

# The Effect of Scleral Contact Lenses on Changes in Intraocular Pressure, Iridocorneal Angle, and Central Corneal Thickness

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**Keywords:** Anterior chamber; intraocular pressure; iridocorneal angle; scleral contact lens; Sirius corneal topography.



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## ABSTRACT

**Objective:** To investigate the impact of mini-Misa scleral contact lenses (SCLs, diameter: 16.5) on intraocular pressure (IOP), anterior chamber, and central corneal thickness (CCT)

**Methods:** Patients diagnosed with keratoconus who had been using SCL for at least 6 months were included. The anterior chamber angle (ACA), anterior chamber volume (ACV), anterior chamber depth (ACD), and CCT were evaluated with Sirius corneal topography [(Sirius CT), CSO, Italy] before and after 5 hours of SCL wear, with the lens in place. Additionally, IOP was measured using a pneumotonometer (Canon TX-20P; Tokyo, Japan) both before lens wear and immediately after removal.

**Results:** The SCL-corrected visual acuity was found to be 0.1 (0-1.3) LogMAR in twenty-four eyes of fourteen patients (4 females, 10 males), with a mean age of 37.9±10.4 years. After 5 hours of SCL wear, CCT values measured through the lens [478.5 (264-685) µm] were significantly higher than pre-wear values [417.0 (269-589) µm] (P<0.001). ACA [51 (38-68)° vs. 49 (38-66)°], ACD [3.74 (2.76-4.61) mm vs. 3.65 (2.57-4.25) mm], and ACV [210 (150-283) mm<sup>3</sup> vs. 196 (132-255) mm<sup>3</sup>] with SCL were also higher than pre-wear values (P=0.001, P<0.001, P<0.001, respectively). After 5 hours of SCL wear, K1 significantly decreased from 48.46 D (44.21-51.47) to 41.64 D (40.12-45.49), and K2 significantly decreased from 56.24 D (50.53-57.12) to 41.83 D (41.10-45.85) (P=0.001 for both). IOP was unchanged between the initial measurement and after removing the SCL [10 (6-20) mmHg vs. 11 (6-21) mmHg, respectively, P>0.05].

**Conclusion:** Besides not affecting IOP, SCLs were associated with an increase in CCT, ACA, ACD, and ACV after 5 hours of wear. These lenses do not appear to adversely affect IOP or narrow the iridocorneal angle.

## INTRODUCTION

Scleral contact lenses (SCL) have become increasingly popular in recent years for correcting refractive errors in conditions like keratoconus (KC), where the refractive errors are insufficient to be managed with standard refraction tests. SCLs are designed to rest on the conjunctival tissue over the sclera, creating a dome over the cornea and limbus. Unlike soft lenses, these SCLs settle on the conjunctival tissue over the sclera.<sup>[1,2]</sup>

Mini-SCLs (diameter: 14.0-16.5 mm) typically have narrower haptic wings and contact a relatively small area of the conjunctiva near the limbus, compared to larger SCLs.<sup>[3]</sup> Depending on the force applied and the concentration of the bearing surface on a smaller area near the limbus, they may compress structures responsible for aqueous humor outflow, such as Schlemm's canal, collector chan-

nels, or episcleral veins.<sup>[4]</sup> The compression of these structures can increase resistance to aqueous humor outflow, thereby raising intraocular pressure (IOP).

Previous studies have demonstrated the effects of SCL use on central corneal thickness (CCT), K-values, and IOP.<sup>[5-7]</sup> However, we have not found a study in the literature that measures the effect of SCL use on the iridocorneal angle using Scheimpflug Sirius Corneal Topography [(Sirius CT), CSO, Italy], except for one study in which optical coherence tomography (OCT) was used.<sup>[8]</sup>

We aim to investigate whether there are any differences in IOP, CCT measured by Sirius CT, iridocorneal angle, and other anterior chamber parameters with the application of SCLs in patients who use them clinically, and to evaluate the relationship between these parameters.

## MATERIALS AND METHODS

### Patients and Study Design

Patients who were diagnosed with KC and were using 16.5 mm mini-Misa SCL Microlens Contact Lens Technology, Arnhem, Netherlands) at our hospital, department of ophthalmology, contact lens unit between August 1, 2020, and June 1, 2024, were included in the study. Only patients who had been using SCL regularly for at least 6 months and had maintained consistent follow-up visits were considered. At the time of enrollment, all participants were clinically verified to have an appropriate lens fit, with no signs of poor fitting such as excessive blanching, inadequate vault, discomfort, or decentration. The patients who underwent Sirius CT examinations both before SCL fitting and after 5 hrs of lens wear were included in the study. According to the mini-Misa SCL guideline and our experience, lens wear beyond 5 hrs is not recommended to prevent a possible decrease in the vault. Therefore, all Sirius CT measurements were obtained on the same day—during SCL fitting and after 5 hrs of lens wear—taken with the lens still in place immediately before removal.

Patients 18 years of age or older with a history of ocular surgery other than corneal cross-linking were excluded from the study. This exclusion also applied to individuals who had undergone any form of keratoplasty. Additionally, patients with chronic eyelid disease, keratitis, active or previous uveitis, congenital cataract, congenital retinal dystrophies, ocular trauma, any systemic disease (including cardiovascular, metabolic, hematologic, or other disorders), or a genetic syndrome were excluded. Only eyes with an axial length between 22 and 25 mm were included.

The detailed ophthalmological examination findings, including autorefractive measurements, SCL-corrected visual acuity using the Snellen chart (converted to LogMAR), and anterior and posterior segment examinations were performed. IOP measurements with a pneumotonometer (Canon TX-20P; Tokyo, Japan) were taken both before SCL fitting, between 8:00 a.m. and 10:00 a.m. to avoid diurnal fluctuations, and immediately after lens removal. The flat K (K1) and steep K (K2) values in the central 3-mm area, anterior chamber angle (ACA), anterior chamber volume (ACV), anterior chamber depth (ACD), and CCT from the Sirius CT examinations were recorded.

Patients with any eye condition other than KC that could impair visual acuity, those with Sirius CT scans of insufficient image quality, and those with incomplete examination history data in the system, resulting in insufficient data for the study, will be excluded from the study.

### Scheimpflug Imaging

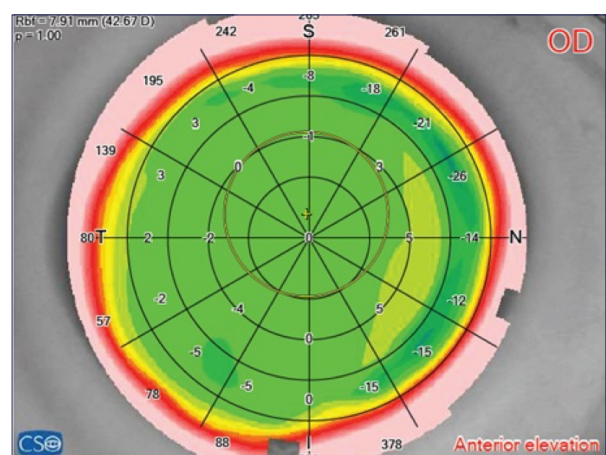
The Sirius Scheimpflug analyzer combines a Placido disc with a mono-rotating Scheimpflug system for corneal photography. It captures up to 100 high-resolution corneal sections to calculate all biometric measurements of the anterior chamber. The high measurement speed minimizes

the effect of eye movement, ensuring high-quality and accurate results. The device provides detailed information on both the anterior and posterior surfaces of the cornea. In two seconds, it acquires approximately 25 Scheimpflug scan images.<sup>[9,10]</sup>

To ensure optimal image quality, three well-focused, aligned, and centered images were captured for each eye using the Sirius CT (CSO, Florence, Italy). Patients were asked to blink before each acquisition to minimize the effect of tear film irregularities. K1, K2, Kmax in the central 3-mm area, ACA, ACD, ACV, and CCT were automatically measured by the device. ACA was defined as the angle between the posterior corneal surface and the anterior iris surface, measured 500  $\mu$ m from the scleral spur in six meridians (6–12, 1–7, 2–8, 3–9, 4–10, and 5–11 o'clock), and the mean value from 12 points was calculated (Fig. 1). ACD was defined as the distance from the corneal endothelium to the anterior lens surface, ACV as the total volume of the AC bounded by the corneal endothelium and the anterior lens surface, and CCT as the thinnest corneal point determined by the pachymetric map.

### Statistical Analysis

The sample size was calculated using G\*Power 3.1.9.6 (Heinrich Heine University, Düsseldorf, Germany) with a power of 0.8 and an  $\alpha$  error of 0.05. For the statistical analysis, IBM SPSS Statistics version 24 (NY, USA) was utilized. To determine if the data followed a normal distribution, the Shapiro-Wilk test was conducted. The Wilcoxon Signed Rank Test was applied to compare the differences between the pre-SCL wearing levels and measurements taken through the lens after 5 hrs of wear. Furthermore, the Spearman correlation test was used to evaluate the correlation between pre-SCL and post-SCL changes in IOP and the anterior chamber values.  $P < 0.05$  was considered the significance level.



**Figure 1.** Six cross-sectional meridians with twelve points where anterior chamber angle measurements were performed.

**Table 1.** Characteristics of eyes included in the study

Patients (female/male)	14 (4/10)
Eyes (right / left)	24 (12/12)
Age (years)*	37.9±10.4
Duration of SCL use (month)*	28.4±22.9 (6-72)
K max (D)†	56.8 (46.58-72.67)

D: Diopter; K max K maximum; SCL: Scleral contact lens.  
\*Mean±standard deviation. †Median (minimum-maximum).

### The Ethics Approval

The study was conducted in accordance with the principles of the Declaration of Helsinki, and written informed consent was obtained from all participants. Ethical approval was granted by Kartal Dr. Lütfi Kırdar City Hospital's scientific research ethics committee under the reference number 2024/010.99/6/6 and date: 26/07/2024.

### RESULTS

Twenty-four eyes (12 right, 12 left) from fourteen patients (4 females, 10 males) diagnosed with KC, with a mean age of 37.9±10.4 years, were included in our study. The duration of SCL use was 28.4±22.9 months (Table 1). The SCL-corrected visual acuity in eyes using SCL significantly improved after 5 hrs of lens wear, increasing from 0.7 (0.2–1.6) LogMAR before wear to 0.1 (0–1.3) LogMAR while wearing them (P<0.001).

A significant increase was observed in the ACA [49 (38-66) vs. 51 (38-68)°], ACD [3.65 (2.57-4.25) mm vs. 3.74 (2.76-4.61) mm], ACV [196 (132-255) mm<sup>3</sup> vs. 210 (150-283) mm<sup>3</sup>], and CCT [417.0 (269-589) µm vs. 478.5 (264-685) µm] values of the eyes included in the study after SCL use compared to before (P=0.001, P<0.001, P<0.001, P<0.001; respectively). Conversely, a significant decrease was noted in K1 [48.46 D (44.21–51.47) vs. 41.64 D (40.12–45.49)] and K2 [56.24 D (50.53–57.12) vs. 41.83 D (41.10–45.85)] values with lens use (both P=0.001). No significant dif-

ferences were observed in IOP levels between measurements taken initially and after SCL removal [10 (6–20) mmHg vs. 11 (6–21) mmHg, respectively, P>0.05] (Table 2). No significant correlations were found between pre- and post-SCL changes in IOP and anterior chamber values (all P>0.05).

### DISCUSSION

This study demonstrated an increase in ACA, ACD, and ACV, as assessed by Sirius CT, in individuals who had been wearing SCL for at least 6 months, observed after 5 hrs of lens wear. Additionally, an increase in CCT values measured by Sirius CT over the lens was noted, along with a decrease in K1 and K2 values. However, no effect of SCL wearing on IOP was observed.

A study showed that mini SCLs were found to improve visual acuity and vision-related quality of life as measured by the National Eye Institute Visual Functioning Questionnaire (NEI VFQ-39) in eyes with KC.<sup>[11]</sup> Another study also found similar results in eyes with KC, pellucid marginal degeneration, and post-keratoplasty astigmatism.<sup>[12]</sup> In our research, a significant improvement in SCL-corrected visual acuity was observed in eyes fitted with SCL, consistent with findings reported in the literature.

Many studies have explored the impact of SCL use on IOP. A study found that wearing a small-diameter (15 mm) SCL for 2 hrs led to no significant difference in IOP, as measured by corneal and scleral pneumotometry.<sup>[3]</sup> A small minority of subjects exhibited an increase in IOP, which was thought to be possibly attributable to tight lens fittings, narrow ACA, and impaired aqueous humor drainage. However, another study reports that properly fitted modern SCLs do not significantly raise IOP in the short term, even though they primarily cause superficial compression of tissue near the scleral spur following 3 hrs of lens wear.<sup>[13]</sup> In another research study, a decrease in IOP was observed after 3 to 8 hrs of SCL wear, as measured by an air-puff tonometer.<sup>[14]</sup> However, depending on the efficiency of aqueous humor drainage, increased IOP

**Table 2.** Measurement changes associated with scleral contact lens wear†

	Pre-SCL	Post-SCL	P*:
SCL-CVA (LogMAR)	0.7 (0.2-1.6)	0.1 (0-1.3)	<0.001
IOP (mm Hg)	10 (6–20)	11 (6–21)	>0.05
ACA (°)	49 (38-66)	51 (38-68)	0.001
ACD (mm)	3.65 (2.57-4.25)	3.74 (2.76-4.61)	<0.001
ACV (mm <sup>3</sup> )	196 (132-255)	210 (150-283)	<0.001
CCT (µm)	417.0 (269-589)	478.5 (264-685)	<0.001
K1 (D)	48.46 D (44.21-51.47)	41.64 D (40.12-45.49)	0.001
K2 (D)	56.24 D (50.53–57.12)	41.83 (41.10-45.85)	0.001

ACA: Anterior chamber angle; ACD: Anterior chamber depth; ACV: Anterior chamber volume; CCT: Central corneal thickness; IOP: Intraocular pressure; SCL: Scleral contact lens; SCL-CVA SCL corrected visual acuity. \*Wilcoxon Signed Rank Test. †Median (minimum-maximum).

during lens wear might stimulate aqueous humor outflow, which could clarify the lower IOP observed after taking off the lenses. Techniques such as the Honan balloon<sup>[15]</sup> and ocular massage before cataract surgery<sup>[16]</sup> show how elevated IOP can be decreased by improving aqueous humor outflow over time. This theory suggests that the effectiveness of aqueous outflow and the degree of IOP elevation during lens use influence the IOP measured after lens removal, thereby explaining why subjects with a normal outflow capacity, unaffected by the lens, may exhibit lower IOP readings.

It has been thought that the increase in IOP might be more pronounced with smaller-diameter lenses and a reduction in the scleral areas, leading to narrower haptic zones.<sup>[3]</sup> Accordingly, a larger lens would distribute contact more broadly across the ocular surface, causing less indentation on the ocular surface. However, a study suggested that SCLs can cause a statistically significant increase of approximately 5 mm Hg in mean IOP after 4 hrs of wear, regardless of lens diameter, in eyes fitted with either a 15.8 mm or 18 mm lens, using transpalpebral Diaton tonometry,<sup>[17]</sup> which is known for its lower concordance with the gold standard, Goldmann tonometry.<sup>[18]</sup> Additionally, Fogt et al.<sup>[19]</sup> investigated how a 15.2 mm and an 18.0 mm SCL diameter affect IOP over 1 hour of lens wear. They measured IOP using both pneumotonometry and transpalpebral tonometry. While pneumotonometry showed no significant change in mean IOP compared to baseline, transpalpebral tonometry revealed a significant difference. In a recent study, the IOP measurements taken from the cornea using pneumotonometry were consistent with baseline levels, showing no significant difference in healthy individuals during 5 hrs of lens wear, and this situation was independent of lens diameter.<sup>[20]</sup> In our study, eyes were treated with 16.5 mm mini-Misa SCL. Consistent with the current research, we measured IOP from the cornea using non-contact pneumotonometry before and after the removal of the SCL, following 5 hrs of wear, and found no significant change in IOP. In addition, IOP correction for CCT tends to underestimate IOP in thin corneas and overestimate it in thick corneas when measured by Goldmann applanation tonometry; however, these corrections are valid only for corneas with intact biomechanics. In eyes with biomechanically compromised thin corneas, such as in keratoconus, IOP measurements may be inaccurate. Furthermore, in edematous corneas that can develop after SCL wear, thick cornea corrections may paradoxically lead to underestimation of IOP.<sup>[21,22]</sup> Therefore, no CCT-based correction was applied in this study, particularly because non-contact tonometry was used.

Additionally, some reports found a statistically significant increase in CCT measured by Pentacam after 8 hrs ( $P=0.001$ )<sup>[6]</sup> and 6 hrs of lens wear before lens removal ( $P=0.06$ ).<sup>[7]</sup> Another study showed no significant difference in CCT values or IOP after SCL wear in eyes with KC or PK measured using the Scheimpflug imaging (CORVIS ST).<sup>[23]</sup> In our current report, we performed Sirius CT while

the SCLs were on the eyes with KC and found a statistically significant increase in CCT ( $P=0.001$ ).

In addition, the mean K1, K2, and Kmax values were found to be significantly lower after lens removal compared to those  $\geq 1$  week after SCL removal using Pentacam in keratoconus patients ( $P=0.037$ ,  $P<0.001$  vs.  $P<0.001$ , respectively).<sup>[24]</sup> A different study demonstrated anterior corneal curvature flattening in keratoconus eyes following 8 hrs of SCL wear.<sup>[25]</sup> Although statistically insignificant, another study also reported a reduction in K1, K2, and Kmax values after 6 hrs of scleral lens wear in eyes with keratoconus.<sup>[7]</sup> In our study, a flattening of K values measured through SCL was observed in keratoconus eyes at the end of 5 hrs, consistent with previous studies ( $P<0.05$ ).

Besides, the only available study examining anterior chamber parameters in patients using SCL reported a statistically insignificant increase in ACA values, measured by OCT, 10 minutes after lens removal following 4 hrs of wear;<sup>[8]</sup> however, it did not include details regarding the measurement process. In the users of mini-SCLs, the pressure exerted and the concentration of force on a smaller area near the limbus can potentially compress structures, including Schlemm's canal, collector channels, or episcleral veins. However, in the current study, no negative effect on IOP was observed when an optimized fitted SCL was used ( $P>0.05$ ). The narrower haptics apply pressure to a small area near the limbus, which may result in perilimbal centripetal compression, leading to an increase in ACA, ACD, and ACV without affecting IOP. In addition, the increases in ACA, ACD, and ACV observed with SCL wear likely reflect the mechanical influence of the lens on corneal curvature and anterior segment morphology. Despite these geometric changes, the absence of any significant alteration in IOP suggests that trabecular outflow dynamics remain largely unaffected. These findings indicate that while short-term SCL use induces measurable anatomical expansion of the anterior segment, it does not appear to pose a clinically relevant risk in terms of IOP. To better assess the impact of SCLs on anterior chamber parameters and IOP, studies comparing different SCL diameters would be beneficial.

Mini-SCLs vault over the cornea and rest on the conjunctiva and sclera, thereby surrounding the limbus without directly contacting the corneal surface. The limbus, forming a ring approximately 1.5–2 mm wide around the cornea, contains the corneal endothelium, scleral vessels, and the initial portion of the trabecular meshwork. Schlemm's canal, located immediately on the scleral side of the limbus, serves as the main pathway for aqueous humor drainage from the anterior chamber into the venous system, with episcleral veins receiving the outflow.<sup>[26,27]</sup> Functionally, mini-SCLs may exert slight pressure on the episcleral veins and lymphatics; however, if properly fitted, venous and lymphatic circulation is generally preserved, and Schlemm's canal and aqueous humor outflow remain typically unaffected.

It is promising that well-fitted SCLs may not cause clinically significant increases in IOP. However, any IOP ele-

vation induced by SCL may still have pathological consequences, particularly in patients with glaucoma and those who wear their lenses regularly and for extended periods. This susceptibility is likely to be higher in patients with thin corneas, such as those with KC.

This study has several limitations, including the lack of access to the cornea and the inability to directly measure corneal IOP while wearing SCL, so we had to rely on IOP measurements taken immediately after lens removal. Additionally, our sample was not evenly distributed between males and females, and the findings of this study may only apply to young patients diagnosed with KC. Since our study included individuals who have been using lenses for an average of approximately 28 months, it may provide an advantage in demonstrating the long-term effects of SCL on IOP. However, although baseline ACA measurements prior to lens wear were available, no longitudinal follow-up was performed. Therefore, evaluating the glaucomatous effect of SCLs based on a single measurement is challenging, which should be acknowledged as another study limitation.

These lenses do not seem to adversely affect IOP or aqueous outflow by narrowing the iridocorneal angle. Studies with an increased number of patients, ensuring a homogeneous age range and gender distribution, including individuals predisposed to glaucoma, as well as the use of lenses with different diameters, will be beneficial.

#### Ethics Committee Approval

The study was approved by the Kartal Dr. Lutfi Kırdar City Hospital Scientific Research Ethics Committee (Date: 26.07.2024, Decision No: 2024/010.99/6/6 and 26/07/2024).

#### Informed Consent

Written informed consent was obtained from all participants.

#### Peer-review

Externally peer-reviewed.

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#### Statements and Declarations

This study was partly presented at the 58th National Congress of the Turkish Ophthalmological Association (TOA), during the TOA-Young Ophthalmologist panel, held in Antalya, Türkiye, from November 20 to 24, 2024.

#### Authorship Contributions

Concept: F.I.S.D., A.P.; Design: F.I.S.D., A.P.; Supervision: A.P.; Data collection &/or processing: F.I.S.D., A.P.; Analysis and/or interpretation: F.I.S.D., A.P.; Literature search: F.I.S.D., A.P.; Writing: F.I.S.D.; Critical review: F.I.S.D., A.P.

#### Conflict of Interest

None declared.

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### Skleral Kontakt Lenslerin Göz İçi Basıncı, İridokorneal Açığı ve Santral Kornea Kalınlığı Üzerindeki Etkisi

**Amaç:** Bu çalışmada, mini-Misa skleral kontakt lenslerin (SKL, çap: 16.5) göz içi basıncı (GİB), ön kamara ve santral kornea kalınlığı (SKK) üzerindeki etkileri araştırılmıştır.

**Gereç ve Yöntem:** En az 6 aydır SKL kullanan keratokonus tanılı hastalar çalışmaya dahil edildi. SKL takılmadan önce ve takıldıktan 5 saat (saat) sonra, lens gözdeyken; ön kamara açısı (ÖKA), ön kamara hacmi (ÖKH), ön kamara derinliği (ÖKD) ve SKK, Sirius kornea topografi cihazı [(Sirius CT), CSO, İtalya] ile değerlendirildi. Ayrıca, GİB ölçümleri lens takılmadan önce ve lens çıkarıldıktan hemen sonra, bir pnömometre (Canon TX-20P; Tokyo, Japonya) ile yapıldı.

**Bulgular:** On dört hastaya (4 kadın, 10 erkek) ait yirmi dört gözde, SKL ile düzeltilmiş görme keskinliği 0.1 (0-1.3) LogMAR bulundu. 5 saatlik SKL kullanımının ardından, lens üzerinden ölçülen SKK değerleri [478.5 (264-685) µm], öncesindeki değerlere göre [417.0 (269-589) µm] anlamlı şekilde daha yüksek bulundu (P<0.001). Lens takılıken ölçülen ÖKA [51 (38-68)° ve 49 (38-66)°], ÖKD [3.74 (2.76-4.61) mm ve 3.65 (2.57-4.25) mm] ve ÖKH [210 (150-283) mm³ ve 196 (132-255) mm³] değerleri de, lens öncesi değerlerden anlamlı olarak daha yüksek bulundu (sırasıyla, P=0.001, P<0.001, P<0.001). SCL kullanımından 5 saat sonra, K1 [48.46 D (44.21–51.47) ve 41.64 D (40.12–45.49); P=0.001] ve K2 [56.24 D (50.53–57.12) ve 41.83 D (41.10–45.85); P=0.001] anlamlı şekilde azaldı. GİB, başlangıç ölçümü ile lens çıkarımı sonrası ölçüm arasında değişiklik göstermedi [10 (6–20) mmHg ve 11 (6–21) mmHg, P>0.05].

**Sonuç:** SKL'ler GİB üzerinde anlamlı bir değişiklik oluşturmazken; 5 saatlik kullanım sonrası SKK, ÖKA, ÖKD ve ÖKH'de artışa neden olmuştur. Bu lensler GİB'i olumsuz etkilememekte ve iridokorneal açının daralmasına yol açmamaktadır.

**Anahtar Sözcükler:** Göz içi basıncı; iridokorneal açığı; ön kamara; Sirius korneal topografisi; skleral kontakt lens.