Title: Photorefractive Keratectomy for Mild-to-Moderate Myopics with Thin Corneas: A 3-Year Follow-up Results

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Abstract:
Background: The purpose of this study was to evaluate the 3-year visual outcomes in mild-to-moderate myopic patients with thin corneas who underwent photorefractive keratectomy (PRK) with or without mitomycin C (MMC).

Methods: Thirty myopic eyes with a mean spherical equivalent (SE) of $-3.76 \pm 1.72$ (range: $-6.50$ to $-1.25$) diopter (D) and a mean corneal thickness of $486.03 \pm 11.93$ (452–499) µm at the thinnest point underwent PRK. MMC was used if they had $> 4.0$ D myopia. All surgeries were performed with the VISX STAR S4 Excimer Laser (Abbott Medical Optics, Abbott Park, Illinois, USA).

Results: Uncorrected visual acuity showed a significant improvement 3 years after surgery when compared to baseline and reached $0.01 \pm 0.04$ LogMAR ($P < 0.001$). Best-corrected visual acuity was $0.00 \pm 0.01$ LogMAR preoperatively and did not change significantly postoperatively. Spherical ($P < 0.001$) and cylindrical ($P < 0.001$) error significantly decreased. Manifest refraction SE showed a significant decrease when compared to before the operation and reached $-0.08 \pm 0.16$ D ($P < 0.001$). At 3 years, mesopic contrast sensitivity was not significantly different from baseline at any spatial frequency. Vertical coma showed a significant decrease and reached $-0.10 \pm 0.27$ µm ($P = 0.004$). Total coma ($P < 0.001$), spherical aberration ($P < 0.001$), and total high order aberrations ($P < 0.001$) also increased significantly.

Conclusions: Based on the 3-year results, PRK (+MMC in patients with SE $> 4.0$ D) is a safe, effective, and predictable treatment option for mild-to-moderate myopic patients whose minimum corneal thickness is $< 500$ µm.

Keywords: Photorefractive keratectomy; Thin cornea; Mesopic vision; Contrast sensitivity; Corneal wavefront aberrations; Long term

Introduction

Different methods such as photorefractive keratectomy (PRK), laser in situ keratomileusis (LASIK), and intraocular refractive procedures are used to correct refractive errors. Due to the risk of post-LASIK ectasia (1-3), PRK is the preferred method for patients with thin corneas (4-6). However, there are reports of refractive regression (6) and complications such as corneal ectasia (7) following PRK, which prompted us to evaluate long-term PRK results. By the end of the 1st year after PRK (8), we observed an improved uncorrected visual acuity (UCVA), decreased refractive error, better contrast sensitivity (CS) in two spatial frequencies of 6 and 12 cycle/degree, and increased high-order aberrations (HOAs). In this report, we present the 3-year results of this procedure and compare them with the pre-operative and 1-year results.

Materials and Methods

As presented in the 1-year report (8), 30 eyes of 15 patients (73.3% female) with a mean age of 29.47 ± 6.10 years, mean spherical equivalent (SE) of $-3.76 \pm 1.72$ (range: $-6.50$ to $-1.25$) D, and a mean minimal corneal thickness of $486.03 \pm 11.93$ (452–499) µm received PRK in this before-after interventional study. In accordance with clinic policy, mitomycin C (MMC) was used in PRK for patients with $> 4.0$ D myopia. The inclusion criterion was refractive stability for 18 months before the surgery. Exclusion criteria were ocular pathology or history of ocular surgery. The patients discontinued wearing contact lenses 4 weeks before the surgery. The local review board reviewed and approved the study. The details of the study were explained to the patients before the operation, and written informed consents were obtained.

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Pre-and post-operative examinations: UCVA and best-corrected visual acuity (BCVA) were evaluated with the Snellen chart, and manifest refraction SE (MRSE) was measured with a retinoscope (HEINE BETA 200, Germany). CS was assessed with the CVS1000 grating charts (VectorVision, Inc., Greenville, OH, USA) without dilation under mesopic (4 lux) conditions with best distance correction. Aberrations were measured with the Allegretto WaveLight Analyzer (WaveLight Laser Technologie AG, Germany) using the 6 mm setting of the device. Measurements were repeated and the best of three measurements was selected for each patient. Among aberrometry indexes, C6 (trefoil), C7 (vertical coma), C8 (horizontal coma), root mean square (RMS) coma$_{\text{total}}$, C9 (trefoil), C12 spherical aberration (SA), and RMS HOA$_{\text{total}}$ (RMS HOA$_T$) were extracted. The following formula was used to calculate RMS coma$_{\text{total}}$: $$\sqrt{C7^2 + C8^2}$$

Repeated measures analysis of variance was used to determine the 3-year changes of the indices. The correlation between two eyes was adjusted. Patients were grouped by baseline MRSE, and changes in different indices were compared between Group A ($< -4.00$ D, $n = 12$ eyes) and Group B ($\geq 4.00$ D, $n = 18$) using independent sample t-test.

Surgical technique: After topical anesthesia with proparacaine hydrochloride ophthalmic solution 0.5%, the corneal epithelium was mechanically scraped with a blunt spatula and no alcohol. VISX STAR S4 Excimer laser (Abbott Medical Optics, Abbott Park, Illinois, USA) software version 5.30 was used for ablation (target fluence: 160 mJ/cm$^2$, laser pulse rate: 10.0 Hz). The selected ablation zone in all patients was 6.0 mm with a blend zone. In eyes with $> 4.0$ D myopia, after laser irradiation, a sponge soaked in MMC 0.02% was applied on the ablated stroma for 10 seconds per diopter of correction and then irrigated with 30cc of sterile balanced saline solution. A bandage contact lens (Air Optix, Ciba Vision) was applied on the eye at the end of the procedure. The post-operative regimen included levofloxacin eye drops 5 mg/ml and betamethasone 0.1% four times daily and preservative-free artificial tears (hypromellose, preservative free) as required. Voltaren was prescribed every 6 hours for 24 hours to decrease inflammation. The contact lens was removed and levofloxacin was discontinued upon reepithelialization, but betamethasone and artificial tears were continued for another 2 weeks. After that, fluorometholone ophthalmic suspension 0.1% was prescribed to be tapered over a 2-month course. Examinations were performed daily until complete epithelial healing was observed.

Results

At 3 years after surgery, one patient (two eyes) was lost to follow-up due to distance and complete satisfaction with vision. We detected no case of corneal ectasia at any time.

UCVA had significantly improved by the end of 3 years when compared to baseline ($P < 0.001$), but no significant change was observed when compared to 1$^{\text{st}}$-year results ($P = 0.381$). Three-year changes in UCVA were not significantly different between Groups A and B ($P = 0.094$).

Pre-operative BCVA was 0.00 ± 0.01 LogMAR with no significant change after the operation. The safety index (post-operative BCVA/pre-operative BCVA) and efficacy index (post-operative UCVA/pre-operative BCVA) were 1.01 ± 0.03 and 1.00 ± 0.03, respectively.

Spherical error, cylindrical error, and MRSE showed a significant decrease at 3 years after versus before the operation (all $P < 0.001$), but all of them had no significant change after the first post-operative year ($P = 0.425$, $P = 0.244$, and $P = 0.126$, respectively). At 3 years, all patients were within ± 0.5 D of emmetropia. Mean residual SE was not significantly different between Group A ($-0.11 ± 0.20$ D) and Group B ($0.07 ± 0.14$ D) ($P = 0.398$). Results in terms of UCVA, BCVA, spherical error, cylinder error, and MRSE are presented in table 1.

Mesopic CS showed no statistically significant change in any spatial frequency compared to baseline, and we found no significant difference between Groups A and B either (all $P > 0.050$). Comparison of 3-year and 1-year results showed insignificant changes as well (Table 2).

The decrease in vertical coma was significant at 3 years compared to baseline ($P = 0.004$) and borderline significant when compared to 1-year results ($P = 0.065$).

<table>
<thead>
<tr>
<th>Variables</th>
<th>Baseline</th>
<th>1 year after surgery</th>
<th>3 years after surgery</th>
<th>P-value*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of eyes</td>
<td>30</td>
<td>30</td>
<td>28</td>
<td></td>
</tr>
<tr>
<td>UCVA (logMAR)</td>
<td>1.29 ± 0.55</td>
<td>0.00 ± 0.02</td>
<td>0.01 ± 0.04</td>
<td>$&lt; 0.001$</td>
</tr>
<tr>
<td>BCVA (logMAR)</td>
<td>0.00 ± 0.01</td>
<td>0.00 ± 0.02</td>
<td>0.01 ± 0.03</td>
<td>NA</td>
</tr>
<tr>
<td>Spherical error (diopter)</td>
<td>$-3.31 ± 1.87$</td>
<td>$0.04 ± 0.15$</td>
<td>$0.02 ± 0.10$</td>
<td>$&lt; 0.001$</td>
</tr>
<tr>
<td>Cylinder error (diopter)</td>
<td>$-0.71 ± 0.65$</td>
<td>$-0.20 ± 0.31$</td>
<td>$-0.14 ± 0.20$</td>
<td>$&lt; 0.001$</td>
</tr>
<tr>
<td>MRSE (diopter)</td>
<td>$-3.76 ± 1.72$</td>
<td>$-0.03 ± 0.12$</td>
<td>$-0.08 ± 0.16$</td>
<td>$&lt; 0.001$</td>
</tr>
</tbody>
</table>

*Based on paired t-test and comparison of pre-operative versus 3 years after surgery. UCVA: Uncorrected visual acuity; BCVA: Best-corrected visual acuity; MRSE: Manifest refraction spherical equivalent; PRK: Photorefractive keratectomy.
Table 2. Changes in mesopic CS following PRK in myopic thin cornea patients

<table>
<thead>
<tr>
<th>Variables</th>
<th>Pre-operative</th>
<th>1 year after surgery</th>
<th>3 years after surgery</th>
<th>P-value*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of eyes</td>
<td>30</td>
<td>30</td>
<td>28</td>
<td></td>
</tr>
<tr>
<td>C3 (cycle/degree)</td>
<td>1.72 ± 0.09</td>
<td>1.75 ± 0.06</td>
<td>1.74 ± 0.09</td>
<td>0.745</td>
</tr>
<tr>
<td>C6 (cycle/degree)</td>
<td>1.88 ± 0.08</td>
<td>1.94 ± 0.10</td>
<td>1.91 ± 0.11</td>
<td>0.343</td>
</tr>
<tr>
<td>C12 (cycle/degree)</td>
<td>1.52 ± 0.14</td>
<td>1.65 ± 0.15</td>
<td>1.57 ± 0.13</td>
<td>0.184</td>
</tr>
<tr>
<td>C18 (cycle/degree)</td>
<td>1.10 ± 0.16</td>
<td>1.12 ± 0.15</td>
<td>1.10 ± 0.16</td>
<td>0.924</td>
</tr>
</tbody>
</table>

*Based on paired t-test and comparison of pre-operative and 3 years after surgery. CS: Contrast sensitivity; PRK: Photorefractive keratectomy

Table 3. Changes in higher order aberrations following PRK in myopic thin cornea patients

<table>
<thead>
<tr>
<th>Variables</th>
<th>Pre-operative</th>
<th>1 year after surgery</th>
<th>3 years after surgery</th>
<th>P-value*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of eyes</td>
<td>30</td>
<td>30</td>
<td>28</td>
<td></td>
</tr>
<tr>
<td>C6 trefoil (µm)</td>
<td>−0.07 ± 0.11</td>
<td>−0.10 ± 0.14</td>
<td>−0.08 ± 0.16</td>
<td>0.874</td>
</tr>
<tr>
<td>C7 vertical coma (µm)</td>
<td>0.07 ± 0.18</td>
<td>−0.03 ± 0.30</td>
<td>−0.10 ± 0.27</td>
<td>0.004</td>
</tr>
<tr>
<td>C8 horizontal coma (µm)</td>
<td>−0.03 ± 0.10</td>
<td>0.07 ± 0.37</td>
<td>0.05 ± 0.34</td>
<td>0.178</td>
</tr>
<tr>
<td>Total coma (µm)</td>
<td>0.21 ± 0.08</td>
<td>0.40 ± 0.23</td>
<td>0.39 ± 0.22</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>C9 trefoil (µm)</td>
<td>0.00 ± 0.10</td>
<td>−0.02 ± 0.10</td>
<td>0.01 ± 0.12</td>
<td>0.707</td>
</tr>
<tr>
<td>C12 SA (µm)</td>
<td>0.01 ± 0.12</td>
<td>0.30 ± 0.17</td>
<td>0.26 ± 0.17</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>RMS total HOAs (µm)</td>
<td>0.32 ± 0.07</td>
<td>0.58 ± 0.23</td>
<td>0.58 ± 0.23</td>
<td>&lt; 0.001</td>
</tr>
</tbody>
</table>

RMS: Root mean square; HOAs: Higher order aberrations; PRK: Photorefractive keratectomy; SA: Spherical aberration

PRK for Myopic Thin Cornea

At 3 years, total coma, total HOAs, and SA were significantly higher than baseline (P < 0.001), but no significant change was observed when compared to 1-year results. Comparison of 3-year changes between Groups A and B indicated more SA increase in Group A compared to Group B (0.32 ± 0.15 vs. 0.18 ± 0.13 µm, P = 0.018) as well as total HOAs (0.45 ± 0.14 vs. 0.14 ± 0.20 µm, P < 0.001) (Table 3).

Discussion

The best surgical method for the correction of refractive errors depends on factors such as patients' corneal thickness, anterior chamber depth, and severity of refractive error. A corneal thickness < 500 µm is a contraindication to LASIK due to the possibility of post LASIK ectasia (1,3,9,10). In these patients, PRK is a treatment option for the correction of myopia (11).

A long-term study of surface ablation procedures, i.e., laser epithelial keratomileusis (LASEK) and PRK, showed acceptable results for the correction of myopia in patients with < 500 µm central corneal thickness (12). Compared to their results, we observed better outcomes, possibly owing to newer laser devices, modern surgical techniques, and the application of MMC in myopia > 4.0 D to prevent corneal haze (13). We detected no case of BCVA loss or refractive regression in our study, while 14 eyes (46.6%) developed late regression in the mentioned study (12).

Similar to other studies, we observed an increase in HOAs after the operation, but changes between the 1st and 3rd year after the operation were not significant, and HOAs remained stable. In a 10-year evaluation of patients with normal corneal thickness, Zhang et al. (21) reported increased HOAs following PRK, which then decreased considerably during 10 years after the operation and approximated pre-operative values. Longer follow-ups may be required to detect changes in thin cornea patients. However, it should be noted that increased HOAs following refractive surgery is a common finding due to reshaping the cornea to oblate (16,22).

This is confirmed by the fact that SA and HOAs showed more increase in the group with higher myopia. Another point is that despite the increase in HOAs, mesopic CS had no significant change. This indicates that visual function is affected by not only aberrations but also neural processes that have an important role in the quality of vision. Vision-related quality of life questionnaires can be helpful to assess the impact of aberrations on visual quality.
In conclusion, based on our 3-year results, PRK (+MMC for patients with SE > 4.0 D) is a safe, effective, and predictable treatment option for mild-to-moderate myopic patients with corneal thickness < 500 μm. It improves visual acuity, corrects refractive errors, and does not affect the visual quality in high mesopic conditions. However, aberrations increase after the operation, but they decrease insignificantly after 1 year.

**Conflict of Interests**

Authors have no conflict of interests.

**Acknowledgments**

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**References**


