

A Two-Year Outcome of Intrastromal Corneal Ring Segment Implantation in Keratoconus: Initial Report in Thai Patients

Suksri Chotikavanich, M.D., Panida Kosrirukvongs, M.D., Jatuporn Duangpatra, M.D., Pinnita Prabhasawat, M.D., Wipawee Booranapong, M.D., Chareenun Chirapapaian, M.D., Sabong Srivannaboon, M.D.

Department of Ophthalmology, Faculty of Medicine Siriraj Hospital, Mahidol University, Bangkok 10700, Thailand.

ABSTRACT

Objective: To determine two-year outcome of intrastromal corneal ring segment (ICRS) implantation in keratoconus in Thai patients

Methods: A retrospective review of medical records of the patients underwent Ferrara-type ICRS implantation (single and two segments) at Siriraj Hospital between November 2013 and December 2017 was conducted. Clinical outcomes were assessed at 1 month, 6 months, 1 year, and 2 years postoperatively.

Results: Of 9 eyes in 8 patients, the mean age of the patients was 24.6 ± 7.5 years. The mean follow-up time was 32.2 ± 9.4 months. Overall, the median visual acuity was significantly improved postoperatively (p value = 0.007). At 2 years, the uncorrected visual acuity (UCVA) improved from 1.00 logMAR to 0.56 logMAR, and the corrected distance visual acuity (CDVA) improved from 0.76 logMAR to 0.10 logMAR. Correspondingly, the median spherical equivalent refraction was significantly improved postoperatively from -7.38 D to -3.13 D ($p < 0.001$). Moreover, the median anterior corneal topographic data significantly changed between visits ($p < 0.02$). The Kmax decreased from 52.65 D to 46.65 D and the Kmean decreased from 48.10 D to 45.40 D at 2 years. Postoperative adverse effects were glare and halos (3 eyes), visually insignificant small white corneal deposits around the segments (2 eyes), extrusion of a ring segment needed removal with reversible to baseline vision (1 eye).

Conclusion: This initial report in Thai patients showed that the ICRS implantation in keratoconus could improve the visual, refractive, and topographic parameters with stability at 2 years. However, appropriate case selection and surgical technique should be considered.

Keywords: Intrastromal corneal ring segment; keratoconus; Thailand (Siriraj Med J 2019; 71: 302-309)

INTRODUCTION

Keratoconus is a progressive ectatic disease resulting in severe visual loss. There is a wide spectrum of treatments for keratoconus including non-surgical options of glasses and contact lenses and invasive surgery of keratoplasty. For the reason to improve spectacle corrected vision or contact lens tolerance and postpone keratoplasty,

minimally invasive surgery of keratoconus by intrastromal ring segment (ICRS) implantation was introduced by Colin et al in 2000¹ and has gained wide acceptance in the previous decade. The explanation to correct the myopia was that adding tissue to the periphery of the cornea with small arc-like implants resulted in flattening the central cornea.^{2,3}

Corresponding author: Suksri Chotikavanich

E-mail: suksri_c@yahoo.com

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ORCID ID: <http://orcid.org/0000-0002-5973-643X>

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Previous studies evaluated the effectiveness of the surgery in their populations.³⁻⁷ To our knowledge, and based on our review of the English-language literature (Ovid, PubMed, ProQuest, Google Scholar, ScienceDirect, and Scopus databases), no previous study has reported on the outcome of the ICRS implantation in keratoconus in Thai patients. We conducted a retrospective record study to demonstrate the clinical outcome and the stability of outcome of the surgery at 2-year follow up.

MATERIALS AND METHODS

Patients

The protocol for this study was approved by the Committee for the Protection of Human Participants in Research at the Faculty of Medicine Siriraj Hospital, Mahidol University, Bangkok, Thailand (Si 787/2558). The study was a longitudinal retrospective analysis of consecutive patients with keratoconus in which ICRS implantation was performed at Siriraj Hospital from November 2013 to December 2017. The inclusion criteria for ICRS implantation in this study were progressive intolerance to contact lenses and a clear cornea with minimum thinnest corneal thickness of over 300 μm . The exclusion criteria were a significant apical corneal opacity and scarring, corneal hydrops, endothelial count less than 2000 cells/ mm^2 , history of glaucoma, patients with intense atopy, autoimmune disease or systemic connective tissue disease. All surgeries were performed by four surgeons (P.K., P.P., S.C., and C.C.).

Preoperative examination

Before the surgery, all patients had a complete ophthalmologic examination including uncorrected (UCVA) and best-corrected (CDVA) distance visual acuity, manifest refraction, slit-lamp biomicroscopy, funduscopy, and Pentacam corneal topography analysis (Oculus Optikgeräte GmbH, Wetzlar, Germany). The following topographic data were evaluated: the thinnest corneal thickness, anterior keratometry, and corneal asphericity (Q value) at 8 mm. The grading of the keratoconus was classified according to Amsler-Krumeich classification⁸, based on preoperative anterior keratometry; grade I: Kmean ≤ 48 D; grade II: Kmean > 48 D to 53 D; grade III: Kmean > 53 D to 55 D; and grade IV: Kmean > 55 D. Surgical technique

The polymethyl methacrylate Ferrara-type ICRS (AJL Ophthalmic, S.A., Spain), which has a triangular cross section (flat basis width = 0.6 mm) that induces a prismatic effect on the cornea, was used in all eyes. The segment has variable thicknesses (150 to 300 μm) and arc lengths (90°, 120°, 140°, 160°, and 210°). The protocol

used for ICRS selection was based on the manufacturer-defined nomogram.

The surgery was performed under local anesthesia. The ICRS tunnel was created manually. The center of the visual axis on the cornea was marked for a reference point for centration by asking the patient to fixate on the corneal light reflex of the microscope light. Then, a 5 mm., optical zone was marked and a small radial incision was made at the most curved meridian by a diamond knife for the ICRS to be implanted. The depth of this perpendicular incision was 80% of the corneal thickness. Preparation of the intrastromal pocket for the ICRS was performed at the side of the incision from its base by the spreader and the 270-degree semicircular (clockwise and counterclockwise) dissectors maintaining a uniform depth. After channel creation, the segment was inserted using the modified McPherson forceps with the flat side of the ring downward.

Postoperatively, levofloxacin eye drops were prescribed four times daily for 2 weeks and topical steroid eye drops four times daily for 2 weeks with tapering of the dose over the following 1 month. Non-preserved artificial tear was also prescribed.

Postoperative assessment

Postoperative follow-up visits were at 1 day; 1, 3, 6 months, and then every year following ICRS implantation. We assessed only the clinical outcomes at 1 month, 6 months, 1 year, and 2 years postoperatively to evaluate effectiveness and stability of the surgery. At each of the follow-up visits, the record of UDVA, CDVA, manifest refraction, slit-lamp biomicroscopy, and corneal topography were reviewed. Visual acuity was measured using the Snellen rating and transformed into the logarithm of the minimum angle of resolution (LogMAR)

Statistical analysis

Data analysis was performed using PASW Statistics (SPSS) 18.0 (SPSS Inc., Chicago, IL, USA). A non-parametric Friedman test was used to compare preoperative and postoperative data at all visits. If the difference was statistically significant, a *post-hoc* paired comparison was implemented using the nonparametric two related sample comparison method with adjusting Bonferroni-corrected alpha level. A *p* value of < 0.05 was considered significant throughout.

RESULTS

Clinical data

Nine eyes in 8 patients were included in the study, and 5 patients were male and 3 patients were female.

One patient received ICRS implantation in both eyes. Four eyes were right eye. The mean age of the patients was 24.6 ± 7.5 years. Considering age group of the patients, 6 eyes were ≤ 30 years and 3 eyes were > 30 years. About grading of keratoconus; 4 eyes were grade I, 2 eyes were grade II, 2 eyes were grade III, and 1 eye was grade IV. The mean thinnest corneal thickness was $442 \pm 45.5 \mu\text{m}$.

Eight eyes had two segments of ICRS implantation (segment thicknesses of $150 \mu\text{m}$ and $200 \mu\text{m}$, arc lengths of 140° and 160°), whereas 1 eye had single segment (segment thicknesses of $200 \mu\text{m}$, arc lengths of 210°). The mean follow-up time of all patients was 32.2 ± 9.4 months. Representative slit-lamp pictures after the surgery were shown in Fig 1. Postoperative symptom of tolerable glare and halos occurred in 3 eyes. Concerning information about scotopic pupil size, centering or depth of the ICRS was not enough to analyze the possible associated factors of those glare and halos. Small white intrastromal deposits which accumulated in the lamellar channel around the segments were found in 2 eyes. There was an extrusion of a ring segment at the incision site in 1 eye at a few weeks after 1 month postoperatively, and both segments in the eye were removed because of the awareness of surgically induced astigmatism. However, 4 months later, her visual acuity and refraction returned back to the baseline before surgery. As the result, eight eyes remained for the data analysis at 6 months, 1 year, and 2 years.

Visual acuity

Visual acuity before and after ICRS implantation at 1 month, 3 months, 6 months, 1 year, and 2 years were presented in Table 1 and Fig 2. Overall, the median UCVA significantly improved after surgery ($p = 0.007$). After *post-hoc* paired comparison, the median UCVA still significantly improved at 2 years postoperatively ($p < 0.02$). Moreover, the median CDVA significantly improved after surgery ($p = 0.001$). After a *post-hoc* paired comparison, the median CDVA significantly improved after 1 year postoperatively ($p < 0.02$). At the last follow up, the median CDVA improved from 0.76 logMAR to 0.10 logMAR.

Manifest Refraction

Manifest refraction before and after ICRS implantation at 1 month, 3 months, 6 months, 1 year, and 2 years were also presented in Table 1 and Fig 2. Overall, the median spherical equivalent of high myopia significantly decreased after surgery ($p < 0.001$). After *post-hoc* paired comparison, the median spherical equivalent significantly decreased at 6 months postoperatively and was still

significantly decreased at 2 years postoperatively ($p < 0.02$). Postoperatively, the median spherical equivalent improved from -7.38 D to -3.13 D. The median refractive astigmatism also decreased after the surgery from -8.75 D to -2.25 D, but did not reach statistical significance.

Corneal topography

Anterior corneal topographic data before and after ICRS implantation at 1 month, 3 months, 6 months, 1 year and 2 years were presented in Table 2 and Fig 2. Representative anterior corneal topographic findings before and after surgery were shown in Fig 3. Overall, the median Kmax, Kmean, and keratometric astigmatism significantly decreased postoperatively ($p < 0.02$). At the last visit, Kmax decreased from 52.65 D to 46.65 D, Kmean decreased from 48.10 D to 45.40 D, and keratometric astigmatism decreased from 6.70 D to 1.40 D. After *post-hoc* paired comparison, Kmax and keratometric astigmatism significantly decreased at 6 months postoperatively and remained significantly decreased at 2 years postoperatively ($p < 0.05$). After *post-hoc* paired comparison, Kmean also significantly decreased at 2 years postoperatively ($p < 0.03$). The median Q value of the anterior cornea changed significantly toward prolateness after surgery ($p = 0.01$). At the last visit, Q value changed from -0.83 to -0.04. After *post-hoc* paired comparison, Q value changed significantly toward prolateness after 1 month postoperatively ($p = 0.01$).

DISCUSSION

To investigate the outcome of ICRS implantation in keratoconus in Thai patients, a two-year retrospective review in 9 eyes was conducted. The result showed that the median visual acuity significantly improved after surgery ($p \leq 0.007$). At the last follow up, the median UCVA improved from 1.00 logMAR to 0.56 logMAR, and the CDVA improved from 0.76 logMAR to 0.10 logMAR, which represented approximately 0.40 logMAR change or 4 lines gain of the vision and considered to be clinically significant. Among publications with the same Ferrara type ICRS and similar follow-up time of 6 months to 2 years, the improvement of CDVA in this study was comparable with others which reported the mean improvement ranged from 0.14 logMAR to 0.40 logMAR.³⁻⁷

Consistent with the visual outcome, the refractive outcome was significantly improved postoperatively in terms of the spherical equivalent ($p < 0.001$). At the last follow up, the median spherical equivalent improved from -7.38 D to -3.13 D. The change of 4.25 D in this study

TABLE 1. Visual acuity and manifest refraction before and after intrastromal corneal ring implantation.

| | Examination | | | | | |
|------------------------|---------------|----------------|--------------|--------------|--------------|---------------------------|
| | Pre-operative | Post-operative | | | | |
| Parameter | | 1 month | 6 months | 1 year | 2 years | P value |
| UCVA (logMAR) | | | | | | |
| Median | 1.00 | 0.50 | 0.50 | 0.70 | 0.56 | 0.007 ^{*,d} |
| Interquartile range | 0.60, 1.30 | 0.40, 1.00 | 0.30, 0.90 | 0.20, 0.90 | 0.20, 0.90 | |
| CDVA (logMAR) | | | | | | |
| Median | 0.76 | 0.30 | 0.20 | 0.10 | 0.10 | 0.001 ^{*,c,d} |
| Interquartile range | 0.30, 0.80 | 0.10, 0.70 | 0.10, 0.70 | 0.00, 0.56 | 0.00, 0.48 | |
| Spherical equivalent | | | | | | |
| Median | -7.38 | -6.38 | -3.13 | -5.13 | -3.13 | <0.001 ^{*,b,c,d} |
| Interquartile range | -14.13,-4.88 | -15.63,-1.75 | -10.00, 1.00 | -9.13, 0.75 | -7.63, 0.50 | |
| Refractive astigmatism | | | | | | |
| Median | -8.75 | -3.50 | -2.75 | -1.50 | -2.25 | 0.052 |
| Interquartile range | -11.00, -7.50 | -7.75, -2.00 | -4.00, -2.25 | -3.50, -1.25 | -4.75, -1.25 | |

*statistically significant by non-parametric Friedman test, ^bstatistically significant with a post-hoc paired comparison using Dunn-Bonferroni test between preoperative examination and postoperative examination at 6 months (p value = 0.013), ^cstatistically significant with a post-hoc paired comparison using Dunn-Bonferroni test between preoperative examination and postoperative examination at 1 year (p value ≤ 0.01), ^dstatistically significant with a post-hoc paired comparison using Dunn-Bonferroni test between preoperative examination and postoperative examination at 2 years (p value <0.02)

TABLE 2. Anterior corneal topographic data before and after intrastromal corneal ring implantation.

| | | Examination | | | | |
|---------------------|--------------|---------------|----------------|--------------|--------------|--------------------------|
| | | Pre-operative | Post-operative | | | |
| Parameter | | 1 month | 6 months | 1 year | 2 years | P value |
| Kmax | | | | | | |
| Median | 52.65 | 47.20 | 46.80 | 46.50 | 46.65 | 0.005 ^{*,b,d} |
| Interquartile range | 50.93, 59.20 | 44.20, 53.53 | 42.45, 52.60 | 44.28, 52.45 | 44.05, 52.20 | |
| Kmean | | | | | | |
| Median | 48.10 | 45.45 | 45.75 | 45.55 | 45.40 | 0.014 ^{*,d} |
| Interquartile range | 47.78, 56.03 | 42.10, 51.55 | 43.50, 50.60 | 43.90, 50.40 | 43.83, 50.55 | |
| Kastigmatism | | | | | | |
| Median | 6.70 | 2.35 | 2.20 | 1.45 | 1.40 | 0.005 ^{*,b,c,d} |
| Interquartile range | 5.25, 8.30 | 1.58, 7.20 | 0.48, 3.75 | 0.73, 2.83 | 0.55, 3.23 | |
| Q value | | | | | | |
| Median | -0.83 | 0.41 | 0.02 | -0.03 | -0.04 | 0.01 ^{*,a,b} |
| Interquartile range | -1.56, -0.46 | -0.96, 0.71 | -0.80, 0.55 | -0.80, 0.49 | -0.81, 0.51 | |

* statistically significant by non-parametric Friedman test, ^a statistically significant with a post-hoc paired comparison using Dunn-Bonferroni test between preoperative examination and postoperative examination at 1 month (p value=0.01), ^b statistically significant with a post-hoc paired comparison using Dunn-Bonferroni test between preoperative examination and postoperative examination at 6 months (p value<0.05), ^c statistically significant with a post-hoc paired comparison using Dunn-Bonferroni test between preoperative examination and postoperative examination at 1 year (p value<0.05), ^d statistically significant with a post-hoc paired comparison using Dunn-Bonferroni test between preoperative examination and postoperative examination at 2 years (p value<0.03)

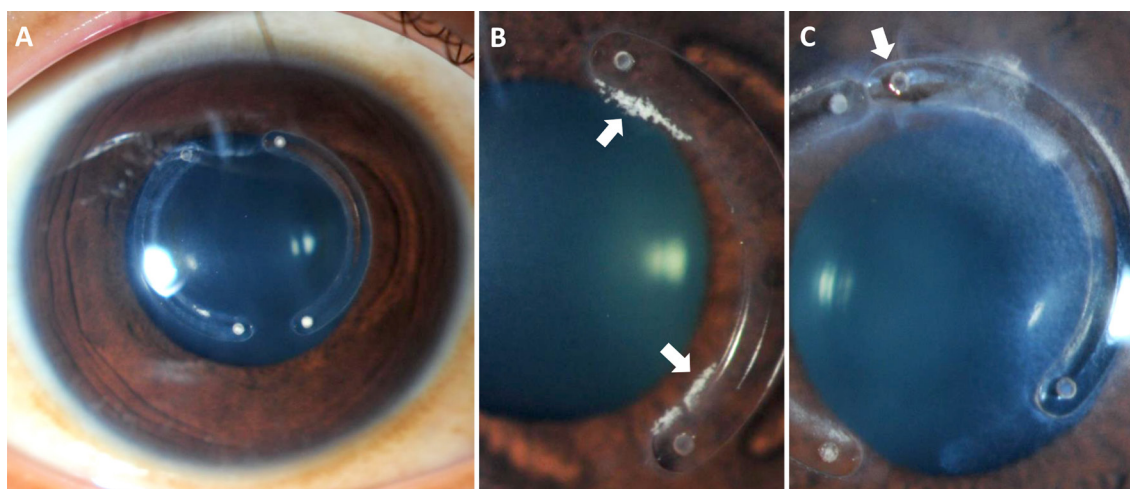


Fig 1. Representative pictures of postoperative intrastromal corneal ring segment implantation. (A) Successful two-segment typed surgery. (B) Small white deposits around the rings (arrows). (C) A complicated case with one segment extrusion (arrow).

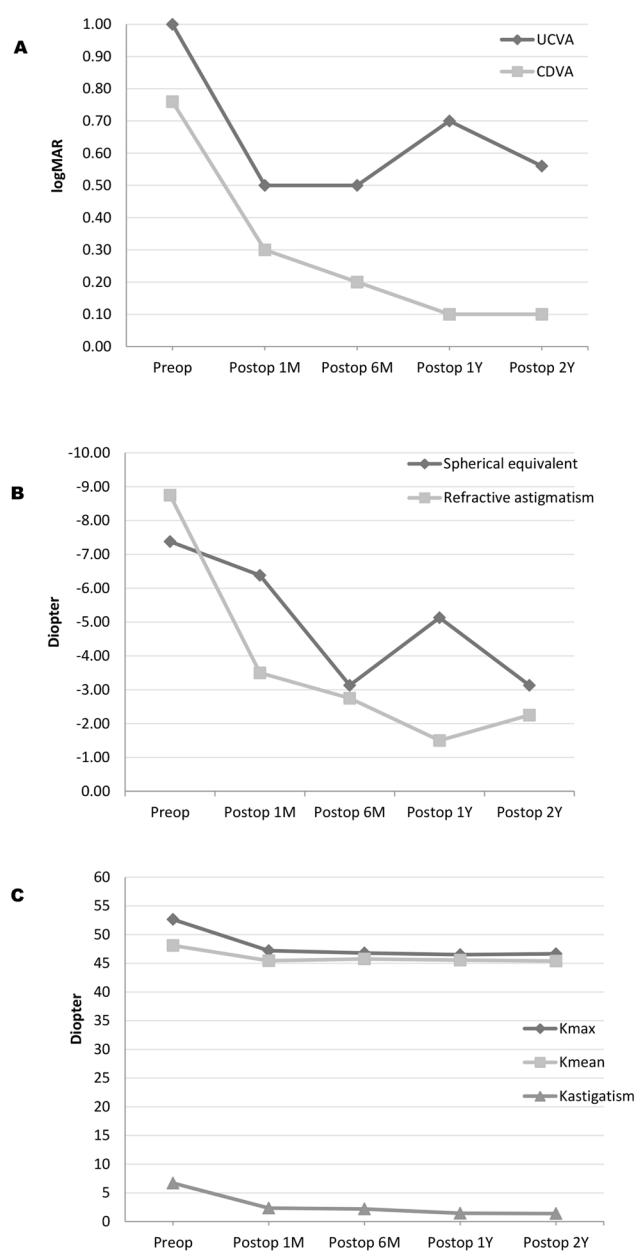


Fig 2. Comparison of (A) visual acuity, (B) refraction, and (C) keratometry between visits.

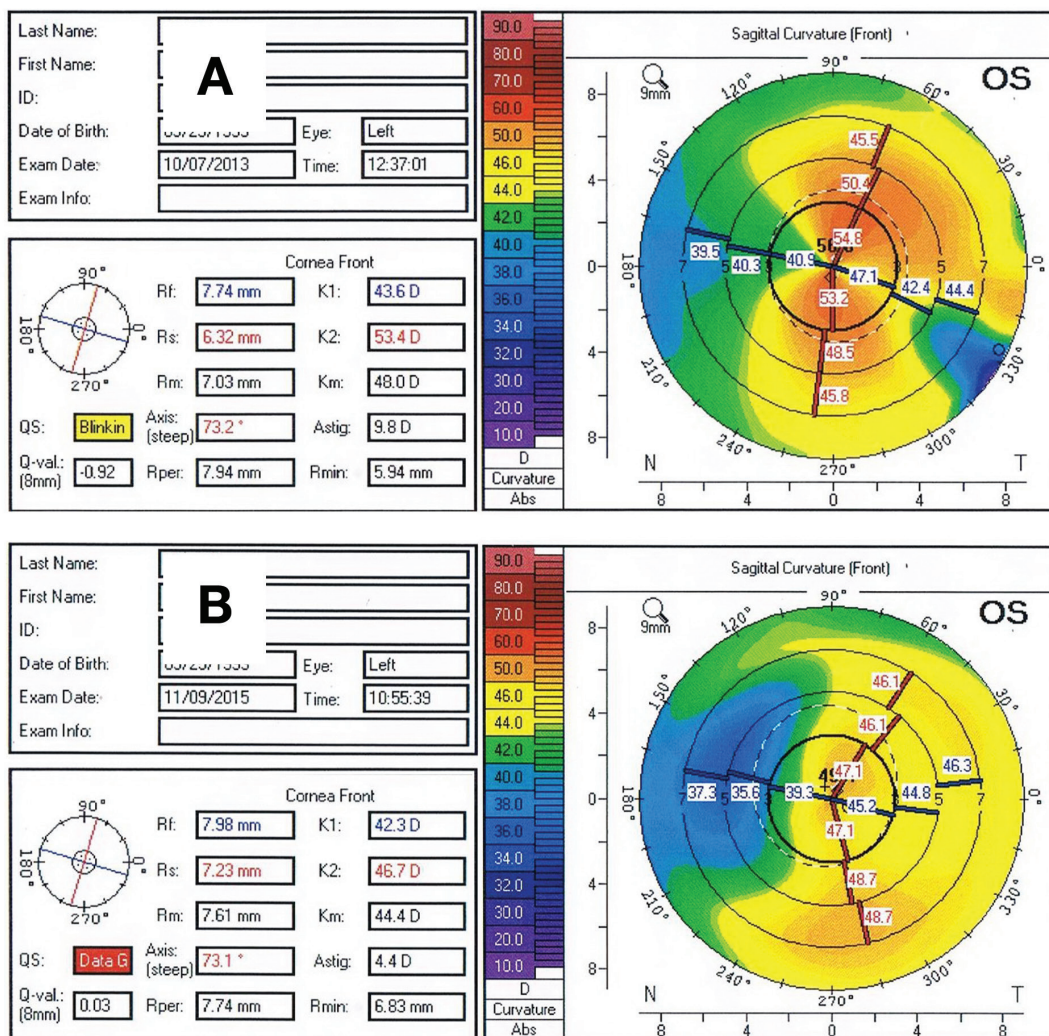


Fig 3. Representative topographic findings (A) before and (B) 2 years after intrastromal corneal ring implantation. The curvature maps showed flattening effect on the central cornea after the surgery. The parameters of the anterior cornea appeared on the left column were recorded.

was comparable with previous studies which reported the change ranged from 3.36 D to 5.8 D.³⁻⁷

Because anterior corneal shape is the most important parameter to determine corneal deformation after ICRS implantation⁹, anterior corneal topographic outcomes were evaluated. There was significant change of keratometry between visits. At the last visit, the median decrease of Kmax was 6.00 D and the median decrease of Kmean was 2.70 D. The results were comparable with a previous report by Ferrara et al⁷ that showed the Kmax change of 5.19 D and the Kmean change of 4.64 D postoperatively. Moreover, other reports of the Ferrara type with 6 months to 2 years follow up found the changes of the Kmean between 0.09 D to 3.82 D.^{5,6,10} Considering the other commonly used Intacs type, the changes of the Kmean were 1.94 D to 7.87 D.¹⁰⁻¹⁶

Besides corneal flattening and improving visual acuity, another goal of the treatment in keratoconus is to improve

quality of vision. Corneal asphericity was reported to increase in keratoconus and was proportional to the severity (grading) of the disease.¹⁷ In this study, after the surgery, the median anterior Q value showed significant change between follow-up visits ($p = 0.01$). The preoperative Q value was -0.83, which demonstrated excessive prolateness of the cornea. Then cornea changed towards an oblate cornea for a while at early postoperative 1 month (Q value 0.41). However, after 6 month postoperatively, the Q value changed toward minimal prolateness of the cornea which was from -0.03 to -0.04 at the last visit. Similar to this study, Torquetti et al reported that the Ferrara ICRS significantly reduced the Q value from -0.85 to -0.32 at their 16-month follow up.¹⁸ To illustrate, the anterior corneal asphericity reduced after ICRS implantation to be more similar to the normal physiologic cornea in which the most commonly accepted value in a young adult population is approximately -0.23 ± 0.08 .¹⁸

Considering comparison of the outcomes between visits, we noted that the major parameters including Kmax, keratometric astigmatism, and spherical equivalent refraction were at their significant outcome or relatively highest effect at 6 months ($p < 0.05$), then the outcomes were still stable with no regression at 2 years ($p < 0.03$). This stability was consistent with the previous publications with the long-term follow up.^{19,20} Torquetti et al showed the good stability of the outcome with the Kmax significantly decreased of 4.41 D at 5 years and later with no regression at 10 years, consistently, and the Kmean with significantly decreased of 3.13 D at 5 years with no regression at 10 years after surgery.²⁰ In contrast, Vega-Estrada et al reported that the K reduction was observed only at 6 month after surgery, then after 6 months there was a regression of Kmax for 3.31 D at 1 year and 3.14 D at 5 years, and a regression of Kmean for 3.14 D at 1 year and 3.36 D at 5 years.²¹

Postoperative adverse effects of glare and halos occurred in 3 eyes. These symptoms were also reported in other studies.^{22,23} However, none of them requested that their implants to be removed. Small white intrastromal corneal deposits around the segments were found in 2 eyes. This was reported to be frequently found (about 70%) and not resulted in alteration of visual performance.²⁴ Ly et al elucidated that the mechanical and physiologic stresses introduced by the implantation lead to the accumulation of lipid deposits in the extracellular matrix of the cornea.²⁵

One case of extruded ICRS, which needed removal, was reported. However, her visual acuity and refractive status could return to preoperative baseline in months. This reversible status was also reported in other studies.²⁶⁻²⁸ In fact, this is an advantage of the surgery that the rings are removable if complicated or poorly tolerated.²⁹ Ferrara et al suggested that this complication could be minimized after mastering the surgical technique, especially in the deep incision and the well-constructed intrastromal tunnel.⁵

This study has some mentionable limitations. One was the retrospective study design. A second limitation was the small sample size. Prevalence of keratoconus varies in different parts of the world, but may be relatively rare in Thailand (no prevalence study in Thai people). Moreover, only some of the patients were eligible for the benefit of ICRS. The strength of this study is that, ICRS implantation has been one of the internationally approved treatment options for keratoconus and its outcomes were firstly reported in Thai patients. Further study could include larger and wider range of patients with keratoconus such as various preoperative grading

and progression. Moreover, the combined treatment of ICRS implantation with the other novel treatment of corneal collagen crosslinking for keratoconus could be another aspect to study.

In conclusion, this initial report in Thai patients with keratoconus showed that the ICRS implantation significantly improved the visual, refractive, and topographic outcomes during the 2-year follow up. The evidence seemed to show that with the appropriate case selection and surgical technique, the ICRS implantation was considered to be an effective and safe procedure in most cases.

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