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Research Letter

Hydrophilic monomer and crosslinker effects on optical and chemical properties of hydrophobic intraocular lenses (IOLs)

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Abstract

An experimental study was conducted to reduce glistening and minimize posterior capsule opacification (PCO) in hydrophobic intraocular lenses (IOLs). This approach involved the copolymerization of hydrophilic 2-hydroxyethyl acrylate (HEA) at various concentrations with hydrophobic monomers, along with incorporating different amounts of ethylene glycol di-methacrylate (EGDMA) as a crosslinker to optimize the chemical, thermal, and optical properties. Sixteen IOL formulations were synthesized and systematically analyzed using equilibrium water content (EWC) measurements, glass-transition temperature (Tg) measurements, and optical evaluation. Optimizing the balance of hydrophilic monomer and crosslinker effectively eliminates glistening and mitigates PCO while maintaining the essential optical property of hydrophobic IOLs.

Introduction

Cataracts are the leading worldwide cause of visual impairment as well as blindness, particularly among aging populations. The condition is characterized by the progressive opacification of the crystalline lens due to protein misfolding, oxidative stress, and metabolic changes in lens fibers.[1] If left untreated, cataracts can severely impair vision and quality of life. Surgical intervention remains the gold standard for cataract treatment, involving the removal of the opacified natural lens and its replacement with an artificial intraocular lens (IOL).

Since Sir Harold Ridley's introduction of the first IOL in 1964, IOL materials have undergone significant advancements. Early IOLs were made from poly (methyl methacrylate) (PMMA), a rigid polymer with excellent optical clarity and biocompatibility. However, its lack of flexibility required large surgical incisions, resulting in delayed recovery times and an increased risk of complications.[2]

This limitation prompted the development of foldable IOLs, made primarily from silicone and acrylic polymers, which allow for minimally invasive implantation through smaller incisions. Among these materials, acrylic IOLs have gained widespread clinical preference due to their higher refractive index, mechanical robustness, and shape memory characteristics, which facilitate surgical handling and effective implantation.

Acrylic IOLs are classified as hydrophobic or hydrophilic based on their water content and polymer composition. Hydrophilic acrylic IOLs, typically containing 18–38% water, exhibit enhanced biocompatibility and a reduced inflammatory response post-surgery. However, these lenses are more susceptible to posterior capsule opacification (PCO), a condition in which residual lens epithelial cells proliferate and migrate onto the posterior capsule of the IOL, leading to secondary visual impairment.[3] To mitigate PCO, hydrophilic IOLs have been modified with sharp-edge designs that inhibit excessive cell migration.[4] Hydrophobic acrylic IOLs, on the other hand, have demonstrated lower PCO prevalence; this phenomenon is attributed to their surface interactions with fibronectin proteins, which inhibit excessive cell adhesion.[5] However, despite their advantages in reducing PCO, hydrophobic IOLs face a major optical challenge, glistening formation.

Glistenings are fluid-filled microvacuoles that are formed within hydrophobic acrylic IOLs due to water infiltration and subsequent phase separation within the polymer matrix. These microvacuoles can scatter light, leading to glare, reduced contrast sensitivity, and potential degradation of optical performance. The degree of glistening formation varies depending on polymer composition, water absorption, and thermal processing conditions. Studies by Thomes and Callaghan[6] (2013) and Werner[7] (2010) demonstrated that hydrophobic IOLs with lower water content tend to exhibit fewer glistenings, whereas excessive polymer cross-linking can create structural inhomogeneities, exacerbating the issue.

To address this challenge, researchers have explored modifications in polymer chemistry to reduce glistening formation without compromising the advantages of hydrophobic IOLs.[6,8] One promising strategy involves incorporating hydrophilic monomers into hydrophobic acrylic formulations, creating hybrid IOL materials that balance low PCO risk with improved optical stability.[9–11] Recent market trends have embraced this approach, leading to the development of IOLs with controlled water content (1, 5–7%), such as Clareon® (Alcon), FineVision HP® (PhysIOL), enVista MX60® (Bausch + Lomb), and Enova® (VSY Biotechnology). These next-generation lenses aim to reduce glistening formation while preserving the mechanical and optical benefits of traditional hydrophobic IOLs.[12–14] Several studies have investigated the impact of hydrophilic monomer incorporation and polymer cross-linking on the optical and mechanical properties of IOLs. Kim *et al*.[9] demonstrated that introducing hydrophilic monomers, such as 2-hydroxyethyl acrylate (HEA), into hydrophobic acrylic matrices significantly reduces glistening formation, while maintaining superior optical properties. Their findings highlighted the importance of optimizing hydrophilic monomer concentration and polymer cross-linking to achieve a balance between mechanical strength and reduced microvacuole formation. In a more recent study, Kim's group[15] evaluated the role of cross-linking agents in controlling glistening behavior. Their results showed that ethylene glycol dimethacrylate (EGDMA), when used in controlled amounts, enhances polymer stability and reduces phase separation, thereby preventing excessive water accumulation in the IOL matrix. These findings emphasize the need for systematic formulation adjustments to improve the overall performance of hydrophobic IOLs.

Building upon these previous studies, our research aims to provide a more comprehensive analysis of hybrid hydrophobic IOL materials by systematically evaluating the effects of hydrophilic monomer concentration and cross-linking density on IOL properties. While earlier research has primarily focused on glistening reduction, we extend the scope by examining a broader set of parameters, including equilibrium water content (EWC), thermal properties, optical stability, and chemical assessments.

This study considered the development of next-generation hydrophobic acrylic IOLs by copolymerizing hydrophobic acrylic monomers with various hydrophilic monomers and cross-linker concentrations. Specifically, we explore the roles of 2-hydroxyethyl acrylate (HEA) as the hydrophilic monomer and ethylene glycol dimethacrylate (EGDMA) as the cross-linker. HEA is selected due to its hydroxyl functionality, which modulates water absorption and biocompatibility, while EGDMA strengthens the polymer network, enhancing mechanical stability without compromising optical performance.

To systematically evaluate the material properties of these formulations, the following characterization techniques were employed:

- equilibrium water content (EWC) measurements – assessing hydration levels and polymer stability
- glass-transition temperature (Tg) analysis – evaluating thermal properties and polymer flexibility
- *in vitro* optical tests – measuring refractive index, transparency, and light transmittance
- glistening analysis – quantifying microvacuole formation under controlled hydration conditions
- fibronectin adhesion assays – investigating surface interactions related to PCO risk
- spectral transmittance measurements – ensuring optimal light transmission for visual clarity

By systematically examining these parameters, our study aims to contribute valuable insights into the development of hybrid hydrophobic IOL materials with optimized optical and mechanical properties. Understanding how hydrophilic monomer content and cross-linking density affect glistening formation, PCO resistance, and biostability will enable the design of advanced IOLs with enhanced long-term performance.

Materials and methods

Materials

2-(2-Ethoxy ethoxy) ethyl acrylate (EEEA) was purchased from Sigma-Aldrich (St. Louis, MO, USA) and used as a hydrophobic monomer. 2-hydroxy ethyl acrylate (HEA, 96.0%) was obtained by Sigma-Adrich and used as a hydrophilic monomer. Ethylene glycol di-methacrylate (EGDMA), azobis iso butyro nitrile (AIBN), and 2-(2'-hydroxy-5'methacryloxy ethyl phenyl)−2H-benzotriazole (UV-090) were utilized as cross-linker, radical polymerization initiator, and UV light blocker, respectively. Phosphate buffer saline (PBS) was purchased from Sigma-Aldrich for use in all preparation steps as well as for hydration and storage purposes.

Hydrophobic acrylic IOL preparation

The IOLs were produced with a cast molding technique using heat-induced radical copolymerization. Formulations for IOL preparation were categorized into two groups. In the first category, the cross-linker concentration remained constant at 2.96 mol% to 2.56 mol%, while the hydrophilic monomer (HEA) concentration increased from 0 mol% to 34.60 mol% (refer to Table S1). Consequently, the concentration of hydrophobic monomers decreased proportionately. In the second category, in the absence of HEA, the cross-linker (EGDMA) concentration varied from 3.10 mol% to 4.78 mol%, while the concentration of the hydrophobic monomer remained constant. The first set of formulations aimed to examine the impact of adding hydrophilic monomers on lens properties, while the second category explored the influence of cross-linker density on the final product properties. Throughout all formulations, AIBN and UV-090 values remained constant. Each group of formulations yielded low, medium, and high diopter IOLs.

Equilibrium water content (EWC) measurement

EWC was analyzed on the IOL samples (details in Table S1). In this process, twenty samples from each formulation underwent a two-hour drying period in a drier oven at 50℃ and were subsequently weighed. The IOLs were then immersed in an isotonic saline solution for 48 h and reweighed. The average weight of each formulation before and after hydration was denoted as W1 and W2, respectively. Equation 1 was applied to compute the EWC for each lens formulation.

$$Water\ content\ (\%) = \left(1 - \frac{W1}{W2}\right) \times 100 \qquad (1)$$

Glass-transition temperature measurement

The glass-transition temperature (Tg) represents the temperature at which the material transitions from its rigid, glassy state to a softer, rubber-like state. Tg is a critical parameter for assessing the mechanical behavior of intraocular lenses during implantation, particularly in shape memory, folding, and unfolding. The Tg values were determined using a thermal analyzer (DSC, 60 series, Shimadzu, Kyoto, Japan). 2 mg of each formulation was placed in an aluminum sample container. Initially, the samples were cooled down to − 70℃ under nitrogen, followed by heating from − 70℃ to + 70℃ at a rate of 5℃/min. For the EGDMA formulation set, three formulations were analyzed (Details in Table S1). Each IOL formulation underwent three measurements, and the average results were subsequently reported.

In vitro optical test

The modulation transfer function (MTF) was assessed using the PMTF (Lambda-X S.A., Nivelles, Belgium) optical bench that complies with ISO standard 11,979–2 requirements to examine the effect of *in vitro* imaging quality.[16] MTF was determined at 100 cycles per degree, employing a pupillary aperture of 3.00 mm. The ISO eye model I cornea, characterized by minimal spherical aberration as per the ISO 11979–2 standard, was used for these measurements. Measurements were conducted on 10 intraocular lenses (IOLs) from each formulation, and the reported values represent the averages obtained from these evaluations.

Glistening test

The glistening tests were conducted at the Intermountain Ocular Research Center (Mamalis/Werner Laboratory), John A. Moran Eye Center, University of Utah. Representing the hydrophobic IOLs, the 16 samples from formulations 1 to 16 (Table S1) were sent to the test laboratory. A commercially available IOL (Alcon Acrysof, Fort Worth, USA) was used as a control sample. The Acrysof IOL is known for its glistening incidences in the market mainly because it is a very hydrophobic lens with a water content of less than 0.5%.[7] The samples were immersed in distilled water for 24 h at 45℃ ± 1℃, and they remained for another 2.5 h at 37℃ ± 1℃. Then, the IOLs were investigated under a light microscope (Olympus BX40, Tokyo, Japan). The first images represented the day 1 glistening results. Then, the IOLs were stored at 37℃ ± 1℃ for a week for light microscope investigation. Lastly, the lenses were dried for 24 h at room temperature for the final light microscopy inspection.

Fibronectin test

The fibronectin tests were conducted with an ELISA test following the protocol described by Schroeder *et al.*[17]. Briefly, the 96-well plates were treated with 1% bovine serum albumin (BSA) at 27℃ for 2 h to prevent non-specific fibronectin binding. The wells were then washed with PBS and dried at room temperature. The fibronectin solution (2.5 µg/mL) was added to the wells and incubated at 37℃ for 2 h. For the control group, lenses incubated with 1% BSA were used. Then, the samples were incubated with anti-fibronectin primer anticore (F3648, Sigma-Aldrich) at 37 ºC for 1 h and washed 3 times with PBS. Next, the washed samples were treated with anti-rabbit IgN peroxide seconder anticore (A0545, Sigma-Aldrich) for 30 min at 37℃. TMB substrate was added before PBS washing 5 times. The reaction ceased after 10–15 min with 2 N sulfuric acid, and the absorbance was determined using a microplate reader (BioTek, Winooski, VT, USA) at 450 nm. The absorbed fibronectin was calculated using a standard 1–5 µg/mL interval curve. Statistical differences were analyzed with ANOVA for different groups, and no significant difference was observed ($p < 0.005$). For this test, all 8 formulations from the first group were investigated. Formulations 10 and 16 were selected to represent the second set group.

Spectral transmittance

The Cary 300 UV–Vis spectrophotometer (Agilent, Santa Clara, CA, USA) was used to assess the spectral transmittance of the samples and generate spectral transmittance curves. Three samples were measured for each formulation group. The typical IOL material should have adequate transparency to visible light and feature UV-blocker properties to protect the eye from UV-induced damage, such as phototoxicity and retinal degeneration.

Results and discussion

In this study, the role of HEA as a hydrophilic monomer and EGDMA as a cross-linking agent in the development of IOLs was systematically examined. Two sets of formulations were prepared: one with increasing HEA concentrations and another with varying EGDMA ratios. The physicochemical and optical properties of these formulations were assessed through equilibrium water content (EWC) measurements, differential scanning calorimetry (Tg analysis), *in vitro* optical evaluation, glistening assessment, fibronectin adhesion tests, and UV spectral

transmittance measurements. The overall results from these tests showed promising potential for using these formulations as posterior capsule intraocular lenses.

Water absorption and hydrophilicity

Water absorption characteristics were quantified using EWC calculations, providing insights into the relationship between hydrophilic monomer incorporation and hydration levels in IOLs. Figure 1(A) illustrates the trend of increasing water content with a rise in HEA concentration. This behavior aligns with expectations, as the presence of hydroxyl (–OH) functional groups in HEA enables hydrogen bonding interactions with water molecules. The interaction mechanism involves the partially positive hydrogen atoms in the hydroxyl groups of HEA, forming hydrogen bonds with the oxygen atoms in adjacent water molecules and increasing the affinity of the polymer for water.

As shown in Fig. 1(A), the highest hydrophilicity was observed in Formulation 8, with an EWC of 7.61%, while Formulation 1 exhibited the lowest EWC (1.53%), representing the most hydrophobic formulation. This outcome is consistent with previous studies, such as Kim *et al*., where HEA incorporation into IOL materials led to an increase in EWC, with the highest recorded value reaching 2.5% at 22% HEA concentration.[9] In comparison, our formulations achieved significantly higher EWC values at similar HEA concentrations, suggesting that other polymer network characteristics, such as cross-linking density and polymer chain interactions, may influence hydration behavior.

Effect of cross-linking density on water absorption

The formulations in the second experimental set (F9-F16) investigated the influence of EGDMA cross-linking density on water absorption. Unlike the HEA-based formulations, the impact of increasing cross-linking density on EWC did not follow a linear trend [Fig. 1(B)]. Typically, higher cross-linker content leads to tighter polymer networks, reducing free space between polymer chains and restricting water uptake. However, our results deviated from this expected trend, as some formulations with increased cross-linker content exhibited higher-than-anticipated water absorption levels.

This anomaly may be attributed to the carbonyl (–C=O) functional groups present in EGDMA, which have a known tendency to attract water molecules. As a result, two competing mechanisms are at play:

1. The increased cross-linking density reduces available free volume within the polymer, limiting water intake.
2. The hydrophilic nature of carbonyl groups enhances water retention by attracting water molecules.

The competition between these two factors appears to balance out the expected decrease in EWC, leading to non-linear trends in water absorption. A similar observation was reported by Song *et al*.; they noted that the increase in EGDMA concentration from 0 to 10 mol% raised Tg significantly (from 14℃ to 47.4℃) but had a complex impact on water absorption due to network entanglements and carbonyl group interactions.[18]

Glass-transition temperature (Tg) and flexibility of IOLs

Tg is a crucial parameter in IOL materials as it determines the mechanical flexibility of the material and the suitability of the material for implantation. An ideal IOL should have a Tg below operating room temperature (18–20℃) to ensure easy folding and smooth delivery into the eye. Rønbeck *et al*. reported Tg values in the range of 14–15.5℃ for hydrophobic acrylic IOLs, which are well below typical operating room temperature conditions; this parameter facilitates the foldability of the material during implantation. Similarly, foldable acrylic IOLs have been widely documented to exhibit Tg values close to or slightly below the operating room temperature, supporting their application in modern cataract surgeries.[28]

The Tg values of the prepared formulations, as shown in Fig. 1(C), indicate that all synthesized materials fall within an acceptable range for IOL production. Among the formulations, formulation 10 exhibited the lowest Tg (− 7.2℃), indicating high flexibility. On the other hand, formulation 16 had the highest Tg (− 1℃), suggesting increased rigidity due to the higher cross-linker content.

The observed trend confirms that increasing EGDMA concentration results in higher Tg values, as the introduction of more cross-links restricts polymer chain mobility. This result is consistent with earlier findings by Kim *et al*.; they showed that the incorporation of cross-linkers such as EGDMA led to increased Tg values, with variations dependent on the type and number of hydrophilic monomers.[9] Similarly, studies on PMMA lenses (Tg ~ 110℃) highlight why their brittleness makes them unsuitable for foldable IOL applications, whereas silicone-based IOLs (− 91.7℃ to − 119.6℃) offer superior flexibility but pose risks due to rapid unfolding post-implantation.[19]

Our findings suggest that by carefully modulating EGDMA content, IOLs with optimal flexibility can be achieved, ensuring both mechanical durability and ease of implantation.

Optical performance: Modulation transfer function (MTF) evaluation

The optical quality of the synthesized IOLs was assessed using MTF analysis; all of the formulations exceeded the minimum threshold of 0.43, as required by ISO 11979–2 standards for monofocal IOLs.[20] The results in Fig. 1(D) confirm that variations in HEA and EGDMA concentrations did not negatively impact optical clarity, making the synthesized formulations viable for high-quality vision correction.

These results align with previous studies, in which commercial IOLs with optimized polymer compositions demonstrated superior MTF performance,[21–26] While many studies focus on comparing commercially available lenses, our work

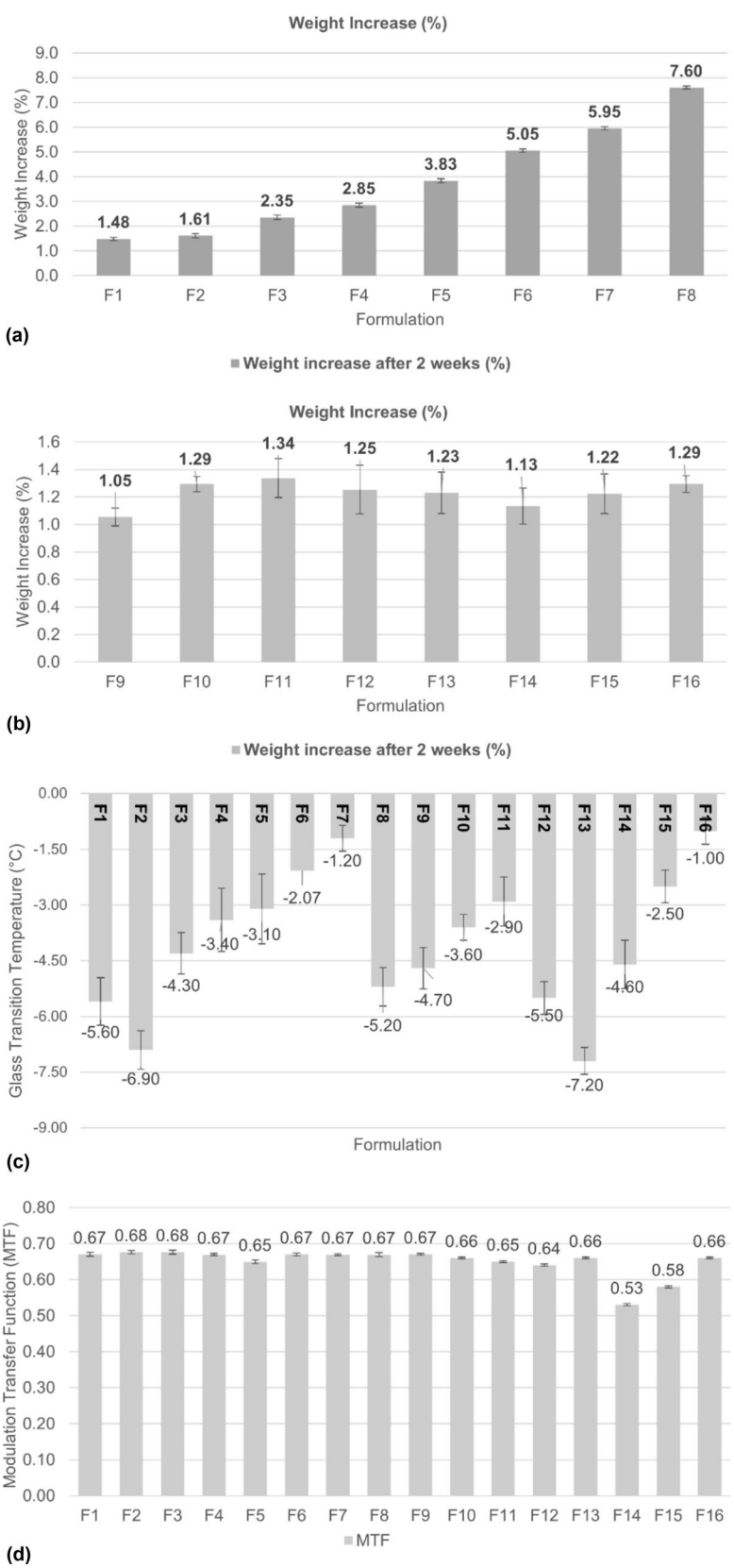

Figure 1. (A) The EWCs of the first set of IOL formulations with varying HEA concentrations as a hydrophilic monomer. (B) The EWCs of the second set of IOL formulations with varying EGDMA concentrations as a cross-linker. (C) Glass-transition temperature values for all of the formulations. (D) Average MTF values for all of the formulations.

emphasizes the importance of optimizing MTF characteristics during material synthesis to ensure excellent optical clarity in new IOL formulations.

Glistening formation and surface stability

The glistening formation was assessed using the Miyata scale by counting the microvacuoles in mm^2. Table S2 shows the results at the end of 24 h and the end of one week. Minimal glistening was observed in formulations from F1 to F6. After a week, the formulations from F3 to F16 showed no glistening formation. The glistening formation remained at the end of a week for formulations F1, F2, and Alcon Acrysof IOL, indicating a positive relation between glistening formation and hydrophobicity. The glistening characteristics are not expected

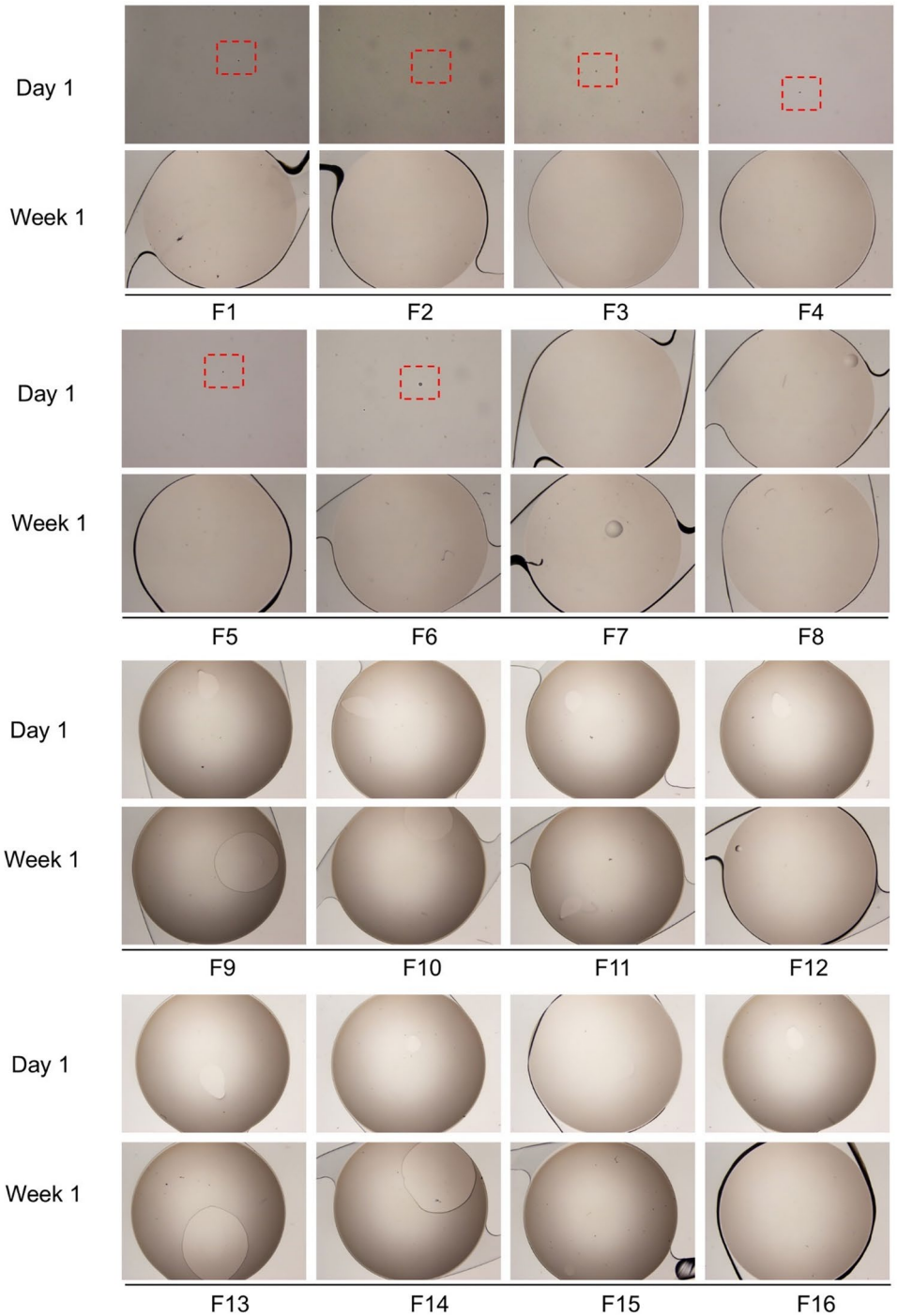

Figure 2. Glistening test images acquired for all of the formulations.

to change after one week, since it is a very long interval for glistening to occur in a steady temperature. Figure 2 shows the detailed glistening inspection images.

The results of the glistening test are parallel with the studies that previously appeared in the literature. Glistening studies conducted by the Werner group showed some glistening formation in Acrysof lenses, indicating correspondence with the present study.[7,27] This study observed a glistening-free characteristic in the formulation with > 2.00% water content, indicating a valuable consideration for IOL manufacturing. Having a more significant amount of water content might be beneficial for enhanced biocompatibility (due to the low initial immune response after the surgery), better optical clarity with a low refractive index, and improved mechanical properties due to the softer nature of the material. To assess the aforementioned benefits, further tests need to be conducted.

Fibronectin adhesion and posterior capsule opacification (PCO) risk

Fibronectin adhesion tests were conducted to assess the likelihood of posterior capsule opacification (PCO) development. Surprisingly, as shown in Fig. 3, no direct correlation was observed between water content and fibronectin adhesion.

Fibronectin adhesion tests were conducted to assess the likelihood of posterior capsule opacification (PCO) development. As shown in Fig. 3, surprisingly, no direct correlation was observed between water content and fibronectin adhesion. While fibronectin binding behavior is critical for intraocular lens (IOL) biocompatibility, there is no standardized numerical range for fibronectin adhesion in the literature. Our findings are consistent with the comparative evaluation approach commonly used in such studies.[29,30] and suggest that additional surface modifications or coatings may be necessary to further reduce PCO risk.[31]

UV light transmittance and biocompatibility

All formulations were evaluated for UV light transmittance according to ISO 11979–2 standards. The results in Fig. 4 indicate that variations in HEA content did not significantly alter UV transmittance, with all formulations achieving adequate light transmission to the retina with a transmittance over 90% at 410 nm. This result confirms that the modifications in monomer composition do not compromise the essential optical properties of IOLs [Fig. 4 (A), (B)].

Conclusions

In conclusion, our formulation trials with varying concentrations of hydrophilic HEA monomer and EGDMA cross-linkers provided crucial insights into intraocular lens (IOL) properties. HEA increased water absorption, while EGDMA showed a contrasting effect, emphasizing the need for careful cross-linker selection. The glass-transition temperature proved suitable; however, caution against excessively low temperatures impacting mechanical properties was highlighted. After one week, glistening and fibronectin binding analyses revealed minimal glistening in F1 to F6 and no glistening in F3 to F16, establishing a positive correlation with hydrophobicity. Notably, formulations F3 to F8 were completely glistening-free. However, no correlation was noted between fibronectin binding and water content. In addition, water content and fibronectin binding did not correlate with ELISA results. This study contributes valuable insights, emphasizing meticulous monomer and cross-linker selection for optimal IOL performance. Future research should refine formulations and explore additional parameters for enhanced intraocular lens safety and effectiveness.

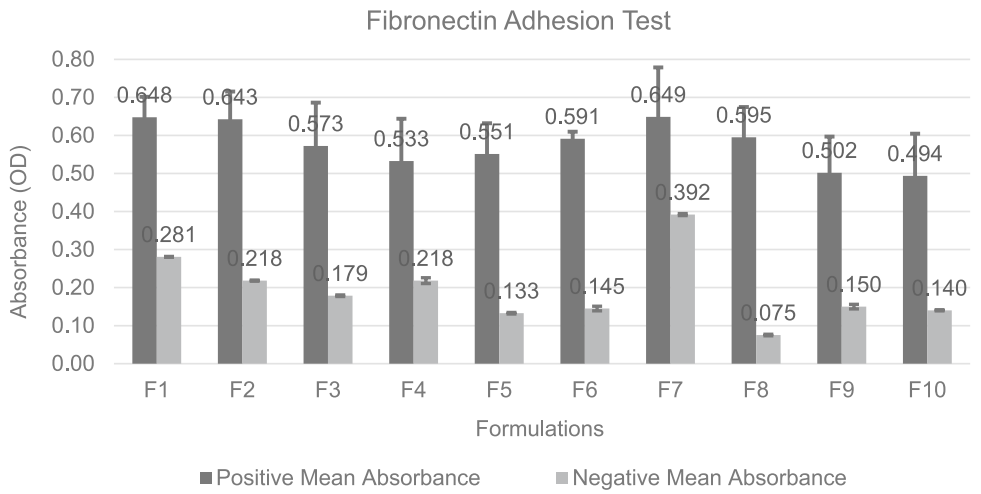

Figure 3. Fibronectin adhesion test results for positive and negative mean absorbances.

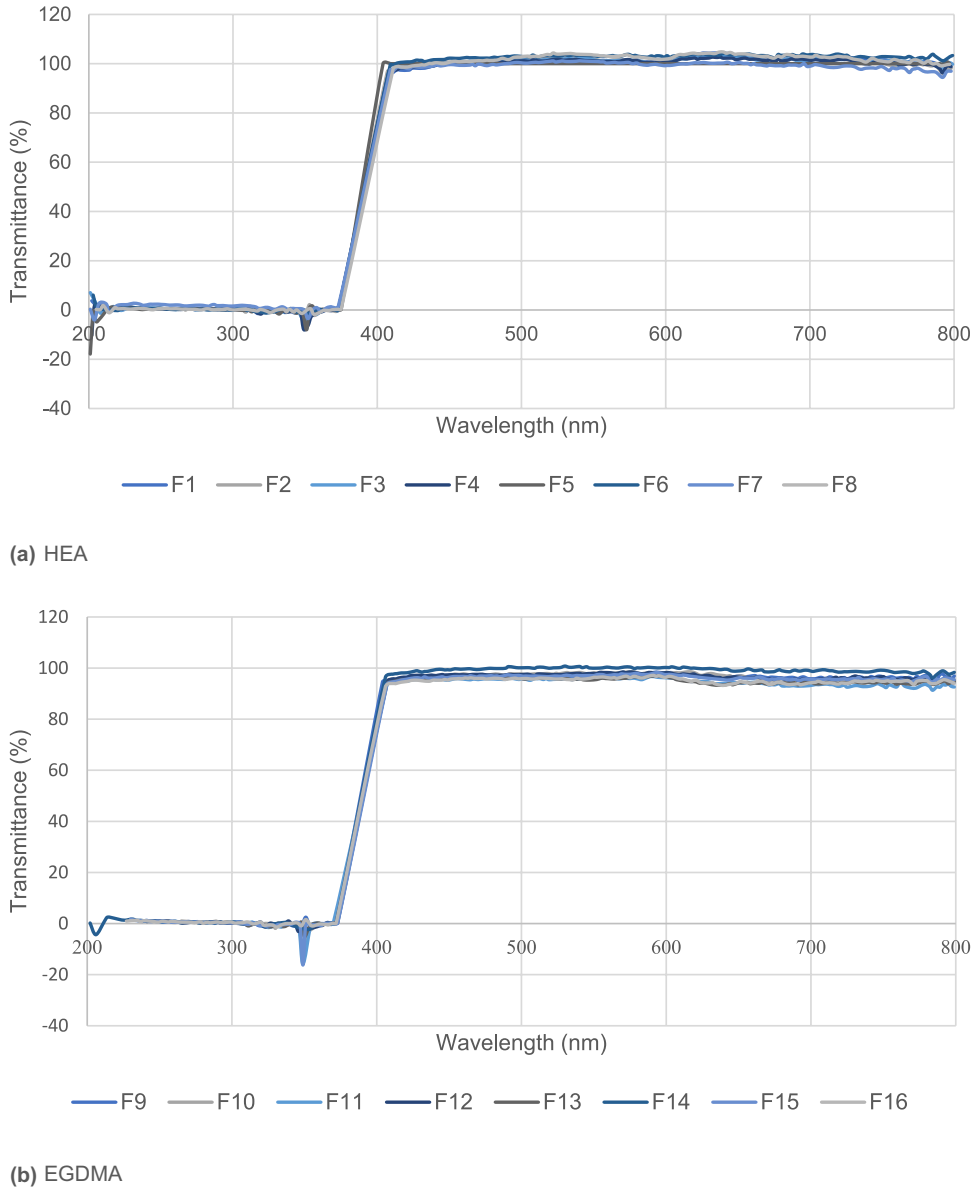

Figure 4. Spectral transmittance spectra of the formulations from (A) F1 to F8 and (B) F9 to F16.

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Author contributions

D Aki (Data curation: Lead; Methodology: Lead; Project administration: Lead; Supervision: Lead; Writing – original draft: Lead; Writing – review & editing: Lead). Esat Can Şenel (Data curation: Supporting; Methodology: Supporting; Validation: Supporting; Writing – original draft: Supporting; Writing – review & editing: Equal). Monireh Esmaeili Rad (Formal analysis: Lead; Methodology: Equal; Project. administration: Equal; Validation: Supporting; Writing – original draft: Supporting). Mesut Celil Onceyiz (Data curation: Supporting; Methodology: Supporting; Validation: Supporting; Writing – original draft: Supporting; Writing – review & editing: Supporting). Melih Can Gokmenoglu (Validation: Supporting; Writing – original draft: Supporting). R Narayan, Prof. (Methodology: Supporting) O Gunduz, Prof. (Methodology: Supporting; Supervision: Equal; Writing –review & editing: Equal).

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Data availability

The data that support the findings of this study are available on request from the corresponding author.

Declarations

Conflict of interests

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Supplementary Information

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