·Clinical Research·

Clinical outcomes after intrastromal corneal ring segments reoperation in keratoconus patients

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Abstract

• AIM: To evaluate the clinical outcomes after Ferrara intrastromal corneal ring segments (ICRS) reoperation in patients with keratoconus.

• METHODS: A total of 37 keratoconus eyes implanted with intrastromal corneal ring segments, which had an ICRS exchange, addition, reposition or removal were evaluated. Uncorrected visual acuity (UCVA), best corrected visual acuity (BCVA), keratometry (K), asphericity (Q) and pachymetry at the thinnest point (PTP) of the cornea were evaluated using a corneal tomography (Oculus Pentacam, USA)

• RESULTS: The mean follow-up time after the reoperation was 30.5±9.7 months. The mean UCVA improved from 20/300 to 20/80 (P=0.005); the mean BCVA improved from 20/160 to 20/50 (P=0.0002), the mean keratometry reduced from 49.33±4.19D to 46.16±3.90D (P=0.0001), the mean pachymetry at the thinnest point increased from 450±42.9μm to 469±40.8μm (P=0.0001). The asphericity increased from −0.84±0.74 to −0.35±0.81 (P=0.15) and the spherical equivalent reduced from −4.64±4.87D to −3.04±3.45D (P=0.137). The changes in the asphericity and spherical equivalent were not statistically significant.

• CONCLUSION: Ferrara ICRS implantation showed to be a reversible and readjustable surgical procedure for keratoconus treatment. Good outcomes can be obtained even after removal, addition, reposition or exchange of ICRS.

• **KEYWORDS:** keratoconus; intrastromal corneal ring segments; reoperation

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INTRODUCTION

Intrastromal corneal ring segments (ICRS) implantation in keratoconus provides favorable visual and refractive results such as decreased corneal surface irregularity, improvement in spectacle corrected vision, and delay or elimination of the need for keratoplasty[1-3].

The Ferrara ICRS are made of polymetilmetacrilate(PMMA) Perspex CQ acrylic segments. They vary in thickness, and are available in 0.15, 0.20, 0.25 and 0.30mm. The segment cross-section is triangular, and the base for every thickness and diameter is 0.60mm. The segments have 90, 120, 160 or 210 degrees of arc.

The reversibility and adjustability of the refractive effect of intracorneal ring segments have been previously studied in myopic eyes and in patients with keratoconus, however only a very small sample of patients was evaluated in theses studies [4,5]. To our knowledge, no studies have demonstrated in detail the behavior of the abnormal keratoconic corneal tissue after different types of reoperation following ICRS implantation.

The purpose of this study is to evaluate the reversibility of the visual, refractive, and topographic changes occurring in keratoconic eyes after ICRS exchange, reposition, addition or removal.

SUBJECTS AND METHODS

This study was approved by the institutional review board of Dr. Paulo Ferrara Eye Clinic, Belo Horizonte, MG, Brazil, and followed the tenets of the Declaration of Helsinki. The procedures were fully explained to each patient, and each provided written informed consent.

Subjects We retrospectively collected the data of 1 073 eyes of 810 consecutive surgical patients that had ICRS implantation from January 2006 to July 2008. Of these eyes,

37 needed a reoperation as follows: ICRS removal (n=6), exchange (n=11), repositioning (n=4), and insertion of an additional ICRS (n=16). The mean age of patients was 29±9.6 (range 17 to 57 years old). Twenty-four patients were male and 13 were female. All patients had uneventful intracorneal ring segment implantation for clear corneal keratoconus; the reoperation was necessary during the follow-up period.

The main indications for the primary surgery were: contact lens intolerance and/or evidence of ectasia progression as measured by worsening of uncorrected distance visual acuity (UCVA) and corrected distance visual acuity (BCVA), progressive intolerance to contact lens wear, and progressive corneal steepening documented by topographical changes. Two or more lines of UCVA and/or BCVA worsening and at least 2 diopters (D) of increase in mean keratometry as measured with a Pentacam (Pentacam HR, OCULUS, Inc., Lynnwood, WA, USA) were required to define progression of the disease. Exclusion criteria included any of the following discovered during the preoperative examination: advanced keratoconus with curvatures over 60D, significant apical opacity and scarring, hydrops, corneas with thickness below 300μm in the ring track as evaluated by Pentacam pachymetry, and intense unresolved atopia.

The main indications for the reoperation were: 1) ICRS removal: superficial segment and/or overcorrection; 2) ICRS exchange: overcorrection or undercorrection; 3) ICRS reposition: migration of segment and/or wrong placement of segment and 4) ICRS addition: undercorrection. Overcorrection was defined as excessive flattening (oblate cornea) after the primary ICRS implantation. Undercorrection was defined as a less than expected cornea flattening, with unsatisfactory UCVA and/or BCVA.

Methods

Clinical measurements A complete ophthalmologic examination was performed before surgery and included UCVA and BCVA assessment, biomicroscopy, fundoscopy, tonometry, corneal topography, pachymetric map, and asphericity measurement using the Pentacam HR. All clinical examinations were performed in a standardized manner by an experienced examiner (PF).

Surgical technique All primary surgeries and reoperations were performed by the same surgeon (PF) using the manual technique, as previously described [3]. The surgery was performed under topical anesthesia after miosis was achieved with 2% pilocarpine. An eyelid speculum was used to expose the eye, and 2.5% povidone iodine eyedrops were instilled onto the cornea and conjunctival cul-de-sac. The visual axis was marked by pressing a Sinskey hook on the central corneal epithelium while asking the patient to fixate on the corneal light reflex of the microscope light. Using a marker tinted with gentian violet, a 5.0mm optical zone and incision site were aligned to the desired axis in which the incision would be made.

The incision site was always the steepest topographic axis of the cornea given by the Pentacam. A square diamond blade was set at 80% of corneal thickness as determined by the pachymetric map at the incision site. It was always considered the pachymetric map obtained after the primary surgery, to define the incision depth. For ICRS removal or exchange, an inverted Sinskey hook was used to engage the segment hole, from beneath, and it was pulled out of the tunnel. For ICRS reposition, the segment was pushed forward into the tunnel after a new dissection. For ICRS addition, a pocket was formed, using the Suarez spreader and the dissecting spatula was inserted through the incision and gently pushed with some, quick, rotary "back and forth" tunneling movements. Following channel creation, the ring segment was inserted using a modified McPherson forceps. The segment was properly positioned with the aid of the Sinskey hook.

The postoperative regimen consisted of moxifloxacin 0.5% (Vigamox®, Alcon, Ft. Worth, TX, USA) and dexamethasone 0.1% (Maxidex®, Alcon) eye drops four times daily for two weeks. The patients were instructed to avoid rubbing the eye and to frequently use preservative-free artificial tears (Systane® 0.4%, Alcon). The patients were examined postoperatively at 1d, 1 month, 3 months, 6 months, and 1 year after the surgery. After the first year, the patients were evaluated annually. The mean follow-up time was based on the time of the last visit.

Statistical Analysis The Statistical Package for the Social Sciences (SPSS, Chicago, IL, USA) was used for descriptive statistics, including means±standard deviations. Student's t-test for paired data was used to compare preoperative and postoperative data. P-values less than 0.05 were considered statistically significant.

RESULTS

One eye each of 37 patients underwent follow-up surgery to remove (n=6), exchange (n=11), reposition (n=4), or insert an additional ICRS (n=16). No patient had reoperation because of subjective complaints (*e.g.* discomfort, dryness, glare, halos). The mean follow-up time after the primary surgery was 7.1±2.8 months. The mean follow-up time between the primary surgery and the reoperation was 8.4±2.2 months. The mean follow-up after the reoperation was 30.5±9.7 months. After the reoperation, the mean UCVA improved from 20/300 to 20/80 (P=0.005); the mean BCVA improved

Table 1 Clinical data according to the type of reoperation (mean values for all data)

	Removal (*n*=6)	Exchange (*n*=11)	Reposition (*n*=4)	Addition (*n*=16)	All cases (*n*=37)
Pre ICRS implantation					
UCVA	20/730	20/700	20/415	20/445	20/570
BCVA	20/130	20/100	20/160	20/115	20/125
Km (D)	49.2	49.8	52.15	46.78	49.48
Post ICRS implantation					
UCVA	20/315	20/260	20/350	20/370	20/325
BCVA	20/110	20/60	20/60	20/60	20/70
Km (D)	43.06	44.93	48.6	45.98	45.64
Post ICRS reoperation					
UCVA	20/150	20/190	20/200	20/450	20/240
BCVA	20/65	20/40	20/50	20/45	20/50
Km (D)	47.63	47.28	49.35	45.12	47.34

Mean values for all data.

from 20/160 to 20/50 (P=0.0002), the mean keratometry reduced from 49.33±4.19D to 46.16±3.90D (P=0.0001), the mean pachymetry at the thinnest point increased from 450±42.9μm to 469±40.8μm (P=0.0001). The changes in the asphericity and spherical equivalent were not statistically significant. The asphericity increased from -0.84±0.74 to -0.35±0.81 (P=0.15) and the spherical equivalent reduced from -4.64±4.87D to -3.04±3.45D (P=0.137).

The data evaluation according with the type of reoperation showed similar results for the different types of surgery (Table 1).

DISCUSSION

Implantation of ICRS is a minimally invasive and reversible surgical procedure that improves the visual acuity by reshaping of the cornea; moreover it prevents or postpones keratoplasty [3]. Successful implantation of ICRS depends on several factors, including correct placement, optical zone diameter, and accurate depth of implantation.

Our postoperative results showed a significant improvement in UCVA and BCVA in reoperation cases. These results are in concordance with most similar papers [1,3,5-10]. In the U.S. Food and Drug Administration phases II and III clinical trials, for Intacs, ICRS removal was required in 4.68% of eyes [11]. The authors of this study concluded that intrastromal ring segments were safely, effectively, and easily extracted, with a return to preoperative refractive status within 3 months. Clinch *et al* [12] evaluated 684 myopic eyes, in which 6.87% needed ICRS removal. The authors concluded that intrastromal corneal ring segment removal was not associated with loss of BCVA, induction of astigmatism, or myopia.

After initial ICRS placement, undercorrection (requiring an additional ICRS implantation, n=16) occurred much more frequently than overcorrection. The reason for insertion of additional ICRS was usually undercorrection, *i.e.* a suboptimal reduction of corneal steepening after implantation of a single ICRS. The causes for these changes (undercorrection and overcorrection) are not well understood but probably are related to corneal biomechanics [13-15]. The cornea rigidity and viscoelasticity can vary in keratoconus and thereby could theoretically be implied in different responses to the ring in patients with similar preoperative topographic patterns. The more elastic the corneal tissue, the greater the ability of intrastromal corneal ring segments to flatten the corneal curvature and correct keratoconus. Studies have shown no change in corneal hysteresis after ICRS implantation, however the use of biomechanic parameters in the nomograms could potentially reduce the risk of undercorrection and overcorrection, thus improving the reproducibility of the technique[15,16]. Moreover, an inaccurate depth of implantation of ICRS can lead to overcorrection and undercorrection.

In all cases, the pre-reoperation UCVA and BCVA was unsatisfactory, with limited improvement after the primary surgery. The mean follow-up time after the primary surgery is relatively short because there are progressive changes after the surgery usually until 6 months postoperatively. Therefore, in most cases we waited up to 6 months to check if any improvement could occur before to proceed to the reoperation. In cases of ICRS removal, the mean keratometry was 43.06D (Table 1) before the reoperation, usually caused by overcorrection, with excessive flattening of the cornea. These patients usually have the worse UCVA and BCVA. This emphasizes the importance of a careful preoperative ring selection, always trying to avoid overcorrection.

We showed that the outcome of patients requiring follow-up surgery due to overcorrection or undercorrection is acceptable. For these patients, there was improvement of UCVA, BCVA, keratometry, and pachymetry. However,

asphericity and spherical equivalent did not improve in these patients undergoing subsequent surgery, perhaps due to the scarring of corneal tissue and/or stroma secondary to the first procedure.

Chan and Khan [17] evaluated the results of ICRS exchange procedures and found satisfactory outcomes, with improvement of at least 1 line of UCVA in all postexchange eyes. As stated in their paper, this enables the surgeon to have a significant "second chance" of obtaining a successful result in patients whose eyes do not have the expected change after the first ICRS placement.

When comparing our reoperation results with studies of primary surgeries, we found slightly worse outcomes in the reoperation cases. Alió *et al* [18] performed a retrospective study to evaluate the long-term (up to 48 months) results after Intacs implantation in patients with keratoconus. After 6 months, the mean UCVA increased significantly (P<0.01), from 0.46 (20/50) preoperatively to 0.66 (20/30), and the average keratometry decreased by 3.13D. Coskunseven *et al* [19] evaluated the results Keraring ICRS in 50 eyes of patients with keratoconus. Of these, 47 had UCVA of 20/40 (range: counting fingers to 20/30). At the last follow-up examination, 14 of the 50 eyes had a UCVA of 20/40 or better (range: counting fingers to 20/25).

Regarding the surgical technique for the reoperation, due to corneal scarring, these procedures can be more demanding to the surgeon. For the ICRS removal, when the primary procedure was recent (less than 10d), the incision can be easily opened, and the segment retrieved using an inverted Sinskey hook, which engages the ICRS hole from below. In longstanding cases, a new incision should be made, over the hole of the ring. For ICRS repositioning, which is usually required soon after the primary surgery because of migration, the segment should be pulled or pushed (according to the desired position), using the Sinskey hook. In cases of ICRS addition, a new incision and a new tunnel should be made, as in primary procedures. In cases of ICRS exchange, the procedure can be made in a single step, *i.e.* removal of the segment followed by immediate insertion of a new segment, or in two separate procedures, removal, followed by insertion in another time. When the reason for ICRS exchange is undercorrection or overcorrection, if the primary segment is well positioned, deeply located in the stroma, the exchange can be made in a single procedure. However, in cases of stromal thinning over a thick segment, it is advisable to remove the segment first, wait at least 3 months, and then proceed to a new ICRS implantation. The choice of the segment to be implanted in a reoperation is based on the surgeon experience, as there are no specific nomograms for reoperations.

In this series of cases, only the manual technique was used for the primary surgery and reoperation. However, reoperation after ICRS implantation assisted by the femtosecond laser has been described [20-23]. The use of the femtosecond laser in corneal tunnel creation makes the procedure easier (especially for inexperienced surgeons). The main advantages of femtosecond-assisted channel creation over the mechanical technique seem to be the precise depth of implantation and symmetry of segments [24,25]. However, these advantages are minimized when the procedure is done by high-volume, experienced surgeons, as in our paper (PF).

In conclusion, ICRS reoperation showed to provide favorable clinical outcomes in keratoconus. The procedure is minimally invasive and yields good visual and keratometric outcomes. Moreover it is a safe technique and does not preclude any future additional treatment or adjustments, if necessary. This study, adds evidence to support the claim of reversibility, readjustability and exchangeability of the ICRS. Further randomized, multi-centric studies, are needed to confirm the results found in the current paper.

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