Q-factor customized ablation profile for the correction of myopic astigmatism

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**Purpose:** To compare the results of Q-factor customized aspheric ablation profile with the wavefront-guided customized ablation pattern for the correction of myopic astigmatism.

**Setting:** Institute for Refractive and Ophthalmic Surgery (IROC), Zurich, Switzerland

**Methods:** Thirty-five patients were enrolled in a controlled study where the non-dominant eye was treated with the Q-factor customized profile (Custom-Q, study group) and the dominant eye wavefront-guided customized (control group). Pre- and 1month-postoperative high contrast, low contrast, and glare visual acuity as well as aberrometry and asphericity of the cornea were compared among the two groups. All eyes received LASIK surgery and the laser treatment was accomplished with the Wavelight Eye-Q 400 Hz excimer laser.

**Results:** In corrections up to –9 diopters of myopia we could not find any statistical significant difference between the two groups regarding any of the visual or optical parameters except coma-like aberrations (3rd Zernike-order) where the wavefront-guided group was at 1 month after surgery significantly better (p=0.002). In corrections up to –5 diopters (spherical equivalent) the Q-factor optimized treated eyes had a significant smaller shift towards oblate cornea: ΔQ₁₅ = 0.25 in Q-factor customized versus ΔQ₁₅ = 0.38 in wavefront-guided treatment (p=0.04).

**Conclusions:** Regarding safety and refractive efficacy Custom-Q ablation profiles are clinically equivalent to wavefront-guided profiles in corrections of myopia up to –9D and astigmatism up to 2.5D. Corneal asphericity is less impaired by the Custom-Q treatment up to –5D in myopia.
Synopsis

Regarding refractive, visual, and optical outcome wavefront-guided and Q-factor optimized customized LASIK treatments seem to be equivalent in corrections of myopic astigmatism.
Corneal refractive surgery is based on the change in corneal curvature to compensate for refractive errors of the eye. After many mechanical approaches such as radial keratotomy, keratomileusis, and astigmatic keratotomies ablative procedures using the excimer laser have become the most successful technique. It was mainly the submicron precision and the high repeatability of the ablation of the cornea accompanied by minimal side effects that guaranteed this success.

Standard ablation profiles for the correction of myopic astigmatism were based on the removal of convex-concave tissue lenticules with sphero-cylindrical surfaces \(^1\). Although these algorithms proved to be effective to compensate for the refractive error the quality of vision deteriorated significantly, especially under mesopic and low-contrast conditions \(^2\) - \(^5\). As a logical consequence, research directed towards aspheric ablation profiles, wavefront analysis of the eyes operated, and the optical aberrations induced by the operations \(^6\) - \(^8\). The results of a preoperative wavefront analysis were used to create individualized ablation patterns in order to compensate also for preexisting aberrations \(^9\),\(^10\), however, this analysis is time-consuming and appears not to be necessary in the majority of the cases. Therefore, new aspheric non-individualized algorithms were designed to compensate for the spherical aberration induced\(^11\) which lead already to an improved visual outcome\(^12\). On the other hand, it is known since many years that any refractive treatment of the cornea must respect the pre and post-operative asphericity of the cornea\(^13\) - \(^15\).

The outer surface of the human cornea is physiologically not spherical but may be approximated by a conoid \(^16\). On average, the central part of the cornea has a stronger curvature than the periphery or, in other words, the refractive power of the outer
corneal surface decreases from central towards peripheral. For this form the term “prolate cornea” has been coined and the opposite form is called “oblate cornea”. The physiologic asphericity of the cornea shows a significant individual variation ranging from mild oblate to moderate prolate\textsuperscript{16}. Therefore, it was worth to introduce a shape factor to characterize the amount of asphericity of the cornea numerically, the so-called Q-factor. Azar and coworkers\textsuperscript{17} as well as Manns and coworkers\textsuperscript{18} emphasized that the pre- and post-operative Q-factors have significant influence on the ablation depth and profile to be used and Manns and coworkers concluded that a minimum of spherical aberration would be obtained at a target Q-factor of approximately –0.4\textsuperscript{18}. These calculations were based on an aspheric eye model and the approximate target value of -0.4 to -0.5 holds for the whole range of myopic corrections up to -10 D.

In this study, we present refractive, optical and visual results of an aspheric ablation algorithm that takes the preoperative and attempted postoperative Q-factor of the cornea to be operated on into account. The non-dominant eye of patients with myopic astigmatism was corrected using this algorithm and the outcome at one month was compared with the dominant fellow eyes that were treated by means of wavefront-guided ablation. Our special interest was focused on the quality of vision and the induced wavefront aberrations.
Materials and Methods

Study Group
Thirty-five patients asking for laser correction at the Institut für Refraktive und Ophthalmochirurgie (IROC) were enrolled in this study. The age of the patients ranged from 23 to 53 years (average age 35.37 ± 8.64 years). The refractive and demographic data is listed in Table 1. All patients underwent LASIK in both eyes, the nondominant eye (study group) being operated first and the dominant eye (control group) one day later. On average, best spectacle-corrected visual acuity (BSCVA) was significantly better in the dominant eye (1.127 ± 0.182 vs. 1.040 ± 0.247, p=0.049). The target refraction was emmetropia in 59 eyes and a slight myopia between −0.5 and −1.25 D in 11 eyes because of intended monovision. After a complete ophthalmic examination and a thorough discussion of the risks and benefits of the surgery the patients gave written informed consent. Exclusion criteria were: any pathology of the eyes, age under 20 years, asymmetric astigmatism detected in corneal topography, central corneal thickness of less than 500 µm and residual stromal thickness of less than 270 µm, and high order wavefront error rmsh of more than 0.35 microns in the non-dominant eye (pupil size 7mm). The study protocol was approved by the review board of the IROC.

Examinations
The complete preoperative ophthalmic examination consisted of autorefractometry and autokeratometry (Humphrey Model 599, Zeiss, Jena, Germany), corneal topography (Keratograph C, Oculus, Wetzlar, Germany, equipped with the Topolyzer software, Wavelight, Erlangen, Germany), manifest refraction using the
fogging technique, unaided (UVA) and best spectacle-corrected visual acuity (BSCVA), glare (GVA) and low contrast (LCVA) visual acuity (Humphrey Model 599, Zeiss, Jena, Germany), wavefront analysis with pupils dilated to at least 7 mm in diameter (Wavefront Analyzer, Wavelight, Erlangen, Germany), applanation tonometry, central ultrasound pachymetry (SP-2000, Tomey, Nagoya, Japan), slitlamp inspection of the anterior and posterior segments of the eyes. All rms-values are reported at a pupil size of 7mm. The determinable GVA- and LCVA-values range on a decimal scale from 0 to 0.8 (equiv. 20/25), whereas for UVA and BSCVA the maximum was 2.0 (equiv. 20/10).

The patients were seen on post-op days one and three (if necessary) and at one month after surgery. At post-op days one and three, we measured UVA and a slitlamp inspection was performed. At the one month follow-up, the examination was identical to preoperative.

Q-factor Analysis and asphericity treatment

Pre- and postoperative Q-factor analysis was performed by means of the corneal topographer. Only automatically taken topographies were accepted. The Q-factor was calculated by the topography soft ware in all 4 main hemimeridians at radial distances of 10, 15, 20, 25 and 30 degrees from the apex of the cornea and for the treatment the average of two opposite hemimeridians was used as the Q-factor in the main axes. The pre- and post-operative Q-factors for numeric evaluation are the averages of all 4 hemimeridians. Since we aimed on a postoperative prolate cornea the target Q-factor was -0.4 within a diameter of 6.5mm in all cases. A typical
ablation pattern attempting an asphericity change of ΔQ = -0.6 within an optical zone of 6.5 mm in diameter is shown in Figure 1.

Surgery

All operations were performed as LASIK-procedures. The microkeratome used was the M 2 (Moria, Antony, France) with appropriate suction rings that were selected according to the specifications of the manufacturer. The laser treatment was performed by means of the Eye-Q excimer laser with the Custom-Q software (Wavelight, Erlangen, Germany). This device works at a repetition rate of 400 Hz and produces a spot size of 0.68 mm (FWHM) with a truncated Gaussian energy profile. Eye-tracking is accomplished with a latency of 6 msec. The optical zone of full treatment had a diameter of 6.5 mm with a transition zone of 1.25 mm in both groups.

After repositioning of the flap the patient was served with a bandage lens that was soaked with preservative-free ofloxacin 0.3% eye drops for 20 min (Floxaal SDU, Bausch&Lomb, Steinhausen, Switzerland). The bandage lens was removed next morning. The surgery in fellow eyes was done on two consecutive days. The postoperative medication consisted of fluorometholone 0.1% (FML, Allergan, Lachen, Switzerland) twice a day for one week and artificial tears (Hylo-Comod, Ursapharm, Saarbrücken, Germany) to the patients discretion.

Statistical Analysis

Pre- and post-operative parameters of the two groups as well as the pre- versus post-operative changes (paired differences) in each group were compared using the paired two-sided t-test. Statistical significance was accepted if p was smaller than 0.05. The
vector analysis of astigmatism correction consisted in the calculation of the change in refractive cylinder in the preoperative axis\textsuperscript{19} and its percentage of the preoperative refractive astigmatism served as a measure for the efficiency of astigmatism correction. Similarly, in order to take the attempted undercorrection in some eyes of the Custom Q-group into account, the spherical correction efficiency was calculated as the percentage of the pre- vs post-operative change in spherical equivalent compared to the target change in spherical equivalent.
Results

The surgery went uneventful in all cases. At post-op day one, two eyes showed a minor diffuse lamellar keratitis which resolved within 3 days using FML-drops 4 times a day. At the one month examination all eyes showed a regular state after LASIK.

The refractive and visual data at the one month follow-up are listed in Table 2. Twenty-eight eyes of the Custom-Q group (80%) and 30 eyes of the wavefront-guided group (86%) were within ± 0.5D from the target refraction. The preoperative statistical significant difference in BSCVA, better in the dominant eye, remained significant 1 month after surgery (p=0.031). Regarding safety, both groups showed an identical distribution of lost vs. gained lines in BSCVA (Table 3). It is worth mentioning that the eyes that lost 2 lines (1 in each group) belonged to one patient suffering from severely dry eyes.

Low contrast visual acuity (LCVA) and visual acuity under glare conditions (GVA) were pre- and postoperatively not statistically different in the two groups (Table 2). Also, the pre- vs. postoperative changes did not demonstrate statistical significance neither for GVA (p=0.724) nor for LCVA (p=0.418).

Regarding the asphericity of the cornea all eyes demonstrated a tendency towards an oblate cornea after surgery (Table 2). The preoperative Q-factor as a function of the radial distance from the apex is shown in Figure 2. The increase in asphericity $\Delta Q = Q_{\text{post}} - Q_{\text{pre}}$ was approximately 4% higher for the Custom-Q group. For all radial
distances the difference in $\Delta Q$ between the groups was not statistically significant. For corrections of $\approx 5$D (spherical equivalent) and less, however, the results are different (Figure 3) showing a significantly smaller shift towards oblate in the Q-factor customized group.

The total higher-order wavefront error rmsh was preoperatively nearly identical in the two groups ($0.242 \pm 0.086$ and $0.237 \pm 0.070$ microns, Table 1) and remained postoperatively similar in both groups: $0.442 \pm 0.142$ microns in the Custom-Q versus $0.381 \pm 0.146$ microns in the wavefront-guided group ($p=0.113$). The only statistically significant difference regarding wavefront errors was obtained in the postoperative coma-like aberrations S3 (rms-sum of 3rd order aberrations) with $0.296 \pm 0.115$ microns in the Custom-Q group versus $0.192 \pm 0.088$ microns in the wavefront-guided group ($p=0.002$). Another important detail is the similar induced spherical aberration (post-op minus pre-op) in the two groups: $0.287 \pm 0.219$ microns versus $0.295 \pm 0.264$ microns ($p=0.457$).
Discussion

Wavefront-guided customized ablation appears to be the gold standard of ablative treatment of myopic astigmatism regarding the optical performance of the postoperative eye\textsuperscript{20,21}. Therefore, it was logic to compare a new algorithm such as the Custom-Q profile with this standard. In order to exclude individual abnormal healing responses we compared fellow eyes, the dominant eye treated wavefront-guided and the non-dominant eye treated Q-factor customized. The choice to treat the dominant eyes wavefront-guided was mainly based on ethical considerations because of the superiority of wavefront-guided algorithms presumed before the study. Regarding refractive and visual outcome of the study, however, we could not find any relevant differences (Tables 2 and 3) and conclude that the two treatment strategies appear to be clinically equivalent. An important result is the only minor decrease in low contrast VA in both groups which is remarkable because after conventional PRK and LASIK low contrast VA shows a significant reduction\textsuperscript{3,22}. Although not statistically significant, the better spherical success index (Table 2) of the wavefront-guided group means that the nomogram for spherical Custom Q-treatments has to be improved, whereas the efficiency regarding astigmatic treatments is nearly equal in both groups. The small differences reported in this study might have become statistically significant if the group size would have been increased, however, a group size of 35 matched pairs is well sufficient to detect a clinically meaningful result.

Although the pre- and postoperative overall optical performance of the eyes treated by the two different profiles was very similar in the two groups we found a
statistically significant difference regarding the outcome of coma-like third order-aberrations S3. Whereas pre- vs. post-operative S3 increased in the Q-factor customized group from 0.181 ± 0.072 microns pre- to 0.296 ± 0.115 microns post-operatively, S3 remained virtually constant in the wavefront-guided group: 0.182 ± 0.094 microns pre- versus 0.192 ± 0.088 microns postoperatively. This result is not surprising because the Q-factor customized approach does not correct coma-like aberrations. On the other hand, the increase in the total wavefront error due to the operation by a factor of 1.83 in the Custom-Q group and 1.67 in the wavefront-guided group compares favourable with the increase factors with standard ablation profiles reported in the literature ranging from 1.92 to 17. Such an increase in wavefront error during myopia correction is usually due to the inevitably induced spherical aberration which was identically small in the two groups. Chalita and coworkers measured higher order aberrations and correlated it with subjective complaints of patients after LASIK surgery. Whereas the total higher order wavefront error and spherical aberration were good quantitative descriptors for starburst and glare, coma was significantly related with double vision. In this study, the postoperative glare VA was on average better compared to preoperative in both groups which is consistent with the relatively small increase in spherical aberration and total wavefront error.

So, if the optical performance of the eyes treated by the two alternative approaches is similar but coma-like aberrations do better using wavefront-guided ablation why should the wavefront-guided approach not be preferred in any case? Wavefront-guided ablation requires a time-consuming preoperative wavefront analysis including dilation of the pupil. In a high-volume refractive surgery practice there is very often
not time enough to do such an intensive examination in any case. Not to speak of refractive surgery in third world-countries where for economic reasons such time-consuming analysis is not well accepted. These and other aspects decrease the market penetrance of wavefront-guided ablation and create the demand for alternative customized ablation profiles.

We would have expected to find a significant difference in postoperative Q-factors between the groups since we aimed on a postoperative Q-factor of –0.4 in the Custom-Q group. Both goals were clearly missed at least in higher corrections because there was an underlying strong shift towards an oblate cornea due to the myopic correction that is linearly related with the amount of myopia correction. The on average 4 % greater shift towards oblate in the Custom-Q group is well explained by the 3 % higher myopia correction in this group compared with the wavefront-guided group (Table 2). A combination of two different reasons have lately been considered to be responsible for this shift towards oblate corneal shape: a peripheral undercorrection due to a reduced laser efficacy and the structural response of the cornea that is biomechanically weakened by the LASIK operation itself. Both ablation profiles used in this study include a so-called correction matrix that compensates for the reduced laser ablation in the peripheral cornea and, therefore, we believe that in our cases the shift is mainly due to biological response of the cornea.

A totally different picture is drawn when considering myopic corrections of -5D and less. The corneas of the Q-factor optimized treated eyes are less oblate for all radial
distances from the apex (Figure 3), statistically significant is this difference only within the inner 3.5 mm of the cornea (Q_{10} and Q_{15}).

As shown in Figure 1 the Q-factor adjustment consists of a kind of additional correction in the mid-periphery of the cornea which resembles a hyperopic correction. In order to avoid such consecutive hyperopic correction the central part must be treated by means of a PTK which enhances the central ablation depth as described before 17. An intended change in Q-factor ΔQ of –0.6 within an optical zone of 6.5 mm requires 28.5 microns more central tissue removal (Fig. 1). This increased central keratectomy depth may limit the application of Q-factor optimized ablation to corrections of only mild to moderate myopia. A stronger attempted asphericity correction, for example a target Q of –1.0, might have yielded more prolate postoperative corneas but, on the other hand, such a strong Q-factor correction would increase the central keratectomy depth by another 30 microns which we esteemed not to be appropriate with respect to the already well-preserved LCVA data in this study.

The study is limited regarding the short follow-up of only one month. We intended to present early postoperative data because the corneal optics may be affected by stromal and epithelial healing. Nevertheless, it would be interesting to observe whether corneal optics undergoes some regression. Also, eyes with high preoperative wavefront errors of higher order (at least of the non-dominant eye) were excluded from the study. Those eyes, however, should be treated by wavefront-guided customized ablation any way.
In summary, this study demonstrates that a Q-factor optimized ablation profile yields visual, optical, and refractive results comparable to the wavefront-guided customized technique for corrections of myopia up to –9 diopters. A significantly better result in corneal optics, however, is obtained only in corrections up to –5 diopters. The Q-factor optimized ablation represents a customized approach that is much less time-consuming compared to the wavefront-guided technique since it is based on preoperative corneal topography which is mandatory in any case to detect keratectatic disorders. The Q-factor optimized profile has, therefore, the potential to replace currently used standard profiles for corrections of myopic astigmatism.
Table 1: Demographic and refractive data of the study group (n=35)

<table>
<thead>
<tr>
<th></th>
<th>Average ± standard deviation</th>
<th>range</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>35.37 ± 8.64 years</td>
<td>23 to 53 years</td>
</tr>
<tr>
<td>Sphere, dominant eyes</td>
<td>-4.65 ± 2.0 D</td>
<td>-1.75 to -9.0 D</td>
</tr>
<tr>
<td>Sphere, non-dom. eyes</td>
<td>-4.96 ± 2.21 D</td>
<td>-1.0 to -9.0 D</td>
</tr>
<tr>
<td>Cylinder, dom. eyes</td>
<td>-0.68 ± 0.75 D</td>
<td>0 to -2.5 D</td>
</tr>
<tr>
<td>Cylinder, non-dom. eyes</td>
<td>-0.62 ± 0.61 D</td>
<td>0 to -2.25 D</td>
</tr>
<tr>
<td>Q-factor 15°, dom. eyes</td>
<td>-0.21 ± 0.12</td>
<td>-0.04 to -0.53</td>
</tr>
<tr>
<td>Q-factor 15°, non-dom. eyes</td>
<td>-0.20 ± 0.14</td>
<td>-0.03 to -0.58</td>
</tr>
<tr>
<td>Rsmh, dom. eyes*</td>
<td>0.242 ± 0.086 µm</td>
<td>0.106 to 0.472 µm</td>
</tr>
<tr>
<td>Rsmh, non-dom. eyes*</td>
<td>0.237 ± 0.070 µm</td>
<td>0.11 to 0.346 µm</td>
</tr>
<tr>
<td>Side: nondominant</td>
<td>15 OD (42.9%) / 20 OS (57.1%)</td>
<td></td>
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</table>

*Rsmh = wavefront error of higher orders (including 3rd to 6th Zernike-order)
Table 2: Refractive and visual outcome at one month after surgery

<table>
<thead>
<tr>
<th></th>
<th>wavefront-guid. group</th>
<th>Custom-Q group</th>
<th>p-value</th>
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<tbody>
<tr>
<td></td>
<td>dominant eyes</td>
<td>non-dominant eyes</td>
<td></td>
</tr>
<tr>
<td>spherical equivalent</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>pre-op</td>
<td>-4.99 ± 2.05 D</td>
<td>-5.28 ± 2.25 D</td>
<td>0.289</td>
</tr>
<tr>
<td>post-op</td>
<td>+0.05 ± 0.44 D</td>
<td>-0.09 ± 0.58 D</td>
<td>0.072</td>
</tr>
<tr>
<td>efficiency</td>
<td>99.4 ± 4.6 %</td>
<td>97.7 ± 10.5 %</td>
<td>0.249</td>
</tr>
<tr>
<td>cylinder</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>pre-op</td>
<td>-0.68 ± 0.75 D</td>
<td>-0.61 ± 0.61 D</td>
<td>0.369</td>
</tr>
<tr>
<td>post-op</td>
<td>-0.11 ± 0.26 D</td>
<td>-0.11 ± 0.21 D</td>
<td>0.457</td>
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<tr>
<td>efficiency</td>
<td>92.6 ± 18 %</td>
<td>92.2 ± 19 %</td>
<td>0.690</td>
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<tr>
<td>BSCVA</td>
<td></td>
<td></td>
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<tr>
<td>pre-op</td>
<td>1.127 ± 0.183</td>
<td>1.040 ± 0.247</td>
<td>0.049</td>
</tr>
<tr>
<td>post-op</td>
<td>1.160 ± 0.201</td>
<td>1.054 ± 0.257</td>
<td>0.031</td>
</tr>
<tr>
<td>Low contrast VA</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>pre-op</td>
<td>0.724 ± 0.099</td>
<td>0.725 ± 0.134</td>
<td>0.480</td>
</tr>
<tr>
<td>post-op</td>
<td>0.704 ± 0.132</td>
<td>0.690 ± 0.182</td>
<td>0.377</td>
</tr>
<tr>
<td>Glare VA</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pre-op</td>
<td>0.565 ± 0.088</td>
<td>0.553 ± 0.140</td>
<td>0.343</td>
</tr>
<tr>
<td>Post-op</td>
<td>0.555 ± 0.133</td>
<td>0.528 ± 0.163</td>
<td>0.246</td>
</tr>
<tr>
<td>Q-factor Q15</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pre-op</td>
<td>-0.21 ± 0.12</td>
<td>-0.20 ± 0.14</td>
<td>0.335</td>
</tr>
<tr>
<td>Post-op</td>
<td>0.47 ± 0.46</td>
<td>0.50 ± 0.49</td>
<td>0.395</td>
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Table 3: Safety of wavefront-guided versus Custom-Q treatment

<table>
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<tr>
<th>VA-type/ groups</th>
<th>lines lost</th>
<th>lines gained</th>
</tr>
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<tbody>
<tr>
<td></td>
<td>2 or more</td>
<td>1 unchanged</td>
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<tr>
<td>BCVA</td>
<td></td>
<td></td>
</tr>
<tr>
<td>wg-group*</td>
<td>1</td>
<td>5</td>
</tr>
<tr>
<td>Custom-Q**</td>
<td>1</td>
<td>5</td>
</tr>
<tr>
<td>Low contrast VA</td>
<td></td>
<td></td>
</tr>
<tr>
<td>wg-group*</td>
<td>1</td>
<td>4</td>
</tr>
<tr>
<td>Custom-Q**</td>
<td>2</td>
<td>4</td>
</tr>
<tr>
<td>Glare VA</td>
<td></td>
<td></td>
</tr>
<tr>
<td>wg-group*</td>
<td>3</td>
<td>5</td>
</tr>
<tr>
<td>Custom-Q**</td>
<td>5</td>
<td>4</td>
</tr>
</tbody>
</table>

* wg-group = wavefront-guided treated eyes

** Custom-Q = Q-factor customized treated eyes
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Legends

Figure. 1
Ablation pattern for an attempted change in asphericity of \( \Delta Q = -0.6 \). In the central part, the ablation depth is virtually constant and resembles a PTK. Towards the periphery a flattening produces the prolate cornea. The central ablation depth is 28.5 microns.

Figure. 2
Preoperative asphericity \( Q \) as a function of the radial distance from the apex of the cornea. A radial distance of 30° is equivalent to an optical zone diameter of approximately 7.5mm.

Figure. 3
Increase in asphericity \( \Delta Q = Q_{\text{post}} - Q_{\text{pre}} \) in the wavefront-guided (quadrats) and the Q-factor customized treated eyes (circles) in myopic corrections of 5D and less. A positive value of \( \Delta Q \) indicates a shift towards an oblate cornea. The bars depict the standard deviation. The difference between the groups is statistically significant for radial distances 10 and 15 degrees from the apex (*).