



Impact of artificial tear viscosity and timing on keratometric measurements in cataract patients with and without dry eye disease: a randomized cross-over study

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ABSTRACT

Background: Accurate keratometric assessment is essential for precise intraocular lens (IOL) power calculation in cataract surgery. Artificial tears are commonly used to optimize the ocular surface, yet their short-term effects on keratometric and biometric measurements remain uncertain. This study evaluated the impact of artificial tears with different viscosities on keratometry and optical biometry parameters in cataract patients with and without dry eye disease (DED).

Methods: This prospective, randomized cross-over study included 40 cataract patients (20 with DED and 20 with normal ocular surfaces). Each participant received high- and low-viscosity artificial tears on separate visits. Keratometric parameters (K_1 , K_2), axial length (AL), anterior chamber depth (ACD), and calculated IOL power were measured using optical biometry at baseline and at 30 s, 2 min, and 5 min after drop instillation.

Results: Participants with DED were significantly older than those with normal ocular surfaces ($P < 0.05$), while sex distribution and intraocular pressure were comparable between groups (both $P > 0.05$). Both formulations induced significant transient changes in keratometric measurements, most evident at 30 s and 2 min post-instillation, with stabilization by 5 min (within-group $P < 0.05$). These fluctuations were more pronounced in eyes with DED, particularly with high-viscosity drops, which showed large within-subject effect sizes. No significant differences in K_1 or K_2 were observed between groups at post-instillation timepoints (all $P > 0.05$). AL and ACD remained stable across all groups and timepoints (all $P > 0.05$). A modest but statistically significant reduction in calculated IOL power was observed only in DED eyes receiving high-viscosity artificial tears ($P < 0.05$).

Conclusions: Artificial tears induce transient alterations in keratometric measurements, particularly within the first 2 min after instillation and in eyes with tear film instability. High-viscosity formulations exert more pronounced effects and may influence IOL power calculations. To ensure accurate optical biometry, keratometry should be deferred for at least 5 min following artificial tear instillation, especially in patients with DED.

KEYWORDS

cross-over trials, artificial tears, viscosities, biometric analysis, topography, corneal, anterior chambers, eye axial length, intraocular lens implantation, phakic intraocular lens

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INTRODUCTION

Accurate preoperative biometry is essential for achieving optimal refractive outcomes following cataract surgery, particularly with the rising use of premium intraocular lenses (IOLs), including toric, multifocal, and extended depth-of-focus designs [1, 2]. The cornea contributes approximately two-thirds of the eye's total refractive power, and even minimal inaccuracies in corneal curvature measurements can result in clinically significant postoperative refractive errors [3–5].

Dry eye disease (DED) is a multifactorial ocular surface disorder characterized by tear film instability, hyperosmolarity, inflammation, and neurosensory abnormalities [6, 7]. Its prevalence is notably high among patients undergoing cataract surgery, particularly in older populations [8]. Tear film instability disrupts the smooth optical interface required for reliable keratometric measurements, thereby increasing measurement variability and reducing repeatability [9–11].

Artificial tears are commonly used to optimize ocular surface conditions prior to biometry; however, their formulations vary considerably in viscosity, osmoprotective properties, and tear film residence time. These differences may transiently alter corneal topography and curvature measurements, further compromising the accuracy of keratometric assessments [11–15]. Moreover, artificial tear instillation is shown to induce transient changes in optical quality, which may contribute to short-term variability in ocular measurements [16].

The present study aims to evaluate the impact of artificial tears with different viscosities on keratometric and biometric measurements in cataract patients with and without DED.

METHODS

This prospective, randomized, two-period, two-treatment (2×2) cross-over interventional study was conducted in Egypt at the Department of Ophthalmology, Port Said University and Damietta Ophthalmology Hospital between May and November 2025. Participants were recruited to include individuals with mild-to-moderate dry eye disease and an equal number of individuals with clinically normal ocular surfaces. The study protocol was approved by the Ethics Committee of the Faculty of Medicine, Port Said University (ERN: MED (3/11/2024) s.no(199) OPT824_005). All procedures adhered to the principles of the Declaration of Helsinki. Written informed consent was obtained from all participants prior to enrollment and before the initiation of any study-related procedures. The trial was prospectively registered with the Pan African Clinical Trials Registry [17].

An a priori sample size calculation was performed using G*Power software (version 3.1; Heinrich Heine University, Düsseldorf, Germany). Based on a repeated-measures design (within-subject factor: time), assuming a large effect size ($f = 0.40$) derived from previously reported tear film-induced variability in keratometric measurements [18], a two-sided significance level (α) of 0.05, and a statistical power of 80%, the required sample size was estimated to be 36 participants. To account for potential attrition and measurement-related exclusions, the sample size was increased by approximately 10%, resulting in a final sample of 40 participants. This number was considered sufficient to detect statistically and clinically relevant differences in keratometric measurements and IOL power calculations [18].

Participants of both sexes were eligible for inclusion if they were aged 40–70 years and represented a predominantly middle-aged population (ages 45–64). All participants were required to have a diagnosis of nuclear or cortical cataract, classified according to a standardized lens opacification grading system, in the absence of any concomitant intraocular comorbidities. Additional eligibility criteria were intraocular pressure (IOP) ≤ 21 mmHg and axial length (AL) 22–26 mm. Participants were stratified according to ocular surface status into those with mild-to-moderate dry eye disease and those with clinically normal ocular surfaces without evidence of dry eye disease. Exclusion criteria were any corneal pathology, such as corneal opacity, dystrophy, degeneration, or keratoconus; eyelid abnormalities or a history of ocular trauma; usage of topical ophthalmic medications within 24 hours prior to examination; individuals who required ongoing topical ocular treatment; severe nasal or ocular allergies, active corneal or conjunctival infection, abnormalities of the nasolacrimal drainage system, and severe dry eye disease (defined as level-4 severity).

This study was designed as a randomized, two-period, two-treatment (2×2) cross-over clinical trial in accordance with CONSORT recommendations. Participants were randomly assigned to intervention sequences using a simple randomization approach, whereby the allocation sequence was generated using a computer-based randomization table. Allocation concealment was ensured through the use of sequentially numbered, sealed, opaque envelopes that were opened only after participant enrollment to prevent foreknowledge of treatment assignment. Masking was implemented at multiple levels: both participants and care providers administering the interventions were blinded to treatment allocation, thereby minimizing performance and detection bias. Each participant received both interventions in a randomized order with a washout period between treatment periods. Figure 1 presents the CONSORT flow diagram of the trial.

A comprehensive medical and ophthalmic history was obtained from all participants prior to enrollment. Each participant subsequently underwent a standardized ophthalmological examination, including assessment of visual acuity, slit-lamp biomicroscopy of the anterior segment, posterior segment evaluation, intraocular pressure (IOP) measurement, and ocular biometry. Uncorrected distance visual acuity (UCDVA) and best-corrected distance visual acuity (BCDVA) were measured monocularly using a Snellen chart (Topcon Healthcare Solutions, Inc., Tokyo, Japan) and recorded in Snellen notation. The anterior and posterior segments were examined using slit-lamp biomicroscopy, and IOP was measured using a non-contact air-puff tonometer (Topcon Co., Tokyo, Japan).

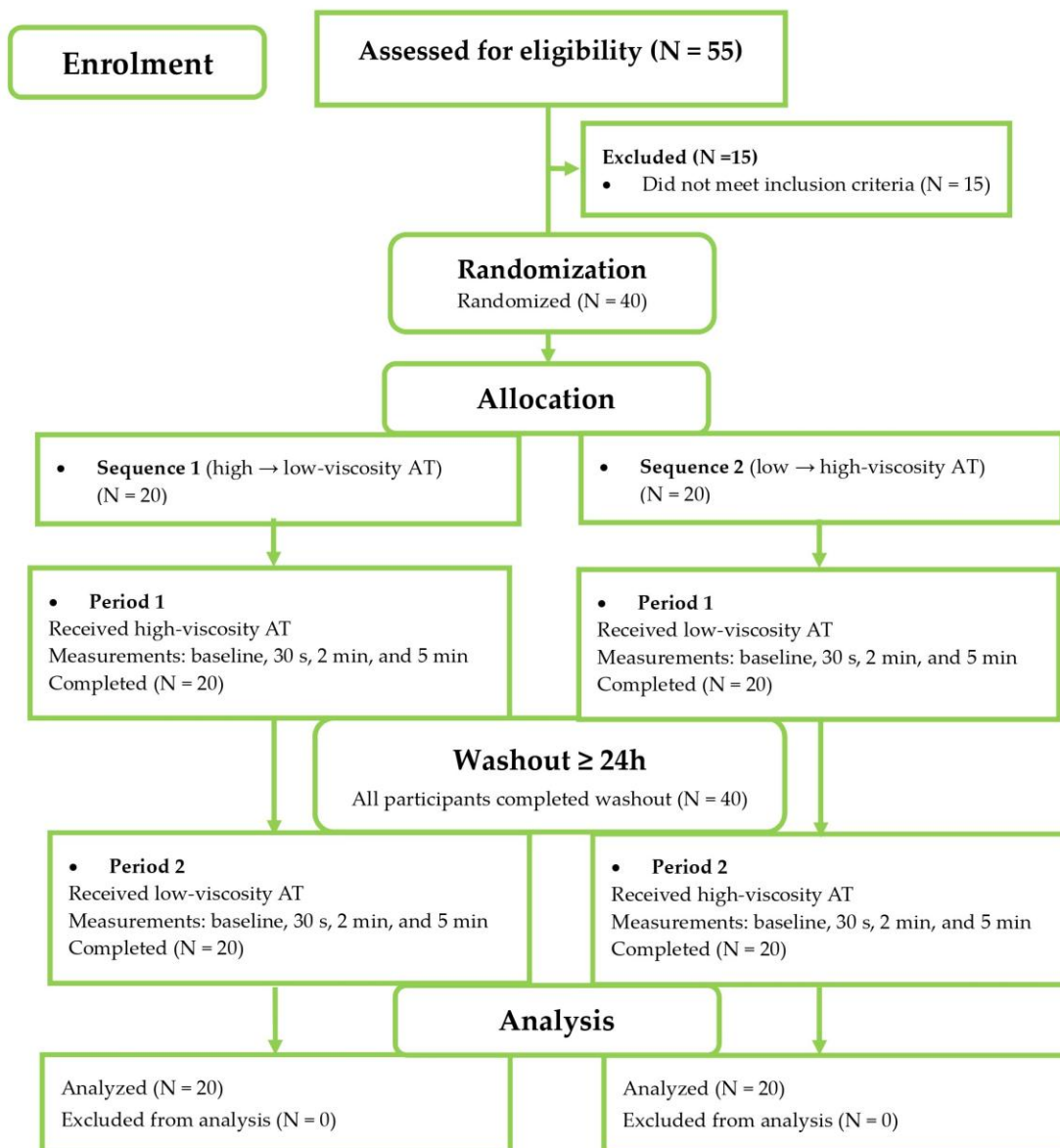


Figure 1. CONSORT flow diagram of participant enrollment, randomization, intervention sequence allocation, and analysis in the cross-over trial. Note: This study was designed as a randomized, two-period, two-treatment (2 × 2) cross-over clinical trial, in which each participant received both artificial tear (AT) formulations in a randomized sequence with a washout interval between treatment periods. The high-viscosity formulation consisted of a hyaluronic acid 0.2% ophthalmic solution (Blink™ Intensive Tears; Bausch + Lomb/Johnson & Johnson Vision Care, Inc.), containing polyethylene glycol 400 (PEG 400) 0.25% and sodium hyaluronate 0.2% as a viscosity-enhancing agent to prolong ocular surface residence time. The low-viscosity formulation consisted of a hyaluronic acid 0.15% ophthalmic solution (Systane® Hydration; Alcon Laboratories, Inc., Fort Worth, Texas, USA) containing polyethylene glycol 400, propylene glycol, and sodium hyaluronate 0.15%.

Dry eye disease was diagnosed using Schirmer test I and tear film break-up time (TBUT), in accordance with the recommendations of the Tear Film and Ocular Surface Society (TFOS) Dry Eye Workshop (DEWS) II report [19, 20]. TBUT was performed first to minimize reflex tearing and ocular surface irritation that could influence subsequent measurements. For TBUT assessment, a fluorescein strip moistened with non-preserved saline was gently applied to the inferior conjunctival sac, taking care to avoid contact with the cornea or eyelashes. Participants were instructed to blink several times to ensure even distribution of the dye, then refrain from blinking while the tear film was being examined under slit-lamp biomicroscopy with cobalt blue illumination. The interval between the last complete blink and the appearance of the first dry spot on the corneal surface was recorded. Measurements were repeated three times, using the mean value for analysis.

A TBUT < 10 s was considered indicative of tear film instability. Schirmer test I was subsequently performed without topical anesthesia to assess both basal and reflex tear secretion. Standardized Schirmer strips were placed at the junction of the middle and lateral third of the lower eyelid (lower fornix), with care taken to avoid corneal contact. Participants were

instructed to gently close their eyes during the test. After 5 min, the strips were removed and the length of wetting was measured in millimeters. Values > 10 mm were considered normal, 5–10 mm borderline, and <5 mm suggestive of aqueous-deficient dry eye. A Schirmer test I value < 10 mm in conjunction with a TBUT < 10 s was considered diagnostic of dry eye disease [21].

Two commercially available artificial tear formulations with differing viscosities were evaluated. Each participant received both formulations in a cross-over manner on separate study visits, with a minimum washout period of 24 hours between administrations. The high-viscosity formulation consisted of a hyaluronic acid 0.2% ophthalmic solution (Blink™ Intensive Tears; Bausch + Lomb/Johnson & Johnson Vision Care, Inc.), containing polyethylene glycol 400 (PEG 400) 0.25% and sodium hyaluronate 0.2% as a viscosity-enhancing agent to prolong ocular surface residence time. The low-viscosity formulation consisted of a hyaluronic acid 0.15% ophthalmic solution (Systane® Hydration; Alcon Laboratories, Inc., Fort Worth, Texas, USA) containing polyethylene glycol 400, propylene glycol, and sodium hyaluronate 0.15%. In both intervention conditions, a single drop was instilled into the inferior conjunctival sac of the study eye at each visit. These formulations were selected based on their widespread clinical use and their differing rheological properties, which are expected to influence precorneal retention and tear film stability [22].

Ocular biometry parameters, including AL, flat keratometry (K_1), steep keratometry (K_2), and anterior chamber depth (ACD), were obtained using an optical low-coherence interferometry device (Aladdin® biometer, Topcon Corp., Tokyo, Japan). IOL power calculations were performed based on AL, employing the Holladay 1 formula for eyes with AL between 22.0 and 24.5 mm and the SRK/T formula for eyes with AL between 24.6 and 26.0 mm. Measurements were obtained at baseline and at 30 s, 2 min, and 5 min following drop instillation. To minimize tear film-related variability, participants were instructed to blink normally immediately prior to each measurement [11].

Statistical analysis was performed using IBM SPSS Statistics for Windows, version 26.0 (IBM Corp., Armonk, NY, USA). Data distribution was assessed for normality using the Shapiro-Wilk test. Continuous variables are presented as mean (standard deviation [SD]) for normally distributed data, or median and interquartile range (IQR) for non-normally distributed data. Categorical variables are expressed as frequencies and percentages. Baseline comparisons between participants with dry eye disease and those with normal ocular surfaces were performed using the independent-samples t-test for normally distributed continuous variables and the chi-square test for categorical variables. To evaluate the effects of treatment (high- vs low-viscosity artificial tears), time (baseline, 30 s, 2 min, and 5 min), and ocular surface status (dry eye vs normal), analyses were conducted using repeated-measures analysis of variance (ANOVA), accounting for within-subject correlations inherent to the cross-over design. The assumption of sphericity was assessed using Mauchly's test; when violated, the Greenhouse-Geisser correction was applied. For significant main effects, post hoc pairwise comparisons were performed with Bonferroni adjustment for multiple testing. For non-normally distributed repeated measures, the Wilcoxon signed-rank test was used for paired comparisons relative to baseline. Effect sizes for repeated-measures analyses were reported as partial eta squared (η_p^2) to quantify the magnitude of within-subject effects. All statistical tests were two-tailed, and a P -value < 0.05 was considered statistically significant.

RESULTS

A total of 40 participants with cataracts were included in the study, comprising 20 eyes with mild-to-moderate dry eye disease and 20 eyes with clinically normal ocular surfaces (Figure 1). Baseline demographic and clinical characteristics are summarized in Table 1. Participants with dry eye disease were significantly older than those with normal ocular surfaces ($P < 0.05$). There were no significant differences between groups in terms of sex distribution or IOP (both $P > 0.05$). BCDVA distribution differed significantly between groups ($P < 0.001$), with poorer visual acuity more frequently observed in the dry eye group. As expected, ocular surface parameters differed significantly, with lower Schirmer test I values and reduced TBUT in the dry eye group. (both $P < 0.001$), consistent with tear film instability and decreased tear production (Table 1).

Baseline analysis evidenced significantly higher K_1 values in the dry eye groups compared with normal eyes ($P < 0.05$; Table 2), whereas K_2 values were comparable between groups ($P > 0.05$; Table 3). Following instillation of artificial tears, both high- and low-viscosity formulations induced transient changes in keratometric measurements, most evident at 30 s and 2 min post-instillation, with stabilization observed by 5 min. These changes were more pronounced in the dry eye groups, suggesting greater tear film-related variability. However, between-group comparisons revealed no statistically significant differences in either K_1 or K_2 measurements at any post-instillation timepoint (all $P > 0.05$) (Tables 2 and 3).

For K_1 measurements, within-group analysis evidenced a significant effect of time across all groups (all $P < 0.05$). The dry eye group receiving high-viscosity drops exhibited a large effect size, expressed as partial eta squared ($\eta_p^2 = 0.596$), indicating substantial temporal variability. Post-hoc analysis indicates K_1 values decreased significantly at 30 s compared with baseline ($P < 0.05$). No significant differences were observed between baseline and either 2 min or 5 min ($P > 0.05$). However, K_1 values at both 2 min and 5 min were significantly higher than at 30 s ($P < 0.05$), with a further significant increase observed at 5 min compared with 2 min ($P < 0.05$). The dry eye group receiving low-viscosity drops showed a smaller but statistically significant effect ($P < 0.05$, $\eta_p^2 = 0.206$). Post-hoc analysis indicates K_1 values decreased significantly at 30 s compared with baseline ($P < 0.05$), whereas no significant differences were observed between baseline and either 2 min or 5 min ($P > 0.05$). No significant difference was found between 30 s and 2 min ($P > 0.05$); however, K_1 values at 5 min were

significantly higher than at 30 s ($P < 0.05$). No significant difference was observed between 2 min and 5 min ($P > 0.05$). Similarly, significant temporal changes were observed in normal eyes, with large effect sizes in the high-viscosity group ($P < 0.001$, $\eta^2_p = 0.604$). Post-hoc analysis indicates K_1 values did not change significantly at 30 s compared with baseline ($P > 0.05$), whereas significant increases were observed at both 2 min and 5 min relative to baseline ($P < 0.05$). K_1 values at 2 min and 5 min were also significantly higher than at 30 s ($P < 0.05$), with a further significant increase at 5 min compared with 2 min ($P < 0.05$). Moderate-to-large effects size was detected ($P < 0.001$, $\eta^2_p = 0.457$) in the normal eye group receiving low-viscosity artificial tears. Post hoc analysis showed that K_1 values at 30 s and 2 min were comparable to baseline ($P > 0.05$), whereas a significant increase was observed at 5 min compared with baseline ($P < 0.05$). No significant difference was found between 30 s and 2 min ($P > 0.05$); however, K_1 values at 5 min were significantly higher than at both 30 s and 2 min ($P < 0.05$) (Table 2).

For K_2 measurements, within-group analysis revealed distinct temporal patterns. The dry eye group receiving high-viscosity drops displayed the greatest variability, with a large effect size ($\eta^2_p = 0.774$), reflecting marked fluctuations over time. Post hoc analysis showed that K_2 values decreased significantly at 30 s compared with baseline ($P < 0.05$), whereas values at 2 min were comparable to baseline ($P > 0.05$). A significant increase was observed at 5 min relative to baseline ($P < 0.05$). K_2 values at both 2 min and 5 min were significantly higher than at 30 s ($P < 0.05$), while values at 5 min were significantly lower than at 2 min ($P < 0.05$). The dry eye group receiving low-viscosity drops showed a smaller but statistically significant effect ($P < 0.05$, $\eta^2_p = 0.179$). Post hoc analysis showed that K_2 values at 30 s, 2 min, and 5 min were comparable to baseline ($P > 0.05$). No significant difference was observed between 2 min and 30 s ($P > 0.05$), yet K_2 values at 5 min were significantly higher than at 30 s ($P < 0.05$). Values at 5 min were comparable to those at 2 min ($P > 0.05$). In normal eyes, the high-viscosity group exhibited moderate temporal variation ($P < 0.05$, $\eta^2_p = 0.327$). Post hoc analysis showed that K_2 values increased significantly at 30 s compared with baseline ($P < 0.05$), whereas values at 2 min were comparable to baseline ($P > 0.05$). A significant increase was also observed at 5 min relative to baseline ($P < 0.05$). No significant difference was found between 30 s and 2 min ($P > 0.05$), but K_2 values at 5 min were significantly higher than at both 30 s and 2 min ($P < 0.05$). In contrast, the low-viscosity group showed no statistically significant change over time ($P > 0.05$), despite a small-to-moderate effect size ($\eta^2_p = 0.068$). Measurements remained relatively stable, ranging from 44.0 (0.8) at baseline to 44.3 (1.1) at 5 min (Table 3).

AL and ACD measurements remained stable across all groups and timepoints, indicating that artificial tears primarily influence anterior corneal surface measurements rather than deeper ocular structures (Figures 2 and 3).

A statistically significant reduction in calculated IOL power was observed only in dry eye patients receiving high-viscosity artificial tears ($P < 0.05$). Though modest in magnitude (Figure 4), this change may be clinically relevant, particularly in patients undergoing premium IOL implantation.

Table 1. Baseline demographic and clinical characteristics of the study participants

Variables	Dry eye (n = 20)	Normal eye (n = 20)	P-value
Age (y), Mean \pm SD	58.5 \pm 7.5	51.1 \pm 4.4	0.001
Sex (Male / Female), n (%)	8 (40.0) / 12 (60.0)	12 (60.0) / 8 (40.0)	0.206
BCDVA (Snellen notation), n (%)	6\12	0 (0.0)	<0.001
	6\18	0 (0.0)	
	6\24	8 (40.0)	
	6\36	9 (45.0)	
	6\60	3 (15.0)	
IOP (mmHg), Mean \pm SD	18.6 \pm 1.7	17.8 \pm 1.3	0.124
Schirmer test I (mm), Mean \pm SD	7.2 \pm 1.3	12.9 \pm 1.6	<0.001
TBUT (s), Mean \pm SD	6.3 \pm 1.2	23.8 \pm 6.5	<0.001

Abbreviations: n, number; y, years; SD, standard deviation; %, percentage; BCDVA, best-corrected distance visual acuity; IOP, intraocular pressure; mmHg, millimeters of mercury; mm, millimeters; TBUT, tear break-up time; s, seconds. Note: P-values < 0.05 are presented in bold.

Table 2. Temporal changes in flat keratometry (K_1) measurements across study groups following artificial tear instillation

Variable	D1 (n = 20)	D2 (n = 20)	N1 (n = 20)	N2 (n = 20)	P-value
K_1 baseline (D), Mean \pm SD	44.1 \pm 1.6 ^{a,b}	44.1 \pm 1.6 ^a	43.1 \pm 0.6 ^a	43.1 \pm 0.6 ^a	0.004
K_1 30 s (D), Mean \pm SD	43.5 \pm 1.6 ^c	43.8 \pm 1.7 ^b	43.1 \pm 0.6 ^a	43.1 \pm 0.6 ^a	0.248
K_1 2 min (D), Mean \pm SD	43.9 \pm 1.6 ^a	45.0 \pm 1.6 ^{a,b}	43.4 \pm 0.7 ^b	43.2 \pm 0.6 ^a	0.147
K_1 5 min (D), Mean \pm SD	44.5 \pm 1.8 ^b	44.1 \pm 1.9 ^a	43.9 \pm 0.7 ^c	43.6 \pm 0.7 ^b	0.208
Within-group comparison over time	* <0.001	* 0.012	* <0.001	* <0.001	

Abbreviations: n, numbers; K_1 , flat keratometry; D, diopters; SD, standard deviation; s, seconds; min, minutes. Note: P-values < 0.05 are presented in bold; D1, dry eye group receiving high-viscosity artificial tears; D2, dry eye group receiving low-viscosity artificial tears; N1, normal ocular surface group receiving high-viscosity artificial tears; N2, normal ocular surface group receiving low-viscosity artificial tears. Repeated-measures analysis of variance (ANOVA) was used to assess within-group changes over time. Post hoc pairwise comparisons were performed with Bonferroni correction. Mean values sharing different superscript letters (a–c) within the same column indicate statistically significant differences ($P < 0.05$), whereas values sharing the same letter are not significantly different. *, Greenhouse-Geisser correction was applied when the assumption of sphericity was violated.

Table 3. Temporal changes in steep keratometry (K₂) measurements across study groups following artificial tear instillation

Variable	D1 (n = 20)	D2 (n = 20)	N1 (n = 20)	N2 (n = 20)	P-value
K₂ baseline (D), Mean ± SD	44.1 ± 1.7^a	44.1 ± 1.7^{a,b,c}	44.0 ± 0.8^a	43.97 ± 0.8^{a,b}	0.975
K₂ 30 s (D), Mean ± SD	43.6 ± 1.7^b	44.1 ± 1.7^{a,b}	44.05 ± 0.9^b	44.06 ± 0.9^{a,b}	0.685
K₂ 2 min (D), Mean ± SD	45.0 ± 1.6^a	44.08 ± 1.6^{a,b,c}	44.21 ± 1.1^{a,b}	44.0 ± 1.1^a	0.952
K₂ 5 min (D), Mean ± SD	44.7 ± 1.8^c	44.6 ± 1.7^c	44.68 ± 1.2^c	44.26 ± 1.1^b	0.671
Within-group comparison over time	< 0.001	0.010	* 0.002	* 0.256	

Abbreviations: n, numbers; K₂, steep keratometry; D, diopters; SD, standard deviation; s, seconds; min, minutes. Note: P-values < 0.05 are presented in bold; D1, dry eye group receiving high-viscosity artificial tears; D2, dry eye group receiving low-viscosity artificial tears; N1, normal ocular surface group receiving high-viscosity artificial tears; N2, normal ocular surface group receiving low-viscosity artificial tears. Repeated-measures analysis of variance (ANOVA) was used to evaluate within-group changes over time, with Bonferroni-adjusted post hoc comparisons: different superscript letters (a–c) within columns indicate statistically significant differences (*P* < 0.05), whereas values sharing the same letter are not significantly different. *, Greenhouse-Geisser correction was applied when Mauchly’s test indicated violation of sphericity.

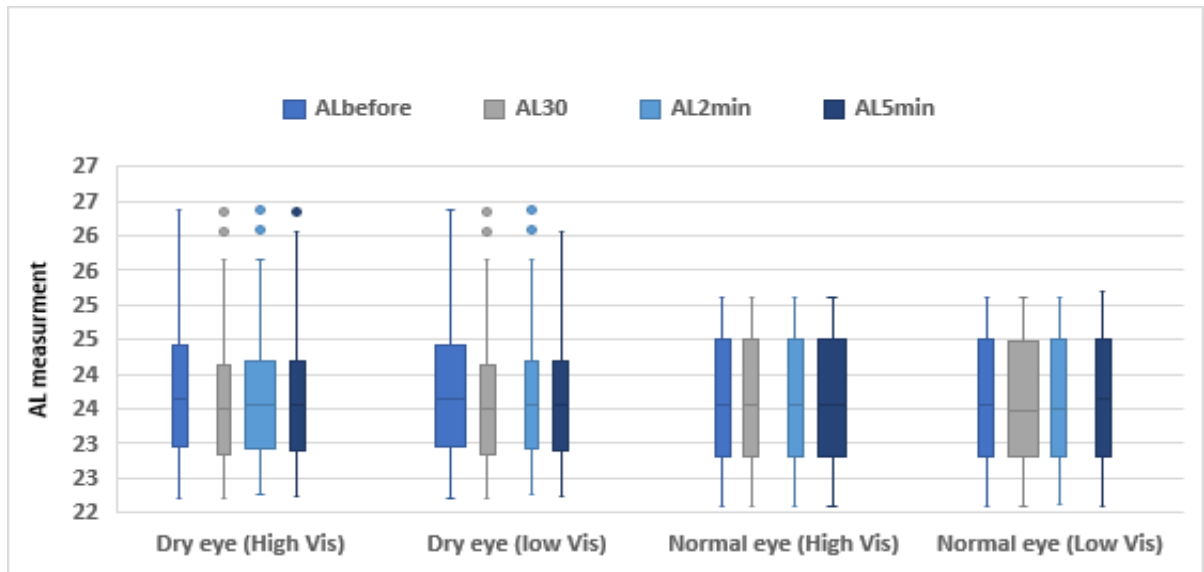


Figure 2. Temporal changes in axial length (AL) measurements in millimeters following instillation of high- and low-viscosity artificial tears in dry eye and normal ocular surface groups. Note: Box plots represent the median (central line), interquartile range (box), and range (whiskers). Individual points denote outliers. Measurements were obtained at baseline (ALbefore), 30 s (AL30), 2 min (AL2min), and 5 min (AL5min) post-instillation. Dry eye (High Vis), dry eye group receiving high-viscosity artificial tears; Dry eye (low Vis), dry eye group receiving low-viscosity artificial tears; Normal eye (High Vis), normal ocular surface group receiving high-viscosity artificial tears; Normal eye (Low Vis), normal ocular surface group receiving low-viscosity artificial tears.

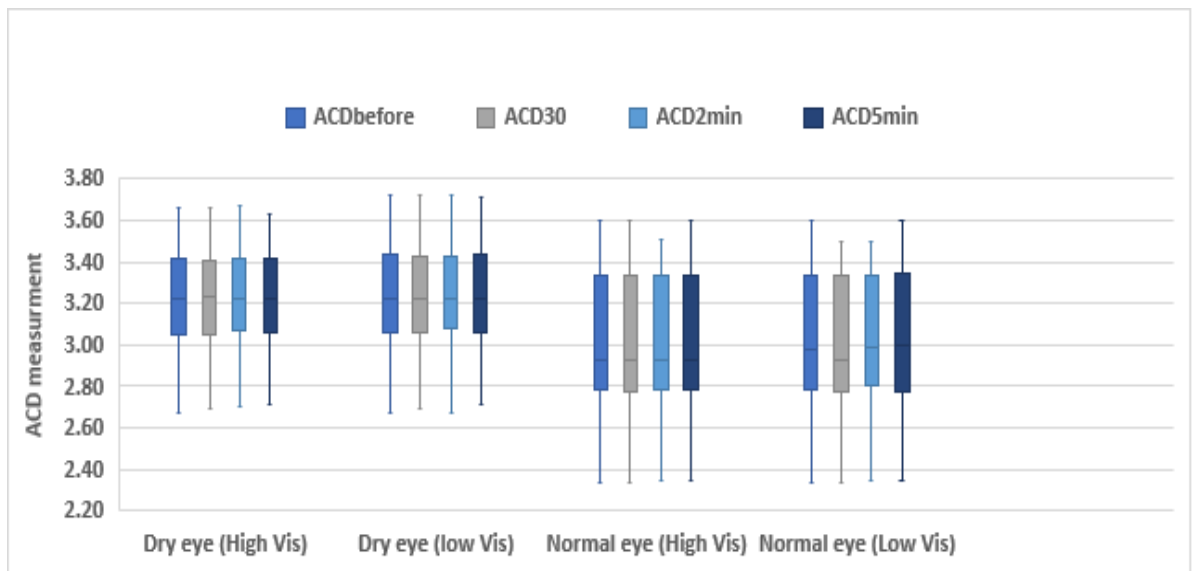


Figure 3. Temporal changes in anterior chamber depth (ACD) measurements in millimeters following artificial tear instillation in dry eye and normal ocular surface groups. Note: Box plots represent the median (central line), interquartile range (box), and range (whiskers). Individual points denote outliers. Measurements were obtained at baseline (ACDbefore), 30 s (ACD30), 2 min (ACD2min), and 5 min (ACD5min) post-instillation. Dry eye (High Vis), dry eye group receiving high-viscosity artificial tears; Dry eye (low Vis), dry eye group receiving low-viscosity artificial tears; Normal eye (High Vis), normal ocular surface group receiving high-viscosity artificial tears; Normal eye (Low Vis), normal ocular surface group receiving low-viscosity artificial tears.

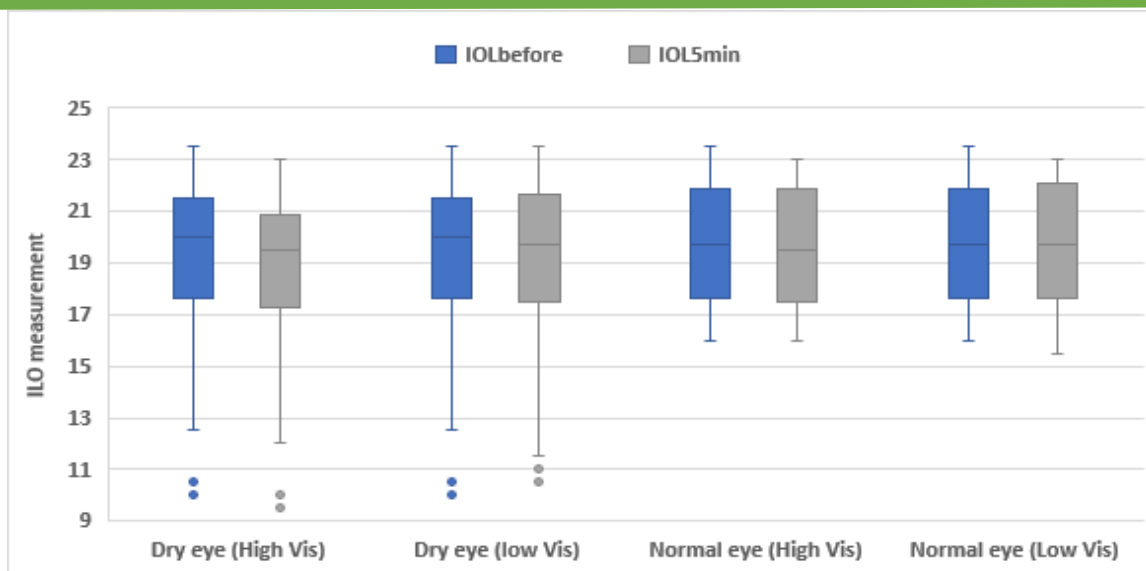


Figure 4. Changes in calculated intraocular lens (IOL) power in diopters before and after artificial tear instillation in dry eye and normal ocular surface groups. Note: Box plots represent the median (central line), interquartile range (box), and range (whiskers). Individual points denote outliers. Measurements were obtained at baseline (IOLbefore) and 5 min (IOL5min) post-instillation. Dry eye (High Vis), dry eye group receiving high-viscosity artificial tears; Dry eye (low Vis), dry eye group receiving low-viscosity artificial tears; Normal eye (High Vis), normal ocular surface group receiving high-viscosity artificial tears; Normal eye (Low Vis), normal ocular surface group receiving low-viscosity artificial tears.

DISCUSSION

This randomized cross-over study showed that artificial tears induce transient alterations in keratometric measurements, particularly within the first 2 min after instillation, with greater variability observed in eyes with dry eye disease. High-viscosity formulations exerted more pronounced effects and were associated with a modest but statistically significant reduction in calculated IOL power. In contrast, AL and ACD remained stable, suggesting that these changes are primarily confined to the anterior corneal surface.

Our findings are highly concordant with those of Roggla et al. [15], who, in a randomized cross-over study of cataract patients stratified into normal and dry-eye groups, showed that instillation of both low- and high-viscosity artificial tears significantly increases variability in keratometric measurements, particularly within the first minutes after application. Consistent with our results, this variability peaked at 30 s and progressively diminished over time, with measurements approaching baseline stability by 5 min. Both studies consistently indicate that these effects are more pronounced in dry eye [15], underscoring tear film instability as a key determinant of measurement reliability; this may contribute to increased variability in corneal power assessment and, consequently, to potential prediction errors in IOL power calculation [23]. Roggla et al. [15] further reported clinically meaningful fluctuations, with astigmatic changes exceeding 0.5 D in 13.2% of normal eyes and 34% of dry eyes following instillation of higher-viscosity formulations—findings that closely align with our observation of larger effect sizes and more pronounced keratometric shifts in the high-viscosity dry eye subgroup. However, they focused primarily on measurement variability and repeatability, whereas our study quantified directional and time-dependent changes in K_1 and K_2 , providing a more detailed characterization of the temporal dynamics of tear film-induced alterations. Moreover, while Roggla et al. [15] did not evaluate downstream biometric consequences, our findings extend this work by evidencing a modest but statistically significant reduction in calculated IOL power in dry eyes exposed to high-viscosity drops, highlighting potential implications for refractive outcomes. Keratometry reflects the optical properties of the tear film-cornea interface and is therefore highly sensitive to transient changes in tear film thickness, smoothness, and regularity following drop instillation [23]. Accordingly, measurement variability peaks early—typically at 30 s—and decreases progressively over time [24]. These studies reinforce that artificial tears, particularly high-viscosity formulations, induce transient instability in keratometric measurements, with peak variability occurring shortly after instillation and diminishing over time—thereby supporting a minimum waiting period of at least 5 min before reliable biometry can be obtained, especially in eyes with compromised tear film integrity.

The present findings partially align with those of Chen et al. [11], who, in a prospective repeated-measures study using swept-source optical coherence tomography (SS-OCT)-based biometry (IOLMaster 700), showed that artificial tear instillation induces time-dependent alterations in multiple ocular parameters, particularly within the first minutes after application, supporting a minimum 5-min delay before measurement. They reported significant intergroup differences in K_1 at 2 and 5 min, along with transient changes in corneal curvature radii (R_1 , R_2). They also observed early increases in ACD at 30 s in both groups and at 2 min specifically within the dry eye group, plus significant within-group changes in central corneal thickness at all post-instillation timepoints, reflecting tear film augmentation and the prolonged ocular surface

residence of sodium hyaluronate. The same study reported no significant difference in AL between dry eye and non-dry eye groups; however, a transient increase in AL was observed at 30 s following artificial tear instillation in both groups. This finding was attributed to the measurement principle of the device, which calculates AL from the tear film-air interface to the retinal pigment epithelium, rendering AL sensitive to temporary increases in tear film thickness after drop instillation [11]. In contrast, our study demonstrated that while keratometric parameters exhibit transient variability—most pronounced within the first 2 min—AL and ACD remained stable across all timepoints, indicating that the influence of artificial tears is predominantly confined to the anterior refractive surface rather than extending to deeper axial measurements. Our findings suggest that under controlled conditions and in an older cataract population, such effects may be negligible or clinically insignificant. This discrepancy likely reflects fundamental differences in measurement principles and study design.

Chen et al. [11] evaluated a single formulation (0.1% sodium hyaluronate, preservative-free), whereas our randomized cross-over design provides novel evidence that tear viscosity is a critical determinant of measurement variability, with high-viscosity formulations inducing larger and more clinically meaningful changes—including a significant reduction in calculated IOL power. This supports the concept that increased viscoelasticity prolongs tear film residence time and enhances optical surface irregularity, thereby amplifying transient refractive shifts. Differences in study populations—young, predominantly healthy individuals versus older cataract patients—together with variations in tear film characteristics, device technology, and experimental design likely account for the broader biometric changes observed by Chen et al. [11]. These complementary findings underscore that both tear film dynamics and formulation properties critically influence biometric accuracy, and that their effects are context-dependent, with important implications for optimizing preoperative measurement protocols.

Our findings are strongly supported by Hiraoka et al. [25], who demonstrated that DED significantly impairs the repeatability of corneal curvature measurements, particularly in the steep meridian, and that this variability is related to tear film instability, as reflected by reduced TBUT. While they quantified this effect through within-session measurement variability, our study extends these observations by showing dynamic, time-dependent alterations in keratometric values following artificial tear instillation, thereby capturing not only reduced precision but also transient shifts in measured corneal power. Findings of both studies may imply that air-tear film interface acts as the primary refractive surface and that instability in this layer introduces optical irregularities that degrade measurement reliability. They [25] further reported correlations between DED severity markers (TBUT and corneal staining) and AL repeatability, suggesting that tear film disruption may influence deeper biometric signals. In contrast, our results demonstrated stable AL and ACD across all timepoints, indicating that, in the context of controlled tear film modulation with artificial tears, the impact is predominantly confined to the anterior corneal surface rather than affecting axial measurements. These differences likely reflect methodological and physiological distinctions. Hiraoka et al. [25] evaluated intrinsic tear film instability without intervention, capturing chronic variability in measurement repeatability, whereas our cross-over design assessed acute tear film modulation, revealing transient, viscosity-dependent optical effects. Moreover, the stronger changes observed in our dry eye cohort—particularly with high-viscosity formulations—support the concept that tear film thickness and viscoelastic properties can transiently reshape the anterior refractive interface, amplifying measurement variability beyond baseline instability alone. While Hiraoka et al. [25] provide foundational evidence that DED compromises measurement precision, our study demonstrates that both tear film instability and its artificial modulation can actively alter keratometric values, with direct implications for IOL power calculation. These complementary findings underscore that both baseline ocular surface status and pre-measurement interventions must be carefully controlled to optimize biometric accuracy in cataract patients.

Our findings are broadly consistent with those of Pandey et al. [26], who evaluated the impact of artificial tears of varying viscosities on keratometric measurements in cataract patients with mild-to-moderate dry eye. They demonstrated that both low- and high-viscosity artificial tears induce statistically significant changes in K_1 at early (1 min) and later (5 min) timepoints, while K_2 and astigmatic axis remained largely stable. This selective effect on the flatter meridian is in close agreement with our observations, supporting the concept that tear film alterations preferentially influence corneal curvature measurements along the flat axis. However, they [26] employed a sequential, cross-sectional design without randomization and assessed only two post-instillation timepoints (1 and 5 min), whereas our randomized cross-over design with repeated measurements at 30 s, 2 min, and 5 min allowed for a more detailed characterization of the early dynamic changes and recovery profile. They reported persistent significant elevation in K_1 even at 5 min, whereas our findings demonstrate that keratometric values generally stabilize by 5 min; this suggests that the temporal profile of tear film normalization may vary depending on study design, measurement technique, and tear formulation. While Pandey et al. focused primarily on keratometric variation [26], our study extends these observations by quantifying effect sizes and revealing downstream clinical implications, including a significant reduction in calculated IOL power in dry eye eyes receiving high-viscosity drops. Both studies support the premise that artificial tears transiently modify the optical properties of the tear film-cornea interface, disproportionately affecting the flatter meridian while leaving K_2 relatively unaffected. These findings reinforce the clinical relevance of tear film dynamics in cataract biometry and highlight that both viscosity and timing are critical determinants of measurement accuracy. They further underscore the need for appropriate timing of keratometric assessment following artificial tear instillation to minimize refractive error in cataract surgery planning.

This study has several strengths, including its randomized cross-over design, inclusion of both dry eye and normal ocular surface groups, and standardized measurement conditions, enhancing internal validity. Limitations are a relatively small sample size and a short observation period ≤ 5 min, precluding assessment of longer-term effects. Future studies with larger cohorts and extended follow-up are warranted to evaluate the persistence of these effects across different formulations and severities of dry eye disease. Additionally, correlating these findings with postoperative refractive outcomes would further establish their clinical significance.

CONCLUSIONS

Artificial tears, particularly high-viscosity formulations, induce significant transient changes in keratometric measurements, with more pronounced effects in eyes with dry eye disease. These findings highlight the importance of timing in optical biometry, suggesting that keratometry should be deferred for at least 5 min following drop instillation to minimize measurement variability. Given the potential impact on IOL power calculations, careful optimization of the ocular surface remains essential for achieving accurate refractive outcomes and enhancing the precision of cataract surgery.

ETHICAL DECLARATIONS

Ethical approval: The study protocol was approved by the Ethics Committee of the Faculty of Medicine, Port Said University (ERN: MED (3/11/2024).s.no(199) OPT824_005). All procedures adhered to the principles of the Declaration of Helsinki. Written informed consent was obtained from all participants prior to enrollment and before the initiation of any study-related procedures. The trial was prospectively registered with the Pan African Clinical Trials Registry [17].

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