# Treatment of Myopia and Myopic Astigmatism by Customized Laser In Situ Keratomileusis Based on Corneal Topography

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***Objective:*** To evaluate the predictability, efficacy, and safety of customized laser in situ keratomileusis (LASIK) based on corneal topography in myopia and myopic astigmatism.

***Design:*** Prospective, noncomparative interventional case series.

***Participants:*** One hundred fourteen patients (eyes) with myopia of −1 to −6 diopters (D) and astigmatism of 0 to −4 D (low myopia group), and 89 patients (eyes) with myopia of −6.10 to −12.00 D and astigmatism of 0 to −4.00 D (high myopia group).

***Intervention:*** LASIK was performed with the Hansatome Microkeratome and the Keracor 217 spot-scanning excimer laser (Bausch & Lomb Surgical Technolas, Munich, Germany). Individual ablation patterns were calculated on the basis of elevation data obtained with the Orbscan II corneal topography system (Bausch & Lomb Surgical, Irvine, CA).

***Main Outcome Measures:*** Manifest spectacle refraction, visual acuity, and change in visual acuity at 3 months after surgery.

***Results:*** At 3 months, 51 patients in the low myopia group and 40 patients in the high myopia group were available. In the low (high) myopia group, 96.1% (75.0%) were within ±0.50 D of emmetropia, and uncorrected visual acuity was 20/20 or better in 82.4% (62.5%), 20/25 or better in 98.0% (70.0%), and 20/40 or better in 100% (95.0%). A loss of two or more lines of spectacle-corrected visual acuity occurred in 3.9% of the low and 5.0% of the high myopia group. In low myopia, spectacle-corrected visual acuity was 20/12.5 or better in 5.9% preoperatively and in 13.7% at 3 months and 20/15 or better in 37.3% and 47.1%, respectively. Differences were statistically significant.

***Conclusions:*** The customized LASIK based on corneal topography used in this study showed high predictability and efficacy in myopia and myopic astigmatism of −1.00 to −6.00 D, and could possibly improve spectacle-corrected visual acuity in myopia of −1.00 to −6.00 D. Predictability and efficacy were somewhat lower in myopia and myopic astigmatism of −6.10 to −12.00 D. In both groups, a small number of patients lost two or more lines of spectacle-corrected visual acuity. *Ophthalmology 2000;107:2072–2076 © 2000 by the American Academy of Ophthalmology.*

Excimer laser surgery provides an accurate tool to reshape the cornea to correct refractive errors.[1–3] Current ablation algorithms are either spherical, some with peripheral transition zones, to correct spherical errors, or elliptical to correct astigmatic errors.[3] They do not allow for customized treatments of corneal irregularities or asymmetries that occur in up to 40% of so-called normal corneas.[4] The recent introduction of spot-scanning excimer lasers provides the technologic platform to perform ablations of any shape.[5] Corneal topography enables us to measure the shape of the individual cornea and possibly to calculate an individualized ablation profile. Could we combine corneal topography and scanning lasers to customize ablations? Experimental results demonstrated the feasibility of this concept,[6] and early clinical data from our group indicated that the concept works clinically, too.[7] We therefore analyzed the predictability, efficacy, and safety of customized laser in situ keratomileusis (LASIK) based on corneal topography in the treatment of myopia and myopic astigmatism.

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## Patients and Methods

### Patient Population

In a prospective, noncomparative case series, we operated on 203 eyes of 203 patients at two different centers (Mannheim, Germany, 51 patients; Munich, Germany, 152 patients) between January 1999 and July 1999. Inclusion criteria were myopia of −1.00 to −12.00 diopters (D) with or without astigmatism of up to −4.00 D. Exclusion criteria were any previous corneal refractive surgery,



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Table 1. Cumulative Spectacle-corrected Visual Acuity before and 3 Months After Customized Laser In Situ Keratomileusis Based on Corneal Topography for Myopia and Myopic Astigmatism of −1.00 to −6.00 Diopters (Group 1, Low Myopia) and Myopia and Myopic Astigmatism of −6.10 to −12.00 Diopters (Group 2, High Myopia)

| | Group 1 (Low Myopia) | | Group 2 (High Myopia) | |
|---|---|---|---|---|
| | *Preoperatively* | *Postoperatively* | *Preoperatively* | *Postoperatively* |
| No. of patients | n = 51 | n = 51 | n = 40 | n = 40 |
| SCVA 20/12.5+ | 5.9% (n = 3) | 13.7% (n = 7)* | 2.5% (n = 1) | 2.5% (n = 1) |
| SCVA 20/15+ | 37.3% (n = 19) | 47.1% (n = 24)† | 32.5% (n = 13) | 30% (n = 12) |
| SCVA 20/20+ | 86.3% (n = 44) | 78.4% (n = 40)‡ | 77.5% (n = 31) | 72.5% (n = 29) |
| SCVA 20/25+ | 98.0% (n = 50) | 98.0% (n = 50) | 95.0% (n = 38) | 90.0% (n = 36) |
| SCVA 20/40+ | 100% (n = 51) | 100% (n = 51) | 100% (n = 40) | 100% (n = 40) |

SCVA = spectacle-corrected visual acuity.

*$P = 0.0002$.

†$P = 0.01$.

‡$P = 0.01$.

corneal scars, chronic corneal diseases such as keratoconus, cataract, amblyopia, and macular degeneration. All patients were informed as to the nature of our study, and written consent was obtained before surgery. The study was approved by the institutional review board of the faculty of clinical medicine Mannheim of the University of Heidelberg. The 203 patients were divided into two groups.

Group 1 (low myopia) consisted of 114 patients with myopia of −1.00 to −6.00 D (mean, −3.83 ± 1.67 D) and astigmatism of 0 to −4.00 D (mean, −1.32 ± 1.06 D). Spectacle-corrected visual acuity was 20/12 or better in 5.9%, 20/15 or better in 37.3%, 20/20 or better in 86.3%, 20/25 or better in 98%, and 20/40 or better in 100% preoperatively (Table 1).

Group 2 (high myopia) consisted of 89 patients with myopia of −6.10 to −12.00 D (mean, −7.83 ± 1.38 D) and astigmatism of 0 to −3.50 D (mean, −1.06 ± 0.92 D). Spectacle-corrected visual acuity was 20/12 or better in 2.5%, 20/15 or better in 32.5%, 20/20 or better in 77.5%, 20/25 or better in 95%, and 20/40 or better in 100% preoperatively (Table 1).

## Surgical Technique

Surgery was performed by two surgeons (MCK, Mannheim; TH, Munich) using topical anesthesia (0.4% oxybuprocaine). The Hansatome microkeratome (Bausch & Lomb Surgical, St. Louis, MO) was used to cut an 8.5-mm hinged flap. The 160-$\mu$m thickness plate was used in all eyes. After the cut, suction was released, and the corneal flap was then carefully displaced upward using a blunt spatula. The coaxial helium-neon-laser of the Keracor 217 excimer laser (Bausch & Lomb Surgical Technolas, Munich, Germany) was centered over the middle of the entrance pupil, and the eye tracker was turned on. The eye tracker, developed by Bausch & Lomb Surgical Technolas, Munich, Germany, uses an infrared video camera to capture the image of the pupil and automatically follows the movements of the eye. Maximum off-center distance was limited to 1.5 mm, because larger decentrations will cause ovalization of the treatment beam with consecutive loss of energy. Repetition rate of the tracking system was about 150 Hz for the maximum off-center distance of 1.5 mm and higher for smaller deflections. The stromal bed was neither irrigated nor dried to avoid changes in hydration, but fluid accumulating at the hinge during the ablation was removed with a Merocel sponge (Merocel Inc., Mystic, CN). After the ablation, the back of the flap and the stromal bed were irrigated and the flap was replaced. Once the flap was aligned, we waited for 2 minutes to ensure proper adhesion. After surgery, gentamicin (3 mg/1 ml) and dexamethasone (1 mg/ml) eyedrops were administered, and the eye was covered with a hard shield for the first night. Topical treatment with gentamicin and dexamethasone eyedrops (one drop three times daily) was continued for 5 days and then discontinued.

## Corneal Topography and Calculation of Ablation

The ablation was based on the preoperative corneal topographic map obtained with the Orbscan II corneal analysis system (Bausch & Lomb Surgical, Irvine, CA). Three different maps were taken, and the one featuring the fewest eye movements was used. The maximum movements considered acceptable was 200 $\mu$m. Patients who did not comply with this requirement because of poor cooperation were excluded. Once the topography was taken, data were copied and a technician from Bausch & Lomb Surgical Technolas, Munich, Germany, calculated the ablation profile on site using a special software called TopoLink (Version 2.9992TL; Bausch & Lomb Surgical Technolas, Munich, Germany). Input values were manifest refraction in minus cylinder format and corneal thickness as measured by the Orbscan II. The target K-value was determined by the software by subtracting the manifest sphere from the K-value in the steep corneal meridian. The target K-value and a preset shape factor of −0.25 defined the target asphere that we planned to achieve after LASIK. The TopoLink software basically compares the shape of the target asphere to the corneal shape actually measured. Simplified, the target shape is fitted from beneath to the actual cornea for a given planned optical zone size. The difference between the two shapes is then ablated. Any "overlap" between target and actual shape must thus be outside the planned optical zone, because tissue cannot be "added" but ablated only. The TopoLink software therefore represents a new and different approach that is not based on Munnerlyn's formula. It rather calculates a certain "lenticle" of corneal tissue to be removed, and the scanning laser used provides the means to remove this tissue even if its shape is asymmetric or even irregular. The diameter of the planned optical zone was 6 to 7 mm. Only in cases in which the ablation required to achieve these optical zones would have left a residual corneal stromal bed of less than 250 $\mu$m was the diameter of the planned optical zone decreased to maintain a residual stromal bed of at least 250 $\mu$m.

On the basis of these data, TopoLink calculated a session file that basically contained information for the scanning laser regarding which ablation pattern to perform. The session file was transferred by disc and loaded into the Keracor 217 excimer laser just

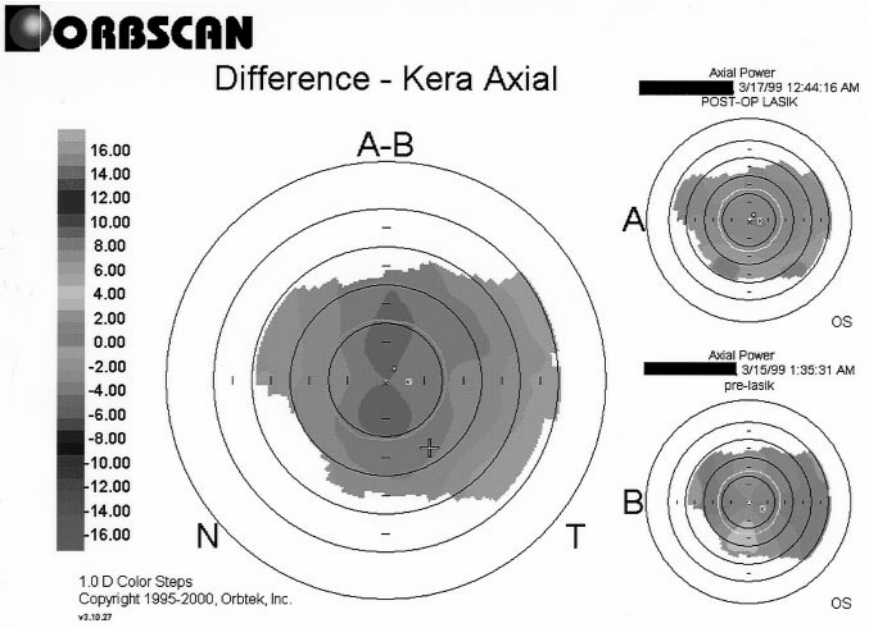


**Figure 1.** TopoLink laser in situ keratomileusis (LASIK) in asymmetric with-the-rule astigmatism. The preoperative map, lower right, shows that the inferior half-meridian is steeper than the superior half-meridian. One day postoperatively, upper right, the asymmetry is no longer visible. The difference map is shown on the left. All maps show tangential keratometric power in 1.00-diopter (D) color steps (Orbscan II topography system).

before treatment. We also received a pictorial, depicting the preoperative corneal topographic map (scale in diopters), the calculated ablation (as a color-coded map, scale in micrometers), and the predicted postoperative corneal topography map (scale in diopters).[7]

We used the Keracor 217 excimer laser. This laser uses a 2-mm beam that is scanned across the cornea at a shot frequency of 50 Hz. It was modified by including an aperture that allows the use of both a 1-mm beam and a 2-mm beam. We used the "TopoLink" software as stated before, which is not commercially available yet. This software splits the total ablation into several (four to eight) cycles. During the first two to four cycles, a 2-mm scanning spot is used; during the remaining two to four cycles, a 1-mm scanning spot is used.

### Manifest Refraction and Visual Acuity

All patients were examined preoperatively, 1 day, 1 month (range, 3–6 weeks), and 3 months (range, 2–4 months) postoperatively. Patients were called immediately in case they missed one scheduled visit to ascertain examination within the respective follow-up periods. We measured subjective spectacle refraction. Uncorrected and spectacle-corrected visual acuity were tested by use of projection charts (Rodamat, Rodenstock, Munich, Germany). Visual loss was calculated as the difference in line number on a logarithmic scale. For each group, the percentages of eyes gaining or losing lines were calculated. All data were recorded on prospectively completed data forms. Statistical analysis was performed using the *t* test.

## Results

Figure 1 gives an example of an eye with slightly asymmetric with-the-rule astigmatism. The inferior half-meridian is steeper than the superior half-meridian (Fig 1, lower right). After TopoLink LASIK, the asymmetry is no longer visible (Fig 1, upper right). No reoperations were performed in these series, and no complications occurred. Follow-up was incomplete in some patients, because patients lived far from the surgical centers and refused to travel for follow-up visits several times.

Manifest refraction and visual acuity data of both groups at 1 and 3 months are given in Table 2. In low myopia, 96.1% were within ±0.50 D, and 82.4% saw 20/20 or better without correction at 3 months. In high myopia, 75.0% were within ±0.50 D, and 62.5% saw 20/20 or better without correction at 3 months. In the low myopia group, two eyes (3.9%) had lost two lines of spectacle-corrected visual acuity, and in the high myopia group one eye (2.5%) had lost two lines and one eye (2.5%) had lost three lines at 3 months.

Spectacle-corrected visual acuities before customized LASIK and at 3 months are compared in Table 1. In low myopia, spectacle-corrected acuity at the higher levels improved compared with preoperative values, and 13.7% (n = 7) had a spectacle-corrected visual acuity of 20/12.5 or better, and 47.1% (n = 24) saw 20/15 or better after customized LASIK compared with the preoperative values of 5.9% (n = 3) and 37.3% (n = 19), respectively. Differences were statistically significant (Table 1). However, comparing mean values (log scale) of spectacle-corrected visual acuity, differences were not significant ($P = 0.2$).

## Discussion

In our study, we used the concept of customized ablations based on corneal topography. The feasibility of this concept was proved experimentally[6] and by our initial clinical results.[7] We used LASIK instead of surface ablation to exclude the possible influence of epithelial thickness, which tends to be nonuniform in postsurgical corneas, and to minimize the healing change and the scarring often associated with repeated surface ablations.[8,9]

Table 2. Refraction, Visual Acuity, Change of Visual Acuity 1 and 3 Months after Customized Laser In Situ Keratomileusis Based on Corneal Topography for Myopia and Myopic Astigmatism of −1.00 to −6.00 Diopters (Group 1, Low Myopia) and Myopia and Myopic Astigmatism of −6.10 to −12.00 Diopters (Group 2, High Myopia)

| | Group 1 (Low Myopia) | | Group 2 (High Myopia) | |
|---|---|---|---|---|
| **Follow-up** | *1 Month* | *3 Months* | *1 Month* | *3 Months* |
| No. of patients | n = 91 | n = 51 | n = 55 | n = 40 |
| Refraction ±0.50 D of target | 91.2% (n = 83) | 96.1% (n = 49) | 70.9% (n = 39) | 75.0% (n = 30) |
| Refraction ±1.00 D of target | 100% (n = 91) | 100% (n = 51) | 100% (n = 55) | 90.0% (n = 36) |
| UCVA 20/20 or better | 59.3% (n = 54) | 82.4% (n = 42) | 52.7% (n = 29) | 62.5% (n = 25) |
| UCVA 20/25 or better | 81.3% (n = 74) | 98.0% (n = 50) | 76.4% (n = 42) | 70.0% (n = 28) |
| UCVA 20/40 or better | 100% (n = 91) | 100% (n = 51) | 92.7% (n = 51) | 95.0% (n = 38) |
| Change of SCVA +3 lines | 0% | 0% | 0% | 0% |
| Change of SCVA +2 lines | 0% | 2.0% (n = 1) | 3.6% (n = 2) | 2.5% (n = 1) |
| Change of SCVA +1 line | 17.6% (n = 16) | 31.4% (n = 16) | 16.4% (n = 9) | 15.0% (n = 6) |
| Change of SCVA 0 lines | 54.9% (n = 50) | 43.1% (n = 22) | 50.9% (n = 28) | 55.0% (n = 22) |
| Change of SCVA −1 line | 24.2% (n = 22) | 19.6% (n = 10) | 23.6% (n = 13) | 22.5% (n = 9) |
| Change of SCVA −2 lines | 3.3% (n = 3) | 3.9% (n = 2) | 3.6% (n = 2) | 2.5% (n = 1) |
| Change of SCVA −3 lines | 0% | 0% | 1.8% (n = 1) | 2.5% (n = 1) |

D = diopters; SCVA = spectacle-corrected visual acuity (change of SCVA compared with preoperative levels reported); UCVA = uncorrected visual acuity.

A customized ablation should theoretically be superior to a standard ablation, because it addresses the corneal asymmetries that are present in about 40% of human corneas.[4] Treating these asymmetries and irregularities should improve vision beyond the levels achievable with a standardized ablation. Our results must therefore be compared with those of others using standardized ablations, and we must compare preoperative and postoperative levels of spectacle-corrected visual acuity to establish possible improvements.

Only a few large series are reported in the literature. Stulting et al[10] reported the incidence of complication in 1062 eyes of 574 patients with myopia of −2.00 to −22.50 D and astigmatism up to 4.00 D. Gimbel et al[11] reported the results of 775 patients at 3 to 6 months with myopia of −1.00 to −19.25 D treated with simultaneous bilateral LASIK. Our results cannot be compared with these series, because we included myopia up to −12.00 D only.

Montes et al[12] reported a comparable series of 396 eyes with myopia of −1.00 to −6.00 D and astigmatism up to 4.00 D treated with the Nidek EC-5000 excimer laser. Of 220 eyes available at 3 months, 92% were within ±0.50 D and 99% within ±1.00 D, 78% saw 20/20 or better, 93% saw 20/25 or better, and 100% 20/40 or better without correction. At 6 months, none of the eyes had lost two or more lines of spectacle-corrected visual acuity. Our results at three months were slightly better only (Table 1), and we observed a loss of two lines in 3.9% (Table 1). However, their study included retreatments, whereas no retreatments were performed in our series.

Besides comparing predictability and efficacy to other studies, we must also look at changes in spectacle-corrected visual acuity compared with preoperative levels. The cited studies did not compare these data. In our study, we found that a significantly larger percentage of patients saw 20/12.5 or 20/15 3 months postoperatively than preoperatively in the low myopia group (Table 1), which may indicate an improvement of spectacle-corrected visual acuity caused by the customized LASIK. In the high myopia group, no improvement was observed, whereas a one-line improvement should be expected because of higher magnification.[13] The lack of improvement in the high myopia group is most likely because corneal refractive surgery in high myopia causes a significant decrease in optical quality of the eye and, consequently, in quality of vision because of the relationship of optical zone size, reversed asphericity, and pupil size.[14,15] Because the diameter of the ablation zone size and thus the optical zone is limited because of the need to avoid an excessive ablation depth, even customized ablations cannot produce perfect optical quality in high myopia. In low myopia, ablation depth and thus the diameter of the optical zone are not limiting factors, and customized ablations may thus be able to improve spectacle-corrected visual acuity beyond the preoperative levels.

There are several limitations to our study. First, follow-up was not available in a considerable number of patients to date, which biases our data. Second, we did not perform a randomized masked trial and are therefore unable to conclude whether customized ablations based on corneal topography are superior to standard ablations. Third, we included all patients undergoing corneal refractive surgery for the first time, which means that many of them had perfectly symmetric aspherical corneas and would fare as well with a standard ablation. On the other hand, we were able to demonstrate that the new approach, to customize ablation based on corneal topography, works clinically at least as well as a standard ablation in normal eyes. This is a significant finding, because our approach is based on a totally different calculation of the ablation: instead of ablations based on Munnerlyn's formula, we defined a target asphere and ablated the difference between this target and the actual cornea. Because our study demonstrated the feasibility of customized ablations, further studies comparing randomized groups are currently under way.

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## Discussion
## by
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With the possible exception of correcting presbyopia, custom corneal laser ablation has become the Holy Grail of refractive surgery. The goal of achieving postoperative visual acuity better than 20/20 has captured the attention of laser manufacturers, refractive surgeons, and increasingly educated potential refractive surgery patients. This study by Knorz and associates constitutes early, preliminary experience with this evolving technology in a self-described noncomparative study.

At this point, numerous formidable hurdles remain in the path of custom laser ablation development. One difficulty involves accurate assessment of the eye's true preoperative refractive status using current videokeratography systems. Wavefront and other higher order aberration analyzers will likely improve such preoperative data gathering. Other obstacles include limitations in current laser aiming and delivery systems, eye tracking, globe stabilization, and, perhaps most importantly, the complex mathematics involved in modeling and designing customized laser ablation patterns.

Although some estimates[1] suggest approximately 40% of "normal" eyes have some degree of asymmetric astigmatism, it is difficult to assess how clinically significant this is for the general population. For some patients, however, the usefulness of custom ablation technology is far removed from (and perhaps more important than) attempts to achieve 20/15 or better postoperative visual acuity. At present, the value of this evolving technology is greatest for postoperative refractive surgery patients with central islands, decentered ablations, or large degrees of asymmetric astigmatism, and others such as corneal transplant recipients with poor spectacle-corrected vision.

For those normal patients seeking "super" vision and surgeons seeking to carefully evaluate systems designed to provide it, there exists one more, often overlooked, obstacle. As Dr. Knorz notes, it is difficult to compare his results with studies of laser in situ keratomileusis using standard, noncustomized ablation patterns. One reason for this is the dearth of studies specifically measuring vision better than 20/20. To date, nearly all published acuity results have been reported using a category of "20/20 or better." The present study finds that 47% of lower myopia patients achieved 20/15 spectacle-corrected acuity or better at 3 months postoperative. However, another recent article using the standard VISX S2 laser without custom ablation found 57% of a similar group of patients achieved 20/16 or better acuity without any correction (Schallhorn SC, Tanzer DJ, Tidwell J, et al. Initial evaluation of LASIK in the US Navy. ARVO Annual Meeting (Abstract 30865), 2000. Invest Ophthalmol Vis Sci 2000;41[Suppl]:688).

What is needed, as custom ablation research of this type advances, are standardized, controlled, randomized, large-scale trials to assess its predictability, safety, and efficacy. Only then can the potential advantages of this type of technology be transformed from theory into reality.

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