Visual quality improvement in refractive surgery
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Citation for published version (APA):

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ADVANCED PERSONALIZED NOMOGRAM FOR MYOPIC LASER SURGERY: FIRST 100 EYES
PURPOSE: To report the results in the first 100 eyes treated for myopia using a new advanced nomogram.

SETTING: Private refractive surgery clinic.

METHODS: This prospective interventional case series comprised 58 patients (100 eyes) consecutively treated for myopia with laser in situ keratomileusis (LASIK) or laser-assisted subepithelial keratectomy (LASEK) performed by the same surgeon. All treatments used a new nomogram for the Zyoptix 217 Z100 excimer laser. Postoperative mean sphere, cylinder, and spherical equivalent (SE) refraction were evaluated 3 months postoperatively. Safety, efficacy, and predictability were also evaluated.

RESULTS: In the LASIK group (34 eyes), the mean postoperative sphere was +0.18 diopters (D) ± 0.47 (SD), the mean postoperative cylinder was -0.10 ± 0.23 D, and the mean postoperative SE was +0.04 ± 0.36 D. In the LASEK group (64 eyes), the respective means were +0.10 ± 0.22 D, -0.05 ± 0.13 D, and +0.03 ± 0.16 D. Hyperopic overcorrection (> +1.00 D) occurred in 4.1% of patients. Ninety-five percent of eyes in the LASIK group and 97% of eyes in the LASEK group had an uncorrected visual acuity of 1.0 (20/20) or better. Patient satisfaction was slightly higher than that of other laser refractive surgery patients at the clinic.

CONCLUSIONS: The use of the advanced nomogram increased treatment accuracy in terms of UCVA and postoperative mean refraction and reduced the rate of hyperopic overcorrection over that in earlier studies. The need for enhancement procedures was reduced, and patient satisfaction was high.

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Journal of Cataract Refractive Surgery 2008; 34:1881–1885; 2008 ASCRS and ESCRs
Customized laser treatment for myopia is an accepted method for treatment of refractive errors. Customized treatments correct the spherical and cylindrical refractive errors as well as higher-order aberrations (HOAs).\textsuperscript{1–5}

Even though the outcomes with wavefront technology are good, some treatments result in overcorrection or undercorrection. Analysis of results shows that hyperopic overcorrections occur in approximately 1 in 4 patients; 8% of these eyes require retreatment.\textsuperscript{5}

In the treatment of the spherocylinder, the nomograms used incorporate an adjustment in which the spherical component is routinely decreased in the treatment to offset changes the cylindrical treatment might have on the sphere. This is called the coupling effect.\textsuperscript{6}

In wavefront ablations, some hyperopic overcorrections are induced from the effect of the treatment of preoperative HOAs on postoperative lower-order aberrations (LOAs) (sphere and cylinder) that were not compensated for in the nomogram.\textsuperscript{5,7} The Advanced Personalized Technology (APT) nomogram, or Rochester nomogram, takes into account the effect the treatment of the preoperative HOAs has on sphere or cylinder and thus induces less postoperative hyperopia. This could be viewed as a type of coupling effect between the preoperative HOA and the postoperative LOA (ie, the sphere and cylinder).\textsuperscript{5,7} The nomogram also incorporates the preoperative manifest refraction and J0/J45 astigmatic terms to improve accuracy.

The Rochester nomogram was developed by Subbaram and MacRae.\textsuperscript{5} In other wavefront platforms, the correlation between the effects of treating the preoperative HOA and the resulting postoperative hyperopic overcorrections have also been noted.\textsuperscript{8–10} Durrie et al.\textsuperscript{8} and Kermani et al.\textsuperscript{9} describe similar adjustments to their nomograms that reduced the rate of postoperative hyperopic overcorrections.

We report our experience with the first 100 eyes treated with the APT nomogram for myopia at our refractive center.

**PATIENTS AND METHODS**

The first 100 consecutive eyes treated for myopia with the APT nomogram were analyzed. All treatments took place at the beginning of 2007.

**Preoperative Patient Examinations**

All patients had a slitlamp biomicroscopic examination, automated keratometry, manifest refraction, tonometry, corneal topography and pachymetry (Orbscan Iiz topographer, Bausch & Lomb), wavefront measurement and pupillometry (Zywave version 5.2, Bausch & Lomb), and dilated fundus examination.

Visual acuity was tested in a high-contrast condensed 3 m lane with Early Treatment of Diabetic Retinopathy Study (ETDRS) charts and recorded in metric standard. Patients were tested without contact lenses and were instructed to stop wearing the contact lenses 2 weeks before the examination. All patients received verbal and written information and signed informed consent forms.
Ultrasonic pachymetry was performed when indicated (corneas ≤ 470 mm on Orbscan). Patients who were not good candidates for laser in situ keratomileusis (LASIK) or laser-assisted subepithelial keratectomy (LASEK) were excluded from treatment according to the guidelines set by the consensus of the Netherlands Society for Refractive Surgery.

**Wavefront Examination**
Five automated Zywave aberrometer measurements were performed, and the best one was chosen. Undilated and dilated (tropicamide 0.5%) wavefront examinations were performed. The pupils of the undilated wavefront examinations were matched for the iris-registration and eye-trackers settings. The dilated examinations were chosen for the wavefront treatment parameters.

**Patient Satisfaction**
Patients were asked to complete a satisfaction questionnaire on a voluntary basis. The questionnaire was part of the clinic’s quality-control system.

On the questionnaire, patients were asked to grade their satisfaction with their visual outcomes on a scale from 0 (bad) to 10 (excellent). The results were compared with those of other patients who had laser surgery during the same period but with a different nomogram. Because the questionnaire was voluntary and was not administered in a randomized masked fashion, the data were not statistically analyzed.

**Surgical Technique**
All LASEK and LASIK procedures were performed by the same surgeon (R.L.G.). Room temperature was between 19°C and 21°C and humidity, between 28% and 34%. The same excimer laser (Zyoptix 217 Z100, Bausch & Lomb) with Keracor 3.21 Dataware, treatment calculator 2.38, and Zywave software version 5.2 was used.

In all LASIK cases, a Zyoptix XP 120 microkeratome (Bausch & Lomb) was used. Laser-assisted subepithelial keratectomy was performed with 20% alcohol solution for 30 seconds. The epithelium was returned to the stromal bed in all cases.

For ablation profiles deeper than 100 mm, mitomycin-C 0.02% was applied for 12 seconds and then irrigated with 30 cc of a balanced salt solution.

**Statistical Analysis**
Statistical analysis was performed using the statistical functions of Excel Windows 2000 (Microsoft Corp.)

**RESULTS**

**Preoperative Data**
One hundred eyes of 58 patients were treated. There were 36 eyes (19 patients) in the LASIK group and 64 eyes (39 patients) in the LASEK group. Fifty percent in the LASIK group and 52% in the LASEK group were women.
In the LASIK group, 25% of eyes had a spherical equivalent (SE) refractive error up to -2.0 diopters (D), 41% between -2.0 D and -4.0 D, 41% between -4.0 D and -6.0 D, and 3% greater than -6.0 D. In the LASEK group, 9% of eyes had an SE refractive error up to -2.0 D, 48% between -2.0 D and -4.0 D, 30% between -4.0 D and -6.0 D, and 13% greater than -6.0 D.

Table 1 shows the preoperative mean sphere, cylinder, and SE refraction in the LASIK and LASEK groups. No eye had a best corrected visual acuity (BCVA) of 1.6 preoperatively. Eleven eyes had a BCVA of 1.25 (20/16), and 82 had a BCVA of 1.0 (20/20). One eye had a BCVA of 0.63 (20/30), 2 eyes of 0.8 (20/25) and 4 eyes of 0.9 (20/22).

**Postoperative Data at 3 Months**

Efficacy Table 2 shows the major outcome indices. The efficacy index was 1.13 in the LASIK group and 1.26 in the LASEK group.

Ninety-five percent of eyes in the LASIK group and 97% of eyes in the LASEK group had an uncorrected visual acuity (UCVA) of 1.0 (20/20) or better. Figure 1 shows the postoperative UCVA compared with the preoperative BCVA.

Predictability Figure 2 shows the percentage of eyes within ±1.00 D, ±0.50 D, and ±0.25 D of the target SE refraction at 3 months. Postoperatively, 90.0% of eyes in the LASIK group and 93.7% of eyes in the LASEK group were within ±0.25 D of the target refraction.
Figure 1. Postoperative UCVA compared with preoperative BCVA (BCVA = best corrected visual acuity; LASEK = laser-assisted subepithelial keratectomy; LASIK = laser in situ keratomileusis; UCVA = uncorrected visual acuity; VA = visual acuity).

Figure 2. Predictability of LASIK and LASIK for +1.0 D, +0.5 D, and +0.25 D (LASEK = laser-assisted subepithelial keratectomy; LASIK = laser in situ keratomileusis).

Figure 3. Safety in terms of lines lost and gained in percentages (LASEK = laser-assisted subepithelial keratectomy; LASIK = laser in situ keratomileusis).

Safety

The safety index was 1.19 in the LASIK group and 1.27 in the LASEK group. Figure 3 shows the lines of UCVA gained or lost compared with the preoperative BCVA. In some cases, lost lines were regained after enhancement procedures.

Four eyes had a significant hyperopic overcorrection (>1.0 D); 2 eyes (1 patient) were in the LASIK group and 2 (1 patient), in the LASEK group. The rate of hyperopic correction was 4.1%, 5.8% in the LASIK group and 3.2% in LASEK group (Table 3).
Follow-up Compliance

Ninety-seven percent of eyes were seen at the 3-month follow-up. Two eyes with LASIK (1 patient) and 1 eye with LASEK were lost to follow-up. When contacted by telephone, the patients reported that they were satisfied and doing well but declined a follow-up visit.

Patient Satisfaction

Twenty-five (43%) of 58 patients completed the voluntary questionnaire. The mean grade was 9.52. Fifty other patients who had laser treatment during the same period with other nomograms filled out the questionnaire; the mean grade was 9.01.

Mitomycin C

Mitomycin-C was applied in 2 eyes of 2 patients. One of the eyes was lost to follow-up; in the other eye, the postoperative UCVA was 1.25 and no haze was seen.

DISCUSSION

In our study, the ATP nomogram, also known as the Rochester nomogram, provided accurate refractive outcomes. Ninety-five percent of LASIK treated eyes and 97% of LASEK-treated eyes achieved a postoperative UCVA of 1.0 (20/20). In a study of the Rochester nomogram by Subbaram and MacRae, 91.5% of eyes were within $\pm 0.50$ D of the target refraction and 100% were within $\pm 1.00$ D. In the Zyoptix U.S. Food and Drug Administration (FDA) trial, 72.6% of eyes were within $\pm 0.50$ D and 90.2% were within $\pm 1.00$ D. In a study by Kohnen et al. of the Zyoptix 3.1 nomogram, 77% of eyes were within $\pm 0.50$ D of target refraction at 1 year and 95% were within $\pm 1.00$ D.

In our study, 93.0% of eyes in the LASIK group were within $\pm 0.50$ D of the target refraction and 97.0% were within $\pm 1.00$ D. In the LASEK group, 95.2% were within $\pm 0.50$ D and 98.4% were within $\pm 1.00$ D. These outcomes reflect the high predictive accuracy of the advanced nomogram.

**Table 3:** Comparison of post-operative mean refractive data, efficacy, and hyperopic overcorrection rates between studies.

<table>
<thead>
<tr>
<th>Study</th>
<th>Mean $\pm$ SD</th>
<th>Percentage</th>
<th>Hyperopic Overcorrection</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Sphere (D)</td>
<td>SE (D)</td>
<td>% $\geq$ 20/20</td>
</tr>
<tr>
<td>Rochester (APT)</td>
<td>+0.04 $\pm$ 0.33</td>
<td>-0.11 $\pm$ 0.34</td>
<td>93.1</td>
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<tr>
<td>FDA trial</td>
<td>+0.31 $\pm$ 0.53</td>
<td>+0.15 $\pm$ 0.53</td>
<td>89.3</td>
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<tr>
<td>Current</td>
<td></td>
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<tr>
<td>LASIK</td>
<td>+0.18 $\pm$ 0.47</td>
<td>+0.04 $\pm$ 0.36</td>
<td>95.0</td>
</tr>
<tr>
<td>LASEK</td>
<td>+0.10 $\pm$ 0.22</td>
<td>+0.03 $\pm$ 0.16</td>
<td>97.0</td>
</tr>
</tbody>
</table>

FDA = U.S. Food and Drug Administration; LASIK = laser in situ keratomileusis; LASEK = laser-assisted subepithelial keratectomy; SE = spherical equivalent *Overall rate, 4.1%
The FDA Zyoptix study used a wavefront nomogram without the spherical correction for the treatment of the HOAs. The study found consecutive hyperopia in 22.3% of cases, one third of which required an enhancement (Table 3). Subbaram and MacRae report a hyperopic overcorrection (>1.0 D) in 2.8% of patients treated with the advanced nomogram. Our study confirms this low rate of hyperopic overcorrection. We had a slightly higher rate (4.1%) of overcorrection. This may be a coincidence or because our study included 100 eyes, while Subbaram and MacRae’s study comprised 175 eyes. It may also be because we had not inserted our own offset factor into the nomogram. Our results were slightly hyperopic in the first 100 eyes. A simple sphere adjustment would probably alleviate this.

The SE postoperative outcomes of +0.04 D and +0.03 D are very close to plano. The standard deviations of these results, of 0.36 D and 0.16 D, respectively, are close to and below the repeatability of the manifest refraction. This means that the advanced personalized nomogram is highly accurate. In clinical practice, this was matched by patient satisfaction.

The differences in outcomes and results between the LASIK group and the LASEK group were small. Discussion of the preferential treatment mode of LASIK versus LASEK is beyond the scope of this paper; thus, these data were not explored or discussed.

The greater accuracy of the nomogram decreased the retreatment rate. The lower retreatment rate increased patient safety and satisfaction. The good efficacy and safety rates in our study reflect the improved postoperative UCVA in our patients. Similar indices were reported by Durrie et al. on the Alcon platform.

Both patients with hyperopic overcorrection were men in their mid-40s. No preoperative risk factor for hyperopic overcorrection could be identified. Further study is needed to determine whether specific clinical characteristics can predict which groups of patients are at risk for hyperopic correction even when the adjusted nomogram is used.

We used the wavefront measurements with the eye pharmacologically dilated for matching with the advanced nomogram. Subbaram and MacRae report that pharmacological pupil dilation may cause a pupil shift, which may cause changes on the wavefront that can be clinically significant. Although the wavefront changes significantly as the pupil dilates and there is an increase in HOAs with wider pupils, the advanced personalized nomogram has a feature in which a measured pupil with a corresponding wavefront can be mathematically extrapolated for a pupil with a 10% larger diameter. This could make it possible to perform wavefront examinations with the pupil undilated, without the need for examination with the pupil dilated. In our clinic, the protocol requires that we perform both undilated and dilated wavefront examinations; we use the pharmacologically dilated wavefront measurements in the actual treatment. The Zywave prediction of phoropter refraction is usually more myopic than the subjective refraction. This effect of instrument myopia is alleviated with cycloplegia. That we use dilated wavefront data with minor cycloplegia may, in theory, affect the hyperopic overcorrection and account for the low rate of hyperopic
overcorrection in our patients. This requires further study. Long-term stability and the possibility for refinement of the advanced nomogram must also be studied.

In conclusion, we found the ATP to be a highly accurate nomogram for treating myopia, leading to SE refractions that were close to plano as well as high patient satisfaction.

REFERENCES


7. Subbaram MV, MacRae SM. Does dilated wavefront aberration measurement provide better postoperative outcome after custom LASIK? Ophthalmology 2006; 113:1813–1817


