Outcome of Keraring Intrastromal Corneal Ring Segment Implantation for the Management of Keratoconus

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Abstract

Objective: To report the outcome of Keraring intrastromal corneal ring segment implantation using mechanical tunnel creation method for the management of keratoconus.

Patients and Methods: This study was conducted during the period from July 2009 to November 2011 at Dhahran Eye Specialist Hospital, Dhahran, Saudi Arabia. It included 38 patients (40 eyes) with keratoconus who underwent Keraring implantation using mechanical method for tunnel creation. Patients who had intraoperative or postoperative complications and/or did not complete at least 6 months of follow-up were excluded. All patients underwent complete ophthalmologic examinations that included measurement of the Uncorrected Visual Acuity (UCVA), Best Corrected Visual Acuity (BCVA), and keratometry before and 1 day, 1 week, 1 month, and 6 months after surgery. The ring segments were chosen based on a nomogram from the manufacturer.

Results: The mean UCVA significantly improve from 0.9 LogMAR (20/160) to 0.5 LogMAR (20/60) (p <0.001). The BCVA significantly improved on first postoperative day and remained stable until 6 months follow-up (p<0.001). The decrease in mean keratometry readings and astigmatism postoperatively was statistically significantly (p<0.001).

Conclusions: In the short term, intrastromal implantation of Kerarings significantly increases UCVA and BCVA in patients with keratoconus and significantly decreases keratometric values and astigmatism.

Key Words: Intrastromal corneal ring segment – Keratoconous – Keraring.

Introduction

KERATOCONUS is a noninflammatory condition, characterized by progressive corneal thinning and protrusion leading to conical shape of the cornea with irregular astigmatism resulted in decreased vision [1,2].

The management of patients with keratoconus in early stage is by spectacles, whereas in moderate cases is by contact lenses [3]. In advanced cases, where there is intolerance to contact lenses and central corneal opacities, penetrating keratoplasty is necessary to achieve a satisfactory visual outcome [4].

Intrastromal Corneal Ring Segment (ICRS) implantation has been recently used for correcting keratoconus by changing the morphological characteristics and flattens the central cornea [5]. It is a reversible procedure with reversal of refractive, visual, and corneal topographic changes to near preoperative levels [6]. The aim of ICRS implantation is to delay keratoconous progression and postpone the need for penetrating keratoplasty in keratoconous patients [7,8].

The objective of this study is to evaluate the effect of keraring implantation in keratoconous patients.

Patients and Methods

A retrospective chart review was performed for 76 patients (83 eyes) who underwent ICRS implantation of Kerarings using mechanical method for tunnel creation during July 2009 to November 2011 in Dhahran Eye Specialist Hospital. One or two ICRS were inserted in the cornea, embracing the keratoconus area. The mean age of patients was 29±7.3 years (range 21 to 40 years).

A total of 38 patients (40 eyes) were included in the study, while 28 patients (33 eyes) were excluded because they had incomplete data or missed their follow-up and 10 patient (10 eyes) were excluded due to postoperative complications (4 eyes had extrusion, 2 had severe glare, 1 had superficial ring required reinsertion, 1 had vascularization and melting, 1 had very large pupil, and 1 had broken segment).
It is to be noted that, we had to exclude all patients with complications since the primary objective of this study was to assess the effect of Keraring intrastromal corneal ring segment implantation on the vision of our keratoconus patients. In case of complications, the Keraring will have to be removed and therefore, the follow-up of complicated patients will be interrupted.

Patients' characteristics are shown in (Table 1). Enrolled patients included keratoconic eyes which had a corneal thickness greater than 400µm at the planned site of ICRS implantation, contact lens intolerance and clear central cornea.

Patients were excluded if any of the following criteria applied: Hydrops, thin cornea less than 400µm at incision site, significant corneal opacity and local infection.

Preoperative and postoperative evaluation included uncorrected (UCVA) and corrected (BCVA) visual acuities, keratometry reading and topographic astigmatism. Corneal topography was obtained by pentacam devices. Postoperative visits were at 1, 7, and 30 days and 6 months. All surgeries were done by the same surgeon (the researcher).

**Surgical technique:**
A Keraring of 5mm optical zone was used with arc length of 160 degrees with variable thickness from 150 to 350µm according to manufacture nomogram. After aseptic technique and topical anesthesia, the central corneal reflex was marked by Sinskey hook, radial incisions were made on the steep corneal meridian based on preoperative corneal topography using diamond knife set at 80% depth of the thinnest corneal thickness in the tunnel. Intrastromal pockets were made using a spreader. Stromal tunnels were created manually by appropriate curve spatula and one or two ring segments were implanted in these tunnels according to preoperative corneal topography and manufacture nomogram.

**Postoperative care:**
After ICRS implantation, a bandage contact lens was used. Topical antibiotics and steroids were used until corneal re-epithelialization at the surgical site was complete. The outcomes were evaluated at 1, 7, and 30 days and 6 months postoperatively.

**Statistical analysis:**
Using the Statistical Package for Social Sciences (SPSS) was used for data entry and statistical analysis. Differences between groups in continuous variables were tested using Student's t-tests. Results were presented as Mean ± SD. p-values less than 0.05 were considered as statistically significant.

**Study limitation:**
Patients included in this study have been operated upon at least 4 years ago. Currently, the operative procedures underwent much development as we currently use the femtosecond laser for tunnel creation of the ring instead of mechanical method followed in this study.

**Results**
A total of 40 eyes of 38 patients with keratoconus were evaluated. One segment was implanted in 6 eyes and 34 eyes received two segments. The mean UCVA significantly improve from 0.9 LogMAR (20/160) to 0.5 LogMAR (20/60) (p=0.001). Of these 40 eyes, the UCVA was decreased in 3 eyes, unchanged in 6 eyes and increased in 31 eyes (Fig. (1)).

BCVA significantly improved on the first postoperative day and remained stable until 6 months follow-up (p<0.001). The mean BCVA preoperatively and postoperatively at 1 day, 1 week, 1 and 6 months are shown in [(Table 2) and Fig. (2)].

The decrease in mean keratometry readings and topographic astigmatism postoperatively was statistically significantly (p<0.001). Preoperative and postoperative keratometry readings and astigmatism are shown in [(Table 3) and Figs. (3,4)].

<table>
<thead>
<tr>
<th>Table (1): Patients' characteristics.</th>
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<tbody>
<tr>
<td>Characteristics</td>
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<tr>
<td><strong>Gender:</strong></td>
</tr>
<tr>
<td>Male</td>
</tr>
<tr>
<td>Female</td>
</tr>
<tr>
<td><strong>No. of eyes:</strong></td>
</tr>
<tr>
<td>Right</td>
</tr>
<tr>
<td>Left</td>
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</table>

| Table (2): Preoperative and postoperative Best Corrected Visual Acuity (BCVA). |
|-------------------------------|----------------|----------------|
| Stage                        | Mean ± SD      | p-values*      |
| Preoperative BCVA            | 0.51±0.32 (20/60) |              |
| Postoperative BCVA:          |                |                |
| One day                      | 0.32±0.14 (20/40) | p<0.001       |
| One week                     | 0.33±0.21 (20/40) | p=0.005       |
| One month                    | 0.32±0.16 (20/40) | p=0.002       |
| Six months                   | 0.31±0.13 (20/40) | p<0.001       |

* Compared with preoperative BCVA values.
Discussion

The aim of ICRS implantation is to improve the visual acuity and to delay if not to prevent the need for keratoplasty. ICRS achieves this effect by reinforcement of the cornea by additive mechanism with improvement of visual acuity and decreasing of the corneal irregularity [8]. Zare et al., [9] reported that ICRS has a flattening effect more than forming a regular surface of the cornea.

In the present study, there were significant improvements in UCVA and BCVA. This finding is similar to that reported in previous studies [11,12].

The postoperative change in astigmatism was statistically significant. This finding is different from findings reported by Siganoetal [15]. And Ali´o et al., [16] which reported no statistically significant changes.

Implantation of ICRS does not always improve visual acuity. In the current study, 3 eyes had

Table (3): Preoperative and postoperative values of topographic astigmatism and K readings (Mean ± SD).

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Preoperative</th>
<th>Postoperative</th>
<th>p-value</th>
</tr>
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<tbody>
<tr>
<td>Astigmatism</td>
<td>4.92±2.27</td>
<td>3.48±2.31</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>K1</td>
<td>47.78±4.43</td>
<td>43.92±3.71</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>K2</td>
<td>52.70±4.32</td>
<td>47.33±4.07</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>K mean</td>
<td>50.33±4.25</td>
<td>45.49±3.77</td>
<td>&lt;0.001</td>
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decrease in UCVA and 6 eyes had no change in UCVA. However, all of them had improvement in their BCVA.

Complications were reported for intrastromal corneal ring segment implantation by mechanical spreaders, including epithelial defects, anterior or posterior corneal perforation with spreaders, superficial placement of the rings, segment movement, infectious keratitis from introduction of epithelial cells into the tunnel, and corneal stromal edema around the channel [13,14].

We excluded 10 eyes from the statistical analysis because of their postoperative complications. One patient had corneal melting, which is a rare complication of ICRS [9,10]. Another eye had superficial ring placement, which occurred in initial case and was the result of the surgeon’s learning curve. Four eyes had extrusion, one had broken segment and three patients complained of severe glare, one of them had very large pupil.

ICRS implantation has been shown to be safe with long-term stability of vision and topography [7,8,17,18].

In conclusion, in the short term, intrastromal implantation of Kerarings significantly improves UCVA and BCVA in patients with keratoconus and decreases keratometric values and significantly decreases astigmatism.

References


3- BARNETT M. and MANNIS M.J.: Contact lenses in the management of keratoconus; Cornea., 30 (12): 1510-6, 2011.


الملخص العربي

أُجريت هذه الدراسة خلال الفترة من يوليو 2009 وتحديداً في نوفمبر 2011، باستمتاع في الدراسة التخصصي للعين، مدينة الظهران، بالملكة العربية السعودية، وشملت 38 مريضاً (40 عينًا) يعانون من القرنية المخروطية، الذين خضعوا لزرع حلقات كيرارينغ باستخدام طريقة ميكانيكية بإنشاء نفق داخل القرنية لهذه الحالات. وقد استهدفت هذه الدراسة مستقبلية إلى أن يصبحون يعانون من القرنية المخروطية، الذين خضعوا لزرع حلقات كيرارينغ باستخدام طريقة ميكانيكية بإنشاء نفق داخل القرنية لهذه الحالات. وقد استهدفت هذه الدراسة من المتالبة بعد الجراحة، وخضع جميع المرضى لفحص العين الذي كان قبل قياس حدة البصر، ودرجة تصد القرنية قبل وبعد يوم، أسبوع، شهر و12 شهراً بعد الجراحة. وأظهرت النتائج أن مستويات حدة الإسوار من غير مصحح قد تحسن بشكل كبير من 0.9 (200/200) لوحجور إلى 5 (20/200) لوحجور (ح أقل من 0.1). ومع التحسين التحسين تصبح بشكل ملحوظ في أول يوم بعد العملية الجراحية وظلت مستقرة لمدة 12 شهراً بعد العملية (ح أقل من 0.1). وقد خلصت هذه الدراسة إلى أن زراعة الحلقات داخل القرنية من نوع كيرارينغ يساهم في تحسين زراعة حادة في حدة إسوار العين، الذين يعانون من القرنية المخروطية ويدل إلى إنخفاض بشكل ملحوظ في درجة تصد القرنية والاستماع.