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# Visual quality with corneo-scleral contact lenses for keratoconus management

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ABSTRACT

*Purpose:* To assess the visual quality achieved by fitting corneo-scleral contact lenses (CScL) for keratoconus management.

*Methods:* Thirty patients with keratoconus presented to have CScL fitted because of the unsatisfactory visual quality they experienced with their contact lenses or spectacles. The eye examination included visual acuity assessment, anterior eye biomicroscopy, ocular fundus examination, corneal topographic analysis, endothelial-cell count, contrast sensitivity and aberrometry. The fitting process was performed using a diagnostic trial set. Subjective visual quality and comfort, and contact lens wear time were also reported. Patients were monitored for one year.

*Results:* Three patients discontinued CScL wear before one year. Therefore, 27 eyes of 27 patients (19 male and 8 female) participated in this study. The mean age was 36.1 ± 13.1 (mean ± SD) years. Statistically significant differences were found in logMAR visual acuity between the best spectacle-corrected vision and after CScL fitting (mean ± SD, 0.23 ± 0.30 and 0.00 ± 0.14, respectively; $p < 0.001$). The total high-order aberrations decreased significantly (55%), and the spatial frequencies of contrast sensitivity all improved to normal range values of the population. Furthermore, high subjective visual quality and comfort ratings, and prolonged usage times (mean ± SD, 13.44 ± 2.38 h a day) were reported. No adverse ocular effects or clinically relevant changes in corneal parameters, visual quality, comfort or usage time were found one year after wearing CScL.

*Conclusion:* This CScL seems to be safe and healthy, providing optimal visual quality, comfort and prolonged usage times in patients with keratoconus.

## 1. Introduction

Keratoconus is typically a progressive, bilateral (usually asymmetrical) corneal disorder characterised by corneal paracentral steepening with apical thinning at the same place [1,2]. The main adverse optical effects induced by keratoconus are the presence of irregular astigmatism and the increase in high order aberrations (HOAs), which can have a devastating effect on the quality of vision [1–3]. Keratoconus causes a significant coma aberration, because the cone is usually displaced from the centre of the cornea which is the most important refractive element of the eye [3–6]. Then ocular symptoms, such as halos, glare, starburst and ghost images, along with decreased contrast sensitivity occur depending on the severity of the disease [1,7,8]

Traditional sphero-cylindrical spectacles do not compensate HOAs [3]. Consequently, when a high number of HOAs appear in keratoconus patients, rigid gas-permeable (RGP; corneal, corneo-scleral and scleral) contact lenses are suggested as the best solution for management. These contact lenses provide a regular refractive surface; moreover, with the tear layer between the posterior lens surface and anterior corneal surface, they can mask corneal surface irregularities [9,10]

Corneal RGP lenses may be a successful option in the management of mainly mild-to-moderate keratoconus cases. However, when comfort decreases or corneal damage appears due to the increase of the corneal irregularity, these contact lenses are no longer well tolerated (excessive movement and/or decentred lens) [11]. In these cases, although other types of contact lenses, such as hybrid lenses or a piggyback contact lens system can be tried, corneo-scleral contact lenses (CScL), which rest partly on the cornea and partly on the sclera, or full scleral contact lenses seem to be a suitable option. In relation to corneal RGP lenses, CScL and full scleral lenses provide excellent comfort, centration and

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stability (due to their large diameter) [12]. These advantages may provide a greater decrease in HOAs and therefore an improvement in visual quality, since factors like lens movement and decentration bring about increasing HOAs [10].

Studies on fitting corneo-scleral contact lenses in patients suffering from keratoconus are not commonly reported in the scientific literature, especially in the case of small diameters (around 13 mm). To the best of our knowledge, only a few cases of fitting CScL have been reported in previous studies, and these had diameters greater than 14 mm. [11,13] However, fitting CScL with small diameters (12.60 mm to 13.50 mm) has significant advantages in relation to other CScL with a greater diameter or full scleral lenses, as they are easier to handle and commonly do not need fluid upon lens placement nor a plunger for removal. They may avoid problems due to scleral toricity on the surface of the eye [14] and, since the clearance is small (30 to 50 μm or less), the quality of vision is typically better, avoiding problems resulting from a greater tear layer behind the lens, such as turbidity [15].

There is little knowledge about the extent to which fitting CScL can provide an improvement in visual quality. It should be noted that despite the apparently normal visual acuity that may be achieved with RGP lenses, patients with keratoconus could still experience a reduction in contrast sensitivity [7,8]. The residual HOAs may remain elevated, which could affect contrast sensitivity, and the quality of vision may decrease [7]. With a view to dealing with this deficiency, the present study describes our experience in fitting a corneo-scleral contact lens with a multi-aspherical geometry design for the management of keratoconus in terms of visual quality.

## 2. Patients and methods

### 2.1. Patients

A total of 30 patients participated in this study. Such patients presented irregular corneas due to keratoconus and they were referred from other ophthalmological centres because of the unsatisfactory visual quality they experienced with the contact lenses or spectacles they were using at that time. They were willing to be fitted with a new corneo-scleral contact lens with a multi-aspherical geometry design to improve their visual quality. None of them presented any ocular-surface disease or associated iatrogenic corneal ectasia. This study complies with the ethical standards required by the University of Valencia which concur with the tenets of the Declaration of Helsinki.

### 2.2. Data collection and contact lenses used

Prior to contact lens fitting, the patients who wore contact lenses discontinued their use for at least 15 days. All patients underwent a comprehensive eye examination at the FISABIO Oftalmología Médica Clinic, which included the best spectacle-corrected visual acuity assessment, anterior eye biomicroscopy, ocular fundus examination, endothelial-cell count with a specular microscope (SP-3000P, Topcon Medical Systems Inc., Japan), and a corneal topographic analysis using the Pentacam HR Eye Scanner (Oculus Inc., Wetzlar, Germany) which also shows central corneal thickness. Data from the corneal topographic patterns and slit-lamp biomicroscopy findings confirmed the diagnosis of keratoconus (the Amsler-Krumeich classification was used to grade keratoconus).

Visual quality was determined with the Vision Contrast Test System (VCTS 6000, Vistech Consultants Inc., Dayton, OH, USA). This is a subjective test that was performed following the guidelines of the manufacturer with the monocular full correction of patients in place, under photopic conditions of 85 cd/m$^2$ and a testing distance of 3 m. Furthermore, an aberrometer was also used for evaluating visual quality, the Alcon LADARWave (Custom Cornea Wavefront System, Alcon Laboratories Inc, Ft Worth, Texas, USA). This is an objective ocular aberrometry test, which was performed in a dark room under monocular conditions in accordance with the guidelines of the manufacturer. To calculate ocular aberrations, the pupil size chosen was 6 mm, since ocular aberrations are mainly manifested under mesopic conditions (e.g. driving at night). To reach a pupil size of almost 6 mm, pharmacological intervention for mydriasis (1% tropicamide eye drops; one drop initially and another drop after 5 min) was used. When full dilatation was reached, aberrometry measurements were performed, including the root mean square in terms of micrometres of deviation (μm) of defocus, astigmatism, coma aberration, spherical aberration and other HOAs.

Once an eye examination was performed, patients were fitted with a corneo-scleral contact lens (Scleracon, Lenticon, Madrid, Spain) based on a multi-aspherical geometry design (spherical in the front surface, and spherical optic zone with aspherical peripheral curves in the posterior surface) with three curves: the base curve, the intermediate or small transition curve and the peripheral or scleral curve. The material used to manufacture these lenses is a highly gas-permeable fluoro-silicone acrylate, (Optimum extreme, Contamac Ltd, Saffron Walden, UK): its oxygen permeability (ISO) is $125 \times 10^{-11}$ (cm$^2$/s) (mlO2)/(ml x mmHg). The average central thickness of the lenses is approximately 0.29 mm (for −3 D) and the fitting parameters are as follows: base curves range from 5.80 to 9.20 mm (in 0.5 mm steps), peripheral or scleral curves range from 5.60 to 11.4 mm (in 0.10 mm steps), diameter ranges from 12.60 to 13.50 mm, and power from +20.00 to − 25.00 D (in 0.25 D steps). Plasma treatment is suggested for these contact lenses.

### 2.3. Fitting procedure

The trial-lens method was used to fit the CScL. This trial-lens set consisted of 35 lenses with a specific back optic zone radius (BOZR) and peripheral curve, and a total diameter of 12.60 mm. According to the suggestions described by the manufacturer, two steps are needed to determine the appropriate lens (first the BOZR and then the peripheral curve).

To determine the BOZR, the first trial lens was commonly selected 0.20 mm steeper than the average central keratometry readings, in accordance with the suggestions of the manufacturer, although other flatter lenses can be chosen depending on the severity of the keratoconus (no guidelines are available). Once the lens had been inserted in the eye for some minutes, a sterile strip impregnated with sodium fluorescein (BioGlo; HUB Pharmaceuticals, Rancho Cucamonga, CA, USA) and moistened with one or two drops of saline solution was used, which was applied touching the superior conjunctiva of the eye. Then the patient was instructed to blink several times to assess the fluorescein pattern between the central cornea and the contact lens (Fig. 1). If this trial lens did not fit correctly, it was replaced by another lens with a steeper or flatter BOZR, until it showed a slight alignment to minimal apical corneal clearance. In most cases, a slight “feather touch” on the apex of the cornea is well tolerated since these lenses usually have little movement (0.5 mm) and do not irritate the apex of the cornea [14]. In some cases, although a strong corneal support may appear to be present, this does not necessarily mean that there is actually “touch”, as fluorescein layers may be present with a thin layer of roughly 20 μm, so the human eye is not able to see it [14]. No grade of the corneal apex staining was permitted. Finally, an over-refraction on the selected trial lens was performed.

The second step consisted of verifying the peripheral curve. If the previously selected trial lens did not show an appropriate fluorescein pattern with an adequate tear exchange, other lenses with a steeper or flatter peripheral curve were tried. The lens should show no compression on the limbus (since stem cells are located in this area and are necessary for corneal health) and/or the conjunctival vessels under the contact lens (Fig. 2) [14]. No grade of limbal and/or conjunctival staining was permitted. The overall diameter of the lens was assessed, which should extend beyond the limbus. If changes in the diameter were necessary, it was decided empirically. Finally, the lens should

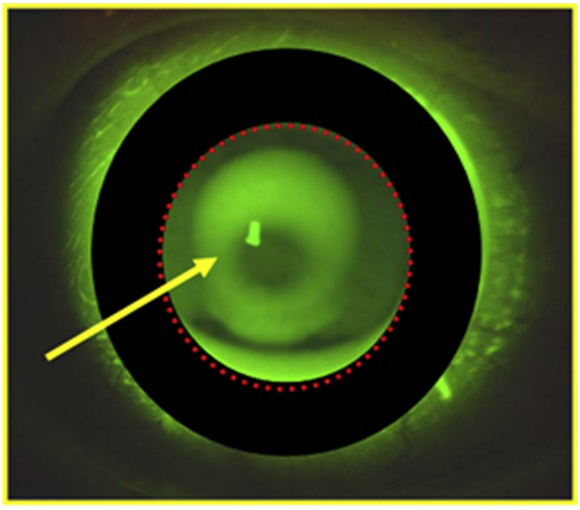

**Fig. 1.** Central fluorescein pattern when fitting a corneo-scleral contact lens in a case of keratoconus (first step in the fitting process).

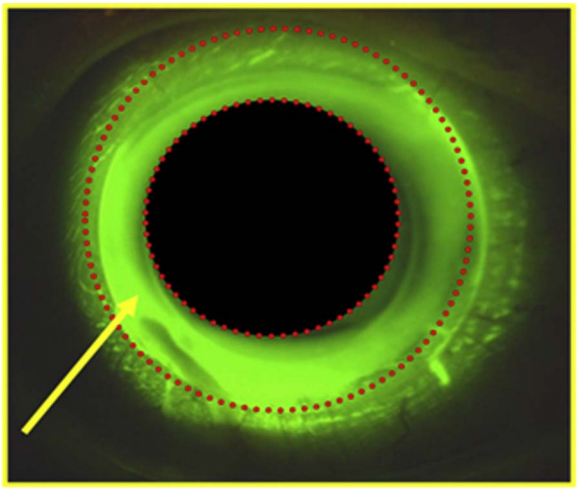

**Fig. 2.** Peripheral fluorescein pattern when fitting a corneo-scleral contact lens in a case of keratoconus (second step in the fitting process).

present a good lens position with optimum lens movement, using the push-up method, indicative of the appropriate peripheral curve. Data from these two steps were needed to manufacture the lenses.

Once the clinic had received the manufactured lenses, the patients were given their next appointment. The contact lenses were inserted and allowed to settle on the eye for 30 min, then visual acuity was recorded and the lens position and movement were evaluated by slit-lamp biomicroscopy. After 2 h wearing the lens, it was ascertained that there were no adverse ocular effects, nor compression on the limbus or conjunctival vessel under the contact lens. If the contact lens provided an acceptable clinical fit, the patients were instructed in lens care (a multipurpose solution and a weekly or fortnightly protein remover were suggested) and handling (similar to corneal-RGP lenses). They were also advised to increase lens-wear time by 1 h a day for seven days. Changes in the BOZR, power, peripheral curve radii and overall diameter were performed until the contact lens was considered optimal for dispensing. The number of contact lenses required and visits performed until achieving the optimal lens are also reported.

After 8 h of CScL wear, the contact lens was checked again and appropriate fit was verified. No adverse ocular events should be seen using the Cornea and Contact Lens Research Unit (CCLRU) grading scale, developed by the School of Optometry and Vision Science at the University of New South Wales, Sydney, Australia, (CCLRU grading

**Table 1**
Criteria of success in fitting corneo-scleral contact lenses.

| Parameters | Complete Success | Partial Success | Unacceptable |
|---|---|---|---|
| – Visual Acuity with CL as regards BSCVA | Improving two decimal lines or more | Improving one decimal line or equal | worse |
| – CL wear time | > 10 h | 10–8 h | < 8 h |
| – Subjective comfort | > 3 | 3 | < 3 |
| – Subjective visual quality | > 3 | 3 | < 3 |

CL, contact lenses; BSCVA, best spectacle-corrected visual acuity; Subjective comfort scale (1, strongly uncomfortable; 2, uncomfortable; 3, neither uncomfortable nor comfortable; 4, comfortable; and 5, very comfortable); Subjective visual quality scale (1, very poor; 2, poor; 3, neither poor nor favourable; 4, favourable; and 5, very favourable).

scale units < 1). Subsequently, visual acuity, contrast sensitivity, and ocular aberrations (on a pupil size of 6 mm with pharmacological intervention for mydriasis) were measured with the contact lenses. This procedure was used to compare the improvement of visual quality before and after fitting these contact lenses.

Follow-up appointments were made for 1, 6 and 12 months later. Data from visual acuity, subjective comfort on a typical five-level Likert scale (1, strongly uncomfortable; 2, uncomfortable; 3, neither uncomfortable nor comfortable; 4, comfortable; and 5, very comfortable), subjective visual quality on a typical five-level Likert rating system (1, very poor; 2, poor; 3, neither poor nor favourable; 4, favourable; and 5, very favourable), and contact-lens wear time were reported. Table 1 shows the criteria of success in fitting this contact lens (complete success when all the parameters improved; partial success when a parameter did not improve or contact lens wear time between 8 and 10 h; and it was deemed unacceptable if a parameter was worse or contact lens wear was < 8 h). The criteria of wearing time as a measure of success was based on the study by Ortenberg et al [16].

After 1 year wearing CScL, corneal parameters, contrast sensitivity and ocular aberrations were again measured with the contact lenses, which made it possible to observe if there were any differences in visual quality and corneal integrity when wearing these contact lenses for 1 year.

All the devices used in this study were calibrated prior to all the sessions, and the measurements were performed by professionals who were expert in handling them; furthermore, the same methodology was always applied.

### 2.4. Data analysis

The SPSS 15.0 software (SPSS Inc., Chicago, IL, USA) was used for statistical analysis. A non-parametric statistical test (the Wilcoxon signed-rank test) was used to analyse the differences in visual acuity with the best spectacle-corrected value, and data from ocular aberrations and contrast sensitivity before and after CScL fitting, as well as after fitting CScL and 1 year of CScL wear. For statistical analysis, all visual acuities were converted to logarithm of the minimum angle of resolution (logMAR). The level for statistical significance was taken as $p < 0.05$.

## 3. Results

Three patients discontinued CScL wear at 1 month of follow-up (two patients with degree 2 of keratoconus decided to go back to their previous soft toric contact lenses and one with degree 1 of keratoconus chose to return to her spectacles). They reported some discomfort with these contact lenses and they felt better with their previous correction, consequently this study comprised 27 eyes of 27 patients who completed a 1-year follow-up. Table 2 shows demographic data of participants in this study.

**Table 2**
Demographic data of the 27 participants in the study.

| Parameters | | Patients (%) |
|---|---|---|
| Sex | Male | 19 (70.37) |
| | Female | 8 (29.63) |
| Age | < 20 years | 4 (14.82) |
| | 21–40 years | 12 (44.44) |
| | 41–60 years | 11 (40.74) |
| Ametropic | Hyperopia (0.00 to +10.00 D) | 3 (11.11) |
| | Low myopia (−0.25 to −6.00 D) | 15 (55.55) |
| | Medium myopia (−6.25 to −10.00 D) | 4 (14.81) |
| | High myopia (> −10.00 D) | 5 (18.52) |
| Average central keratometry | ≤ 48 D (Stage I AK) | 18 (66.67) |
| | 48–53 D (Stage II AK) | 7 (25.92) |
| | 53–55 D (Stage III AK) | 0 (0.00) |
| | > 55 D (Stage IV AK) | 2 (7.41) |
| Corneal astigmatism | 0.00 a 2.00 D | 12 (44.45) |
| | 2.25 a 4.00 D | 8 (29.63) |
| | 4.25 a 6.00 D | 4 (14.81) |
| | > 6.00 D | 4 (14.81) |

AK, Amsler-Krumeich clasification.

**Table 3**
Clinical outcomes of the patients and the fitted parameters with corneo-scleral contact lenses (27 eyes).

| Parameters | | Mean ± SD | Range |
|---|---|---|---|
| Clinical | Spherical equivalent with BSCVA(dioptres) | −5.18 ± 6.88 | +7.36 to −22.5 |
| | Corneal astigmatism (dioptres) | 3.01 ± 1.95 | 0.10–7 |
| | Average central keratometry (dioptres) | 46.79 ± 4.67 | 41.50–62.10 |
| | Endothelial-cell count (cell/mm$^2$) | 2621 ± 351 | 1764–3312 |
| | Central corneal thickness (μm) | 475 ± 45 | 343–540 |
| Contact lens | BOZR (mm) | 7.55 ± 0.49 | 6.40–8.20 |
| | Total diameter (mm) | 12.94 ± 0.30 | 12.60–13.50 |
| | Power (dioptres) | −4.15 ± 6.33 | +9.25 to −21 |

BSCVA, the best spectacle-corrected visual acuity; BOZR, back optic zone radius.

The mean age of the 19 men and 8 women was 36.1 ± 13.1 years (mean ± SD; ages ranged between 16 and 60 years) and they were all Caucasian. Table 3 shows the mean ± SD of the spherical equivalent with the best spectacle-corrected value, corneal astigmatism, average central keratometry, endothelial-cell count, central corneal thickness, as well as the parameters when fitted with CScL (BOZR, total diameter, and power lens). An average of 2.52 ± 0.70 visits (range 2–4) was needed to complete the fitting process and 1.37 ± 0.56 lenses per eye (range 1 to 3) until deemed optimal for dispensing.

The mean ± SD of logMAR visual acuity before (with the best spectacle-corrected value) and after fitting CScL was 0.23 ± 0.30 (range 1.0 to 0.0) and 0.00 ± 0.14 (range 0.4 to −0.2), respectively; statistically significant differences were found ($p < 0.001$). Visual acuity improved two decimal lines or more with respect to the best spectacle-corrected value in 85% of eyes (23 of 27 eyes). The mean of wearing time was 13.44 ± 2.38 h a day (range 8 to 16). A percentage of 96.3% (26 of 27 eyes) wore these contact lenses ≥ 10 h a day. High levels of subjective comfort (4, comfortable; and 5, very comfortable) were reported (74.07%; 20 of 27 eyes), as well as subjective visual quality (4, favourable; and 5, very favourable) in 66.66% of eyes (18 of 27 eyes). Therefore, complete success (see Table 1) was achieved in 66.66% of eyes (18 of 27 eyes), partial success in 29.62% of eyes (8 of 27 eyes), and the result in 1 eye out of 27 was deemed unacceptable.

Fig. 3 shows the mean of ocular aberrations before and after fitting CScL. Statistically significant differences were found in all ocular aberrations except spherical aberration (p = 0.855). It should be noted that total HOAs decreased 55%. Fig. 4 shows the average of spatial frequencies of contrast sensitivity (1.5, 3, 6, 12 and 18 cycles/degree) before (with the best spectacle-corrected value) and after fitting the CScL. Statistically significant differences were found in all spatial frequencies.

After 1 year of follow-up, the values of central corneal thickness, average central keratometry, and contrast sensitivity scores were maintained with respect to initial fitting of the CScL (no statistically significant differences were found). However, endothelial-cell count improved slightly with statistically significant differences. The total HOAs improved slightly, though no statistically significant differences were found; however, spherical and other HOAs improved significantly (see Table 4).

## 4. Discussion

The Scleral Lens Education Society classified scleral lenses on the

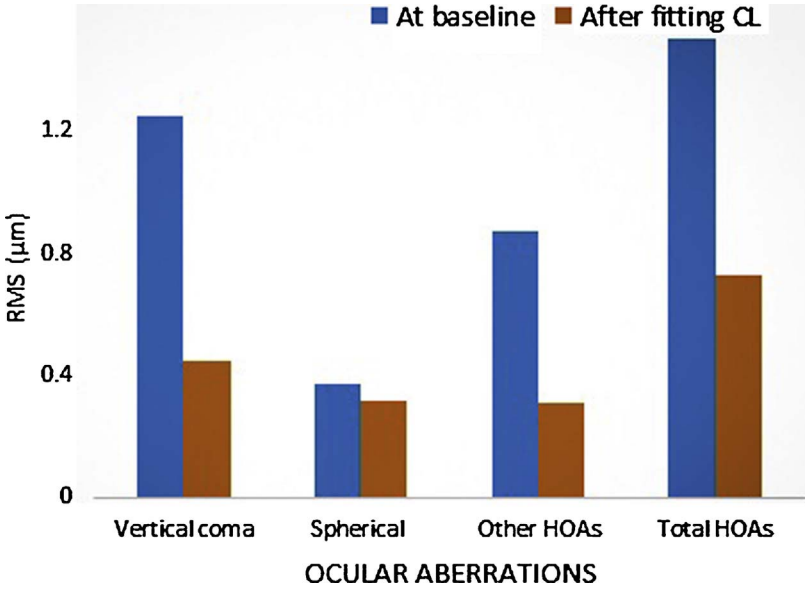


**Fig. 3.** Differences in ocular aberrations between before and after fitting corneo-scleral contact lenses (27 eyes with a pupil diameter of 6 mm).

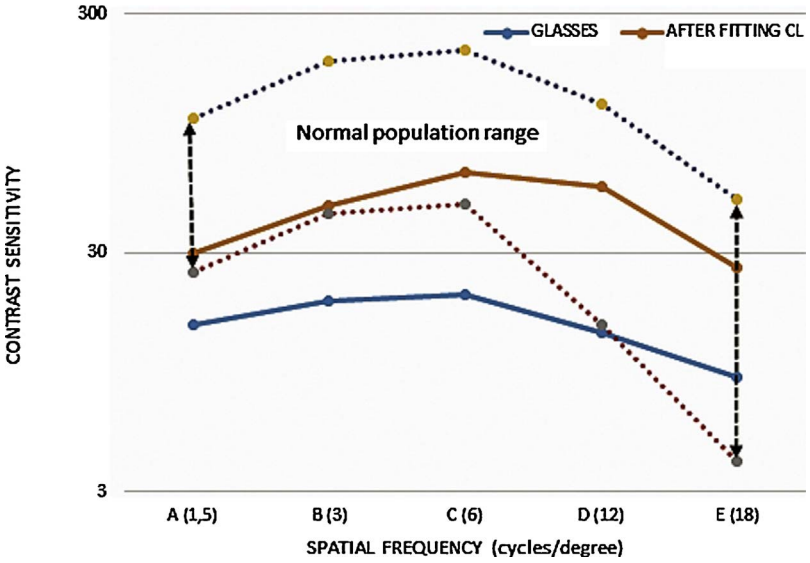


**Fig. 4.** Differences in spatial frequencies between before (with the best spectacle-corrected value) and after fitting corneo-scleral contact lenses (27 eyes).

**Table 4**
Differences in corneal integrity, contrast sensitivity scores and ocular aberrations between the initial fitting and after 1 year wearing corneo-scleral contact lenses (27 eyes).

| | Initial fitting Mean ± SD | After 1 year Mean ± SD | P value[a] |
|---|---|---|---|
| Corneal integrity | | | |
| Km (D) | 46.79 ± 4.67 | 46.55 ± 4.90 | 0.467 |
| ECC (cell/mm$^2$) | 2621 ± 351 | 2650 ± 361 | 0.022[b] |
| CCT (μm) | 475 ± 44 | 471 ± 54 | 0.423 |
| Contrast sensitivity | | | |
| A (scores) | 4.8 ± 1.5 | 4.9 ± 1.4 | 0.180 |
| B (scores) | 5.1 ± 1.3 | 5.0 ± 1.3 | 0.102 |
| C (scores) | 4.8 ± 1.6 | 4.9 ± 1.7 | 0.527 |
| D (scores) | 5.1 ± 1.8 | 5.2 ± 1.8 | 0.257 |
| E (scores) | 5.0 ± 2.1 | 5.2 ± 1.8 | 0.160 |
| Ocular aberrations | | | |
| Total coma (μm) | 0.45 ± 0.40 | 0.43 ± 0.36 | 0.199 |
| Spherical (μm) | 0.32 ± 0.22 | 0.25 ± 0.20 | 0.000[b] |
| Other HOAs (μm) | 0.31 ± 0.13 | 0.26 ± 0.09 | 0.010[b] |
| Total HOAs (μm) | 0.73 ± 0.44 | 0.70 ± 0.39 | 0.171 |

Km, average central keratometry; ECC, endothelial-cell count; CCT, central corneal thickness; HOAs, high order aberrations.
[a] P value from the Wilcoxon signed-rank test.
[b] Statistically significant differences.

basis of the resting zone area of the lens on the ocular surface [17]. They defined CScL as those lenses that rest partly on the cornea and partly on the sclera, and scleral lenses as those that rest entirely on the sclera. However, this classification can be confounding when dealing with keratoconus management, since the same lens, depending on its fit, can act as a CScL or scleral lens depending on whether there is a slight "feather touch" or not. In this study, the contact lens fitted was deemed a corneo-scleral contact lens, since in most cases it was difficult to avoid this "feather touch" because of their small diameter. However, according to other terminology based on the lens diameter, these lenses can be classified as semi-scleral lenses (diameter between 12.5 to 15.0 mm) [18].

At the outset of this study, all the patients presented an unsatisfactory quality of vision with the glasses or contact lenses they were using at that time. Therefore, we proposed to ascertain to what degree CScL can provide an improvement in visual quality.

The results of this study show that visual acuity improved significantly, which concurs with previous studies on fitting scleral or CScL on corneal irregularities [11,13,19]. Moreover, the patients reported high levels of subjective comfort and prolonged usage times, 26 of 27 eyes wore these contact lenses ≥10 h a day. This period of time allows day-long work activities and travelling, thereby achieving an improvement in the quality of life of these patients [16]. In a previous study fitting the same CScL on irregular corneas of post-LASIK eyes, high levels of subjective visual quality were also reported (4, favourable; and 5, very favourable) in 16 of 18 eyes, therefore these lenses appear to improve subjective visual quality significantly on irregular corneas [19]. With respect to other CScL, a previous study in which Rose K2 XL were fitted in 12 eyes with keratoconus, the authors used a questionnaire (VF-14) to evaluate visual function [13]. They found that it improved with respect to previous corneal RGP lenses. However, these previous studies [11,13] on fitting CScL did not report specific tests for evaluating the objective and subjective quality of vision.

This study shows that the subjective visual quality, using a contrast sensitivity test, improved after fitting CScL. Although low and intermediate spatial frequencies presented low levels, which concurs with previous studies [7,8], they were within the normal population range (see Fig. 4). With respect to objective visual quality, residual HOAs remained slightly elevated when compared with normal eyes after fitting CScL [3]. The total HOAs had an average of 0.73 μm, however this value should be 0.471 μm or less in a normal healthy population between the ages of 30 and 39 years, with a mesopic pupil diameter of 6 mm [3]. In particular, vertical coma and other HOAs were higher than normal eyes (although they were reduced 2.8 times), however spherical aberration presented nearly normal levels [3]. Although these CScL have a spherical geometry design in the optic zone, spherical aberration does not appear to be a significant factor in the increased residual HOAs. These results suggest, as did those of previous studies, that although RGP contact lenses have a significant effect in masking corneal surface irregularities, internal aberrations and possibly posterior corneal aberrations remain uncompensated [6,7].

In fact, when fitting these CScL on irregular corneas of post-LASIK eyes [19], the outcomes showed a greater decrease of the total HOAs (78%) than the present study (55%). The main differences in ocular aberrations before fitting the CScL were in vertical coma (approximately 2.5 times higher, 0.52 to 1.25 μm) and other HOAs (approximately 5.5 times higher, 0.16 to 0.87 μm). After fitting CScL, normal values of residual HOAs were achieved in post-LASIK eyes, whilst as discussed previously, they were slightly elevated in the patients in this study. These differences may be due to posterior corneal aberrations, which may be higher in keratoconus eyes than in post-LASIK eyes with a more regular posterior corneal surface.

After one year wearing CScL, visual quality was maintained, although statistically significant differences were found in spherical

aberration and other HOAs, which improved slightly, however these do not appear to be clinically relevant. Corneal integrity was also maintained in relation to the initial fitting, although a slight increase, though not clinically relevant, was found in the endothelial-cell count. These lenses continued showing good fit characteristics. It should be noted that although the parameters of these lenses seem to be stable, replacement in a period between 12 and 18 months is suggested.

Neither were any significant adverse events of the cornea manifested during one year of CScL wear, and only three eyes presented mild adverse events. They had slight conjunctival hyperaemia, which was resolved with a lubricant and weak hypotonic ophthalmic solution (0.1% of sodium hyaluronate) without preservatives, along with removal and cleaning of the lens after 6 h of wear.

With regard to the fitting procedure, these CScL may prove to be a challenge for eye practitioners, however the process is similar to fitting corneal RGP, with regard to the number of visits and the number of lenses ordered that were necessary to achieve the precise fit [11,19]. A guideline that can help to determine the first trial lens, in accordance with the specific characteristics of the CScL fitted in this study (multi-aspherical geometry design and diameter), is the correlation observed between the BZOR and the average keratometric values. For an average keratometric value < 43 D, the BOZR tended to steeper values, while if this value was > 43 D, the BOZR tended to flatter values which increased with the severity of keratoconus.

There has been some doubt as to whether these lenses are safe and have a healthy effect, which is why they have not become popular in clinical practice. The major concern is if these lenses, due to their movement or mechanical pressure, can traumatise the apex of the cone or limbal area where the stem cells are located (necessary for corneal health). However, as discussed previously, applying an adequate fitting procedure makes it possible to minimise mechanical pressure on these areas, thereby avoiding corneal physiological impairment. After 1 year of fitting these lenses, no staining was observed in these areas, therefore no traumatic effects were present.

Other favourable factors of these lenses are the high oxygen permeability of the material, and using smaller diameter lenses that tend to favour tear exchange under the lens, which may resolve or diminish the incidence of corneal oedema [20]. Therefore, these contact lenses are recommended as a safe and effective procedure.

In summary, the CScL fitted in this study appear to provide adequate visual quality, although they showed slightly elevated residual HOAs. In particular, for cases with high residual HOAs, developing customised contact lenses may be an effective option to improve visual quality, although they may lead to significant cost and complexity [7,21].

Therefore, the CScL in this study may be suggested as an alternative option for the management of mild to moderate keratoconic eyes. They seem to be safe and healthy, providing optimal visual quality, comfort and prolonged usage times in patients with keratoconus.

## Conflicts of interest

The authors declare that there is no conflict of interest.

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