Customized LASIK Treatment for Myopia Based on Preoperative Manifest Refraction and Higher Order Aberrometry: The Rochester Nomogram

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ABSTRACT

PURPOSE: To develop and test the efficacy of myopic treatment, based on preoperative manifest refraction and higher order aberrations, in enhancing the postoperative refractive error following customized LASIK treatment and compare results with the manufacturer-recommended sphere offset Zyoptix treatment nomogram, which does not account for the preoperative higher order aberrations.

METHODS: One hundred seventy-five myopic eyes (89 patients) were treated based on the Rochester nomogram, which specified the amount of myopia to be treated based on preoperative manifest refraction and higher order aberrations, including third order aberrations and spherical aberration. Postoperative refractive error was measured at 1 month and compared to that theoretically estimated with the Zyoptix nomogram.

RESULTS: The mean preoperative sphere and cylinder were $-4.52 \pm 2.05$ diopters (D) and $-0.81 \pm 0.70$ D, respectively. The mean postoperative spheres were $+0.04 \pm 0.33$ D and $+0.31 \pm 0.54$ D, using the Rochester and Zyoptix nomograms, respectively. The mean postoperative spherical equivalent refractions were $-0.11 \pm 0.34$ D and $+0.15 \pm 0.53$ D using the Rochester and Zyoptix nomograms, respectively. The Rochester nomogram reduced the range of postoperative spherical equivalent to $\pm 1.00$ D, which was significantly better than that using the Zyoptix nomogram ($t=5.46, P<0.0001$), which would have resulted in 8% of eyes with a postoperative spherical equivalent refraction $>\pm 1.00$ D. Using the Rochester nomogram, 93.1% of eyes attained a postoperative UCVA $\geq 20/20$. The percentage of postoperative hyperopic overcorrection decreased to 2.8% in the Rochester nomogram group from 22.3% using the Zyoptix nomogram, which only adjusts spherical values based on preoperative sphere and does not account for preoperative aberrations.

CONCLUSIONS: The Rochester nomogram compensates for the effect of preoperative higher order aberrations on sphere and provided reduced range of postoperative spherical equivalent refraction. [J Refract Surg. 2007;23:435-441.]

Several studies have reported the safety and efficacy of customized LASIK treatment for myopia. Customized LASIK has been shown to treat lower order (sphere and cylinder) and high order aberrations (3rd order and higher). Despite such advanced technology, 24.1% of eyes treated using customized LASIK have postoperative spherical equivalent $>\pm 0.50$ diopters (D), and approximately 8% of these eyes required retreatment. The etiology of postoperative refractive error following custom LASIK has been attributed to the corneal healing response and laser ablation characteristics.

Our previous study measured significant aberration interaction effect, ie, interactions between preoperative myopia and high order aberrations, especially coma, trefoil (3rd order), and spherical aberration (4th order), on postoperative spherical equivalent refraction (Fig 1). Eyes with increased preoperative higher order aberrations tend to have greater postoperative refractive error (spherical equivalent refraction $>\pm 0.50$ D). For instance, eyes with increased preoperative positive spherical aberration tend to be overcorrected (postoperative hyperopia, spherical equivalent refraction $>\pm 0.50$ D) following custom treatment. Durrie et al noted a similar trend with customized retreatments particularly in eyes with greater preoperative positive spherical aberration using the Alcon CustomCornea system (Alcon Laboratories Inc, Ft Worth, Tex) and recommend reducing the myopic spherical laser setting to reduce spherical overcorrections. We previously reported that eyes with greater preoperative myopia had greater postoperative positive spherical aberration and 3rd order ab-

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Thus, the aberration interaction goes both directions, namely treatment of preoperative 2nd order sphere may induce postoperative 4th order spherical aberration and treatment of preoperative 3rd (coma or trefoil) or 4th (spherical aberration) order may affect postoperative 2nd order sphere.

We hypothesized that the correction of preoperative higher order aberrations might interact with the 2nd order aberrations (sphere and cylinder), resulting in postoperative refractive error. Understanding and compensating for such interactions may provide a treatment nomogram that can improve and better predict postoperative refractive outcome following customized LASIK correction for myopia. This article discusses the efficacy and validity of such a nomogram designed to compensate for the effect of preoperative higher order aberrations on postoperative refractive error.

**MATERIALS AND METHODS**

**The Rochester Nomogram**

The Rochester nomogram is based on multiple regression analyses of data on 112 eyes, treated by a single surgeon (S.M.M.), as part of the 340-eye Bausch & Lomb (Rochester, NY) Zyoptix US Food and Drug Administration (FDA) trial. The Rochester nomogram calculates the amount of sphere to be treated based on preoperative manifest refraction (sphere, cylinder, and axis), represented in vector format (SE, J0, and J45), and preoperative higher order aberrations (3rd through 5th order). The magnitude of astigmatism correction is determined by the Zywave refraction and was not altered due to manufacturer and FDA regulations.

**Study Groups**

The Rochester nomogram group comprised 175 myopic eyes (89 consecutive patients) with a mean preoperative spherical equivalent refraction of $-4.89 \pm 2.06$ D (range: $-1.13$ to $-10.25$ D). The maximum amount of preoperative astigmatism treated was $-4.25$ D (mean: $-0.81 \pm 0.70$ D), and mean preoperative higher order aberration was $0.53 \pm 0.16 \mu m$. The treatment sphere was calculated using the Rochester nomogram.

The Zyoptix nomogram group comprised 175 eyes (same as the Rochester group) whose 1-month postoperative spherical equivalent refraction was theoretically estimated using the manufacturer-recommended sphere offset Zyoptix nomogram. The Zyoptix nomogram suggested reducing the sphere treatment by 7% based on data analysis on pre- and postoperative LASIK sphere and cylinder values among eyes previously treated by the same surgeon. This 7% sphere offset was based on a linear regression model of pre- and postoperative sphere and cylinder values and did not include analysis of preoperative higher order aberrations.

The last group comprised 112 myopic eyes treated by the same surgeon, laser, and software as part of the Zyoptix FDA trial. The mean preoperative spherical equivalent refraction was $-3.41 \pm 1.44$ D (range: $-1.25$ to $-7.50$ D) with maximum astigmatism of $-3.25$ D and mean preoperative higher order aberration of $0.45 \pm 0.18 \mu m$. The laser setting was 100% of the measured wavefront refraction and no nomogram adjustments to sphere or cylinder were used for these treatments.

**Study Measurements**

The clinical measurements performed during the study include preoperative manifest subjective refrac-
tion; preoperative corneal topography using Orbscan II topographer (Bausch & Lomb); preoperative 2.5% neosynephrine dilated, wavefront aberrations @ 6-mm aperture using the Zywave aberrometer (Bausch & Lomb); postoperative 1-month uncorrected visual acuity (UCVA) using Snellen chart; postoperative 1-month best spectacle-corrected visual acuity (BSCVA) using Snellen chart; and postoperative 1-month manifest subjective refraction.

All surgeries were performed by a single surgeon (S.M.M.) using the same method under a controlled environment (temperature 70°F±3°F and humidity 40%±3%). The same laser (Bausch & Lomb Technolas 217Z), room, and microkeratome (Low Compression Hansatome, Bausch & Lomb) were used in all patients. All patients signed an informed consent prior to the treatment procedure. Institutional review board approval was obtained for 112 eyes treated in the FDA trial in accordance with FDA guidelines.

OUTCOME VARIABLE
The Rochester nomogram was tested for efficacy based on its ability to predict postoperative refractive error (Rochester nomogram group) relative to target postoperative spherical equivalent refraction, through compensation of the aberration interaction effect, and compared to that theoretically estimated when using the manufacturer-recommended sphere offset nomogram (Zyoptix nomogram group). The results of the two groups were then compared with the results in the previous Zyoptix FDA trial by the same surgeon (Zyoptix FDA trial group).

The theoretical estimate of the postoperative spherical equivalent refraction was calculated as the preoperative difference in the recommended sphere correction between the Rochester nomogram and Zyoptix nomogram and the clinically measured postoperative 1-month spherical equivalent refraction. This technique was validated on the other 288 of 340 eyes, treated by 2 other surgeons, in the original Zyoptix FDA study.

DATA ANALYSIS
All pre- and postoperative refractive error data were converted to vector format (SE, J0, and J45). Paired t test was used to compare differences in 1-month postoperative refractive error (spherical equivalent refraction and sphere) between the Rochester nomogram and that theoretically estimated with the Zyoptix nomogram, whereas a standard Student t test was performed to compare the difference in mean postoperative results between the 175 eyes in the Rochester nomogram group and previous Zyoptix FDA trial group. Correlation analyses were performed to evaluate predictability of postoperative spherical equivalent refraction by the Rochester nomogram and Zyoptix nomogram.

RESULTS

POSTOPERATIVE VISUAL ACUITY
All 175 (100%) eyes were evaluated 1 month postoperatively and all eyes were available for data analysis. Only the percentage of eyes with postoperative UCVA ≥20/20 was compared between the current 175 eyes treated using the Rochester nomogram and 112 eyes in the previous Zyoptix FDA trial. In the Rochester nomogram group, 161 (93.1%) of 175 eyes attained 1-month postoperative UCVA ≥20/20 whereas 98.3% (172 of 175 eyes) of eyes attained BSCVA ≥20/20. (Two eyes were treated for mini-monovision of −0.25 D and were correctable to ≥20/20 and were excluded in this analysis.) In the Zyoptix FDA trial group, 89.3% (100 of 112 eyes) attained UCVA ≥20/20 (Table 1).

POSTOPERATIVE SPHERE
The mean 1-month postoperative spherical error was +0.04±0.33 D using the Rochester nomogram and significantly less hyperopic than that theoretically estimated with the Zyoptix nomogram (mean +0.30±0.54 D, P<.0001) (Fig 2). The range of 1-month postoperative sphere was −0.75 to +1.25 D for the Rochester nomogram group and −0.79 to +2.21 D for the Zyoptix nomogram group. The mean 1-month postoperative sphere in the Zyoptix FDA trial group was more hyperopic (mean +0.37±0.56 D; range: −0.75 to +1.75 D), compared to the Rochester nomogram group (P<.0001, Table 1).

POSTOPERATIVE SPHERICAL EQUIVALENT
One month postoperatively, the mean spherical equivalent refraction was −0.11±0.34 D in the Rochester nomogram group, which was significantly less than the theoretically estimated mean spherical equivalent refraction of +0.15±0.53 D in the Zyoptix nomogram group (P<.0001, see Fig 2) and +0.26±0.50 D in the Zyoptix FDA trial group (P<.0001). The range of postoperative spherical equivalent refraction in the Rochester nomogram group was ±1.00 D and significantly smaller than the range theoretically estimated in the Zyoptix nomogram group (−1.04 to +1.81 D, P<.001) and Zyoptix FDA trial group (−0.75 to +1.75 D, P<.001, Table 2).

DISTRIBUTION OF 1-MONTH POSTOPERATIVE SPHERICAL EQUIVALENT REFRACTION
In the Rochester nomogram group, 160 (91.5%) of 175 eyes were within ±0.50 D and all 175 (100%) eyes
were within ±1.00 D of the target spherical equivalent refraction. Five (2.9%) of 175 eyes had an overcorrection or residual hyperopia (spherical equivalent refraction >+0.50 D), whereas 10 (5.7%) eyes had undercorrection or residual myopia (spherical equivalent refraction >−0.50 D) (Table 2).

In the Zyoptix nomogram group, 121 (69.1%) of 175 eyes were theoretically estimated to be within ±0.50 D of target spherical equivalent refraction. Thirty-nine (22.3%) of 175 eyes would have obtained residual overcorrection (hyperopia >+0.50 D) and 15 (8.6%) eyes would have had undercorrection (myopia >−0.50 D) postoperatively (Table 2).

In the Zyoptix FDA trial group, 80 (71.4%) of 112 eyes were within ±0.50 D of target spherical equivalent refraction. Thirty (26.8%) of 112 eyes attained postoperative overcorrection (hyperopia >+0.50 D) and 2 (1.8%) of 112 eyes had undercorrection (myopia >−0.50 D).
### TABLE 2

<table>
<thead>
<tr>
<th>1-Month Spherical Equivalent Refraction (SE) (D)</th>
<th>Rochester Nomogram (n=175 eyes)</th>
<th>Zyoptix Nomogram (n=175 eyes)</th>
<th>Zyoptix FDA Trial (n=112 eyes)</th>
</tr>
</thead>
<tbody>
<tr>
<td>SE &gt; −1.00 D (greater undercorrection) (%)</td>
<td>0</td>
<td>1.1 (2/175)</td>
<td>0.9 (1/112)</td>
</tr>
<tr>
<td>−1.00 D ≤ SE ≤ −0.50 D (mild undercorrection) (%)</td>
<td>5.7 (10/175)</td>
<td>7.4 (13/175)</td>
<td>0.9 (1/112)</td>
</tr>
<tr>
<td>SE within ±0.50 D (%)</td>
<td>91.4 (160/175)</td>
<td>69.1 (121/175)</td>
<td>71.4 (80/112)</td>
</tr>
<tr>
<td>+0.50 D &lt; SE ≤ +1.00 D (mild overcorrection) (%)</td>
<td>2.8 (5/175)</td>
<td>15.4 (27/175)</td>
<td>17.9 (20/112)</td>
</tr>
<tr>
<td>SE &gt; +1.00 D (greater overcorrection) (%)</td>
<td>0</td>
<td>6.9 (12/175)</td>
<td>8.9 (10/112)</td>
</tr>
</tbody>
</table>

*Note. An overcorrection results in the 1-month postoperative SE of > +0.50 D, whereas undercorrection (hyperopia) represents eyes that attained a 1-month postoperative SE of − ≤ −0.50 D (residual myopia).*

### DISCUSSION

The Rochester nomogram yielded a higher percentage of eyes with UCVA ≥20/20 (93.1%) than in the previous Zyoptix FDA trial (89.3%). Preoperatively, the eyes in the Rochester nomogram group were on average more myopic (difference in mean spherical equivalent refraction: −1.40 D) with higher astigmatism (difference in mean: −0.20 D), and greater higher order aberrations (difference in mean: 0.08 μm root-mean-square) than the Zyoptix FDA trial group (Table 1).

The Rochester nomogram offered better accuracy and reduced range of postoperative refractive outcome following customized LASIK for myopia (Rochester nomogram group vs Zyoptix nomogram and Zyoptix FDA trial groups, P<.0001). The Rochester nomogram provided 91.5% of eyes to be within ±0.50 D and 100% within ±1.00 D. This is significantly greater than the theoretically estimated 69.1% and 92% to be within ±0.50 D and ±1.00 D, respectively, of target spherical equivalent refraction in the Zyoptix nomogram group (P<.001). In the Zyoptix FDA trial group, 72.6% of eyes were within ±0.50 D and 90.2% within ±1.00 D of target spherical equivalent refraction at 1 month postoperatively. The use of the Rochester nomogram increased the predictability of postoperative spherical equivalent refraction to 81% (Fig 3A) from 39% using the Zyoptix nomogram (Fig 3B) and reduction in range of postoperative spherical equivalent refraction to ±1.00 D.

A significant reduction was noted in the standard deviation in postoperative sphere from 0.54 D (Zyoptix nomogram group) to 0.33 D (Rochester nomogram group), which we believe is related to compensation of preoperative higher order aberrations (P<.001). The standard deviation of 0.33 D is close to the repeatability of the manifest refraction and indicates the enhanced outcome with the Rochester nomogram. This suggests that compensation of the effect of preoperative higher order aberrations and the use of manifest refraction improves the predictability of postoperative sphere.

Using the manifest refraction may offer better outcomes as it may represent the best refractive correction that compensates for aberration interactions and other previously reported potential retinal image quality interpretation by the brain. The wavefront refraction measured by the Zywave aberrometer, on the other hand, measures only the optical aberrations in the retinal image and does not incorporate the aberration interaction effect or the interpretation of the retinal image by the brain. The interaction among preoperative optical refractive error, higher order aberrations, and neural interpretation is a topic for future investigation and beyond the scope of this article.

Our previous analyses on myopic eyes treated in the Zyoptix FDA trial showed significant correlations between preoperative higher order aberrations and postoperative spherical equivalent refraction and the tendency for overcorrection with greater preoperative higher order aberrations (22.3%). However, using the Rochester nomogram, no significant correlation was obtained between preoperative higher order aberrations and postoperative refractive error. This combined with the enhanced predictability (see Fig 3A) of the postoperative refractive error using the Rochester nomogram was achieved from the compensation of preoperative higher order aberrations and use of manifest refraction on postoperative spherical equivalent refraction. A significant reduction occurred in the incidence of postoperative overcorrection to 2.8% and range of postoperative spherical equivalent refraction (±1.00 D) following custom LASIK with the Rochester nomogram.
The Rochester nomogram, albeit providing much improved and predictable postoperative refractive outcome, is limited by a multitude of factors that curb further reduction in range of postoperative outcome. These factors can be broadly classified into preoperative factors such as age,\textsuperscript{19} repeatability of manifest refraction, and repeatability and stability of wavefront aberrations\textsuperscript{20,21}; surgical parameters such as laser characteristics,\textsuperscript{22-24} decentration in laser ablation,\textsuperscript{25,26} and eye movements\textsuperscript{27,28}; postoperative factors such as corneal healing response and biomechanics\textsuperscript{10,11,29}; and environmental factors such as temperature and humidity.\textsuperscript{30} A more thorough understanding of the aberration interaction effect between preoperative higher order aberrations and sphere and cylinder should enable better treatment options on eyes that suffer from increased higher order aberrations and irregular corneas (after corneal graft, after refractive surgery, keratoconus, etc). The aberration interactions derived from our data analyses on the Zyoptix FDA trial eyes were also validated by optical convolution methods. Based on our work, we believe that preoperative higher order aberrations may affect sphere and probably cylinder. The relationship between higher order aberrations and cylinder is the subject of a future report. However, we express caution
in using the Rochester nomogram across different laser platforms because of the differences in the algorithms to measure and treat higher order aberrations.

REFERENCES


