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Performance and predictability of a new large diameter contact lens design in keratoconic corneae

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ABSTRACT

Objectives: To evaluate the clinical performance and predictability using corneal topography in the fitting of a new large-diameter rigid gas permeable (RGP) contact lens design in eyes with keratoconus (KCN).

Methods: This study presents a review of eyes fitted with Alexa ES lenses for nonsurgical optimisation of visual correction. Anterior steep simulated keratometry (sim-K steep), corneal diameter (HVID), the Curvature at the apex in diopters (Cc), and distance from the corneal apex to the centre of the cornea (Lc) in millimetres derived from the Cone Location and Magnitude Index (CLMI) were recorded. Visual acuity, mean wearing time, final sagittal depth and adverse events were also recorded. Correlations between topographic indices and base curve were evaluated using the Pearson correlation coefficient.

Results: Forty-six eyes from 26 patients (19 males/ 7 females) were included. Mean visual acuity improved from 0.49 ± 0.32 with glasses, to -0.02 ± 0.10 with the contact lens. The mean daily wear time was 12.19 ± 1.96 hours. No complications were detected in 95.65% of the eyes [95% CI (83.9%-99.2%)] but two episodes of non-infectious keratitis. The average sagittal depth of the lenses fitted was 0.425 ± 0.15 mm, and it was positively correlated with the Cc value ($r^2 = 0.66$, $p < 0.0001$, $n = 46$) derived from the CLMI index of the pre-fitting topography.

Conclusions: Corneoscleral RGP contact lenses are a safe, and effective alternative for managing KCN patients to corneal lenses. Also, clinical data derived from the corneal topography could be used to help to decide the first diagnostic lens to be assessed, easing the overall fitting process.

1. Introduction

Keratoconus (KCN) is as a bilateral but typically asymmetric non-inflammatory ectasia characterised by progressive thinning of the corneal stroma [1]. Most of the patients with this condition need to wear contact lenses to achieve adequate vision and, according to different studies, from 65 to 91% of cases are optically managed with them [2–6]. Corneal rigid gas permeable (RGP) contact lenses have been considered the primary modality of correction as they can render excellent vision [7]. Corneal irregularities associated with KCN, nevertheless, may induce decentration, dislocation, and lack of comfort with corneal RGP contact lenses preventing its use. Furthermore, Barr et al. [8,9] found that corneal RGP contact lens wear has been associated with a 2-fold increase in the risk of scarring in these eyes. New contact lens modalities have been introduced to mitigate these clinical quandaries [10].

Large-diameter RGP lenses form a heterogeneous group that encompasses several corneoscleral as well as scleral designs. These have been added to the market after the development of new materials, making them very useful for nonsurgical visual rehabilitation in cases of irregular corneae [11,12]. In corneoscleral contact lenses the aim is to rest a part of the weight of the lens on the cornea, obtaining a light feather touch relation with the apex. Overall diameter can further use to subcategorise these lenses into miniscleral and large or true sclerals [13]. In both groups, the fitting goal is to align the peripheral section with the sclera and to vault over the cornea with a larger fluid-filled reservoir. In the former, it is possible to attain a closer relationship with the corneoscleral limbus and some alignment be feasible. Bergmanson et al. [14] informed that patients with KCN well accept scleral lenses as high levels of comfort, and visual improvement can be achieved. Furthermore, a recent study has reported better visual acuity than with corneal RGP lenses [15]. Most previous studies in this field assessed contact lens performance through obtained visual acuity and wearing time with disparate outcomes as well as different fitting philosophies (Table 1) [15,16,25–27,17–24].

This study aimed to evaluate the clinical performance of Alexa ES contact lens (Laboratorios Tiedra, Alcorcón, Spain) in patients with KCN. Secondly, to assess possible correlations between several corneal

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Table 1
Reports with Large-diameter RGP Lenses According to Recent Published Studies.

Author	Contact Lens Design	Mean Total Diameter (mm)	Length of Wear Per Day (h)	Visual Acuity with the Lens (Log MAR)	Intended Centre Vault Relationship
De Luis Aguileor et al. [16]	Rose K2 XL	14.60	9.33 ± 2.99	0.06 ± 0.07	0.1–0.3 mm
Romero-Jimenez et al. [17]		14.66	9.3 ± 2.2	0.09	"feather touch"
Kim et al. [15]	MSD	15.80	10.1 ± 2.3	0.10 ± 0.11	0.25–0.35 mm
Visser et al. [18]	Bitangential Scleral Lens	19.9	Not reported	Snellen 20/25	0.200 mm
Montalt et al. [19]	Scleracon	12.94	13.44 ± 2.08	0.00 ± 0.14	"feather touch"
Otten et al. [20]	Bitangential Miniscleral Lens	16.00	14.00	0.02	0.260 mm
Dimit et al. [21]	PROSE	15.00–24.00	Not reported	0.21	"to barely clear the steepest point of the cornea."
Lee et al. [22]		Not reported		0.08 ± 0.10	Not available
Baran et al. [23]				0.09 ± 0.15	
Arumagan et al. [24]		19.15 ± 0.56		0.23 ± 0.30	0. 1–0.2 mm
Pecego et al. [25]	Jupiter	15.0–24.0	Not reported	Not reported	"corneal clearance without the presence of "feather touch."
Ortenberg et al. [26]	Microlens Scleral	18.5	10	0.20 ± 0.14	"shallow but definite clearance of the cornea and the limbus."
Suarez et al. [27]	ICD	16.5	9.2 ± 2.8	0.44 ± 0.45	"The corneal clearance had to be one- third to one-half of the corneal thickness."

parameters derived from the topographical analysis and the prescribed lenses.

2. Materials and methods

A retrospective chart review was carried out to identify keratoconic patients who had been fitted with Alexa ES (Laboratorios Tiedra, Alcorcon, Spain) contact lenses between October 2014 and January 2016 at Centro Fernández-Velázquez of Madrid (Spain). The minimal criteria used to diagnose KCN were either the corneal distortion as observed with retinoscopy or the topography analysis as shown with a positive CLMI (Cone Location and Magnitude Index) [28]. All patients recruited had completed at least six months of follow-up. The study was conducted in accordance with the tenants of the Declaration of Helsinki.

The variables analysed included primary demographic data, corneal topographical indices, previous contact lens history, and pertinent information related to the contact lenses dispensed. Patients with the following characteristics were excluded from the study: the presence of any other ocular disease, previous history of hydrops, corneal decompensation, an active infectious ulcer, persistent epithelial defect or a keratoplasty.

Prefitting topographical evaluations were performed with the Keratron Scout version 4.1.0 (Optikon 2000 S.p.a., Rome, Italy), which is a Placido-based corneal videokeratography system with a reported similar precision than other topographers in KCN [29].

2.1. Contact lens characteristics

This contact lens is a prolate spheric-progressive design which has a fixed diameter of 15.0 mm and is fitted based on sagittal depth measurements primarily designed for the management of corneal ectasia. The Alexa ES lens is composed of four zones, a 9.1 mm central zone that is fitted to avoid bearing on the cornea, two curves that encompass the midperipheral area with the goal of clearing the cornea-scleral limbus and a 1.25 mm scleral landing zone. All lenses were made from Paflufocon D (Paragon Vision Science, Mesa, Arizona, USA) with a permeability Dk value of 101 (cm^2/s) (mL O_2/mL × mmHg) × 10^{-11} (ISO/ANSI Method).

2.2. Contact lens fitting procedure

Prescription lenses were designed based on an on-eye evaluation of diagnostic trial lenses following the manufacturer's recommendations. Lenses were fitted by taking into consideration the sagittal height based on the corneal clearance principle. Initially, the vaulting of the lens over the cornea was evaluated using a 45° degree oblique slit beam and comparing its width with the central thickness of the trial lenses, which remain constant (230 µm) for all lenses. An initial vaulting depth of 0.3–0.4 mm was intended. Once it was achieved, the lens was left on the patient's eye for an additional 30-min setting period, and re-evaluated with an OCT Maestro (Topcon Corp, Tokyo, Japan) using an anterior segment strategy that measured a 6.0 mm zone. The final objective was to identify the lens that provided a 0.25-mm central vaulting. The limbal transition zone and the landing zones were also evaluated using two strategies. The first, employed biomicroscopy under diffuse white light to observe the vascular compression patterns of the bulbar conjunctiva with the goal of minimising lens-induced compression of conjunctival blood vessels and enable unobstructed blood circulation and also using anterior segment OCT. The design was fitted in close alignment with the limbus, and some light touching was considered acceptable if no corneal staining was found after removing the lens. Contact lens power was determined after performing an over-refraction to obtain the best possible visual acuity.

After the prescribed lenses arrived at the clinic, patients were scheduled for a dispensing visit. On that visit, the lens was evaluated after three hours of wear. If the fitting was considered as clinically correct (acceptable fit, vision and comfort), the patient was instructed on how to manipulate the lens, advised to wear the lens on a daily basis and to progressively increase lens use before being scheduled for a follow-up seven days later. Lens care consisted of cleaning, wetting and disinfection with standard RGP lens solutions systems. In all cases, patients were instructed to fill the bowl of the lens with a non-preserved saline solution prior to insertion.

2.3. Outcome measurements

Demographic information such as age, gender and previous history of intracorneal ring segment (ICRS) implantation were recorded. Distance high contrast visual acuity with best spectacle correction (CDVA) and after contact lens fitting (CLVA), daily contact lens wear time, biomicroscopic findings, and the sagittal depth of the dispensed lens were also evaluated and recorded. Additionally, the following data extracted from the initial topographies were also analysed: Anterior steep simulated keratometry (sim-K steep), corneal diameter (HVID), and indices derived from the Cone Location and Magnitude Index (CLMI) [28]. This index is regarded as a robust index for screening keratoconus with high sensitivity, specificity, and accuracy [30]. An example of the CLMI index in a keratoconic cornea is provided in Fig. 1. Safety was assessed evaluating biomicroscopic findings [31].

2.4. Statistical analysis

Data entry was entered into Excel worksheets and analysis was performed using GraphPad Prism version 5.00 (GraphPad Software, San Diego, USA) with the statistical significance level set at $p < 0.05$. Results are presented as mean ± SD and ranges. The normality of the sample was checked using the Kolmogorov–Smirnov test. The paired Student *t*-test was used to determine statistically significant changes in visual acuity. The relationship of corneal topographical indices to the base curve of the lenses was evaluated using the Pearson correlation.

Table 2
Characteristics of the Study Sample.

Parameters	Results
Age, years, Mean ± Standard deviation (range)	42.88 ± 11.84 (22–71)
Gender, male:female	19 (73%):7 (27%)
Previous contact lens correction	
Corneal RGP, n (%)	20 (77%)
Soft, n (%)	3 (11.5%)
Hybrid, n (%)	1 (3.8%)
Piggy-back, n (%)	1 (3.8%)
Reason to quit previous contact lens	
Physiological complications	10 (38.4%)
Unacceptable comfort	10 (38.4%)
Unacceptable visual acuity	4 (15.3%)
Other (i.e. frequent loss or limitation in sports activity).	2 (7.6%)

3. Results

Forty-six eyes from 26 patients (19 males/7 females) entered in the study. In this cohort, five eyes (11%) had prior ICRS surgery. Pre-fit demographic data from the patients are shown in Table 2. Most patients had been fitted previously with rigid gas permeable contact lenses. The Keratoconus severity of the eyes according to the Amsler–Krumeich classification is shown in Table 3 [32], as well as pertinent topographical pre-fitting information in Table 4.

In this cohort, improvement in CLVA compared with CDVA occurred in 95.6% of eyes (44/46; 95% CI [84%–99%]). The two eyes that did not gain additional visual acuity already had a high level of BCVA (logMAR −0.1). The mean CDVA was 0.49 ± 0.32 logMAR (median 0.40) and the CLVA was −0.02 ± 0.10 logMAR (median −0.1). There was a significant improvement with lenses compared to spectacle visual acuity in all eyes ($p < 0.0001$) (Mean difference = −0.50, 95% CI [−0.60 to −0.40]). There was no difference in CLVA between primary keratoconus eyes and eyes with ICRS implantation. The mean wearing time among all fitted patients was 12.19 ± 1.96 h per day (median 12.00 h).

No eye experienced complications during the follow-up period. Forty-four of 46 eyes (95.65%, 95% CI [83.9%–99.2%]) experienced no

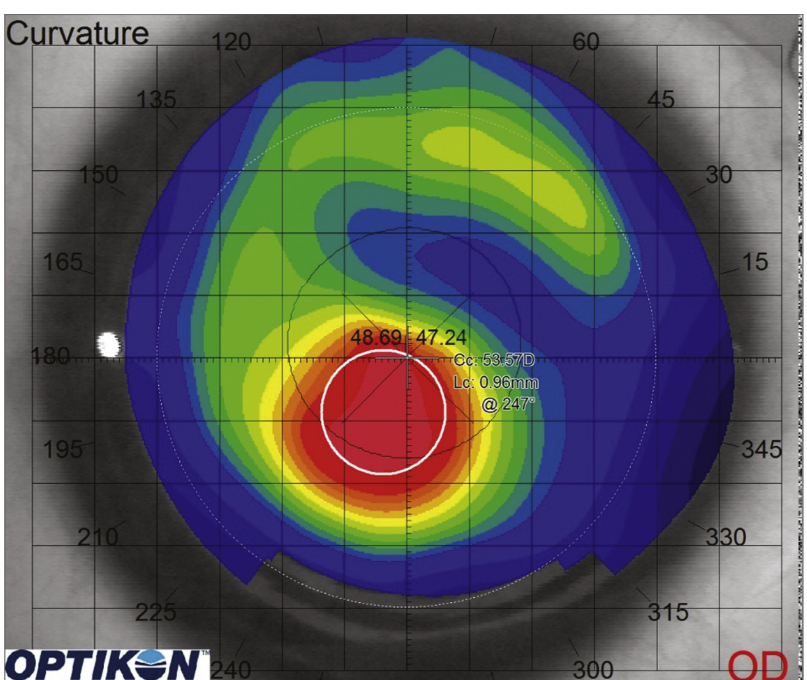

Fig. 1. Sample of a topographical map showing a positive CLMI index (Cc = 53.57 D, Lc = 0.96 mm) in a keratoconic cornea.

Table 3
Keratoconus Severity of the Study Sample [33].

Grade	Number of eyes (%)
I	11 (24%)
II	16 (34.8%)
III	4 (8.5%)
IV	15 (32.5%)

Table 4
Pre-fitting Keratron Topographical Information.

Parameters	Mean ± Standard deviation (range)
Sim-K steep (D)	51.86 ± 5.09 (62.63–41.91)
HVID (mm)	11.40 ± 0.25 (12.20–10.90)
Cc (D)	58.37 ± 6.30 (81.95–47.59)
Lc (mm)	1.40 ± 0.78 (2.99–0.14)

Abbreviations: **Cc (D)** = Corneal power at the apex of the keratoconus, CLMI index; **Lc (mm)** = Distance in mm from the apex to the center of the cornea, CLMI index **D** = Diopter; **mm** = millimetres; **Sim-K steep** = Simulated steep corneal dioptric power for the 3.0 mm central zone.

adverse events. There were 2 cases of noninfectious keratitis (2 eyes) with mild punctate epithelial erosions. These cases were successfully managed with topical lubrication and the discontinuation of contact lens wearing for a short period.

The average sagittal depth of the dispensed lenses was 0.425 ± 0.153 mm. In this cohort, this value highly correlated with the Cc index ($r^2 = 0.66$, $p < 0.0001$, $n = 46$) (Fig. 2). Although, also a positive correlation was found with this HVID ($r^2 = 0.39$, $p < 0.0001$, $n = 46$), this was considered weak. There was no correlation with the Sim-K steep ($r^2 = 0.05$, $p = 0.11$, $n = 46$), as well as with the Lc index ($r^2 = 0.04$, $p = 0.16$, $n = 46$). An average of 3.6 ± 1.6 diagnostic trial lenses per eye (range 1–5) was needed to decide the final lens.

4. Discussion

This single-centre retrospective case review sought to assess the clinical performance of the Alexa ES, a 15-mm RGP mini-scleral contact lens, in patients with keratoconus; A recent review by Fadel [13] has evaluated the putative advantages of these designs versus their large scleral counterparts. To the author's knowledge, this is the first time that clinical experience with this lens is reported. This design was found to increase visual acuity with a high level of comfort and to be free of significant ocular complications. Notably, novel data relating to the efficacy of corneal topographical analysis to predict the parameters of the fitted contact lenses was discovered.

In this cohort, 20 eyes (77%) had used corneal RGP lenses previously but discontinued because of several reasons, mainly lack of comfort and physiological complications, such as repeated corneal erosions. Patients achieved significantly better visual acuity (−0.02 ± 0.10 logMAR) with this design compared to spectacles. CLVA was indeed better than the one previously reported with other large RGP designs [15,23]. Similarly, Visser et al. [33] reported a high proportion of eyes with excellent visual acuity despite keratoconus. Wearing time has been referred to as a factor to measure the success of scleral lenses [14]. The mean wearing time in this study was 12 h per day, which is consistent with other reports regarding ectasic corneae fitted with this rubric of contact lenses [14,16,27]. Bergmanson et al. [14] claimed that better levels of comfort and increased wearing times could be obtained with larger lenses than the ones in this study, but an outcome of this work is that it is possible to attain excellent results with smaller lenses. A possible explanation for this clinical conundrum is that a limited amount of limbal contact could be reasonable without adverse outcomes based maybe on regional differences in fitting philosophies between European and American colleagues. Although we have to bear in mind, that is important also to consider the HVID of the cornea to fit, in the present study an average of 11.40 mm; however, in the Bergmanson study omitted so it could be hypothesised regional differences, as well, in ocular parameters as another source of the discrepancy. By and large, based on the author's experience, bigger sizes might also induce a deleterious effect as will interact with a more distant scleral shape which is usually more irregular. In this study, an average of 3.6 diagnostic trial lenses was needed to determine the final lens, which matches with previous reports [15,25].

Most of the patients did not show biomicroscopic complications of importance to remark, none the less, two eyes developed mild punctate epithelial erosions. The author was unable to identify the exact

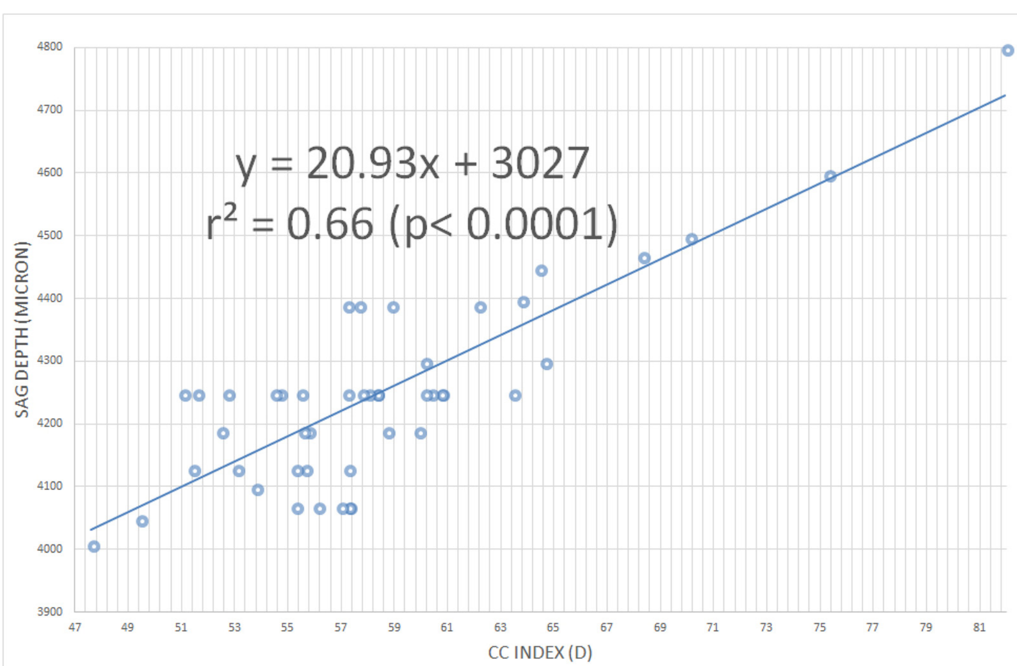

Fig. 2. Correlation between sagittal depth of the prescribed lenses and the Cc index derived from the topography. The Pearson correlation coefficient is depicted as r^2.

aetiology; however, manipulation issues could be a potential cause. It is imperative with this modality of lens wear to educate patients on how to insert the lens correctly to avoid trapped air bubbles.

A significant association has been identified between the sagittal depth of the prescribed contact lenses and the topographical index Cc (curvature at the apex) obtained from the Keratron topographical images, with steeper Cc values calling for lenses with deeper sagittal depth with an approximate increment of 0.1 mm for every five diopters of change in this topographical index. The relationship between both parameters was strongly linear ($r^2 \geq 0.50$). To the author's understanding, this is the first time that such a predictive factor is obtained as a lack of an strong correlation between corneal topographical measurements and contact lens parameters found in previous studies with this type of lenses [15,34]. One possible explanation for this finding is the fact that this was a relatively smaller lens than in other papers, which might lead to a less determinant scleral shape effect in the final fit. Practitioners willing to use this relation to choose the sagittal depth of the first initial lens can benefit for shorter periods of chair time as probably the overall process could be faster and with fewer lenses involved bearing in mind the specific parameters of the lens in this report. Furthermore, the lack of a reliable predictive relationship with the corneal diameter is also compelling, as, in a previous study, a strong correlation was found in keratoconus and normal corneas [35]. Moreover, no correlation was evident between the Lc index and the parameters of the lenses. Downie [36] observed the magnitude of vertical decentration influenced the required lens skirt curvature in a well-known hybrid contact lens; as apex was more distant, steeper soft peripheries needed. Although valuable information, the author believes that is information is not feasible in translating into scleral lenses for the intricacies and differences between both rubrics.

This study has several strong points, including the size of the sample, which allowed obtaining firm conclusions regarding the outcomes in patients with this type of ectasia. Anterior segment OCT was used to choose the final lens; this technique is useful in measuring the exact fitting relationship between the posterior surface of the lens and the cornea, although it is still not widely used in clinical practice worldwide. The application of the positive correlation between a topographical index and the parameters of the dispensed contact lenses could expedite the overall fitting process avoiding superfluous chair-time.

Study limitations should also be mentioned. One apparent weakness is that it was designed as a retrospective study, was not masked and was performed in a single institution. On the other hand, the small number of ICRS cases has made it impossible to obtain statistically significant results on naturally-occurring keratoconus. Future studies ought to consider if other topographical indices integrated into different platforms, and related to the ones studied in this study, could also serve as a viable indicator as well as this clinical correlation found in this investigation could apply to other designs.

In conclusion, it could be mentioned that clinical outcomes with large diameter RGP designs, like the one used in the present study, in keratoconus patients are encouraging. These patients can attain excellent levels of visual acuity with an acceptable wearing period and a low incidence of complications. The use of proper topographical information can accelerate the fitting process by improving the clinician's ability the determine the first lens to evaluate.

Conflict of interest

There are no conflicts of interest that could have influenced the results of this work.

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