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Standardised *Tagetes Erecta* Lutein and Zeaxanthin for Macular Health and Visual Performance: A Narrative Review

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Abstract: Lutein and zeaxanthin are the xanthophyll carotenoids of the human macular pigment; because neither is synthesised in the body, the retina depends on dietary and supplemental intake. Marigold (Tagetes erecta) flowers are the principal natural feedstock for commercial lutein and its fatty-acid esters, placing this plant at the centre of nutritional eye care. This review assesses the clinical literature on T. erecta-derived lutein and zeaxanthin and the potential for standardising their use in vision supplements. In cellular and animal models, the mechanism of action is consistent with ocular protection through blue-light screening and antioxidant activity: lutein and zeaxanthin counter oxidative stress and damage to retinal pigment epithelium cells and photoreceptors, reduce inflammation, and support mitochondrial function via Nrf2/HO-1 pathways. In human randomised controlled trials, increased macular pigment optical density (MPOD) is linked to improved contrast sensitivity and visual performance under glare or photostress. Two independent meta-analyses found that dietary supplementation raised MPOD more in patients with age-related macular degeneration (AMD) and improved visual function, with a possible reduction in progression risk. Recent interventional studies in computer users report mostly positive effects on visual comfort and eye dryness, though largely from self-reported data and considered preliminary. AREDS2 established lutein/zeaxanthin as a lower-risk alternative to beta-carotene that may slow progression in certain AMD patients but does not prevent eye disease generally. Further research is needed to define clinically relevant doses, and few studies have examined finished T. erecta products rather than isolated extract components.

Keywords: *Tagetes erecta*; lutein; zeaxanthin; macular pigment; visual performance; retinal protection; digital eye strain; ocular nutrition.

1. Introduction

The range of complaints about vision is broad, varying from mild, short-term discomfort due to prolonged computer use to the irreversible loss of central vision resulting from age-related macular degeneration (AMD) [31,43]. On the lower end of the severity scale, the spectrum of visual discomfort caused by digital device usage has become a common concern and increased the interest in nutrients that may protect eyesight and support visual performance [16,23].

The retina is uniquely susceptible to oxidative stress because of high levels of metabolic activity, a large pool of polyunsaturated fatty acids that are involved in photo transduction, and exposure to potentially damaging visible wavelengths of light. Photo oxidative stress and mitochondrial dysfunction play a prominent role in retinal ageing [28,29], contributing to AMD progression through lipid peroxidation, accumulation of bisretinoid fluorophores, such as A2E, chronic inflammation, and cellular senescence [29]. Macular carotenoids are critical antioxidant molecules that are particularly vulnerable to photo oxidative stress.

The concentration of carotenoids in the eye is dependent on dietary intake since humans lack endogenous lutein and zeaxanthin synthases [26]. Thus, higher dietary/lifestyle intakes of lutein/zeaxanthin are associated with greater macular pigment optical density (MPOD) and better visual performance, while reduced MPOD is linked to AMD progression [40,43]. The protective mechanism is multifactorial, but it primarily relates to counteracting blue light's harmful effects. In the macula, zeaxanthin and lutein (with smaller but significant contributions from meso-zeaxanthin) form a carotenoid network in which individual components have unique roles. Their hydrophobic tails are attached to retinal cells' membranes while the conjugated double bonds in the molecule are responsible for blue light's absorption and neutralising reactive oxygen species (ROS) [24,25,26].

Tagetes erecta is the primary plant source of lutein and zeaxanthin, with flower petals containing the major proportion of seed-derived carotenoids, most of which are present in the form of diesters. Finely ground Tagetes erecta petals are a significant commercial source of lutein for the nutraceutical industry [2,5]. This review discusses the phytochemistry of T. erecta carotenoids, the quality of dietary supplements containing those carotenoids, the ocular effects of supplementation, and the relevance of carotenoid composition to clinical studies. The review separates the discussion of marigold extracts from the broader topic of lutein and zeaxanthin, pays special attention to the differences between clinical and preclinical research, and adopts a conservative approach in general by focusing on the studies that explicitly mention T. erecta and its extracts.

2. Review methodology

We used PubMed, PubMed Central, Google Scholar, Web of Science, Scopus, and Crossref databases to find literature. We did not employ general multi-word searches, because they usually yield too broad results. Instead, for each of the themes (composition, extraction, bioavailability, mechanism, macular pigment, screen exposure, and AMD), we performed an individual search using single-concept queries. We de-duplicated the results to obtain a final list of publications. Some of the search terms were specific to the topic and outcome, for example, Tagetes erecta lutein, marigold extract zeaxanthin, lutein visual performance, lutein digital eye strain, lutein macular pigment, zeaxanthin retinal protection, marigold carotenoids blue light, lutein age-related macular degeneration. For all publications, we requested full texts via publisher's websites.

The eligibility criteria were publication in peer-reviewed journals and addressing of marigold or macular xanthophyll carotenoids' composition, extraction, standardisation, bioavailability, and/or ocular mechanisms, and/or function, and/or ocular-surface health, and/or retina ageing and AMD. We included both the direct studies on T. erecta and the ones using lutein/zeaxanthin carotenoids from other sources; however, the latter option was always specifically mentioned. For each article, we evaluated the validity of claims and correctness of references according to PubMed and publishers' databases. 43 articles (2001 – 2026) compose the core list, which is presented below by study types and forms the basis of our evidence claims. There were five more reviews/publications (44–48) acting as supporting background evidence for carotenoid digestion, transport, and retinal metabolism; these were evaluated similarly but not included in the core set. Table 1. The evidence base by study type.

Evidence category	Example references
Human clinical trials	1, 15, 16, 17, 18, 19, 20, 22, 31, 32, 33, 35, 36, 37
Systematic reviews/meta-analyses	38, 39, 40, 41, 42, 43
Animal studies	10, 12, 13, 14, 27, 29
Cell-culture studies	6, 11, 30
Bioavailability studies	1
Analytical / formulation studies	4, 5, 6, 7, 8, 9
Safety studies	2, 3
Mechanistic/narrative reviews	23, 25, 26, 28

3. Botanical and commercial relevance of *Tagetes erecta*

Tagetes erecta L. (Asteraceae), the African or Aztec marigold, is an annual plant which has large, densely petalled heads of yellow to deep orange colour. This colouration is due to the presence of xanthophylls; petals are the site of pigment synthesis. In the flowers, the carotenoids are concentrated mainly as lutein esters, which dominate in the proportion of total carotenoids in the dried flowers, being represented predominantly by lutein esters, on average, accounting for the majority of them [4,5]. Native to America, it

is now widely cultivated in many countries: India, China, Mexico, Peru, and Africa are the leading producers of marigold. Flowers of this plant are traditionally used in large-scale agricultural production as a source of natural pigments, while recently, lutein extracted from them is used as a nutraceutical ingredient for the food and pharmaceutical industries [2,5].

The value of marigold flowers as a source of lutein is determined by the fact that macular pigment is highly dependent on the supply of xanthophylls in the diet, while marigold flowers are the most cost-effective source of lutein among available options [1,2]. In other words, Tagetes erecta is the preferred choice for the development of any vision health functional food or pharmaceutical product, and the quality of the extract directly depends on the characteristics of the raw material used. One of the most critical aspects of marigold cultivation is that the content of carotenoids in it varies significantly. Thus, in the study conducted on ten marigold varieties, it was found that the content of carotenoids varied within approximately two orders of magnitude. Among the varieties studied, the highest content of lutein was found in Durango Red and Superboy Orange [5]. In the study involving two species of marigold, including Tagetes patula, significant inter-individual differences in the content of lutein and zeaxanthin were also noted [9]. Thus, it is extremely important to consider these differences when selecting varieties for breeding work. For the production of nutraceuticals, a standardised extract of marigold is used, which actually presupposes the existence of certain genetic differences.

4. Phytochemical profile of *Tagetes erecta*

Lutein is the active ingredient, which in the intact petal is present in the form of mono- and diesters with C16 fatty acids, mainly palmitate and myristate; lutein dipalmitate and mixed myristate-palmitate esters are the most prevalent diesters. The content of individual esters affects the following processing and determines the choice of the target form for the finished product (ester or free lutein) [5]. The purified crystalline lutein concentrate from marigold flowers may contain up to 86% lutein + zeaxanthin, according to one report [2]. The isomer ratio varies depending on the source, but the zeaxanthin content is generally lower than lutein, and therefore, when selecting a raw material for pharmaceutical production, it is necessary to consider what proportion of isomers is needed for the corresponding clinical application since both are present in the macula lutea [2].

However, marigold flowers contain other carotenoids, namely flavonoids and phenolic compounds, among which quercetagetin has been isolated and studied [8]. In addition, the method of processing influences the content of various carotenoids in the final product; specifically, for the production of tablets, the total content of polyphenols and lutein in the concentrate was evaluated [14]. However, whether these substances have an additional effect on eye health remains controversial. The antioxidant activity of marigold lipid extracts was confirmed experimentally, and simultaneous administration of lutein/zeaxanthin with quercetagetin protected the retina from photo-oxidative damage in a mouse model [5]. Still, in vitro assays cannot claim to reflect the physiological interactions that occur in the human body. Thus, the evidence for the synergistic effect is not absolute, and it would be wrong to overestimate the benefits of combination preparations.

Finally, flower colour, variety, and ripening stage, as well as drying and processing technologies, affect the carotenoid content in petals and, accordingly, their content in the final product [4]. Therefore, by adjusting agricultural techniques and raw material processing, it is possible to affect the concentration of individual carotenoids in the finished drug [5].

5. Extraction, purification and standardisation

Conventional production involves drying and grinding the petals followed by solvent extraction of the oleoresin with hexane and saponification and purification steps; while effective, this method has led the field to turn towards more sustainable practices due to toxic by-products, which has led to the development of two main alternative routes [7]. Ultrasound-assisted extraction into food-grade sunflower oil was optimised to yield high amounts of lutein while simultaneously improving the oxidative stability of the carrier oil [7], while microwave-assisted extraction into coconut oil also yielded high lutein concentrations with the added benefit of the extract being non-toxic to human ARPE-19 retinal cells in vitro [6].

As petals contain mainly esterified lutein, the saponification of the extract is necessary to obtain the free form of the compound, which should be done with caution to avoid isomerisation and oxidative loss of the fragile molecule [4]. While frequently postulated to be superior in terms of bioavailability, the free versus ester question seems to have been answered negatively in the case of marigold; a human crossover trial found no significant differences in serum response to 6 mg/day of either free or esterified lutein [1], making other considerations such as stability, manufacturing and labelling requirements more

pressing. Further processing is necessary to obtain either concentrated standardised extract or isolated lutein in crystal form, and lutein's instability in the face of light, heat and oxygen makes the production of microcapsules a preferred option in some cases; the encapsulated marigold extract has been shown to possess greater oxidative stability than its powdered counterpart and the use of optimal oil-to-wall ratios has also been recommended to maximise both encapsulation efficiency and lutein content [4,6]. Separation and identification of carotenoids in general, and lutein in particular, is achieved by reversed-phase HPLC with diode-array detection, or, in some cases, more nuanced and powerful practices such as UHPLC-Q-Orbitrap-HRMS analysis [4,6].

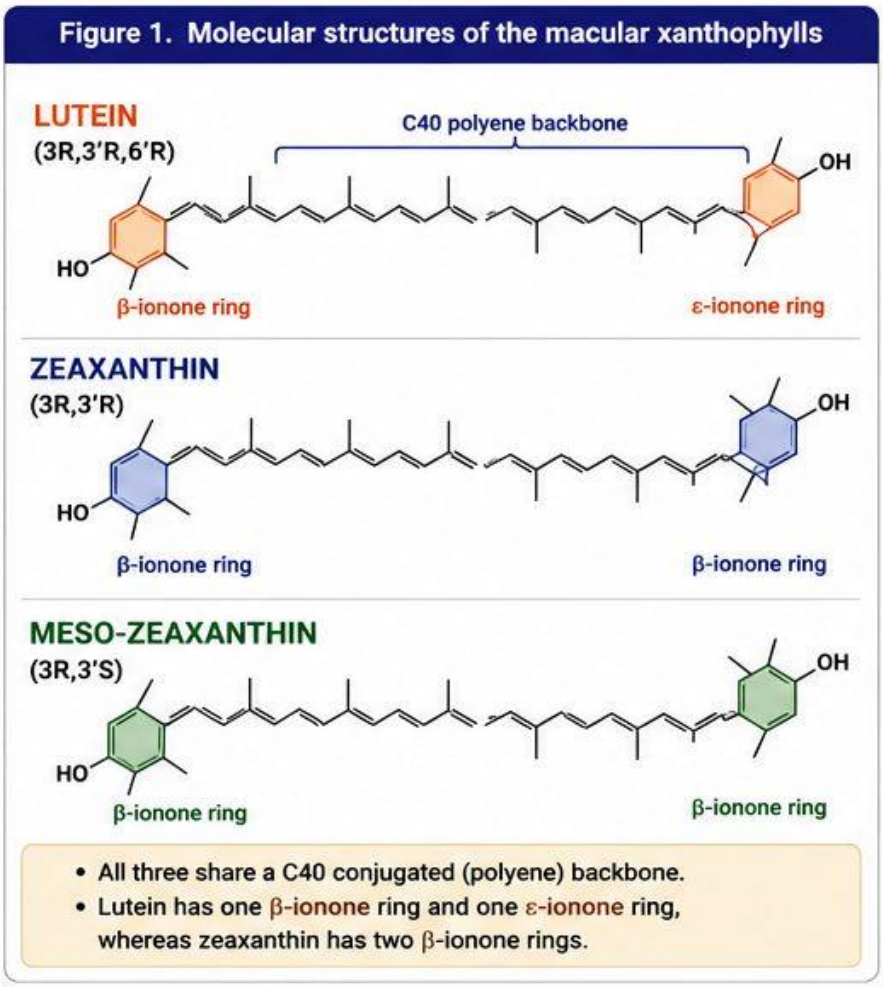

Fig 1: Molecular structures of the macular xanthophylls. Side-by-side chemical structures of lutein, zeaxanthin and meso-zeaxanthin, highlighting the shared C40 polyene backbone and the position of the hydroxyl-bearing end rings, with a note on the difference between lutein (one ε-ring) and zeaxanthin (two β-rings).

Standardisation, meanwhile, is a necessary procedure to ensure the quality of both the extract and lutein isolates; a survey of 34 commercial marigold products found only 10 to contain the levels of lutein stated by the manufacturer [4]. A properly standardised vision-support formulation must therefore make use of the botanical assay methods to establish the plant's identity and a chemical assay to determine its carotenoid content alongside the considerations made in Table 4 below.

6. Bioavailability of marigold-derived lutein and zeaxanthin

Lutein and zeaxanthin are lipophilic molecules that must be released from the dietary or supplemental matrix and incorporated into mixed bile-salt micelles during digestion before undergoing intestinal absorption, with esterified lutein requiring hydrolysis by intestinal esterases for uptake [44]. Following incorporation into mixed micelles, carotenoids are taken up into enterocytes, with some being transported via facilitated, scavenger-receptor–mediated processes and eventually incorporated into chylomicrons, which are then catabolized to generate free carotenoids and other lipoproteins that circulate in the plasma,

delivering them to peripheral tissues, including the retina [44]. Notably, systemic lipoprotein transport is a critical determinant of carotenoid status in the body.

The eye, however, exhibits a degree of selectivity in accumulating lutein and zeaxanthin. The macula selectively accumulates carotenoids, with the levels typically being much higher than those found in the circulation, potentially due to the action of xanthophyll-binding proteins, including glutathione S-transferase P1 and StARD3, which may mediate the preferential uptake of zeaxanthin and lutein, respectively, into the macula [26,45,46,47]. This is the physiological basis of the observed ability of supplementation to increase MPOD over prolonged periods of treatment [22,36]. Concerning the effect of supplementation, it is worth noting that free lutein can be directly incorporated into mixed micelles for transport and that oral doses of 6 mg of lutein daily can increase serum lutein content by approximately 2.4 -fold within 15 days of supplementation, with the effect being sustained thereafter [1]. More bioavailable formulations can increase MPOD and the contrast-sensitivity function [20]. On the other hand, esterified lutein is hydrolysed and is utilised comparably well to free lutein, an effect that may explain the lack of differences in serum response between the two formulations [1]. Overall, the absorption of lutein and zeaxanthin is dependent on the lipid environment, meaning that the concomitant consumption of dietary fat can significantly impact the extent of absorption, with the use of oil suspensions, emulsions, and oil-filled capsules being the norm in most formulations [44]. It is also important to note that the response to supplementation is highly variable and depends on baseline carotenoid and MPOD status, with individuals with lower baseline values responding better to supplementation, as well as age, smoking status, lipid metabolism, body composition, gastrointestinal function, genetic background, and the duration of supplementation [22].

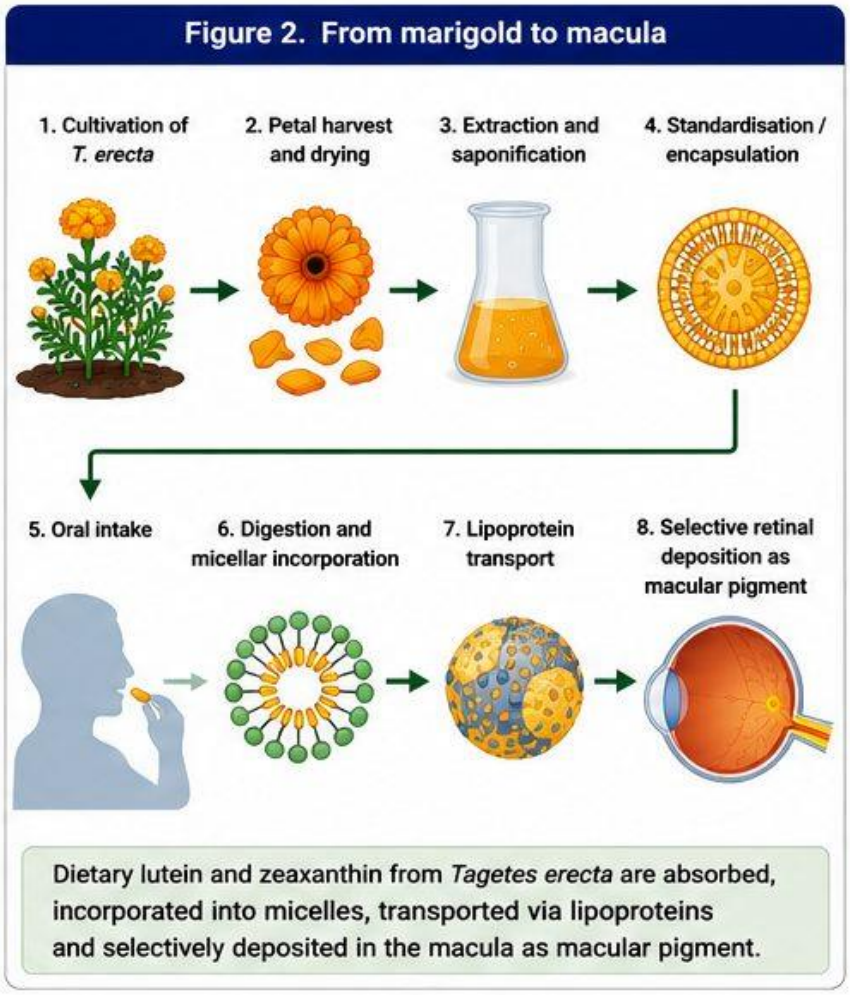

Fig 2: From marigold to macula. A horizontal schematic tracing the pathway from cultivation of *T. erecta* → petal harvest and drying → extraction and saponification → standardisation/encapsulation → oral intake → digestion and micellar incorporation → lipoprotein transport → selective retinal deposition as macular pigment.

7. Macular pigment and visual physiology

The macular pigment is a collection of three xanthophylls (lutein, zeaxanthin and meso-zeaxanthin), which when deposited in the central retina endow it with a yellow colouration and hence provide dietary-linked protection over the photoreceptors [26,45]. These carotenoids are not distributed uniformly, exhibiting relative enrichment in zeaxanthin/meso-zeaxanthin at the foveal centre and lutein increasing towards the periphery, possibly to meet differing functional requirements [26,45] (see Figure 3). The optical density of the macular pigment, estimated non-invasively by flicker photometry or reflectometry, is a key functional indicator, being increased by lutein/zeaxanthin intake and related to various visual performance indices, being an intermediate variable between intervention and vision outcomes [16,19,39,40].

The macular pigment appears to have two primary functions: namely, the ability to absorb short-wavelength (blue) light, thus limiting its access to the photoreceptor–retinal pigment epithelium (RPE) complex, and the capacity to quench singlet oxygen and scavenge other reactive oxygen species (ROS) [25]. Both these functions have been demonstrated for lutein and zeaxanthin in vitro, although the former appears to be more efficient than the latter in lipid emulsions at filtering blue light [24]. A likely reason for the presence of these carotenoids in the macula is their combined ability to modulate photo-oxidative stress, with lutein and zeaxanthin both being capable of scavenging ROS while reducing the amount of light energy reaching the photoreceptors and the RPE [26]. The protection afforded by the macular pigment is of significant importance to visual function since photo-oxidative stress damages photoreceptors in animal models [27], while blue light exposure in humans leads to accumulation of oxidative DNA damage in RPE cells [11,30]. The latter is of particular relevance since the RPE is indispensable for photoreceptor survival and function and is among the first sites to be affected during ageing [26]. Indeed, increased MPOD has been linked to better contrast sensitivity, glare recovery and photostress recovery, which reflect the overall visual performance under enhanced luminance conditions [16,19].

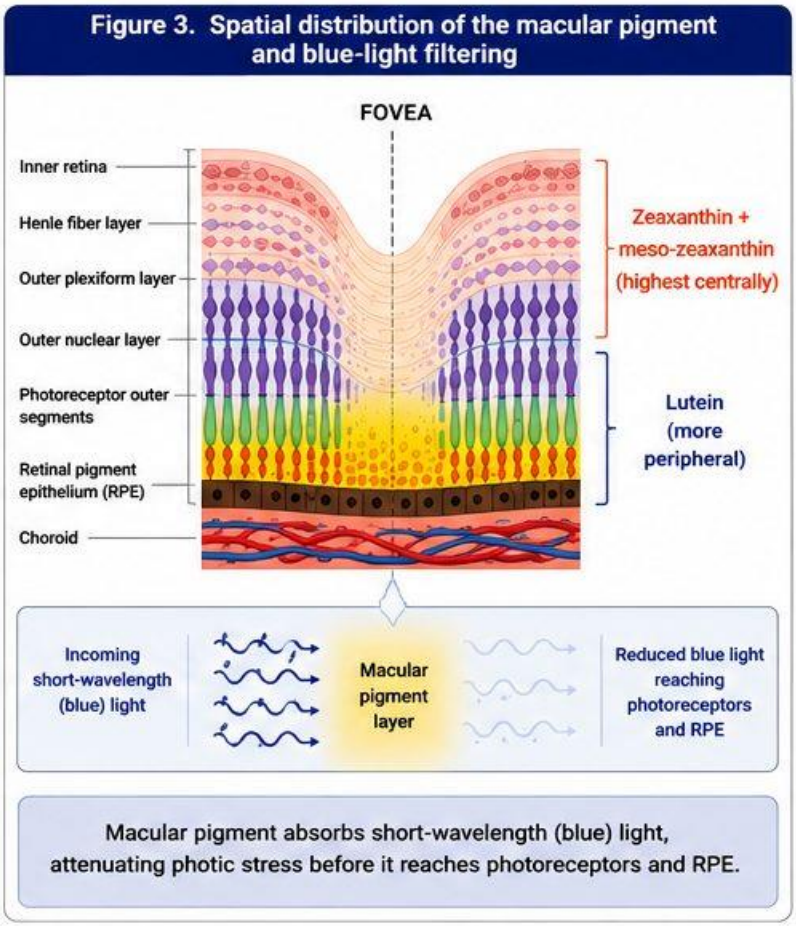

Fig 3: Spatial distribution of the macular pigment and blue-light filtering. A retinal cross-section/foveal schematic showing zeaxanthin and meso-zeaxanthin concentrated centrally and lutein more peripherally, with incoming short-wavelength light attenuated at the pigment layer before reaching photoreceptors and RPE.

8. Mechanisms supporting ocular health

The mechanistic rationale for macular carotenoids is remarkably coherent, and it is productive to review it in detail, as all subsequent considerations are based on it. The most salient effect is the optical one: lutein and zeaxanthin preferentially absorb high-energy blue light in the inner retina before it reaches the photoreceptor and RPE layers, an effect that has been demonstrated in membrane models, in which lutein, in particular, showed higher absorption capacity [24,25]. However, the carotenoids are not only light filters; they are powerful antioxidants that can directly neutralise singlet oxygen, which is one of the reasons why they have been rationalised as the xanthophylls of choice for the macula, and they also scavenge other reactive oxygen species (ROS), leading to decreased ROS levels in cellular and animal models [25,26,27,30]. The retina is especially susceptible to oxidative stress due to the abundance of polyunsaturated fatty acids in photoreceptor membranes, which makes the observed decreases in lipid peroxidation products, such as malondialdehyde, and the concomitant increases in antioxidant enzyme levels, especially noteworthy [13,14].

The protective effect of macular carotenoids extends to the mitochondrial level, as a marigold extract, rich in lutein and zeaxanthin, was shown to recover mitochondrial membrane potential and morphology, and reduce oxidative stress in blue-light-exposed retina and ARPE-19 cells [12]. Remarkably, the protective effect was mediated by the Nrf2/HO-1 pathway, as demonstrated by the ability of Nrf2 inhibition to abolish the effect, which suggests that the pathway is integral to the response [12]. Similar results were obtained with a combination of lutein/zeaxanthin and quercetagetin, which also regulated Nrf2 and HO-1, this time in a photo-oxidative model of the retina [14]. The anti-inflammatory effects of carotenoids are also evident, as the treatment with lutein/zeaxanthin and quercetagetin decreased the levels of inflammatory cytokines, such as IL-6 and VEGF, in human RPE cells and reduced NF-κB-mediated signaling in the retina, evidenced by the decreases in ICAM, GFAP, and MCP-1 [14,30]. The anti-inflammatory effect is part of the broader protective effect of carotenoids on the retina, which also manifests in the reduced rate of apoptosis and cellular senescence. Specifically, lutein and zeaxanthin decreased the levels of SA-β-galactosidase and γH2AX foci in cells and animals and reduced TUNEL-positive photoreceptors in mice [27,30]. Two major cell types present in the retina, the RPE and the photoreceptors, were also shown to benefit from the treatment; thus, a T. erecta extract was shown to prevent PM2.5-induced epithelial–mesenchymal transition in the RPE by downregulating the ROS-dependent TGF-β/MAPK pathway [11], and the outer nuclear layer thickness and electroretinography responses were preserved in photoreceptors in mice subjected to light stress [14,27]. The findings are summarized in Figure 4.

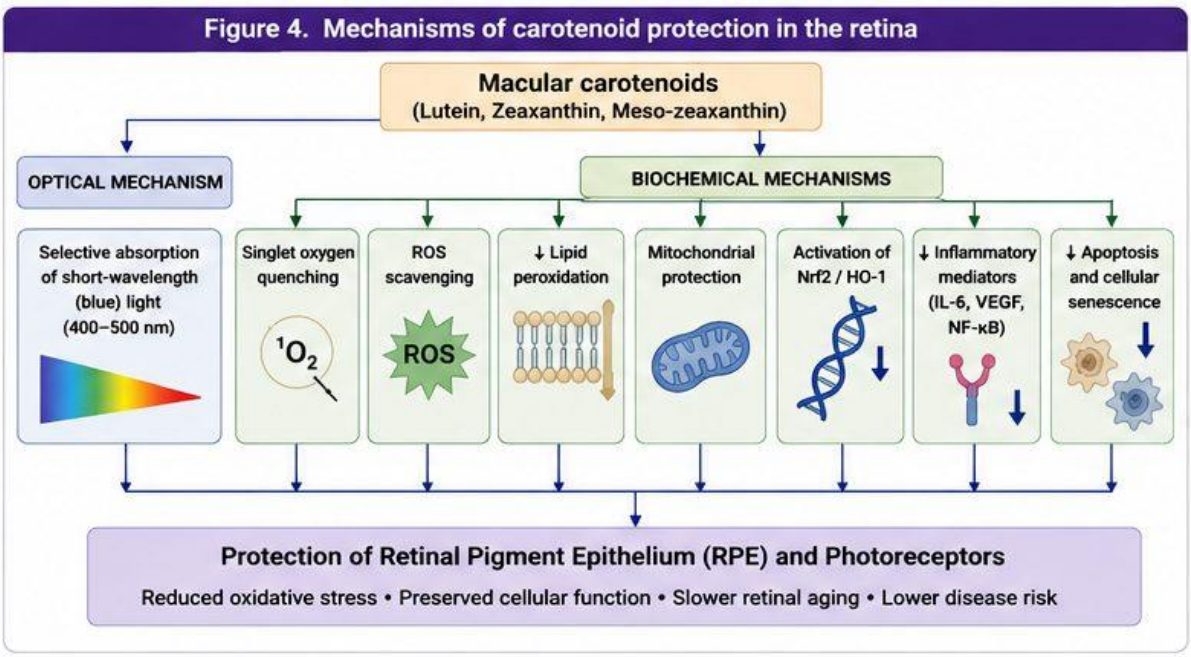

Figure 4. Mechanisms of carotenoid protection in the retina. A mechanistic map dividing actions into "optical" (blue-light absorption) and "biochemical" (singlet-oxygen quenching, ROS scavenging, ↓ lipid peroxidation, mitochondrial protection, Nrf2/HO-1 activation, ↓ IL-6/VEGF/NF-κB, ↓ apoptosis and senescence), converging on protected RPE and photoreceptors.

9. Protection against photo-oxidative and blue-light stress

Humans are exposed to short-wavelength light from sunlight as well as an increasing number of man-made sources such as LEDs and screens: the latter emit light of much lower irradiance than sunlight, which is relevant to the interpretation of findings [12,16]. Located in the retina, macular pigments are precisely positioned to absorb blue light: membrane model studies confirm the protective effect while demonstrating the role of optical density of carotenoids [24]. Controlled exposure to blue light (in vitro experiments with human RPE cells, rodent exposure studies, or both) consistently demonstrates the protective role of carotenoids. Marigold extract protected the retina of rats and ARPE-19 cells [12], while carotenoids reduced blue-light damage in ARPE-19 cells [30]; lutein and zeaxanthin isomers protected mice against light-induced retinopathy [27]. In each case, reduction in oxidative stress (ROS, MDA levels) and restoration of antioxidant enzymes, mitochondrial membrane potential, reduction in senescent cells and abrogated pro-inflammatory signalling were reported [12,13,27,30].

It is crucial to note that these protective effects are observed in response to intense exposure, which is higher than what can be delivered by consumer electronics. Thus, while these studies provide strong rationale for the proposed role of carotenoids in the context of blue-induced damage, the extrapolation of these findings to everyday exposure is not supported. In other words, these findings do not demonstrate that the everyday use of electronics leads to long-term damage or that counteracting it with food supplements would be beneficial. This conclusion, however, does not dismiss the possibility of such a relationship; it simply restricts the interpretation to a purely mechanistic one [12,30].

10. Digital eye strain and prolonged screen exposure

Digital eye strain, also called computer vision syndrome or digital asthenopia, is a symptomatic syndrome of tired eyes and dryness associated with intermittent blurring, glare sensitivity and headache after prolonged viewing of digital screens, the aetiology of which is multifactorial, involving oxidative and inflammatory mechanisms superimposed on visual-ergonomic factors [23]. Two of the latter are pertinent here: reduced blink rate/completeness in near-work leading to evaporative dry eye [17,23] and reduced contrast causing visual fatigue, both of which can be ameliorated by carotenoids. The macular pigment acts as a filter, reducing the amount of blue light reaching the retina, and thereby decreases glare and scatter of light in the eye, explaining its associations with improved glare tolerance and reduced visual discomfort [16,19]. While carotenoids are unlikely to have an effect on the accommodative system directly, their impact on contrast and vision processing may reduce the perceptual cost of near-work [16].

Several randomised intervention studies have enrolled participants reporting high screen usage. One showed that six months of supplementation with macular carotenoids improved MPOD, visual performance, sleep and physical symptomology in young adults with high screen time [16]. Another reported that a 5:1 marigold lutein/zeaxanthin extract enhanced MPOD, visual contrast sensitivity, and sleep quality in similarly recruited participants [18]. A lutein/zeaxanthin intervention also improved objective visual function in high electronic-screen users [17]. Subjective visual symptoms including eye fatigue, headache, photostress recovery and sleep improvements were consistently reported as beneficial across these trials [16,18,19]. However, the results are not entirely consistent: one study found objective visual improvements in the active group without corresponding subjective symptom changes [17]. The overall quality of this line of evidence is still emerging, with small sample sizes, short duration interventions and mixed outcome measures; a large multi-arm trial addressing some of these limitations is ongoing but has not yet published findings [21]. In summary, the evidence is suggestive but not definitive.

11. Effects on visual performance

It is more accurate to talk about “visual performance” than purely improved eyesight since the beneficial effects are related to specific, usually difficult tasks. The evidence for contrast sensitivity, which is the ability of the eyes to tell the difference between an object and the background, is the most consistent: it increases after supplementation with carotenoids in several randomised trials, including the 16-week study of high-bioavailable lutein, a marigold complex trial in screen users, and a meta-analysis [18,20,38]. The tolerance to glare increases and disability due to glare decreases with increased MPOD (macular pigment optical density) and reduced intraocular scatter [19, 20]. Moreover, the time needed for vision to recover from a bright light (photostress recovery) decreases after supplementation [16,19]. An improvement in chromatic contrast and colour discrimination is also possible [19].

The improvements in standard visual acuity are less consistent and depend on the population: while in people with age-related macular degeneration (AMD), the visual acuity is reported to improve in meta-analyses, in healthy participants, it rarely changes [38,41]. This suggests that carotenoids usually

benefit acuity when it is already reduced, rather than preventing minor age-related declines. On the retinal level, a two-year supplementation of lutein and/or zeaxanthin in patients with early-stage AMD resulted in increased macular pigment quantities and, for lutein, an increased retinal sensitivity, according to multifocal electroretinography [36]. Similarly, the improvements for the healthy population were seen in the parameters related to MPOD, glare tolerance, photostress recovery, and contrast sensitivity. The differences in the effect on AMD patients vs. the general population support the speculation that they have different baselines and room for improvement [36,38,40]. Note that human studies discussed in the section are presented in Table 2.

Table 2: Selected human studies of lutein/zeaxanthin relevant to macular support.

#	Study (first author, year)	Design	Population	Intervention / daily dose	Duration	Principal outcomes
1	Olmedilla-Alonso 2024	RCT, cross-over	24 adults	Marigold lutein, free vs ester, 6 mg	~2 months/arm	Serum lutein ↑ ~2.4× by day 15; no free-vs-ester difference; contrast threshold link [1]
16	Stringham 2017	RCT, placebo	48 high-screen adults	Lutein + zeaxanthin + meso-zeaxanthin, 24 mg	6 months	↑ MPOD, visual performance, sleep; ↓ eye strain, headache [16]
17	Lopresti 2025	RCT, DB, placebo	70 high-screen users	Lutein 10 mg + zeaxanthin isomers 2 mg	6 months	↑ tear tests, photostress recovery, tear break-up; self-report unchanged [17]
18	Bharadwaj 2025	RCT, cross-over	60 prolonged-screen users	Marigold L/Z complex 5:1 (10 mg + 2 mg)	up to 8 months	↑ MPOD, contrast sensitivity, sleep quality [18]
19	Hammond 2014	RCT, DB, placebo	115 healthy young adults	Lutein 10 mg + zeaxanthin 2 mg	12 months	↑ MPOD, chromatic contrast, photostress recovery [19]
20	Machida 2020	RCT, DB, placebo	59 healthy adults	Lutein 12 mg (high bio-accessibility)	16 weeks	↑ MPOD, contrast and glare sensitivity [20]
31	AREDS2 2013	RCT, DB, placebo	4203 at-risk of advanced AMD	Lutein 10 mg + zeaxanthin 2 mg (± ω-3)	~5 years	No further ↓ advanced AMD in primary analysis; L/Z favoured over β-carotene [31]
36	Huang 2015	RCT, DB, placebo	112 early AMD	Lutein ± zeaxanthin (10–20 mg)	2 years	↑ MPOD; lutein ↑ retinal sensitivity (mfERG) [36]

DB, double-blind; L/Z, lutein/zeaxanthin; MPOD, macular pigment optical density; mfERG, multifocal electroretinography.

12. Ocular-surface health, dryness and irritation

Oxidative stress and inflammation are implicated in the pathogenesis of eye surface disorders, including dry eye, thus providing a rationale for antioxidant carotenoids' beneficial effects on the eye [10,23]. The most compelling evidence involves marigold in a murine model of desiccation stress: an orally administered T. erecta flower extract normalized the tear production decreased by desiccation stress, reduced corneal epithelial damage (as measured by fluorescein staining), and prevented lacrimal-gland inflammation, with the dose comparable to cyclosporine A in its anti-inflammatory effects [10]. Human studies are limited to observational studies in screen users, reporting objective improvements, such as in Schirmer's test and tear-film break-up time, following lutein/zeaxanthin supplementation [17]. Thus, the animal evidence directly translates to humans in terms of ocular surface status, despite the lack of interventional trials with marigold. Again, the subjective and objective symptoms were not always aligned, necessitating caution in interpreting patients' comfort [17].

13. Retinal ageing and degenerative change

Cumulative oxidative stress damages the retina over time, impacting the function of the retinal pigment epithelium (RPE) as well as the photoreceptors. Age, and specifically the age-related decrease in macular carotenoids, increases the retina's susceptibility to photo-oxidative damage [25,28]. A significant part of this process involves the accumulation of lipofuscin and bisretinoid fluorophores, including A2E and iso-A2E in the RPE, which leads to blue-light toxicity. In a study conducted on a mouse model with increased deposits of lipofuscin, the administration of lutein and zeaxanthin reduced A2E/iso-A2E accumulation and improved visual function, establishing a link between carotenoids and the prevention of said pathology [29]. RPE dysfunction is one of the earliest precursors to AMD; research demonstrates that carotenoids protect human RPE cells from oxidative, blue-light, and particulate matter-induced damage [11,30]. Similarly, photoreceptor degeneration can be partly prevented by preserving their structure and function on a cellular level and reducing stress-related damage [27]. Mitochondrial dysfunction, another contributor to the development of AMD, can be addressed by the mitochondrial protection afforded by marigold extract [12]. Finally, the chronic, low-grade inflammation characteristic of the ageing process can be reduced by decreasing the expression of pro-inflammatory cytokines, specifically interleukin-6, vascular endothelial growth factor, and NF-κB-related pathways [14,30]. A review of studies conducted on animal models concluded that lutein and zeaxanthin offer protection for multiple tissues and structures within the eye in the context of AMD progression [28].

14. Age-related macular degeneration

AMD is a degenerative disease that destroys the eye's central vision due to oxidative damage, RPE dysfunction, and drusen formation, which can lead to geographic atrophy or choroidal neovascularization and poor macular function. The depletion of protective macular carotenoids is implicated in AMD development [28,29]. The relationship between diet and AMD is complex – while higher dietary lutein/zeaxanthin intake was not associated with a lower risk of early AMD in a meta-analysis of cohort studies, it was protective against late AMD, possibly by reducing the risk of progression [43].

The interventional evidence primarily stems from the AREDS2 study, which found that adding lutein/zeaxanthin to the treatment regimen did not provide an additional benefit in terms of reducing the progression to advanced AMD. However, the review highlighted the importance of lutein/zeaxanthin as a safer alternative to beta-carotene, which was linked to increased lung-cancer risk in former smokers [31]. The switch to lutein/zeaxanthin was justified, as an analysis comparing the carotenoids directly found lutein/zeaxanthaoin to be more beneficial than beta-carotene in regards to AMD [32]. Furthermore, the findings were corroborated by the 10-year follow-up analysis, which again demonstrated the safety of the intervention and reduced progression to late AMD [33]. Additionally, a post-hoc analysis of AREDS and AREDS2 found that oral antioxidant therapy and lutein/zeaxanthin attenuated GA progression towards the fovea, potentially by increasing foveal sparing [34].

The carotenoids seem to be most beneficial as an intervention in early AMD. The double-masked trial found that lutein and/or zeaxanthin supplementation for two years resulted in increased macular pigment and improved retinal sensitivity in patients with early AMD [36], while the Veterans LAST trial found similar improvements in visual acuity, contrast sensitivity, and macular pigment density in patients with atrophic AMD [35]. Additionally, a 2026 meta-analysis found that lutein-based supplementation tended to most benefit patients with early AMD, with monotherapy being preferable to combination treatments in a dose-dependent manner [42]. On the other hand, not all interventive trials have yielded consistent results – the LIMPIA trial found no improvement in macular pigment density after 6 months of treatment with carotenoid-rich extract in children at risk of AMD [37]. Overall, the benefits of carotenoid supplementation are mostly seen in patients with early AMD.

It is unclear if the benefits of carotenoids extend to all populations or if they merely mask the risk factors of AMD. While the review suggests that lutein/zeaxanthin can reduce progression in some patients, the evidence on their efficacy as a preventative measure is conflicting. The study on LIMPIA found that at-risk patients had higher serum carotenoid levels after six months of treatment, but no improvement in macular pigment density [37]. The majority of clinical studies that found benefits in lutein/zeaxanthin intervention were focused on specific populations, varying in treatment regimen and duration, and used either isolated carotenoids or whole T. Erecta extract [31,34,42]. Therefore, the evidence is insufficient to suggest that carotenoid supplementation universally prevents or treats AMD, but it may be considered as an option for certain patients with early AMD, as a complement to specific treatments under a doctor's guidance.

15. Relevance to vision-support formulations

This review was undertaken, in part, to provide a scientific basis for the Vision+ vision-support supplement, containing 500 mg standardized Tagetes erecta flower extract per dose, developed by Biotex Life Solutions Private Limited (Secunderabad, India) and containing 500 mg active ingredient of standardised marigold per dose. The discussion below uses this formulation as an example of a standardised-marigold product, and adheres to the conservative claim framework of Section 20. Two considerations are largely responsible for establishing the basis for a marigold-based ingredient: first, that marigold is the most concentrated viable source of lutein and its esters, and second, that macular pigment relies on dietary xanthophylls, making the species a logical choice for a lutein/zeaxanthin formulation, and providing the product with a 'botanical source' claim [2,5]. Several design considerations then follow from this evidence. Standardisation is an important consideration, since unstandardised concentrates are known to be inconsistent with labelled content, and only standardised extracts can provide the required level of consistency [4]. The concentration should follow the doses used in positive trials, typically corresponding to 10 mg lutein with 2 mg zeaxanthin, or up to 12–20 mg lutein, to provide the labelled amount of lutein/zeaxanthin and allow for the inclusion of clinically relevant doses of lutein in the formulation [19,20,40].

Other considerations relate to the formulation and manufacturing practices, and their impact on the product's efficacy. Free and esterified lutein can be used interchangeably at equivalent doses, but the choice between them is guided by manufacturing and labelling considerations, due to differences in stability [1]. The ratio of lutein to zeaxanthin is a design consideration, due to the differential use of these xanthophylls in the macula and the potential benefits of including meso-zeaxanthin in the formulation; ratios seen in positive trials (5:1, or 10:2) can provide a reasonable basis for selection [18,19]. Delivery in lipid vehicles is another design consideration, due to the impact of lipids on the absorption of carotenoids; lipid-based formulations have been shown to increase MPOD and contrast sensitivity [20]. Similarly, encapsulation, antioxidant excipients, and protective packaging are required to prevent oxidation and light exposure, which can lower lutein content and compromise the labelled dose [4,6]. Finally, the selection of the cultivar and manufacturing practices also impact the final product, and should be selected to provide consistency between batches [4,5,9]. Notably, none of the considerations discussed above can replace the necessity of product-specific clinical studies. At best, mechanism and ingredient-level evidence can provide a reasonable basis for a vision-support claim, or support specific formulations (e.g., those containing meso-zeaxanthin), but a product-specific clinical trial is required to establish the benefits of a particular formulation, at a particular dose [1,15,21].

Application to a standardised marigold formulation (Vision+). The considerations discussed above can be used to establish the scientific basis for Vision+, a vision-support formulation containing 500 mg of standardised marigold extract, developed by Biotex Life Solutions Pvt. Ltd. The considerations discussed above allow for the following claims to be made about the product: that it provides naturally derived lutein and zeaxanthin, supporting macular pigment and visual performance; that it delivers carotenoids that filter blue light from the macula, supporting visual comfort and reducing eye strain from digital device use; and that it supports retinal function and macular health at the mechanistic and preclinical levels, but not necessarily clinical outcomes in patients with age-related macular degeneration (AMD). These statements reflect the strongly supported, moderately supported, and qualified categories, respectively, of the claim framework in Section 20 and **Table 4.**

Two considerations apply specifically to the communication around this formulation. First, the claim framework in Section 20 allows for several statements to be excluded from consideration, due to a lack of evidence in their support. Specifically, Vision+ cannot make claims about restoring or improving eyesight, strengthening eye muscles, repairing the retina, or curing AMD. Particularly, there is no evidence that lutein or zeaxanthin support extraocular or ciliary muscles in any manner, and benefits to the eye should be qualified as support for vision performance and comfort, rather than vision improvement per se. Second, the amount of lutein and zeaxanthin in the formulation should be specified, since the 500 mg of standardised extract corresponds to a particular content of carotenoids. Ideally, the label should specify the content of lutein and zeaxanthin, or lutein equivalents, in the formulation, to allow for comparison with the doses used in positive trials. These typically correspond to 10 mg lutein with 2 mg zeaxanthin, or up to 12–20 mg lutein [1,19,20,40]. As noted elsewhere, mechanism and ingredient-level evidence can support Vision+, but they cannot replace the need for product-specific clinical trials to evaluate the efficacy and dose of the formulation [15,21].

16. Complementary nutrients in vision formulations

Complementary actives should be discussed only if there is scientific justification for their role in macular support, with the caveat that the evidence for one does not imply evidence for the whole. Meso-zeaxanthin is the macular pigment component most closely associated with increased pigment levels [39], and the combination of long-chain omega-3 PUFA with lutein/zeaxanthin was tested in AREDS2 and similar clinical trials: while omega-3 on its own did not prevent the progression of age-related macular degeneration (AMD), the combination with lutein/zeaxanthin improved visual function in some analyses, and the omega-3 fatty acids are otherwise linked with dry-eye management [31,37,41]. The antioxidant vitamins C and E, and the minerals zinc (with copper), are the other components of the AREDS/AREDS2 background formulation, with zinc in particular having consistent evidence for its role in reducing the progression of AMD [31,33].

Some actives that may be found in commercial ophthalmic nutraceuticals were not included in the present consideration, and it is important to note this limitation when interpreting the results. Astaxanthin and the saffron carotenoids (crocin/crocetin) are not supported by any of the references that informed this review, and so their inclusion in this context cannot be recommended or defended; bilberry anthocyanosides appear in the literature on computer vision syndrome management in a narrative review [23]. The combination of carotenoids with other antioxidants and omega-3 PUFA all have theoretical support for additive or synergistic roles in supporting macular function through various mechanisms, including light filtration, ROS quenching, reduction of inflammation, and membrane stabilization [14,41], but theoretical support is not empirical evidence, and broad statements regarding synergy should be avoided until clinical evidence on the specific combination can be reviewed [31,41].

17. Dosage and duration of supplementation

Doses in positive trials fall within a clearly discernible range. The most common lutein dose is 10 mg/day, while 6 mg/day is used in bioavailability studies and higher (12 mg/day or more) when greater increases in pigment are desired; zeaxanthin is most commonly 2 mg/day, with the combination of 10 mg lutein + 2 mg zeaxanthin in AREDS2 being an established standard for AMD treatment [1,19,20,31,40]. The timing of administration is also important, although not as straight forward, with serum levels of lutein increasing rapidly after ingestion while levels in the macula take up to several months to alter significantly; thus, trials that report on the MPOD (macular pigment optical density) mostly use 16-week periods or longer (up to 6-12 months), making the duration of administration an important consideration [1,16,19,20,40]. Both the meta-analysis and individual trials show that there is a dose-dependent response, although the evidence is fairly mixed, with most studies reporting some benefit across all tested doses, and more prominent effects seen at higher doses (20 mg/day or more of lutein) with little to no response noted below 5 mg/day [40,38]. Due to the gradual build-up and down-regulation of the pigment, compliance is essential for obtaining benefit, and some research has been done on the subject in relation to screen use [18]. The baseline level is yet another important consideration, as increasing MPOD in subjects with low baseline levels provides the most benefit, which has implications for determining the most suitable starting point (which may well differ from person to person) [22].

18. Safety and tolerability

The safety profile is generally favourable, as shown by both the preclinical and clinical evidence. According to a safety evaluation, the crystalline lutein from T. erecta was found to be safe and GRAS for the intended use [2]. In rats, treatment with lutein and its ester at a dose of up to 400 mg/kg for 13 weeks did not cause mortality or toxic effects on major organs, haematological indices, or biochemical markers of toxicity, which speaks volume about the safety profile of the substance [3]. In human trials, lutein supplementation did not lead to serious adverse events at any of the tested doses, while liver, kidney, lipid, and haematological function tests were within normal ranges after several months of treatment. Moreover, lutein caused no greater gastrointestinal tract discomfort than the placebo [17,20]. As all carotenoids, lutein, when taken in extremely high doses, might cause carotenodermia – a harmless condition characterized by yellowish discoloration of the skin. This effect, however, is generally dose-dependent and is not associated with any toxicity [28]. Due to the botanical origin of the ingredient, lutein might potentially trigger allergic reactions in individuals with marigold or Asteraceae family allergies. Moreover, due to a lack of evidence, caution is advised in pregnant and breastfeeding women, as well as children, and lutein is not considered safe in these populations. Lastly, lutein is not known to interact with any medications directly, but its absorption is dependent on fat intake, meaning that lutein might not be adequately absorbed in individuals with fat malabsorption syndromes. Clinical evidence from the AREDS2 study confirms the long-term safety of lutein and zeaxanthin, highlighting the benefits of the intervention while also linking beta-carotene to an increased risk of lung cancer in former smokers [33].

19. Quality and regulatory considerations

Quality must start with identity: correct species (T. erecta) and part (flower/petal) must be established to ensure that the material corresponds to the label claims [2,4]. Products should then be standardized on lutein and zeaxanthin content (expressed as free-lutein equivalents and meso-zeaxanthin, respectively), as determined by validated chromatographic methods, since concentrates are often under-supplied with carotenoids from the label claim [4]; produced under GMP conditions to ensure consistency and traceability; and formally tested for stability, since lutein is light- and oxidation-sensitive and needs appropriate packaging and encapsulation to maintain potency [4,6]. Labelling should indicate the actual content of lutein and zeaxanthin, expressed as free lutein equivalents and meso-zeaxanthin, respectively, consistent with the analytical results, so that the dose can be related to clinical trials [1,4]. Table 3 shows the proposed specifications.

The claims also need special consideration. A statement of the ingredient source ("naturally derived" or "from marigold") should be supported by authentication procedures [2]; visual claims should be related to the strength of the supporting evidence and possibly specify the formulation and dosage used to achieve the clinical result [16,38,40]. A careful distinction should be made between permissible and impermissible claims, since in the US structure/function claims are allowed for supplements but not disease treatment or prevention [31,34]. Claims related to structure/function ("supports macular pigment and normal visual function") are distinguishable from disease claims ("treats/prevents macular degeneration"). Evidence at the level of the whole formulation is required for permitted claims, since ingredient-level and mechanism-based evidence, while supportive, are not sufficient for making specific structure/function claims regarding a particular product [1,15,21].

Table 3: Recommended quality-control specifications for a standardised *T. erecta* vision-support extract.

Parameter	Purpose
Botanical identity (*T. erecta*) and plant part	Confirms correct source; guards against adulteration [2,4]
Quantified lutein content	Defines the principal active; enables trial-comparable dosing [4]
Quantified zeaxanthin content	Sets the L:Z ratio relevant to the macula [2]
Lutein-ester profile	Informs free-vs-ester processing and labelling [1,5]
Residual solvents	Safety of extraction process [7]
Heavy metals	Contaminant safety limits
Pesticide residues	Agricultural-input safety limits
Microbial quality	Product safety and stability
Oxidative stability	Retention of potency across shelf life [4,6]
Shelf life / stability data	Substantiates expiry and label accuracy [4,6]

20. An evidence-based claim framework

Because this is where science meets communication, it is essential to differentiate between claims that are consistently supported by human studies or meta-analyses, those that are reasonably backed by evidence, and those that are not. Statements that are consistently supported by human studies or meta-analyses include the assertion that a standardised extract provides naturally derived lutein and zeaxanthin [2], supports macular pigment [16,39,40] and retinal antioxidant defence [25,30], helps maintain healthy visual function [38], supports contrast sensitivity [20,38], and supports recovery after bright-light exposure [19]. Claims that are reasonably but less consistently supported by evidence originate from human studies as well but appear to be applicable to specific populations or situations only. These include the statements about visual comfort during prolonged screen use [16,18], possible reduction of some eye-fatigue symptoms [16], tear-film stability [17] and glare tolerance [19], where the evidence is largely objective. The statements

that require further qualification before they can be considered valid include the claims that the ingredient protects against blue-light-associated oxidative stress [12,30], supports retinal protection [27,28], and reduces the risk of age-related visual decline [31,34,43]. Some of these statements are based on preclinical studies only, and some only apply to specific populations. Claims that should be avoided altogether originate from unsubstantiated and, in some cases, outright incorrect assertions, such as that the ingredient can restore eyesight, strengthen eye muscles, repair retinal damage, cure macular degeneration, glaucoma, or diabetic retinopathy, or completely protect the eyes from screens.

Table 4: Tiered evidence-based claim framework.

Tier	Example statements	Support
Strongly supportable	Provides lutein/zeaxanthin; supports macular pigment; supports retinal antioxidant defence; supports contrast sensitivity; supports photostress recovery	Human RCTs, meta-analyses [16,19,20,38,39,40]
Moderately supported	Supports visual comfort during screen use; may reduce some eye-fatigue symptoms; supports tear-film stability; supports glare tolerance	Emerging RCTs; objective > subjective [16,17,18,19]
Requires qualification	Helps protect against blue-light oxidative stress; supports retinal protection; may reduce risk of age-related visual decline	Largely preclinical, or selected patients [12,27,28,30,31,34,43]
To avoid	Restores eyesight; strengthens eye muscles; repairs retinal damage; cures AMD; treats glaucoma/diabetic retinopathy; fully screen-proofs the eyes	Unsupported/implausible

21. Limitations of the current evidence

Several limitations to the present findings must be recognised. Firstly, few studies evaluated the vision benefits of standardised whole T. erecta preparations in humans, with most of them addressing the role of individual carotenoids or their combination only [1,15,38,40]. Secondly, considerable variability in the carotenoid content between different commercial preparations was reported due to differences in botanical sources, agricultural practices, and manufacturing processes [4,5,9]. Additionally, variations in formulations, dosing regimens, and ratios of individual carotenoids were noted [1,18,20]. Further, the relevance of carotenoids for visual function in a screen user population was mostly assessed in small studies with a short follow-up duration, thus potentially missing out on the gradual accumulation of carotenoids in the macula [16,18,37]. Moreover, the outcome measures used in the trials were inconsistent, ranging from assessments of macular pigment optical density (MPOD) to various questionnaires and electrophysiological tests [22,38]. The number of published controlled trials in normal healthy subjects is limited, and the results were often inconsistent across studies [17,21]. Lastly, the majority of the included studies did not specifically assess the effect of a given finished product, but rather its active pharmaceutical ingredients [15,21]. Overall, several of the analysed studies were industry-sponsored, and although this does not necessarily undermine the validity of their findings, it raises questions about the objectivity of the results, thus warranting further independent investigations [17,18]. The preclinical mechanisms potentially contributing to the clinical effects of T. erecta extracts are summarised in Table 5.

Table 5: Representative preclinical studies and mechanisms.

#	Model	Key finding/mechanism
24	Liposome membrane model	Lutein and zeaxanthin filter blue light; lutein more effective [24]
27	Light-exposed BALB/cJ mice	Preserved photoreceptors via ↓ oxidative and ER stress, ↑ Nrf2 [27]
12	Rat retina + ARPE-19, blue light	Protection via NRF2/HO-1; Nrf2 inhibition abolished it [12]

#	Model	Key finding/mechanism
30	ARPE-19, blue light	↓ ROS, DNA damage, senescence, IL-6/VEGF [30]
11	ARPE-19, PM2.5	*T. erecta* extract blocked EMT via ↓ ROS-TGF-β/MAPK [11]
14	Rat LED photo-oxidative injury	L/Z + quercetagetin restored Nrf2/HO-1, neuroplasticity markers [14]
29	Abca4/Bco2 knockout mice	Lutein/zeaxanthin ↓ A2E/iso-A2E; ↑ visual performance [29]
13	Rats, L/Z 10:1	↑ antioxidant enzymes and macular pigment, dose-dependent [13]
10	Murine desiccation dry-eye	*T. erecta* extract restored tear production; ↓ corneal damage, inflammation [10]

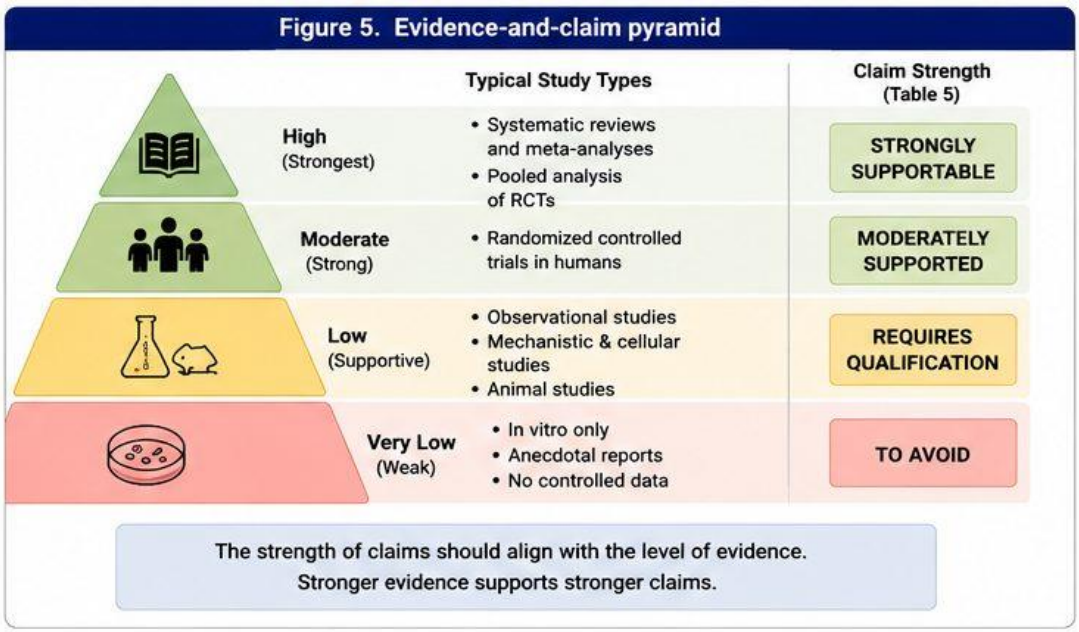

Fig 5: Evidence-and-claim pyramid. A tiered pyramid aligning evidence strength (mechanistic/preclinical → human RCTs → meta-analyses) with the claim tiers of Table 4 (strongly supportable → moderately supported → requires qualification → to avoid).

22. Future research directions

The priorities were identified on the basis of the gaps. Rigorous randomised trials of the defined standardised marigold extracts, and, more importantly, of the final products, would be of utmost importance to the field, providing efficacy at the level of the product [1,15,21]. Trials contrasting the free and ester forms across multiple outcomes and populations would be needed to optimise the formulations beyond the current serum response equivalency [1]. Systematic dose–response studies would be critical to identify optimal amounts and proportions of lutein, zeaxanthin and meso-zeaxanthin needed for a given outcome [39,40]. There is a need for longer trials among digital device users to establish treatment effects on subjective visual comfort, fatigue and macular pigment [16,21], while specific trials in populations with dry eye syndrome should be considered given the promising preclinical and tear film data [10,17]. Likewise, specific studies in patients with early and intermediate AMD are needed to firmly establish the role of supplements in the natural history of the disease, as the intervention may be most beneficial during this period [36,42]. Trials evaluating the role of the supplements in the context of retinal and systemic oxidative stress would help elucidate mechanisms, while a detailed analysis of pharmacokinetics and tissue distribution would be required for optimal dosing [1,20]. Given the large interindividual variability in the response, it may be informative to explore the concept of nutritional precision medicine, utilising the individual differences in the baseline MPOD, genetic profile and microbiome composition as stratification factors. This would build upon the already planned multi-arm trial, which will include these exploratory

analyses [21,22]. Carefully designed studies would be needed to assess the potential synergistic effects of the combination of carotenoids and other active ingredients used in the supplements, moving beyond the pooled analyses of the individual components [41]. Finally, long-term safety analyses, including the follow-up of the AREDS2 participants, would be of benefit to the field [33].

23. Discussion

Tagetes erecta is a unique meeting point of agro-industry, nutrition and eye health. Its pre-eminent position as the source of lutein and lutein esters, the carotenoids specifically accumulated (and not endogenously synthesised) in the macula, makes it an excellent candidate for clinical investigations [2,5,26]. The rationale for macular carotenoids is singularly convincing in terms of mechanism and ranges from selective absorption of blue wavelengths to photoprotection via singlet oxygen quenching and mechanisms related to mitochondrial function, the Nrf2/HO-1 pathway, inflammation, and RPE/photoreceptor protection [12,14,24,27,30]. What it lacks, however, is clinical confirmation from human studies and, until such evidence emerges, lutein's role in eye health should be considered as primarily hypothetical [11,12,30].

The functional link between macular pigment and vision is reasonably well-established – increased MPOD is consistently associated with improved performance in tasks requiring high levels of visual acuity, contrast sensitivity, glare recovery and photostress adaptation [19,20,38,39,40]. There is growing evidence, albeit from a limited number of studies, that lutein positively impacts visual performance in screen users [16,17,18]. At the same time, the evidence for lutein's ability to prevent or slow down age-related macular degeneration remains mixed, largely stemming from the AREDS2 study, which identified lutein/zeaxanthin as a safe but only moderately effective option with limited indications [31,32,33,34]. The discussion around the role of lutein in eye health, and especially its impact on common conditions such as AMD, is further complicated by the combination of indirect evidence from isolated carotenoids and inconsistent results from various commercial formulations, many of which may have been designed with industry-specific biases in mind [4,15,17]. Notably, the formulation of the dietary supplement plays a critical role in the delivery of active compounds to the target tissues. Thus, considerations such as standardised production, bioavailability, lipid-based formulation and oxidation resistance become vitally important, with finished product analyses being the most important indicators of efficacy [1,4,6,15,21]. Lastly, it is important to note that a balanced, evidence-based yet cautious approach to the benefits of lutein is the safest option in most cases, avoiding unsubstantiated claims while acknowledging the existing evidence without overstating it [22].

24. Conclusion

Tagetes erecta is an excellent source of lutein and lutein esters, while marigold carotenoids play an essential role in macular pigment and retina defence against oxidative stress [2,5,25]. Human studies demonstrate functional vision benefits, including improvements in contrast sensitivity, glare recovery, photostress recovery, and macular pigment optical density; meta-analyses confirm the dose-response relationships for these parameters [19,20,38,40]. Evidence is emerging but still limited for eye fatigue, tear-film function, and visual comfort, particularly related to digital-screen use, with more objective evidence than subjective reports [16,17,18]. In patients with age-related macular degeneration, lutein and zeaxanthin act as macular protectants and may slow the progression of the disease in some cases, though they are not a cure or universal protection for everyone at risk [31,34,42]. It is not yet clear if the potential benefits will emerge for a specific population and in what conditions, which requires additional well-controlled clinical trials of standardised extracts and, most importantly, of finished products such as Vision+ to bridge the gap between theoretical mechanisms and practical application [15,21].

Declarations

Conflict of Interest

The authors are affiliated with Biotex Life Solutions Pvt. Ltd. This affiliation did not influence the evidence synthesis; all conclusions are drawn from independent, peer-reviewed literature, and claims are framed to avoid unsubstantiated statements.

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Author Contributions

All authors contributed to the conception of the review, literature identification and appraisal, synthesis and interpretation of evidence, and manuscript drafting and critical revision. All authors approved the final version and agree to be accountable for the accuracy and integrity of the work.

Ethics Statement

Not applicable. This is a review article involving no new studies on human or animal subjects.

Use of Artificial Intelligence

Artificial intelligence and digital tools were used to prepare this article for grammar, formatting, and figure illustration. The authors verified all content and take full responsibility for the work.

Data Availability

Not applicable. All data discussed derive from the cited, publicly available published literature.

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