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ORIGINAL ARTICLE

Relevance of a New Integral Keratoconus Grading System for the Outcomes of Intracorneal Ring Segment Implantation

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ABSTRACT

Purpose: To report a new grading system of Keratoconus according to visual limitation and to provide the intrastromal corneal ring segments (ICRS) outcomes that can be expected based on preoperative visual impairment.

Keywords: Keratoconus, Cornea, Corneal dystrophy, Ferrara rings, Femtosecond laser, Intacs, Intrastromal corneal ring.

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INTRODUCTION

Keratoconus is an ectatic corneal disorder characterized by a progressive corneal thinning that results in corneal protusion, irregular astigmatism and decreased vision.[1] It is one of the most common corneal diseases, the prevalence and the annual incidence in the general population is 54 to 230 and 2 per 100,000, respectively.[1-3] Clinical signs depend on the severity of the disease, moderate to advanced keratoconus cases can be diagnosed easily and symptoms are clearly observed by the patients with a significant distorsion accompained by profound visual loss. Incipient and subclinical keratoconus require an accurate diagnosis and symptoms may not appear.

The management of this pathological condition can be achieved by rigid gas permeable contact lenses,[3] corneal collagen cross-linking,[4] intrastromal corneal ring segment (ICRS) implantation[5] or keratoplasty.[6] The aim of ICRS surgery is to induce a geometric change in the central curvature, thus improving the refractive status of the patient.

Several grading systems have been described in the literature in order to classify the severaty of keratoconus.[7] Nevertheless, most of these grading systems have been developed taking into account the topographic morphology of the disease, the corneal keratometry readings and corneal aberrometry,[8,9] without considering other clinical data that are closely related with the visual disability caused by keratoconus.[10-17] Thus, the success or failure of implanting ICRS for the treatment of KCN have been analyzed in most of the cases taking into consideration the geometric assessment of the cornea which is unpredictable due to response of keratoconic eyes[18-20] and not the visual function of the patients.

We report herein a study which describes a detailed clinical characterization of keratoconus[21] to define a new classification system based on the functional performance of the patient's vision. In addition, we analyzed the therapeutic consideration related to success of implanting ICRS for the management of keratoconus,[22] based on the new classification that takes into consideration the performance of the visual system of the patient.

PATIENTS AND METHODS

Patients

This multicenter retrospective study compromised a total of 776 consecutive keratoconic eyes of 507 patients and 611 eyes of 361 patients treated with ICRS implantation. All the cases were included after a retrospective review of all cases with the diagnosis of keratoconus in different ophthalmologic centers.

The presence of keratoconus was diagnosed using the corneal topography and the slit-lamp examination. The data was recorded when an asymmetric bow-tie pattern with or without skewed axes and at least one keratoconus sign, such as stromal thinning, conical protrusion of the corneal at the apex, Fleischer ring, Vogt striae or anterior stromal scar.[1] Cases implanted with ICRS (Keraring, Mediphacos Ltd, and Intacs, Addition Technology Inc) using either femtosecond laser technology or mechanical corneal dissection were included. Patients with previous ocular surgery or an active disease were excluded from the study. The ICRS implantation was indicated when patients had poor motivation to wear contact lenses or contact lens intolerance.

Following the tenets of the Helsinki declaration, informed consent to include their clinical information in scientific studies was taken from the participants. In addition, institutional ethical board committee approval was obtained.

Examination Protocol

A comprehensive ophthalmologic examination was performed in all cases. The examination included uncorrected distance visual acuity (UDVA), corrected distance visual acuity (CDVA), manifest refraction (sphere and cylinder), slit-lamp biomicroscopy, Goldmann tonometry, fundus evaluation, ultrasonic pachymetry (DHG500 US Pachymeter, DGH Technology, Inc.) and corneal topographic analysis. Three corneal topography systems were used for corneal examination: CMS 100 Topometer (G Rodenstock Instrument GmbH, Ottobrunn, Germany), CSO (Costruzione Strumenti Oftalmici, Firenze, Italy) and Orbscan IIz (Bausch & Lomb, Rochester, NY).[17] The following topographic data were evaluated and recorded: Corneal dioptric power in the flattest meridian for the 3.0 mm central zone (K1), corneal dioptric power in the steepest meridian for the 3.0 mm central zone (K2) and mean corneal power in the 3 mm zone (mean K).

Corneal aberrometry was recorded and analyzed only in eyes examined with the CSO topography system. The device's software (EyeTop 2005) automatically converts the corneal elevation profile into corneal wavefront data using Zernike polynomials with an expansion up to the seventh order. In this study, the aberration coefficients and root mean square (RMS) values were calculated for a 6.0 mm pupil in all cases. The corresponding root mean square (RMS) values were calculated for the following types of aberrations: Higher order (RMS HOA), coma-like (RMS coma-like) (computed for third, fifth and seventh order Zernike terms) and spherical-like (RMS Sph-like) (computed for fourth and sixth order Zernike terms).

Corneal biomechanics were evaluated using the ocular response analyzer (version 2.02). This device delivers an air pulse to the eye which causes two applanation states. The difference between these applanations is the corneal hysteresis (CH). The corneal resistence factor (CRF) is calculated using a proprietary algorithm and is related to the elastic properties of the cornea.[23]

The internal astigmatism (IA) was calculated as the vectorial difference between the refractive astigmatism (calculated to the corneal plane) and the corneal astigmatism.[24,25] IA is also known as intraocular,[26] lenticular,[27] noncorneal astigmatism[28] and ocular residual astigmatism.

Surgical Technique

Surgical procedures were performed by two different methods, mechanical dissection and femtosecond laser assisted, such as in our previous reports.[5,17,22,29] A total of 464 eyes (75.80%) were operated with femtosecond laser-assisted technique, while the remaining 147 eyes (24.20%) were performed with the mechanical dissection.

Regarding the ICRS type, Intacs (Addition Technology, Inc, Fremont, California, USA) were implanted in a total of 314 eyes (51.45%) whereas Kerarings (Mediphacos, Belo Horizonte, Brazil) were implanted in 297 eyes (48.54%).

Level of Visual Limitation

Those patients who underwent to ICRS implantation were divided into five groups according to this new grading system based on the limitation of preoperative visual acuity. In order to evaluate the efficacy of the surgical procedure it was defined success and failure indices. These indices were considered 6 months after surgery:

a. An improvement or a lost in one or more lines in UDVA or CDVA.
b. A decrease/increase in 2 or more diopters of spherical equivalent.
c. A decrease/increase of at least one micron of the RMS corneal HOA or coma-like aberrations.

A best case group was defined taking into account patients who were operated with femtosecond laser, kerarings ICRS and surgery planning performed by the same surgeon (JLA, Vissum Alicane, Spain).

RESULTS

A new grading system[21] was obtained after a consistent linear predictive model of the visual limitation (CDVA) in which were considered visual, refractive, pachymetric, IA, topographic data, corneal aberrations and the corneal biomechanical parameters ($r^2 = 0.71$; adjusted $r^2 = 0.69$; Durbin Watson 1.60; $p < 0.01$).

The 25th, 50th, and 75th percentiles for the variable CDVA were 0.9 (18/20), 0.65 (13/20) and 0.40 (8/20), respectively. With a total of 776 eyes of 507 patients with a mean age of 35.16 ± 11.90 (SD), 4 groups were formed based on this percentiles: Group 1, CDVA better than 0.90; group 2, CDVA between 0.9 and 0.65 ($0.9 \leq CDVA > 0.65$); group 3, CDVA between 0.65 and 0.40 ($0.65 \leq CDVA > 0.40$); group 4, CDVA worse or equal than 0.40. Table 1 shows the visual, refractive, pachymetry, tonometry, IA, and topographic data in these four groups. Statistically significant between group differences were found in all parameters ($p \leq 0.01$) except intraocular pressure (IOP) ($p = 0.08$). Table 2 shows the aberrometric data according to the level of visual limitation.

Based on this classification, an accurate analyze of 611 eyes of 361 patients treated with ICRS, ranging in age from 10 to 73 years old (mean age: 35.15 ± 11.62 years) were evaluated. A fifth group was created, group plus, CDVA worse than 0.20 (4/20) and a modification in a group 4 ($0.40 < CDVA \geq 0.20$) in order to include all the cases. A total of 37 eyes were classified as grade I (13.80%), 87 eyes as grade II (32.46%), 74 eyes as grade III (27.61%), 43 eyes as grade IV (16.04%) and 27 eyes as grade plus (10.07%).

Table 1: Visual acuity, refractive, pachymetry, tonometry, IA, and topographic data according to level of visual limitation

Parameter	*CDVA group*				*p-value**
	Group 1 (CDVA > 0.90)	*Group 2 (0.9 ≤ CDVA > 0.65)*	*Group 3 (0.65 ≤ CDVA > 0.40)*	*Group 4 (CDVA ≤ 0.4)*	
Age (y)					
Mean ± SD	32.69 ± 10.05	35.74 ± 12.40	33.28 ± 12.09	37.38 ± 11.74	0.01
Range	11 to 61	14 to 77	14 to 70	15 to 64	
95% CI	30.77 to 34.62	33.55 to 37.94	30.97 to 35.58	35.51 to 29.25	
UDVA					
Mean ± SD	0.27 ± 0.30	0.22 ± 0.37	0.12 ± 0.32	0.05 ± 0.25	<0.01
Range	1.00 to 0.02	0.9 to 0.017	0.60 to 0.002	0.80 to 0.001	
95% CI	0.34 to 0.21	0.27 to 0.17	0.15 to 0.09	0.08 to 0.04	
Sphere (D)					
Mean ± SD	–1.67 ± 2.88	–1.91 ± 3.39	–2.50 ± 3.95	–4.76 ± 5.49	<0.01
Range	–11.00 to +11.50	–18.00 to +4.75	–15.00 to +6.00	–23.00 to +6.00	
95% CI	–2.10 to –1.25	–2.39 to –1.43	–3.12 to –1.88	–5.48 to –4.05	
Cylinder (D)					
Mean ± SD	–1.72 ± 1.34	–3.33 ± 2.06	–2.50 ± 2.46	–4.07 ± 2.57	<0.01
Range	–11.00 to 0.00	–11.00 to 0.00	–16.00 to 0.00	–15.00 to 0.00	
95% CI	–1.92 to –1.53	–3.62 to –3.04	–4.90 to –4.13	–4.41 to –3.74	
K1 (D)					
Mean ± SD	43.92 ± 2.14	44.65 ± 2.99	46.30 ± 3.79	49.51 ± 6.10	<0.01
Range	33.71 to 53.46	38.26 to 66.02	38.22 to 59.11	33.73 to 79.08	
95% CI	43.61 to 44.24	44.23 to 45.07	45.71 to 46.90	48.72 to 50.31	
K2 (D)					
Mean ± SD	46.22 ± 2.67	48.32 ± 3.63	51.37 ± 4.75	55.01 ± 7.30	<0.01
Range	40.60 to 56.90	41 to 70.16	43.56 to 71.15	41.50 to 90.12	
95% CI	45.83 to 46.62	47.80 to 48.83	50.63 to 52.11	54.06 to 55.96	
K_m (D)					
Mean ± SD	45.08 ± 2.23	46.48 ± 3.16	48.84 ± 4.00	52.27 ± 6.54	<0.01
Range	40.35 to 54.49	40.38 to 68.09	41.15 to 62.30	37.95 to 83.52	
95% CI	44.75 to 45.40	46.03 to 46.93	48.21 to 49.47	51.42 to 53.12	
AST (D)					
Mean ± SD	2.30 ± 1.87	3.67 ± 1.97	5.07 ± 3.04	5.50 ± 3.26	<0.01
Range	0.00 to 14.50	0.33 to 11.78	0.51 to 17.71	0.34 to 20.50	
95% CI	2.03 to 2.57	3.39 to 3.94	4.59 to 5.54	5.07 to 5.92	
IA (D)					
Mean ± SD	1.87 ± 1.87	2.49 ± 2.16	3.61 ± 3.59	4.13 ± 3.46	<0.01
Range	0.02 to 12.12	0.19 to 10.86	0.18 to 19.18	0.23 to 17.94	
95% CI	1.59 to 2.14	2.18 to 2.79	3.04 to 4.17	3.68 to 4.58	
IOP (mm Hg)					
Mean ± SD	12.57 ± 2.81	12.69 ± 2.94	12.23 ± 3.22	11.99 ± 3.21	0.08
Range	5 to 24	6 to 28	5 to 28	5 to 32	
95% CI	12.10 to 13.05	12.20 to 13.17	11.60 to 12.86	11.45 to 12.52	
CCT (µm)					
Mean ± SD	502.39 ± 38.21	483.70 ± 52.61	460.00 ± 48.37	443.46 ± 61.98	<0.01
Range	415 to 589	321 to 606	336 to 563	219 to 605	
95% CI	495.27 to 509.51	474.61 to 492.80	450.45 to 469.55	432.86 to 454.05	

AST: Corneal astigmatism in the central 3.0 mm zone; CCT: Central corneal thickness; CI: Confidence interval; IA: Internal astigmatism; K1: Corneal dioptric power in the flattest meridian in the central 3.0 mm zone; K2: Corneal dioptric power in the steepest meridian in the central 3.0 mm central zone; K_m: Mean corneal power in the 3.0 mm zone; UDVA: Uncorrected distance visual acuity
*Intergroup; all Kruskal-Wallis except CCT (1-way analysis of variance)

Visual Acuity, Spherical Equivalent, Keratometry and Anterior Corneal Higher Order Aberrations

All groups showed an increase in UDVA from preoperative mean value to postoperative. CDVA improved except in grade I in which it decreased significantly from a mean preoperative value of 0.97 ± 0.06 to a mean postoperative value of 0.86 ± 0.18 ($p < 0.01$). Analysis of the mean spherical equivalent (SE) showed a statistically significant reduction in all grades of keratoconus 6 months after the primary surgery ($p \leq 0.02$). The flattest (K1), steepest (K2) and mean keratometry (Km) readings also decreased postoperatively in all grades ($p \leq 0.01$). The anterior corneal higher order aberrations (HOA) showed that even when there was a postoperatively reduction in all types of aberrations under investigation, only the RMS coma-like in grade III was in the limit of statistically significance ($p = 0.05$). Tables 3 to 5 shows the mean values of UCVA, CDVA, SE, K1, K2, Km, RMS HOA, RMS coma-like and RMS spherical-like by level of grade preoperatively and after 6 months of follow-up.

Table 2: Corneal aberrometry data according the level of visual limitation

Parameter	*CDVA group*				*p-value**
	Group 1 (CDVA > 0.90)	*Group 2 (0.9 ≤ CDVA > 0.65)*	*Group 3 (0.65 ≤ CDVA > 0.40)*	*Group 4 (CDVA ≤ 0.4)*	
Eyes (n)	134	114	89	128	-
HO RMS (µm)					
Mean ± SD	1.64 ± 1.18	2.43 ± 1.36	3.29 ± 1.50	4.36 ± 2.83	0.01
Range	0.22 to 6.93	0.48 to 9.15	0.46 to 7.14	0.43 to 20.71	
95% CI	1.29 to 1.68	1.94 to 2.46	2.81 to 3.49	3.74 to 4.82	
Primary SA (µm)					
Mean ± SD	0.27 ± 0.30	0.22 ± 0.37	0.12 ± 0.32	0.05 ± 0.25	<0.01
Range	1.00 to 0.02	0.9 to 0.017	0.60 to 0.002	0.80 to 0.001	
95% CI	0.34 to 0.21	0.27 to 0.17	0.15 to 0.09	0.08 to 0.04	
Primary coma RMS (µm)					
Mean ± SD	–1.67 ± 2.88	–1.91 ± 3.39	–2.50 ± 3.95	–4.76 ± 5.49	<0.01
Range	–11.00 to +11.50	–18.00 to +4.75	–15.00 to +6.00	–23.00 to +6.00	
95% CI	–2.10 to –1.25	–2.39 to –1.43	–3.12 to –1.88	–5.48 to –4.05	
HO residual RMS (µm)					
Mean ± SD	–1.72 ± 1.34	–3.33 ± 2.06	–2.50 ± 2.46	–4.07 ± 2.57	<0.01
Range	–11.00 to 0.00	–11.00 to 0.00	–16.00 to 0.00	–15.00 to 0.00	
95% CI	–1.92 to –1.53	–3.62 to –3.04	–4.90 to –4.13	–4.41 to –3.74	
Spherical-like RMS (µm)					
Mean ± SD	43.92 ± 2.14	44.65 ± 2.99	46.30 ± 3.79	49.51 ± 6.10	<0.01
Range	33.71 to 53.46	38.26 to 66.02	38.22 to 59.11	33.73 to 79.08	
95% CI	43.61 to 44.24	44.23 to 45.07	45.71 to 46.90	48.72 to 50.31	
Coma-like RMS (µm)					
Mean ± SD	46.22 ± 2.67	48.32 ± 3.63	51.37 ± 4.75	55.01 ± 7.30	<0.01
Range	40.60 to 56.90	41 to 70.16	43.56 to 71.15	41.50 to 90.12	
95% CI	45.83 to 46.62	47.80 to 48.83	50.63 to 52.11	54.06 to 55.96	

CDVA: Corrected distance visual acuity; HO: High order; RMS: Root mean square; SA: Spherical aberration
*Intergroup comparison; all Kruskal-Wallis test

Tabla 3: Preoperative and postoperative outcomes after ICRS surgery according to the preoperative visual limitation

Parameters	*Grade*					
	I (CDVA > 0.90)			*II (0.90 ≤ CDVA > 0.65)*		
	Pre	*Post*	*p-value*	*Pre*	*Post*	*p-value*
UDVA						
Mean ± SD	0.36 ± 0.26	0.45 ± 0.24	0.04	0.27 ± 0.21	0.44 ± 0.24	<0.01
CDVA						
Mean ± SD	0.97 ± 0.06	0.86 ± 0.18	<0.01	0.71 ± 0.08	0.75 ± 0.22	0.04
SE (D)						
Mean ± SD	–2.86 ± 2.68	–1.76 ± 2.57	<0.01	–3.88 ± 3.58	–2.07 ± 2.68	<0.01
K1 (D)						
Mean ± SD	43.75 ± 2.95	41.95 ± 2.13	<0.01	45.09 ± 4.44	43.17 ± 4.47	<0.01
K2 (D)						
Mean ± SD	45.91 ± 3.87	44.71 ± 2.20	<0.01	47.41 ± 5.42	46.08 ± 5.25	<0.01
K_m (D)						
Mean ± SD	44.90 ± 2.96	43.35 ± 1.69	<0.01	46.24 ± 4.13	44.52 ± 4.41	<0.01
RMS HO (µm)						
Mean ± SD	2.26 ± 1.28	1.80 ± 0.93	0.69	3.26 ± 1.79	3.01 ± 1.53	0.15
RMS coma-like (µm)						
Mean ± SD	2.07 ± 1.20	1.60 ± 0.94	0.97	2.97 ± 1.52	2.76 ± 1.46	0.07
RMS spherical-like (µm)						
Mean ± SD	0.85 ± 0.51	0.74 ± 0.36	0.64	1.19 ± 1.14	1.10 ± 0.64	0.23

UDVA: Uncorrected distance visual acuity; CDVA: Corrected distance visual acuity; SE: Spherical equivalent; K1: Corneal dioptric power in the flattest meridian in the central 3.0 mm zone; K2: Corneal dioptric power in the steepest meridian in the central 3.0 mm zone; K_m: Mean corneal power in the 3.0 mm zone; HO: Higher order; RMS: Root mean square

Table 4: Preoperative and postoperative outcomes after ICRS surgery according to the preoperative visual limitation

Parameters	*Grade*					
	III (0.65 ≤ CDVA > 0.40)			*IV (0.40 ≤ CDVA> 0.20)*		
	Pre	*Post*	*p-value*	*Pre*	*Post*	*p-value*
UDVA						
Mean ± SD	0.16 ± 0.14	0.24 ± 0.16	<0.01	0.13 ± 0.09	0.20 ± 1.55	<0.01
CDVA						
Mean ± SD	0.45 ± 0.53	0.57 ± 0.22	<0.01	0.27 ± 0.05	0.50 ± 0.22	<0.01
SE (D)						
Mean ± SD	–5.25 ± 4.33	–2.82 ± 4.06	<0.01	–6.35 ± 5.04	–4.18 ± 5.42	<0.01
K1 (D)						
Mean ± SD	48.10 ± 6.00	44.56 ± 4.90	<0.01	51.41 ± 6.69	45.94 ± 4.62	<0.01
K2 (D)						
Mean ± SD	49.88 ± 6.71	47.68 ± 5.68	<0.01	51.89 ± 6.69	49.34 ± 5.74	<0.01
K_m (D)						
Mean ± SD	48.93 ± 5.67	44.52 ± 4.41	<0.01	51.65 ± 6.06	47.64 ± 4.87	<0.01
RMS HO (µm)						
Mean ± SD	4.20 ± 2.39	3.84 ± 1.72	0.15	4.03 ± 1.95	3.43 ± 2.08	0.70
RMS coma-like (µm)						
Mean ± SD	3.86 ± 2.23	3.47 ± 1.60	0.05	3.70 ± 1.91	3.00 ± 2.02	0.43
RMS spherical-like (µm)						
Mean ± SD	1.46 ± 1.17	1.53 ± 0.89	0.40	1.44 ± 0.83	1.52 ± 0.85	0.18

UDVA: Uncorrected distance visual acuity; CDVA: Corrected distance visual acuity; SE: Spherical equivalent; K1: Corneal dioptric power in the flattest meridian in the central 3.0 mm zone; K2: Corneal dioptric power in the steepest meridian in the central 3.0 mm zone; K_m: Mean corneal power in the 3.0 mm zone; HO: Higher order; RMS: Root mean square

Table 5: Preoperative and postoperative outcomes after ICRS surgery according to the preoperative visual limitation

Parameters	*Grade*		
	Plus (CDVA ≤ 0.20)		
	Pre	*Post*	*p-value*
UDVA			
Mean ± SD	0.05 ± 0.04	0.14 ± 0.14	0.03
CDVA			
Mean ± SD	0.09 ± 0.05	0.38 ± 0.26	<0.01
SE (D)			
Mean ± SD	–7.43 ± 6.10	–3.93 ± 5.63	0.02
K1 (D)			
Mean ± SD	53.13 ± 8.10	47.73 ± 4.97	<0.01
K2 (D)			
Mean ± SD	55.68 ± 9.15	50.24 ± 5.11	<0.01
K_m (D)			
Mean ± SD	54.40 ± 8.00	48.81 ± 4.39	<0.01
RMS HO (µm)			
Mean ± SD	6.03 ± 4.02	4.60 ± 2.72	0.11
RMS coma-like (µm)			
Mean ± SD	5.53 ± 3.45	4.10 ± 2.56	0.11
RMS spherical-like (µm)			
Mean ± SD	2.16 ± 2.33	1.84 ± 1.37	0.20

UDVA: Uncorrected distance visual acuity; CDVA: Corrected distance visual acuity; SE: Spherical equivalent; K1: Corneal dioptric power in the flattest meridian in the central 3.0 mm zone; K2: Corneal dioptric power in the steepest meridian in the central 3.0 mm zone; K_m: Mean corneal power in the 3.0 mm zone; HO: Higher order; RMS: Root mean square

Success and Failure according to the Visual Limitation

Tables 6 and 7 show the distribution of the cases according to the success and failure indexes as mentioned previously. Patients with more advandced keratoconus are the ones that gain more lines of CDVA.

DISCUSSION

For several years, the characterization of keratoconus was carried out using different technologies,[7,9-11,13-16] being topographic analysis of the anterior corneal surface the main tool. Taking the geometry and optical properties of the anterior corneal surface into account, several indices,

Table 6: Percentage of successes according to preoperative visual impairment

Grades	*Gain ≥ 1 line UCDVA*	*Decrease ≥ 2 D SE*	*Gain ≥ 1 line BCDVA*	*Decrease ≥ 1 micron RMS-HOA*	*Decrease ≥ 1 micron RMS coma-like*
I	65.51%	36.11%	13.51%	21.05%	21.05%
II	67.21%	40.96%	49.42%	16.21%	18.91%
III	63.46%	50.00%	54.05%	25.00%	28.57%
IV	73.07%	59.52%	81.39%	29.41%	23.52%
Plus	77.77%	60.00%	85.18%	20.00%	20.00%

Table 7: Percentage of failures according to preoperative visual impairment

Grades	*Lost ≥ 1 line UCDVA*	*Increase ≥ 2 DSE*	*Lost ≥ 1 line BCDVA*	*Increase ≥ 1 micron RMS-HOA*	*Increase ≥ 1 micron RMS coma-like*
I	14%	5.55%	51.00%	10.52%	10.52%
II	29.5%	10.84%	29.88%	8.1%	8.1%
III	21.15%	12.00%	18.91%	14.28%	17.85%
IV	15.38%	7.14%	9.30%	5.88%	5.88%
Plus	5.55%	12.00%	11.1%	0%	0%

algorithms, and even neural network aproaches have been developed for keratoconus diagnosis and detection.[9,10,16,30-33] Furthermore, a mathematic model has been described[34] that takes corneal elevation data to reconstruct the corneal shape. Corneal biomechanics is also alterated in eyes with keratoconus inducing changes in the geometry and the optical properties of the anterior corneal surface,[15,35] posterior corneal surface,[11,12,14-16] corneal volume[36] and pachymetry.[21,36]

We report a complete classification of the keratoconus in a large population (776 eyes) considering not only conventional clinical data but also anterior corneal aberrations, internal astigmatism and corneal biomechanicals properties and their correlation with patient's visual perception.[21] In addition, we also analyzed the outcomes of ICRS surgery[22] for the management of the keratoconus based on patient's preoperative visual impairment.

In the first part of the current study, we analyzed keratoconus of different severity (776) finding corneal steepening, central thinning, corneal aberrometric increases and significant toricity of the anterior corneal surface like the classic definition of keratoconus describe.[1] As the corneal shape can be distorted easily, we found a reduced mean value for the CH and CRF parameters but the differences between mild and normal corneas were minimum. For this reason, these parameters are poor screening factors but they should be considered when seeking to form a more detailed characterization. A large mean internal astigmatism value was found, being bigger than normal populations[37,38] and after laser *in situ* keratomileusis.[25] Taking into account that the patients analyzed had transparent crystalline lens and internal astigmatism results from the combination of the toric components of the crystalline lens and the posterior corneal surface, we can conclude that the corneal posterior surface is affected in keratoconic eyes as other authors have reported.[11-16]

The mean keratometry (K_m) is still considered a crucial parameter for grading the severity of keratoconus and it was significantly correlated with CDVA, corneal astigmatism and internal astigmatism. Advanced keratoconus presents large values of K_m and consequently worse CDVA, high corneal and internal astigmatism and irregular corneal aberrometric profile. On the other hand, moderate and mild keratoconus have lower values of K_m and the parameters mentioned above are also affected but to a lesser extent. Corneal HOA play a relevant role in the visual degradation but other factors, such as corneal scattering or the optical degradation of the posterior corneal surface must be observed in the final visual outcomes.

The aim was to determine whether keratoconus cases could be differentiated according to visual limitation using all available clinical data and how could be used this new classification when we studied a treatment for the management of keratoconus, such as ICRS surgery. Thus, in the second part of the article, the success or failure of this surgical technique was analyzed using keratoconus classification based on the functional performance of the patient's visual system.[22]

The effectiveness of ICRS implantation has been studied by a large number of authors[5,18-20,39-45] and it has been demonstrated that there is a flattening of the central cornea after the procedure. We found a statistical reduction in the K_m in all the grades of keratoconus, being largest in those cases with the most severe disease.[45] There was a significant improvement in the UDVA after the surgery[20,39,40,44-47] and 65% of our patients gain at least 1 line.[29,41,45,47,48] Patients classified as grade plus showed

Table 8: Classification of keratoconus according to the visual limitation

Parameters	*Grades*				
	I	*II*	*II*	*IV*	*V*
CDVA (decima notation)	>0.90	≤0.90 > 0.65	≤0.65 > 0.40	≤0.40 > 0.20	≤0.20
K_m (D)	<46.50	≥46.50 < 49.00	≥49.00 < 53.00	≥53.00 < 57.00	>57.00
IA (D)	<2.50	≥2.50 < 3.50	≥3.50 < 4.50	≥4.50 < 5.50	>5.50
RMS coma-like (µm)	<2.50	≥2.50 < 3.50	≥3.50 < 4.50	≥4.50 < 5.50	>5.50
Corneal opacity	–	–	–	–	Yes

CDVA: Corrected distance visual acuity; K_m: Mean corneal power in the 3.0 mm zone; IA: Internal astigmatism; RMS: Root mean square

the most significant increase, gaining in 77% of cases, 1 or more lines of UDVA (Tables 6 and 7).

When we analyzed the results by level of CDVA we found that patients with milder (grade I) form of keratoconus had a decreament in the CDVA but other parameters, such as SE, K_m, RMS HOA, RMS coma-like and RMS spherical-like improve. Some authors[39,40,43,44,46-49] describe that ICRS implantation in keratoconus eyes results in an improvement of the CDVA, however, in garde I we found somewhat different to these previous reports. This might be related to the fact that the degree of visual impairment has not been considered. Besides, patients classified as grades II and III improved in all the parameters but in terms of CDVA the difference between preoperative and postoperative was less. In addtion, the percentage of successes was lower in these three first grades (Table 6). Nevertheless, the index of failure was higher in patients with milder and moderate keratoconus (Table 7). Postoperatively, grade IV and plus were the ones that gain more lines of CDVA becoming one grade minus. Patients with grade IV became grade III and patients with grade plus became grade IV after the intervention. This observation will also support the evidence that patients who benefit the most of implanting ICRS for the correction of keratoconus are those with the most advance form of the disease.

CONCLUSION

The new classification (Table 8) of keratoconus, according to the degree of visual limitation, allows us to know how to better treat the keratoconus taking into account the patient's point of view and several relevant characteristic findings, not only in the anterior corneal surface but also in the posterior surface, corneal thickness and corneal biomechanical properties. Therefore, it would be useful especially in the most incipient cases of keratoconus because, as we have seen, the implanting of ICRS in these cases would not be advisable when we are not sure, if patients will have an improvement of the visual performance. Thanks to this new classification, we can carry out an analysis of the ICRS surgery for the management of the keratoconus, when the procedure should be performed and which grade would be better.

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