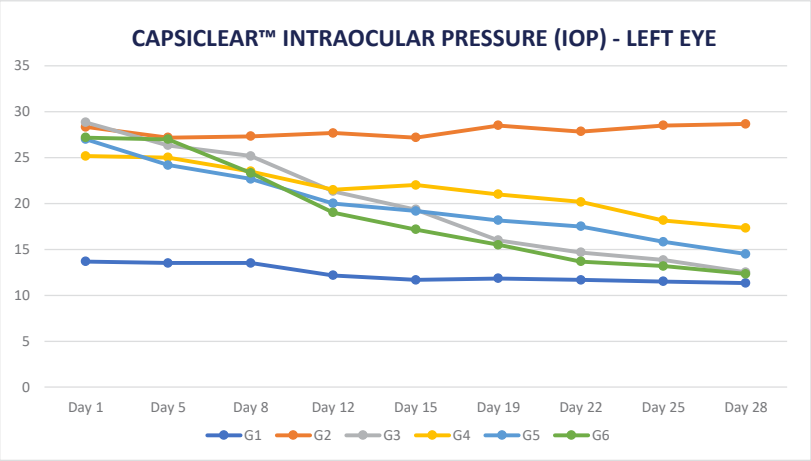
This protocol was approved by the Institutional Animal Ethics Committee (IAEC) vide protocol number VIP/IAEC/145/2019. The experiments were conducted as per the recommendation of the Committee for the Purpose of Control and Supervision of Experiments on Animals (CPCSEA) guidelines on the regulation of scientific experiments on animals, Ministry of Environment & Forests (Animal Welfare Division) Government of India, June 2007.

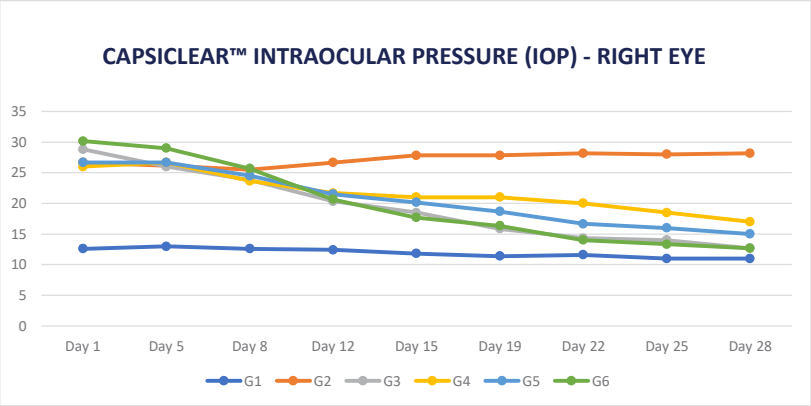
Study Outcome

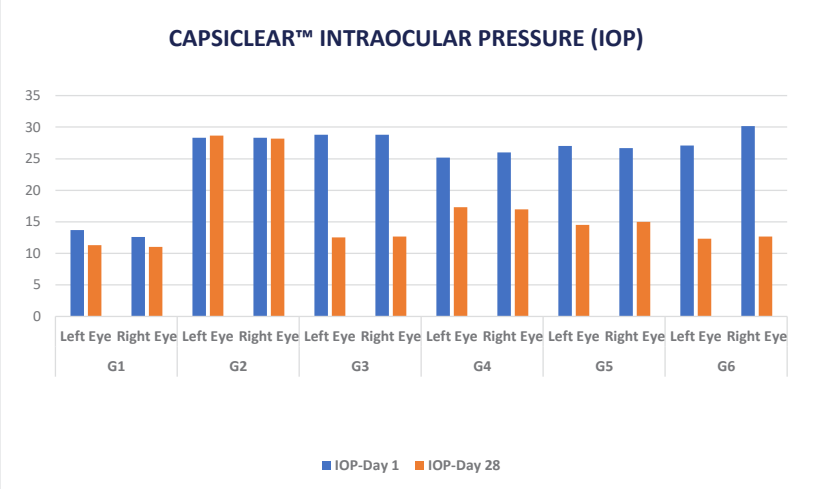
1. Intraocular pressure was induced by intraocular administration of Carbomer, 0.6% v/v solution.
2. The digital tonometer was used to measure the IOP during the study period.
3. CapsiClear™ was administered orally at 20, 40 and 80 mg/kg for 28 days.
4. Pilocarpine 2% topical was used as a positive control.
5. Animals were observed for mortality, clinical signs of toxicity, changes in body weight, and food consumption. The IOP was measured twice a week during the study period.
6. At the end of the treatment period, hematology, clinical chemistry, antioxidant parameters, gross and histopathology parameters were evaluated. The results showed that 28-day repeated administration of CapsiClear™ at dose levels of 20, 40 and 80 mg/kg reduced from day 8 onwards up to 28 days. The IOP was returned to the level almost equal to the untreated groups.

   CapsiClear™ did not result in clinical signs of toxicity, mortality, changes in body weight and food 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.

   The results also showed that CapsiClear™ did not cause any adverse effects in Wistar rats. There was no treatment related mortalities and changes in clinical chemistry parameters. This shows that the dose is safe enough for the treatment of IOP without affecting other parameters.







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

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CapsiClear™– Clinically Tested for Efficacy6

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

Study Outcome

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

After the retina is overloaded with a pen light (think response after looking at the sun), 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.

MACULAR PIGMENT OPTICAL DENSITY

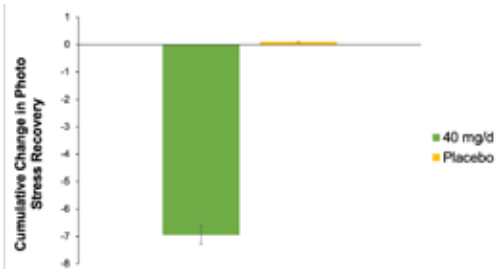
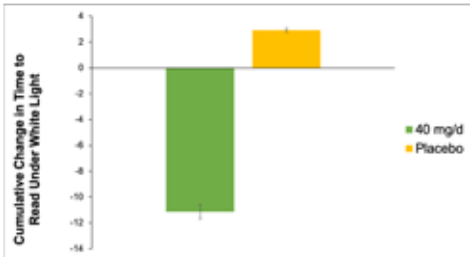


PHOTO STRESS RECOVERY

Cumulative Reading under Blue and White light (Lower number Better or Higher Negative Better):

Light exposure and ability to read was performed. In this case a more negative number means a faster recovery 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 1 random passage under blue flight 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.



READING UNDER BLUE LIGHT

READING UNDER WHITE LIGHT

Safety of CapsiClear™7

Capsanthin single oral administration at the level of 2000 mg/kg body weight, to two groups each of three female Sprague Dawley rats 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.
- No body weight gain was observed.
- No abnormality detected at necropsy.

The treatment with test item CapsiClear™ from Unibar Corporation at the dose level of 2000 mg/kg body weight to Sprague Dawley rats had no noteworthy effects on general health of the animals, 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.

Salient Features

1. The first-ever highly enriched Capsanthin for more 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 (IOP)

4. Clinically tested for and proved for macular health benefits by increased MPOD and decreased photo stress recovery time.

5. Safe to use as the oral dose LD50 is greater than 2000mg/kg/b.wt.

6. Self-Affirmed GRAS

Conclusion

CapsiClear™ – a ground breaking new Capsanthin Carotenoid 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 human eyes.

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

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An oral supplementation animal study reveals **CapsiClear™ greatly reduces and maintains optimum internal eye pressure*** and thus helps prevent optical nerve damage*.

In fact, double-blind clinical research suggests **CapsiClear™ helps 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 also increases macular pigment optical density*.

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6. 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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