One-year Results of Custom Laser Epithelial Keratomileusis With the Nidek System

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ABSTRACT

PURPOSE: To evaluate long-term results of custom laser epithelial keratomileusis (LASEK) for correction of myopia and hyperopia using the Custom Ablation Transition Zone (CATz) software and hyaluronic acid masking fluid (Laservis) for final corneal smoothing.

METHODS: We conducted a prospective study of 297 eyes of 167 patients. All eyes had LASEK for correction of myopia or hyperopia. The Nidek EC-5000 excimer laser, FinalFit software, and CATz ablation profile was used in all eyes. Laservis was used as masking fluid to remove corneal micro-irregularities during the final phase of the treatment.

RESULTS: Mean preoperative spherical equivalent refraction was -5.46 ± 2.57 D (range -14.13 to +3.50 D). At 1 year after LASEK, mean spherical equivalent refraction was -0.15 ± 0.50 D (range -4.00 D to +1.00 D).

CONCLUSIONS: LASEK with the Nidek EC-5000 excimer laser, FinalFit and Custom Ablation Transition Zone (CATz) software, with corneal smoothing, was safe and effective at 1 year after surgery. [J Refract Surg 2004;20(suppl):S699-S704]

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Aberrometry-based custom excimer laser ablation to correct refractive error is now entering its mature phase, with a steady number of positive reports.1-5 However, several factors may still play a role in hindering full achievement of planned refractive results. Irregularities of the ablated corneal surface may enhance collagen deposition and therefore affect the final refractive result.6-8 On the contrary, a smooth ablated surface induces less refractive response, leading to less haze formation and better refractive predictability.6,9 We introduced corneal smoothing in the final phase of refractive treatment, based on results in previous studies in 1998.6,9

The transition zone is particularly important for the creation of a new optical surface with excimer laser ablation. This zone makes the transition between the new central and the unchanged peripheral corneal curvatures. After excimer laser refractive surgery, marked variation of curvature in this peripheral portion may induce a reparatory response that physiologically reduces this curvature variation but may also induce regression and restriction of the effective optical zone.

We considered the aforementioned concepts and the results of our previous studies and designed a surface corneal ablation strategy for custom laser epithelial keratomileusis (LASEK) to increase predictability by reducing the biomechanical and reparative responses of the cornea. We present 1-year results of our prospective study of custom LASEK.

PATIENTS AND METHODS

We prospectively evaluated myopic and hyperopic eyes that had LASEK. All patients were 18 years of age or older. Exclusion criteria included systemic, metabolic, or collagen diseases, tear film defects, and topographic asymmetry features that could indicate the presence of a form frustes keratoconus.

All patients underwent complete preoperative ophthalmologic examination, cycloplegic refraction, pupillometry, endothelial cell count, corneal topography with C.S.O. topographer (C.S.O., Florence, Italy), and evaluation with the Nidek OPD aberrometer (Nidek, Gamagori, Japan). All patients signed an informed consent document. All patients received oral supplements containing amino acids starting 1 week after surgery until re-epithelialization was complete.10 The butterfly LASEK technique was used for all eyes.11,12

Surgery was performed with the Nidek EC-5000 excimer laser (Nidek, Gamagori, Japan), by the
Table
Refraction Before and After LASEK With Smoothing, Using the Nidek EC-5000 Laser With FinalFit and CATz

<table>
<thead>
<tr>
<th></th>
<th>Preoperative (297 eyes)</th>
<th>1 mo (207 eyes)</th>
<th>3 mo (207 eyes)</th>
<th>6 mo (112 eyes)</th>
<th>12 mo (95 eyes)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean sphere (D) ± SD</td>
<td>-5.03 ± 2.57</td>
<td>0.12 ± 0.65</td>
<td>0.08 ± 0.54</td>
<td>0.00 ± 0.46</td>
<td>-0.05 ± 0.50</td>
</tr>
<tr>
<td>Range (D)</td>
<td>-13.50 to +4.00</td>
<td>-3.00 to +2.00</td>
<td>-2.50 to +2.00</td>
<td>-3.00 to +1.00</td>
<td>-3.00 to +1.00</td>
</tr>
<tr>
<td>Mean cylinder (D) ± SD</td>
<td>-0.88 ± 0.76</td>
<td>-0.39 ± 0.82</td>
<td>-0.17 ± 0.55</td>
<td>-0.15 ± 0.35</td>
<td>-0.21 ± 0.41</td>
</tr>
<tr>
<td>Range (D)</td>
<td>-4.50 to +1.00</td>
<td>-1.00 to +1.50</td>
<td>-1.00 to +1.00</td>
<td>-1.50 to +1.00</td>
<td>-1.50 to +0.00</td>
</tr>
<tr>
<td>Mean spherical equivalent refraction (D)</td>
<td>-5.46 ± 2.57</td>
<td>-0.08 ± 0.72</td>
<td>-0.03 ± 0.56</td>
<td>-0.08 ± 0.48</td>
<td>-0.15 ± 0.50</td>
</tr>
<tr>
<td>Range (D)</td>
<td>-14.13 to +3.50</td>
<td>-4.00 to +3.00</td>
<td>-2.75 to +2.00</td>
<td>-3.50 to +1.75</td>
<td>-4.00 to +1.00</td>
</tr>
</tbody>
</table>

Figure 1. FinalFit ablation software with Custom Ablation Transition Zone (CATz) software. Ablation includes a component for treatment of spherical error (radial symmetric aberrations), a toric component for treatment of astigmatism (linear symmetric aberrations), and a flying spot component for treatment of high order aberrations (irregular components).

same surgeon (PV), with incorporation of FinalFit ablation software, featuring the Nidek Custom Ablation Transition Zone (CATz) software, on the basis of topographic and aberrometric data. Ablation included an aspherical component for treatment of the spherical defect (radially symmetric aberrations), a toric component for treatment of astigmatism (linearly symmetric aberrations), and a flying spot component for treatment of high order aberrations (irregular components) (Fig 1). The transition zone diameter was 10 mm.

Information on surface and total aberrometry
generated in photopic, scotopic, and mesopic conditions by the Nidek OPD integrated aberrometer, refractometer, topographer, and pupillometer, was integrated through FinalFit software to provide a complete aberrometric optimization of the ablated corneal profile. The CATz ablation pattern of the FinalFit software optimizes in the central 4.5 mm all OPD-detected ocular aberrations, particularly spherical aberration. The curvature of the remaining cornea is then gradually modified in order to achieve a constant curvature gradient up to the external 10-mm margin of the ablation, maintaining at the same time the best possible reduction of ocular aberrations. An advanced use of FinalFit was adopted for custom ablation in our study. The segmental ablation for treatment of high order components was applied first. This part of the treatment may change both axis and power of the cylinder, thus at this point, the new axis and astigmatism power were estimated. Finally, the resulting spherical component to be treated was calculated.

After ablation, smoothing was performed to remove corneal micro-irregularities smaller than the spot size (0.89 mm) and to the height of ablation (0.25 μm), in order to achieve a regular stromal bed, as similar as possible to the physiological Bowman's layer. Smoothing was performed by applying a hyaluronic acid masking fluid (Laservis, Chemedica, Munich, Germany), continuously distributed over the corneal surface, with Buratto's spatula. The smoothing diameter was 10 mm, and thus involved the entire ablation diameter. To avoid overheating the tissue, frequency was set at 10 Hz, and ablation depth at 30 μm. After completing the smoothing, the retractor/protector was removed, the epithelial flaps were gently repositioned over the corneal surface, a protective contact lens was placed in position, and cyclolentolate chlorhydrate 1%, netilmicin sulphate 0.3%, and a tobramycin-dexamethasone combination were administered topically before removal of the lid speculum. All patients underwent a complete ophthalmologic examination with corneal topography at 1, 3, 6, and 12 months.

Refractive data were managed with Datagr@ph Med software (Wendelstein, Germany) and statistical evaluation was performed with Student's t-test.

RESULTS

We treated 297 eyes of 167 patients; 101 (60.5%) patients were females. Mean patient age was 35.0 ± 6.3 years (range 20 to 49 yr). Preoperative and postoperative refraction at all follow-up intervals are presented in the Table and Figure 2. Mean preoperative spherical equivalent refraction was -5.46 ± 2.57 diopters (D), with a range of -14.13 to +3.50 D. At the 1-year examination, mean spherical equivalent refraction was -0.15 ± 0.50 D, with a range of -4.00 to +1.00 D. No eye required retreatment. Two eyes with initial refraction greater than -10.50 D achieved a final, moderately myopic refraction (-3.00 and -4.00 D); this result was targeted preoperatively due to limited corneal thickness and myopia in the fellow eye. Safety of the procedure, assessed by lines of visual acuity gained, unchanged, or lost, is presented in Figure 3. Efficacy, with percentage of uncorrected visual
acuity (UCVA) calculated in LogMAR units is presented in Figure 4. A scattergram of attempted versus achieved correction is presented in Figure 5. Corneal haze, graded according to Epstein, was absent at the 1-year postoperative examination.13

**DISCUSSION**

Customized ablation, either based on surface or total aberrometry, is receiving increasing interest among refractive surgeons. Nevertheless, the target of a perfectly predictable treatment often remains elusive. Several factors may be taken into account when considering the limits of custom ablation. The ablation patterns available with different excimer lasers and the overlapping of their spots generate a corneal surface with micro-irregularities, and these irregularities induced by excimer ablation may cause aberrations.14 After surface ablation, the corneal epithelium attempts to solve macro- and micro-irregularities through several layers of epithelial cells and/or collagen deposition.6,8,9 Variation of curvature in the peripheral portion of the ablation may also lead to collagen deposition, a phenomenon that aims at reducing this unnatural curvature variation, but induces regression. All these factors reduce the predictability of the targeted correction.

Roberts has presented an interesting theory on
the influence of corneal biomechanical properties on refractive result after surface or stromal surgery, proposing that the central severing of elastic corneal lamellae following surface or stromal surgery induces relaxation of the peripheral residual lamellae, decompression of the extracellular matrix, and increase in curvature and thickness of peripheral stroma. This apparently results in tangential traction forces on the underlying lamellae, which in the central cornea constitute the postoperative corneal surface, resulting in a central flattening not related to the ablation profile. This would lead to a hyperopic shift. Results of myopic treatments will thus be increased, and hyperopic ones decreased. This phenomenon will be more marked in laser in situ keratomileusis (LASIK), where the number of severed lamellae is tenfold that in PRK, and contribute to the unpredictability of refractive surgery. In our described surgical approach, we tried to overcome the unpredictability caused by micro-irregularities and corneal biomechanical response.

This surgical method offers several advantages. The amount of tissue removed was limited, even with a wide final transition zone diameter, and it was distributed over most of the corneal surface, reducing the biomechanical effect. The final corneal curvature gradient was constant. In usual myopic ablations, the sudden and marked variation in corneal curvature gradient between the central treated and peripheral untreated cornea is expressed topographically by a red ring, visible on instantaneous algorithm, as well as by the aberro-

metric red ring of spherical aberration. With FinalFit software, the corneal curvature gradient from center to periphery is reduced, made more gradual, and positioned in the extreme periphery, beyond 9 mm, where the cornea is thicker and flatter. Thus, the topographical red ring—not actually red but of cooler colors—will appear of limited width and intensity, and will be peripherally located. Furthermore, spherical aberration will be reduced, providing excellent vision quality, even with dilated pupils.

Apparently, smoothing at the end of surgery provides a regular stromal bed for the corneal epithelium, reducing collagen deposition, as well as haze formation with consequent possible reduction of imparted correction. This has been confirmed by PRK and LASEK studies. The positive results of LASEK reported in this study are comparable with those of other LASEK studies evaluating large number of eyes, as well as comparable to LASEK with postoperative aberrometric analysis.

After the introduction of LASIK, surface refractive surgery has received less interest due to observed regression, haze, and postoperative pain. However, due to possible variations in flap size and thickness, the biomechanical factors at play in LASIK may render custom ablation less predictable, as well as containment of induction of aberrations less effective. The risk of late-onset postoperative corneal ectasia remains a rare but troublesome possibility.

With the advent of LASIK, surface excimer laser refractive surgery was abandoned mostly due to problems related to postoperative pain, haze formation, regression, and poor vision. Nevertheless, it retained part of its interest because it offered advantages such as a wider range of refractive correction and easier retreatments. Apparently, creating a regular postoperative surface with smoothing can contain haze formation, and the regression problem can now to be solved by different management of the transition zone facilitated by better understanding of biomechanical forces at play in the cornea. If confirmed by additional studies, we think the refractive surgery strategy presented in this paper may increase the recently renewed interest in surface refractive surgery.

REFERENCES
2. Gimbel HV, Sofinski SJ, Mahler OS, van Westenbrugge JA,


