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Outcomes of 320-degree intrastromal corneal ring segment implantation for advanced keratoconus

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Abstract:

PURPOSE: The purpose of this study is to investigate visual and tomographic outcomes and complications of long-arc length intrastromal corneal ring segment (ICRS) implantation for the treatment of advanced keratoconus.

MATERIALS AND METHODS: This retrospective study enrolled 10 eyes of 9 subjects. All patients received 320-degree ICRS (320-ICRS) implantation with femtosecond laser-assisted technique based on their advanced grading with preoperative high keratometry (K) value, asphericity (Q), and astigmatism. Medical records and corneal tomography changes of consecutive patients were reviewed at baseline, 1, and 3 months after treatment.

RESULTS: There are 6 female and 3 male patients with a mean age of 29.6 ± 7.8 years in this study. Mean K (Km) reduced from 59.01 ± 5.81 D preoperatively to 50.7 ± 5.3 and 50.2 ± 3.66 postoperatively (after 1 month and 3 months respectively, $P < 0.001$). The changes in mean K, K1, K2, and maximum K (Kmax) reading were all statistically significant (all $P < 0.001$). Mean uncorrected distance visual acuity (UCVA) improved from 20/400 to 20/200. Mean best-corrected distance visual acuity (BCVA) improved from 20/100 to 20/60. Both UCVA and BCVA showed a trend of improvement at postoperative month 3, though insignificant in BCVA ($P = 0.114$). Mean Q improved from −1.59 ± 0.62 preoperatively to −0.48 ± 1.08 and −0.11 ± 1.04 postoperatively (after 1 month and 3 months respectively, $P = 0.016$, 0.002). No intraoperative or postoperative complications were observed.

CONCLUSIONS: The present results suggest that implanting a 320-ICRS is a safe and effective procedure for treating patients with advanced keratoconus. Preoperative corneal measurements and the selection of types and thickness of ICRS are important to prevent unpredictable results.

Keywords:

Corneal tomography, intrastromal corneal ring segment, keratoconus

Introduction

Keratoconus is a progressive, bilateral noninflammatory ectasic disease characterized by corneal steepening and thinning, generating a high degree of myopia and irregular astigmatism, and thus severely impairing visual acuity.[1] Treatment begins foremost with contact lenses, progressing to surgery such as cross-linking, intrastromal corneal ring segments (ICRS), and corneal transplantation as contact lens intolerance develops.[2,3]

The management of early cornea ectasia is well established in the literature, but the management of advanced corneal ectasias (ACEs) is still challenging since there are no definitive guidelines. ICRS is a method of regularizing the morphological alterations present in the cornea thus improving CL tolerance and best-corrected visual acuity (BCVA) for patients with corneal ectasia.[2,4,5] It is commonly indicated for cases with moderate keratoconus as a safe and reversible technique for improving the visual function and the quality of life of patients. The first intracorneal ring design was composed of a 360° ring that

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led to several complications. Since then, many different types of ICRS with variable thickness, geometries, and diameters have been developed with the benefit to work more effectively in cases of moderate-to-severe keratoconus.[4,6] The 320-arc length Ferrara ICRS (AJL, Vitoria, Spain) (320-ICRS) is a new unique intracorneal ring design specially developed for more advanced types of keratoconus, which is available in a diameter of 5.7 mm and a thickness range of 150–300 mm.

Since only few studies reported the clinical outcomes with 320-ICRS,[7,8] the purpose of the present study is to investigate the visual and tomographic outcomes of 320-ICRS implantation as a therapeutic option in the treatment of patients with advanced keratoconus.

Materials and Methods

Data source and ethnic declaration

We retrospectively reviewed the medical records of patients with implantation of a 320-ICRS in Keelung Chang Gung Memorial Hospital. Our study was approved by the Institutional Review Board of Chang Gung Medical Foundation (IRB: 201801393B0). Patient consent to review their medical records was waived due to the retrospective nature of the study. The data of participants were anonymized and maintained with confidentiality. We conducted our studies in compliance with recognized international standards and the principles of the Declaration of Helsinki.

The inclusion criteria of this study were as followed: patients diagnosed with keratoconus, poor spectacle-corrected visual acuity (corrected distance visual acuity (CDVA) ⩾ 0.3 logMAR), inability to wear contact lenses, minimum Kmax of 58.0 D, and received implantation of a 320-ICRS. We excluded patients with prior corneal surgical procedures, such as keratorefractive surgery, crosslinking, or keratoplasty, and those with a history of any corneal diseases other than keratoconus and active ocular disease.

Surgical technique

The 320-ICRS was implanted using femtosecond laser–assisted procedure. The ring segment thickness was decided according to the nomogram of the manufacturer. Purkinje reflex was chosen as the central point and was marked. The channel for 320-arc length Ferrara ICRS placement was created using the IntraLase (Abbott Medical Optics) with a pulse energy of 300 nJ. The depth of the ring channel was set to 75% of the thinnest corneal thickness 3 millimeters from the light reflex center. The inner and outer tunnel diameters were preset to 4.9 mm and 5.9 mm, respectively, depending on the K reading and ring thickness. In addition, a 1.35 mm radial entry incision was created. The 320-ICRS was inserted using a modified McPherson forceps and properly positioned with the aid of a Sinskey hook. After implantation of the 320-ICRS, the incision was sutured for one stitch with 10-0 nylon. Topical antibiotics with steroids were applied four times daily for 4 weeks.

Statistical analysis

All analyses were computed by using PASW Statistics 18 software (Version 18.0. Chicago: SPSS Inc.). Differences of VA, K values and Q values between baseline and every visit were evaluated by paired t-test. A p-value less than 0.05 is considered statistically significant.

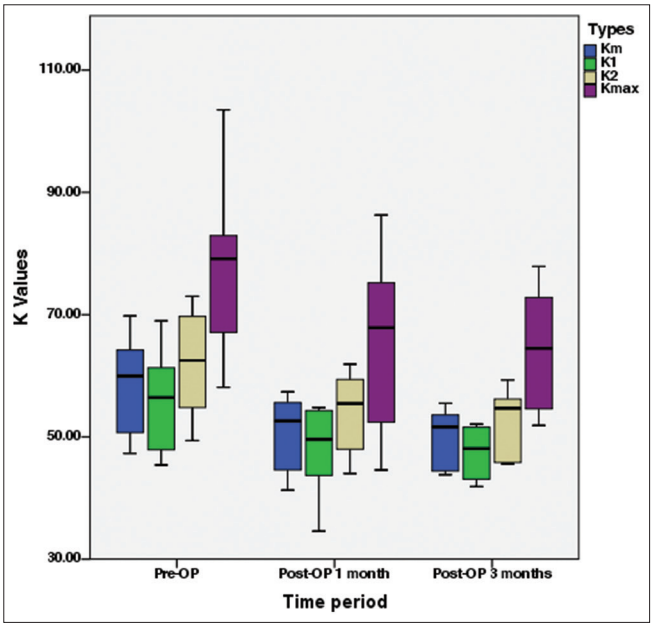

Figure 1: Box plot of keratometry value

Table 1: The changes of ophthalmic parameters before and after intracorneal ring segment implantation

Parameters, mean± SD (IQR)	Pre	Post-1	Post-3	*P*1	*P*2
Km	59.01±5.81	50.70±51.3	50.20±3.66	0.007*	<0.001*
Keratometry 1	56.14±5.49	48.11±5.13	47.66±3.21	0.026*	0.001*
Keratometry 2	62.44±6.28	53.53±5.62	53.00±4.37	0.001*	<0.001*
Kmax	71.32±9.06	64.54±11.51	59.37±7.9	<0.001*	<0.001*
Q	−1.59±0.62	−0.48±1.08	−0.11±1.04	0.016*	0.002*
UCVA	1.61±0.43	1.45±0.62	1.13±0.52	0.201	0.029*
BCVA	1.06±0.72	0.84±0.72	0.77±0.56	0.252	0.143

*Significant difference among groups (*P*<0.05) by paired-*t*-test. *P*1=The difference between pre-and post-1, *P*2=The difference between pre- and post-3, IQR=Interquartile range, UCVA=Uncorrected distance visual acuity, BCVA=Best-corrected distance visual acuity, Kmax=Maximum K, Km=Mean K

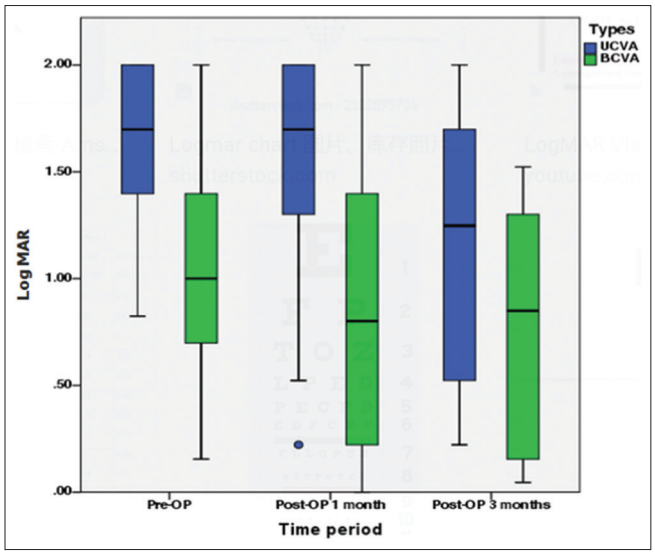

Figure 2: Box plot of visual acuity. UCVA: Uncorrected distance visual acuity, BCVA: best-corrected distance visual acuity

Result

A total of 10 eyes of 6 female and 3 male patients with a mean age of 29.6 ± 7.8 years (range: 21–59 years) were included in this study. Preoperative and postoperative visual and tomographic outcomes are summarized in Table 1. All patients were categorized into advanced keratoconus as Grade III and IV according to the Amsler-Krumeich keratoconus grading system, except for one patient with Grade II keratoconus. Mean K (Km) reduced from 59.01 ± 5.81 D preoperatively to 50.7 ± 5.3 and 50.2 ± 3.66 postoperatively (after 1 month and 3 months respectively, $P < 0.001$). The changes in mean K, K1, K2, and maximum K (Kmax) readings were all statistically significant ($P < 0.001$) [Figure 1]. Mean uncorrected distance visual acuity (UCVA) improved from 20/400 to 20/200. Mean BCVA improved from 20/100 to 20/60. Both UCVA and BCVA showed a trend of improvement at postoperative month 3, though insignificant in BCVA ($P = 0.114$) [Figure 2]. Mean Q improved from −1.59 ± 0.62 preoperatively to −0.48 ± 1.08 and −0.11 ± 1.04 postoperatively (after 1 month and 3 months respectively, $P = 0.016$, 0.002) [Figure 3]. No intraoperative or postoperative complications were observed. Two patients developed ocular hypertension at postoperative months 1 and 3 with intraocular pressure (IOP) measured 28 mmHg and 29 mmHg, respectively. The IOP became normal after short-term treatment of antiglaucoma eye drops. At postoperative 3 months, three patients had undesired mean asphericity postoperative result of > −0.23 ± 0.08, and two of them loss one or more lines of UCVA or BCVA. Fifty percentage of eyes gained one or more lines of both UCVA and BCVA.

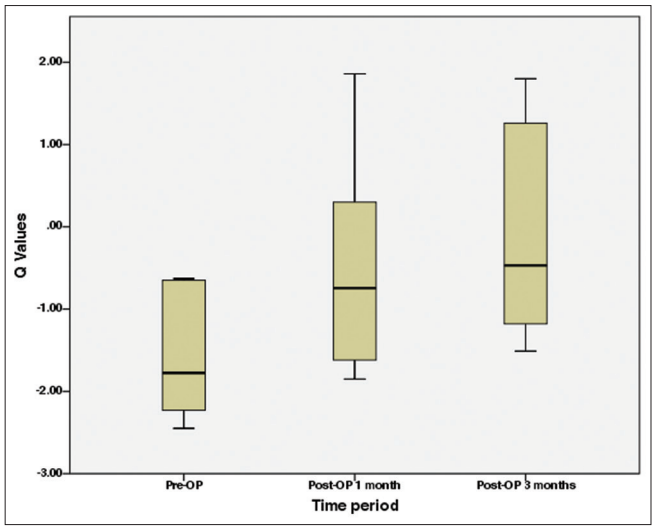

Figure 3: Box plot of Q value

Discussion

Most of the authors observed a central flattening of the cornea after implantation of ICRS with a mean reduction of the keratometric readings between 3 and 5.5 D.[2,6-9] In our current study, a mean reduction of Km was 8.8 D, which revealed better improvement than previous researches with 320-ICRS.[7,8] This can be explained by the higher baseline K value and advanced stage of our study group. On the aspect of visual outcome, due to the high heterogeneity of the presented studies with different stages and types of ICRS used, the results were variable in the literature.[10] Besides, the correlation between visual outcomes and tomographic parameters was still debated. The change of visual acuity was −0.49 ± 0.56 logMAR without correction and −0.29 ± 0.62 logMAR with correction at 3 months of follow-up in our patients, which demonstrated a greater improvement compared to a systemic review of 18 studies reported by Izquierdo *et al*.[10] However, only 50% of eyes gained one or more lines of both UCVA and BCVA, which was similar to a 340° arc report[11] but much lower than 85.29% reported by Rocha *et al*. with most patients had the classification of keratoconus grades I and II using 320-ICRS.[8] We considered this may be related to the advanced stage and shorter follow-up period of our patient.

It is noteworthy that the mean Q improved significantly from −1.59 ± 0.62 to −0.11 ± 1.04, in correspondence with previous results of better asphericity improvement of higher arc length.[8,9,12] This stronger effect overcorrected the corneal prolatism and produced undesirable results of the oblate cornea in three of our patients. Among them, one had the highest Km value (69.8D) and one had the lowest Km value (47.3D) classified as Grade II keratoconus and the other one was oval-type keratoconus with high astigmatism (5.1D/8.3D). The latter two further loss one

or more lines of UCVA or BCVA at 3-month follow-up. These findings indicated the significant changes in Q and Km after the use of 320-ICRS may yield more unpredictable results when the patient has an extreme K value, only mild-to-moderate stage of disease or oval cone. Besides, the uniform flattening effect of long-arc ICRS leads to the persistence of asymmetry cornea for the oval cone, contributing to irregular surface, residual high astigmatism, and poor visual outcome. Therefore, choosing the appropriate ring for a particular stage and type of cone can considerably improve the outcome. Factors that directly impact on visual outcomes after ICRS surgery are not fully elucidated.

There are various nomograms in practice for ICRS selection considering the tomographic pattern, refractive parameters, and corneal aberrations.[13-16] In our study, group of extreme steep cornea, however, almost half of patients could not obtain refractive parameters (sphere, cylinder, and spherical equivalent) with autorefractometer, which are used to be an important basis of ring selection. The present results suggest surgical planning based on mean asphericity, despite the small sample of patients, could still achieve favorable outcomes. However, overcorrected, undesired mean asphericity is predictive of a poor visual outcome with 320-ICRS.

For ACEs, surgeries such as penetrating keratoplasty and lamellar keratoplasty are still considered gold standards for visual rehabilitation. Only few investigators compared ICRS implantation to corneal transplantation for advanced keratoconus with variable results.[17-19] Our findings suggest 320-ICRS is a promising therapeutic option in ACEs, avoiding corneal graft and its inherent risks of rejection and other significant complications, which is especially unneglectable for this relatively young population. Besides, the BCVA in our study was corrected with spectacles. After 320-ICRS insertion, a complementary treatment of contact lens fitting to improve BCVA is more feasible while corneal surface irregularity decreased, which may further improve the final visual outcome.

There was no migration, ring extrusion, corneal thinning, corneal melting, or infective keratitis developed in our cases. This finding correlates well with previous studies,[7,8] revealing 320-ICRS a safe operation, which may contribute to the 40-degree gap preventing segment proximity to the surgical incision.

Conclusions

The current study suggests that implantation of 320-ICRS is a useful alternative to possibly defer or avoid keratoplasty for moderate-to-severe keratoconus, achieving significant corneal applanation, regularity, and a more physiologic shape. It should be selected with caution particularly among those with asymmetric cone or mild-to-moderate keratoconus due to the possibility of overcorrection or unpredictable results. Further, studies with a larger sample size and a longer follow-up of effectiveness and safety should be performed in the future.

Data availability

The datasets generated during and/or analyzed during the current study are available from the corresponding author on reasonable request.

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Nil.

Conflicts of interest

Prof. Chi-Chin Sun, a section editor at *Taiwan Journal of Ophthalmology*, had no role in the peer review process of or decision to publish this article. The other author declared no conflicts of interest in writing this paper.

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