



Effects of Scleral Contact Lenses for Keratoconus Management on Visual Quality and Intraocular Pressure

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Martina Formisano 
Federica Franzone
Ludovico Alisi
Santino Pistella
Leopoldo Spadea 

Eye Clinic, Department of Sense Organs,
University of Rome Sapienza, Policlinico
Umberto I, Rome, Italy

Purpose: To evaluate the visual acuity level achieved by scleral contact lens (CL) fitting in patients affected by keratoconus and to evaluate possible intraocular pressure (IOP) changes during the scleral CL wear using a transpalpebral tonometer.

Methods: In a prospective case series a comparison was made between visual acuity obtained with glasses, RGP and 16.8mm diameter scleral CL in 30 consecutive patients affected by keratoconus. IOP was tested during scleral CL wear by transpalpebral Diaton Tonometer (DT) and also by Goldmann Applanation Tonometer (GAT) before and after scleral CL wear.

Results: The mean logMAR visual acuity improved from $0.2 \pm 0.25SD$ with glasses and $0.1 \pm 0.02SD$ with RGP, to $-0.002 \pm 0.041SD$ when using the scleral CL ($p < 0.05$). The mean IOP value before scleral CL wear was $12.93mmHg \pm 2.20SD$ when measured with GAT and $7.85mmHg \pm 2.27SD$ when measured with DT. During scleral CL wear, IOP was assessed through DT, with a mean value of $8.86mmHg \pm 2.36SD$; values were stable after 8 hours of scleral CL use. Immediately after scleral CL removal, the mean IOP measured with GAT was $12.85mmHg \pm 2.40SD$ and the mean IOP measured with DT was $7.66mmHg \pm 1.88SD$. Therefore, during scleral CL wear, it was evidenced a small but statistically significant increase of the mean IOP value ($1.01mmHg$; $p < 0.01$), with a reversion to values prior to application when scleral CL was removed.

Conclusion: Scleral CLs remarkably improved visual acuity in keratoconus patients when compared to glasses or RGP contact lenses. Even if it was evidenced a small increase of the mean IOP value during their wear, it may not be significant in otherwise healthy eyes. Statistical analysis demonstrated good agreement between GAT and DT but their numerical values presented a constant gap, that should be taken into account when there is a need to relate the DT values to the reference ones.

Keywords: keratoconus, higher-order aberrations, IOP, scleral contact lens

Introduction

Keratoconus is a non-inflammatory corneal disease that causes a gradual and progressive corneal ectasia. The disease typically involves both eyes.¹ In keratoconus, all cornea layers, particularly the stroma, are characterized by a disruption in the arrangement of collagen fibrils, alterations in proteoglycans expression, and unstable interconnectivity of collagen lamellae, with varying degrees of severity.² Changes in stromal biomechanics result in paracentral steepening of the cornea, apical thinning, and conic shaping of the cornea.³ The displaced optic zone leads to

Correspondence: Leopoldo Spadea
Eye Clinic, Policlinico Umberto I, "Sapienza"
University of Rome, Via Benozzo Gozzoli 34,
Rome 00142, Italy
Tel +039 06 519 3220
Fax +39 06 8865 7818
Email leopoldo.spadea@uniroma1.it

irregular astigmatism, significant coma aberration, and a remarkable reduction in the quality of vision.⁴

Traditional sphero-cylindrical spectacles do not provide significant visual improvement in keratoconus patients, due to higher-order aberrations (HOAs) typical of the keratoconic cornea. Consequently, when a high number of HOAs appear in keratoconus patients, rigid gas permeable (RGP; corneal, corneoscleral, and scleral) contact lenses are suggested as soon as they create a more regular refractive surface.⁴ However, corneal RGP lenses may not be suitable for advanced corneal irregularity and can be associated with corneal scarring at the point of contact between the lens and cornea.⁵

Piggyback contact lenses, intended as rigid gas-permeable lenses that are fitted over soft contact lenses, are suggested for people who cannot tolerate rigid gas permeable lenses, but they are more expensive and have complex maintenance and storage.⁶

Scleral lenses are large-diameter rigid gas-permeable lenses, which vault over the cornea and limbal area and rest on the conjunctival tissue overlying the sclera, which provides a major comfort during their use. The mid-peripheral and peripheral parts of the lenses are customizable to improve stabilization. Even if scleral CLs share the same composition as RGP contact lenses, the entrapment of a thick layer of fluid beneath the scleral contact lens alters the relationship between the cornea and the lens, and also provide relief in case of dry eye.⁷

Scleral CLs can have different diameters but generally, inferior diameter scleral CLs (previously referred to as mini-scleral CL) have easier handling⁸ and are more proximal to structures involved in the aqueous humour outflow than larger diameter lenses.⁶

The indication for surgery is usually due to contact lenses intolerance or a limitation of the best spectacles or contact lenses-corrected visual acuity.⁹ Nonetheless, high levels of aberrations may not be eliminated with surgery, and have been reported in keratoconus patients treated with intrastromal corneal ring segments, cross-linking, radial keratotomies and lamellar or penetrating keratoplasty.^{10,11} Contact lenses also may be needed after surgical intervention for keratoconus to address the HOAs still present.

In this study, we evaluated the effects of a 16.8mm diameter scleral CL wear in keratoconus eyes in terms of visual acuity and intraocular pressure, the latter measured through a transpalpebral tonometer.

Methods

The present study was designed as a prospective case series. The study was approved by the ethical board of the Sapienza University of Rome, Umberto I Hospital, and was conducted in accordance with the tenets of the Declaration of Helsinki. Written informed consent was obtained by all the patients. The patients attended a dedicated keratoconus department in our university hospital (Policlinico Umberto I, Rome) for 1-year (from June 1st, 2018 to June 1st, 2019). The study included 60 eyes of 30 consecutive patients (9 females and 21 males) with a mean age of 38.4 ± 11.8 years (range 26–62ys). All the patients were affected by different grades of keratoconus in both eyes and they were visually unsatisfied after correction with traditional spectacles or corneal RGP (Table 1). We classified keratoconus using Krumeich classification: keratometric measurements <48 D were graded as “stage 1” keratoconus, measurements <53 D were graded as “stage 2” keratoconus, measurements >53 D were classed as “stage 3” keratoconus, and measurements >55 D were graded as the ultimate stage, “stage 4”.¹² Subjects were free of any systemic or concomitant ocular disease. They were not known as being at risk for glaucoma and had no familial history for this pathology, and they had no previous eye surgeries. Subjects who were contact lens wearers were instructed to stop wearing contact lens at least ten days before the evaluation day. Objective and subjective refraction was conducted with trial frame lenses under standardized room and chart illumination conditions by one of the authors (MF). The distance corrected visual acuity (DCVA) was measured using an ETDRS chart and given as a logarithm of minutes of arc resolution (logMAR). Baseline findings for anterior central and posterior corneal curvature, corneal pachymetry, iridocorneal angle, as well as anterior chamber depth and volume, using different maps were taken with Preciso

Table 1 Eyes Divided in 4 Groups Based on Krumeich Classification

n=60	K < 48D Stage I	K >48 <53D Stage II	K >53D <55D Stage III	K >55D Stage IV
Number of eyes with keratoconus at a specific stage	5	14	18	23

Abbreviations: n, sample size (eyes studied); K, keratometric measurements; D, diopters.

2 tomographer (iVIS Technologies, Taranto, Italy). IOP values before scleral CL wear were assessed by both GAT (Haag-Streit AT900, USA) and DT (BICOM Inc, Long Beach, NY, USA), to have comparable measurements before and after the contact lenses wear.¹³

Then, a customized scleral contact lens (Medlac 16.8mm diameter; MedLac, Avellino, Italy) was prescribed to the 30 enrolled subjects. These Medlac lenses were chosen because of their ease of use given by their intermediate diameter, which is essential for patients requiring daily usage. Moreover, these lenses allowed us to maintain a safety distance of 2mm between the corneal limbus and the lens landing zone, to avoid a possible compression of the angle structures.

Patients with a corneal diameter greater than 12.30mm or less than 11.80mm have been excluded since the manufacturer indicates the 16.80mm diameter suitable for medium-sized horizontal visible iris diameter (HIVD). The 16.8mm overall diameter scleral CL not fenestrated were used for this study made by Tisilfocon A, with DK of 180, and a flexure modulus of 1341Mpa. Lenses were manufactured with 220µm center thickness. The landing zone angle was assessed through AS-OCT. It ranged from 48° to 52°. The landing zone angle was established to avoid edge compression or impeachment in the conjunctiva tissue and to avoid excessive edge lift to the sclera portion. An experienced examiner (BS) performed all fitting following the manufacturer's guide. Subjects with a difference between HIVD and vertical visible iris diameter (VVID) of more than 0.5mm, were fitted with scleral LC Conica Evolution design, with an elliptical-shaped corneal chamber; allowing to control the distance between the lens landing and the limbus in each sector. Scleral CLs were inserted with preservative-free saline and sodium fluorescein and then assessed using a slit-lamp biomicroscope. The relationship between the central lens and the cornea was evaluated, checking that the lens was without air bubbles. Lenses with smaller or larger back optic zone radii of curvature were tested progressively until the highest point of the cornea (apex) showed a light feather apical clearance (Figure 1). Once centering was achieved, the settling of the lens on the conjunctiva was observed to avoid over-pressure on the conjunctival vessels, a settling of the scleral portion on the conjunctiva was considered normal within a range of 100–150µm, evaluated by the anterior segment module of Spectralis OCT (Heidelberg engineering Inc, USA). This procedure was followed by a final slit-lamp examination to assess



Figure 1 Slit-lamp examination of a patient's eye fitting a scleral lens (Medlac 16.8mm diameter). It's visible a thin tear layer between the posterior lens surface and the corneal apex.

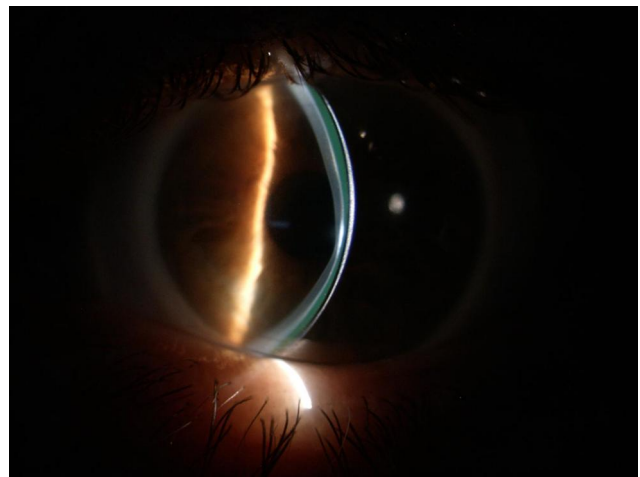


Figure 2 Scleral lenses were inserted with preservative-free saline and sodium fluorescein, which helped the analysis of the tear allocation under the lens. The colored tear layer is homogeneous and air-bubbles free.

ocular health (Figure 2). Lissamine Green stain was used to check any signs of conjunctival distress during lens wear as well as after the lens removal.

The intraocular pressure (IOP) during scleral CL wear was evaluated through the DT at baseline and 8 hours after. Comfort and visual acuity with the scleral CL were documented. The scleral lenses were then carefully removed by using a small plunger to avoid inducing excessive pressure on the ocular surface during the process.¹⁴ Then, just after lens removal, we measured again the IOP with both GAT and DT.

The Diaton tonometer has a U-shaped tip designed to adapt to the eyelid and obtain IOP measurements through a freely moving rod inside the tonometer, which falls

freely onto the elastic surface of the eyeball through the eyelid. Thus, the instrument measures the resistance of the eyelid, the conjunctiva, and sclera through the backward acceleration after interaction with the sclera via the eyelid and converts it to an estimate of intraocular pressure. The Diaton automatically displays the average measurement of up to 6 readings. The measurements in our study were taken with the examiner and the patient facing the same direction. During the DT, the patients were sitting with their heads reclined, looking at an index finger to obtain primary gaze fixation. The upper eyelid was retracted so that the lid margin was 1mm above the superior limbus and the tonometer's tip was placed perpendicularly onto the tarsal plate, at about 2mm behind the superior lid margin, careful to avoid placing the tonometer above the scleral lens when applied. When the tip of the tonometer touched the eyelid correctly, the measurement was noted automatically. The tonometer is tilted back from vertical to reset the scale for each of the two following measurements after which the average of the three was displayed digitally on the screen. In this study, all DT measures were made by the same experienced observer to reduce the variability in the measurement process.^{15,16}

Statistical analysis with Student's *t*-test for paired data was performed to investigate the effect on IOP of scleral CL repeating the measurement before, during and after the application. Bland-Altman method was repeatedly employed to evaluate the level of agreement between DT and GAT before scleral CL wearing, and after their removal (95% limits of agreement was calculated as mean difference \pm 1.96SD). All analyses were performed averaging measurement obtained in both eyes.

Results

The mean logMAR visual acuity improved from 0.2 \pm 0.25SD with glasses and 0.1 \pm 0.02SD with RGP to -0.002 ± 0.041 SD in all the eyes wearing scleral CL ($p<0.05$). All the patients found the scleral CL to be comfortable with a mean daily wear time of more than 6 hours. Average IOP values before, during, and after scleral CL wear are listed in Table 2. The high *p*-value shows that there is not a significant difference in IOP before lens wearing and after their removal for both GAT ($p=0.45$) and DT ($p=0.31$).

t-test performed on DT results before and during the lens wearing showed a significant increase in IOP (p -value <0.01). Similar results were obtained when comparing IOP measured with DT during and after lens removal (p -value <0.01). These

Table 2 Average IOP Obtained with GAT and DT Before, During and After Scleral CL Wear. Results are Expressed in Millimeters of Mercury Along with the Standard Deviation Value

n = 60 Eyes Affected by Keratoconus	GAT (Mean \pm Standard Deviation)	DT (Mean \pm Standard Deviation)
Without scleral CL	12.93 \pm 2.20	7.85 \pm 2.27
During scleral CL wear	Not evaluable	8.86 \pm 2.36
After scleral CL removal	12.85 \pm 2.40	7.66 \pm 1.88

Abbreviations: n, sample size; GAT, Goldmann applanation tonometry; DT, Diaton tonometry; CL, contact lenses.

results indicate that scleral CLs induce a small but statistically significant DT increase in IOP. Using the Bland-Altman method, the upper and lower limits of agreement between DT and GAT were found to be +7.8 and +2.5, respectively, before contact lens wearing. Upper and lower limits of agreement between DT and GAT were found to be +8.4 and +1.8, after lens removal (Figure 3).

Discussion

The efficiency of scleral lenses in correcting aberrations due to keratoconus is well demonstrated by many studies.^{6,8,17–19} In this study, our patients achieved a significantly better visual acuity with scleral CL when compared with spectacles or RGP contact lenses, providing an additional non-surgical option for the treatment of the pathology.

Besides, comfort was one of the primary advantages of scleral CL. Indeed, all the patients experienced relief from dryness and were able of tolerating at least a scleral CL wear of 6 hours daily. Scleral CLs regularized the corneal surface by vaulting the irregular keratoconic cornea with their surface and the tear reservoir underlying the lens. Differently, RGP contact lenses do not create a tear reservoir which vaults the cornea and their contact with the cornea, could compromise visual acuity and contact lenses tolerance.⁵

IOP changes in these patients wearing scleral CL were also investigated. Unlike soft lenses, scleral CL compress and settle into conjunctival tissue. During each blink, the pressure from the lid may press the lens farther into the conjunctiva.²⁰ In general, large-diameter scleral lenses (≥ 18.0 mm in diameter) have relatively wide haptics or landing zones (up to 2mm wide), with a broader distribution of the lens-bearing force on the eye. Thus, large-diameter scleral lenses may be less likely to compress any structures within or adjacent to the anterior

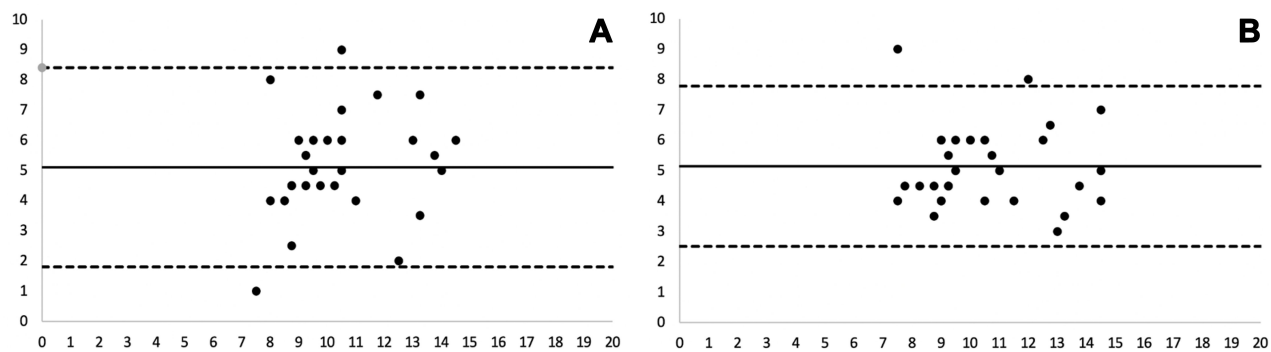


Figure 3 Bland-Altman plot on Diaton tonometry vs Goldmann tonometry, before the scleral lens application (A) and after their removal (B). Dotted black lines show upper limits of agreement (ULO) and lower limits of agreement (LLO). Continuous black line shows mean difference. (A) mean: +5.15, ULO: +7.8, LLO: +2.5; (B) mean: +5.10, ULO: +8.4 LLO: +1.8. Diff: difference. Results are shown in mmHg.

chamber angle. However, small-diameter scleral lenses (14.0 to 16.5mm in diameter) generally have limited haptic widths and diameters, and they contact the conjunctiva closer to the limbus than do the larger lenses. The concentration of the bearing surface over a smaller area close to the limbus may presumably compress structures responsible for aqueous humor outflow as the Schlemm canal, the collector channels, or the episcleral veins and consequently increase intraocular pressure.²⁰ Nonetheless, it is hypothesized that the functional diameter and the chord where the lens lands on the conjunctiva, are more important than the overall lens diameter.² Compression of the structures of the anterior chamber angle could be indirectly related to signs of tight-fitting in the periphery such as blanching of the conjunctival blood vessels, conjunctival flush and marked suction between the lens and the conjunctival tissue that is difficult to break on lens removal.²² Ideally, well-fitted scleral lenses, which do not create excessively tight bearing zones as they settle, should not significantly elevate IOP.²³ Apart from the degree of lens fit tightness, any IOP elevation associated with scleral fittings appears to be linked to individual patient characteristics. For example, eyes with reduced scleral thickness and/or rigidity appear likely to be more easily applanated at zones of tight scleral lens bearing.¹⁶ Anyway, eyes that are susceptible to baropathic diseases such as glaucoma, axial myopia, and corneal thinning diseases, such as keratoconus, could have pathological adverse events due to scleral CLs induced elevation of IOP.²² In literature, there are many studies regarding the relationship between scleral lens wear and IOP but results and methods range widely. Indeed, some studies conducted on lenses with a diameter between 15mm and 18mm, did not find a significant rise in IOP during the SLs wear using a -pneumotonometer²⁰ or after the scleral CLs wear, using GAT, a Tonopen, or a non-contact tonometer.^{24–26} Differently, other

authors found a rise in IOP (average of 5mmHg) following scleral lens removal (diameter between 14.6mm and 18mm) using GAT, DT, or Icare tonometer and during scleral CLs wear using DT or a rebound tonometer.^{21,27–29}

Authors who found an IOP elevation consequently to scleral CL application supposed that such findings might be a consequence of increased susceptibility to scleral lens-induced IOP elevation due to having thinner scleral tissue. Indeed, a thinner sclera would be easier to applanate or indent by bearing areas of scleral lenses. Tight fittings might also explain such effects. Any rise in IOP may also depend on aqueous drainage facility, which might be restricted in some individuals. In addition, aqueous drainage may be compromised by lenses with bearing areas at the limbus.²⁰

In the present study, we found a small (1.01mmHg) but statistically significant increase of the IOP measured with DT during the scleral CL wearing. We decided to use DT because, even if GAT represents the gold standard in the IOP measurement, it does allow IOP measurement while wearing scleral contact lenses, and measuring IOP after lens removal can only be indirectly relevant to lens-in situ IOP.³⁰ The Diaton tonometer is a handheld device capable of measuring IOP through the upper eyelid, avoiding corneal contact.³¹ However, the transpalpebral tonometer is a novel and still not well-standardized technique to measure IOP in eyes wearing scleral CL. For the Diaton, the manufacturer describes a possible error of ± 2 mmHg for eyes with IOP between 5 and 20mmHg, and an error of 10% of the current IOP for IOP between 20 and 60mmHg.^{21,26} Even if there was good agreement between DT and GAT, we found that DT usually gives a lower IOP value (about 5mmHg) compared to GAT results. From a clinical perspective, the differences are significant; indeed, it is not possible to relate values obtained with DT to reference values. Other studies

reported poor agreement between DT and GAT,³² under or overestimation of the IOP,³³ and a significant influence of the positioning on the IOP measurement with the DT.³⁴ A moderate correlation between AT and DT was found when used on a normal eye in a study³⁵ and when corrected for central corneal thickness in another study.³¹

Conclusions

Scleral CLs could be successfully used to treat corneal diseases such as keratoconus. They give a valid alternative to surgery with quality of vision and comfort superior to other actual devices. Even if 16.8mm diameter scleral CLs have easier handling than larger diameter scleral CLs, their landing zone is closer to structures involved in the aqueous humor outflow. We demonstrated that well-fitted scleral CLs, checked by AS-OCT and biomicroscopic examination, do not usually cause any signs of distress on the eye, rendering unlikely a compression of the structures of the anterior chamber angle.

The IOP values acquisition during scleral CL wear has been possible thanks to a new transpalpebral tonometer. Even if the methodic is new and still not standardized, its parallel use to GAT before and after scleral CL use allowed a better interpretation of the results. Statistical analysis showed good agreement between the two instruments but a constant numeric difference between values obtained with GAT and DT. This should be considered when relating DT values to reference ones.

The DT showed a small but significant (1.01mmHg; $p < 0.01$) raise of the IOP during scleral CL wear. We believe that this small raise is unlikely to cause any glaucomatous damage in the eyes otherwise normal. Moreover, changes in the DT position should be occurred trying to avoid contact with the part of the superior lid overlying the scleral CL. Finally, it is recommendable for a proper selection and follow-up of the patients during the use of the scleral CLs. More studies with a wider casuistry are also needed.

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Disclosure

The authors report no conflicts of interest in this work.

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