

## 1. INTRODUCTION

The term corneal ectasia includes a group of conditions characterized by progressive thinning, bulging and distortion of the cornea. Keratoconus (KC) is the most prevalent corneal ectasia which affects the surface, structure and transparency contributing towards the conical shape of the cornea [1]. Laser-assisted refractive procedures have become very popular in the last decades. As a result, some patients present altered corneal properties. Similar to KC, ectasia after refractive surgery shows topographic asymmetric inferior corneal steepening [2].

The progression of ectasia increases low-order aberrations (LOA), including myopic spherocylindrical refractive values, and high-order aberrations (HOA). This mainly produces vertical coma aberration due to the loss of rotational symmetry of corneal surfaces. When the cone is displaced inferiorly, the vertical coma is negative, which is induced by the anterior corneal surface [3]. The increase in HOA, reduces the optical quality and therefore the quality of life in comparison with healthy subjects [4]. Surgery treatments, with the goal of stabilization include cross-linking, intrastromal corneal ring segments (ICRS) and keratoplasty. The fitting of rigid gas permeable contact lenses (RGP) is the gold standard treatment of ectasias. The front surface of corneal RGP on an ectatic cornea provides a refractive surface much more regular profile and a post-RGP lens tear film that has the capability to mask both LOA and HOA [5-7]. However, it is difficult for some patients to tolerate these lenses for enough hours to perform their activities [8]. When this occurs, the alternative contact lens options include soft contact lenses (SCL), piggy-back, hybrid and scleral lenses.

25 In recent years, scleral RGP prescribing has increased due to significant  
26 advantages over corneal RGP including improved comfort and stability. Scleral  
27 RGP are designed to vault over the cornea and limbus. This create a fluid  
28 reservoir between the lens and the cornea neutralizing surface irregularities [9].  
29 While scleral lenses offer several advantages, in some cases their size and  
30 application and removal sometimes pose a problem.

31 Previous studies have shown that the visual acuity (VA) achieved using a SCL is  
32 often better than the outcome predicted by aberrometry coefficients. Moreover,  
33 they can achieve higher comfort levels compared to other lenses [10-12].  
34 Carballo-Alvarez et al. [13] reported that soft toric contact lenses (STCL) are a  
35 viable option for good vision in keratoconic eyes with moderate irregularity after  
36 ICRS implantation. Several reports indicate that a high central thickness of the  
37 SCL seems to decrease the HOA and to improve the visual function in irregular  
38 cornea [7, 14-16]. To fully correct the HOA of both anterior and posterior corneal  
39 surfaces in keratoconic patients, customized wavefront-guided contact lens  
40 designs have been developed as an option to improve optical quality in KC [12,  
41 17-22]. Other authors used asymmetric SCL to correct vertical coma aberration  
42 in keratoconic patients [23-25].

43 As previously observed in eyes with an irregular cornea [10, 11], the clinical  
44 experience indicates that in some patients, STCL besides offering high comfort,  
45 leads to better visual function than predicted by corneal HOA indicators and could  
46 be an alternative to RGP lens. The purpose of this study was to assess the  
47 feasibility of STCL fitting in corneal ectasias and their impact on optical quality  
48 and visual performance.

## 50        **2. METHODS**

51    The sample includes twenty participants, all of them previously successfully fitted  
52    with the molded STCL used in this study. The group with irregular cornea  
53    included 11 eyes of 9 subjects with previously diagnosed corneal ectasia with  
54    moderate irregularity, corneal RGP intolerant and transparent central cornea. In  
55    order to analyse the STCL fitting differences between ectatic and healthy  
56    corneas, a group of 11 eyes of 11 patients with regular and healthy cornea was  
57    included.

58    Participants were recruited from the Optometry Clinic of the Complutense  
59    University of Madrid (UCM). Exclusion criteria were a history of any systemic  
60    conditions and any other co-existing forms of ocular disease as well as the use  
61    of systemic or topical ophthalmic medications. This study was conducted in  
62    accordance with the tenets of the Declaration of Helsinki and was approved by  
63    the institutional review board of the Hospital Clínico San Carlos of Madrid (code  
64    18/537-E). All participants were voluntarily included in the study after signing  
65    written informed consent forms.

66

### 67    **2.1 Soft toric contact lenses**

68    A molded STCL (Biofinity toric, CooperVision, USA) was fitted. These silicone-  
69    hydrogel lenses with a prism-ballast design are made of comfilcon A (48% water),  
70    8.7mm of base curve, overall diameter of 14.50 mm, Young's modulus value of  
71    0.75 MPa and Oxygen Transmissibility of 116 Dk/t (at -3.00 D). The design  
72    features of the STCL are described in patent (US6467903B1) [26]. The design  
73    shows a prism ballast and a thickness profile. The anterior surface of the lens

74 shows a peripheral zone, an inner zone circumscribed by the peripheral zone,  
75 and a central optic zone. The ballast portion increases in thickness along a  
76 superior-inferior line parallel to a vertical meridian. Due to the thickness profile,  
77 the inferior portion of the inner zone presents 250  $\mu\text{m}$  more than the upper.  
78 Theoretically, the optic zone is independent of the thickness profile, however  
79 Sulley et al. [27] reported that it presents a trend of  $0.77 \pm 0.05$  base-down  
80 prismatic diopters (for -3.00 sph -1.25 cyl x 180°). Moreover, the analysis with  
81 NIMO TR 1504 (Lambda-X, Belgium) shows that the prismatic effect increases  
82 progressively from the upper to the lower zone, which has the highest prismatic  
83 power. The sagittal height of the fitted STCL presents a high value compared with  
84 other frequent replacement silicone hydrogel lenses [28], this could advantage  
85 an adequate lens behavior in ectatic corneas. Moreover, the design presents the  
86 greatest thickness close to the inferiorly displaced corneal apex. Probably, this  
87 could improve the anterior corneal surface regularization.

88 Initial lens power was calculated from the refraction obtained after referencing the  
89 corneal plane. After ten minutes of fitting, a slit-lamp evaluation was performed  
90 to check that each lens was positioned acceptably in terms of centration and toric  
91 marker alignment. Next, over-refraction was evaluated and if a VA improvement  
92 was observed, a new STCL was prepared based on the lens power plus the over-  
93 refraction, with a new sphere, cylinder and axis.

94

## 95 **2.2 Ocular aberrations, pupillometry and keratometry**

96 The measurement of ocular aberrations, expressed by Zernike polynomials, was  
97 captured from the 2nd to the 5th order by using the sensor of the Visionix-VX110

98 system (Luneau Technology, France). It combines a Hartmann-Shack  
99 aberrometer and a Placido disk corneal topographer. In order to measure the  
100 aberrations, under mesopic conditions for physiological pupil diameter, the  
101 instrument decreased the illumination level of the Placido disc rings projected  
102 onto the corneal surface with the room lighting turned off. Furthermore, the  
103 aberrometric values were calculated for a 3mm pupil diameter. Pupillometry,  
104 keratometry over the anterior surface of the cornea (3mm central zone) and  
105 symmetry index of front corneal curvature were assessed using the same  
106 instrument. The symmetry index defined as the difference (expressed in diopters)  
107 between the mean power of two circular zones centered in the vertical axis.  
108 Positive values indicate a steeper inferior hemisphere, whereas negative values  
109 indicate a steeper superior hemisphere

110

111 The study used the right-hand coordinate reference frame and the double-index  
112 convention for naming Zernike coefficients and polynomials recommended by the  
113 Optical Society of America/Vision Science and its Applications Standards  
114 Taskforce. The signs of bilaterally asymmetrical Zernike coefficients in left eyes  
115 affected by enantiomorphism (Oblique primary astigmatism  $45^\circ$ ; horizontal coma;  
116 oblique trefoil; oblique quadrafoil and oblique secondary astigmatism) were  
117 reversed to allow comparison between right eyes and left eyes [29].

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### 119 **2.3 Visual performance**

120 Visual performance was measured with best spectacle correction and after STCL  
121 fitting under photopic ( $85 \text{ cd/m}^2$ ) and mesopic ( $\leq 3 \text{ cd/m}^2$ ) conditions. High-(96%)

122 and low-(10%) contrast visual acuity (HCVA and LCVA respectively) were  
123 assessed using an ETDRS illumination cabinet (Precision Vision, USA) placed at  
124 4 m. For the mesopic luminance level required, illumination was reduced by using  
125 a large filter designed for use in the ETDRS cabinet with the room lighting turned  
126 off. For photopic conditions, the normal room lighting was left on.

127 The cylinder axis values affected by enantiomorphism were recalculated in left  
128 eyes (180 minus axis value) to allow comparison between right and left eyes.  
129 Next, the relative power vector values of M,  $J_0$ , and  $J_{45}$  were obtained. The  
130 method uses 3 fundamental vectors, including  $M = S + C/2$ ,  $J_0 = (-C/2) \cos 2\alpha$ ,  
131 and  $J_{45} = (-C/2) \sin 2\alpha$ , where S is the sphere power, C is the cylinder power,  $\alpha$   
132 is the cylinder axis, and J is the Jackson astigmatic vector. M is the spherical lens  
133 equal to the spherical equivalent of the refractive error.  $J_0$  value is the cylinder  
134 power set at 90 and 180 degrees and  $J_{45}$  value refers to a cross-cylinder set at  
135 45 and 135 degrees.

136 Contrast sensitivity (CS) was assessed using the Pelli-Robson chart (Clement  
137 Clarke International, UK) placed at 1 m distance. The test was externally  
138 illuminated with a halogen lamp behind a screen and connected to a  
139 potentiometer to adjust the exact voltage needed to reach an adequate mesopic  
140 luminance level with the room lighting turned off. This setup provided uniform  
141 luminance over the entire chart. For photopic conditions, the normal room lighting  
142 was left on. Luminance measurements for the tests were obtained using a Mavo-  
143 Spot 2 USB luminance meter (Gossen, Germany).

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146 **3. STATISTICAL ANALYSIS**

147 All statistical tests were performed using Statgraphics Centurion-XVIII software.  
148 Descriptive statistics, including the mean and standard deviations of the  
149 quantitative data, were calculated. The normality of all data samples was checked  
150 using the Saphiro-Wilk test. A paired t-test was used for normally distributed data.  
151 Non-normally distributed data were evaluated with the Wilcoxon signed-ranks  
152 test. Statistical significance was set at a level of 0.05 (\*p<0.05; \*\*p<0.005;  
153 \*\*\*p<0.001).

154

155 **4. RESULTS**

156 The study evaluated 22 eyes: 11 eyes with corneal ectasia, intolerant to corneal  
157 RGP contact lenses and satisfactorily fitted with STCL (5 eyes of 5 patients with  
158 a KC grade I according to the Amsler-Krumeich classification. [30] 4 eyes of 2  
159 patients with KC grade I in one eye and KC grade II, with flattened keratometric  
160 parameters after ICRS implantation, in the contralateral eye and 2 eyes of 2  
161 patients with corneal ectasia post refractive surgery). The healthy group included  
162 the eye with better visual acuity of 11 subjects with regular cornea and refractive  
163 cylinder from -0.75 D to -2.25 D.

164 The baseline characteristics including physiological pupil diameters and  
165 keratometric powers in the 3mm anterior corneal central zone are detailed in  
166 Table 1. In the eyes with corneal ectasia, mean mesopic pupil diameter was 1.28  
167 mm smaller (p=0.01), whereas mean corneal power was 1.74 D (p=0.03) and  
168 1.65 D (p=0.02) higher in K1 and K2 respectively. The symmetry index was

169 higher in the ectatic corneas ( $p=0.002$ ) with a steeper inferior hemisphere,  
 170 whereas the healthy corneas showed a steeper superior hemisphere  
 171

Table 1: Baseline characteristics in both groups of eyes . Mean  $\pm$  SD.

	Corneal ectasia	Healthy cornea
<b>n</b>	11	11
<b>Male/Female</b>	2/9	3/8
<b>Age (years)</b>	37.9 $\pm$ 7.2	30.2 $\pm$ 9.2
<b>Right/left eye</b>	7/4	4/7
<b>Photopic pupil diameter(mm)</b>	2.96 $\pm$ 0.61	3.12 $\pm$ 0.58
<b>Mesopil Pupil diameter(mm)</b>	4.96 $\pm$ 1.04	6.25 $\pm$ 0.96
<b>K1 (D)</b>	44.96 $\pm$ 1.75	43.22 $\pm$ 1.78
<b>K2 (D)</b>	46.87 $\pm$ 2.04	44.85 $\pm$ 1.66
<b>Symmetry Index (D)</b>	2.47 $\pm$ 3.96	-0.28 $\pm$ 1.00

K1:flatter keratometry value. K2:steeper keratometry value (3mm central zone)

172  
 173 In five eyes with corneal ectasia, the spherical and/or cylindrical contact lens  
 174 values were adjusted after over-refraction to achieve the best VA. In the healthy  
 175 corneas, it was not necessary to change the contact lens refractive parameters  
 176 after over-refraction in any case. Table 2 shows the obtained relative power  
 177 vector values M,  $J_0$  and  $J_{45}$  in both groups of eyes. Statistically and clinically  
 178 significant differences were found between ectatic and healthy corneas regarding  
 179 M ( $p=0.04$  and  $p=0.04$  comparing spectacles and contact lens values  
 180 respectively).

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Table 2. Relative power vector values M, J<sub>0</sub> and J<sub>45</sub> in both group of eyes. Mean± SD.

Refraction (D)	Corneal ectasia		Healthy cornea	
	Spectacles	Contact lens	Spectacles	Contact lens
<b>M</b>	-3.55 ± 1.52	-3.25 ± 1.25	-0.98 ± 3.48	-0.88 ± 3.33
<b>J<sub>0</sub></b>	-0.37 ± 0.79	-0.18 ± 0.77	0.25 ± 0.67	0.19 ± 0.65
<b>J<sub>45</sub></b>	0.29 ± 0.52	0.12 ± 0.24	0.03 ± 0.13	-0.07 ± 0.12

182

183 Table 3 shows the aberrometric values with statistically significant difference pre  
 184 and after contact lens fitting, assessed with 3mm and the different mesopic pupil  
 185 diameters between both groups. With respect to LOA, statistically significant  
 186 differences were only found in the group with corneal ectasia: mean oblique  
 187 astigmatism increased with a change of  $0.15 \pm 0.17\mu\text{m}$  and  $0.34 \pm 0.36\mu\text{m}$  for  
 188 3mm and mesopic pupil diameter, respectively. However, mean defocus  
 189 decreased  $1.41 \pm 0.36\mu\text{m}$  and  $2.17 \pm 0.85\mu\text{m}$  for the same diameters.

190 With respect to HOA, vertical trefoil showed a statistically significant decrease in  
 191 the healthy corneas with a mean change of  $0.03 \pm 0.04\mu\text{m}$  for mesopic pupil  
 192 diameter. Moreover, more positive values of vertical coma were found after  
 193 contact lens fitting in the ectatic corneas with a mean change of  $0.05 \pm 0.06\mu\text{m}$   
 194 and  $0.12 \pm 0.10\mu\text{m}$  for 3mm and mesopic pupil diameters respectively as well as  
 195 in the healthy corneas for mesopic pupil diameter with a mean change of  $0.18 \pm$   
 196  $0.10\mu\text{m}$ . With respect to horizontal coma, a statistically significant increase only  
 197 emerged in the healthy group for mesopic pupil diameter with a mean change of  
 198  $0.06 \pm 0.08\mu\text{m}$ .

199 In addition, other statistically significant changes were found in mesopic  
 200 conditions. In the healthy group, mean oblique secondary astigmatism increased  
 201  $0.02 \pm 0.03\mu\text{m}$ , whereas mean horizontal secondary coma changed  $-0.02 \pm$   
 202  $0.02\mu\text{m}$ . Finally, mean vertical secondary trefoil worsened  $-0.04 \pm 0.06\mu\text{m}$  in the

203 ectatic corneas. Comparing mean changes between both groups, with 3mm pupil  
 204 aperture, statistically significant differences were detected in oblique astigmatism  
 205 (p=0.01), defocus (p<0.001), vertical secondary trefoil (p=0.01) and horizontal  
 206 secondary coma (p=0.03).

Table 3: Aberrometric values with statistically significant difference assessed with 3mm and mesopic pupil diameters pre and after STCL fitting in both groups of eyes. Mean ± SD.

ZERNIKE (μm)	Pupil diameter	Corneal ectasia	Corneal ectasia after STCL fitting	Healthy cornea	Healthy cornea after STCL fitting
<b>Z<sub>2</sub><sup>-2</sup></b> Oblique astigmatism	<b>3mm</b>	0.01 ± 0.38	0.16 ± 0.37	0.01 ± 0.11	-0.01 ± 0.09
	<b>Mesopic</b>	-0.02 ± 0.62	0.32 ± 0.74	0.03 ± 0.18	0.06 ± 0.32
		p=0.01*		P=0.30	
		p=0.004**		p=0.74	
<b>Z<sub>2</sub><sup>0</sup></b> Defocus	<b>3mm</b>	1.67 ± 0.50	0.26 ± 0.37	0.30 ± 1.13	-0.06 ± 0.17
	<b>Mesopic</b>	2.74 ± 0.98	0.57 ± 0.93	0.57 ± 2.80	-0.09 ± 0.71
		p<0.001***		p=0.33	
		p<0.001***		p=0.50	
<b>Z<sub>3</sub><sup>-3</sup></b> Vertical Trefoil	<b>3mm</b>	0.03 ± 0.09	0.06 ± 0.09	-0.02 ± 0.04	0.00 ± 0.03
	<b>Mesopic</b>	0.05 ± 0.17	0.07 ± 0.16	-0.07 ± 0.07	-0.04 ± 0.09
		p=0.11		p=0.05	
		p=0.12		p=0.04*	
<b>Z<sub>3</sub><sup>-1</sup></b> Vertical Coma	<b>3mm</b>	-0.10 ± 0.09	-0.05 ± 0.08	0.02 ± 0.04	0.04 ± 0.03
	<b>Mesopic</b>	-0.22 ± 0.24	-0.10 ± 0.22	0.10 ± 0.13	0.28 ± 0.18
		p=0.02*		p=0.17	
		p=0.003**		p<0.001***	
<b>Z<sub>3</sub><sup>1</sup></b> Horizontal Coma	<b>3mm</b>	0.004 ± 0.06	0.008 ± 0.09	-0.01 ± 0.04	0.01 ± 0.03
	<b>Mesopic</b>	-0.006 ± 0.18	-0.008 ± 0.23	0.01 ± 0.09	0.07 ± 0.14
		p=0.73		p=0.01*	
		p=0.94		p=0.02*	
<b>Z<sub>4</sub><sup>-2</sup></b> Oblique secondary astigmatism	<b>3mm</b>	-0.02 ± 0.03	-0.01 ± 0.01	0.00 ± 0.01	0.004 ± 0.007
	<b>Mesopic</b>	-0.05 ± 0.05	-0.04 ± 0.05	-0.001 ± 0.03	0.02 ± 0.03
		p=0.36		p=0.32	
		p=0.60		p=0.02*	
<b>Z<sub>5</sub><sup>-3</sup></b> Vertical secondary Trefoil	<b>3mm</b>	0.003 ± 0.006	-0.007 ± 0.01	0.001 ± 0.003	0.00 ± 0.004
	<b>Mesopic</b>	0.002 ± 0.02	-0.04 ± 0.07	0.002 ± 0.02	-0.005 ± 0.03
		p=0.06		P=0.51	
		p=0.04*		p=0.22	
<b>Z<sub>5</sub><sup>1</sup></b> Horizontal secondary Coma	<b>3mm</b>	0.00 ± 0.02	-0.01 ± 0.02	0.005 ± 0.01	0.00 ± 0.003
	<b>Mesopic</b>	-0.006 ± 0.03	-0.02 ± 0.04	0.01 ± 0.02	-0.01 ± 0.03
		P=0.20		P=0.16	
		p=0.15		p=0.03*	

207 Statistically significant difference: \*p<0.05; \*\*p<0.005; \*\*\*p<0.001.

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209 Mean differences in HCVA, LCVA and CS are shown in Table 4. Significant  
210 improvements (Figure 1) were found in the ectatic corneas after STCL fitting for  
211 all outcome measures, except photopic CS which was close to significance  
212 ( $p=0.05$ ). Thus, mean photopic HCVA increased  $0.09 \pm 0.11$  logMAR (4.5 letters,  
213 near to clinical significance) and mean photopic LCVA improved  $0.12 \pm 0.15$   
214 logMAR (6 letters). In mesopic conditions, mean HCVA, LCVA and CS improved  
215  $0.11 \pm 0.12$  logMAR (5.5 letters),  $0.18 \pm 0.15$  logMAR (9 letters) and  $0.11 \pm 0.07$   
216 log. units, respectively. Regarding the spectacles outcomes, all the mean values  
217 were significantly better in the healthy group. When the contact lens outcomes  
218 were compared, mean values in photopic LCVA, photopic CS, mesopic HCVA  
219 and mesopic LCVA were significantly better in the healthy group, whereas  
220 photopic HCVA and mesopic CS did not show significant differences.

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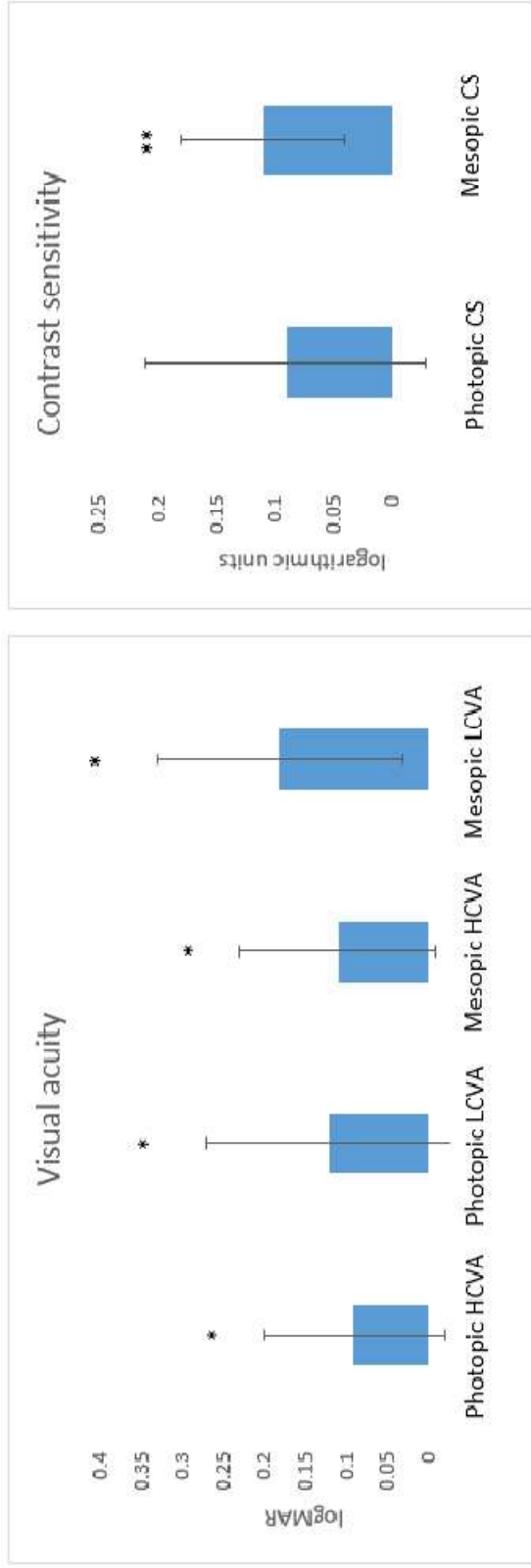
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Table 4: High- and Low- contrast visual acuity (logMAR) and contrast sensitivity (log. units) assessed in both eyes groups, in photopic and mesopic conditions, pre and after-STCL fitting. Mean  $\pm$  SD.

	Photopic conditions						
	HCVA		LCVA		CS		
	Spectacles	STCL	Spectacles	STCL	Spectacles	STCL	
<b>Corneal ectasia</b>	0.08 $\pm$ 0.22	-0.01 $\pm$ 0.14	0.36 $\pm$ 0.26	0.24 $\pm$ 0.20	1.62 $\pm$ 0.10	1.71 $\pm$ 0.13	p=0.05
		p=0.02*		p=0.03*			
<b>Healthy cornea</b>	-0.06 $\pm$ 0.07	-0.06 $\pm$ 0.05	0.07 $\pm$ 0.07	0.05 $\pm$ 0.04	1.97 $\pm$ 0.06	1.98 $\pm$ 0.04	P=1.00
		P=0.86		P=0.49			
	p=0.03*	p=0.59	p=0.008*	p=0.008*	P<0.001***	P<0.001***	
Mesopic conditions							
	HCVA		LCVA		CS		
	Spectacles	STCL	Spectacles	STCL	Spectacles	STCL	
	0.32 $\pm$ 0.28	0.21 $\pm$ 0.19	0.62 $\pm$ 0.26	0.44 $\pm$ 0.19	1.48 $\pm$ 0.14	1.59 $\pm$ 0.09	
<b>Corneal ectasia</b>		p=0.02*		p=0.005*			p=0.001**
<b>Healthy cornea</b>	0.06 $\pm$ 0.08	0.06 $\pm$ 0.05	0.32 $\pm$ 0.12	0.29 $\pm$ 0.11	1.67 $\pm$ 0.15	1.67 $\pm$ 0.09	P=1.00
		P=0.88		P=0.54			
	p=0.01*	p=0.02*	p=0.005**	p=0.04*	p=0.007*	p=0.06	

HCVA: High Contrast Visual Acuity. LCVA: Low Contrast Visual Acuity. CS: Contrast sensitivity. Statistically significant difference: \*p<0.05, \*\*p<0.005, \*\*\*p<0.001.

Figure 1: Visual improvements in photopic and mesopic conditions produced after STCL fitting compared to spectacle values in the group with corneal ectasia. Vertical lines indicate standard deviation.



HCVA: High Contrast Visual Acuity. LCVA: Low Contrast Visual Acuity. CS: Contrast sensitivity. Statistically significant change: \* $p < 0.05$ ; \*\* $p < 0.005$

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## 5. DISCUSSION

237 In the present study, non-customized STCL were fitted in ectatic and healthy  
238 corneas. Although theoretically, standard STCL have limited effectiveness for the  
239 irregular cornea patient, further benefits of these STCL are an easy  
240 manufacturing process thereby reducing costs, many replacement options, their  
241 easy access, along with acceptable comfort. Only a few studies have addressed  
242 molded STCL fitting in eyes with corneal ectasia, and most have examined only  
243 a small number of eyes [10, 11].

244 In five eyes with corneal ectasia, the refractive results of the STCL were not as  
245 predicted by spectacles power (after referencing to the corneal plane). In no case  
246 was necessary to fit a STCL cylinder higher than 2.25D, even when the spectacle  
247 cylinder was greater. A possible explanation for this is that the optical quality of  
248 the eye plus contact lens, besides depending on the optics of the eye, will also  
249 depend on the optical properties of the lens and its interaction with the cornea  
250 and tear film. Further influential factors include partial correction of anterior  
251 corneal surface HOA, which is related to the modulus of the contact lens, the  
252 thickness profile [10, 14, 16], and the interactions between LOA and HOA [31-  
253 33]. Theoretically, it would be possible to change the final power with different  
254 materials and designs. Nepomuceno et al. [11] described a case of a keratoconic  
255 patient after Intacs implantation fitted with a molded disposable STCL (Etalfincon  
256 A). Spectacle refraction was  $-1.25$  sph  $-5.00$  cyl and VA was 0.12 logMAR.  
257 However, final STCL power was  $-2.00$  sph  $-1.25$  cyl and VA was  $-0.08$  logMAR.  
258 Roncone [10] fitted a postoperative LASIK keratoectasia patient with high and  
259 irregular astigmatism with a disposable STCL (Methafilcon B). The final STCL  
260 sphere was +1.00D more positive than the spectacles and the VA improved from

261 0.60 to 0.00 logMAR. In the study of Carballo-Alvarez et al. [13], 23 keratoconic  
262 eyes were fitted satisfactorily with STCL (Hioxylfilcon A) after ICRS implantation.  
263 In agreement with the findings of this study, STCL refractive power and the  
264 significantly improved VA were not those expected for STCL in eyes with regular  
265 cornea [13]. The studies of Jinabhai et al. [34] and Katsoulos et al. [23] with  
266 customized and non-customized STCLs fitted in keratoconic patients, found that  
267 the lower-order sphere and cylinder terms, measured objectively using  
268 Hartmann–Shack aberrometry, did not correspond with the sphere and cylinder  
269 powers measured during a subjective refraction. Jinabhai et al. attributed this  
270 variability at the wavefront sensors and described the importance of a subjective  
271 over-refraction result to determine the powers of the STCL.

272 The eyes with ectatic cornea of this study showed moderate degrees of corneal  
273 irregularity and mesopic pupil diameters, which leads to moderate values of 3<sup>rd</sup>  
274 order coma aberration [4]. Vertical coma results in the ectatic corneas after STCL  
275 fitting both with 3mm pupil aperture and mesopic conditions were similar to those  
276 reported by Naderal et al. [35] in 150 healthy eyes ( $-0.05 \pm 0.25 \mu\text{m}$ ), although  
277 with a large degree of variability in mesopic conditions. The more positive vertical  
278 coma values showed after STCL fitting, are probably related to the optic zone of  
279 the STCL presents a prismatic power base-down. Berntsen et al. [36] fitted 30  
280 healthy eyes with the spherical and toric SCL of four different brands. The only  
281 toric lens with a dual thin-zone stabilization design showed the lower amount of  
282 on-eye vertical coma ( $-0.04\mu\text{m}$ ; 6mm aperture) compared with the three prism-  
283 ballast design toric lenses, which ranged from 0.11 to 0.23 $\mu\text{m}$ . In addition, the  
284 three STCLs with prism-ballast designs had a clinically greater vertical coma than  
285 their sphere counterparts and showed better HCVA than the STCL with a thin-

286 zone design. As several authors concluded [31, 33], one possible explanation is  
287 that other aberrations combined with coma can result in better image quality.  
288 Carpena-Torres et al. [25] proved that base-down prismatic soft contact lenses  
289 generate a statistically significant decrease in defocus which was directly  
290 proportional to prism value as well as an increase in vertical coma, which is  
291 positive and is directly proportional to prism value. This supposes the possibility  
292 of partially correcting the HOA associated with irregular corneas, whose visual  
293 performance is mainly affected by negative vertical coma aberration, with STCL.  
294 Nevertheless, Katsoulos et al. [23] suggested that in order to correct the corneal  
295 negative vertical coma, the thicker part of the optical zone of the contact lens  
296 should be the upper one, and the thinnest part should be the lower one. Jeong et  
297 al. [37] measured a conventional STCL (-4.50 sph -1.75 cyl) with a Hartmann-  
298 Shack wave-front sensor. The contact lenses showed a prismatic stabilization  
299 (base-down) and were placed in a wet cell filled with lens solution. In accordance  
300 with the aforementioned suggestion of Katsoulos et al. a negative vertical coma  
301 of  $-0.20 \pm 0.04\mu\text{m}$  was observed by the authors. Nonetheless, previous reports  
302 [22, 25] and the clinical experience, shows that once the STCL with base-down  
303 prism has been fitted in contact with the anterior corneal surface, a significant  
304 positive shift is found in the ocular vertical coma.

305 Although the coma correction found in the group with corneal ectasia was not  
306 complete, previous studies seem to confirm that partial HOAs correction could  
307 be more appropriate than total correction to achieve better visual performance.  
308 As Chen and Yoon [32] reported, on average, 22%, 24%, and 14% of the anterior  
309 corneal coma were compensated by the posterior cornea in the advanced,  
310 moderate, and mild keratoconic eyes, respectively. Furthermore, crystalline lens

311 may be responsible for some of the residual aberrations measures after RGP or  
312 customized contact lens fitting. This may explain the relatively poor VA obtained  
313 in some eyes with RGP contact lenses, which correct only anterior corneal  
314 aberrations [32]. Other studies with customised lenses suggested that  
315 overcorrect vertical coma generates residual aberration that decreases the visual  
316 performance. Furthermore, the decentration and rotation of a partial correction of  
317 optics aberrations produces a greater visual benefit than total correction or  
318 sphero-cylindrical corrections [12, 38, 39].

319 Regarding the group with corneal ectasia, an improvement in visual performance  
320 after STCL fitting was detected. The photopic CS ( $1.71 \pm 0.13$  log. Units) was  
321 lower than reported by Puell et al. [40] ( $1.93 \pm 0.04$  log. units) for healthy subjects  
322 at the same age range. Conversely, mean mesopic HCVA ( $0.21 \pm 0.19$  logMAR)  
323 was better than the values reported by Hiraoka et al. [41] ( $0.39 \pm 0.12$  logMAR)  
324 for healthy subjects, although such differences may be due to the different test  
325 used between these the studies.

326 As clinical experience demonstrates, the visual function and hence the quality of  
327 life of patients with aberrated eyes is more affected in low contrast and mesopic  
328 conditions. However, mean results of mesopic LCVA ( $0.44 \pm 0.19$  logMAR) and  
329 mesopic SC ( $1.59 \pm 0.09$  log.units) after STCL fitting in the ectatic corneas were  
330 similar to those described in previous studies of healthy eyes. Barrio et al. [42]  
331 reported a mean measurement of  $0.44 \pm 0.11$  logMAR in mesopic LCVA,  
332 meanwhile Puell et al. [40] found a mean value of  $1.60 \pm 0.07$  log. units in mesopic  
333 CS at the same age range as this study. [40]

334 The present study has some limitations that could be improved upon in future  
335 studies. It would be necessary: to increase the sample, to examine corneal

336 surface interactions between low and high order aberrations, long-term neural  
337 adaptation and the use of different materials and designs of STCL.

338 Unlike the group with healthy cornea, the obtained visual performance in the  
339 experimental group was improved over spectacles. Probably, they did not match  
340 the visual performance improvement of other modalities like corneal or scleral  
341 RGP contact lenses. However, it was possible to achieve a satisfactory visual  
342 performance after molded STCL fitting besides offering high comfort and easy  
343 handling. In conclusion, the analyzed molded soft toric contact lens is a feasible  
344 option for good vision in corneal ectasia with moderate irregularity and negative  
345 vertical coma.

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