• Meta-Analysis •

Clinical outcomes of scleral lenses in keratoconus: a systematic review and Meta-analysis

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Abstract

● **AIM:** To evaluate the efficacy and safety of scleral lenses (SLs) in patients with keratoconus.

● **METHODS:** Electronic databases including PubMed, Scopus, Web of Science, Embase, and Cochrane Library were systematically searched to find the articles on visual function and patient satisfaction following SLs fitting. A random-effects model was applied to specify the pooled values.

● **RESULTS:** Of 833 studies, 19 articles (704 eyes) and 14 studies (475 eyes) were included in qualitative and quantitative synthesis, respectively. Pooled mean difference (PMD) of best corrected visual acuity (BCVA) was -0.37 [95% confidence interval (CI), -0.48 to -0.26] logMAR in favor of SLs treatment. SLs markedly reduced ocular and corneal higher-order aberrations and increased the quality of vision. The overall pooled values for comfort, visual quality and patient satisfaction with SLs were 4.19 (95%CI, 3.83 to 4.55), 4.30 (95%CI, 3.97 to 4.64), and 80.83% (95%CI, 71.54% to 90.13%), respectively. The most reported complications were lens breakage (26.1%) and conjunctival injection (11.4%–15.8%).

● **CONCLUSION:** SLs fitting leads to improved visual outcomes and patient satisfaction in patients with keratoconus.

● **KEYWORDS:** keratoconus; satisfaction; safety; scleral lens

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INTRODUCTION

Keratoconus is a degenerative, non-inflammatory corneal ectatic disorder characterized by irregular astigmatism and significant reduced vision resulting from stromal thinning and protrusion[1]. It typically develops during adolescence and continues into early adulthood, significantly influencing daily activities, visual performance, and overall quality of life[2-3]. Despite improvements in early detection and treatments aimed at slowing progression, the highly irregular corneal shape and poor tolerance to conventional optical corrections make visual rehabilitation in keratoconus particularly difficult[4].

Optical management in keratoconus presents significant challenges, with treatment modalities varying from spectacles and rigid gas permeable (RGP) contact lenses in its early stages to scleral lenses (SLs) in more advanced situations[5]. Spectacles and soft contact lenses typically do not sufficiently correct the irregular astigmatism associated to moderate to advanced keratoconus[6]. Rigid gas-permeable lenses, though traditionally used to improve visual acuity, are frequently associated with discomfort and limited wearing time, particularly in cases of advanced ectasia[7].

SLs have recently become an important tool in the treatment of keratoconus, providing significant improvements in optics and therapy. These lenses with a diameter of larger than horizontal visible iris diameter that rest entirely on the scleral tissue and create a fluid-filled reservoir between the lens and the corneal surface[8-9]. This unique design allows SLs to cover corneal irregularities, neutralize astigmatism and ultimately, improving visual acuity, comfort, and vision-related quality of life, especially in patients with advanced disease or those who are intolerant to other types of lenses[4,10].

These lenses are typically used when previous lenses have been unsuccessful and can be very helpful in managing advanced keratoconus[11]. In addition, recent studies suggest that SLs wearing may offer therapeutic advantages, including

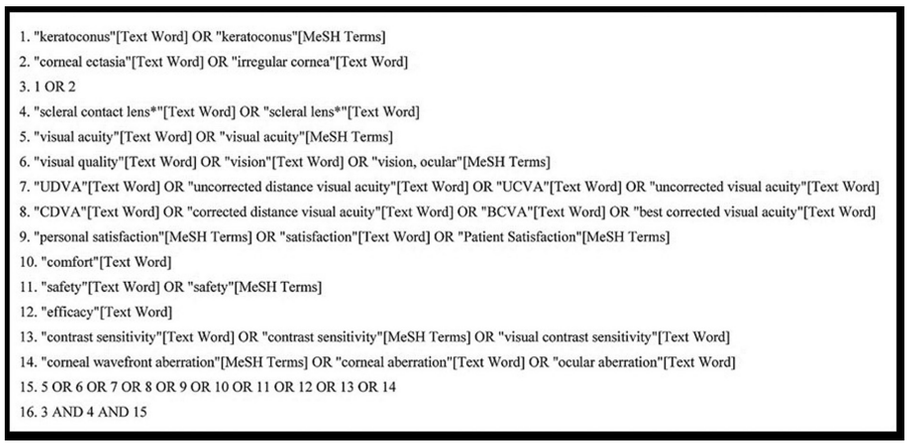


Figure 1 Search strategy MeSH: Medical subject headings.

improved corneal regularity and more stable tomographic parameters over time[12-13].

With the continuing progress in SL technology, these lenses have shifted from being used solely for vision correction to serving as important therapeutic tools for a range of corneal and ocular surface disorders. However, despite their increasing acceptance, studies remain dispersed and inadequate. The purpose of this systematic review and Meta-analysis is to bring together the available evidence, focusing specifically on visual outcomes, safety and satisfaction of patients with keratoconus following SLs fitting.

MATERIALS AND METHODS

Search Strategy The following electronic databases were searched up to January 22, 2025 without any language restriction: Web of Science, PubMed, Scopus, Embase and Cochrane Library. Search strategy is illustrated in Figure 1. First, it was created for PubMed and then was applied in the rest of databases.

Inclusion/Exclusion Criteria The PICO of this study was defined as follows: Population: individuals with keratoconus; Intervention: scleral lenses; Comparison: without scleral lenses; Outcome: best corrected visual acuity (BCVA), efficacy, higher order aberrations (HOAs), contrast sensitivity (CS), safety, comfort and satisfaction.

Studies which were performed in patients with ocular pathologies other than keratoconus or a history of ocular surgery were excluded. Animal or laboratory studies, conference abstracts, case reports, and review articles were also excluded.

Study Selection and Data Extraction The extracted articles were entered into EndNote X6. After removing duplicates, two reviewers (Pakbin M and Dashti M) independently screened the studies according to the inclusion criteria. Initially, screening of title and abstract and then full text was performed. Any disagreements were resolved by a third reviewer (Rahmani S). The following information were extracted and entered into an Excel sheet: the first author's name, publication year, study location, study design, lens diameter, duration of lens wearing, sample size, quality assessment, age of the participants and the study outcomes (before and after lens fitting).

Quality Assessment The STROBE checklist was applied for assessing the quality of included studies. This checklist contains 22 items for evaluation of methodology of observational studies. Each item received a score of 0 or 1 and total score was calculated in percent. According to this percent, the articles were categorized into following 5 groups: very high quality (>80%), high quality (60% to 80%), moderate quality (40% to 60%), low quality (20% to 40%) and very low quality (<20%). Low quality studies were removed from the Meta-analysis.

Outcome Efficacy was the primary outcome and safety, comfort and satisfaction with the lens were the secondary outcomes. BCVA was the main outcome for efficacy. HOA and CS were the other outcomes of visual function. Safety was determined as complications and adverse events experienced by patients at last follow up. Due to the high heterogeneity and lack of data, Meta-analysis was not possible for HOA, CS, and the complications data of lens wearing.

Statistical Analysis The STATA version 14.0 (College Station, Texas) was used for analysis. The mean difference was calculated to determine the difference of BCVA between before and after lens fitting. The Cochrane's Q test was used to determine between-study heterogeneity and its value was calculated by I^2 statistic. I^2>50% indicated that there was a high heterogeneity. A random effect model was applied to assess the pooled values. The level of significance was set at 0.05 for all analyses.

RESULTS

Initially, 833 records identified through databases until January 22, 2025. After removing duplicates, 426 studies were screened. Then, screening of the titles, abstracts and full texts of remaining records led to exclusion of 398 irrelevant

studies. A further 9 studies were excluded because they did not report the results of keratoconus population, separately[14], their participants had history of cross-linking[12,15-16] or intracorneal ring segment implantation[17] and Prosthetic Replacement of the Ocular Surface Ecosystem (PROSE) was used in their studies[18-20]. Also one study had been found twice due to its different order of its authors[21].

Nineteen articles were included in the systematic review and Meta-analysis of BCVA was performed by excluding 9 further studies. Three studies were excluded despite having inclusion criteria because they did not report the BCVA in logarithm of the minimum angle of resolution (logMAR)[21-23]. One study was excluded due to its low quality[24]. One other study was also excluded because of the suspicious visual acuity (VA) data. Despite the BCVA was reported before and after SL wearing, it seems that the pre-lens application data was related to the initially lens fitting[25]. Two studies[26-27] reported median for VA data which were not comparable with other studies. Habitually corrected visual acuity (HCVA) was reported in one study[28] which could not be analyzed alongside data from other studies that reported BCVA. Eventually, 1 study reported only the visual quality and patients satisfaction with SL and did not have BCVA results[29] (Figure 2).

Study Characteristics Table 1 shows the characteristics of studies included in the systematic review. Fourteen studies with total sample size of 475 eyes were included in the Meta-analysis. The highest and lowest sample size were 157[30] and 13[25] eyes, respectively. The minimum and maximum age of the studies participants were 11[31] and 62y[32], respectively. Seven studies were of moderate quality[4,21-22,26-27,33-34] and 11 were of high quality[23,25,28-32,35-38]. Eleven studies were prospect ive[4,21,23-24,27,29,32,35-38] and 5 articles have retrospective[22,30-31,33-34] design.

Visual Acuity Visual outcomes of each study and pooled mean difference (PMD) of BCVA (after lens application minus before) were demonstrated in Table 1 and Figure 3, respectively. The overall PMD of the BCVA was -0.37 logMAR (95%CI, -0.48 to -0.26), indicating a statistically significant difference in favor of SL application. The maximum and minimum logMAR visual gain were -0.78 (95%CI, -1.63 to -0.07)[31] and -0.01 (95%CI, -0.47 to 0.45)[38], respectively. Subgroup analysis based on the study design showed a better BCVA improvement with SL in retrospective studies compared with prospective ones (-0.37 versus -0.36 logMAR; Figure 4).

Higher Order Aberrations Two studies evaluated HOA changes with SLs. Kumar *et al*[27] reported a significant reduction in ocular HOAs using SLs. Tarutta *et al*[24] observed that the level of all aberrations in keratoconic eyes have been dropped to nearly normal values after lens fitting. Spherical aberration was changed from negative to positive in both studies (Table 2).

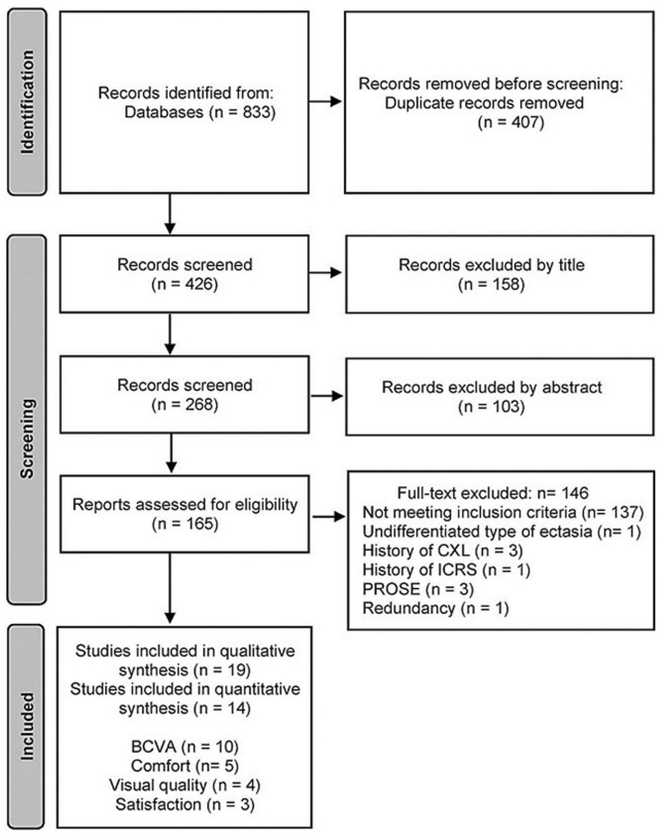


Figure 2 Study flow chart of selection process ICRS: Intrastromal corneal ring segments; CXL: Corneal cross-linking; BCVA: Best-corrected visual acuity; PROSE: Prosthetic Replacement of the Ocular Surface Ecosystem.

Contrast Sensitivity CS was assessed only by Bagature Vurgun *et al*[23]. They evaluated CS using SLs with 2 different diameters (15 mm and 16.50 mm), before and during 4h after lens fitting. The authors reported a significant improvement in CS after lens application (the 15 mm group: 0.43±0.34 to 1.25±0.23, P<0.001 and the 16.5 mm group: 0.56±0.24 to 1.30±0.20, P<0.001) which was followed by a significant decrease after 2h (P=0.02) in both groups. However, no significant difference was observed in CS between the two lens groups at any time point.

Comfort and Satisfaction Table 3 outlines the comfort, visual quality and satisfaction reported by patients with keratoconus while wearing SLs. All studies showed a relatively good to high comfort, visual quality and satisfaction levels.

Two studies[29,36] used 100-mm VAS (visual analog scale) to evaluate the comfort and visual quality with SLs which 100 representing the highest level of comfort and 0 representing the poorest comfort. Three studies[21-23] reported comfort and visual quality using a 5-point Likert scale (5 indicating the highest level of comfort and visual quality). They also measured the overall satisfaction with SLs by 100-mm VAS.

Figures 5-7 demonstrates that the overall pooled values for comfort, visual quality and satisfaction of patients with SLs

Table 1 Characteristics and best corrected visual acuity (logMAR) reported by studies in the systematic review mean±SD

Author	Publication year	Country	Design	Study quality (%)	Age (range, y)	Lens diameter (mm)	Number of case (eye)	KC grade	BCVA before lens application	BCVA after lens application	*P*
Akkaya Turhan[21]	2020	Türkiye	Prospective & observational	53.33	29.9±8.5 (15–41)	16.5 20	13 (23)	I=1 (43%) II=12 (45.2%) III=6 (26%) IV=4 (17.5%)	0.4±0.2 (Snellen)	0.8±0.1 (Snellen)	<0.0001
Akkaya Turhan[22]	2020	Türkiye	Retrospective	56.66	25.2±5.9 (17–36)	16–18.2	24 (29)	III=3 (55.2%) IV=4 (17.2%)	0.4±0.14 (Snellen)	0.93±0.12 (Snellen)	<0.0001
Bagatur Vurgun[23]	2025	Türkiye	Prospective, randomized, comparative	66.66	24.4±5.4 (16–32)	15	10 (17)	-	0.36±0.15 (Snellen)	0.92±0.07 (Snellen)	<0.001
					21.7±4.5 (18–29)	16.50	10 (15)		0.35±0.20 (Snellen)	0.81±0.18 (Snellen)	0.001
Baudin[35]	2021	France	Prospective & observational	80	33.5±13.8	17 18	24 (41)	I=8 (20%) II=16 (39.2%) III=10 (24%) IV=7 (17%)	0.5±0.4	Visual gain (-0.4±0.4)	<0.001
Carracedo[25]	2017	Spain	Experimental	66.66	35.22±6.98 (27–48)	16.5	13 (13)	-	0.14±0.14	0.25±0.12	<0.001
Esen[36]	2017	Türkiye	Prospective & observational	60	27.9±7.7	16.5 17.5	11 (22)		0.36±0.4	0.13±0.1	<0.001
Formisano[32]	2021	Italy	Prospective	60	38.4±11.8 (26–62)	16.8	30 (60)	I=5 (8.33%) II=14 (23.33%) III=18 (30%) IV=23 (38.33%)	0.2±0.25	−0.002±0.041	<0.05
Fuller[30]	2020	USA	Retrospective	66.66	34.8±11.7 (14–64)	15.8±0.6	86 (157)	I=1 (0.6%) II=17 (10.82%) III=60 (38.21%) IV=41 (26.11%) V=36 (22.92%) Unknown=2 (1.27%)	0.5±0.3	0.08±0.1	<0.0001
Hadimani[4]	2024	India	Prospective	50	28.66±6.57 (21–50)	16	14 (28)	-	0.47±0.25	0.03±0.07	<0.001
Jun[33]	2022	Korea	Retrospective	50	32.22±10.87 (16–55)	14.7 14.9	24 (44)	I=9 (20.45%) II=22 (50%) III=9 (20.45%) IV=4 (9.09%)	0.43±0.38	0.09±0.08	<0.001
Kim[34]	2017	Korea	Retrospective	57.14	32.8±4.5 (19–55)	15.8	38 (38)	-	0.85±0.78	0.10±0.11	<0.0001
Knoeri[37]	2024	France	Prospective	60	34.3±8.8	16.5	14 (25)	IV=80%	0.5±0.4	0.1±0.19	<0.0001
Lee[28]	2023	Korea	Retrospective	73.33	29.90±7.85 (17–45)	14.1 14.7 14.9	19 (26)	-	HCVA 0.75±0.79	0.12±0.20	<0.001
Rocha[31]	2021	Brazil	Retrospective	63.33	27.57±11.47 (11–52)	16–18.2	14 (14)	IV	1.01±0.48	0.23±0.12	0.001
Serramito[29]	2019	Spain	Prospective	76.66	37.7±7.91 (18–62)	16.5	30 (30)	I or II	-	-	-
Tarrutta[24]	2022	Russia	Prospective	33.33	18–37	14.9 15.2 15.6	20 (39)	I=8 (20.51%) II=3 (7.69%) II/III=12 (30.76%) III=16 (41.02%)	0.54±0.07 (Snellen)	0.95±0.08 (Snellen)	-
Uysal[38]	2021	Türkiye	Longitudinal prospective	60	27.6±4 (21–32)	16.5–17	16 (16)	I or II	0.33±0.21	0.32±0.25 (1mo) 0.34±0.17 (3mo) 0.34±0.22 (6mo)	0.0911
Fan[26]	2023	China	Cross-sectional	56.66	22 (20, 23)[a]	14.50	20 (28)	Moderate=28	0.2 (0.1, 0.2)[a]	0.05 (0.1, 0.2)[a]	-
					21 (17.5, 23)[a]		20 (24)	Severe=24	0.4 (0.4, 0.7)[a]	0.1 (0.06, 0.21)[a]	-
Kumar[27]	2021	India	Prospective	53.33	25±5 (19–33)	15.9 16.4	- (15)	Mild=5 (33.33%) Moderate=8 (53.33%) Severe=2 (13.33%)	0.3 (0.20, 0.4)[b]	0.00 (0.00, 0.07)[b]	<0.01

[a]Median (Q_1, Q_2); [b]Median (95% confidence interval of the median). BCVA: Best corrected visual acuity; HCVA: Habitually corrected visual acuity; SD: Standard deviation; KC: Keratoconus.

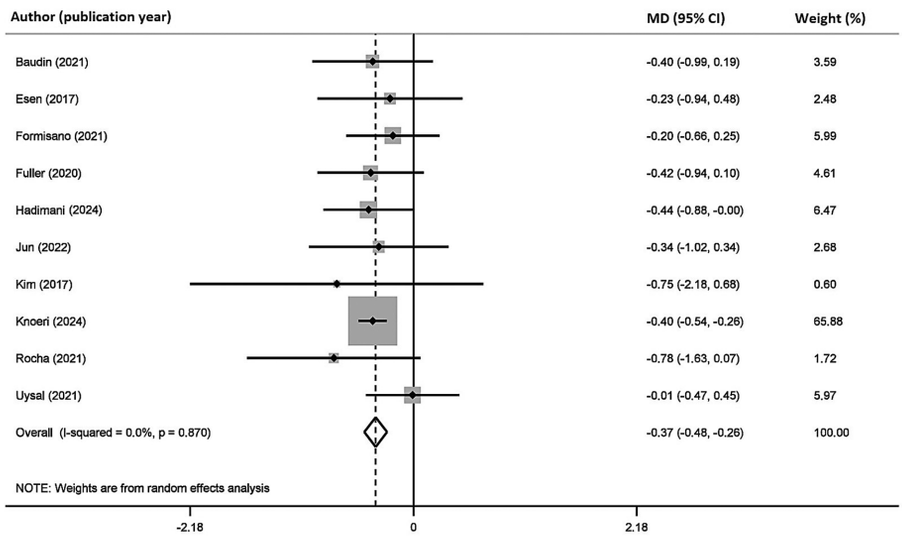


Figure 3 PMD of BCVA before and after scleral lens application BCVA: Best corrected visual acuity; CI: Confidence interval; PMD: Pooled mean difference.

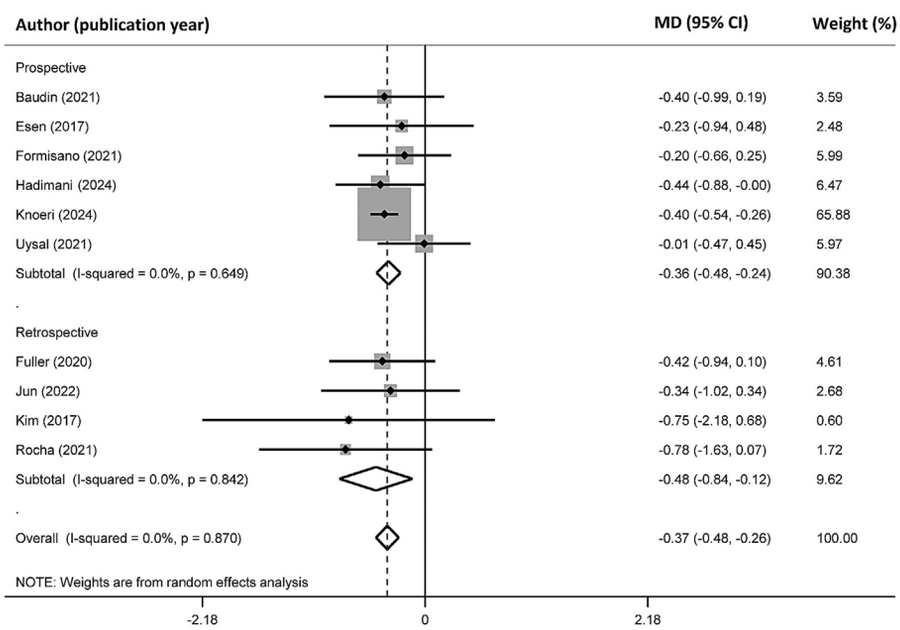


Figure 4 Subgroup analysis of BCVA before and after scleral lens application based on study designs BCVA: Best corrected visual acuity; CI: Confidence interval; MD: Mean difference.

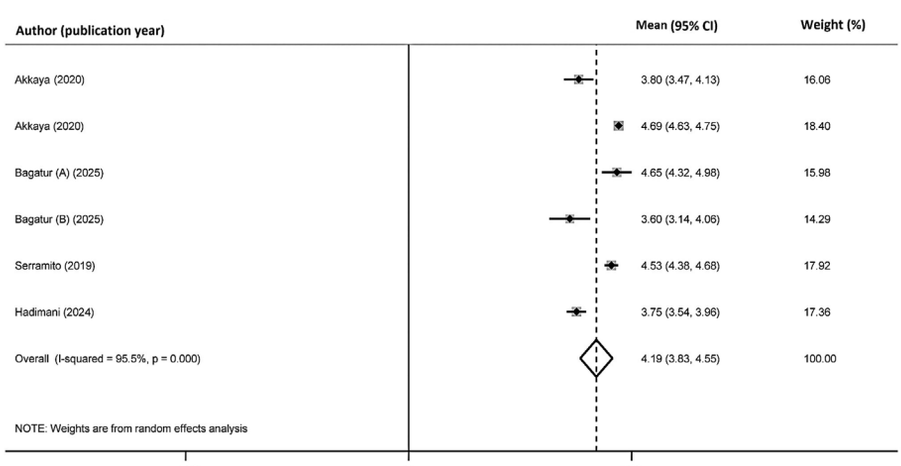


Figure 5 Pooled scores of comfort after scleral lens wearing CI: Confidence interval.

Table 2 RMS of HOA outcomes for included studies

Author	Evaluation time	HOA	SA	Secondary astigmatism	Trefoil	Horizontal coma	Vertical coma	Coma
Kumar[a][27]	Pre-SL fitting	1.30 (0.95, 1.81)	-0.02 (-0.32, 0.06)	0.21 (0.14, 0.42)	0.55 (0.25, 0.75)	-0.12 (-0.23, -0.06)	-0.42 (-0.95, -0.29)	0.89 (0.74, 1.27)
	Post-SL fitting	0.47 (0.37, 0.58)	0.08 (0.07, 0.14)	0.08 (0.04, 0.12)	0.09 (0.06, 0.17)	0.10 (0.06, 0.21)	0.22 (0.19, 0.27)	0.35 (0.31, 0.52)
Author	Evaluation time	HOA	SA	Trefoil 6	Trefoil 9	Coma 7	Coma 8	
Tarrutta[b][24]	Pre-SL fitting	3.14±1.75	-1.1±0.07	0.37±0.40	-0.03±0.24	-1.32±0.72	-0.18±0.60	-
	Post-SL fitting	1.06±0.90	0.31±0.05	-0.01±0.03	-0.001±0.030	0.01±0.03	0.007±0.030	-

[a]Median (95%CI) of ocular aberrations. [b]Mean±SD of corneal aberrations. HOA: Higher-order aberrations; RMS: Root mean square; SA: Spherical aberration; SL: Scleral lens; CI: Confidence interval; SD: Standard deviation.

Table 3 The score of comfort, visual quality and overall satisfaction reported by patients of included studies

Author	FU duration	Comfort		Visual quality		Satisfaction (100-mm VAS)
		Score	Scale	Score	Scale	
Akkaya Turhan[21]	4h	3.8±0.8	5-point Likert scale	3.8±0.6	5-point Likert scale	68.7±19.1
Akkaya Vurgun[22]	Not clear	4.69 (4–5)	5-point Likert scale	4.62 (3–5)	5-point Likert scale	88.1 (70–100)
Bagatur[23]	4h	4.65±0.7	5-point Likert scale	4.76±0.4	5-point Likert scale	95.7±6.0
		3.60±0.9	5-point Likert scale	3.73±0.7	5-point Likert scale	65.3±20.3
Serramito[29]	1mo	Baseline 86.14±15.98 Last FU 90.78±8.5	100-mm VAS	Baseline 83.21±12.87 Last FU 89.69±9.64	100-mm VAS	-
Esen[36]	8h	77	VAS (0–10)×100	-	-	-
Hadimani[4]	3mo	7.5±1.16	Scale of 1–10	-	-	-
Kim[34]	1y	*n* (%); 1: 21 (55%); 2: 16 (42%); 3: 1 (3%)	Asking in general: 1. very comfortable; 2. comfortable; 3. mild irritating	-	-	-

FU: Follow up; VAS: Visual analog scale.

Table 4 The complications reported by patients of included studies

Author	Follow-up duration	Adverse events and or complications
Fuller[30]	At least 1y	Physiological adverse events: 15 (9.6%) Hydrops (3.2%), pingueculitis (1.3%), CIE's (1.3%), CLARE (1.3%), abrasion (1.3%), phlyctenulosis (1.3%) and microbial keratitis (0.6%) Lens related adverse events: 87 (55.4%) Broken lens (26.1%), lens deposits (8.9%), intolerance (7.6%), reservoir clouding (7%), handling (3.8%) and poor lens welting (1.9%) Decreased VA due to KC progression: 23 (14.6%)
Jun[33]	3mo	Conjunctiva injections: 5 (11.4%) Hyperemia: 2 (4.54%) Handling difficulty: 2 (4.54%) Punctate keratitis: 1 (2.3%)
Kim[34]	1y	Injection or compression: 6 (15.8 %) Handling difficulty: 2 (5.3%) Lens discontinue: 1 (2.6%)
Rocha[31]	6mo	Lens intolerance and gradually reducing the time of use: 1 (7.14%)
Lee[28]	3mo	Lens discontinue: 7 (14.9%)
Uysal[38]	6mo	No adverse event

VA: Visual acuity; CIE's: Corneal infiltrate events; CLARE: Contact lens acute red eye; KC: Keratoconus.

were 4.19 (95%CI, 3.83 to 4.55), 4.30 (95%CI, 3.97 to 4.64) and 80.83% (95%CI, 71.54% to 90.13%), respectively. The comfort and visual quality values converted to the 5-point Likert scale for drawing their forest plots.

Kim *et al*[34] determined the lens comfort by asking the patients in 3 categories. Two studies[4,35] evaluated the quality of life changes with SLs after 3mo using the National Eye Institute Visual Function Questionnaire. Hadimani *et al*[4] found that overall median scores were increased from 1735 to 2930 and Baudin *et al*[35] observed an improvement of this scores by 19.50±19.1 points on average.

Complications Complication of SLs were reported by 4 studies. Fuller and Wang[30] divided adverse events into two categories of physiological and lens related. They found physiological adverse events in 9.6% and lens-related ones in 55.4% of their participants. Hydrops (3.2%) and broken lens (26.1%) were introduced as the most frequent physiological and lens-related adverse events, respectively. Conjunctival injection was the most frequently complications occurred in the studies of Jun and Lee[33] and Kim *et al*[34] with the frequency of 11.4% and 15.8%, respectively (Table 4).

DISCUSSION

Clinical outcomes of SLs in patients with keratoconus were evaluated in this systematic review and Meta-analysis. The overall results suggested that SLs enhance the optical quality and comfort.

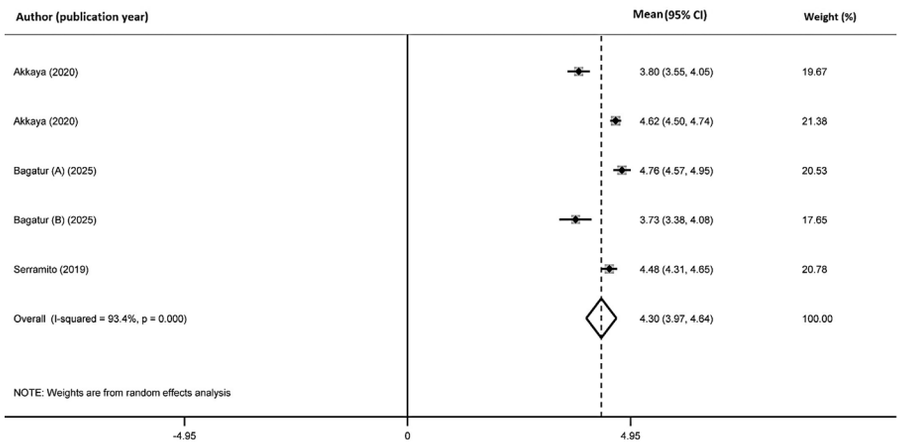


Figure 6 Pooled scores of visual quality after scleral lens wearing CI: Confidence interval.

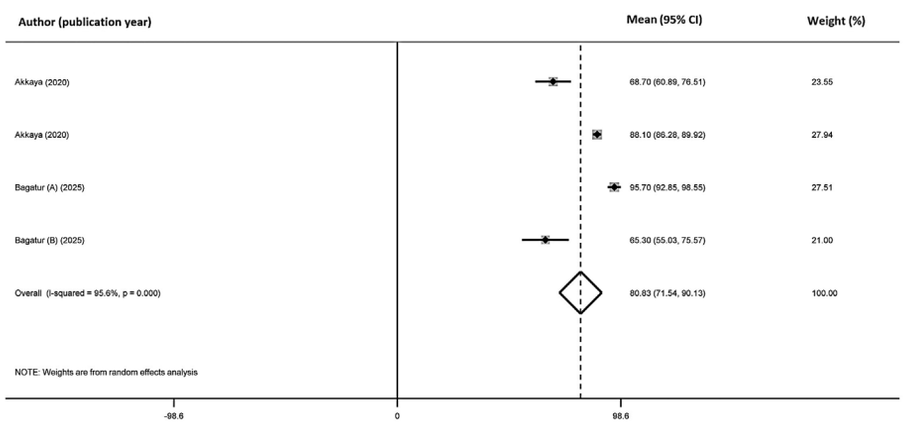


Figure 7 Pooled scores of patient satisfaction after scleral lens wearing CI: Confidence interval.

Included studies showed improvement in mean BCVA with SLs. Rocha *et al*[31] reported significant mean visual gain from 1.01±0.48 logMAR with spectacles to 0.23±0.12 logMAR with SLs (P=0.001) in patients with advanced keratoconus. Likewise, Lee *et al*[19] found a significant improvement in mean logMAR values from HCVA (0.85±0.78) to best lens-corrected visual acuity (0.10±0.11; P<0.001). In consistent with other studies, Akkaya Turhar *et al*[22] reported that mean Snellen VA was increased from 0.4±0.14 with glasses to 0.93±0.12 with SLs (P<0.0001). Fan *et al*[26] demonstrated a significant improvement in median logMAR values of BCVA during SL wear in patients with moderate (from 0.2 with glasses to 0.05 with SLs) to severe (from 0.4 with glasses to 0.1 with SLs) keratoconus. These findings were confirmed by recent reviews[10,39].

While several studies support the VA improvements in keratoconic eyes, only few of them reported HOAs and CS results following SLs corrections with a vast heterogeneity. For instance, Kumar *et al*[27] pointed out that SLs wear mitigate the ocular higher order root mean square error (HO-RMS) in patients with keratoconus and therefore enhance the optical quality. They mentioned a significant reduction with median values from 1.30 to 0.47 (P<0.01). Coma (0.89 *vs* 0.35, P<0.01) and trefoil (0.55 *vs* 0.09, P<0.001) aberrations (the most elevated errors in patients with keratoconus) showed the most prominent improvements. Similarly, Tarrutta *et al*[24] observed such improvements with SLs in keratoconic eyes but the reported values were belonging to the corneal not ocular. Spherical aberration was not changed dramatically reflecting less responsiveness of SA to SL correction.

Although Bagatur Vurgun *et al*[23] demonstrated a significant improvement in CS by SLs, 4h after lens wear observed a significant decrease in CS. They suggested that midday fogging may responsible for this finding which could not have detected by standard VA assessment.

A comprehensive review conducted by Barone *et al*[39] indicating that SLs are effective treatment in rehabilitation of visual function in subjects with irregular cornea. Although, meibomian gland dysfunction and tear-film instability can affect SL comfort, fogging, conjunctival injection, and wearing time. Recent systematic review and Meta-analysis studies conducted by Chen *et al*[40-41] revealed that thermal pulsation therapy provides relevant context for managing ocular surface factors that influence SL success and patient satisfaction. Some keratorefractive procedures[42] and punctal occlusion[43] as a tear-film support, prevent dry-eye-related visual outcomes and may result in SL comfort, ocular surface protection, and long-term lens tolerance.

In the present study all the included studies exhibited relatively good subjective performance of SLs in management of subjects with keratoconus. Bagatur Vurgun *et al*[23] reported both 15 mm and 16 mm SL wearing, lead to a high level of comfort (4.65 & 3.60), visual quality (4.76 & 3.73) and general satisfaction (95.7 & 65.3). However significantly higher results were found in lens group with smaller diameter. The study of Kim *et al*[34] demonstrated that SLs were comfortable in 42% and very comfortable in 55% of keratoconic eyes. Only one patient found this lens mildly irritating and discontinued to wear it after 3mo. Akaya Turhan *et al*[22] reported the high scores for comfort (4.9), visual quality (4.62) and overall satisfaction (88.1) using 5-point Likert and 100-mm VAS, respectively. Advanced stage of keratoconus was observed in majority (72.4%) of their participants. Improved visual function on NEI-VFQ questionnaires in patients with keratoconus were demonstrated by Baudin *et al*[35] and Kreps *et al*[44] after 3 and 6mo SLs wearing, respectively. Recent review[39] and systematic review[45] highlighted the ability of SLs to markedly enhance the quality of vision, patient satisfaction and quality of life.

Included studies exhibited good safety of SLs however, patients were monitored from 3mo to 1y. Fuller and Wang[30] found broken lens as the most frequent lens related adverse event in one year follow up and decreased vision because of keratoconus progression was observed in 14.6% of their participants. No SLs related adverse event was detected by Uysal *et al*[38] over a 6mo period. Keratoconic patients (grade of I or II) with SLs daily wear time of 8h were included in their study. Rocha *et al*[31] evaluated SLs in advanced keratoconic eyes (stage IV based on the tomographic keratoconus classification) for at least 6mo and noted that only 1 eye (7.14%) was intolerant to use of SLs. Longer-term follow ups in different stages of keratoconus may reveal undetected complications due to the disease progression.

The most important limitation of this systematic review and Meta-analysis was limited number of relevant studies. All included studies were observational and almost half of them had retrospective design with a potential bias. In addition, visual improvement was evaluated using SLs in comparison with the spectacles. Therefore, quantitative synthesis primarily reflects effectiveness of SLs compared to the spectacles (pre-post improvement) not comparative against RGP lenses, hybrids, or corneal procedures. Randomized controlled trials (RCTs) and studies having both treatment and control groups lead to robustness of the available evidence. Lack of long-term studies was another limitation of this study. Due to the progressive nature of keratoconus, some long-term outcomes such as complications and lens intolerance rates could not be well detected in short-term follow ups. Moreover, our study suffered from high degree of heterogeneity among evidences. Differences in sample sizes, SLs diameters, reported outcomes such as visual acuity, vision quality scales and questionnaires made analysis of pooled data impossible. Finally, very few studies reported HOAs and CS. Regardless of these limitations, the present study provided valuable information about SLs performance in keratoconic eyes. However, this systematic review and Meta-analysis presented pooled BCVA change after SLs wearing. Also provided satisfaction outcomes, HOA and CS changes and summary of reported complications following SLs application. It was the first study to present all this evidence together.

In conclusion, this systematic review and Meta-analysis showed that SLs provide an improvement in VA, HOAs, CS, comfort and quality of life in subjects with keratoconus. while available literature demonstrates good efficacy and safety of these lenses, RCTs should be conducted and follow the participants for a longer period to confirm the durability of SL success. Additionally, patient adaptation and comfort with SLs will be addressed by long-term studies with different stages of keratoconus.

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