Effects of Intracorneal Ring Segment on Corneal Biomechanics in Keratoconic Eyes

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Abstract

Purpose: To evaluate the biomechanical changes of cornea after intracorneal ring segment (ICRS) implantation in keratoconic eyes

Methods: In this study, 1 or 2 ICRS were inserted in 17 keratoconic eyes. Best spectacle-corrected visual acuity (BSCVA), uncorrected visual acuity (UCVA), refraction, and keratometry were evaluated preoperatively and 1 and 3 months after surgery. Corneal hysteresis (CH) and corneal resistance factor (CRF) were also measured preoperatively and postoperatively with ocular response analyzer (ORA).

Results: ICRS was inserted in 17 keratoconic eyes (12 patients). Mean UCVA significantly increased from 0.72±0.37 logMAR to 0.54±0.27 logMAR (P=0.027) and 0.46±0.30 logMAR (P=0.01) 1 and 3 months after surgery, respectively. Mean BSCVA increased from 0.41±0.29 logMAR to 0.32±0.26 logMAR at the end of the 1st month and 0.32±0.27 logMAR at the end of 3rd month postoperatively. These changes were not significant. Spherical equivalent (SE) significantly decreased from -5.64±3.21 Diorper (D) to -3.36±2.74 D (P=0.009) 1 month and -3.51±2.04 D (P=0.002) at the 3 months after surgery. Mean keratometry also significantly decreased from 49.82±4.33 D to 48.10±3.64 D (P=0.010) and 47.40±3.47 D (P=0.003) at 1- and 3- month follow-ups, respectively. Mean CH was 7.48±1.65 mmHg and mean CRF was 5.98±2.06 mmHg, preoperatively. At 1-month follow-up, their values were 7.13±1.56 mmHg and 5.74±1.60 mmHg, respectively. At 3-month follow-up, their values were 7.20±1.72 mmHg and 5.80±1.72 mmHg, respectively. The CH and CRF changes at 1- and 3-month follow-ups were not significant.

Conclusion: After ICRS insertion in keratoconic eyes, no significant changes were observed in mean values measured with the ORA at 1- and 3-month follow-ups.

Keywords: Intracorneal Ring Segment, Keratoconic Eyes, Best Spectacle-Corrected Visual Acuity, Uncorrected Visual Acuity, Corneal Hysteresis, Corneal Resistance Factor


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Received: June 6, 2010
Accepted: October 14, 2010

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The authors have no proprietary interest.
**Introduction**

Keratoconus is an idiopathic non-inflammatory ectatic corneal disorder which is characterized by para-axial thinning and para-central steepening of cornea.\(^1\) Severe cases are treated with rigid gas-permeable (RGP) lenses. In order to avoid or delay corneal graft in patients who can not tolerate RGP lenses, Colin et al, used intracorneal ring segment (ICRS) for the first time.\(^4\) Other studies showed the safety and efficacy of ICRS insertion in keratoconic eyes.\(^5\)-\(^7\)

ICRS flattens the anterior surface of the cornea by decreasing the arc length of central cornea and may provide a biomechanical support for the thin cornea.\(^8\),\(^9\)

Ocular response analyzer (ORA, Reichert Ophthalmic Instruments) measures the biomechanical properties of cornea in vivo. Corneal hysteresis (CH) and corneal resistance factor (CRF) are measured by the ORA using a dynamic bidirectional applanation process.\(^10\)

CH is described as the viscous damping due to the viscoelastic resistance of cornea to deformation pulse caused by an air jet of tonometer.\(^11,12\) CRF is the linear function of inward and outward applanation pressure values.\(^11\) CH mostly reflects corneal viscosity and CRF predominately relates to elastic properties of the cornea.\(^11,12\)

Studies done by Luce, Ortiz et al, and Goldich et al on corneal biomechanical properties of keratoconic eyes showed that CH and CRF values in these eyes are significantly less than normal eyes.\(^10,13,14\)

Considering the hypothesis regarding the effects of ICRS on biomechanical properties of cornea, the aim of this study was to evaluate the biomechanical properties of cornea after ICRS insertion in keratoconic eyes through CH and CRF measurements with the ORA.

**Methods**

This prospective interventional case series comprised 17 eyes of 12 patients. Inclusion criteria were early keratoconic eyes (stage less than 4 based on Krumeich\(^15\) classification) with clear central corneas and contact lens intolerance.

Preoperative and postoperative examinations included uncorrected visual acuity (UCVA), best spectacle-corrected visual acuity (BSCVA), manifest refraction, slit-lamp biomicroscopy, Goldman applanation tonometry, dilated fundus exam, keratometry, and pachymetry.

Corneal topography was performed preoperatively. CH and CRF were measured by ORA preoperatively and at the end of the 1\(^{st}\) and 3\(^{rd}\) months. ORA measurement was performed at least 4 times. Disqualified scale values were deleted. Measurements were repeated and mean values were recorded.

Intacs (Intracorneal ring segment, Addition Technology Inc.) rings in some eyes and SK (severe keratoconus, Addition Technology Inc.) rings in others were inserted.

One 0.45 mm ICRS for those with inferior cone and two 0.45 mm ICRS segments for those with central cone were inserted.

Minimum thickness for ICRS insertion was considered to be 400 \(\mu\) in central cornea and 500 \(\mu\) in peripheral cornea. All patients signed an informed consent.

**Surgical technique**

The procedures were performed using a standard technique with mechanical channel dissection. After prep and drep, under topical anesthesia, the geographic center of cornea was marked with the sinsky hook. The site of incision was marked with a zone marker. Corneal thickness at incision site was measured by ultrasonic pachymetry. The diamond knife was set at 70% of corneal thickness at the incision site. A 1.5 mm radial incision perpendicular to the steep meridian was made. From the base of the incision, a glide blade was used to create corneal pocket(s) in the stroma. Using blunt dissector and vacuum centering guide (VCG), one or two channels around the center of the cornea were made. After insertion of the ring(s), the wound was closed with a 10-0 nylon suture. Topical antibiotic and corticosteroid were administered for 1 week postoperatively. The corneal suture was removed 6 to 8 weeks after surgery.

**Statistical analysis**

Statistical differences between preoperative data and 1- and 3-month follow-ups were analyzed by repeated measures test (SPSS, version 16, SPSS Inc.). P-value less than 0.05 was considered to be statistically significant.
Results
Seventeen eyes (12 patients) were studied. Five patients (42%) were operated bilaterally at the same time. Ten patients were males (83.3%) and 2 were females (16.7%). Mean age was 26.58±5.50 years (range: 18-37). Keratoconus staging was as follows: stage I: 7 eyes (41%), stage II: 5 eyes (29.5%), and stage III: 5 eyes (29.5%).

SK ring was inserted for 6 eyes (35%, 5 patients) and Intacs for 11 eyes (65%, 7 patients). For 2 eyes in the SK ring group and 2 eyes in the Intacs group two segments were inserted. No intraoperative or postoperative complications were observed.

Postoperative 1- and 3-month follow-ups showed a statistically significant improvement in UCVA, and reduction in SE, sphere and mean keratometry (P<0.05) (Table 1).

Postoperative improvement in BSCVA and reduction in refractive cylinder in 1- and 3-month follow-ups were statistically significant (P>0.05). (Table 1)

CH changes from 7.48±1.65 mmHg preoperatively to 7.13±1.56 mmHg after 1 and 3 months, respectively, were not significant (P>0.05) (Table 2).

CRF changes from 5.98±2.06 mmHg preoperatively to 5.74±1.60 mmHg and 5.80±1.72 mmHg after 1 and 3 months were not significant (P>0.05) (Table 2). Also, CH and CRF changes from the first month (P=0.62) to the third month (P=0.77) were not significant.

Subgroup analysis based on number of segments inserted did not show a significant difference between postoperative CH and CRF values and preoperative values (P>0.05) (Tables 3 and 4).

Subgroup analysis based on inserted ring type, did not show significant changes in CH and CRF values (P>0.05) (Tables 5 and 6).

Analysis of CH and CRF values based on keratoconus stage comparing 1- and 3-month follow-ups with their preoperative values did not show a significant change(P>0.05) (Table 7).

Table 1. Preoperative and postoperative data (Mean±SD)

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Preoperative</th>
<th>1 Month</th>
<th>3 Months</th>
</tr>
</thead>
<tbody>
<tr>
<td>UCVA (logMAR)</td>
<td>0.72±0.37</td>
<td>0.54±0.27</td>
<td>0.46±0.30</td>
</tr>
<tr>
<td>BSCVA (logMAR)</td>
<td>0.41±0.29</td>
<td>0.32±0.26</td>
<td>0.32±0.27</td>
</tr>
<tr>
<td>SE (D)</td>
<td>-5.64±3.21</td>
<td>-3.36±2.74</td>
<td>-3.51±2.04</td>
</tr>
<tr>
<td>Mean K (D)</td>
<td>49.82±4.33</td>
<td>48.10±3.64</td>
<td>47.4±3.47</td>
</tr>
<tr>
<td>Sphere (D)</td>
<td>-4.01±2.62</td>
<td>-2.00±2.42</td>
<td>-1.57±1.44</td>
</tr>
<tr>
<td>Cylinder (D)</td>
<td>-4.01±2.30</td>
<td>-2.79±1.55</td>
<td>-3.86±2.64</td>
</tr>
</tbody>
</table>

UCVA: Uncorrected visual acuity
BSCVA: Best spectacle-corrected visual acuity
SE: Spherical equivalent
D: Dioptr
K: Keratometry

Table 2. Corneal hysteresis and Corneal resistance factor: preoperative and postoperative values (Mean±SD)

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Preoperative</th>
<th>1 Month</th>
<th>3 Months</th>
</tr>
</thead>
<tbody>
<tr>
<td>CH (mmHg)</td>
<td>7.48±1.65</td>
<td>7.13±1.56</td>
<td>7.20±1.23</td>
</tr>
<tr>
<td>CRF (mmHg)</td>
<td>5.98±2.06</td>
<td>5.74±1.60</td>
<td>5.80±1.72</td>
</tr>
</tbody>
</table>

CH: Corneal hysteresis
CRF: Corneal resistance factor
Table 3. One segment group: preoperative and postoperative data (Mean±SD)

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Preoperative</th>
<th>1 Month</th>
<th>3 Months</th>
</tr>
</thead>
<tbody>
<tr>
<td>CH (mmHg)</td>
<td>7.25±1.38</td>
<td>6.85±1.36 (P=0.27)</td>
<td>6.98±1.03 (P=0.23)</td>
</tr>
<tr>
<td>CRF (mmHg)</td>
<td>5.75±1.70</td>
<td>5.53±1.38 (P=0.55)</td>
<td>5.03±1.56 (P=0.13)</td>
</tr>
</tbody>
</table>

CH: Corneal hysteresis
CRF: Corneal resistance factor

Table 4. Two segment group: preoperative and postoperative data (Mean±SD)

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Preoperative</th>
<th>1 Month</th>
<th>3 Months</th>
</tr>
</thead>
<tbody>
<tr>
<td>CH (mmHg)</td>
<td>8.25±2.42</td>
<td>8.05±2.03 (P=0.75)</td>
<td>7.90±1.73 (P=0.48)</td>
</tr>
<tr>
<td>CRF (mmHg)</td>
<td>6.75±3.18</td>
<td>6.45±2.30 (P=0.66)</td>
<td>5.97±2.30 (P=0.18)</td>
</tr>
</tbody>
</table>

CH: Corneal hysteresis
CRF: Corneal resistance factor

Table 5. Intacs group: preoperative and postoperative data (Mean±SD)

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Preoperative</th>
<th>1 Month</th>
<th>3 Months</th>
</tr>
</thead>
<tbody>
<tr>
<td>CH (mmHg)</td>
<td>7.63±1.89</td>
<td>7.29±1.75 (P=0.35)</td>
<td>7.24±1.41 (P=0.12)</td>
</tr>
<tr>
<td>CRF (mmHg)</td>
<td>5.94±2.43</td>
<td>5.52±1.78 (P=0.37)</td>
<td>5.83±1.82 (P=0.51)</td>
</tr>
</tbody>
</table>

CH: Corneal hysteresis
CRF: Corneal resistance factor

Table 6. SK ring group: preoperative and postoperative data (Mean±SD)

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Preoperative</th>
<th>1 Month</th>
<th>3 Months</th>
</tr>
</thead>
<tbody>
<tr>
<td>CH (mmHg)</td>
<td>7.21±1.20</td>
<td>6.85±1.23 (P=0.53)</td>
<td>7.11±0.94 (P=0.77)</td>
</tr>
<tr>
<td>CRF (mmHg)</td>
<td>6.06±1.32</td>
<td>6.15±1.27 (P=0.77)</td>
<td>5.75±1.30 (P=0.18)</td>
</tr>
</tbody>
</table>

CH: Corneal hysteresis
CRF: Corneal resistance factor

Table 7. Keratoconus stage: preoperative and postoperative data (Mean±SD)

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Preoperative</th>
<th>1 Month</th>
<th>3 Months</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Stage I</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CH (mmHg)</td>
<td>8.08±2.02</td>
<td>7.30±1.87 (P=0.13)</td>
<td>7.41±1.55 (P=0.17)</td>
</tr>
<tr>
<td>CRF (mmHg)</td>
<td>6.18±2.67</td>
<td>5.51±2.15 (P=0.10)</td>
<td>5.74±2.19 (P=0.15)</td>
</tr>
<tr>
<td><strong>Stage II</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CH (mmHg)</td>
<td>8.14±0.40</td>
<td>7.74±1.16 (P=0.57)</td>
<td>7.60±0.59 (P=0.14)</td>
</tr>
<tr>
<td>CRF (mmHg)</td>
<td>6.54±0.84</td>
<td>6.58±0.45 (P=0.90)</td>
<td>6.40±1.45 (P=0.52)</td>
</tr>
<tr>
<td><strong>Stage III</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CH (mmHg)</td>
<td>6.00±0.87</td>
<td>6.30±1.32 (P=0.46)</td>
<td>6.50±1.10 (P=0.11)</td>
</tr>
<tr>
<td>CRF (mmHg)</td>
<td>5.16±2.07</td>
<td>5.24±1.38 (P=0.93)</td>
<td>5.10±1.07 (P=0.64)</td>
</tr>
</tbody>
</table>

CH: Corneal hysteresis
CRF: Corneal resistance factor
Discussion

Colin et al were the first to report the use of ICRS in keratoconic eyes. Through an arc-shortening effect, the ICRS flattens the central part of the cornea and decreases its irregularity. Several literature reviews on ICRS insertion in keratoconic eyes reported the method to be efficacious in terms of visual outcome.

Postoperatively, UCVA improvement and the decreases in sphere, spherical equivalent (SE) and mean keratometry were not significant. These findings are similar to results in earlier studies. Unlike other studies, BSCVA improvement was not statistically significant. Similar to reports by Siganos et al and Alió et al, the decrease in refractive cylinder after surgery in 1- and 3-month follow-ups was not significant in comparison with the preoperative values.

In an eye-bank study on ICRS flattening effect performed by Burris et al in 1990s, a theory was introduced expressing that after ICRS insertion, a decrease in arc length of collagen fibers of the corneal lamella may provide a biomechanical support in thin cornea.

At that time, measurement of biomechanical properties of cornea could not be done in vivo. After introduction of ORA by Luce, assessment of these properties is possible today. In this study, effects of ICRS insertion (in keratoconic eyes) on biomechanical properties of cornea were evaluated through CH and CRF measurements. Preoperative values of CH and CRF in keratoconic eyes were in consistence with other studies.

One month and three-month follow-up values of CH and CRF were not significantly different from baseline. Subgroup analysis based on the number of inserted segments and used ring type also did not show a significant change in CH and CRF values compared to baseline.

Analysis of postoperative CH and CRF changes based on the stage of keratoconus also were not significant.

Considering the proposed mechanism of ICRS effects, an improvement in biomechanical properties of cornea was expected. In relation to the results, a few points can be cited:

First, ICRS insertion technique requires radial incision and channel dissection of the cornea. Lack of significant changes in biomechanical properties of cornea could be due to annihilation of possible supportive ICRS effects with early weakening effects of insertion process.

Second, supportive effects of ICRS on biomechanical properties of cornea may be a long-term process and it may need a period longer than the 3-month follow-up of this study to demonstrate its effects.

Third, no improvement in biomechanical properties of cornea may be due to keratoconus progression in the studied eyes. However, considering the relatively short-term of follow-up, this hypothesis is less probable.

Fourth, it is also possible that after ICRS insertion, the ORA may not be sensitive enough to measure CH and CRF correctly. Hence, the obtained results may be due to the inaccuracy in measurements.

Finally, it is likely that ICRS insertion substantially does not improve biomechanical properties of cornea (measured with ORA device).

Since this study is the first to evaluate biomechanical property changes of cornea after ICRS insertion, a comparison can not be made with other studies. Determination of the accuracy of above mentioned hypotheses requires another study with a larger sample size, longer follow-ups and a randomized clinical trial design.

Conclusion

In summary, this study showed that up to a 3-month follow-up, insertion of ICRS in keratoconic eyes caused no significant changes in biomechanical properties of cornea measured with ORA. The number of segments, ring type and the stage of keratoconus did not affect the results.
References