• Clinical Research •

Impact of a three-month period of mini-scleral lens usage on intraocular pressure and the anterior chamber angle in patients with keratoconus

Parvin Esmaili–Badrabadi[1], Payam Nabovati[1], Morad Amir Ahmad[2], Abdollah Farzaneh[1], Asgar Doostdar[1], Abbasali Yekta[3], Mahdi Mahmoodi[4], Mohammad Saeid Hoseinzade[5], Mehdi Khabazkhoob[6]

[1]Department of Optometry, Rehabilitation Research Center, School of Rehabilitation Sciences, Iran University of Medical Sciences, Tehran 1449614535, Iran

[2]Department of Optometry, Department of Physiotherapy, Erbil Technical & Medical Health Collage, Erbil Polytechnic University, Erbil, Kurdistan Region 44001, Iraq

[3]Department of Optometry, School of Paramedical Sciences, Mashhad University of Medical Sciences, Mashhad 1394491388, Iran

[4]Noor Ophthalmology Research Center, Noor Eye Hospital, Tehran 1983963113, Iran

[5]Noor Research Center for Ophthalmic Epidemiology, Noor Eye Hospital, Tehran 1983963113, Iran

[6]Department of Medical Surgical Nursing, School of Nursing and Midwifery, Shahid Beheshti University of Medical Sciences, Tehran 1983969411, Iran

Correspondence to: Abdollah Farzaneh. Department of Optometry, Rehabilitation Research Center, School of Rehabilitation Sciences, Iran University of Medical Sciences, Tehran 1449614535, Iran. farzaneh.ab@iums.ac.ir

Received: 2025-07-29 Accepted: 2026-02-04

Abstract

● **AIM:** To investigate the long-term effects of mini-scleral lens wear on intraocular pressure (IOP) and anterior chamber angle (ACA) in patients with keratoconus (KCN).

● **METHODS:** A convenience sampling method was adopted to enroll KCN patients between November 2023 and April 2024. All participants had a definitive KCN diagnosis and were eligible for mini-scleral lens fitting. Baseline optometric examinations included visual acuity measurement, objective and subjective refraction, and slit-lamp biomicroscopy. Mini-scleral lenses were fitted with trial lenses. Participants returned for a 3-month follow-up, where all examinations were repeated.

● **RESULTS:** Seventeen KCN patients (12 males) were enrolled, aged 20–53y with a mean age of 38.09±12.86y. Mean IOP rose by 0.33±1.60 mm Hg after mini-scleral lens wear, without statistical significance (P=0.525). The nasal ACA increased by 0.73°±2.69° (*P*=0.390), whereas the temporal ACA decreased by −1.46°±3.10° (*P*=0.152). In severe KCN cases, mean IOP elevated from 7.60±0.96 to 8.60±1.14 mm Hg after lens fitting. By contrast, mild-to-moderate KCN patients showed a slight IOP decline from 11.58±2.50 mm Hg at baseline to 11.33±2.42 mm Hg post-fitting. Females presented a statistically significant reduction in temporal ACA after lens wear (*P*=0.020). Older baseline age was negatively correlated with temporal ACA width (β=−0.719, *P*=0.041).

● **CONCLUSION:** Patients with advanced KCN face higher risks of IOP elevation after mini-scleral lens fitting. ACA changes induced by mini-scleral lenses vary by sector, with temporal angle narrowing being more prominent. Clinicians should closely monitor potential temporal angle narrowing, especially in female and older KCN patients during mini-scleral lens fitting.

● **KEYWORDS:** keratoconus; mini-scleral lens; intraocular pressure; anterior chamber angle

DOI:10.18240/ijo.2026.08.08

Citation: Esmaili-Badrabadi P, Nabovati P, Ahmad MA, Farzaneh A, Doostdar A, Yekta A, Mahmoodi M, Hoseinzade MS, Khabazkhoob M. Impact of a three-month period of mini-scleral lens usage on intraocular pressure and the anterior chamber angle in patients with keratoconus. *Int J Ophthalmol* 2026;19(8):1510-1517

INTRODUCTION

Keratoconus (KCN) is a progressive condition that typically affects both eyes asymmetrically and is classified as a corneal ectatic disorder[1-2]. It is characterized by thinning of the corneal stroma and an increase in central corneal curvature, which results in myopia, irregular astigmatism, the induction of higher-order aberrations (HOAs), and a subsequent decline in visual acuity[3]. Globally, the average prevalence of KCN is estimated to be 1.38 cases per 1000 individuals, with significant regional variations; higher prevalence rates have been particularly noted in South Asia and Middle Eastern countries, including Iran[4-6]. In the initial stages of this disease, the use of corrective spectacles significantly enhances visual acuity. However, as the disease advances, the cornea's shape becomes increasingly irregular, leading to diminished effectiveness of spectacles in improving patients' vision[7]. When patients with KCN exhibit substantial HOAs, the application of rigid gas permeable (RGP) contact lenses is advised to create a more uniform refractive surface and facilitate improved vision correction[8-11]. Nonetheless, despite the optical advantages of RGP contact lenses, their use may not be suitable for all patients, as challenges such as lens decentration, increased risk of corneal ulcers, and patient discomfort can significantly limit their applicability[12].

In contemporary practice, mini-scleral lenses have emerged as a preferred method for optical correction in patients with KCN, particularly when traditional approaches such as spectacles and RGP contact lenses have proven inadequate[13-15]. These lenses are also recognized for their potential to postpone or avert the need for corneal transplantation in individuals with KCN[13]. Characterized by their rigid and oxygen-permeable design, mini-scleral lenses possess a larger diameter that encompasses the cornea and limbal region in a dome-like configuration, ensuring no direct contact with these areas. Instead, they rest on the conjunctival tissue that covers the sclera, thereby enhancing comfort during wear[16]. The fluid between the mini-scleral lens and the cornea serves to rectify surface irregularities, leading to a substantial improvement in visual acuity[8]. Although mini-scleral lenses offer various advantages and function effectively, several adverse effects have been documented. The most significant concerns include challenges associated with insertion and removal due to their large diameter, elevated costs, and the necessity for frequent replacement of the fluid beneath the lens. Additionally, the removal of these lenses can lead to damage to the limbal stem cells and corneal hypoxia, which arises from a diminished oxygen supply to the corneal tissue[17-18].

The application of mini-scleral lenses theoretically may lead to alterations in intraocular pressure (IOP) and anterior chamber angle (ACA). These lenses are positioned on the perilimbal conjunctiva over the sclera, which encompasses structures critical to the drainage of aqueous humor. Consequently, they have the potential to interfere with the equilibrium of IOP by obstructing the outflow of aqueous humor from the eye. Such pressure on these anatomical regions can compromise the iridocorneal angle, thereby influencing IOP levels[19-20].

The existing literature on the impact of mini-scleral lenses on IOP and ACA is limited and presents inconsistent findings[21-24]. Most prior research has focused on the immediate effects of mini-scleral lens fitting using trial lenses, with limited attention to the effects of mini-scleral lens wear over follow-up periods beyond the initial fitting[10,13,15,25-26]. Furthermore, it remains uncertain whether pre-fitting parameters influence these changes. Identifying the factors that affect variations in IOP and ACA is crucial for enhancing patient selection and follow-up visits when fitting mini-scleral lenses. In light of this, the present study aimed to assess the alterations in IOP and ACA following three months of continuous mini-scleral lens wear in patients with KCN, as well as to investigate the relationship between pre-fitting parameters and these changes.

PARTICIPANTS AND METHODS

Ethical Approval This research adhered to all ethical guidelines outlined in the Declaration of Helsinki. The objectives of the study, along with each stage of the research, were thoroughly explained to the participants. Written informed consent was secured from all individuals involved in the study. The study protocol received approval from the Ethics Committee of Iran University of Medical Sciences (ethics code: IR.IUMS.REC.1402.719).

Study Design and Participants This prospective interventional study was carried out from November 2023 to April 2024, utilizing a convenience sampling method among KCN patients attending a specialized eye hospital in Tehran, Iran (Bina Eye Hospital). A total of 17 patients, all of whom had received a definitive diagnosis of KCN through corneal topography as assessed by a corneal specialist, were recruited for the study. All participants expressed dissatisfaction with their spectacle-corrected vision or were unable to tolerate RGP contact lenses, thereby qualifying them for the trial involving mini-scleral lenses. Initially, the objectives and steps of the research were thoroughly explained to the participants, who subsequently provided their written consent. Following this, demographic data and case history information including prior ocular and systemic diseases, surgical interventions, contact lens usage, previous ocular trauma, and the use of ocular and systemic medications were collected through interviews. Subsequently, the participants underwent comprehensive pre-fitting ocular examinations.

Pre-Fitting Evaluation Uncorrected distance visual acuity was assessed using the M&S vision chart at a distance of 4 m. Subsequently, objective refraction was obtained using the KR-8900 auto-refractometer (Topcon, Japan). Following this, subjective refraction was conducted, beginning with the objective refraction as the starting point and utilizing Jackson's cross cylinder with dioptric powers of 0.5 and 1 D. The process culminated in achieving optimal spherocylindrical correction, with the best-corrected distance visual acuity. The subsequent procedure involved corneal imaging, which was carried out using the Sirius topographer (SCHWIND eye-tech-solutions, Germany). This topographic system integrates a rotating Scheimpflug camera with a Placido disk to evaluate the anterior segment by capturing 25 radial sections of the cornea and anterior chamber. During this assessment, the subject was instructed to blink three times before fully opening the eyelids and focusing on the central point of the device. If the patient's tear film was inadequate, artificial tears were administered, and evaluations were repeated after a five-minute interval. Additionally, the evaluation of the ACA was performed in a horizontal orientation across two sectors: nasal and temporal, using Sirius topography. The following step involved the measurement of IOP, which was conducted automatically using the non-contact air-puff tonometer (NT-530, Nidek, Japan). The device's height was adjusted to ensure that no pressure was exerted on the vessels in the head and neck region. The subjects were then instructed to breathe normally without holding their breath, ensuring that no pressure was applied to the eyes during tonometry. Measurements were taken three times, and the average of these values was recorded as the IOP. To account for daily fluctuations, IOP measurements were consistently performed between 9:00 *a.m*. and 12:00 *p.m*.

Mini-Scleral Lens Fitting Procedure Mini-scleral lens fitting was conducted in accordance with the manufacturer's protocol (Hakim-Maram Corp, Iran). This process entailed evaluating the mean central (3 mm) keratometry, in conjunction with the degree of KCN severity, to determine the initial lens with a suitable sagittal depth. The initial lens was positioned on the eye, followed by an assessment of central pooling, the fluid exchange beneath the lens, and the pressure exerted by the lens on the limbal and peripheral regions. Based on these evaluations, a preliminary decision was made. The volume of fluid present between the lens and the cornea varies among different manufacturers, typically ranging from 300 to 500 μm immediately post-fitting, and decreasing to 100 to 300 μm after the lens has settled. As per Hakim-Maram's recommendations, an optimal initial fluid thickness of 200–300 μm is desired, with a post-settling measurement of 100–150 μm; it is crucial that this fluid layer remains free of air bubbles and that the lens does not contact the cornea or limbal area. Once an acceptable initial positioning was achieved, the lens was worn for a duration of 40min, after which the evaluations were repeated. Ultimately, after permitting a minimum of 40min for the lens to settle, the volume of fluid located behind the lens was measured using anterior segment optical coherence tomography (AS-OCT; Cirrus 5000 HD-OCT, Carl Zeiss Meditec, Germany). Furthermore, the landing zone was carefully evaluated using a slit-lamp biomicroscope to prevent any undue pressure on the conjunctiva. Once a satisfactory fit was confirmed, the order for the lens was placed. Comprehensive training was provided to the individual regarding the proper usage of the lens. The individual was instructed to wear the lens for a minimum of 6h daily. The fitting of the lenses was conducted by a qualified and experienced optometrist, while a masked operator carried out corneal imaging and assessed IOP.

Post-Fitting Evaluation Following a three-month period of mini-scleral lens usage, patients were invited for a follow-up assessment. All evaluations, including optometric assessments, Sirius imaging, and tonometry, were conducted using the same protocols established prior to lens fitting. To ensure consistency, patients were requested to attend the hospital at a time when their routine lens usage remained unchanged. The follow-up examinations were performed at least 30min after the lenses had been removed from the eyes.

Exclusion Criteria The exclusion criteria were a documented history or presence of any ocular pathology aside from KCN, prior corneal surgeries such as intrastromal ring segment implantation or corneal transplants, previous utilization of scleral lenses, a history of ocular trauma, and the use of ocular or systemic medications known to influence IOP and ACA. Additionally, an IOP exceeding 20 mm Hg was also a criterion for exclusion.

Statistical Analysis Statistical analyses were performed using version 24 of SPSS software. The Shapiro-Wilk test was employed to assess the normality of the data. Based on the distribution characteristics of the variables, either the paired *t*-test or the Wilcoxon signed-rank test was applied to compare the means of the variables before and after the use of the mini-scleral lens. Subgroup analyses were conducted according to the severity of KCN, as well as age and sex. KCN was categorized into two distinct groups: mild to moderate (mean K≤48.00 D) and severe (mean K>48.00 D), according to its severity. A *P*-value of less than 0.05 was deemed statistically significant.

RESULTS

This study involved 17 patients diagnosed with KCN, comprising 12 males (70.6%). Participants' ages ranged from 20 to 53y, with a mean age of 38.09±12.86y. Table 1 illustrates the comparative analysis of study variables, including IOP and ACA in both the nasal and temporal sectors, prior to and 3mo after using the mini-scleral lens across the entire sample.

As seen in Table 1, the mean IOP exhibited an increase of 0.33±1.60 mm Hg following the application of the mini-scleral lens; however, the statistical analysis revealed no significant difference in IOP when comparing measurements taken before and after lens application (*P*=0.525). In terms of the ACA, the average ACA in the nasal sector rose by 0.73±2.69 degrees post-lens application (*P*=0.390), whereas the average ACA in the temporal sector experienced a decrease of -1.46±3.10 degrees (*P*=0.152). Nonetheless, the alterations in the ACA for both the nasal (P=0.390) and temporal (P=0.152) sectors were not statistically significant. Analysis indicated that 41.2% of participants (7 individuals) experienced no change or a decrease in IOP after lens application, while 58.8% (10 individuals) exhibited an increase of at least 1 mm Hg.

Table 2 illustrates the variations in average IOP and the ACA in relation to the severity of KCN. In this study, 47% of the eyes (8 eyes) exhibited severe KCN prior to the mini-scleral fitting, while 53% (9 eyes) presented with mild to moderate KCN. For those with severe KCN, the average IOP increased from 7.60±0.96 to 8.60±1.14 mm Hg. Nevertheless, this 1.00 mm Hg rise in average IOP did not reach statistical significance. Among the individuals with severe KCN, 37.5% (3 eyes) showed an increase of 1 mm Hg, 25% (2 eyes) experienced a rise of 2 mm Hg, another 25% (2 eyes) had an increase of 3 mm Hg, and 12.50% (1 eye) demonstrated a decrease in IOP following lens application. In cases of mild to moderate KCN, the average IOP shifted from 11.58±2.50 mm Hg before fitting to 11.33±2.42 mm Hg after lens use. However, this alteration was also not statistically significant. Among the mild to moderate KCN cases, 22.2% (2 eyes) maintained a stable IOP, while 33.3% (3 eyes) experienced a reduction of 1 mm Hg, 22.2% (2 eyes) noted a decrease of 1.5 mm Hg, and 22.2% (2 eyes) recorded an increase of 1 mm Hg post-lens application.

In cases with severe KCN, the ACA in the nasal sector exhibited a slight widening following lens application; however, this change lacked statistical significance. Among the subjects with severe KCN, 62.5% (5 eyes) demonstrated an increase in the nasal ACA, while a decrease was observed in 37.5% (3 eyes). Moreover, the average ACA in the temporal sector experienced a reduction post-lens application, yet this change also did not reach statistical significance. Specifically, the ACA in the temporal sector decreased in 62.5% (5 eyes) of cases with severe KCN, remained unchanged in 25% (2 eyes), and increased in 12.5% (1 eye).

In cases of mild to moderate KCN, there was a slight increase in the average ACA within the nasal sector; however, this change was not statistically significant. Among the mild to moderate KCN cases, 4 eyes (44%) exhibited an increase, 2 eyes (22%) experienced a decrease, and 3 eyes (33%) demonstrated no change in nasal ACA following lens application. Additionally, the average ACA in the temporal sector experienced a slight reduction, which also lacked statistical significance. Specifically, 5 eyes (55%) in the mild to moderate KCN category showed a decrease in temporal ACA, 3 eyes (33%) remained unchanged, and 1 eye (11%) displayed an increase in the ACA in the temporal sector.

Table 3 illustrates the variations in IOP and ACA associated with the application of a mini-scleral lens, categorized by gender. The data indicate that the mean IOP for males rose from 9.44±2.57 to 9.88±2.30 mm Hg; however, this alteration lacked statistical significance. Among the male participants, 33.3% (4 eyes) experienced an increase of 1 mm Hg, 16.7% (2 eyes) exhibited a rise of 1.50 mm Hg, another 16.7% (2 eyes) showed an increase exceeding 3 mm Hg, while 16.7% (2 eyes) recorded a decrease of 1 mm Hg. Additionally, 8.3% (1 eye) decreased by 1.5 mm Hg, and another 8.3% (1 eye) decreased by 2 mm Hg. In contrast, the average IOP for females remained relatively stable before and after the use of the mini-scleral lens, with no significant changes observed. Specifically, 60% of women (2 eyes) exhibited no change in IOP, while 20% (1 eye) experienced a 1 mm Hg increase, and another 20% (1 eye) demonstrated a decrease of 1 mm Hg.

Table 1 Comparison of IOP and ACA before and 3mo after using mini-scleral lens across the entire sample mean±SD

Parameters	Before fitting	After lens use	Difference	P
IOP (mm Hg)	9.77±2.80	10.10±2.34	0.33±1.60	0.525
ACA in nasal (degrees)	47.27±6.65	48.00±5.02	0.73±2.69	0.390
ACA in temporal (degrees)	42.64±6.47	41.18±4.71	-1.46±3.10	0.152

IOP: Intraocular pressure; ACA: Anterior chamber angle; SD: Standard deviation.

The mean ACA in the nasal sector for men exhibited an increase of 1.00±6.43 degrees following the application of the mini-scleral lens; however, this change was not statistically significant. Among the male participants, 66.7% (8 eyes) experienced an increase in the nasal ACA, while 33.3% (4 eyes) demonstrated a decrease in the nasal ACA post-lens usage. Conversely, the average temporal ACA for men showed a slight reduction, which also lacked statistical significance. Specifically, 50% of men (6 eyes) recorded a decrease in the temporal angle, 25% (3 eyes) exhibited no change, and 25% (3 eyes) experienced an increase. In contrast, the average ACA in the nasal sector for women remained unchanged after lens application. In this group, 40% (2 eyes) showed an increase, another 40% (2 eyes) showed a decrease, and 20% (1 eye) exhibited no change in the nasal ACA. Notably, the mean temporal ACA for women significantly decreased after the lens was used, a finding that was statistically significant (P=0.020). All women in the study experienced a reduction in the ACA in the temporal sector following the use of the mini-scleral lens.

In order to investigate the correlation between age and the ACA prior to lens fitting with the subsequent alterations in IOP, a variable termed IOP change was established. This variable represents the difference in IOP measured after lens application compared to that measured before lens fitting (IOP after−IOP before). The analysis employed multiple linear regression to explore the relationship between age and pre-fitting ACA with

Table 2 Comparison of IOP and ACA before and 3mo after using mini-scleral lens by severity of KCN mean±SD

Parameter	KCN severity	Before lens fitting	After lens use	Difference	*P*
IOP (mm Hg)	Mild to moderate	11.58±2.50	11.33±2.42	-0.25±2.46	0.597
	Severe	7.60±0.96	8.60±1.14	1.00±1.05	0.319
ACA in nasal (degrees)	Mild to moderate	46.00±5.37	46.50±4.09	0.50±4.77	0.542
	Severe	48.90±8.32	49.80±5.89	0.90±7.21	0.576
ACA in temporal (degrees)	Mild to moderate	41.83±5.95	40.33±4.27	-1.50±5.18	0.304
	Severe	43.60±7.64	42.20±5.49	-1.40±6.65	0.404

KCN: Keratoconus; IOP: Intraocular pressure; ACA: Anterior chamber angle; SD: Standard deviation.

Table 3 Comparison of IOP and ACA before and 3mo after using mini-scleral lens by gender mean±SD

Parameter	Gender	Before lens fitting	After lens use	Difference	*P*
IOP (mm Hg)	Male	9.44±2.57	9.88±2.30	0.44±2.44	0.519
	Female	10.67±3.77	10.67±2.89	0.00±3.36	1.00
ACA in nasal (degrees)	Male	47.25±7.38	48.25±5.31	1.00±6.43	0.394
	Female	47.33±5.51	47.33±5.13	0.00±5.32	1.00
ACA in temporal (degrees)	Male	42.50±7.50	42.00±5.01	-0.50±6.38	0.664
	Female	43.00±3.46	39.20±3.61	-3.80±3.54	0.020

IOP: Intraocular pressure; ACA: Anterior chamber angle; SD: Standard deviation.

Table 4 Multiple linear regression for the association between three-month variations in intraocular pressure following the application of a mini-scleral lens, in relation to the age and the ACA prior to lens fitting

Independent variable	Standard error	Standardized β	Degree of freedom	*P*
Age	0.450	-0.126	-0.349	0.738
ACA (nasal sector)	0.114	0.258	0.544	0.603
ACA (temporal sector)	0.131	0.542	1.023	0.340

ACA: Anterior chamber angle.

Table 5 Multiple linear regression for the association between three-month variations in ACA following the application of a mini-scleral lens, in relation to the age and IOP prior to lens fitting

Parameters	Standard error	Standardized β	Degrees of freedom	*P*
Model 1 (ACA in the nasal sector as dependent variable)				
Age	0.082	-0.242	-0.620	0.552
IOP	0.376	0.241	0.616	0.555
Model 2 (ACA in the temporal sector as dependent variable)				
Age	0.076	-0.719	-2.294	0.041
IOP	0.348	0.321	1.026	0.335

IOP: Intraocular pressure; ACA: Anterior chamber angle.

IOP change. However, none of the findings yielded statistically significant results (Table 4).

Table 5 illustrates the variations in the ACA across different sectors (ACA after lens usage−ACA before lens fitting) in relation to age and IOP prior to lens fitting. The data indicate that neither age nor pre-fitting IOP significantly influenced the changes in the ACA within the nasal sector. In contrast, older age prior to lens fitting was linked to a more pronounced ACA narrowing in the temporal sector.

DISCUSSION

This research investigated the impact of 3mo of mini-scleral lens usage on IOP and the ACA in individuals diagnosed with KCN. To date, there has been a scarcity of studies focusing on alterations in IOP associated with mini-scleral lens application. Previous studies have primarily concentrated on short-term changes in IOP, particularly immediately following lens insertion, and have predominantly involved young, healthy subjects. It is important to highlight that earlier investigations have yielded inconsistent findings, with some indicating an increase in IOP[21-23], others a decrease[27], and some reporting no change at all[24,28] after lens application. These discrepancies among studies may be attributed to variations in measurement techniques, differing timeframes for evaluation post-lens removal, and general methodological inconsistencies across the studies.

The variation in outcomes may also be linked to the influence of sub-atmospheric pressure, which arises from the suction effect of scleral lenses. This phenomenon can significantly impact IOP[29]. To detach the scleral lens from the ocular surface, a force ranging from 75 to 200 g is required to counterbalance the negative pressure, which is estimated to be between 5 and 18 mm Hg beneath the lens, particularly in cases of tight fitting. Furthermore, the reduction of tear volume beneath the scleral lens by approximately 100 μm after several hours of wear contributes to an increase in sub-atmospheric pressure over time[30]. Consequently, the fitting characteristics of the scleral lens, along with the various designs and materials employed in different studies, could play a crucial role in influencing IOP changes.

While the overall assessment of IOP did not reveal any significant changes, our subgroup analysis of the impact of the mini-scleral lens on IOP, particularly in relation to the severity of KCN, yielded intriguing findings. In cases of mild to moderate KCN, we noted a reduction in the mean IOP following the use of mini-scleral lenses. In contrast, patients with severe KCN exhibited an increase in average IOP of approximately 1 mm Hg after the application of the mini-scleral lens. Additionally, a significant number of patients with severe KCN experienced a marked rise in IOP, exceeding 2 mm Hg, subsequent to lens application. These findings highlight the importance of considering the severity of KCN when fitting scleral lenses. This observation can be elucidated by recognizing that individuals with KCN exhibit an increase in central corneal curvature, which is associated with a corresponding flattening of the peripheral corneal regions. This phenomenon is part of a compensatory mechanism referred to as biomechanical coupling. The primary role of this mechanism is to reduce substantial changes in the overall surface area of the cornea, thereby improving its capacity to withstand the mechanical stress resulting from ectasia-related stretching. It is crucial to emphasize that, in this context, the mechanical pressure applied by the scleral lens has the potential to significantly narrow the iridocorneal angle due to the peripheral flattening of the cornea.

The present study revealed that the use of a mini-scleral lens did not result in any significant alterations in the iridocorneal angle, corroborating the results of previous research that assessed the ACA during and following scleral lens application, which similarly found no significant changes[24,27-32]. However, upon conducting a sectoral analysis of the ACA in the nasal and temporal regions, we observed distinct sectoral variations in the pattern of ACA changes following the application of the mini-scleral lens. Specifically, in the nasal sector, the average change in ACA exhibited an increase of 0.5 degrees, whereas in the temporal sector, the average change reflected a decrease of 1.4 degrees[33]. Several hypotheses may explain this trend, including potential asymmetry in scleral thickness and rigidity between the nasal and temporal quadrants[33] and the common inferior-temporal location of the KCN cone, which might make the temporal sector more susceptible to mechanical influences of the lens. Given that such anatomical and biomechanical characteristics were not directly measured in this study, these explanations should be interpreted as possible hypotheses rather than confirmed mechanisms[34]. While our subgroup analyses suggest that temporal ACA narrowing may be more pronounced in women and older individuals, and that IOP elevation may be more frequent in severe KCN, these observations are based on small subgroup sizes and borderline statistical significance. As such, they should be interpreted cautiously and viewed as preliminary signals for future investigation not as established associations.

Although previous literature indicates that women may have a naturally narrower ACA[34], the gender-related differences in ACA responsiveness to mini-scleral lenses identified here should similarly be regarded as exploratory. One hypothesis is that inherent biomechanical differences in the cornea potentially influenced by sex hormones such as estrogen may underlie these observations. Prior studies have shown that fluctuations in estrogen levels during menstruation and pregnancy can affect corneal biomechanics, including increased corneal thickness and reduced corneal hysteresis and resistance factor[35-37]. However, because corneal biomechanical properties and hormonal status were not measured in this study, these explanations represent theoretical interpretations rather than mechanisms supported by our dataset. The present research exhibits both advantages and drawbacks. A notable strength of this study is its extended follow-up duration in comparison to earlier investigations, as well as the subgroup analysis performed by pre-fitting parameters. However, a significant limitation is the small sample size, which has resulted in many analyses failing to achieve statistical significance, despite some observed changes appearing clinically relevant. Additionally, the selection of participants from a single center limits the generalizability of the results. Another important limitation concerns the measurement of IOP: non-contact air-puff tonometry is known to be less reliable in irregular corneas and may underestimate IOP in KCN patients, making Goldmann applanation or dynamic contour tonometry more appropriate reference standards[38]. Moreover, ACA measurements obtained using the Sirius topographer cannot capture angle structures with the same precision as AS-OCT or ultrasound biomicroscopy (UBM); therefore, any sectoral interpretation of these findings should be considered with caution. Furthermore, the predominance of male participants (70%) presents another limitation; this imbalance is largely attributable to the higher incidence of KCN among Iranian men and the sampling methodology employed, which constrained our ability to address this issue. Consequently, the potential for gender bias must be taken into account when interpreting the results.

In conclusion, the impact of mini-scleral lenses on IOP among patients with KCN remains inconsistent and does not adhere to a definitive trend. While some individuals exhibit no change in IOP post-application of these lenses, others may experience either an elevation or a reduction in IOP levels. The severity of KCN is a significant factor influencing the variations in IOP observed following the use of mini-scleral lenses, with those presenting with more advanced KCN being at a higher risk for notable increases in IOP. Therefore, it is advisable to conduct regular monitoring of IOP following mini-scleral lens fitting, particularly for patients with severe KCN. The alterations in the ACA following the application of mini-scleral lenses exhibit a dependency on the specific sector, with a pronounced tendency for narrowing to occur in the temporal sector. Consequently, a comprehensive evaluation of the ACA should extend beyond an overall ACA assessment to include a detailed sectoral ACA analysis. Therefore, it is advisable to utilize imaging technologies capable of measuring ACA in a sector-specific manner when fitting scleral lenses for patients with KCN. Additionally, although our data hint at a possible increased susceptibility to temporal ACA narrowing in women and older individuals and to IOP elevation in severe KCN these patterns remain exploratory due to limited statistical power. Future studies with larger, balanced cohorts are needed to validate these signals and clarify their clinical relevance.

ACKNOWLEDGEMENTS

Authors' Contributions: Design and conduct of the study (Khabazkhoob M, Ahmad MA, Esmaili-Badrabadi P); collection, management of the data (Nabovati P, Khabazkhoob M, Farzaneh A, Doostdar A); analysis and interpretation of the data (Mahmoodi M, Khabazkhoob M); preparation, review, and approval of the manuscript (Esmaili-Badrabadi P, Nabovati P, Ahmad MA, Farzaneh A, Doostdar A, Yekta A, Mahmoodi M, Hoseinzade MS, Khabazkhoob M).

Data Availability Statement: The datasets used and/or analyzed during the current study available from the corresponding author on reasonable request.

AI-Generated Content Disclosure: This content was not generated by AI.

Foundation: Supported by Iran University of Medical Sciences.

Conflicts of Interest: Esmaili-Badrabadi P, None; **Nabovati P,** None; **Ahmad MA,** None; **Farzaneh A,** None; **Doostdar A,** None; **Yekta A,** None; **Mahmoodi M,** None; **Hoseinzade MS,** None; **Khabazkhoob M,** None.

REFERENCES

1 Santodomingo-Rubido J, Carracedo G, Suzaki A, *et al*. Keratoconus: an updated review. *Cont Lens Anterior Eye* 2022;45(3):101559.

2 Soltan-Dehghan H, Hashemi H, *et al*. Topographic factors associated with anterior chamber angle narrowing in patients with keratoconus. *Int J Ophthalmol* 2025;18(1):67-73.

3 Yekta A, Hashemi H, Ostadimoghaddam H, *et al*. Anterior and posterior corneal higher-order aberrations in early diagnosis and grading of keratoconus. *Clin Exp Optom* 2023;106(3):263-270.

4 Alqudah N, Jammal H, Khader Y, *et al*. Characteristics of keratoconus patients in Jordan: hospital-based population. *Clin Ophthalmol* 2021;15:881-887.

5 Hashemi H, Heydarian S, Hooshmand E, *et al*. The prevalence and risk factors for keratoconus: a systematic review and meta-analysis. *Cornea* 2020;39(2):263-270.

6 Hashemi H, Jamali A, Pakbaz F, *et al*. Keratoconus profile in the elderly: prevalence and clinical indices. *Cornea* 2026;45(6):686-693.

7 Angelo L, Gokul A, McGhee CNJ, *et al*. Keratoconus management in the community: a survey of optometrists. *Eye Contact Lens* 2024;50(1):10-15.

8 Lim L, Lim EWL. Current perspectives in the management of keratoconus with contact lenses. *Eye* (*Lond*) 2020;34(12):2175-2196.

9 Swartz G, Alam K, Gentle A, *et al*. Impact of contact lens correction on wavefront aberrations and vision quality in keratoconus. *Ophthalmic Physiol Opt* 2025;45(7):1811-1828.

10 Barba-Gallardo LF, Jaramillo-Trejos LM, Agudelo-Guevara AM, *et al*. Binocular vision parameters and visual performance in bilateral keratoconus corrected with spectacles versus rigid gas-permeable contact lenses. *J Optom* 2024;17(3):100514.

11 Wei SS, Li Y, Wu ZQ, *et al*. Characteristics of corneal aberration in patients with bilateral keratoconus and unilateral corneal Vogt's striae. *Int J Ophthalmol* 2024;17(12):2316-2320.

12 Itoi M, Itoi M. Management of keratoconus with corneal rigid gas-permeable contact lenses. *Eye Contact Lens Sci Clin Pract* 2022;48(3):110-114.

13 Kreps EO, Pesudovs K, Claerhout I, *et al*. Mini-scleral lenses improve vision-related quality of life in keratoconus. *Cornea* 2021;40(7):859-864.

14 Kaushik J, Goyal S, Singh A, *et al*. Efficacy of mini-scleral lenses in visual rehabilitation for corneal disorders: a prospective study. *BMC Ophthalmol* 2025;25(1):329.

15 Sinha R, Anjum S, Dwivedi S, *et al*. Mini-scleral lens: an effective mode of visual rehabilitation in eyes with resolved hydrops. *Eye Contact Lens Sci Clin Pract* 2024;50(8):361-367.

16 Fuller DG, Wang YR. Safety and efficacy of scleral lenses for keratoconus. *Optom Vis Sci* 2020;97(9):741-748.

17 Fadel D. Scleral lens issues and complications related to a non-optimal fitting relationship between the lens and ocular surface. *Eye Contact Lens Sci Clin Pract* 2019;45(3):152-163.

18 Rodriguez-Garcia A, Jimenez-Perez JC, Ruiz-Lozano RE, *et al*. Scleral lenses and PROSE: indications, complications, and future challenges. *Med Hypothesis Discov Innov Ophthalmol* 2025;14(3):73-106.

19 Formisano M, Franzone F, Alisi L, *et al*. Effects of scleral contact lenses for keratoconus management on visual quality and intraocular pressure. *Ther Clin Risk Manag* 2021;17:79-85.

20 Walker MK, Schornack MM, Vincent SJ. Anatomical and physiological considerations in scleral lens wear: conjunctiva and sclera. *Cont Lens Anterior Eye* 2020;43(6):517-528.

21 Aitsebaomo AP, Wong-Powell J, Miller W, *et al*. Influence of scleral lens on intraocular pressure. *J Contact Lens Res Sci* 2019;3(1):e1-e9.

22 Cheung SY, Collins MJ, Vincent SJ. The impact of short-term fenestrated scleral lens wear on intraocular pressure. *Cont Lens Anterior Eye* 2020;43(6):585-588.

23 Kramer EG, Vincent SJ. Intraocular pressure changes in neophyte scleral lens wearers: a prospective study. *Cont Lens Anterior Eye* 2020;43(6):609-612.

24 Obinwanne CJ, Echendu DC, Agbonlahor O, *et al*. Changes in scleral tonometry and anterior chamber angle after short-term scleral lens wear. *Optom Vis Sci* 2020;97(9):720-725.

25 Akcay BIS, Kockar A, Limon U, *et al*. Comparison of clinical and topographic outcomes of hybrid and scleral lenses in advanced keratoconus. *Beyoglu Eye J* 2021;7(1):59-65.

26 Bolac R, Yıldız MB, Alpogan O, *et al*. The effect of extended periods of mini-scleral lens wear on the conjunctival/episcleral and scleral thickness. *Cont Lens Anterior Eye* 2025;48(1):102289.

27 Shahnazi KC, Isozaki VL, Chiu GB. Effect of scleral lens wear on central corneal thickness and intraocular pressure in patients with ocular surface disease. *Eye Contact Lens Sci Clin Pract* 2020;46(6):341-347.

28 Nau CB, Schornack MM, McLaren JW, *et al*. Intraocular pressure after 2h of small-diameter scleral lens wear. *Eye Contact Lens* 2016;42(6):350-353.

29 Schornack MM, Vincent SJ, Walker MK. Anatomical and physiological considerations in scleral lens wear: intraocular pressure. *Cont Lens Anterior Eye* 2023;46(1):101535.

30 McMonnies CW. A hypothesis that scleral contact lenses could elevate intraocular pressure. *Clin Exp Optom* 2016;99(6):594-596.

31 McMonnies CW, Schief WK. Biomechanically coupled curvature transfer in normal and keratoconus corneal collagen. *Eye Contact Lens* 2006;32(1):51-62.

32 Michaud L, Lipson M, Kramer E, *et al*. The official guide to scleral lens terminology. *Cont Lens Anterior Eye* 2020;43(6):529-534.

33 Teeuw GJ, Vergouwen DPC, Ramdas WD, *et al*. Assessment of conjunctival, episcleral and scleral thickness in healthy individuals using anterior segment optical coherence tomography. *Acta Ophthalmol* 2024;102(5):573-580.

34 Schuster AK, Pfeiffer N, Nickels S, *et al*. Distribution of anterior chamber angle width and correlation with age, refraction, and anterior chamber depth-the Gutenberg health study. *Invest Ophthalmol Vis Sci* 2016;57(8):3740-3746.

35 Foster PJ, Broadway DC, Garway-Heath DF, *et al*. Intraocular pressure and corneal biomechanics in an adult British population: the EPIC-Norfolk eye study. *Invest Ophthalmol Vis Sci* 2011;52(11):8179.

36 Giuffrè G, Di Rosa L, Fiorino F, *et al*. Variations in central corneal thickness during the menstrual cycle in women. *Cornea* 2007;26(2):144-146.

37 Narayanaswamy A, Chung RS, Wu RY, *et al*. Determinants of corneal biomechanical properties in an adult Chinese population. *Ophthalmology* 2011;118(7):1253-1259.

38 Qian YY, Liu L, Shi YH, *et al*. Assessment of anterior chamber by ultrasound biomicroscopy and anterior segment optical coherence tomography in patients with inflammatory glaucoma. *J Int Med Res* 2019;47(12):5950-5956.