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# The effect of soft contact lens thickness in visual function after intracorneal ring segments surgery

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ABSTRACT

*Objective:* To study the influence of soft contact lens (SCL) central thickness and material in keratoconus on visual function after intracorneal ring segment (ICRS) surgery.

*Methods:* A pilot, experimental, prospective, cross-sectional and double-blind study was performed. Fourteen keratoconus patients with age range of 34.75 ± 9.22 years (7 males and 7 females) with ICRS implanted were involved in the study. Two different SCL materials [Hioxifilcon A (G-5X/p-GMA/HEMA) and Lucifilcon A (silicone-hydrogel)] with four different central thicknesses (0.1, 0.2, 0.3 and 0.4 mm) were fitted in one eye per patient, selected randomly. High and low corrected distance visual acuity (CDVA) and contrast sensitivity (CS), corneal topography and corneal and total aberrometry were measured.

*Results:* Corneal spherical like, coma like and root mean square (RMS) decreased significantly for 0.3 and 0.4 mm in both SCL materials ($p < 0.05$). Total RMS decreased significantly for 0.4 mm with both SCL materials ($p < 0.05$). High and low CDVA improved for 0.4 mm of thickness for both materials ($p < 0.05$). Statistically increasing were found in all thicknesses studied for CS in both materials ($p < 0.05$).

*Conclusion:* A central thickness of the SCL equal or superior to 0.4 mm seems to decrease the ocular high order aberration (HOA) and to improve the visual function in keratoconus patients implanted with ICRS. However, the modulus of rigidity of the SCL would not influence the HOA correction.

## 1. Introduction

Keratoconus is the most prevalent corneal ectasia. It is characterized by a stromal thinning that causes a corneal protusion [1]. The optical result of this protusion is an increase in both ocular low-order aberrations (LOA), producing high values of myopic sphero-cylindrical errors, and high-order aberrations (HOA), mainly producing, however, abnormal values of coma aberration [2,3]. These HOA reduce visual function in keratoconic eyes below normative data [4]. Nowadays, there are two types of optical treatment: contact lenses fitting and intracorneal ring segment (ICRS) implantation.

ICRS implantation is a surgical procedure recommended to re-establish the corneal regularity [5]. ICRS are implanted in the corneal stroma in order to flatten the cone and to strengthen the cornea, resulting in a decrease of astigmatism and HOA which increases the visual function [6]. Despite the fact that the optical quality of the eye improves after the ICRS surgery [7], there is still a residue of HOA, mainly coma and spherical aberration, often due to partially decentered and superimposed ICRS on the pupil diameter respectively. This residual HOA reduces visual function in comparison with healthy eyes. In most cases after the surgery, the patients need to be compensated with contact lenses in order to decrease corneal HOA.

Rigid gas permeable (RGP) contact lenses fitting is the gold standard method for compensating HOA on ICRS implanted corneas [8]. RGP lenses create a tear meniscus between its posterior surface and anterior corneal surface that reestablishes the regularity of the optical anterior segment [9,10]. There are different designs in RGP materials, such as corneal [10], scleral [11], corneo-scleral [12] and hybrid contact lenses [13]. Despite HOA correction, patients occasionally report discomfort with corneal RGP [14,15] and insertion difficulty with scleral lenses. These factors could induce intolerance to RGP lenses. Therefore, soft contact lenses (SCL) fitting is an option to improve comfort and visual satisfaction after ICRS implantation [16].

Apart from spectacles correction, conventional SCL with spherical and toric designs are usually fitted in incipient keratoconic eyes. However, in advanced stages or after ICRS implantation, the visual benefit of conventional SCL fitting is not widely reported [17–19]. Carballo-Álvarez et al. [19] found an improvement in visual function with spherical and toric SCL after ICRS implantation. High-contrast corrected distance visual acuity (CDVA) values in these groups were

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similar to the piggy-back system (which includes both SCL and corneal RGP lenses) group. Furthermore, high thickness SCL is an alternative option in order to reestablish the symmetry of the optical anterior segment and decrease the HOA. In addition, high thickness SCL improves comfort during its wear and quality of life on irregular corneas [20–29]. Fernández-Velázquez and Fernández-Fidalgo [29] demonstrated an increase in high-contrast CDVA with high thickness SCL after ICRS implantation, these values being close to normative data.

The influence of SCL thickness in ocular HOA has never previously been described. For this reason, the purpose of this study was to study the effect of SCL central thickness and material on HOA correction in keratoconus after ICRS surgery. Furthermore, its influence on visual function was evaluated. The hypothesis was that central thickness and modulus of rigidity of SCL are directly proportional to HOA correction in keratoconus patients after ICRS surgery.

## 2. Methods

### 2.1. Study design

A pilot, experimental, prospective, cross-sectional and double-blind study was made. The study was conducted in compliance with good clinical practice guidelines, institutional review board regulations and following the tenets of the Declaration of Helsinki, reviewed and actualized in 2008 [30]. All participants were voluntarily included in the study after signing a written informed consent where complications associated to SCL wearing were explained. Participants were free to leave the study at any time. All the trials were performed in the Clinic of Optometry of the Faculty of Optics and Optometry (Complutense University of Madrid) by two different optometrists. The lenses were provided to the researchers with a coded label and without lens parameters data; only what measurement should be done with each lens. Then, neither the optometrist who perform the trials nor the patient knew the lens material and central thickness. Ocular wavefront aberrometry, corneal topography and visual function were measured before (PRE) and during different SCL wear.

### 2.2. Sample

Fourteen keratoconus patients (7 males and 7 females) with ICRS implanted were involved in the study. The measurements were performed in one eye per patient, selected randomly in the case that both were implanted with ICRS. The average age of participants was 34.75 ± 9.22 years, ranging from 19 to 48 years. The rest of their demographic characteristics are detailed in Table 1.

Inclusion criteria were keratoconus patients with Keraring® (Mediphacos, Brazil) ICRS implanted 2.5 mm (5 mm of diameter) from corneal apex, understanding and signing the informed consent and knowing the indications and risks of wearing SCL. Exclusion criteria were any contraindication to wearing contact lens, any ocular pathology (except keratoconus), any other type of ICRS implanted and the use of systemic or ocular drugs that could affect the results.

**Table 1**
Demographic characteristics of participants in the study.

| Parameter (mean (SD)) | Keratoconus |
|---|---|
| Number of eyes (patients) | 14 (14) |
| Age (years) | 34.75 (9.22) |
| Age range (years) | [19. 48] |
| Gender (male/female) | [7. 7] |
| Sphere (D) | −4.50 (4.99) |
| Cylinder (D) | −5.19 (2.31) |
| High contrast BCVA (LogMAR) | 0.43 (0.18) |
| Low contrast BCVA (LogMAR) | 0.69 (0.20) |
| Contrast sensitivity (Log units) | 1.03 (0.33) |
| Mean keratometry (D) | 50.52 (3.34) |
| Flat K (D) | 48.54 (3.58) |
| Steep K (D) | 52.49 (3.05) |

(p value < 0.05. Wilcoxon for paired samples. For details see Methods.

**Table 2**
Characteristics of contact lenses used during the study.

| Parameter | Contact lenses | |
|---|---|---|
| Material (USAN) | Hioxifilcon A | Lucifilcon A |
| Material | p-GMA/HEMA | Silicone- Hydrogel |
| Dk (35 °C. Fatt Units) | 21 | 60 |
| % water content | 59 | 69 |
| Modulus index | 0.8 | 1.3 |
| Refractive index | 1.401 | 1.385 |
| Base curve (mm) | 7.10 to 8.90 (steps of 0.30) | |
| Central Thickness (mm) | 0.1; 0.2; 0.3; 0.4 | |
| Diameter (mm) | 14.50 | |
| Power | Plano | |

### 2.3. Soft contact lenses fitting

Two SCL different materials [Hioxifilcon A (G-5X/p-GMA/HEMA) and Lucifilcon A (silicone-hydrogel)] with four different central thicknesses (0.1, 0.2, 0.3 and 0.4 mm) and were provided by Lenticon Laboratories (Madrid, Spain). All contact lenses had a spherical design in both anterior and posterior surfaces. Their diameters were 14.50 mm and available base curve radii were 7.10 to 8.90 mm (steps of 0.30 mm). The base curve fitted for lenses of 0.1 and 0.2 mm of central thickness was Flat K + 0.3 mm. The base curve fitted for lenses of 0.3 and 0.4 of central thickness was Flat K, following manufacturer guidelines. Then, all patients wore the four central thickness for both contact lens materials. More technical details of contact lenses are shown in Table 2.

Before SCL fitting, the healthy state of the anterior surface was evaluated with a SL-D4 slit-lamp (Topcon, Tokyo, Japan). Ten minutes after lens insertion, once the tear secretion was normalized, the centration and movement were assessed. Then, measurements were performed. Two lenses were evaluated in each visit with 2 h of wash out period between lenses. In total, the patients were evaluated in four visits.

### 2.4. Ocular wavefront aberrometry analysis

All the aberrometric variables were expressed by Zernike polynomials according to the pyramidal criteria of the American National Standards Institute (ANSI) [31]. The analysis of ocular wavefront aberrometry was carried out from 3rd to 7th order. A 5 mm pupil diameter was chosen for the analysis, because the diameter of the ICRS implanted was 5 mm. Before measuring, patients were in a room under mesopic conditions for ten minutes in order to obtain the largest pupil size as possible. The device L80 Wave + (Visionix, Chartres, France) was used for measuring the ocular, both total and corneal, wavefront aberrations. Total aberrations were measured three consecutive times with a Hartmann-Shack sensor, which uses near-infrared light of 780 nm wavelength. Corneal aberrations were measured with a Placido rings topography system. Both measurements were performed two seconds after blinking.

Aberrometric variables analyzed were spherical like, coma like and root means square (RMS) HOA. They were calculated by the following expressions:

$$SPHERICAL\ \ LIKE = \sqrt{(Z_{12})^2 + (Z_{24})^2} \quad (1)$$

Where $Z_{12}$ and $Z_{24}$ are the Zernike coefficients of spherical aberration of 4th and 6th order respectively.

$$COMA\ \ LIKE = \sqrt{(Z_7)^2 + (Z_8)^2 + (Z_{17})^2 + (Z_{18})^2 + (Z_{31})^2 + (Z_{32})^2} \quad (2)$$