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Original Article

Comparison of Clinical and Topographic Outcomes of Hybrid and Scleral Lenses in Advanced Keratoconus

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Abstract

Objectives: To evaluate and compare the effects of hybrid contact lenses (HCLs) and mini-scleral contact lenses (MSCLs) on visual acuity, spherical equivalent, topographic astigmatism, and higher-order aberrations (HOAs) in eyes with advanced keratoconus.

Methods: We reviewed the medical records of 43 eyes of 27 patients diagnosed with advanced keratoconus fit hybrid contact lenses (AirFlex®) and mini-scleral contact lenses (Mini-misa®). Pre-fitting examinations included best corrected visual acuity (BCVA), spherical equivalent, topographic findings (topographic astigmatism, maximum keratometry, mean keratometry, central corneal thickness, thinnest corneal thickness, and corneal HOAs. Post-fitting examinations included lens corrected visual acuity, spherical equivalent, topographic astigmatism, corneal HOAs, and contact lens-related discomfort symptoms.

Results: Mean BCVA (log MAR) improved significantly from 0.65±0.27 to 0.14±0.09 with HCL and 0.58±0.25 to 0.15±0.13 with MSCL ($p<0.05$). The mean spherical equivalent and topographic astigmatism measurements decreased significantly in both groups ($p<0.05$). Eight patients in the HCL group experienced lens-related discomfort. Root-mean square HOA decreased significantly in both groups ($p<0.05$).

Conclusion: Significant improvements in visual acuity, spherical equivalent, topographic astigmatism, and HOAs were observed with both lenses. However, higher patient comfort with scleral lenses may lead to higher compliance in patients with advanced keratoconus.

Keywords: Contact lenses, higher-order aberration, keratoconus

Introduction

Keratoconus is the most common noninflammatory corneal ectasia characterized by corneal protrusion and thinning, leading to irregular astigmatism and myopia. It has an estimated prevalence of 54 per 100,000 people in the United States (1, 2). In the early stages of keratoconus, spectacles can correct regular astigmatism. However, in moderately or severely affected patients with irregular astigmatism, contact lenses are considered one of the most effective treatment options (3).

Contact lenses reduce the irregularity of the cornea and create a new regular front surface to the optical system in every stage of keratoconus (4). Rigid gas-permeable contact lenses (RGPLs) reduce higher-order aberrations (HOAs) and improve visual acuity by creating a refractive layer between the lens and the cornea, thus providing a regular refractive surface in front of the cornea (5). However, initial discom-

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fort, corneal scarring at the contact point of the lens and cornea, and lens decentration are the main complications leading to decreased patient compliance (6). Hybrid contact lenses (HCLs) and scleral contact lenses (SCLs) have been introduced into clinical practice for the visual rehabilitation of patients with keratoconus. The main advantage of HCLs and SCLs over RGPLs is that they allow the anterior surface of the cornea to the vault, thus preventing apical corneal touch and providing a better fit (7, 8).

HCLs have a central rigid zone with a circumferential peripheral soft skirt to utilize the visual performance of hard lenses and the comfort and stability of soft lenses (9). SCLs are large-diameter gas-permeable contact lenses designed to vault over the entire cornea and limbus and rest on the sclera. The SCLs that are no more than 6 mm larger than the horizontal visible iris diameter are called mini-scleral contact lenses (MSCLs) (10). This clinical study evaluated and compared the effects of HCLs and MSCLs on HOAs and refractive correction in advanced keratoconus.

Methods

Ethical Approval

The study was conducted by the tenets of the Declaration of Helsinki and was approved by the Ethics Committee of Umraniye Training and Research Hospital (number: B.10.1.TKH.4.34.H.GP.0.01/104; dated: April 8, 2020), İstanbul, Turkey.

Demographic and Clinical Data

The clinical records of the 43 eyes of 27 patients diagnosed with advanced keratoconus and who had been selected to fit HCLs and MSCLs between May 2017 and January 2021 were reviewed. The diagnosis of keratoconus was based on the history of decreased visual acuity in one or both eyes caused by progressive irregular astigmatism and slit-lamp examination findings (Fleischer's ring, Vogt's striae, increased visibility of the corneal nerves, and/or Rizzuti's sign and corneal scarring). Abnormal corneal steepening was confirmed using Sirius (Costruzione Strumenti Oftalmici, Florence, Italy). Patients with other corneal disorders and anterior segment pathologies including vernal keratoconjunctivitis, giant papillary conjunctivitis, dry eye, and previous history of ocular surgery were excluded from the study.

Examination Protocol

Subjective refraction was conducted with trial frame lenses under standardized chart illumination conditions. An autorefractokeratometer (KR 8000, Topcon, Japan) and Snellen chart were used to assess the spherical equivalent and visual acuity levels of the patients. Best corrected visual acuity (BCVA) and lens corrected visual acuity (LCVA) were assessed using the Snellen chart and were converted to the logarithm of minimal angle of resolution (log MAR) notation for statistical analysis. Topographic findings such as topographic astigmatism, maximum keratometry (Kmax), mean keratometry (Kmean), central corneal thickness (CCT), and thinnest corneal thickness (TCT) were recorded before and after lens fitting.

Sirius Corneal Topography and Abberometry System

Sirius is a combination of Scheimpflug and Placido topography. It uses a single 3D Scheimpflug camera and a Placido disk to measure 30,000 points from the posterior and anterior corneal surfaces in less than 1 s. The diagnosis and classification of advanced keratoconus were established according to the Amsler–Krumeich classification. Patients with a mean central keratometry (Kmax) >55.00, with or without central corneal scarring of any size, and corneal thickness of <200 µm were included in the study.

Corneal wavefront analysis was performed using the Sirius Corneal Topography and Aberrometry system. Corneal wavefront errors were analyzed over a 6-mm optical zone and decomposed into Zernike polynomials to the sixth order (11). Among the aberration data expressed in Zernike polynomials, the following were evaluated before and after lens fitting: total HOAs (third to sixth order), spherical aberration ($Z^{0}4$), total root-mean square (RMS) for coma ($Z\pm3^{1}$), total RMS for trefoil ($Z\pm3^{3}$), and total RMS for astigmatism ($Z\pm2^{2}$).

Contact Lens Types

The HCL and MSCL trial procedures were performed according to the manufacturer's instructions. Airflex Hybrid (SwissLens, Prilly, Switzerland) and Mini-misa Mini-scleral (Misa Scleral Lens-Microlens, Arnhem, The Netherlands) contact lenses (CL) were fitted to the eyes of the study subjects. A single experienced examiner performed all fittings according to the manufacturer's fitting guide (BİSA).

Hybrid Lens Fitting Procedure

Airflex hybrid lens features include RGP center (Roflufocon D, ultraviolet [UV] blocker) and soft skirt [(Filcon V3), DK: 100, water content: 50%, diameter: 14.9–15.5 mm, base curves: 5.5–10.0 mm in 0.05-mm steps]. The central vault parameter was chosen according to the steepest K value for the initial CL fitting. For proper fitting, the CL must cover the entire corneal surface and have sufficient movement on the corneal surface with each blink (Fig. 1).

The fitting of the central RGP portion was assessed using fluorescence pooling. The base curve was flattened with excessive fluorescence pooling. On the other hand, if the fluorescence pooling was insufficient, the base curve was steepened. The base curve of the trial lens was determined to be 0.2 mm steeper than the mean keratometric value.

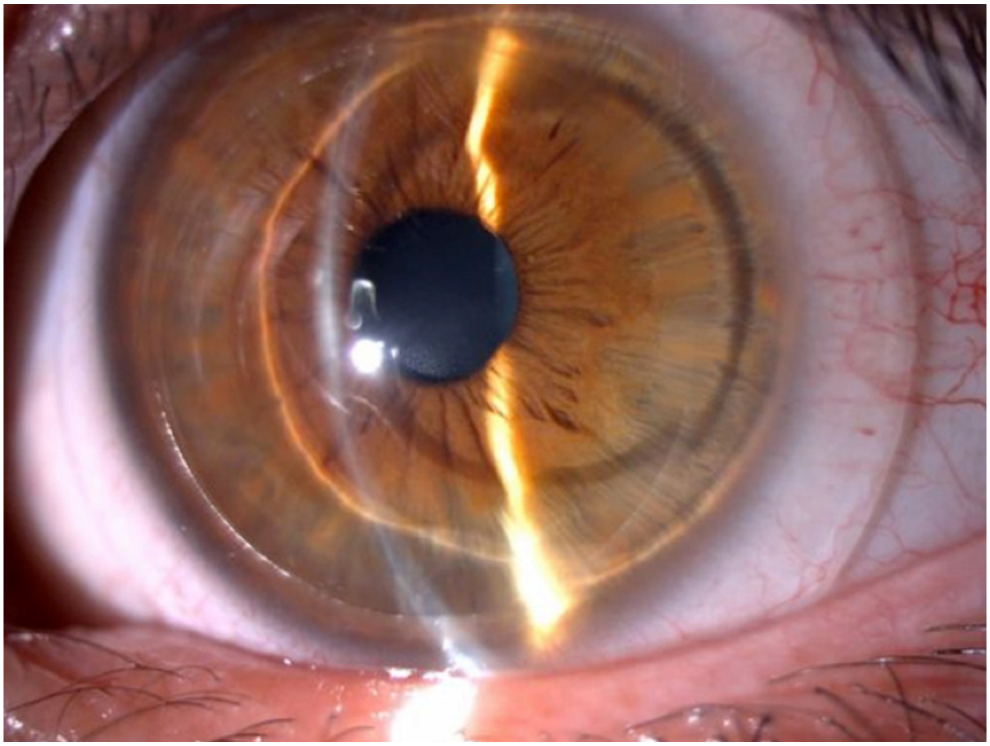

Figure 1. Hybrid lens fitting.

Mini-scleral Lens Fitting Procedure

Mini-misa scleral lens features include fluorosilicone acrylate with hydrophilic monomers: DK: 122, diameter: 16.5–17 mm, sagittal vault: 325–400 µm, base curve: 7.8, 8.3, and 8.8 mm, scleral aperture diameter: 13 mm (normal) and 13.5 mm (wide), scleral curve: standard 13.5 mm, with scleral toricity with 0.75 mm difference. In the first stage of the trial, the sagittal vault value was selected according to the steep keratometry readings. Clearance was approximately 0.25 mm (approximately half of the corneal thickness) at the apex of the cornea. The sagittal vault decreased if excessive clearance or central bubbles were detected, and the sagittal depth was increased in case of corneal touch. The base curve was determined in the second stage of the lens. The landing zone, which is the part of the lens that lands on the sclera without touching the limbal area, is determined according to the diameter of the cornea at the third stage. The normal landing zone of 13.0 mm was used for the average corneal diameter, and the wide landing zone (13.5 mm) was used when the corneal diameter was larger than 11.5 mm. The scleral curve was evaluated in the final stage after approximately 2 h of wearing the trial lens. The good alignment between the scleral curve and sclera indicates that the conjunctiva did not move upon rotation of the lens with the finger, and the patient was comfortable. The lens power was determined during the last phase of the trial for both lenses (Fig. 2).

After the lenses were prescribed to the patients, LCVA, refractive, and topographic measurements were evaluated with lenses in the first-month follow-up examinations. All patients were asked about CL-related discomfort (foreign body sensation, burning sensation, and watery eyes).

Statistical Analysis

All statistical analyses were performed using SPSS (Statistical Package of the Social Sciences, SPSS Inc., Chicago, IL), version 25.0 software. The data were analyzed using the SPSS 25.0 package program. Using the Kolmogorov–Smirnov test, it was found that the data were not normally distributed. In the analysis of the study data, the Mann–Whitney U test was used to compare nonparametric data between groups in addition to descriptive statistical methods (mean, standard deviation, and frequency). The Wilcoxon signed-rank test was used for each group to compare the results before and after lens wear. The p-value of <0.05 was considered significant.

Results

A total of 43 eyes of 27 patients were included in the study. The mean age was 29.81±9.33 (18–47) years; 16 patients (59.2%) were male and 11 patients were female (40.7%). Thirty-three eyes were previously treated with CXL. Sixteen patients were fitted bilaterally (9 patients in the HCL group and 7 patients in the SCL group), and 11 (3 in the HCL group and 8 in the SCL group) patients were fitted unilaterally. There were no statistically significant differences between the groups with respect

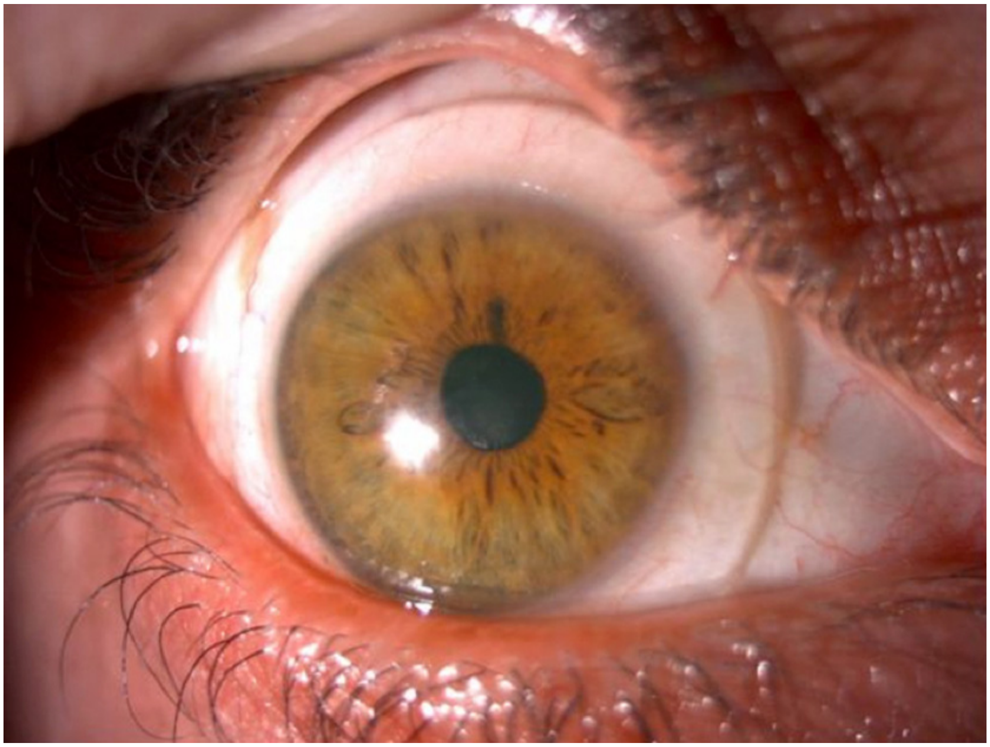

Figure 2. Mini-scleral lens fitting.

to age, sex, and CXL history. The best spectacle corrected visual acuity, SE, and topographic findings (topographic astigmatism, Kmax, Kmean, CCT, and TCT) were not statistically different between the groups (p>0.05). Between-group comparisons of the demographic data, BCVA, SE, and topographic findings including topographic astigmatism, Kmax, Kmean, CCT, and TCT before lens fitting are presented in Table 1.

Mean LCVA (log MAR) improved significantly from 0.65±0.27 to 0.14±0.09 with HCL and 0.58±0.25 to 0.15±0.13 with MSCL (p<0.05). The mean spherical equivalent (−6.24±3.70 D in HCL and −7.01±4.01 D in MSCL) decreased significantly with both lenses (1.1±0.4 D in HCL and −1.24±1.62 D; p<0.001 for both groups). LCVA values were comparable between the HCL and MSCL groups. To-

Table 1. Demographic data, BCVA, SE, and topographic findings

	HCL group (mean±SD)	MSCL group (mean±SD)	Both groups (mean±SD)	p
n (eye)	21	22	43	0.352
Sex (female/male)	8/7	6/6	14/13	0.561
CXL history	11	12	33	0.321
BCVA (log MAR)	0.65±0.27	0.58±0.25	0.72±0.26	0.307
Spherical equivalent (D)	–6.24±3.70	–7.01±4.01	–6.62±3.83	0.265
Topographic astigmatism (D)	4.03±1.39	3.29±1.44	3.66±0.45	0.135
Kmax (D)	63.03±5.19	63.37±3.89	63.20±4.52	0.636
Kmean (D)	53.16±3.18	52.89±3.38	53.02±3.25	0.865
CCT (µm)	448±31	452±36	440±34	0.269
TCT (µm)	440±42	431±35	446±39	0.422

Kmax: Maximum keratometry reading; Kmean: Mean keratometry reading; D: Dioptri; BCVA: Best corrected visual acuity; CCT: Central corneal thickness; TCT: Thinnest corneal thickness; HCL: Hybrid contact lens; MSCL: Mini-scleral contact lens; SD: Standard deviation.

pographic astigmatism measurements decreased significantly from 4.03±1.39 D to 0.90±0.80 D in HCL and from 3.29±1.44 D to 0.69±0.12 D in MSCL for both groups (p<0.05). Eight patients in the HCL group experienced lens-related discomforts such as foreign body sensation, burning sensation, and watery eyes. Between-group comparisons of the LCVA, SE, topographic findings, and discomfort after the lens trial are presented in Table 2.

The values of HOAs between the two groups were comparable before fitting (p>0.05). The RMS of the total HOAs significantly decreased from 2.14±0.58 to 0.97±0.32 (Δ: 1.17±0.26) in HCL and from 2.45±0.74 to 1.34±0.62 in MSCL (Δ: 1.11±0.12) after fitting (p=0.031, p=0.027, respectively). The RMS of coma decreased significantly after fitting in the HCL and MSCL groups (Δ: 1.1±0.13, p=0.027 and Δ: 1.16±0.19, p=0.01, respectively). Spherical aberration changed from negative to positive values in both groups. However, a statistically significant change was found only in the MSCL group after fitting (Δ: 0.26, p=0.042±0.1). The changes in trefoil, quatrefoil, and RMS of secondary astigmatism were statistically insignificant. The post-fitting values of HOAs were comparable between the two groups (p>0.05). The values of the HOAs before and after fitting for each group are presented in Table 3.

Discussion

Contact lenses remain to be an effective and safe option for improving visual acuity in keratoconus. Current designs and materials have significantly expanded the application options for patients with keratoconus (12, 13). According to the 2015 Global Keratoconus Consensus Report, RGP lenses have significantly improved the visual acuity and three-

Table 2. LCVA, SE, topographic findings, and discomfort after the lens trial

	HCL group (mean±SD)	MSCL group (mean±SD)	Both groups (mean±SD)	p
LCVA (log MAR)	0.14±0.09	0.15±0.13	0.14±0.11	0.745
Spherical equivalent (D)	−1.59±1.21	−1.24±1.62	−1.414±3.21	0.054
Topographic astigmatism (D)	0.90±0.80	0.69±0.12	0.79±0.32	0.078
Discomfort (foreign body sensation, burning itching, dryness)	8	0	8	<0.001*

D: Dioptri; LCVA: Lens corrected visual acuity; HCL: Hybrid contact lens; MSCL: Mini-scleral contact lens; SD: Standard deviation.

Table 3. Values of the HOAs before and after fitting for each group

	HCL group (mean±SD)	MSCL group (mean±SD)	p
Before fitting			
RMS of coma (μm)	1.66±0.62	2.18±0.77	0.101
RMS of trefoil (μm)	0.75±0.42	0.73±0.43	0.458
Spherical abberation (μm)	−0.07±0.34	−0.09±0.35	0.343
Total RMS of HOA (μm)	2.14±0.58	2.45±0.74	0.253
Total RMS for astigmatism (μm)	1.08±1.29	0.51±0.94	0.159
After fitting			
RMS of coma (μm)	0.56±0.86	1.02±0.62	0.207
RMS of trefoil (μm)	0.24±0.69	0.13±0.62	0.356
Spherical abberation (μm)	0.08±0.47	0.17±0.62	0.923
Total RMS of HOA (μm)	0.97±0.32	1.34±0.62	0.101
Total RMS for astigmatism (μm)	0.85±0.13	0.62±0.62	0.123

HOA: Higher-order aberration; RMS: Root-mean square; SD: Standard deviation.

dimensional depth perception than glasses in moderate to advanced keratoconus (14). However, apical scarring and lens-related discomfort secondary to RGP lens use may lead to the noncompliance of this patient group (9, 15, 16). Intolerance and complications secondary to RGP lenses have led to the development of safer and more comfortable designs, such as scleral and hybrid lenses. This retrospective study evaluated and compared the topographic parameters and corneal HOAs between mini-scleral and hybrid lens designs in patients with advanced keratoconus.

This study has identified that fitting the Airflex Hybrid and Mini-misa Mini-scleral lenses improved the CDVA (0.51±0.11 log MAR and 0.44±0.14 log MAR, respectively), reduced the cylinder (3.13±0.13 D and 2.6±0.1 D, respectively), SE (4.65±1.04 D and 5.77±1.12 D, respectively), and RMS HOA (1.17 μm and 1.11 μm, respectively). Kumar et al. investigated the effects of Rose K2 XL semi-scleral contact lenses on visual acuity and HOAs in eyes with irregular corneas. They reported that fitting the Rose K2 XL lenses improved the corrected distance visual acuity by a mean 0.51 log MAR, decreased the cylinder (3.6 D), and reduced the RMS HOA (1.1 μm). Consistent with our results, they reported an effective improvement in vision and reduced ocular aberrations with semi-scleral contact lenses (17). Romero-Jiménez and Flores-Rodríguez also reported a significant improvement in corrected distance visual acuity with SCLs in a variety of irregular corneal conditions (18).

Increased HOAs are optical consequences of keratoconus that induce diminished quality of vision in both visual acuity and contrast sensitivity measurements. Therefore, improving the HOAs in keratoconus patients is likely to increase the visual function significantly (19–21). Assadpour et al. compared corneal HOAs between mini-scleral and hybrid lenses in patients with keratoconus. They found that the change in RMS HOA was −0.33±0.26 in the MSCL group and was −0.41±0.46 in the HCL group. In our study, the change in RMS HOA was 1.17±0.26 in the HCL group and 1.11±0.12 in the MSCL group. As our study consisted of advanced keratoconus cases, the pre-fitting HOA values were higher, and the difference between the pre- and the post-fitting HOA values was greater. Similar to our results, they concluded a significant reduction in the total RMS HOAs and vertical coma after fitting both lens designs and the RMS of spherical aberration with mini-scleral lenses (22). Significant coma is particularly relevant for improving visual quality because coma is the dominant form of HOAs in keratoconic eyes (23).

The effect of new generation lenses in improving visual quality and correcting HOAs can be explained by better correction of anterior segment irregularities compared to soft toric or corneal hard gas-permeable lenses because of lesser decentration and rotation of lenses on the corneal surface.

The main limitation of this study is its cross-sectional design and short settling time for post-fitting evaluation of outcomes for both lenses. Long-term studies with a larger number of patients are recommended to validate the possible effects of these lenses on topographic parameters, HOAs, and long-term complications.

There are limited studies comparing HOAs in different lens designs in patients with advanced keratoconus. This study appears to be the first to compare the post-fitting refractive, topographic, and HOA outcomes of hybrid and mini-scleral lenses. We concluded that both lens designs resulted in significant improvement in visual acuity, spherical equivalent, topographic astigmatism, and HOAs. However, patients were significantly more likely to express lens-related discomfort with HCLs than with SCLs. SCLs completely vault the cornea and limbus and rest on the sclera. This results in better comfort and stability, leading to higher patient compliance.

Disclosures

Ethics Committee Approval: The study was conducted by the tenets of the Declaration of Helsinki and was approved by the Ethics Committee of Umraniye Training and Research Hospital (Number: B.10.1.TKH.4.34.H.GP.0.01/104; dated: April 8, 2020), İstanbul, Turkey.

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Conflict of Interest: None declared.

Authorship Contributions: Involved in design and conduct of the study (BISA, AK, UL); preparation and review of the study (BISA, EK); data collection (ADD); and statistical analysis (BISA).

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