Changes in the total corneal refractive power after insertion of intrastromal rings in patients with keratoconus in short, medium and long term

Mudanças no poder refrativo total da córnea após a inserção de anéis intrastromais em pacientes com ceratocone a curto, médio e longo prazo

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ABSTRACT

Objective: To analyze the short, medium and long-term efficacy and stability in 46 eyes with keratoconus, operated with Ferrara intrastromal corneal ring segments.

Methods: The primary endpoint was the mean keratometry of total corneal refractive power. We also studied the effects of age, degree of keratoconus and clinical phenotype on the results, as well as the following keratometry variations and aberrometry variations: flattest, most curved, mean, maximum, astigmatism, root mean square of primary coma aberration and root mean square of secondary coma aberration.

Results: The immediate postoperative reduction in mean keratometry of total corneal refractive power was 3.08±1.51 diopters (D) (p<0.001). At 4 years, the mean keratometry of total corneal refractive power increased to 0.57±0.96D (p=0.005). Between 4 and 7 years, there was no change in mean keratometry of total corneal refractive power (p=0.727). The degree of keratoconus was a factor affecting the efficacy of the intrastromal corneal ring segments, achieving a greater effect in those with a greater degree of keratoconus (p=0.012 between groups). The immediate postoperative reduction was 1.77±1.88D for the flattest, 3.91±2.30D for the most curved, 2.76±1.63D for the mean, 4.42±3.26D for the maximum, 2.15±2.68D for astigmatism, 1.03±0.83µm for root mean square of primary coma aberration and root mean square of secondary coma aberration (p<.001 in all cases). At 4 years, most curved increased by 0.42±0.78D (p=0.001), mean increased by 0.54±0.64 (p<0.001) and root mean square of primary coma aberration decreased 0.14±0.27µm (p=0.020).

Conclusion: Ferrara intrastromal corneal ring segment implantation is an effective and stable long-term treatment for patients with keratoconus. There is, however, partial regression in the medium term.

RESUMO

Objetivo: Analisar a eficácia e a estabilidade a curto, médio e longo prazo em 46 olhos com ceratocone, operados com segmentos de anel intrastromal corneano de Ferrara.

Métodos: A meta primária foi a ceratometria média de poder refrativo total da córnea. Também estudamos os efeitos da idade, grau de ceratocone e fenótipo clínico nos resultados, bem como as seguintes variações de ceratometria e variações de aberrometria: mais plana, mais curva, média, máxima, astigmatismo, raiz quadrada média da aberração comática primária e raiz quadrada média da aberração comática secundária.

Resultados: A redução pós-operatória imediata da ceratometria média do poder refrativo total da córnea foi de 3,08±1,51 dioptrias (D) (p<0,001). Aos 4 anos, a ceratometria média do poder refrativo total da córnea aumentou para 0,57±0,96D (p=0,005). Entre 4 e 7 anos, não houve mudança na ceratometria média da potência refrativa total da córnea (p=0,727). O grau de ceratocone foi um fator que afetou a eficácia dos segmentos do anel intrastromal da córnea, alcançando um efeito maior naqueles com maior grau de ceratocone (p=0,012 entre grupos). A redução pós-operatória imediata foi de 1,77±1,88D para a mais plana, 3,91±2,30D para a mais curva, 2,76±1,63D para a média, 4,42±3,26D para a máxima, 2,15±2,68D para o astigmatismo, 1,03±0,83µm para a raiz quadrada média da aberração comática primária e raiz quadrada média da aberração comática secundária (p<0,001 em todos os casos). Aos 4 anos, a maioria das curvas aumentou 0,42±0,78D (p=0,001), a média aumentou 0,54±0,64 (p<0,001) e a raiz quadrada média da aberração comática primária diminuiu 0,14±0,27µm (p=0,020).

Conclusão: O implante de anel intrastromal corneano Ferrara é um tratamento eficaz e estável a longo prazo para pacientes com ceratocone. Há, no entanto, uma regressão parcial a médio prazo.

INTRODUCTION

Keratoconus is a chronic and progressive ectatic corneal disease that progresses with changes in corneal curvature, causing (to a greater or lesser degree) irregular astigmatism, myopia, and corneal protrusion, which lead to a reduction in visual quality.[1]

Surgical treatment of keratoconus with the implantation of intrastromal corneal ring segments (ICRS) is an additive, reversible, safe, and effective surgical procedure that regularizes the corneal curvature, decreases the refractive error and induced astigmatism and improves the visual quality.[2]

There have been numerous studies[3-9] confirming the safety and efficacy of Ferrara ICRS implants (AJL, Ophthalmic, Spain) in patients with keratoconus, but few have analyzed the procedure's stability in the short, medium and long term. Most of the studies[10-17] have reported a maximum follow-up of 5 years, showing evidence of improved visual, refractive, and topographical quality. A number of these studies[11,13,15,17] have concluded that this improvement remains stable at 5 years. The study by De Araujo et al.[14] corroborated the efficacy of ICRS, but its effect did not remain stable for patients younger than 21 years old.

The total corneal refractive power (TCRP) map obtained with the Pentacam® system encompasses the anterior/posterior corneal curvature, pachymetry, and spherical aberration values.[18] The mean keratometry of TCRP (Km TCRP) and its variation over time would be valuable and useful for analyzing the efficacy and stability of the effect of ICRS.

Numerous studies[19-22] have verified that the Km TCRP measurement is valid and has high repeatability.[23] In their analysis of healthy patients, Hoshikawa et al.[24] suggested that conventional keratometry overestimates the measurement compared with Km TCRP.

The main objective of this study was to analyze the efficacy of implanting Ferrara ICRS in patients with keratoconus and to determine its stability in the short, medium and long term. The primary efficacy variable was obtaining a significant reduction in Km TCRP and analyzing whether it was stable over time. Additionally, we determined the factors that could affect the possible regression, according to age, degree of keratoconus and its clinical phenotype at the time of surgery. We also analyzed the topographical keratometric and aberrometry variations for 6.0 mm of pupil size, all on the anterior corneal surface.

METHODS

This retrospective longitudinal study was conducted according to the principles of the Declaration of Helsinki. Approval was obtained from the Ethics Committee of Hospital Clinico Universitario San Carlos. All patients signed the informed consent document before the surgery.

The inclusion criteria were a diagnosis of primary keratoconus, treated with Ferrara ICRS in Hospital Clinico Universitario San Carlos, and a postoperative follow-up of 72 months with the Pentacam® system (Oculus, Wetzlar, Germany).

We excluded patients who previously or during the follow-up underwent any type of eye surgery or presented any complication. In none of the included cases, the use of any chronic treatment for dry eye or allergy was reflected in the clinical history.

We obtained data on demographics, the surgical procedure, ICRS, and potential complications. From the Pentacam® system, we extracted the Km TCRP and the following keratometry and aberrometry values: flattest (K1), most curved (K2), mean (Kmean), maximum (Kmax), astigmatism (Ast), root mean square of primary coma aberration (RMS coma) and root mean square of secondary coma aberration (RMS coma-like). We performed two or more consecutive examinations, properly focused, aligned and centered, attempting to complete the Placido's disks, and it was necessary to obtain a quality specification value as close as possible to the best measurement quality.

We classified keratoconus according to the Amsler-Krumeich system, prioritizing the Kmean value in cases of questionable stages and according to the clinical phenotypes defined by Alfonso et al.[25]

Data were recorded at various times: preoperative, at 3 months or discharge, 2 years, 4 years and 7 years. We analyzed the variations in the intervals: preoperative to 3 months (to analyze the efficacy); 3 months to 2 years and 2 years to 4 years (to analyze the short-term stability); 3 months to 4 years (for medium-term stability) and 4 years to 7 years (for long-term stability).

Surgical procedure

In all cases, the surgery was performed by experienced surgeons of the Hospital Clinico Universitario San Carlos, with the patient under topical anesthesia, following the center's protocol. The technique employed was manual dissection, with Ferrara ICRS implantation in the optical area of 5.0mm.

The location of the ICRS was calculated following the nomogram recommended by the manufacturer, assessing (based on the Pentacam® data) the position and clinical phenotype of the cone, the keratometric meridian, the comatic axis, and the sphericity and considering the regimens recommended for each keratoconus phenotype published by Fernández-Vega et al.[25]

Postoperative check-ups were performed 2 days after the surgery, between 7 and 15 days, 1 month, and 3 months after the surgery. Subsequent annual check-ups were recommended.

Statistical analysis

The statistical analysis was performed using the IBM Statistical Package for the Social Sciences (SPSS) version 25 application. The normality of the data was analyzed with the Shapiro-Wilk test. To study the statistical significance of the overall variations between two time periods, we used Student's *t*-test for paired samples and the non-parametric Wilcoxon signed-rank test. In the study of the variations in relation to age groups, degree of keratoconus and phenotype, we used the parametric analysis of variance (Anova) F-test for those cases of samples where the normal distribution was not rejected, as well as the non-parametric Kruskal-Wallis test in those cases of samples with no statistical normality. Statistical significance was established at $p<0.05$.

RESULTS

Due to the long follow-up, the initial sample of 46 eyes was reduced to 26 eyes from 24 patients, 11 of whom were men (45.8%) and 13 of whom were women (54.2%). In all periods analyzed, only the 26 eyes that completed long-term follow-up were included. The mean age was 33.7±13.1 years (17 to 61 years).

The periods analyzed were preoperative (2±1 months prior to surgery), 3 months (3±1 months after surgery), 2 years (24±12 months after surgery), 4 years (48±12 months after surgery), and 7 years (84±12 months after surgery).

The complications were extrusion of two ICRS (7.8%), which required withdrawal and subsequent replacement of the ICRS, and three cases (11.5%) of migration, with subsequent repositioning.

Variations in mean keratometry of total corneal refractive power

Table 1 shows the Km TCRP values for the various study periods. The mean postoperative Km TCRP (pre-3 months) decreased significantly in all cases. The mean reduction was 3.08±1.51D ($p<0.001$). In the 3 months to 2 years and the 2 years to 4 years intervals, the mean variations were 0.38±0.94D and 0.19±0.49D, respectively, which were not statistically significant ($p=0.052$ and $p=0.056$, respectively).

However, in the medium term (3 months to 4 years), there was a mean increase of 0.57±0.96D ($p=0.005$), with the Km TCRP decreasing in four cases (15.4%) and increasing in 22 cases (84.6%).

In the long-term (4 to 7 years), there were no statistically significant changes ($p=0.727$).

Multivariate analysis of mean keratometry of total refractive corneal power

The degree of keratoconus was a highly influential variable in the effect obtained after implanting ICRS. Thus, the reduction in Km TCRP in the period between the preoperative baseline situation and 3 months after surgery was greatest for grade IV, followed by grade III, II, and grade I. The patient's age and clinical phenotype were not influential in any of the time intervals ($p>0.05$ between groups in all cases). Table 2 shows the variations in Km TCRP according to age, degree of keratoconus, and phenotype.

Keratometric, astigmatism and aberrometric variations

Table 3 shows the keratometric and aberrometric values for the various periods. After surgery, the keratometric values decreased significantly by 1.77±1.88D for K1 (decreasing in 23 [88%] cases and increasing in 3 [12%]), 3.91±2.30D for K2 (decreasing in 24 [92%] cases and increasing in 2 [8%]), 2.76±1.63D for Kmean (decreasing in all 26 [100%] cases),

Table 1. Preoperative and postoperative mean keratometry values of total corneal refractive power after implanting Ferrara intrastromal corneal ring segments

| Km TCRP (D) | Preop | 3 months | 2 years | 4 years | 7 years | p-value* | | | | |
						Preop-3 months	3 months-2 years	2-4 years	3 months-4 years	4-7 years
Mean±SD	47.33±2.52	44.25±1.89	44.63±1.91	44.82±1.89	44.78±1.68	<0.001	0.052	0.056	0.005	0.727
Range	43.10-51.70	40.40-48.30	41.00-48.10	40.95-48.15	41.95-48.00					

Preop: 2±1 months prior to surgery; 3 months: 3±1 months after surgery; 2 years: 24±12 months after surgery; 4 years: 48±12 months after surgery; and 7 years: 84±12 months after surgery.
*Statistically significant *p*-values are <0.05
Km TCRP: mean keratometry of total refractive corneal power; SD: standard deviation.

Table 2. Influence of age, degree of keratoconus, and clinical phenotype on the change in mean keratometry of total corneal refractive power after Ferrara intrastromal corneal ring segments implantation

Change Km TCRP (D)	Time intervals				
	Pre-3 months	3 months 2 years	2-4 years	3 months-4 years	4-7 years
Age*, years					
≤20	-3.48±1.03	-0.08±1.40	-0.50±0.30	-0.13±1.41	0.28±0.35
21-35	-3.78±1.07	0.51±0.85	0.15±0.58	0.66±0.84	0.07±0.63
36-50	-1.88±0.90	0.23±0.87	0.32±0.48	0.55±0.57	-0.27±0.51
≥51	-2.45±2.61	0.79±0.69	0.45±0.44	1.24±0.81	-0.47±0.82
KC grade†					
I	-2.46±1.14‡	0.63±0.80	0.25±0.55	0.88±0.74	-0.03±0.63
II	-2.89±1.35‡	0.09±1.09	0.08±0.27	0.166±1.81	0.10±0.50
III	-4.51±1.34‡	0.21±0.98	0.20±0.81	0.41±0.34	-0.21±0.83
IV	-6.10‡	1.10	0.75	1.85	-0.95
Clinical phenotypes§					
Croissant	-2.71±1.62	0.65±0.83	-0.02±0.40	0.63±0.97	-0.03±0.70
Duck	-3.22±1.40	0.20±0.89	0.43±0.52	0.63±0.77	-0.22±0.60
Snowman	-3.48±2.33	-0.68±1.23	0.30±0.40	-0.38±1.11	0.50±0.28
Nipple	-	-	-	-	-
Bow-tie	-3.62±0.71	0.98±0.45	0.15±0.70	1.13±1.12	-0.08±0.30

* Groups according to statistical results; † keratoconus grade according to the Amsler-Krumeich system; ‡ p-value between groups: p comparison between groups obtained after analysis of variance <0.05; § classification published by Fernández-Vega. [25]
Results expressed as mean ± standard deviation.
Km TCRP: values mean keratometry of total refractive corneal power

Table 3. Preoperative and postoperative flattest, most curved mean, maximum, astigmatism, root mean square of primary coma aberration and root mean square of coma aberration values after Ferrara intrastromal corneal ring segments implantation

	Preoperative	3 months	2 years	4 years	7 years	p-value				
						Preop-3 months	3 months-2 years	2-4 years	3 months-4 years	4-7 years
K1 (D)										
Mean±SD	46.90±3.64	45.13±3.31	45.54±2.78	45.72±2.89	45.67±3.06	<.001	.057	.227	.920	.791
Range	41.20-57.00	38.50-52.90	40.10-51.20	40.00-51.90	39.60-51.30					
K2 (D)										
Mean±SD	52.22±4.53	48.30±2.75	48.47±2.52	48.73±2.86	48.83±2.73	<.001	.427	.285	.001	.423
Range	44.70-63.80	44.20-54.50	44.60-54.30	44.90-56.10	44.70-55.20					
Kmean (D)										
Mean±SD	49.39±3.89	46.63±2.97	46.95±2.56	47.17±2.77	47.19±2.77	<.001	.118	.170	<.001	.833
Range	43.80-60.20	41.40-53.70	42.60-52.30	42.60-53.40	42.70-53.20					
Kmax (D)										
Mean±SD	58.65±7.39	54.23±5.33	54.51±4.49	55.18±5.01	55.18±4.88	<.001	.618	.206	.069	.991
Range	45.73-80.70	47.03-70.10	48.98-66.30	47.79-67.53	47.55-68.48					
Ast (D)										
Mean±SD	5.33±2.41	3.18±1.54	2.94±1.42	3.02±1.54	3.16±1.91	<.001	.114	.745	.453	.561
Range	0.70-12.70	0.70-6.30	0.20-5.50	0.20-5.80	0.60-9.10					
RMScoma (µm)										
Mean±SD	3.42±2.11	2.39±2.09	2.36±1.96	2.25±1.95	2.31±2.04	<.001	.572	<.001	.0.020	.208
Range	0.51-11.64	0.41-8.75	0.48-8.38	0.22-8.37	0.20-8.93					
RMScoma-like (µm)										
Mean±SD	3.44±2.11	2.41±2.09	2.40±1.94	2.31±1.93	2.35±2.02	<.001	.824	<.001	.0.069	.273
Range	0.51-11.64	0.42-8.77	0.57-8.39	0.35-8.40	0.33-8.95					

Preoperative: 2±1 months prior to surgery; 3 months: 3±1 months after surgery; 2 years: 24±12 months after surgery; 4 years: 48±12 months after surgery; and 7 years: 84±12 months after surgery.
All values measured from the anterior corneal surface.
p-values between groups: p comparison between groups obtained after analysis of variance <0.05.
K1: flattest keratometry; SD: standard deviation; K2: most curved keratometry; Kmean: mean keratometry; Kmax: maximum keratometry; Ast: astigmatism; RMScoma: root mean square of primary coma aberration; RMScoma-like: root mean square of secondary coma aberration.

4.42±3.26D for Kmax (decreasing in 25 [96%] cases and increasing in 1 [5%]), and 2.15±2.68D for Ast (decreasing in 22 [85%] cases and increasing in 4 [15%]), and 1.03±0.83µm for RMS coma and RMS coma-like (decreasing in 25 [96%] cases and increasing in 1 [4%]).

In the short term (3 months to 2 years and 2 years to 4 years), only the aberrometric variations were significant, decreasing RMScoma 0.11±0.14µm and RMScoma-like 0.09±0.12µm between 2 and 4 years. In the medium term (3 months to 4 years), K2 increased by 0.42±0.78D, Kmean increased by 0.54±0.64D and RMScoma decreased 0.14±0.27µm. In all cases, the variation was significant. In the long term (4 to 7 years), all parameters remained stable.

DISCUSSION

The efficacy of Ferrara ICRS in patients with keratoconus has been demonstrated in numerous studies,[3-19] but the procedure's long-term stability is less defined. Most related studies have analyzed short-term results (1 to 2 years),[3,4,6,8] and few have analyzed medium (5 years)[10-15,17] to long-term (10 years) results.[12,16]

The aim of this study was to evaluate the effect induced by Ferrara ICRS on patients with keratoconus and analyze its stability in the short, medium and long term (2, 4 and 7 years) according to the variation in Km TCRP. Our study tested the efficacy of Ferrara ICRS in patients with keratoconus, with a statistically significant (p<.001) mean reduction in Km TCRP of 3.08±1.51D and a reduction in 100% of the cases. Other authors[3,4,6-10,12] have obtained similar results, with a statistically significant mean reduction in anterior keratometry of 3.61D (2.03 to 5.94D).

The short-term variations in Km TCRP revealed overall stability for the procedure, with a certain non-significant tendency towards regression in certain cases. The mean variation was 0.38±0.94D (p=0.052), with decreases in 9 cases (35%) and increases in 17 (65%). Similar results were obtained by Torquetti et al.,[10] although with a non-significant tendency towards a reduction of the effect of 0.17D. Between 2 and 4 years, this slight tendency towards regression of 0.19±0.49D (p=0.056) remained but was non-significant, showing a certain loss of efficacy. Our results confirmed those reported by Torquetti et al.,[10] with a tendency towards progression of 0.26D and by Fernández Vega et al.[13] of 0.30D. In the medium term, however, there was significant worsening, although scarcely relevant, of 0.57±0.96D (p=0.005) in the effect induced by the ICRS.

It is worth noting the study by Torquetti et al.,[10] which reflected the procedure's stability in the medium term, with a non-significant increase of 0.37D, between 1 year (45.88±4.52D) and 5 years (46.25±5.89D). The sample included 35 eyes, and the patients' mean age was 39 years. When comparing that article with our study, only the mean age differed; their sample was slightly older. Keratoconus tends to stabilize around the third decade of life, and, therefore, we cannot determine whether the stability is due to the prolonged effect of the ICRS or to the increase in age.

It is worth noting that, in our series, the long-term (4 to 7 years) changes showed a minimal non-significant regression of 0.04±0.61D. When analyzing the percentage of cases in which the Km TCRP decreased, we observed that the decrease was greater in the long term than in the medium term (54% *versus* 15%), which indicates a tendency towards control of the disease's progression.

In this respect, we need to account for certain limitations in the study, such as the sample's heterogeneity (mean age, 33.69±13.12 years), which makes it difficult to determine whether the progression is halted in the long term because of the effects of the ICRS, due to being a stable keratoconus or due to the effects of natural or physiological cross-linking produced with age.[26]

The study by Torquetti et al.[12] with a 5-year follow-up included 36 eyes, with a mean age of 39 years and no differentiation between stable and progressive keratoconus. The authors analyzed the efficacy of Ferrara ICRS at 5 years and the long-term stability, comparing the values between 5 and 10 years. As with our results, the variation was not statistically significant, with an increase of 0.12D. The results of another long-term study by Moscovici et al.[16] are not comparable with our results because the authors did not define the study time, analyzing results between 3 and 16 years but with no defined study period.

In our study, the analysis of the variables that could affect the variations in Km TCRP showed that the degree of keratoconus affected the efficacy of the ICRS, with a greater reduction as the degree of keratoconus increased (p=0.012 between groups).

In the medium-term analysis, none of the variables was statistically significant with the sample of 26 eyes (7-year follow-up); however, in the sub-analysis of 46 eyes (4-year follow-up), the degree of keratoconus affected this regression. Due to this result and the fact that the sample was not homogeneous by degree, the results cannot be considered conclusive; however, they do provide information that, in more advanced (grade IV) keratoconus, the effect induced by the ICRS and the medium-term regression can be greater. This finding needs to be confirmed in prospective studies with larger samples.

The results of the keratometric variables (K1, K2, Kmean, Kmax and Ast) also demonstrated the efficacy of the ICRS, with a statistically significant reduction in all of them in the short term, along with a tendency towards regression in the medium term, and a statistically significant increase only in K2 and Kmean. In the long term, this variation remained stable. The stability that K1, Kmax, and Ast presented in the medium term could be explained as indicated by Pesando et al.[11] in their study at 5 years.

After the ICRS implantation, there is a corneal remodeling and regularization effect, obtaining more spherical and regular topographical maps, which could be due to

the elastic reorganization of the cornea after the effect induced by the ICRS. This finding also agrees with the results De Araujo et al.[14] who, at 5 years, observed a statistically significant variation in Kmax but only for patients younger than 21 years.

The aberrometric results (RMScoma and RMScoma-like) confirmed the efficacy of ICRS, which maintained and even reduced aberration in the short and medium terms. These results should be verified with further studies, as they differ from those obtained by Costa et al.[17] Moreover, we must take into account that this could be due to the great variability of the topographic examinations performed in this type of eyes with keratoconus and with ICRS, as they may vary according to the centering and the quality of the measurement.

Although the variation of Km TCRP was minimal and not clinically relevant in the medium term, the statistical results showed this variation was significant; therefore, it was considered a procedure that is not stable in the medium term. We must take into account the limitations of our study such as not delimiting the sample according to the stage of progression of keratoconus. It would therefore be appropriate to conduct additional studies with more homogeneous samples, delimited in terms of keratoconus progression, age, and ICRS characteristics, in addition to a meticulous control in taking measurements.

CONCLUSION

In conclusion, Ferrara intrastromal corneal ring segment implantation in patients with keratoconus is an effective procedure, given that it has achieved a statistically significant postoperative reduction in total corneal refractive power, which remained stable in the short term. In the medium term, there was a loss of the achieved effect, which remained stable once again in the long term.

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