A Prospective Clinical Evaluation of a New Scleral Contact Lens for Patients with Distorted Corneas

Philip Fine, Ariela Gordon-Shaag, Esther Leibowitz, Ayelet Chen Lahav, Steven Jackson, Renana Halperin, Liat Gantz

ABSTRACT

Objectives: A prospective clinical evaluation of the physiological fit and visual performance of a novel commercially available rigid gas permeable (RGP) scleral contact lens in subjects suffering from distorted corneas is described.

Materials and Methods: The physiological fit and visual performance of 23.5 mm and 21 mm RGP scleral contact lenses were assessed in 14 subjects (22 eyes) and nine subjects (12 eyes), respectively. All but one participant with a distorted cornea as a result of an infection, suffered from varying grades of keratoconus. In a subset of seven subjects (8 eyes), the higher order aberrations were measured with and without the scleral lenses.

Results: The 23 mm RGP scleral lens improved visual performance in 82% of the participants and eight subjects were satisfied with the lenses. The 21 mm lens improved visual performance in 83% of the participants, and four subjects were satisfied with the lenses. Subjects that were satisfied with the lenses tended to lack other forms of visual correction. In the seven subjects that were included in the sub-study, the total lower order, higher order, coma, and tetrafoil root mean square were significantly reduced (p<0.05) with the scleral contact lenses, whereas the total trefoil was not.

Conclusion: RGP scleral lenses can be comfortably worn for approximately 7 hours, improve visual acuity, and reduce higher order wavefront aberrations. The lenses can be fit easily by the practitioner, though a trial lens set is necessary. The lenses are recommended in cases where other forms of visual correction can no longer be tolerated and as a long-term or temporary alternative to corneal transplant.

Keywords: Contact lens, Keratoconus, Corneal distortion, Clinical evaluation, Higher order aberration.


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Conflict of interest: Philip Fine—Consultant to Soflex Contact Lens, Ltd. Manufacturer of lenses used in this study.
Liat Gantz—Received a research grant from Soflex Contact Lens Ltd. anAcre, Israel.

INTRODUCTION

Keratoconus (KC) is a progressive, bilateral, often asymmetric corneal disease characterized by thinning, weakening and alteration of the stroma layer of the cornea.1,2 Because the stroma comprises the majority of the composition of the cornea, it is mainly responsible for the noninflammatory thinning that leads to a conical-shaped protrusion.3,5

Irregular astigmatism and higher order aberrations resulting from severe KC are common causes of reduced quality of vision in most KC patients and some patients with a history of complicated refractive surgery, penetrating keratoplasty or ocular surface disease.2 Visual rehabilitation of patients with irregular astigmatism is challenging because conventional methods of optical correction often do not provide satisfactory quality of vision.

In early stages of the disease, spectacle or soft contact lens corrections suffice.8 However, as the disease progresses and the astigmatism increases, rigid gas permeable (RGP) contact lenses offer a more optimal solution.6 The tear film that is created between the back surface of the RGP lenses and the front surface of the cornea acts as a substitute refractive surface instead of the cornea. The front surface of the RGP lens is typically spherical, thereby compensating for the corneal distortions of the KC cornea and offering enhanced visual quality and performance for keratoconic patients.7,8 When the disease progresses to a stage where RGP contact lenses no longer offer an optimal solution to the patients due to the inability to obtain a physiologically acceptable fit, scleral contact lenses become a preferred option.5,9 Scleral lenses may be recommended even before this point, due to the fact that RGP contact lens wear has been found to be a risk factor for corneal scarring in patients with KC.10

Scleral contact lenses are large rigid gas permeable contact lenses of diameter of up to 23,11 which rest on the sclera of the eye and cover the cornea of the eye like a dome lid.12 Scleral lenses create a tear film between the back surface of the lens and the front surface of the cornea, thereby compensating for the aberrations in the cornea.13 On insertion of the scleral contact lenses, air bubbles may occasionally get trapped behind the lens,7,14,15 which may cause discomfort, visual disturbances and even small dry spots on the corneal surface. The buildup of deposits on the inner lens surface can also affect the comfort and vision.16 In addition, RGP scleral lenses form a sealed vacuum on the ocular surface making removal of the lens cumbersome.15

In this paper, we present results of a prospective clinical study in which we evaluated the clinical performance and
visual acuity outcomes of novel 23.5 and 21 mm diameter RGP scleral contact lens designed by the Israeli contact lens company Soflex (Acre, Israel) on a cohort of subjects with distorted corneas who were unable to tolerate or achieve satisfactory visual acuity with regular RGP lenses. The back surface of the lens is aspheric (with different radii of curvature in the center and the periphery, flattening toward the periphery), which reduces spherical ocular aberrations in high refractive errors common in keratoconic patients. The lenses are manufactured with a polish-free technique, creating a uniform lens polish that prevents the lens from becoming contaminated and improves optic quality.

We report an improvement in visual acuity outcomes and reductions in higher order aberrations alongside an acceptable physiological fit of the new scleral contact lenses and recommend their use for fitting patients suffering from distorted corneas for which a physiologically acceptable fit cannot be achieved or who are unable to tolerate other types of correction.

MATERIALS AND METHODS

Subjects

Subjects between the ages of 18 to 67 with various types of corneal distortions who were unable to achieve satisfactory vision using glasses or other types of contact lenses were recruited for this study. Subjects with ocular pathologies (other than KC), such as cataracts, macular degeneration, diabetic retinopathy, etc. or systemic pathologies that may affect the eyes (such as multiple sclerosis) were not included. The corneal distortions included advanced KC, postpenetrating keratoplasty or KC with other surgical complications. Inclusion criteria for manifest KC were presence of paracentral steepening of the cornea or irregular bowtie astigmatism on topography (video keratoscope), and at least one of the following signs: Stromal thinning, Fleischer’s ring or Vogt’s striae observed by slit-lamp examination (adapted from Gordon-Shaag et al), and a cone apex equal to or larger than 50 DS, and inferior superior dioptric difference equal to or above 3.5 DS (adapted from Millodot et al). The study protocol was approved by the Hadassah Academic College Ethics Committee and subjects signed a statement of informed consent prior to their participation in the study.

Scleral Contact Lens Fitting

All examinations took place in the same testing rooms using the same examination equipment at Hadassah Academic College’s contact lens clinic and were performed by a licensed optometrist. All subjects initially underwent a thorough ocular examination, which included a detailed history including past contact lens wear and ocular history and unaided and aided visual acuity using a Snellen chart at 6 meters. In addition, all subjects were examined for a contact lens fitting with a slit-lamp examination of the external and internal structures of the eye using the Efron grading scale for contact lens complications and a corneal topographic examination using the Shin-Nippon corneal topographer CT-1000 (Shin-Nippon Commerce Inc., Japan). For nine eyes of seven subjects that agreed to participate in an additional round of testing, the ocular aberrations were measured with and without the scleral contact lens correction using the L-80 Wave + aberrometer (Visionix, Luneau, Chartres, France) to examine the wavefront aberrations in the corrected vs the uncorrected state.

Soflex RGP scleral contact lenses are manufactured from Hexafocon A (commercially known as Boston XO USAN) material with a diameter of 23.5 mm, or 21 mm (the 21 mm lenses are FDA approved), back surface radii of 13.5 or 14.2 mm, and a DK of 100. A successful RGP scleral lens fit was based on the fluorescein pattern, with the following criteria: No contact between lens and cornea, corneal clearance with fluorescein visible up to 1 to 2 mm past the circumference of the limbus, and scleral alignment at the periphery of the contact lens (Figs 1A and 1B).

RGP scleral lenses from the trial set were selected based on the inspection of the corneal ectasia and presence of Munson sign (greater ectasia and presence of the Munson sign requires a larger number in the trial set according to the manufacturer’s instructions). When a satisfactory fit based on the aforementioned criteria was obtained, an over-refraction was performed in order to determine the final lens power.

Approximately 1 to 4 weeks after the fitting visit, subjects returned for a follow-up visit at which they received their RGP scleral contact lens. A slit-lamp examination was conducted and the fluorescein pattern was analyzed to confirm a satisfactory fit. Visual acuity with the lenses was measured using a Snellen chart at 6 meters. In addition, subjects received a detailed explanation on how to correctly insert, remove and maintain the lenses on a day to day basis and were given a wearing schedule. The wearing schedule included 2 hours of RGP scleral lens wear per day for 2 days followed by an additional hour of wear for 2 consecutive days until obtaining a total wear time of 5 hours per day. Subjects returned for an additional follow-up visit approximately 1 week after receiving the lenses. During this follow-up visit, subjects were examined with a slit-lamp and fluorescein to detect any existing problems that may have been caused by the contact lens wear. If all was found to be satisfactory, the participant was permitted to continue building up the contact lens wear time according to the...
A Prospective Clinical Evaluation of a New Scleral Contact Lens for Patients with Distorted Corneas

wearing schedule. Subjects were monitored monthly over a period of at least 5 months from lens wear commencement. Subjects were advised to remove the lenses for cleaning and refilling with saline solution every 4 to 5 hours, if they experienced discomfort and/or blurred vision after a few hours of lens wear. If the discomfort was not relieved after cleaning and refilling the lenses, subjects were instructed to remove the lenses and contact the research team immediately. If unsatisfactory findings arose during any follow-up examination, subjects were instructed to discontinue lens use until a lens with modified parameters was received. Once participants received the modified lens, a new lens wear schedule commenced.

Statistical Analysis
The visual acuity outcomes using a decimal Snellen fraction with optimal correction prior to the RGP scleral contact lens were compared to the visual acuity outcomes with the RGP scleral contact lenses using a two-tailed paired t-test, after verifying that the data is normally distributed using the Anderson-Darling normality test. The hours of wear of the previous correction type were compared to the hours of wear with the RGP scleral contact lenses using a two-tailed paired t-test, after verifying that the data is normally distributed using the Anderson-Darling normality test.

The total root mean square (RMS) of the higher order aberrations of nine eyes of seven subjects was compared with and without the RGP scleral contact lens correction. Finally, we report the general comfort and satisfaction levels of the subjects using these novel lenses.

RESULTS
Twenty-two eyes of 14 subjects (eight male, six female), between the ages of 23 to 66 [mean age: 39.8 ± 13.1 (SD)] were fitted with 23.5 mm diameter RGP Soflex scleral contact lenses and were followed over a course of 5 months. Eight eyes had KC that could not be corrected with spectacles and required specialty lenses, six eyes were post-PKP, two of these were postcataract as well. One eye had undergone a corneal ring procedure for KC, which was reversed and had undergone cross-linking in the same eye. The ages, genders and other outcome measures relating to this study are summarized in Table 1. The mean follow-up time for all 22 eyes was 4.6 ± 1.6 months (range: 1-6). Seven subjects opted to discontinue participation prior to the expected 5 months follow-up for varying reasons, as will be detailed below. Mean wear time for the RGP scleral contact lenses was 7.5 ± 2.7 hours daily (median: 8, range: 2-12).

Visual Acuity Outcomes
The visual acuity (in Snellen fraction) obtained with the RGP scleral lenses and with the prior correction can be seen in Figure 2. Positive slopes indicate improvement in visual acuity, whereas negative slopes indicate worsening visual acuity. Although the visual acuity improved for all subjects, there was a clinical improvement of at least one line (0.2 in Snellen decimal fraction) in 82% of the participants. For one subject there was no change in visual acuity with the scleral lens when compared to the prior correction, and for another two the visual acuity improved by less than a full line in the Snellen decimal fraction. The mean visual acuity in Snellen fraction prior to the scleral contact lens correction was 0.42 and with the scleral lenses was 0.8, which was significantly improved (t-test, p_{df=21} <0.001).

Hours of Wear
The average wear time with the 23.5 mm RGP scleral contact lenses was 7.6 ± 2.5 hours. The hours of wear of the previous
correction were significantly longer than the hours of wear of the scleral lenses (two-tailed paired t-test, \( p_{df=21} < 0.05 \)). However, when spectacle wearers were removed, the hours of wear of the previous correction and the scleral lenses were not significantly different* (\( p_{df=21} \leq 0.5 \)).

Large diameter scleral contact lenses are more difficult to insert and remove than semiscleral lenses and most certainly traditional RGP or piggyback lenses. As a result, the majority of complaints regarding the RGP scleral lenses were due to difficulty in insertion and removal.

### Higher Order Aberrations

As seen in Table 2, the average total RMS of all the wavefront aberrations for all the subjects was significantly lower with the scleral contact lenses than without correction (\( n = 8 \), Mann–Whitney test, \( p < 0.05 \)). The total higher order RMS, total coma RMS, and total tetrafoil RMS were all significantly reduced with the scleral contact lenses (two-tailed paired t-test, \( p_{df=21} < 0.03 \), \( p_{df=21} < 0.03 \), \( p_{df=21} < 0.05 \) respectively). The total trefoil RMS was not significantly improved with the scleral contact lenses (two-tailed paired t-test, \( p = 0.08 \)). The improvement of the wavefront of a subject with and without the lenses can be seen in Figure 3, and the improvement in the subject’s point spread function with the scleral contact lenses can be seen in Figure 4.

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**Table 1:** The main outcomes for all the eyes that participated in the study

<table>
<thead>
<tr>
<th>Subject number and eye</th>
<th>Age</th>
<th>Gender</th>
<th>Hours prior correction</th>
<th>Prior correction type</th>
<th>Hours scleral</th>
<th>Follow-up (months)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1_OD^A</td>
<td>35</td>
<td>M</td>
<td>11</td>
<td>Uncorrected when began trial</td>
<td>6</td>
<td>5</td>
</tr>
<tr>
<td>1_OSA^A</td>
<td>35</td>
<td>M</td>
<td>11</td>
<td>Uncorrected when began trial</td>
<td>6</td>
<td>5</td>
</tr>
<tr>
<td>2_OD^*</td>
<td>48</td>
<td>F</td>
<td>8</td>
<td>Piggyback</td>
<td>8</td>
<td>5</td>
</tr>
<tr>
<td>2_OSA</td>
<td>48</td>
<td>F</td>
<td>8</td>
<td>Piggyback</td>
<td>8</td>
<td>5</td>
</tr>
<tr>
<td>3_OD^*</td>
<td>66</td>
<td>F</td>
<td>12.50</td>
<td>Scleral</td>
<td>11</td>
<td>6</td>
</tr>
<tr>
<td>3_OSA</td>
<td>66</td>
<td>F</td>
<td>12.50</td>
<td>Scleral</td>
<td>11</td>
<td>6</td>
</tr>
<tr>
<td>4_OSB</td>
<td>28</td>
<td>F</td>
<td>10</td>
<td>RGP</td>
<td>7</td>
<td>2</td>
</tr>
<tr>
<td>5_OD</td>
<td>34</td>
<td>M</td>
<td>5</td>
<td>Scleral</td>
<td>5</td>
<td>1</td>
</tr>
<tr>
<td>6_OSC^C</td>
<td>36</td>
<td>M</td>
<td>0</td>
<td>Uncorrected when began trial</td>
<td>3</td>
<td>7</td>
</tr>
<tr>
<td>7_OD</td>
<td>58</td>
<td>M</td>
<td>12</td>
<td>Glasses</td>
<td>8</td>
<td>5</td>
</tr>
<tr>
<td>8_OD</td>
<td>52</td>
<td>M</td>
<td>0</td>
<td>Uncorrected when began trial</td>
<td>8</td>
<td>5</td>
</tr>
<tr>
<td>8_OSA</td>
<td>52</td>
<td>M</td>
<td>0</td>
<td>Uncorrected when began trial</td>
<td>8</td>
<td>5</td>
</tr>
<tr>
<td>9_OD</td>
<td>26</td>
<td>F</td>
<td>12</td>
<td>RGP</td>
<td>8</td>
<td>2</td>
</tr>
<tr>
<td>10_OS^D</td>
<td>23</td>
<td>F</td>
<td>12</td>
<td>Glasses</td>
<td>2</td>
<td>5</td>
</tr>
<tr>
<td>11_OD^E</td>
<td>32</td>
<td>M</td>
<td>12</td>
<td>Glasses</td>
<td>5</td>
<td>3</td>
</tr>
<tr>
<td>11_OSE</td>
<td>32</td>
<td>M</td>
<td>12</td>
<td>Glasses</td>
<td>5</td>
<td>3</td>
</tr>
<tr>
<td>12_OD</td>
<td>32</td>
<td>M</td>
<td>12</td>
<td>Glasses</td>
<td>7.5</td>
<td>6</td>
</tr>
<tr>
<td>12_OSE</td>
<td>32</td>
<td>F</td>
<td>12</td>
<td>Glasses</td>
<td>7.5</td>
<td>6</td>
</tr>
<tr>
<td>13_OD</td>
<td>51</td>
<td>F</td>
<td>12</td>
<td>Semi-scleral</td>
<td>12</td>
<td>6</td>
</tr>
<tr>
<td>13_OSE</td>
<td>51</td>
<td>F</td>
<td>12</td>
<td>Piggyback</td>
<td>12</td>
<td>6</td>
</tr>
<tr>
<td>14_OD^F</td>
<td>28</td>
<td>M</td>
<td>12</td>
<td>RGP</td>
<td>6</td>
<td>1</td>
</tr>
</tbody>
</table>

*Patient also tried the 21 mm RGP scleral lens which he could comfortably wear for 7 hours. Patient required 15 hours and ceased wearing scleral lenses; ^Patient also tried the 21 mm lens but was unhappy with both types; ^Patient had an eye infection and stopped wearing the scleral lenses; ^Moved overseas; ^Past corneal transplant surgery.

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*Spectacles do not come in direct contact with the cornea and can be assumed to be more comfortable than contact lenses. As such it can be assumed that spectacle wear can be tolerated for more hours than contact lens wear.
Table 2: Lists the average and standard deviation of each aberration term in the uncorrected state and with the scleral contact lens corrections as well as the p-value.

<table>
<thead>
<tr>
<th></th>
<th>Uncorrected</th>
<th>Scleral correction</th>
<th>Average reduction</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Average</td>
<td>SD</td>
<td>Average</td>
</tr>
<tr>
<td>Total RMS*</td>
<td>6.01</td>
<td>3.95</td>
<td>2.10</td>
</tr>
<tr>
<td>Lower order astigmatism RMS*</td>
<td>1.90</td>
<td>1.34</td>
<td>0.67</td>
</tr>
<tr>
<td>Total HO RMS</td>
<td>1.78</td>
<td>1.05</td>
<td>0.65</td>
</tr>
<tr>
<td>Total coma RMS*</td>
<td>1.57</td>
<td>0.96</td>
<td>0.55</td>
</tr>
<tr>
<td>Total trefoil RMS</td>
<td>0.39</td>
<td>0.35</td>
<td>0.14</td>
</tr>
<tr>
<td>Total HO spherical aberration*</td>
<td>0.20</td>
<td>0.18</td>
<td>0.08</td>
</tr>
</tbody>
</table>

The double-asterisks (**) by the p-value state that the statistical test performed was the Mann-Whitney test, otherwise the statistical test performed was a two-tailed paired t-test.

Compliance

A total of seven subjects did not comply with the experimental protocol for the following reasons. Two subjects received the RGP scleral contact lenses but did not return for the 1 week follow-up examination and were not included in the analysis. One of them ceased participation due to personal reasons, whereas the other was unable to comply with the wear schedule. A third subject that participated in one follow-up visit ceased participation due to personal reasons. Two additional subjects ceased participation due to dissatisfaction with the lenses. One of them was able to wear the lenses for at least 6 hours daily, but suffered from discomfort in the left eye due to corneal touch. Although a modified lens was ordered, the subject did not return to the follow-up examination to receive the modified lens. The other subject developed an infection while wearing the scleral lens, which was treated by an ophthalmologist. Although the subject was given permission by the ophthalmologist to continue to wear the scleral lenses, the subject opted not to continue his participation. Another subject ceased participation due to corneal transplant surgery. All subjects that returned for at least one follow-up visit and for whom there was visual acuity and hours of wear data were included in the analysis.

Smaller Diameter Lenses

To test if a smaller lens would yield similar results to the 23.5 mm lens, a subset of nine subjects (12 eyes, five male, four female) that either completed the 23.5 mm RGP scleral lens study (six subjects) or were newly recruited (three subjects) were fit with a smaller 21 mm diameter scleral lenses with otherwise identical parameters. Two of the newly recruited subjects had KC, and the third was a postcorneal transplant patient due to acanthamoeba. The ages, genders and other outcome measures relating to this substudy are summarized in Table 3.

Eight subjects were successfully fit with the 21 mm, two of whom were newly recruited. One of the newly
Philip Fine et al

recruited subjects ceased participation for personal reasons and never picked up the lenses that were ordered after the initial fitting session. Visual acuity improved by at least one line (0.2 in Snellen decimal fraction) in 83% of the participants. The visual acuity did not change for one subject, was less than one line worse with the scleral lens for another subject, and was improved by less than one line for a third subject. As seen in Figure 5, the mean visual acuity prior to the 21 mm RGP scleral contact lens for all the eyes included in the analysis was 0.3 (6/20) whereas the visual acuity with the 21 mm RGP scleral contact lens was 0.7 (6/8.6), which was significantly improved (p < 0.0001). The average hours of wear of the 21 mm RGP scleral lenses was 7.7 ± 2.8 (range: 2-12). There was no significant difference between the hours of wear of the prior correction versus the 21 mm RGP scleral lens correction (p = 0.6), also when the spectacle wearers were removed (p = 0.08). The mean follow-up time for these subjects was 2.8 ± 1.5 months (range: 1-5).

Six subjects were fit with both 23.5 and 21 mm lenses. Three of these subjects did not prefer one lens over the other, one subject preferred the 21 mm lens over the 23.5 mm lens, and two subjects discontinued wearing scleral contact lenses entirely. Of the two subjects that discontinued participation, one did not manage with any of the lenses whereas the other was not satisfied with the total wear time of 7 hours with the RGP scleral lenses and preferred his previous mode of correction which granted him 15 hours of wear time. The 21.00 mm lens has become now the first choice lens due the relative ease in handling.

DISCUSSION

This paper reports the results of a prospective clinical evaluation of novel 23.5 and 21 mm scleral contact lenses fitted to a cohort of subjects suffering from corneal distortions. Visual acuity improved by at least one line in 83% of 22 eyes of 14 subjects that participated in the 23.5 mm evaluation, and in 82% of 11 eyes of eight subjects that participated in the 21 mm evaluation. In addition, the lenses could be comfortable worn for an average of 7.35 hours with the 23.5 mm lens and 7 hours with the 21 mm lens; which make them a viable option for visual correction in corneal disease. The total higher order wavefront aberrations that were measured in a subset of eight subjects were found to be significantly reduced with the scleral lenses. The improvement in total higher order aberrations not only provides improved visual acuity, but also improves the subjective visual comfort and overall contrast sensitivity.20

Comparison with Other Studies

Table 4 summarizes the findings of previous evaluations of other types of RGP scleral lenses. It is difficult to directly compare between the studies as some were retrospective, whereas this evaluation was prospective. Furthermore, some investigations included both PMMA and RGP scleral lenses,
## Table 4: Summary of clinical studies on scleral contact lenses

<table>
<thead>
<tr>
<th>Study name</th>
<th>Study type</th>
<th>Lens type</th>
<th>Number of subjects (number of KC subjects)</th>
<th>Average hours of RGP scleral lens wear</th>
<th>Follow-up (months)</th>
<th>Improvement in visual acuity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Schein, Rosenthal and Ducharme, 1992</td>
<td>Prospective</td>
<td>Custom-made</td>
<td>15 (10)</td>
<td>12.3 ± 3</td>
<td>23.3 ± 17</td>
<td>93%</td>
</tr>
<tr>
<td>Tan, Pullum, Buckley, 1995</td>
<td>Retrospective</td>
<td>Variety of scleral lenses including PMMA scleral lenses</td>
<td>85 (38 eyes)</td>
<td>6 patients up to 4 hours, 12 patients between 4 and 7 hours, 15 patients between 8 and 11 hours, 33 patients between 12 hours and more</td>
<td>15.3</td>
<td>72% achieved 6/12 or better</td>
</tr>
<tr>
<td>Pullum and Buckley, 1997</td>
<td>Retrospective</td>
<td>PMMA and RGP scleral lenses</td>
<td>530 (281)</td>
<td>Not given</td>
<td></td>
<td>22% did not continue to wear scleral lenses—9.3% during the process, 8.7% during follow-up</td>
</tr>
<tr>
<td>Vreugdenhil, Geerards and Vervaet, 1998</td>
<td>Prospective</td>
<td>RGP semiscleral 17.2 mm diameter</td>
<td>29 eyes (17 eyes)</td>
<td>Approximately 10-15</td>
<td></td>
<td>States that all either maintained the same visual acuity or improved, but specific numbers are not supplied</td>
</tr>
<tr>
<td>Romero-Rangel, Panagiota, Cotter, Rosenthal, Balatzis and Foster, 2000</td>
<td>Retrospective</td>
<td>Boston scleral lens of varying diameters (15.5-23 mm)</td>
<td>49 (0)</td>
<td>13.7 ± 3</td>
<td>33.6</td>
<td>States that the majority improved, but specific numbers are not supplied</td>
</tr>
<tr>
<td>Rosenthal and Croteay, 2005</td>
<td>Retrospective</td>
<td>Boston scleral lens of varying diameters (15.5-23 mm)</td>
<td>501 eyes (262)</td>
<td>Not given</td>
<td>2 months—18 years</td>
<td>States that all either maintained the same visual acuity or improved, but specific numbers are not supplied</td>
</tr>
<tr>
<td>Pullum, Whiting, Buckley, 2005</td>
<td>Retrospective</td>
<td>Non-fenestrated RGP scleral lenses custom-made</td>
<td>1003 (934)</td>
<td>Not given</td>
<td>Not given</td>
<td>48% achieved VA of 6/24 or better</td>
</tr>
<tr>
<td>Visser, Visser, van Lier and Otten, 2007</td>
<td>Prospective</td>
<td>Procornea spherical, front-surface toric, back-surface toric RGP scleral lenses and bitoric RGP scleral lenses</td>
<td>178 subjects, 284 eyes (143 eyes)</td>
<td>Median 16 hours (range 3-19)</td>
<td>Subjects wore these scleral lenses for 10 months</td>
<td>States that all either maintained the same visual acuity or improved, but specific numbers are not supplied</td>
</tr>
<tr>
<td>Schornack and Patel, 2010</td>
<td>Retrospective</td>
<td>Jupiter RGP sclerals (23 eyes) &amp; custom-made (7 eyes)</td>
<td>32, only 19 participated</td>
<td>Not given</td>
<td>22.5</td>
<td>77% of all study subjects improved in visual acuity. Study reports that 87% achieved 20/40 or better</td>
</tr>
<tr>
<td>Severinsky and Milloot, 2010</td>
<td>Retrospective</td>
<td>Microlens custom-made</td>
<td>97 (88 eyes)</td>
<td>27.5</td>
<td>11 (all eyes), 11.9 (KC eyes)</td>
<td>Studies that all either maintained the same visual acuity or improved, but specific numbers are not supplied</td>
</tr>
<tr>
<td>Fine, Gantz, Leibowitz, Lahav, Jackson, Halperin, Gordon-Shaag, 2012</td>
<td>Prospective</td>
<td>Soflex RGP scleral lens 23 mm diameter</td>
<td>(17 patients, 22 eyes)</td>
<td>7.55 ± 2.7</td>
<td>4.6 ± 1.6</td>
<td>States that all either maintained the same visual acuity or improved, but specific numbers are not supplied</td>
</tr>
</tbody>
</table>
whereas we only used RGP scleral lenses. Other investigations evaluated only custom-made scleral contact lenses, whereas we evaluated a contact lens with constant parameters that were not individually designed for the participants. The advantage of retrospective studies is the large number of participants and the ability to determine the long-term satisfaction with the lenses, which we are unable to report. The mean follow-up for our subjects (4.6 ± 1.6 months) is shorter than in the other studies, though we also required a shorter time commitment from our subjects at the commencement of the study.

However, a prospective study like ours has advantages over retrospective studies in terms of the uniformity of the research and experimental procedures, as well as uniformity in the examiners.

The improvement in visual acuity with both types of lenses is similar to improvement rates reported by other studies. The percentage of improvement is much higher than Pullum and Buckley\textsuperscript{21} and Romero-Rangel et al\textsuperscript{11} which may be due to the fact that the prior study included over 500 participants with various types of corneal distortions and the latter included only other types of corneal distortions and not KC subjects.

Though the range of wear time of 7.6 ± 2.5 for the 23.5 mm lens and 7 ± 2.9 for the 21 mm lens is similar to that found for 18 of 85 subjects in one study,\textsuperscript{22} it is lower than reported by most other studies. The longer wear time found by two of the studies\textsuperscript{23,24} may be due to the fact that they custom-made the lenses for each participant, whereas we used lenses in which only the central curvature, the total diameter and the back vertex power could be modified for the patients. The longer wear time reported by Vreugdenhil et al\textsuperscript{25} could be due to the fact that they did not conduct the study with full scleral lenses but rather with semiscleral contact lenses with smaller diameters (17.2 mm). The longer wear time reported by Romero-Rangel et al\textsuperscript{11} could be due to the fact that they fit a variety diameters to the participants making a direct comparison with our study difficult. As stated above, comparisons to other studies are confounded by differences in the methodologies, such as the cohort of patients, the variety of lens types, some lenses being custom-made, etc. Whereas custom manufactured lenses that are molded to the individual are likely to yield higher wear times and overall comfort, they are more expensive, and require a longer manufacturing process. The advantage of the novel Soflex RGP scleral lenses is that they are commercially available and are therefore more affordable and have a quicker production and supply.

### Subjective Experience with Lenses

For eye care practitioners, the lenses are relatively easy to fit. Drawbacks of the fitting process include the need to use a trial set of lenses, and that inexperienced practitioners may require several trial lenses to achieve an acceptable fluorescein picture. However, after gaining experience in this study, a physiologically acceptable fit was obtained after trying approximately two trial lenses. In addition, patients must be trained in the insertion and removal technique to ensure a homogenous saline tear film layer to provide optimum visual acuity.

From the patient’s prospective, one recurrent complaint was the need to remove the lens and replace the saline in the lens well every few hours. This is due to the large diameter dome-like lens in which deposits and waste are often trapped between the lens and the cornea thereby obscuring vision. At the same time, these lenses offered a visual solution for subjects with highly degraded vision and greatly distorted corneas. So much so, that one subject who was fit with the lens on only one eye (due to the presence of a corneal scar in the contralateral eye) requested that it be fit on the fellow eye as well.

### Dropout and Follow-up Rate

In the 23 mm group, two subjects did not return after the initial visit, while in the 21 mm group one subject did not return after the initial visit. It is possible that these subjects opted not to continue participation due to the length of the optometric examination and fitting procedure, or due to the experience that they had with the scleral contact lenses during the fitting process. These subjects were not included in subsequent analyses.

If lens success is defined by a wear time of more than 6 hours a day alongside an improvement in visual acuity outcomes, then the 23.5 mm lens was successful in eight subjects and the 21 mm lens was successful in six subjects.

Despite the objective success of the scleral lens in terms of hours of comfortable wear and visual acuity outcomes, many subjects did not continue to use the lenses. Six subjects from the 14 that participated in the 23.5 mm study, one of whom was also a subject in the 21 mm study, did not continue to wear any of the scleral lenses. One additional subject from the 21 mm study discontinued participation because of discomfort with the lens.

We informally observed that the subjects that were dissatisfied with the lenses and opted not to continue because of subjective discomfort were subjects that were obtaining a visual acuity of at least 6/9 in one eye with their prior form of correction. Conversely, subjects that were content with the scleral lenses were subjects that could not tolerate
any form of correction and were legally blind without correction. As such, we recommend these large diameter lenses only in cases where other forms of specialty lenses (e.g. piggyback, miniscleral or keratoconic RGP lenses) can no longer offer an optimal solution and as a temporary or long-term alternative to corneal transplant.

Higher Order Aberrations

A summary of previous studies that examined the higher order aberration terms of keratoconic subjects with contact lens corrections can be found in Table 5. To the authors’ knowledge this is the first study to report the effects of scleral contact lenses on higher order aberrations. In accordance with the findings reported here, most studies find a reduction in lower order and higher order total wavefront aberrations with contact lens correction. Most of the other studies measured the wavefront aberrations in keratoconic eyes that were fitted with custom-made soft contact lenses that corrected varying amounts of low order aberration terms, and compared them to the wavefront aberrations obtained with scleral lens corrections.

CONCLUSION

The new scleral contact lenses are advantageous for patients with comprised corneas that cannot tolerate other forms of visual correction. They provide approximately 7 hours of comfortable wear, improve visual acuity outcomes, reduce higher order aberrations, are quick to fit and relatively affordable. These lenses can provide a long-term or temporary alternative to corneal transplant.

Table 5: A summary of previous studies that examined the higher order aberration terms of keratoconic subjects with contact lens corrections

<table>
<thead>
<tr>
<th>Study name</th>
<th>Number of subjects</th>
<th>Lens type</th>
<th>Type of aberrometer</th>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Negishi26</td>
<td>10 KC (13 eyes)</td>
<td>Spherical or aspherical RGP</td>
<td>OPD-scan wavefront aberrometer (model ARK 10000, Nidek, Aichi, Japan)</td>
<td>Significant reduction of total RMS HOA RMS third order RMS, fourth order</td>
</tr>
<tr>
<td>Chen and Yoon27</td>
<td>3 KC (3 eyes)</td>
<td>Back surface customized soft CL</td>
<td>Shack-Hartmann Wavefront Sensor</td>
<td>~23% reduction of total RMS HOA</td>
</tr>
<tr>
<td>Marsack et al28</td>
<td>6 KC (7 eyes)</td>
<td>RGP</td>
<td>Hartmann-Shack complete ophthalmic analysis system (COAS) Wavefront analyzer (WaveFront Sciences, Albuquerque, NM, USA)</td>
<td>Did not directly compare with and without lenses. With the lenses, most subjects fall outside range of normal corneas for total RMS HOA, total RMS coma, total RMS Sec. astigmatism, total RMS tertiary astigmatism</td>
</tr>
<tr>
<td>Marsack et al29</td>
<td>3 KC (3 eyes)</td>
<td>RGP and Wavefront guided soft CL</td>
<td>Hartmann-Shack COAS Wavefront analyzer</td>
<td>~78% reduction RMS HOA both with RGP lenses and customized wavefront guided soft CLs</td>
</tr>
<tr>
<td>Katsoulos30</td>
<td>6 KC (8 eyes)</td>
<td>Custom-made prism ballast soft hydrogel lenses</td>
<td>Hartmann-Shack COAS Wavefront analyzer</td>
<td>64% average reduction of vertical coma and 34% reduction total RMS HOA</td>
</tr>
<tr>
<td>Gumus31</td>
<td>39 distorted cornea patients (56 eyes)</td>
<td>RGP scleral CL</td>
<td>NIDEK OPD Scan II</td>
<td>Statistically significant reduction of total RMS (average 87% reduction), total RMS HOA (average 77% reduction)</td>
</tr>
<tr>
<td>Jinabhai32</td>
<td>3 KC (3 eyes)</td>
<td>Spherical RGP</td>
<td>Hartmann-Shack aberrometer IRX-3</td>
<td>Average 81% reduction of total RMS HOA, 41% reduction of fourth order RMS error, 83% reduction of third order RMS error</td>
</tr>
<tr>
<td>Jinabhai et al33</td>
<td>22 KC (22 eyes)</td>
<td>RGP (16 eyes), toric soft CLs (22 eyes), spectacles (6 eyes)</td>
<td>Hartmann-Shack aberrometer IRX-3</td>
<td>27% reduction in total HO RMS, 28% reduction in third order coma RMS, 34% reduction in third order trefoil RMS, 27% reduction in third order RMS, 43% reduction fourth order spherical aberration, 43% reduction fourth order secondary cylinder RMS, 30% reduction fourth order RMS, 27% reduction fifth order RMS, However: Second order cylinder RMS worsened by 33%</td>
</tr>
<tr>
<td>Present study</td>
<td>7 distorted corneas (9 eyes)</td>
<td>Scleral RGP CL</td>
<td>Hartmann-Shack aberrometer—L80 wave+</td>
<td>Statistically significant reduction of total RMS (average 65% reduction) total RMS HOA (average 64% reduction) total RMS Coma (average 65% reduction) total RMS tetrafoil (average 58% reduction)</td>
</tr>
</tbody>
</table>
ACKNOWLEDGMENTS

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REFERENCES


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