• Clinical Research •

Preliminary results of a new intrastromal corneal ring segment as a tissue saving procedure in photorefractive keratectomy to correct moderate to high myopia

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Abstract

● **AIM:** To evaluate the clinical results after implantation of a new intrastromal corneal ring segment (ICRS) associated with photorefractive keratectomy (PRK) to correct high myopia (HM) patients with thin corneas.

● **METHODS:** We evaluated 42 eyes of 23 HM patients that had ICRS implantation followed by PRK. The mean age of patients was 29.1±7.12y (range 18 to 40 years old). Uncorrected visual acuity (UCVA), best corrected visual acuity (BCVA), keratometry, spherical equivalent, pachymetry, and aberrometry were compared using ANOVA with repeated measurements evaluated preoperatively and at last follow-up visit after the procedures. The refractive predictability and simulated/real corneal ablation were also assessed.

● **RESULTS:** The mean follow-up time after PRK was 6.8±1.6mo. The mean preoperative UCVA improved from 20/800 preoperative to 20/100 after ICRS and 20/35 after PRK. The mean preoperative BCVA was 20/25 (range from 20/30 to 20/20) and remained unchanged after ICRS implantation. Following the PRK the mean BCVA was 20/25 (range from 20/30 to 20/20). The mean spherical equivalent decreased from -7.25±1.12 (range -5.00 to -9.00) preoperatively to -3.32±1.0 (range -2.00 to -5.00) postoperatively (*P*<0.001) after ICRS implantation and decreased from -2.44±1.51 preoperatively to 0.32±0.45 (range -0.625 to 0.875) postoperatively (*P*<0.001) after PRK. The change in BCVA and topographic astigmatism was statistically significant (*P*<0.0001).

● **CONCLUSION:** ICRS in HM associated with PRK can be a tissue saving procedure and an alternative surgical option for correction of moderate to high myopia.

● **KEYWORDS:** high myopia; intrastromal corneal ring segments; photorefractive keratectomy

INTRODUCTION

Myopia correction can be achieved by many surgical procedures nowadays[1-5]. However, high myopia (HM) limits the number of safe and effective surgical options. Small ablation zones may induce spherical aberration and cause significant issues with night vision. Phakic intraocular lenses (PIOL) have been considered as the procedure of choice for HM corrections[6]. PIOL implantation being an intraocular procedure may pose some risks, including endothelial cell loss and long-term cataract formation caused by progressive increasing of the crystalline lens thickness[7-8].

Intrastromal corneal ring segments (ICRS) has an important management of keratoconus. Several studies about ICRS implantation demonstrated promising results in topographic regularity and uncorrected visual acuity (UCVA) and best corrected visual acuity (BCVA), indicating its effect in avoiding or at least postpone corneal transplantation in keratoconus patients[9-14]. The main advantages of ICRS are safety[10], reversibility[15], stability[16], and the fact that the surgical process does not affect the central corneal visual axis. ICRS HM is a 320-arc length ICRS (AJL, Vitoria, Spain; 320-ICRS) with a new unique intracorneal ring design (Figure 1), based on Intacs (Addition Technology; Figure 2) specially developed for myopia correction. It is hexagonal in cross-section, the diameter is 5.7 mm and it has a 400 μm thickness. This is the first report on the effect of insertion or implantation of ICRS HM on the refractive postoperative outcome.
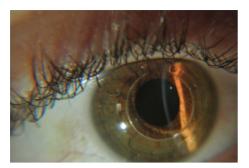
Figure 1 ICRS HM (slit lamp).

Figure 2 Anterior segment OCT.

This study aims to evaluate the clinical outcomes after implantation of a new ICRS in HM patients with thin corneas, followed by photorefractive keratectomy (PRK). The main advantages of this combined procedure are to save cornea tissue (less cornea ablation after ICRS placement), while being an extraocular procedure (comparing with phakic IOL) avoiding inherent risks associated with intraocular procedures.

SUBJECTS AND METHODS

Ethical Approval This prospective study evaluated the clinical results of implantation of ICRS HM followed by PRK in 42 eyes of 23 patients with HM. The patients were evaluated and operated at Ennio Coscarelli Eye Clinic (Belo Horizonte-Brazil). All patients were informed about inclusion in the study, full descriptions of ICRS implantation and PRK procedures, including the potential advantages, disadvantages, side effects and complications. The patients provided informed consent in accordance with the Declaration of Helsinki. Additionally, the study was approved by the local ethics committee (Ennio Coscarelli Eye Clinic Review Board). Clinical trial registration number 00095-2017.

The main inclusion is listed as: spherical myopia ranging from -5.00 to -9.00 diopters (D), with or without regular astigmatism up to -3.5 D; BCVA of 20/30 or better, stable refraction in the past 12mo and age between 18 and 40y. The PRK procedure was performed at least 6mo after ICRS implantation (to wait for the full correction induced by the ICRS). The surgical procedures were performed in both eyes simultaneously.

Exclusion criteria included prior corneal or intraocular surgical procedures, patients with a history of any ocular disease and unstable refraction. Four eyes lost to follow-up and were excluded from the study.

Clinical Measurements

Preoperative and postoperative evaluation All patients had a complete ophthalmological examination preoperatively and postoperatively. The outcome analysis comprised the UCVA, BCVA, spherical equivalent (SE), central pachymetry, refractive error, topographic corneal astigmatism, aberrometry and minimum-maximum keratometry (K) values. All data were obtained before, at the last visit after ICRS implantation and at the last visit after PRK. The BCVA, slit lamp evaluation, refraction, corneal topography, fundoscopy, and tonometry were performed at each control visit. Before the preoperative examination, contact lenses were discontinued for at least 3wk in rigid lens wearers and for at least 1wk in soft contact lens wearers. Preoperative and postoperative higher-order aberrations (HOAs) were measured in scotopic conditions after 10min of dark adaptation. Data were calculated within 5 mm analysis diameter. The anterior segment parameters and aberrometry were obtained by a corneal tomographer (Oculus Pentacam, Germany). All clinical examinations were performed in a standardized manner according to the guidelines of the 320-ICRS multicentric study[17].

After ICRS implantation the patient was evaluated, postoperatively at: 1d, 1, 3 and 6mo. On the first postoperative day, patients were evaluated to check about healing of the wound and migration of the segment. At the last follow-up examination, manifest refraction, UCVA and BCVA, slit lamp, and topographic examinations were performed.

Photorefractive keratectomy nomogram The surgical planning (ablation) was the full refractive error in cases with less than -3.00 D (SE). In cases of more than -3.00 D of SE, 75% of correction was planned. This was based on our personal experience (unpublished data) of PRK after 5 mm optical zone ICRS implantation.

Surgical Technique

ICRS implantation-femtosecond laser technique The surgical procedure was carried out under sterile conditions and topical anesthesia. Purkinje reflex was chosen as the central point and was marked. A 6-mm marker was used to locate the exact ring channel. Tunnel depth was set at 75% of the thinnest corneal thickness on the tunnel location in the femtosecond laser. A 60-kHz femtosecond laser (LDV, Ziemer, Switzerland) used to create the ring channel. The channel's inner diameter was set to 5.55 mm, the outer diameter was 7.32 mm, the ring energy used for channel creation was 1.30 J, and the entry cut energy was 1.30 J. Channel creation timing with the femtosecond laser was 24s. The ICRS HM (400 µm) was implanted immediately after channel creation before the disappearing of the bubbles. Following channel creation, the ICRS HM was inserted using a modified McPherson forceps and positioned with the aid of a Sinskey hook.

Photorefractive keratectomy All cases were performed at least 6mo after ICRS implantation. The surgery was performed
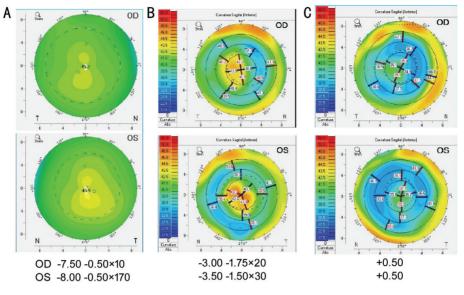
Figure 3 Refraction and topography A: Preoperative; B: After ICRS implantation; C: After PRK.

under topical anesthesia, with proparacaine eyedrops. Corneal epithelium was gently debrided after exposure to ethanol 20% in a balanced salt solution for 30s. Laser aspheric ablation was performed using the Schwind Amaris excimer laser (Eye-Tech Solutions, Germany) in a 5.3 mm optical zone. Mitomycin C 0.02% (MMC) was used in all eyes with application time is from 12 to 20s. Immediately after MMC, the ocular surface was rinsed with chilled saline for 30s.

The postoperative regimen consisted of moxifloxacin 0.5% (Vigamox®, Alcon, USA) and dexamethasone 0.1% (Maxidex®, Alcon, USA) eye drops four times daily for two weeks. The patients were instructed to avoid rubbing the eye and to use preservative-free artificial tears frequently-polyethylene glycol 400 (0.4%, Systane®, Alcon, USA).

Statistical Analysis Statistical analysis was carried out using the Instat Graphpad (2017, La Jolla, USA). The data were checked for normality using the Kolmogorov-Smirnov test (SPSS for Mac version 24) before statistical evaluation. Analysis of variance (ANOVA) with repeated measurements was used to compare the parameters between baseline, after ICRS and after PRK.

RESULTS
We evaluated 42 eyes of 23 patients that had ICRS HM implantation followed by PRK. There were 13 females and 10 males with a mean age of 29.1±7.12 (range 18 to 40 years old). The mean follow-up time after PRK was 6.8±1.6mo. The mean preoperative UCVA improved from 20/800 preoperative to 20/100 after ICRS and 20/35 after PRK. The mean preoperative BCVA was 20/25 (range from 20/30 to 20/20) and remained unchanged after ICRS implantation. Following the PRK the mean BCVA was 20/25 (range from 20/30 to 20/20). The mean SE decreased from -7.25±1.12 (range -5.00 to -9.00) preoperatively to -3.32±1.0 (range -2.00 to

-5.00) postoperatively (P<0.001) after ICRS implantation and decreased to 0.32±0.45 (range -0.625 to 0.875; P<0.001) after PRK. The mean Km reduced from 44.4±1.53 D (range 42.25 to 47.20 D) preoperatively to 41.5±1.96 D (range 38.5 to 45.3 D) postoperatively (P<0.001), after ICRS. Following PRK the mean K was 37.7±1.40 D (range 34.8 to 40.14 D, P<0.001; Figure 3). The change in BCVA and topographic astigmatism was statistically significant (P<0.0001). After the two procedures, the mean central pachymetry decreased from 521±27 μm (range 467 to 552) preoperatively to 484±31 μm (range 432 to 532; P<0.001) postoperatively. Two or more lines of BCVA were gained in 11% of eyes. Four percent of eyes lost 1 line of vision (Figure 4), due to cornea irregularity after PRK. All these eyes had preoperative BCVA better than 20/30.

No intraoperative or postoperative complications were observed for both surgical techniques (ICRS implantation and PRK). The average simulated corneal ablation in case of a single procedure (if the patient had PRK without previous ICRS implantation) was 109±22.4 (range 72 to 141) μm. The real average corneal ablation (PRK after ICRS implantation) was 34±10.8 (range 20 to 60) μm (70% tissue saving). The vectorial analysis of refraction showed poor predictability of results after implantation of ICRS HM and good predictability after PRK (Figures 5 and 6).

Wavefront Aberration Mean postoperative root mean square (RMS) wavefront aberration values after ICRS implantation were significantly greater than those obtained preoperatively (P<0.05; Table 1). The changes in vertical coma and trefoil after ICRS were not statistically significant. Horizontal coma and spherical aberration reduced significantly after ICRS implantation (P<0.05). After PRK, the changes in wavefront variables were statistically significant except for trefoil.
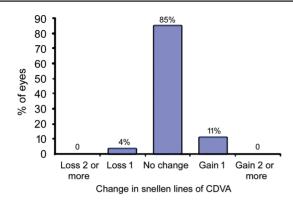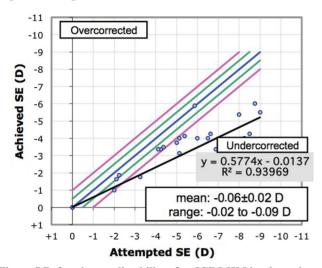
Figure 4 Change in Snellen lines of CDVA.

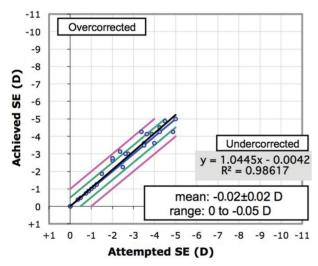Figure 5 Refractive predictability after ICRS HM implantation.

Figure 6 Refractive predictability after PRK.

Slit Lamp Examination At the last postoperative follow-up visit, the ICRS was well implanted in all eyes and no eye presented corneal haze. All patients reported to be very satisfied with the clinical outcomes. No patient required reversion of the procedure (removal of the ICRS).

DISCUSSION

The main modern option for surgical treatment of moderate to HM is the implantation of PIOL. Despite being a very effective procedure, there are several reports of long-term complications with the use of PIOL[17].

Table 1 Aberrometry before and after ICRS and after PRK

Wavefront	Before ICRS	After ICRS	After PRK	P
Vertical coma	-0.02±0.13	-0.06±0.61	0.11±0.41	0.06
Horizontal coma	-0.03±0.26	-0.44±0.33	0.05±0.59	<0.05
Trefoil	-0.06±0.18	0.05±0.42	- 0.06±0.59	0.07
Spherical aberration	0.08±0.10	-0.75±0.49	0.30±0.19	<0.05
RMS	1.42±0.71	6.72±1.64	3.35±0.93	<0.05

ICRS: Intrastromal corneal ring segments; PRK: Photorefractive keratectomy; RMS: Root mean square.

Jonker et al[18] showed that ten years after rigid iris fixated PIOL implantation, the BCVA and UCVA decreased significantly as a result of significant myopization caused by an increased axial length unrelated to the PIOL. In this same paper they showed a 10% rate of PIOL explantation due to cataract formation. The recent reintroduction of a long arc ICRS has the primary objective of increasing corneal flattening, especially in advanced keratoconus cases. Few publications are available, and first results were recently published. Jadidi et al[19] published his results and complications using a 355-degree arc ICRS and recently, Torquetti et al[20] published the first results of a multicentric study using a 320-arc ICRS.

In patients with HM and thin corneas, the sequential treatment of ICRS HM followed by PRK reduces the amount of laser ablation necessary for full treatment by a mean of 70%. This allows a safe treatment of patients with moderate to HM. Moreover it can be useful in cases of thin corneas. The ICRS may enhance the effect of PRK. Moreover, the implantation of ICRS in thin corneas, at least in theory, may also provide structural and biomechanical stability and lower the risk of ectasia. This is especially important in keratoconus suspects undergoing PRK. Unlike in intraocular surgery for HM, there is no risk of cataract formation, retinal detachment, and endophthalmitis.

We could observe a progressive flattening effect of the ICRS HM. This can be explained by its significant arc length, which produces a "new limbus" in the cornea, which changes progressively after the implantation. The cornea changes after ICRS HM occur in the whole are central to the ICRS, for this reason, we could consider this segment as a "new limbus". Previous studies with long arch ICRS showed that these segments could induce a progressive flattening effect for up to 6mo[19]. Ideally, we should wait, at least 6mo after the ICRS placement, before proceeding to PRK, to reduce the risk of consecutive hyperopia.

There were 3 cases of postoperative (after PRK) hyperopia. We hypothesized that PRK may have potentialized the effect of ICRS in these cases with consecutive hyperopia. After these cases, we aimed to undercorrect the laser correction to avoid consecutive hyperopia.

We observed that 11% of eyes gained 1 or more lines of BCVA and 4% of eyes lost 1 line of BCVA. These data reinforce the safety of the combined procedure along the time. Eyes with loss of BCVA had induction of high order aberrations.

Proximity between the ICRS and the incision is the leading risk factor for extrusion, infection and corneal melting. The ICRS HM, having 320-arc length is supposed to be 20 degrees on each side, far the incision, what makes it safer to be used.

Although selecting a small optical zone (OZ) diameter (less than 6.0 mm) will decrease the risk of haze formation, it may create new problems including regression, spherical aberrations, decreased contrast sensitivity, and some other optical phenomena. We did not observe these adverse side effects in the evaluated patients.

An OZ of 5.3 mm was used for PRK to reduce the risk of haze. PRK after 5 mm OZ ICRS poses a high risk of haze. A 6 mm OZ associated with a small OZ of ablation turns it safe in terms of haze prevention. Based on our personal experience of PRK in patients with mild keratoconus implanted with ICRS, when the laser is done over the ICRS itself, there is a high incidence of haze, which would be more common in small OZ segments (5.0 mm). There is cornea flattening in the ICRS body and steepening in the center of the cornea. The optical area of the cornea, which contains the ametropia to be treated, is confined to the very center of the cornea. For that reason, the ablation should be done in the described OZ.

The ablation transition zone is 0.75 mm. As it is not the main zone of ablation, the tissue removal on this area is minimal (less than 10 μm) as shown by anterior segment OCT images after ICRS and after PRK (Figure 7). The total treatment size is 6.05 mm, considering 5.30 mm of main ablation and 0.75 mm of transition zone.

Increasing HOAs is associated with poor visual quality in patients with HM. In our study, we found changes in HOA after ICRS, but most of them were partially corrected by PRK, which increases the safety and efficacy of this association of techniques.

Our personal experience about ICRS associated with PRK showed that there is a tendency to overcorrection in cases of ablation more than 30 μm. Therefore, in these cases we aimed to undercorrect (75% of the total SE) to avoid consecutive hyperopia. There were no cases of plano refraction after ICRS implantation.

We choose 400 μm ICRS for every case to standardize this parameter and avoid a possible bias related to ICRS thickness, as this is only a preliminary report. In most cases the relation ICRS thickness/cornea thickness (ICRS-T/Cornea-T) in the track was about to 60%. Classically, 50% has been considered as the safe number to avoid future extrusion in keratoconus cases, using the manual technique.
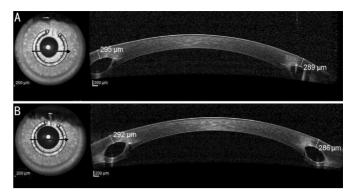

Figure 7 Anterior segment OCT after ICRS (A) and after PRK (B), in the same eye, in the same location.

As the corneas of this study are not keratoconus corneas (therefore, stiffer corneas), the technique employed was the femtosecond laser and the OZ is larger (6 mm-when compared with the thin keratoconic OZ of 5 mm), we can safely consider 60% of relation ICRS-T/Cornea-T.

As the long arc ICRS causes significant corneal flattening, it should be reserved for moderate to HM only. We could observe that the steeper the cornea, the more significant the K and refractive change after ICRS HM implantation. It should be avoided in cases of low myopia, as it can overcorrect and produce unpredictable/unreasonable results and consecutive hyperopia. One limitation of the study was the lack of a control group. However, several studies[21-23] in the literature describe the results of other ICRS designs and arc length that could be compared to these first results of the 320-ICRS[20]. Our study is limited by the short-term follow-up and a relatively small sample. We are planning to follow the patients for at least 2y to assess the long-term refractive stability of the combination of procedures.

ICRS HM implantation followed by PRK is an alternative in reducing spectacle dependence in moderate to HM with low complication rates. It could be considered in HM with anterior chamber depth or endothelial cell count incompatible with phakic IOLs implantation. Besides it can be an option in myopic patients with thin/suspect corneas unsuitable for LASIK. It shows promising results as a tissue-saving procedure in patients with moderate to HM and relatively thin corneas. This combination of treatment could be a safe option to LASIK or phakic IOL for surgical vision correction in selected myopic patients.

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