

## Original Research Article

DOI: <http://dx.doi.org/10.18203/2349-2902.ijssurgery20191265>

# Safety and effectiveness of intrastromal corneal ring segment implantation at Al-Dharan Eye Specialist Hospital, Al-Dharan, Saudi Arabia

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Received: 22 January 2019

Accepted: 28 February 2019

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## ABSTRACT

**Background:** Intrastromal corneal ring segment (ICRS) implantation is one of the treatment options of keratoconus. This study is aiming to evaluate safety and effectiveness of ICRS implantation at Al-Dharan Eye Specialist Hospital.

**Methods:** This study is a descriptive retrospective case series study. The target population of this study is patients diagnosed with corneal ectasia who underwent ICRS implantation in Al-Dharan Eye Specialist Hospital, Al-Dharan, Saudi Arabia. Preoperative and postoperative data about uncorrected visual acuity (UCVA), best spectacle-corrected visual acuity (BSCVA), manifest refraction, keratometry, applanation tonometry, corneal topography, and slit-lamp biomicroscopy and indirect ophthalmoscopy were retrieved from medical records of department of Medical Archive. Paired students t-test was used to compare preoperative and postoperative means of study variables.

**Results:** The total number of recruited patients in this study was 57 patients where 62% of them were males. Sixty-six treated eyes were included in this study where no intra-operative complications were recorded. Upon comparing the mean preoperative data to the mean postoperative data at three months, six months and one year intervals, an overall improvement in the measured outcomes was witnessed. UCVA, BSCVA, and keratometric readings exhibited a statistically significant improvement when comparing preoperative with one-year postoperative findings ( $p<0.001$ ).

**Conclusions:** The findings of this study indicate that ICRS implantation is a safe and effective treatment for keratoconus.

**Keywords:** Safety, Effectiveness, Intrastromal corneal ring segment, Keratoconus

## INTRODUCTION

Keratoconus is a bilateral, non-inflammatory corneal ectasia characterized by a proceeding corneal thinning and progressive loss of visual acuity. Progressive deterioration of visual acuity caused by this condition cannot be compensated for using spectacles.<sup>1</sup> Keratoconus is mostly an isolated disease. However, association with other genetically induced disorders has been reported.<sup>2</sup>

Keratoconus affects individuals who belong to different age groups, genders and ethnicities. However, prevalence of the disease has been suggested to be influenced by several factors. A review by Gokhale indicated a difference in the prevalence of the disease depending on geographical, environmental, and diagnostic variations.<sup>3</sup> Severe presentation of the disease has been reported during the second decade of age.<sup>4</sup> The incidence of keratoconus was reported to be higher in south Asian populations (1 in 4000) compared to white Europeans (1

in 30000).<sup>5</sup> Similarly, south Asians were reported to have earlier presentation of the disease compared to Europeans.<sup>6</sup>

An epidemiological evidence of prevalence of keratoconus in Saudi Arabia is lacking. However, a study investigated incidence and severity indicator of the disease in Assir Province in Saudi Arabia. This study reported that incidence of the disease is 1 in 5000 which is similar to South Asians incidence. Additionally, the mean age of cases presented with advanced stage of the condition in the study's population was 17.7 (SD: 3.6).<sup>7</sup>

A 20-year period retrospective review of Eye Bank records of King Khalid Eye Specialist Hospital in Riyadh, Saudi Arabia was conducted to identify indicators of corneal transplants. Between 1983 and 1988, keratoconus was an indication for corneal transplant for only 7.6% of cases. However, between 1997 and 2002, keratoconus became the leading indicator for coreanal transplant (40.2%).<sup>8</sup>

Treatment of the disease varies between use of spectacles or contact lens, penetrating keratoplasty, and intracorneal ring segments. However, use of spectacles or contact lens can be beneficial in early stages of the disease and subsequent deterioration of the disease is associated with contact lens intolerance.<sup>9</sup> Contact lens intolerance is augmented by weather conditions where dry and hot climates are associated with high risk of vernal keratoconjunctivitis. This is likely to reduce the effectiveness of using contact lens to treat keratoconus in Saudi Arabia.<sup>8</sup>

Most recently, several management options became available for keratoconus including collagen crosslinking (CXL), topography guided ablation, intrastromal corneal ring segment (ICRS) implantation and keratoplasty. Performing less invasive surgical interventions such as ICRS is favoured to minimize the occurrence of post-operative complications that are likely to occur with invasive techniques such as keratoplasty.<sup>10,11</sup> Since 2012, ICRS implantation has been introduced in Al-Dharan Eye Specialist Hospital to treat keratoconus patients. This study is aiming to evaluate safety and effectivness of ICRS implantation at Al-Dharan Eye Specialist Hospital through measurement of complications incidence and comparison between pre-operative and post-operative levels of visual acuity, keratometric readings and refractive error.

## METHODS

This study is a descriptive retrospective case series study. The target population of this study is patients diagnosed with corneal ectasia who underwent ICRS implantation in Al-Dharan Eye Specialist Hospital, Al-Dharan, Saudi Arabia between January 2012 and December 2014. Ethical approval to conduct this study was granted by the ethics committee at Al-Dharan Eye Specialist Hospital.

The inclusion criteria of this study were restricted to patients who had a record of diagnosis of corneal ectasia, underwent ICRS implantation and availability of their follow up records. Keratoconus diagnosis was based on evaluation of treating physicians concerning presenting clinical signs, refractive error and corneal topographic finding using Pentacam (Oculus Optikgera" te GmbH, Wetzlar, Germany). A description of criteria used to diagnose keratoconus is explained in a literature review by Romero-Jimenez et al.<sup>1</sup>

Data were retrieved from medical records of department of Medical Archive. Data about uncorrected visual acuity (UCVA), best spectacle-corrected visual acuity (BSCVA), manifest refraction, keratometry, applanation tonometry, corneal topography, and slit-lamp biomicroscopy and indirect ophthalmoscopy were recorded pre-operatively through ophthalmic examination

### Surgical procedure

Intracorneal ring segment implantations were performed by five surgeons using topical anesthesia (oxybupracaine hydrochloride 0.4%) and the same surgical technique. Surgeries were performed in same location in the hospital. Standard prepping and draping were performed and the procedures were performed under the surgical microscope. The tunnels were created using the femtosecond laser (Abbott Medical Optics Inc, Santa Ana, California). The femtosecond laser parameters were as follows: Energy= 1.7  $\mu$ J, Depthh from 80 to 90% of cornea. The docking ring of the laser was centered on the cornea and suction applied. The patient was positioned under the laser, and the docking cone was lowered and positioned on the cornea for applanation. The laser was activated, and a 360°, 80 to 90% depth of channel, with the incision at the steep topographic axis was created. Suction was released, and the cone, docking ring, and speculum were removed from the eye. The patient was moved to the surgical microscope where the ring segments were inserted. Two types of corneal rings was used KeraRings (Mediphacos, Belo Horizonte, Brazil), Intacs (Addition Technology Inc, Des Moines, Illinois) depending on physician preference. Prednisolone acetate 1.0% drops and moxifloxacin hydrochloride 0.5% drops were administered and continued for four times a day each for the following 14 days. Steroid drops were then tapered gradually over the following 14 days.

### Follow up

A complete follow up examinations were performed for all patients where uncorrected visual acuity (UCVA), best spectacle-corrected visual acuity (BSCVA), manifest refraction, keratometry, applanation tonometry, corneal topography, and slit-lamp biomicroscopy and indirect ophthalmoscopy were recorded. Patients were followed up over 1-month, 3-month, 6-month, and one year intervals.

### Statistical analysis

Data analysis was performed by IBM SPSS software version 22 (IBM Corp, Armonk, NY, USA). Frequencies and proportions were utilized to summarize categorical variables. Means and standard deviations (SD) and range were used to summarize continuous variables. Paired students t-test was used to compare preoperative and postoperative means of study variables. A p value of 0.05 or less was designated as statistically significant for applied statistical tests.

### RESULTS

Table 1 illustrates characteristics of patients recruited in this study. The total number of recruited patients in this study was 57 patients where 62% of them were males. Sixty-six treated eyes were included in this study where no intra-operative complications were recorded.

**Table 1: Characteristics of recruited patients operated for keratoconus at Al-Dharaan Eye Specialist Hospital between 2012 and 2014.**

<b>Number of patients</b>	57
<b>Number of eyes</b>	66
<b>Gender N (%)</b>	Males: 41 (62.1) Females: 25 (37.9)
<b>Eyes N (%)</b>	Right eyes: 36 (54.5) Left eyes: 30 (45.5)
<b>Age</b>	Mean (SD): 30.79 (7.8) Age range: 18-58 years

**Table 2: Mean preoperative visual data of (n=57).**

<b>Visual data</b>	<b>Mean</b>	<b>SD</b>	<b>Range</b>
<b>UCVA</b>	0.21	0.16	0.05 to 0.71
<b>BSCVA</b>	0.43	0.21	0.05 to 0.9
<b>K2</b>	52.82	4.56	42.7 to 63.3
<b>K1</b>	47.76	3.65	41.6 to 55.7
<b>Sphere</b>	-3.1	3.17	-15 to 1.5
<b>Cylinder</b>	-3.81	1.8	-9 to 0.0
<b>Spherical equivalent</b>	-4.95	3.26	-13.75 to 0.0
<b>Thinnest location</b>	437.1	33.1	377 to 520

Mean preoperative data are summarized in Table 2. Upon comparing the mean preoperative data to the mean postoperative data at three months, six months and one year intervals, an overall improvement in the measured outcomes was witnessed (Table 3). UCVA and BSCVA exhibited a statistically significant incremental improvement where the mean UCVA was 0.21 preoperatively compared with 0.36 after one year. Similarly, mean BSCVA improved from 0.43 preoperatively to 0.56 after one year. Intra ocular pressure readings were within normal range preoperatively and postoperatively for all patients.

Vertical (K2) and horizontal (K1) diaopter readings shows a reduction in the diaopter when comparing mean preoperative readings to mean postoperative data. However, the magnitude of the reduction is not consistent when comparing data of three months, six months and one year intervals. This can be mostly explained by variation in number of patients who had their keratometric readings recorded during their follow up sessions. The number of patients whom had their keratometrics reading recorded was smaller than those who had their UCVA and BSCVA readings recorded.

Sphere readings showed a statistically significant but limited improvement when comparing preoperative data to three-month postoperative data and also showed marginal statistical significance ( $p=0.089$ ) when compared to one-year postoperative data. Similarly, cylinder readings witnessed a statistically significant but minimal improvement when comparing preoperative data to three-month and one-year postoperative data but not when compared to six-month postoperative data. Additionally, spherical equivalent improvement during the three-month follow up session was statistically significant but marginal in the 6-month and 1-year follow up sessions. This variation in the effects could be due to the variation in number of eyes measured for sphere and cylinder at each follow up session. Unlike most of the recorded variables, the thinnest location did not exhibit any improvement postoperatively and its mean value is similar to the preoperative mean value.

Although the study findings indicate a statistically significant improvement observed on several variables, several patients required further interventions. Among the recorded 57 patients, 5 required further deep lamellar keratoplasty, 1 patient required penetrating keratoplasty, 1 patient required intracollamal lens implantation and 2 patients suffered ring segment migration and had their rings removed. Additionally, 3 patients reported night vision impairment postoperatively who had not suffered from the condition preoperatively.

To investigate the possibility of differences in patients' characteristics among those who required further interventions after the ICRS implantation, we performed a sensitivity analysis to assess any deviations in the findings (Table 4). Changes in the associations of the study were observed when the study sample was reduced to those who did not require further interventions. Most of the study findings remained similar to the findings observed in Table 3. However, several associations that were statistically significant became non-significant due to sample size reduction. Nonetheless, a slight increase in the mean UCVA and mean BSCVA during three-month, six-month and one-year intervals occurred. This sensitivity analysis indicates that those omitted cases were less likely to witness improvement of the UCVA and BSCVA after the ICRS implantation in comparison to those who did not require further interventions.

**Table 3: Comparison between preoperative visual, refractive, and keratometric outcomes.**

Variables	3 months			6 months			1 year		
	No. of eyes	Mean (SD)	P value	No. of eyes	Mean (SD)	P value	No. of eyes	Mean (SD)	P value
<b>UCVA</b>	61	0.32 (0.17)	0.000000	62	0.31 (0.18)	0.000008	57	0.36 (0.2)	0.000000
<b>BSCVA</b>	60	0.53 (0.2)	0.000000	62	0.52 (0.21)	0.000302	57	0.56 (0.21)	0.000000
<b>K2</b>	36	48.6 (3.6)	0.000000	31	50.96 (4.52)	0.000001	41	49.3 (3.53)	0.000000
<b>K1</b>	36	45.18 (3.38)	0.000000	31	46.32 (3.4)	0.001	41	46.1 (2.86)	0.003
<b>Sphere</b>	42	-2.14 (3.03)	0.01	40	-2.17 (3.08)	0.214	46	-2.51 (3.27)	0.089
<b>Cylinder</b>	40	-1.91 (2.16)	0.000236	35	-3.14 (1.91)	0.143122	43	-3.36 (1.13)	0.03
<b>Spherical equivalent</b>	37	-3.8 (3.12)	0.000009	34	-3.60 (2.43)	0.067	42	-4.15 (2.98)	0.068
<b>Thinnest location</b>	36	440 (36.8)	0.498454	31	430 (34.2)	0.247	40	433.8 (34.6)	0.309

**Table 4: Comparison between preoperative data and 3 months, 6 months and 1 year postoperative data.**

Variables	3 months			6 months			1 year		
	No. of eyes	Mean (SD)	P value	No. of eyes	Mean (SD)	P value	No. of eyes	Mean (SD)	P value
<b>UCVA</b>	51	0.32 (0.17)	0.000000	52	0.32 (2.18)	0.000000	49	0.38 (0.19)	0.000000
<b>BSCVA</b>	50	0.54 (0.2)	0.007	52	0.53 (0.19)	0.001	49	0.57 (0.2)	0.000000
<b>K2</b>	28	48.61 (3.9)	0.000000	27	51.15 (4.6)	0.000000	34	49.35 (3.6)	0.000000
<b>K1</b>	28	45.18 (3.6)	0.000000	27	46.27 (3.4)	0.003	34	46.15 (3)	0.008
<b>Sphere</b>	35	-2.26 (2.9)	0.071	34	-2.39 (3.2)	0.301	39	-2.83 (3.3)	0.142
<b>Cylinder</b>	33	-2 (2.14)	0.001	30	-3.32 (1.2)	0.185	35	-3.4 (1.07)	0.077
<b>Spherical equivalent</b>	29	-5.15 (3)	0.032	29	-3.61 (2.5)	0.076	34	-4.33 (3.1)	0.102
<b>Thinnest location</b>	28	443 (31.7)	0.611	27	432 (36.9)	0.237	33	435 (36)	0.090

## DISCUSSION

This study is a retrospective case series study where a total of 66 treated eyes (of 57 patients) were included. Patients had their variables measured preoperatively and postoperatively at three intervals, whereby the findings indicated improvement of surgical outcomes after ICRS implantation. Most of the improvements were related to UCVA, BSCVA and keratometric readings. Other variables related to sphere, cylinder refractive errors and spherical equivalent showed slight clinical improvement but did not reach statistical significance. The thinnest location did not exhibit clinically important changes when comparing preoperative to postoperative values.

An absence of intra-operative complications reported in this study is consistent with the findings of other studies.<sup>12-14</sup> Additionally, this study did not detect incidence of any postoperative infections. The less invasive nature of ICRS implantation minimised the incidence of postoperative infection is seen in comparison with more invasive interventions such as penetrating keratoplasty.<sup>15</sup>

Several prospective and retrospective case series indicated similar pattern of improvement in visual acuity, keratometric readings and spherical, cylindrical refractions.<sup>16-21</sup> In general, the findings of the current study are consistent with those findings where a statistically significant improvement is detected when comparing between preoperative and postoperative variables. However, the study by Gharaibeh et al reported that statistically significant improvement is likely to occur during the first three months postoperatively where the improvement is sustainable but not incremental when comparing six-month postoperative findings to those at the three-month postoperative interval.<sup>21</sup> The findings of our study do support the statement made by Gharaibeh et al, as it was witnessed that there is no difference in the means of the current study variables when comparing six-month postoperative findings to those at the three-month postoperative interval. However, there is a noticeable improvement in the UCVA, BSCVA and keramometric readings of the current study when comparing one-year postoperative findings to three-month postoperative ones. This notion is further augmented by another study where an incremental improvement was not only limited to the first three-month postoperative period.<sup>22</sup>

Out of the 57 patients recruited in this study 9 required further interventions after their ICRS implantation. The overall success rate in the current study was 85%. The study by Hellstedt et al reported a success rate of 92% where 4 cases had their rings removed and 7 required further refractive adjustments after the ICRS implantation to improve visual and surgical outcomes.<sup>23</sup> Similarly, a study by Coskunseven et al indicated that 3 treated eyes (6%) suffered segment migration and further positioning was required.<sup>20</sup>

Most of the studies performed to measure the efficacy and safety of ICRS implantation reported an overall improvement in visual and surgical outcomes. However, methodological variations existing between studies do have an effect on the magnitudes of statistical improvement. For example, our study included subjects who required further interventions after ICRS implantation whereas other studies excluded those who had postoperative complications.<sup>21</sup>

The findings of the current study have several clinical and research implications. Given the limited effect of spectacles and contact lenses in treating keratoconus, due to reasons related to disease nature and environmental characteristics in Saudi Arabia, and due to postoperative complications induced by other surgical options, ICRS implantation appears to be a suitable, safe, and effective treatment for patients with keratoconus. There were no intraoperative complications reported in this study. However, several patients did not benefit from the procedure and required further interventions. This mandates the importance of setting more strict criteria indicating patients who are suitable for ICRS implantation and to avoid subjecting patients to further surgical interventions. Furthermore, 3 patients reported night vision impairment after the procedure but the reasons for this impairment remains unclear and require further investigation.

This study has multiple areas of strengths and limitations. The strengthening points are mostly related to the clinical and surgical implications of evaluating the effectiveness and safety of ICRS implantation at the Al-Dharan Eye Specialist Hospital and the length of the follow up period. The inherited limitations of this study are mainly related to its retrospective nature and its heavy dependence on the quality of medical records. Although patient follow up ranged from 85-92% throughout the study intervals, the measurements of several study variables were not recorded for many patients. For example, keratometric readings were only recorded for half of those who attended the follow up sessions at six-month intervals.

## CONCLUSION

This study indicates that ICRS implantation is a safe and effective treatment for keratoconus. No intrapreoperative complications were recorded. Improvement of visual

acuity and keratometric readings were clinically and statistically significant.

*Funding: No funding sources*

*Conflict of interest: None declared*

*Ethical approval: The study was approved by the Institutional Ethics Committee*

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**Cite this article as:** Alaqsam A, AL-Jindan M, Almahmod A, Gosadi I. Safety and effectiveness of intrastromal corneal ring segment implantation at Al-Dharan Eye Specialist Hospital, Al-Dharan, Saudi Arabia. *Int Surg J* 2019;6:1295-300.