Refractive and Aberrometric Outcomes of Intracorneal Ring Segments for Keratoconus: Mechanical versus Femtosecond-assisted Procedures

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Objective: To compare visual, refractive, and corneal aberrometric outcomes in keratoconic eyes implanted with intracorneal ring segments (ICRS) implantation using either a mechanical or a femtosecond laser-assisted procedure.

Design: Retrospective, consecutive case series.

Participants: A total of 146 consecutive eyes of 106 patients with the diagnosis of keratoconus (68 unilateral and 39 bilateral) were included. Two groups were created according to the surgical technique used for corneal tunnelization: Mechanical group (mechanical tunnelization, 63 eyes) and Femtosecond group (femtosecond laser-assisted tunnelization, 83 eyes). Intracorneal ring segments implantation was indicated because of the existence of reduced best spectacle-corrected visual acuity (BSCVA) or contact lens intolerance.

Methods: Intracorneal ring segments implantations were performed by 6 surgeons following the same protocol except for the incision location. A total of 55 eyes were implanted with Intacs (Addition Technology, Inc, Fremont, CA) and 8 eyes were implanted with KeraRings (Mediphacos, Belo Horizonte, Brazil) in the Mechanical group, and 25 eyes were implanted with Intacs and 58 eyes were implanted with KeraRings in the Femtosecond group. Mean follow-up was 10.66±8.20 months, ranging from 1 month to 24 months.

Main Outcome Measures: Uncorrected visual acuity (UCVA), BSCVA, refraction, keratometry, and root mean square (RMS) for different kinds of corneal aberrations.

Results: By reporting only for statistically significant changes, UCVA improved in both groups at 6 months ($P \leq 0.02$) and BSCVA improved in the Femtosecond group ($P < 0.01$). The refraction improved in both groups at 6 months ($P \leq 0.02$). The cornea on average was flatter in both groups at 6 months ($P < 0.01$). Root mean square astigmatism was reduced in the Femtosecond group ($P = 0.03$), but there was an increase in some higher-order aberrations ($P = 0.03$). Significant differences were found between the 2 groups for eyes implanted with Intacs for primary spherical aberration, coma, and other higher-order aberrations, favoring the Femtosecond group ($P \leq 0.01$). A significant negative correlation was found between the preoperative corneal aberrations and the postoperative BSCVA in the Mechanical group ($r > 0.63$, $P \leq 0.04$).

Conclusions: Intracorneal ring segments implantation using both mechanical and femtosecond laser-assisted procedures provide similar visual and refractive outcomes. A more limited aberrometric correction is observed for eyes with mechanical implantation.

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Keratoconus is an ectatic corneal disorder characterized by a progressive corneal thinning that results in corneal protrusion, irregular astigmatism, and decreased vision.[1] The management of patients with keratoconus must include visual rehabilitation because the visual function is devastated as a result of the significant increase in all ocular aberrations.[2–5] Spectacle correction is only adequate for early cases, whereas in advanced or moderate cases, contact lenses or surgical solutions are necessary to achieve a satisfactory visual outcome. Rigid gas-permeable and hybrid contact lenses provide good visual quality.[6] However, some patients can become intolerant to contact lenses[7] or achieve an unacceptable visual performance.[8]

Intrastromal corneal ring segments (ICRS) have been proposed and investigated as an additive surgical procedure for keratoconus correction,[9–28] providing an interesting alternative aiming at delaying and preventing corneal graft in patients with keratoconus.[15,16] This type of surgical treatment has proved to be effective in improving visual acuity, reducing the refractive error and mean keratometry. The addition of extra material at the corneal mid-periphery induces a displacement of the local anterior surface forward at

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this area and a flattening of the central portion of the anterior cornea because of the morphologic structure of corneal lamellae (arc-shortening effect).[29] The use of short arc-length ring ICRS has proved to be effective for the correction of astigmatism,[9,13,25] because this kind of procedure induces less corneal flattening and a significant change in corneal toricity as a result of the corneal architecture (predicted by finite element modeling).[30]

Mechanical dissection was the first method described for facilitating the insertion of ring segments (mechanical procedure).[26–28] Good visual results and reduced complications rates have been reported using the mechanical procedure in early to moderate keratoconus.[10,11,14–17,19–28] However, the use of femtosecond laser for corneal tunnelization became widely accepted after the approval of its use by the Food and Drug Administration in the United States.[31] This laser allows the surgeon to program the tunnelization at a predetermined depth with a high degree of precision. Theoretically, this femtosecond laser-assisted procedure would generate a more accurate stromal dissection, reducing surgical error and leading to better visual and refractive results. However, in 2 studies[32,33] comparing both femtosecond and mechanical tunnelization procedures in ectatic eyes, no differences in visual and refractive outcomes were detected. However, the follow-up period was no greater than 12 months.

The aim of the present study was to compare visual, refractive, and corneal aberrometric outcomes in keratoconic eyes in which ICRS implantation was facilitated using either the mechanical or the femtosecond-laser assisted procedure with a follow-up period up to 24 months.

Patients and Methods

Patients

In the current study, a multicenter retrospective analysis of a nonrandomized consecutive series of cases was performed. Data of all patients who underwent ICRS implantation for keratoconus treatment from September 2000 to June 2007 in 6 different ophthalmologic centers, 5 Spanish (Vissum Alicante, Vissum Sevilla, Vissum Albacete, Vissum Almería, University Clinic of University of Navarra) and 1 Turkish (Refractive Surgery Department of Dunya Eye Hospital, Istanbul), were reviewed and analyzed comprehensively. Table 1 summarizes the contribution of each participating center to the current study. A total of 146 consecutive eyes of 106 patients diagnosed with keratoconus (68 unilateral and 39 bilateral cases) were included. Two different groups were created according to the surgical technique used for creation of corneal channels: eyes operated using mechanical tunnelization (Mechanical group: 63 eyes, 43.15%) and eyes operated using femtosecond laser-assisted tunnelization (Femtosecond group: 83 eyes, 56.85%). In all cases, ICRS implantation was indicated because of the existence of reduced best spectacle-corrected visual acuity (BSCVA) or contact lens intolerance.

A comprehensive examination was performed in all cases before ICRS implantation to ensure the viability of the surgery. This examination included Snellen uncorrected visual acuity (UCVA) and BSCVA (decimal notation), manifest refraction, slit-lamp biomicroscopy, Goldman tonometry, fundus evaluation, ultrasonic pachymetry, and corneal topography. Keratoconus diagnosis was based on corneal topography and slit-lamp observation: asymmetric bowtie pattern with or without skewed axes and presence of stromal thinning, corneal conical protrusion at the apex, Fleischer ring, Vogt striae, or anterior stromal scar.[1]

Table 1. Contribution of Each Participating Ophthalmologic Center to this Retrospective Study

Investigator	Surgeon	Ophthalmologic Center	Eyes Implanted with ICRS
1	Dr Alió	Vissum Alicante (Spain)	116
2	Dr Coşkunseven	Refractive Surgery Department of Dunya Eye Hospital, Istanbul (Turkey)	14
3	Dr Morbelli	Vissum Albacete (Spain)	6
3	Dr Uceda	Vissum Sevilla (Spain)	4
4	Dr Maldonado	University Clinic, University of Navarra	3
5	Dr Cuevas	Vissum Almería (Spain)	3

ICRS = intracorneal ring segments.

Because topographic data were collected from different periods and different centers, 3 different corneal topographic systems were used for corneal examination: CMS 100 Topometer (G. Rodenstock Instrument GmbH, Ottobrunn, Germany), CSO (CSO, Firenze, Italy), and Orbscan IIz system (Bausch & Lomb, Rochester, NY). The first 2 devices are Placido-based systems, and the Orbscan IIz is a combined scanning-slit and Placido-disc topographic system. Although agreement between these specific devices has not been reported, Orbscan and Placido-based devices have been proved to provide similar accuracy and precision on calibrated spherical test surfaces.[34] In the study, the following topographic data were evaluated and recorded with all corneal topographic devices: the corneal dioptric power in the flattest meridian for the 3 mm central zone (K1), corneal dioptric power in the steepest meridian for the 3 mm central zone (K2), mean corneal power in the 3 mm zone (KM), and inferosuperior asymmetry index, calculated as the difference between the dioptric power at 3 mm below and above the corneal geometric center.

Corneal aberrometry was also recorded and analyzed only in those patients examined at all visits with the CSO topography system (85 eyes), because this device was the only one with the capability to calculate directly this specific information. The CSO topography system analyzes a total of 6144 corneal points of a corneal area enclosed in a circular annulus defined by an inner radius of 0.33 and an outer radius of 10 mm in respect to corneal vertex. The software of this system, the EyeTop2005 (CSO), automatically performs the conversion of corneal elevation profile into corneal wavefront data using the Zernike polynomials with an expansion up to the seventh order. In this study, aberration coefficients and root mean square (RMS) values were always calculated for a 6-mm pupil. The following aberrometric parameters were recorded and analyzed: higher-order RMS (computed for third to seventh Zernike terms), primary coma RMS (computed for the Zernike terms $Z_3^{\pm 1}$), coma-like RMS (computed for third, fifth, and seventh-order Zernike terms), spherical-like RMS (computed for fourth and sixth-order Zernike terms), and residual RMS (computed considering all Zernike terms except those corresponding with primary coma and spherical aberration). The corresponding Zernike coefficient for primary spherical aberration (Z_4^0) was also reported with its sign.

Table 2. Nomogram for Intacs (Addition Technology, Inc, Fremont, CA) Implantation Based on Corneal Topographic Pattern and Defined by our Research Group[36]

Corneal Topography Pattern	Indication
Steepening area not involving the 180-degree meridian of the cornea (inferior cone)	1 segment of 0.45-mm thickness
Steepening extending at least 1 mm above and beyond the 180-degree meridian (central cone)	2 segments: 0.45-mm thickness segment inferiorly and 0.25-mm thickness segment superiorly

This nomogram was used in the current study.

Ethical board committee approval of our institution (Vissum Instituto Oftalmologico de Alicante) was obtained for this investigation. In addition, during the process of consent for this surgery, consent was taken to later include clinical information in scientific studies.

Surgery

Surgical procedures were performed by 6 surgeons, 1 from each participating center in the study (JLA, Vissum Alicante; EC, Dunya Eye Hospital; HM, Vissum Albacete; AUM, Vissum Sevilla; MML, University of Navarra; and DC, Vissum Almería). In all cases an antibiotic prophylaxis was prescribed before surgery, consisting of topical ciprofloxacin (Oftacilox; Alcon Cusí, Barcelona, Spain) every 8 hours for 2 days. All procedures were performed under topical anesthesia.

The mechanical surgical procedure was initiated marking a reference point for centration (pupil center) and performing a radial incision of approximately 1.8 mm in length. After this, a calibrated diamond knife was set at approximately 70% of the mean corneal thickness determined by ultrasonic pachymetry. From the base of the incision, pocketing hooks were used to create corneal pockets on each side of the incision, taking care to maintain a uniform depth. A device containing a semiautomated suction ring was placed around the limbus, guided by the previously marked reference point on the cornea. Two semicircular dissectors were placed sequentially into the lamellar pocket to be steadily advanced by a rotational movement (counterclockwise and clockwise dissectors).[35] In the femtosecond laser-assisted surgical procedure, the disposable glass lens of the laser system was first applanated to the cornea to fixate the eye and help maintain a precise distance from the laser head to the focal point.[13] Then, a continuous circular stromal tunnel was created at approximately 80% of corneal depth (if this depth was $<$400 μm; if not, a channel was dissected exactly at 400 μm) within 15 seconds with no corneal manipulation.[13] The 30-kHz IntraLase femtosecond system was always used (IntraLase Corp, Irvine, CA), which could not dissect more than 400 μm. Incision location was dependent on the surgeon criteria: on the steepest meridian in 122 eyes (83.56%) and on the flattest meridian in 24 eyes (16.44%).

In regard to the ICRS type, Intacs (Addition Technology, Inc, Fremont, CA) were implanted in 80 eyes (54.79%) and KeraRings (Mediphacos, Belo Horizonte, Brazil) were implanted in 66 eyes (45.21%). In the Mechanical group, 55 eyes were implanted with Intacs (37.67%) and only 8 eyes were implanted with KeraRings (5.48%). In the Femtosecond group, 25 eyes (17.12%) were implanted with Intacs and 58 eyes were implanted with KeraRings (39.73%). A tunnel with an inner diameter of 6.6 mm and an outer diameter of 7.8 mm was planned for Intacs implantation, and a tunnel with an inner diameter of 4.8 mm and an outer diameter of 5.7 mm was planned for KeraRings implantation.

The selection of the number (1 or 2) and thickness of Intacs segments was performed following the criteria defined and reported by our research group[35] (Table 2). In regard to KeraRings, arc-length, thickness, and number of segments were selected considering the nomogram defined by the manufacturer[13] (Table 3). Only 1 ring segment was implanted in 26 eyes (17.81%), whereas 2 segments were necessary in the other 120 eyes (82.19%).

Only 2 intraoperative complications were reported in our series: a microperforation in 1 eye (0.68%) using the mechanical spreader and decentered channels with segments over the pupillary area using the IntraLase technology in another eye (0.68%). In addition, in another eye operated using the mechanical tunnelization, a superficial channel was created and finally had to be explanted (extrusion at 1 month).

Topical tobramycin and dexamethasone eye drops (TobraDex; Alcon Laboratories, Inc., Fort Worth, TX) were used postoperatively every 6 hours for 1 week and stopped. Topical lubricants were also prescribed every 6 hours for 1 month (Systane, Alcon Laboratories, Inc.).

Follow-up Evaluation

Postoperative visits were scheduled for the first postoperative day and for months 1, 3, 6, 12, and 24 postoperatively. On the first postoperative day, UCVA measurement and slit-lamp examination (intracorneal rings position and corneal integrity) were performed. Snellen UCVA and BSCVA measurement, manifest refraction, slit-lamp examination, and corneal topography were performed in the rest of postoperative examinations. The mean follow-up was

Table 3. Nomogram for KeraRings (Mediphacos, Belo Horizonte, Brazil) Implantation Proposed by the Manufacturer (2007)[13]

Spherical Equivalent (D)	All Ectasia Is Limited to One Half of the Cornea	75% of the Ectasia in One Half of the Cornea and 25% Situated in the Other Half	Two Thirds of the Ectatic Area in One Half of the Cornea and One Third in the Other Half	Ectasia is Distributed Evenly in Both Corneal Halves
>−10 D	25/35	25/35	30/35	35/35
−8 to −10 D	20/30	20/30	25/30	30/30
−6 to −8 D	15/25	15/25	20/25	25/25
−2 to −6 D	0/20	0/20	15/20	20/20

D = diopters.
This nomogram was created for 160-degree arc-length segments only, and it provided a selection of segment distribution and thickness based on spherical equivalent and corneal topographic pattern (distribution of ectasia). For defining the distribution of the ectasia, the cornea is divided into 2 halves using the steepest meridian as axis of separation. Nomogram notation: 25/35 = upper segment thickness/lower segment thickness (0.25 mm/0.35 mm).

Table 4. Distribution of Keratoconus Cases According to the Amsler-Krumeich and Alió-Shabayek Classifications in the Mechanical and Femtosecond Groups

	Grade I	Grade II	Grade III	Grade IV
Mechanical				
Amsler-Krumeich	30 (47.62%)	16 (25.40%)	5 (7.94%)	12 (19.05%)
Alió-Shabayek	6 (28.6%)	9 (14.3%)	1 (1.6%)	5 (7.9%)
Femtosecond				
Amsler-Krumeich	38 (45.78%)	21 (25.30%)	10 (12.05%)	14 (16.87%)
Alió-Shabayek	22 (36.1%)	18 (29.5%)	8 (13.1%)	13 (21.3%)

10.66±8.20 months, ranging from 1 month to 24 months. A total of 39 eyes completed the 24-month follow-up. In a total of 38 eyes, ring segments were explanted or repositioned, and the 24-month follow-up could not be completed. The postoperative visits after ring reposition or explantation were not included in the analysis to avoid bias. In addition, corneal crosslinking was performed in 6 eyes during the follow-up; data were not included from visits after corneal crosslinking.

Main Outcome Measures

Uncorrected visual acuity, BSCVA, spherocylindrical refraction, keratometry, and corneal aberrometry were the main outcome measures.

Statistical Analysis

The Statistical Package for the Social Sciences version 15.0 for Windows (SPSS, Chicago, IL) was used for statistical analysis. Normality of all data samples was first checked by means of the Kolmogorov–Smirnov test. When parametric analysis was possible, the Student *t* test for paired data was performed for all parameter comparisons between preoperative and postoperative examinations or consecutive postoperative visits, whereas the Student *t* test for unpaired data was performed to compare outcomes obtained with mechanical and femtosecond-assisted techniques.

When parametric analysis was not possible, the Wilcoxon rank-sum test was applied to assess the significance of differences between preoperative and postoperative data, and the Mann–Whitney test was performed for the comparison of outcomes with both techniques, using the same level of significance ($P<0.05$) in all cases. Statistical analysis of differences in each complication rate between the Mechanical and Femtosecond groups was performed by the chi-square test.

Correlation coefficients (Pearson or Spearman depending if normality condition could be assumed) were used to assess the correlation between different variables. Finally, the efficacy index was calculated as the ratio of the postoperative UCVA to the preoperative BSCVA, and the safety index was calculated as the ratio of the postoperative BSCVA to the preoperative BSCVA.

Results

A total of 146 eyes of 106 patients with a mean age of 31.44±10.29 years (range, 15–64 years) were included. Sixty-three patients were male (59.43%), and 43 patients were female (40.57%). There was a balanced distribution of right and left eyes (74 vs. 72 eyes). Opacity of the cone area was observed in only 12 eyes (8.22%). According to the Amsler–Krumeich grading system,[3] 68 eyes had cone grade I (46.58%), 37 eyes had cone grade II (25.34%), 15 eyes had cone grade III (10.27%), and 26 eyes had cone grade IV (17.81%) (Table 4). By considering the corneal aberrations and according to the Alió-Shabayek grading system,[3] 28 eyes had cone grade I (32.94%), 27 eyes had cone grade II (31.76%), 10 eyes had cone grade III (11.77%), and 20 eyes had cone grade IV (23.53%) (Table 4).

Mechanical Group

Table 5 summarizes the visual, refractive, and keratometric outcomes in eyes implanted with ICRS using the mechanical tunnelization (Mechanical group). At 6 months postoperatively, a statistically significant reduction was found in sphere, cylinder, and spherical equivalent (all $P\leq0.02$, Wilcoxon test). No statistically significant changes were observed in these refractive parameters during the rest of follow-up ($P\geq0.34$, Student *t* and Wilcoxon tests), although a small but insignificant regression of the achieved spherical correction was observed at 12 months ($P = 0.34$, Wilcoxon test).

Table 5. Summary of Visual, Refractive, and

Parameter (Range)	Preoperative	3 Mos
UCVA	0.18±0.18 (0.01–0.60)	0.30±0.19 (0.05–0.70)
Sphere (D)	−3.41±3.70 (−14.00 to +2.50)	−1.91±4.06 (−12.00 to +3.50)
Cylinder (D)	−4.33±2.33 (−11.00 to 0.00)	−2.48±1.74 (−6.00 to 0.00)
SE (D)	−5.58±3.85 (−15.00 to +0.50)	−3.15±4.36 (−13.75 to +1.75)
BSCVA	0.52±0.29 (0.05–1.15)	0.55±0.25 (0.05–1.00)
K1 (D)	47.91±4.80 (40.60–59.11)	45.63±3.82 (39.70–54.84)
K2 (D)	53.16±6.00 (42.88–67.90)	50.01±4.49 (43.00–58.56)
KM (D)	50.08±5.20 (39.90–60.65)	46.92±4.26 (40.70–56.70)
ISAI (D)	9.38±6.27 (0.74–24.00)	7.48±5.18 (−2.38 to 19.88)
No. of eyes	63	33

BSCVA = best spectacle-corrected visual acuity; D = diopters; ISAI = inferosuperior asymmetry index; K1 = corneal dioptric power in the flattest 3-mm zone; SE = spherical equivalent; UCVA = uncorrected visual acuity.
Ranges are shown in brackets below each mean value.

A statistically significant improvement was found in UCVA at 6 months ($P<0.01$, Wilcoxon test), with no significant changes during the rest of follow-up ($P\geq0.66$, Wilcoxon test). In contrast, BSCVA did not change significantly after surgery ($P\geq0.33$, Student *t* test); 41.18% of eyes at 6 months and 42.11% of eyes at 24 months gained ≥2 lines of BSCVA (Fig 1), and 35.29% of eyes at 6 months and a similar percentage of eyes (36.84%) at 24 months lost lines of BSCVA (Fig 1). Two eyes losing lines of BSCVA had a significant cone opacity, and 2 eyes presented a corneal melting at the incision area with a posterior ring segment extrusion (in both cases, segments were explanted). Mean efficacy and safety indices at 6 months were 0.59±0.31 (range, 0.14–1.40) and 1.14±0.63 (range, 0.17–2.67), respectively. These indices increased to 0.80±0.67 and 1.35±0.80, respectively, at 24 months.

Mean keratometry decreased significantly from 50.08 diopters preoperatively to 45.55 diopters at 6 months after surgery ($P<0.01$, Student *t* test). There was a regression of this flattening effect at 12 months, but it was not statistically significant ($P = 0.37$, Student *t* test). In addition, no significant changes were found in inferosuperior asymmetry index after surgery ($P\geq0.71$, Student *t* test).

Table 6 summarizes corneal aberrometric outcomes in the Mechanical group. At 6 months, no statistically significant changes were found in any corneal aberrometric parameter, although a slight but insignificant reduction was observed in the RMS for higher-order, astigmatism, primary coma, and coma-like aberrations ($P\geq0.31$, paired Student *t* and Wilcoxon tests). There was an insignificant increase in higher-order, primary coma, spherical-like, and coma-like RMS between months 6 and 12 ($P\geq0.35$, paired Student *t* test). In addition, no significant changes were detected between months 12 and 24, although there was a tendency toward a reduction in higher-order, primary coma, spherical-like, and coma-like RMS ($P\geq0.11$, paired Student *t* and Wilcoxon tests).

Negative significant correlations were found between postoperative BSCVA at 6 months and several preoperative corneal aberrometric parameters: higher-order ($r = -0.67$, $P = 0.02$), primary coma ($r = -0.66$, $P = 0.02$), spherical-like ($r = -0.81$, $P<0.01$), and coma-like ($r = -0.63$, $P = 0.03$) RMS. Significant correlations were also observed between postoperative BSCVA at 12 months and the same aberrometric parameters: higher-order ($r = -0.75$, $P<0.01$), primary coma ($r = -0.63$, $P = 0.04$), spherical-like ($r = -0.85$, $P<0.01$), and coma-like ($r = -0.72$, $P = 0.01$) RMS.

Figure 1. Changes in lines of BSCVA postoperatively in eyes operated with the mechanical procedure. Gains of ≥2 lines of BSCVA were found in 41.18% of eyes at 6 months, 40.63% of eyes at 12 months, and 42.11% of eyes at 24 months. BSCVA = best spectacle-corrected visual acuity.

Femtosecond Group

Table 7 summarizes the visual, refractive, and keratometric outcomes in eyes implanted with ICRS using the femtosecond laser-assisted tunnelization (Femtosecond group). A statistically significant reduction was found in sphere, cylinder, and spherical equivalent at 6 months ($P<0.01$, Wilcoxon test). During the remainder of the follow-up, no significant changes in these parameters were found, although a slight but insignificant additional reduction was observed between months 12 and 24 ($P\geq0.13$, Wilcoxon test).

Statistically significant improvements in UCVA and BSCVA were found at 6 months ($P\leq0.02$, Wilcoxon test), remaining stable during the rest of the follow-up ($P\geq0.33$, Wilcoxon test); 46.55% of eyes gained ≥2 lines of BSCVA at 6 months, whereas 5 eyes lost lines of BSCVA (Fig 2). Ring segment extrusion occurred in 2 of those eyes with BSCVA loss, and an irregular position of the ring with no manifest extrusion was observed in 1 eye (tilted ring, not positioned in the correct plane). Mean efficacy and safety indices at 6 months were 0.77±0.72 (range, 0.07–3.73) and 1.61±1.66 (range, 0.50–12.00), respectively. These indices increased to 0.99±1.94 and 1.96±2.51, respectively, at 24 months.

A statistically significant central flattening was found 6 months postoperatively ($P<0.01$, Wilcoxon test). No significant changes

Keratometric Outcomes in the Mechanical Group

6 Mos	12 Mos	24 Mos
0.36±0.23 (0.05–0.85)	0.33±0.25 (0.02–0.90)	0.35±0.25 (0.02–0.90)
−1.26±2.71 (−11.00 to +3.00)	−2.09±4.19 (−16.00 to +3.00)	−2.15±4.35 (−12.00 to +2.50)
−2.56±1.76 (−6.00 to 0.00)	−2.86±1.75 (−6.00 to 0.00)	−2.03±1.99 (−7.00 to 0.00)
−2.48±2.74 (−11.00 to +1.00)	−3.52±4.17 (−16.00 to +1.00)	−3.16±4.52 (−14.25 to +0.75)
0.60±0.28 (0.05–1.00)	0.53±0.27 (0.05–1.00)	0.59±0.27 (0.20–1.00)
43.97±2.82 (40.05–50.52)	46.37±5.28 (36.82–60.88)	46.75±4.71 (40.84–55.49)
48.07±4.01 (41.50–56.49)	49.97±5.47 (41.89–62.07)	50.01±4.92 (43.05–59.09)
45.55±3.31 (39.60–52.03)	47.90±5.22 (39.36–61.80)	47.89±4.66 (42.20–56.07)
8.77±1.47 (7.44–11.47)	8.84±4.48 (2.15–16.82)	5.22±4.13 (−1.00 to 12.18)
32	30	18

meridian for the 3-mm central zone; K2 = corneal dioptric power in the steepest meridian for the 3-mm central zone; KM = mean corneal power in the

Table 6. Summary of the Corneal Aberrometric

Parameter	Preoperative	3 Mos
Higher-order RMS (μm)	3.62±1.65 (0.91–5.99)	3.74±1.64 (1.19–7.32)
RMS astigmatism (μm)	3.30±1.92 (1.42–7.35)	2.48±1.11 (0.79–4.61)
Primary coma RMS (μm)	3.18±1.61 (0.57–5.65)	3.13±1.64 (1.05–7.08)
Z_4^0 (μm)	−0.25±0.65 (−1.90 to 0.78)	−0.88±0.72 (−2.04 to 0.36)
Residual RMS (μm)	1.44±0.73 (0.38–3.06)	1.60±0.69 (0.42–2.60)
Spherical-like RMS (μm)	1.06±0.47 (0.42–2.00)	1.41±0.63 (0.43–2.48)
Coma-like RMS (μm)	3.45±1.62 (0.62–5.86)	3.43±1.61 (1.11–7.10)
No. of eyes	22	13

RMS = root mean square.
Ranges are given in brackets below each mean value. Aberrometric definitions: primary coma, terms $Z_3^{\pm 1}$; primary spherical aberration, term Z_4^0; residual fifth, and seventh order.

were detected in keratometry during the rest of the follow-up ($P \geq 0.08$, Student *t* and Wilcoxon tests). In addition, no significant changes were found in inferosuperior asymmetry index after surgery ($P = 0.82$, Student *t* test). In regard to corneal aberrometry (Table 8), a statistically significant reduction in the RMS for astigmatism was observed ($P = 0.03$, Wilcoxon test) at 6 months. A significant increase in residual higher-order RMS was observed ($P = 0.03$, Wilcoxon test) at 6 months. A progressive reduction in higher-order, primary coma, and coma-like aberrations RMS was also observed during the follow-up, but these changes did not reach statistical significance ($P \geq 0.34$, Student *t* and Wilcoxon tests). No significant correlations were found between postoperative BSCVA and preoperative corneal aberrometric parameters.

Mechanical versus Femtosecond

Comparison of outcomes obtained with the mechanical and femtosecond-guided procedures for each segment type (Intacs and KeraRings) and for each keratoconus grade was planned initially to avoid the possible variability introduced by these 2 factors. However, only this comparison was feasible for cases of early to moderate keratoconus (grade I and II) implanted with Intacs (mechanical subgroup 24 eyes vs. femtosecond subgroup 19 eyes) because the samples in the remaining groups were not large enough for plausible statistical testing. Only 8 eyes were implanted with KeraRings using the mechanical procedure, 6 eyes with keratoconus grade I and 2 eyes with keratoconus grade II (only 2 of these 8 eyes with available aberrometric data). In addition, only 2 cases of advanced keratoconus were implanted with Intacs using the IntraLase system. Therefore, only comparison of outcomes achieved with Intacs in early to moderate keratoconus (grades I and II) using the mechanical and femtosecond-guided procedures was performed because of these sample limitations.

Preoperatively, statistically significant differences between the mechanical and the femtosecond Intacs subgroups for early to moderate keratoconus were found only in sphere, K2, and KM ($P \leq 0.03$, unpaired Student *t* and Mann–Whitney tests). Because significant differences were present preoperatively, these parameters were not compared postoperatively. In regard to UCVA, cylinder, BSCVA, and K1, no statistically significant differences were found postoperatively between the mechanical and the femtosecond Intacs subgroups ($P \geq 0.06$, unpaired Student *t* and Mann–Whitney tests). The postoperative spherical equivalent only differed significantly at 12 and 24 months, with a mean higher value in the Femtosecond group ($P \leq 0.04$, unpaired Student *t* and Mann–Whitney tests). Significant differences in corneal asymmetry were found at 6 months postoperatively ($P = 0.02$, unpaired Student *t* test, mechanical 8.28±1.08 vs. femtosecond 4.41±4.76 diopters), with a higher asymmetry in those eyes operated using the mechanical dissection. The trend of higher asymmetry in eyes from the mechanical subgroup was maintained at 12 and 24 months postoperatively, but differences between the mechanical and the femtosecond subgroups did not reach statistical significance ($P \geq 0.20$, Mann–Whitney test).

In regard to the aberrometric analysis, no significant postoperative differences were found in RMS corneal astigmatism ($P \geq 0.13$, unpaired Student *t* and Mann–Whitney tests), although mean postoperative values were higher in all visits for the me-

Table 7. Summary of Visual, Refractive, and Keratometric

Parameter (Range)	Preoperative	3 Mos
UCVA	0.26±0.25 (0.01–0.90)	0.29±0.21 (0.01–0.75)
Sphere (D)	−3.60±4.88 (−20.00–+3.00)	−2.54±5.09 (−20.00–+4.00)
Cylinder (D)	−3.67±2.50 (−9.00–0.00)	−2.72±1.60 (−7.00–0.00)
SE (D)	−5.42±5.17 (−22.00–+1.25)	−3.88±5.24 (−22.00–+3.13)
BSCVA	0.51±0.28 (0.03–1.00)	0.62±0.27 (0.10–1.20)
K1 (D)	46.53±4.61 (39.78–60.20)	44.98±5.20 (37.00–59.18)
K2 (D)	51.39±5.85 (42.14–68.53)	48.62±5.54 (38.70–63.25)
KM (D)	49.02±5.10 (41.30–63.25)	46.79±5.19 (37.85–60.71)
ISAI (D)	10.28±7.12 (−1.65–37.67)	10.30±9.25 (−3.02–46.50)
No. of eyes	83	46

BSCVA = best spectacle-corrected visual acuity; D = diopters; ISAI = inferosuperior asymmetry index; K1 = corneal dioptric power in the flattest 3 mm zone; SE = spherical equivalent; UCVA = uncorrected visual acuity.
Ranges are shown in brackets below each mean value.

Outcomes in the Mechanical Group

6 Mos	12 Mos	24 Mos
2.99±0.86 (1.66–4.50)	4.10±2.10 (2.30–9.49)	3.51±1.38 (1.83–5.17)
3.00±1.95 (1.65–7.09)	2.85±1.43 (0.87–6.32)	2.40±1.35 (0.83–3.93)
2.62±0.77 (1.47–4.01)	3.20±1.51 (1.28–6.53)	2.50±1.08 (1.26–3.89)
−0.47±0.70 (−1.34 to 0.45)	−1.09±1.11 (−3.13 to −0.10)	−0.95±0.47 (−1.50 to −0.43)
1.21±0.29 (0.68–1.55)	1.98±1.52 (1.03–6.33)	2.10±1.23 (0.84–4.12)
0.95±0.41 (0.56–1.52)	1.83±1.41 (0.57–5.25)	1.46±0.75 (0.69–2.69)
2.83±0.79 (1.56–4.24)	3.59±1.73 (1.92–7.91)	3.18±1.21 (1.70–4.41)
10	18	10

aberrations, all Zernike terms except $Z_3^{\pm1}$ and Z_4^0; spherical-like aberrations, terms from fourth and sixth order; coma-like aberrations, terms from third,

chanical subgroup. Higher-order RMS was significantly higher for the mechanical subgroup at 6 months postoperatively ($P = 0.03$, Mann–Whitney test, mechanical 3.24±1.95 vs. femtosecond 1.74±1.06 μm). Primary spherical aberration was significantly more negative in the mechanical subgroup at 1, 3, 6, and 24 months postoperatively ($P \leq 0.03$, unpaired Student *t* and Mann–Whitney tests). Figure 3A shows the postoperative changes in primary spherical aberration and spherical-like RMS in the mechanical and femtosecond Intacs subgroups. As can be observed in this graph, a significant negativization of primary spherical aberration occurred after Intacs implantation using the mechanical procedure ($P = 0.03$, Wilcoxon test). Spherical-like aberration RMS also increased postoperatively, especially in the mechanical subgroup, but differences between the mechanical and femtosecond subgroups did not reach statistical significance ($P \geq 0.07$, unpaired Student *t* test). Mean postoperative values of coma, residual, and coma-like RMS were higher at all postoperative visits for the eyes operated using the mechanical procedure (Fig 3B), and the differences reached statistical significance only for primary coma and coma-like aberration RMS at 3 and 6 months postoperatively ($P \leq 0.02$, unpaired Student *t* and Mann–Whitney tests). In addition, differences between the mechanical and femtosecond subgroups were significant at 12 months for primary coma at 12 months ($P = 0.05$, unpaired Student *t* test).

Complications

Complications in the Mechanical and Femtosecond groups are summarized in Table 9. Segment ring explantation was performed in 12 eyes (18.46%) of the Mechanical group and 11 eyes (13.25%) of the Femtosecond group (Table 9). The reasons for ring segment explantation were extrusion (8 eyes), corneal melting (3 eyes), corneal neovascularization (2 eyes), and very poor visual outcomes. All extrusion and melting cases (Table 9) showed a significant increase in corneal irregularity with large amounts of corneal higher-order aberrations (Figs 4 and 5). Extrusion occurred at 6 months or later in 5 eyes that underwent mechanical tunnelization and in 3 eyes operated using the femtosecond laser. Ring reposition was performed in a total of 11 eyes with the aim of improving the ring effect and the visual and refractive outcomes. Seven of these repositioned segments were finally explanted because of extrusion or poor visual outcomes. Infectious keratitis occurred in 1 eye at 6 months postoperatively, which was appropriately treated with an intensive fortified antibiotic and corticosteroid combination. In this eye, an extrusion of superior ring segment occurred and it was finally explanted.

When comparing the level of complications in the mechanical and femtosecond procedures for eyes with early to moderate keratoconus implanted with Intacs, we found similar rates for extrusion (mechanical 8.33% vs. femtosecond 10.52%), corneal melting (mechanical 4.17% vs. femtosecond 0.00%), neovascularization (mechanical 4.17% vs. femtosecond 0.00%), infection (0.00% in both groups), and ring reposition (mechanical 4.17% vs. femtosecond 0.00%) ($P \geq 0.37$, chi-square test). The explantation rate was higher in the mechanical subgroup (mechanical 20.83% vs. femtosecond 10.53%), but differences did not reach statistical significance ($P = 0.36$, chi-square test).

Outcomes in the Femtosecond Group

6 Mos	12 Mos	24 Mos
0.36±0.26 (0.03–1.00)	0.35±0.25 (0.02–1.00)	0.29±0.22 (0.05–0.90)
−2.45±4.57 (−20.00–+3.50)	−2.24±2.48 (−7.50–+1.50)	−1.17±2.12 (−6.00–+2.75)
−2.81±1.68 (−6.75–0.00)	−3.08±1.86 (0.00–−8.00)	−2.67±1.40 (−7.00 to −1.00)
−3.88±4.71 (−22.00–+2.00)	−3.79±3.56 (−16.00–+0.88)	−2.51±2.11 (−7.00–+2.25)
0.65±0.28 (0.05–1.20)	0.66±0.25 (0.10–1.00)	0.70±0.25 (0.30–1.00)
44.76±3.89 (36.88–54.20)	45.09±4.70 (38.05–59.17)	45.41±4.93 (39.33–58.54)
48.39±4.75 (40.43–61.93)	48.34±5.04 (40.65–62.32)	48.67±5.18 (42.29–61.41)
46.57±4.23 (39.89–57.34)	46.68±4.71 (40.29–60.59)	47.04±4.99 (41.37–59.97)
9.93±6.79 (−3.28–28.96)	8.02±6.93 (−15.98–26.71)	7.20±5.30 (−3.00–14.03)
58	36	19

meridian for the 3 mm central zone; K2 = corneal dioptric power in the steepest meridian for the 3 mm central zone; KM = mean corneal power in the

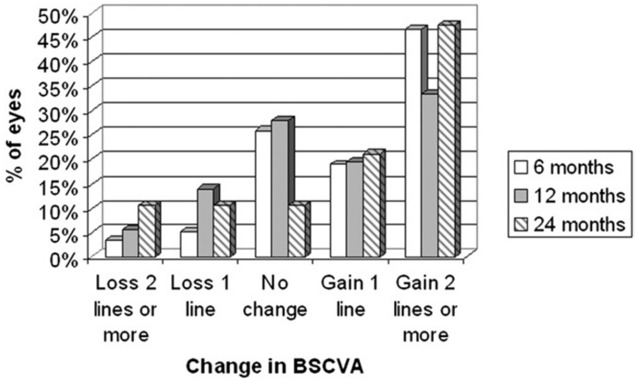


Figure 2. Changes in lines of BSCVA postoperatively in eyes operated with the femtosecond-assisted procedure. Gains of ≥2 lines of BSCVA were found in 46.55% of eyes at 6 months. BSCVA = best spectacle-corrected visual acuity.

Discussion

The current study analyzed the refractive and corneal aberrometric effect of ICRS in keratoconic eyes. We have also studied how this effect can be influenced by the surgical technique used for corneal tunnelization: mechanical (Mechanical group) or femtosecond laser-assisted (Femtosecond group). A significant reduction in manifest sphere, cylinder, and spherical equivalent was found after surgery using both surgical procedures for creation of corneal channels. These refractive changes are in concordance with those reported by previous authors.[9–13,16–20,35] In the Mechanical group, a slight but insignificant regression of spherical correction occurred at 12 months. A similar variability in sphere in a medium to long-term follow-up was also observed previously after Intacs implantation using the mechanical procedure.[15,16,19,23] Part of this variability in spherical correction could be due to the loss of effect of ring segments leading to postoperative complications, such as extrusion or corneal melting (most complications occur at ≥6 months).

Uncorrected visual acuity significantly improved after surgery in both the Mechanical and Femtosecond groups, which is consistent with the significant reduction achieved in refraction. This visual improvement was also reported in other studies on ICRS in corneal ectasia.[9–14,18–20,23,24,26,27,33,35] BSCVA improved significantly only in the Femtosecond group, which supports the findings of other authors.[9,11–13,18] However, there are published reports citing an improvement in BSCVA with ICRS using the mechanical procedure, which is contradictory to the findings of the present study.[10,14,16,17,19,20,23,24,26,33,35] Several factors could explain the difference between our findings and the previous findings. For example, we may have included more moderate and severe cases and observed more complications in the Mechanical group compared with previous studies. Nevertheless, the safety indices of both surgical techniques proved to be excellent with 41.18% (Mechanical group) and 46.55% (Femtosecond group) of eyes gaining ≥2 lines of BSCVA at 6 months.

In regard to corneal curvature, a significant central flattening was achieved in both surgical techniques, in keeping with previous studies on ICRS for keratoconus management.[9–20,23,35] This flattening is responsible for the reduction of refraction and increase in UCVA. However, a regression of the achieved corneal central flattening was observed at 12 months in those eyes implanted with ICRS using the mechanical surgical procedure. This change did not reach statistical significance, but it was consistent with the regression in myopic spherical correction also observed at 12 months. This regression of the central flattening achieved with ICRS implanted using the mechanical procedure in a medium to long-term follow-up has been reported.[15,16,23] Inferosuperior asymmetry also decreased in both groups, but changes did not reach statistical significance because of the high variability of this parameter (not all cones were decentered inferiorly).

In addition to visual and refractive outcomes, changes in anterior corneal aberrations were also evaluated in this study. To the best of our knowledge, this is the first study comparing the corneal aberrometric performance of ICRS implanted using 2 different surgical procedures: mechanical and femtosecond laser-assisted techniques. It should be remembered that anterior corneal aberrometric analysis is an important tool in clinical practice for evaluating the ocular optical quality because the first refractive interface (air–cornea) is the most important contributor to the total power of the eye because of the large difference in refractive index existing at this point. In highly aberrated corneas,

Table 8. Summary of the Corneal Aberrometric

Parameter	Preoperative	3 Mos
Higher-order RMS (μm)	3.35±2.02 (0.33–10.66)	3.19±1.87 (0.72–8.60)
RMS astigmatism (μm)	2.93±2.09 (0.20–10.86)	2.65±1.72 (0.33–8.59)
Primary coma RMS (μm)	2.83±1.94 (0.04–10.07)	2.62±1.88 (0.28–8.46)
Z_4^0 (μm)	−0.14±0.84 (−1.86–2.69)	−0.17±0.71 (−1.75–0.98)
Residual RMS (μm)	1.35±1.01 (0.17–8.10)	1.39±0.95 (0.40–5.72)
Spherical-like RMS (μm)	1.10±0.82 (0.28–6.38)	1.13±0.79 (0.36–4.41)
Coma-like RMS (μm)	3.11±1.93 (0.17–10.46)	2.90±1.83 (0.53–8.50)
No. of eyes	64	34

RMS = root mean square.
Aberrometric definitions: primary coma, terms $Z_3^{\pm 1}$; primary spherical aberration, term Z_4^0; residual aberrations, all Zernike terms except $Z_3^{\pm 1}$ and Z_4^0; Ranges are shown in brackets below each mean value.

such as in keratoconus, the corneal aberrations of the anterior corneal surface are the most important source of optical errors in the eye. In the current study, we found the effect on the corneal aberrations was dependent on the mechanism used to create the tunnel. After ICRS implantation using the mechanical surgical procedure, no significant changes were achieved in any corneal aberrometric parameter, although reduction was achieved in astigmatism, primary coma, and coma-like aberrations. At 12 months, a significant increase was found in higher-order, primary coma, spherical-like, and coma-like aberrations in the Mechanical group. Furthermore, an increase in primary spherical aberration, higher-order residual, and spherical-like aberrations was induced with ICRS in this group, although changes did not reach statistical significance. Therefore, there was a significant variability in corneal aberrations after ICRS implantation using the mechanical procedure, which implies that corneal irregularity is not well controlled with this kind of surgical intervention. This supports the marginal improvement in BSCVA observed in the Mechanical group.

In corneas implanted with ICRS using the femtosecond-assisted surgical procedure, a significant reduction was observed in the RMS for astigmatism after surgery. In addition, a significant increase in higher-order residual aberrations was found postoperatively. Total higher-order, primary coma, and coma-like aberrations were also reduced postoperatively, but changes did not reach statistical significance. During all follow-up sessions, no significant regressions in the achieved aberrometric correction were observed, confirming the stability of ICRS effect on corneal irregularity in the Femtosecond group. These findings support the conclusions reached by Shabayek and Alió,[13] who found a statistically significant reduction in higher-order RMS for those eyes with a relatively high preoperative RMS (≥3.0 μm) and implanted with KeraRings using the femtosecond laser for corneal tunnelization.

Part of these differences in the aberration profile between the Mechanical and Femtosecond groups, as well as in the refractive and keratometric parameters, could be due to the different ring segment profile implanted in each group (e.g., Intacs were implanted in 87.30% of eyes in the Mechanical group and in 31.25% of eyes in the Femtosecond group). It should be remembered that 2 different kinds of ring segments were used, Intacs and KeraRings, each with a different cross-sectional profile and diameter of implantation. Another factor to consider is the severity of the ectatic disease because higher rates of complications and poorer outcomes have been reported for eyes with advanced keratoconus implanted with ICRS.[17,20] For all these reasons, a comparative analysis of the outcomes achieved with the mechanical and femtosecond-based techniques for each segment type and for early to moderate and advanced keratoconus cases was initially planned to avoid the possible variability introduced by these 2 factors. With this detailed analysis, the aberrometric and refractive variability induced by the technique of corneal tunnelization could be evaluated. However, this comparative analysis was only feasible for eyes with early to moderate keratoconus (grades I and II) implanted with Intacs (mechanical subgroup 24 eyes vs. femtosecond subgroup 19 eyes) because the remaining samples were not large enough to perform a plausible statistical analysis. Examples of the limitations are as follows: Only 8 eyes were implanted with KeraRings using the mechanical procedure (only 2 of these 8 eyes with aberrometric data), and only 2 eyes with advanced keratoconus were implanted with Intacs using the IntraLase system. This study is a retrospective analysis of a consecutive case series and as such has its own limitations. For example, there were an unequal number of Intacs and KeraRings cases implanted with the mechanical and femtosecond-guided procedures.

When comparing the mechanical and femtosecond subgroups in early to moderate keratoconus eyes implanted with Intacs, no significant differences were found in the visual outcomes and magnitude of astigmatic correction. Significant differences were found at 6 months postoperatively in the magnitude of corneal asymmetry. Furthermore, after surgery there was a tendency toward a greater extent of asymmetry in those eyes operated with the mechanical technique. This trend was maintained at 12 and 24 months, but the differences did not reach statistical significance. This greater asymmetry in the mechanical subgroup was consistent with the significantly greater magnitude of primary coma found in this subgroup at 3, 6, and 12 months. In addition, significant differences between the mechanical and the femtosecond subgroups were found in other aberrometric parameters, such as higher-order RMS, coma-like RMS, and primary spherical aberration. Primary spherical aberration changed significantly in the initial postoperative

Outcomes in the Femtosecond Group

6 Mos	12 Mos	24 Mos
3.17±2.21 (0.75–10.39)	3.07±1.54 (0.81–6.78)	2.65±1.19 (0.63–5.44)
2.72±1.87 (0.81–8.83)	2.71±1.58 (0.34–6.95)	2.22±0.90 (0.82–4.05)
2.50±2.04 (0.31–9.08)	2.45±1.56 (0.16–6.38)	2.12±1.36 (0.22–4.87)
0.04±0.85 (−3.28–1.67)	−0.09±0.71 (−2.30–1.61)	−0.16±0.68 (−2.03–0.70)
1.58±1.16 (0.51–6.25)	1.49±0.83 (0.50–4.77)	1.18±0.53 (0.35–2.13)
1.28±0.99 (0.45–5.28)	1.15±0.55 (0.49–2.78)	1.02±0.49 (0.28–2.30)
2.83±2.08 (0.58–9.35)	2.79±1.56 (0.62–6.51)	2.39±1.20 (0.56–4.93)
41	39	18

spherical-like aberrations, terms from fourth and sixth order; coma-like aberrations, terms from third, fifth, and seventh order.

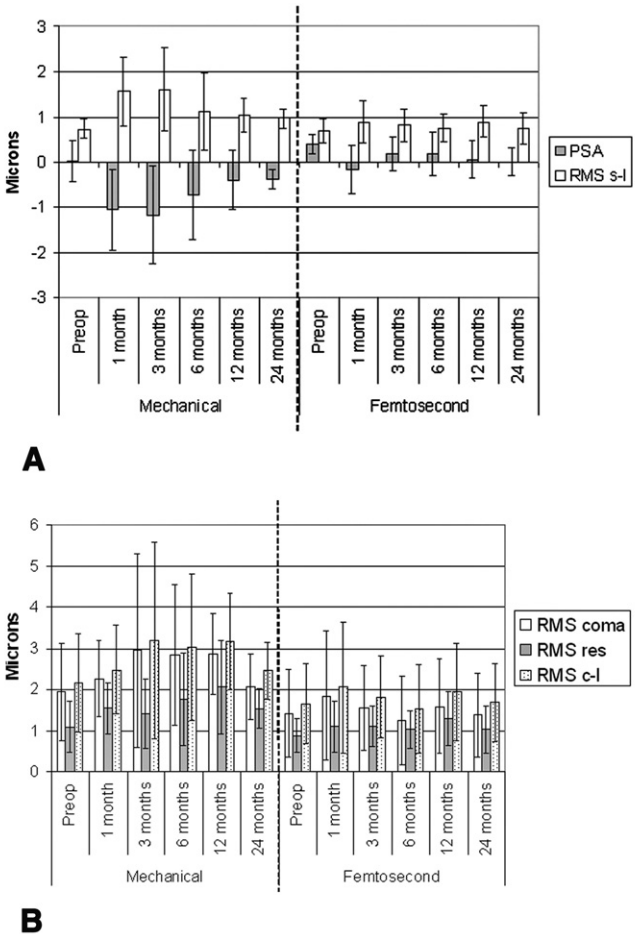


Figure 3. Comparison of corneal aberrometric outcomes after Intacs (Addition Technology, Inc, Fremont, CA) implantation in eyes with early to moderate keratoconus (grades I and II) using the mechanical (*left*) and femtosecond-guided procedures (*right*). **A,** Changes in primary spherical aberration (*grey bars*) and spherical-like (*white bars*) RMS. **B,** Changes in primary coma (*white bars*), residual (*grey bars*), and coma-like (*dotted bars*) RMS. RMS = root mean square; PSA = primary spherical aberration; s-l = spherical-like; res, residual; c-l = coma-like.

period (3 and 6 months) in those eyes operated using the mechanical procedure, with an insignificant regression between 12 and 24 months. The spherical-like and higher-order residual aberrations also were higher for the mechanical subgroup, but differences did not reach statistical significance.

The mechanical tunnelization procedure may lack sufficient precision, and this may affect corneal aberrations, leading to reduced optical performance in the Intacs subgroup. In addition, the impact on corneal biomechanics may lead to instability of the implantation, and this would affect visual quality with more limited visual outcomes. It should be remembered that primary spherical aberration and coma have been proved to have a negative impact on visual acuity because of the optical blur that they induce.[36] Therefore, the limited improvement in BSCVA for eyes implanted with ICRS using the mechanical procedure could be related to the induction of aberrations. Several factors could explain the better aberrometric performance of ring segments implanted using the femtosecond laser, for example, less surgical trauma, better corneal biomechanical control, or more accurate positioning of implants. All of these issues should be considered when performing the surgery. In addition to these conclusions concerning the aberrometric performance, a slight improvement in the aberrometric outcomes was observed at 12 to 24 months in the mechanical Intacs subgroup. This slight improvement observed in the medium term could have several explanations. There was better stability of the implants inside the created tunnels. All cases with complications as extrusions or corneal melting were already explanted at this time or even the smaller sample achieved in the study for these late visits (several cases were excluded as explants, repositions, or crosslinking-treated eyes, and there were some dropouts).

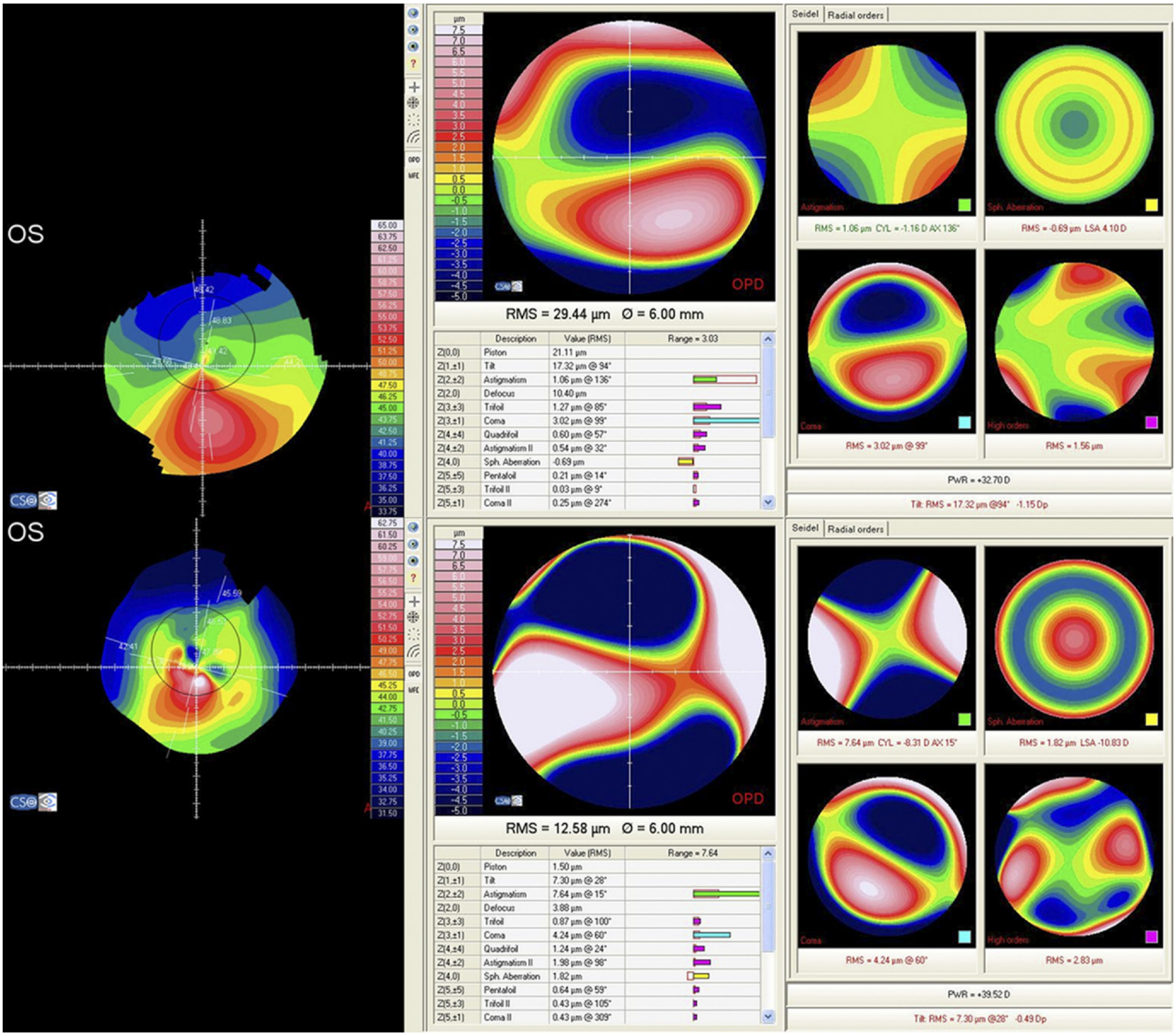
Higher-order, primary coma, spherical-like, and coma-like aberrations were found to be inversely correlated with postoperative BSCVA (6 and 12 months) only in the Mechanical group. This means that visual outcomes are very sensitive to the preoperative level of corneal aberrations in eyes implanted with ICRS using the mechanical procedure. Because a poorer corneal aberrometric performance was achieved in the Mechanical group, less improvement in BSCVA was expected in the most aberrated eyes of this group.

Extrusion, corneal neovascularization, and corneal melting were more frequent complications in eyes implanted with ICRS using the mechanical technique. These complications were associated with a more significant corneal irregularity and higher levels of corneal aberrations. One potential limitation of these outcomes and of

Table 9. Complications in Mechanical and Femtosecond Groups

Event	Mechanical Intacs/KeraRings 55 Eyes/8 Eyes		Femtosecond-assisted Intacs/KeraRings 25 Eyes/58 Eyes	
Extrusion	5 eyes (7.94%)	1 eye (1.52%)	2 eyes (2.41%)	2 eyes (2.41%)
Corneal melting	4 eyes (6.35%)	0 eyes (0.00%)	0 eyes (0.00%)	0 eyes (0.00%)
Reposition	6 eyes (9.23%)	0 eyes (0.00%)	1 eye (1.20%)	4 eyes (4.82%)
Explantation	11 eyes (17.46%)	1 eye (1.52%)	5 eyes (6.02%)	6 eyes (7.23%)
Corneal neovascularization	2 eyes (3.17%)	0 eyes (0.00%)	0 eyes (0.00%)	0 eyes (0.00%)
Infectious keratitis	0 eyes (0.00%)	0 eyes (0.00%)	0 eyes (0.00%)	1 eye (1.20%)

Ring extrusion, corneal melting, and neovascularization incidence, as well as the percentage of repositions and explantations, are shown. Each complication rate is given for each segment type: Intacs and KeraRings.



	Description	Value (RMS)	Range = 3.03
Z(0,0)	Piston	21.11 µm	
Z(1,±1)	Tilt	17.32 µm @ 94°	
Z(2,±2)	Astigmatism	1.06 µm @ 136°	
Z(2,0)	Defocus	10.40 µm	
Z(3,±3)	Trifoil	1.27 µm @ 85°	
Z(3,±1)	Coma	3.02 µm @ 99°	
Z(4,±4)	Quadrifoil	0.60 µm @ 57°	
Z(4,±2)	Astigmatism II	0.54 µm @ 32°	
Z(4,0)	Sph. Aberration	-0.69 µm	
Z(5,±5)	Pentafoil	0.21 µm @ 14°	
Z(5,±3)	Trifoil II	0.03 µm @ 9°	
Z(5,±1)	Coma II	0.25 µm @ 274°	

	Description	Value (RMS)	Range = 7.64
Z(0,0)	Piston	1.50 µm	
Z(1,±1)	Tilt	7.30 µm @ 28°	
Z(2,±2)	Astigmatism	7.64 µm @ 15°	
Z(2,0)	Defocus	3.88 µm	
Z(3,±3)	Trifoil	0.87 µm @ 100°	
Z(3,±1)	Coma	4.24 µm @ 60°	
Z(4,±4)	Quadrifoil	1.24 µm @ 24°	
Z(4,±2)	Astigmatism II	1.98 µm @ 98°	
Z(4,0)	Sph. Aberration	1.82 µm	
Z(5,±5)	Pentafoil	0.64 µm @ 59°	
Z(5,±3)	Trifoil II	0.43 µm @ 105°	
Z(5,±1)	Coma II	0.43 µm @ 309°	

Figure 4. Corneal topography and aberrometric analysis of a keratoconus implanted with Intacs (mechanical procedure) and with both ring segments extruded (superior and inferior) 12 months after surgery. Corneal topographic (*left*) and aberrometric (*right*) maps 4 months before ring segments extrusion (*up*) and when extrusion was detected are shown (*down*). Each corneal aberrometry includes different maps simulating the wavefront considering, from left to right and from up to down, the following optical errors: all aberrations, astigmatism, primary spherical aberration (Z_4^0), primary coma ($Z_3^{\pm 1}$) and the residual aberrations without considering the astigmatism, primary coma, and primary spherical aberration. In addition, the RMS associated with the described optical error is provided below each map. As can be observed, there is a large increase in primary spherical aberration (it becomes more negative, increase of 2.51 μm) and coma (increase of 1.22 μm). RMS = root mean square.

the current study is the learning curve of the surgeon. We have compared the outcomes from different surgeons, and their learning curve could be a potential source of variability, especially for corneal tunnelization with the mechanical device, because it is highly dependent on surgeon manual dexterity. A higher magnitude of variability with 1 specific surgical procedure would imply that this surgical procedure is less reproducible and highly dependent on surgeon skills, leading to less predictable outcomes. Part of the variability in refractive and aberrometric outcomes observed during the follow-up in the Mechanical group could be attributed to this limiting factor: the learning curve of the surgeon. In addition, we have observed that no significant differences were present in the explantation, reposition, corneal neovascularization, corneal melting, extrusion, and infection rates between the mechanical and the femtosecond Intacs subgroups, although the explantation rate was slightly higher for the mechanical subgroup. This could be associated with other patient-related factors.

In conclusion, intracorneal ring segments implantation with Intacs or KeraRings is an effective option for the treatment of spherocylindrical error and corneal irregularity in keratoconus. As other authors have found,[32,33] there were

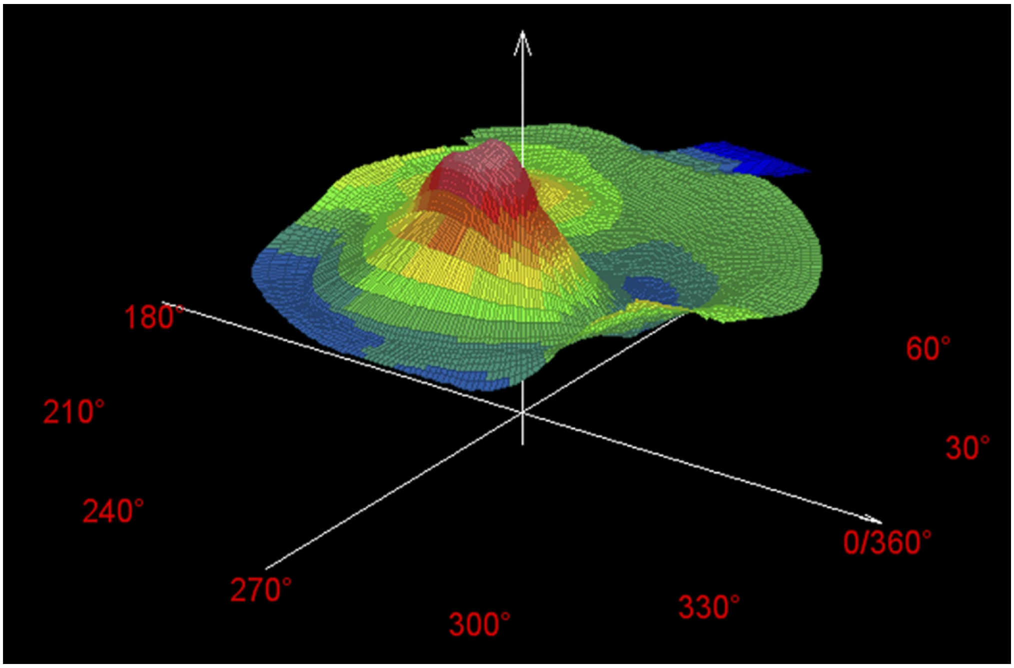


Figure 5. Three-dimensional postoperative corneal profile of a cornea implanted with KeraRings (Mediphacos, Belo Horizonte, Brazil). In this corneal examination, extrusion of the inferior ring segment was present.

no significant differences in refractive and visual outcomes between the mechanical and the femtosecond-assisted surgical techniques for ICRS implantation. Furthermore, it has been demonstrated that final visual outcomes with ICRS (mostly Intacs) implanted using mechanical tunnelization were dependent on the preoperative magnitude of corneal irregularity, exerting a more limited visual improvement in highly aberrated eyes. The use of mechanical tunnelization specifically for Intacs implantation in eyes with early to moderate keratoconus has been demonstrated to limit the potential aberrometric correction of these implants because the procedure itself generates new aberrations, especially negative primary spherical aberration and primary coma. This trend could not be specifically confirmed for KeraRings segments because of the limitations of this retrospective study in the sample size for this segment type. In addition, the impact of the surgical technique specifically in advanced keratoconus should be addressed in future studies with a more complete series of advanced keratoconus cases (homogeneous samples of eyes implanted with Intacs and KeraRings). Longer follow-up is needed to corroborate the stability of visual, refractive, and aberrometric outcomes achieved by these implants using both surgical techniques, mechanical and femtosecond-assisted implantation.

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