

Maximum permissible torsional misalignment in aberration-sensing and wavefront-guided corneal ablation

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Purpose: To determine the maximum permissible torsional misalignment in wavefront-guided refractive surgery.

Setting: University of Zurich, Department of Ophthalmology, Zurich, Switzerland.

Methods: The effect of torsionally misaligned ablations on the optical outcome was simulated using measured wavefront aberration patterns (2nd to 6th orders) in 130 normally aberrated eyes. The calculations were done for 3.0 mm, 5.0 mm, and 7.0 mm pupils. The optical quality of the simulated correction was rated by the root-mean-square residual wavefront error.

Results: The required accuracy of torsional alignment is higher for the correction of higher-order aberrations than for cylindrical treatments only. To improve the optical performance to the level of the best 10% of a normal, untreated population, ablation would have to occur within a tolerance range of 4.0 degrees for 7.0 mm pupils.

Conclusions: The tolerance range for torsional alignment in wavefront-guided higher-order corrections depends on the amount of original optical error in each eye. Rough centration based on the surgeon's judgment may not be accurate enough to achieve significantly improved optical quality in a high percentage of treated eyes.

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Customized treatments such as wavefront-guided refractive surgery are under clinical investigation. These individualized treatment techniques aim to improve the optical properties of the human eye by taking higher-order optical aberrations into consideration in

the ablation profile calculation.¹⁻⁷ However, clinical results indicate that the attempted correction of these higher-order aberrations (HOAs) is insufficient because it lacks predictability.^{8,9} Misalignment of the ablation on the cornea, whether caused by an initial placement error or by intraoperative eye movements by the patient, plays an important role in this context.¹⁰⁻¹³ Alignment of the procedure relative to the eye is a task with 6 degrees of freedom (Figure 1). Besides lateral shifts (with a horizontal and a vertical component) and axial movements, rotations with potential components in 3 axes have to be taken into account.

This study focused on the problem of torsional misalignment of the ablation; ie, a rotation of the ablation pattern around the longitudinal axis of the eye. Such a displacement might occur due to cyclotorsion

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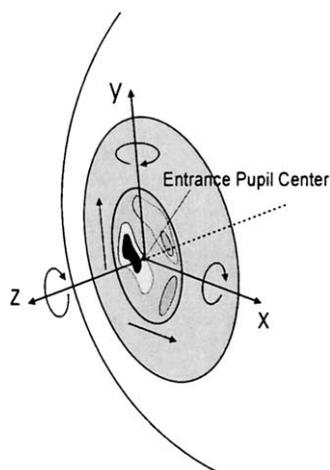


Figure 1. (Bueeler) Measured wavefront aberrations relative to the line of sight. The alignment has to be done in 6 degrees of freedom relative to a reference coordinate system predefined in the previous measurement. Lateral shifts (with a horizontal and a vertical component) and axial shifts as well as rotations around 3 axes have to be taken into account.

Table 1. Demographic and refractive data of the study eyes.

Parameter	Value
Mean age, y (range)	32.9 ± 11.3 (18 to 63)
Sex, n (%)	
Female	82 (63.1)
Male	48 (36.9)
Eye, n (%)	
OD	64 (49.2)
OS	66 (50.8)
Mean manifest refraction, D (range)	
Sphere	-1.70 ± 2.16 (-7.50 to +2.25)
Cylinder	-0.44 ± 0.49 (0 to -2.75)

Means ± SD

of the eye between the seated and the supine position or a slight lateral tilt of the patient’s head.

The degree of torsional alignment accuracy required to avoid degrading ideal optical corrections below certain specified levels was studied in the case of spherocylindrical only and spherocylindrical plus HOA wavefront-guided refractive corrections. Based on measurement data from normally aberrated eyes (2nd to 6th orders), the required torsional alignment accuracies needed to improve the ocular optics to a certain level were numerically investigated for refractive treatments designed to correct spherocylindrical errors as well as HOAs up to the 6th Zernike order.

Subjects and Methods

Data from 130 eyes were taken from an earlier study of normally aberrated eyes.¹⁴ The subjects were not interested in refractive surgery. Briefly, the mean age of the 90 subjects enrolled in the study was 32.9 years (range 18 to 63 years). The subjects (eyes) were eligible for the study if they were at least 18 years of age and free of ocular disease; had a best spectacle-corrected visual acuity of 20/20 or better, a spherical equivalent refraction between -8.0 diopters (D) and +2.0 D, and a manifest refractive cylinder less than 3.0 D; and had wavefront measurements on 7.0 mm pupils using the technique described.

The median of the 2nd- to the 6th-order root-mean-square (RMS) wavefront aberration error was 0.830 μm with a 25th percentile of 0.498 μm and a 75th percentile of 2.370 μm. Without the spherocylindrical errors, the median of the higher-order (3rd to 6th orders) RMS wavefront error for the 7.0 mm pupils was 0.230 μm with a 25th percentile of 0.167 μm and a 75th percentile of 0.297 μm. The demographic and refractive data of the subjects are summarized in Table 1.

Wavefront Sensing

A Tscherning-type wavefront sensor was used in the study. The sensor has been described.¹⁵⁻¹⁷ Briefly, a collimated laser beam (532 nm wavelength) illuminates a mask with regular matrix pinholes that form a bundle of thin parallel rays. The rays form a spot pattern on the retina that is distorted according to the optical errors of the eye. This retinal spot pattern is imaged onto the sensor of a low-light video camera using the principle of indirect ophthalmoscopy. The beam pattern attenuated by the shutter is centered on the line of sight by a second video camera depicting the iris while the examined eye is fixating on a target aligned coaxially with the optical axis of the measuring device.

From the deviations between the observed retinal spot positions and their ideal positions, the actual wavefront aberrations were calculated in Zernike polynomials ($Z_n^{\pm m}$) up to the 6th order. The wavefront aberrations were measured in pupils larger than 7.0 mm in diameter. These data were processed to obtain the wavefront aberrations for virtual pupils of 3.0 mm, 5.0 mm, and 7.0 mm. The nomenclature for the Zernike representation follows the standards of the Optical Society of America.¹⁸

The optical quality was rated using the RMS wavefront error as a single-value representation of the calculated wavefront aberrations. The RMS wavefront error is the square root of the variance of the deviations between the real wavefront and the ideal reference wavefront over the entrance pupil plane. It is a conventional statistic to describe the overall performance of an optical system and is the sum of the squared Zernike coefficients.

Before measurement of the subjects, the calibration and reproducibility were tested using an artificial eye including

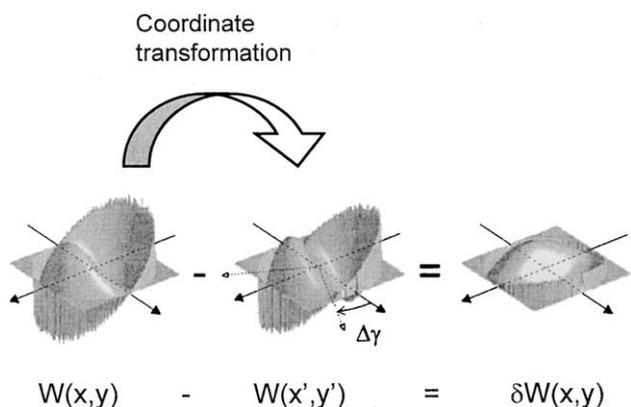


Figure 2. (Bueeler) Principle of the mathematical procedure to simulate misaligned refractive treatments. The original wavefront aberration surface $W(x,y)$ is described relative to a slightly rotated coordinate system [$\rightarrow W(x',y')$]. This new surface is subtracted from the original wavefront error $W(x,y)$, and the residual wavefront aberration $\delta W(x,y)$ can be numerically analyzed.

several phase plates (WaveLight Laser Technologie AG) with defined wavefront aberrations. The reproducibility of the total RMS wavefront error in the case of a defined aberration of RMS = 1.14 mm was ± 0.08 mm at a pupil size of 6.0 mm.

Numerical Simulations

Rotations of the measured wavefront aberration patterns $z = W(x,y)$ relative to the eye were calculated by means of coordinate transformations.¹⁹ Equation 1 represents a rotation of the measured data around the longitudinal axis z through the entrance pupil center by the angle $\Delta\gamma$.

$$\begin{aligned} x' &= x \cos(\Delta\gamma) + y \cos(\pi/2 - \Delta\gamma) \\ y' &= x \cos(\pi/2 + \Delta\gamma) + y \cos(\Delta\gamma) \\ W(x',y') &= z' = z \end{aligned} \quad (1)$$

Torsions up to $\Delta\gamma_{\max} = 45$ degrees were simulated using increments of 0.5 degree. Calculations were done for 3.0 mm, 5.0 mm, and 7.0 mm pupil data considering the 2nd to 6th Zernike orders. Piston and tilt (Zernike orders 0 and 1) terms were not considered. Any rotationally symmetric component

of the Zernike polynomial is not affected by rotations around the longitudinal axis. Thus, defocus and 4th- and 6th-order spherical aberrations did not affect the results.

Each transformed wavefront aberration surface $W(x',y')$, which can be considered a wavefront correction pattern, was numerically subtracted from the original surface $W(x,y)$ (Figure 2) to simulate a systematically displaced ablation. Subtraction of the 2 patterns results in a residual wavefront aberration $\delta W(x,y)$:

$$\delta W(x,y) = W(x,y) - W(x',y') \quad (2)$$

Zernike polynomials ($Z_n^{\pm m}$) up to the 6th order were numerically fitted to the residual wavefront aberrations using a 3-dimensional least-square-fit routine in Matlab (Software version 6, The MathWorks, Inc.). Correction of the 2nd to 6th error orders (spherocylindrical and higher orders) recorded by the wavefront measurement was assumed. In the case of an ideal, ie, perfectly aligned, treatment, the residual wavefront error would be zero over the entire entrance pupil zone [$\delta W(x,y) = 0$ for all x and y].

The amount of the RMS residual wavefront error (2nd to 6th Zernike orders) was studied as a function of the alignment error parameter $\Delta\gamma$ for each examined eye [RMS (δW) = $f(\Delta\gamma)$].

Rating Criteria

The RMS wavefront error resulting from a misaligned wavefront correction was rated by 3 image-quality criteria as summarized in Table 2.

The so-called Maréchal (MA) criterion states that in a well-corrected, diffraction-limited optical system, the RMS wavefront error does not exceed $1/14$ of the wavelength. In our case, an RMS value of 0.038 μm served as the MA criterion corresponding to the wavelength of 0.532 μm used for the wavefront measurements. The MA is the strictest rating criterion and therefore very difficult to achieve, especially in pupils as large as 7.0 mm.

The lower 10th percentile of the preoperative higher-order (3rd to 6th orders) RMS wavefront errors at a specific pupil size served as another rating criterion (P_{10}). This is the 10% of eyes that have the lowest amount of HOAs (ie, best

Table 2. Summary of the RMS error criteria used to rate the retinal image quality.

Criterion	Definition	Value (μm)		
		3.0 mm	5.0 mm	7.0mm
MA	Maréchal criterion @ 532 nm. A diffraction-limited optical system has an RMS wavefront aberration not exceeding $\lambda/14$.	—	0.038	—
P_{10}	10th percentile of the higher-order (3rd to 6th Zernike orders) RMS wavefront aberrations.	0.075	0.078	0.131
OT	Each eye's total (2nd to 6th Zernike orders) untreated RMS wavefront aberrations.	0.054—3.130	0.098—3.875	0.216—5.184

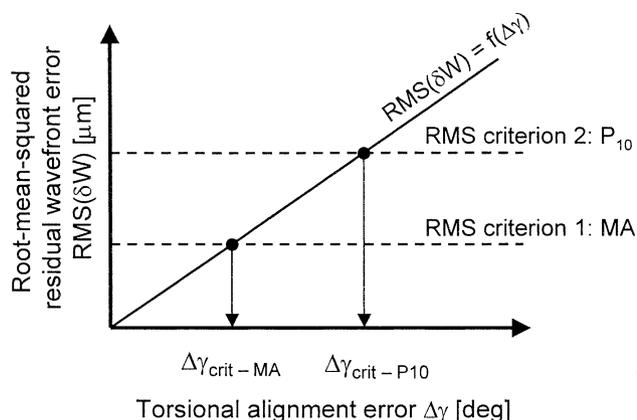


Figure 3. (Bueeler) Schematic illustration of the relationship between the RMS residual wavefront error $RMS(\delta W)$ and the torsional alignment error $\Delta\gamma$ in a single eye. Intersecting this function with the RMS rating criteria results in the alignment error angle $\Delta\gamma_{crit}$ at which the corresponding criterion is violated.

optical quality) in the group. The value for the P_{10} criterion was $0.075 \mu\text{m}$ for the 3.0 mm pupil, $0.078 \mu\text{m}$ for the 5.0 mm pupils, and $0.131 \mu\text{m}$ for the 7.0 mm pupil. The 1st- and 2nd-order wavefront aberrations were not considered in the P_{10} criterion as their comparably high values would render the criterion too mild.

In addition to the 2 criteria above, each eye's total preoperative RMS wavefront aberration (2nd to 6th orders) at the respective pupil size (OT) was used as a third criterion to provide information about the alignment accuracy required to not degrade the optical quality compared to the "preoperative" state (ie, not increase the RMS value through the treatment). Thus, for most eyes, the OT can be expected to be the mildest criterion to rate the effect of misalignment.

The MA criterion is extremely strict in the evaluation of refractive corrections, especially within treatment zones as large as 7.0 mm. The 2 statistical values derived from the measurement data (criteria P_{10} and OT), however, are more realistic thresholds to rate the optical outcome after corneal ablations. Degrading vision below the original error (as represented by the criterion OT) is not acceptable in any refractive treatment. However, the criterion OT was chosen to establish a boundary for a worst-case scenario. The MA criterion, which represents the best optical quality achievable in theory, provided the data for the other end of the quality spectrum.

Investigation Based on Measurement Data

Intersecting the function $RMS(\delta W) = f(\Delta\gamma)$ for each eye with the rating criteria results in the alignment error angle $\Delta\gamma_{crit}$ at which the corresponding criterion is violated (Figure 3). Small values of the critical angle indicate a high sensitivity of the particular eye for torsional alignment errors. For each of the 3 pupil sizes, a set of 130 $\Delta\gamma_{crit}$ values was obtained (corresponding to the 130 examined eyes) for the 3 criteria MA, P_{10} , and OT. Each set was then split into

percentile values (increments of 5%), and the corresponding statistical distribution of the $\Delta\gamma_{crit}$ values was summarized.

The torsional alignment accuracies required to meet the criteria MA and P_{10} for wavefront-guided treatments were correlated with the original cylinder in each examined eye. The simulations reported above were repeated for refractive treatments designed to correct only spherocylindrical errors using the 7.0 mm pupil data. The HOAs, which were left uncorrected in these simulations, were not considered when calculating the RMS residual wavefront aberration as their correction was not planned. Again, the torsional alignment accuracies needed to meet the criteria MA and P_{10} were correlated with the original cylinder. Comparison of the 2 cases was intended to illustrate the effect of treating HOAs on the required torsional alignment accuracy.

Results

The correlation of the original cylinder in each eye with the corresponding torsional alignment accuracy for 7.0 mm pupils is shown in Figure 4 for treatments designed to correct only spherocylindrical errors and for treatments to correct spherocylindrical errors and HOAs. In Figure 4, *left*, the optical quality after the treatment was expected to fulfill the MA criterion. The P_{10} criterion was met for 7.0 mm pupils in all cases depicted in Figure 4, *right*. An exponential fit with $R^2 > 0.999$ was found for the data of the pure spherocylindrical treatments (solid lines in Figure 4). Since correction of the HOAs was not planned in these cases, the RMS value after the treatment was rated relative to the preoperative RMS value only. An original cylinder of -1.0 D was found to tolerate torsional misalignments of up to 8 degrees before the P_{10} criterion was violated and up to 2 degrees before the MA criterion was violated with a 7.0 mm pupil.

Data points of the treatments to correct spherocylindrical and HOAs are scattered and located primarily below the curve for the pure cylinder, as shown in Figure 4. The nonrotationally symmetric HOAs render the corrections more sensitive to torsional misalignments than to pure cylindrical corrections. In some cases with small amounts of original cylinder (< 1.0 D), the alignment tolerance range can decrease from 30 to 5 degrees (data points formerly located on the solid line moved downward in Figure 4, *right*) when trying to achieve the same improvement in image quality through the treatment (P_{10} criterion in this case).

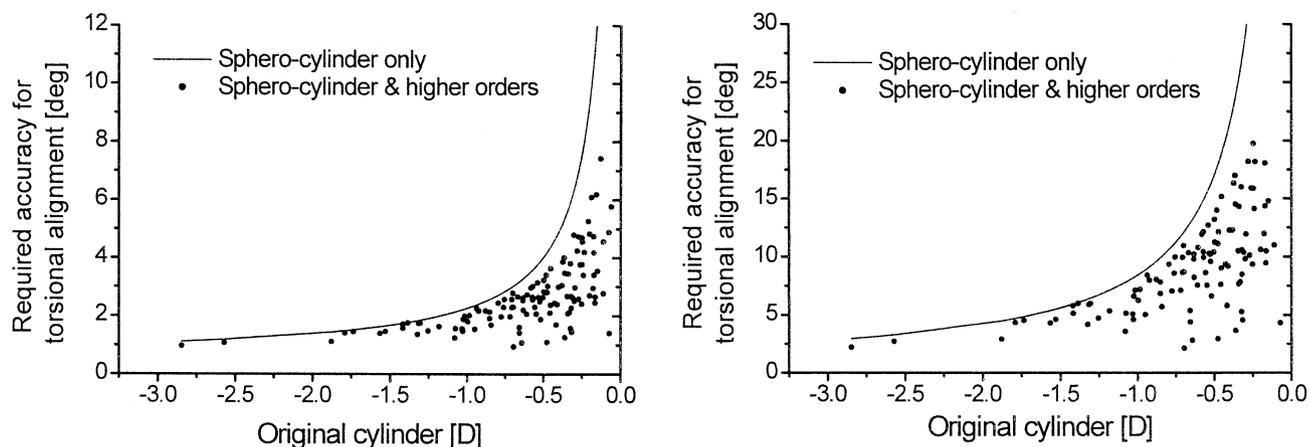


Figure 4. (Bueeler) Correlation of the original (ie, preoperative) cylinder in each eye and the required torsional alignment accuracy (7.0 mm pupil data) for treatments designed to correct only sphere and cylinder and for treatments to correct spherocylindrical and HOAs. *Left:* The image quality after the treatment was expected to fulfill the MA criterion. *Right:* The image quality after the treatment was expected to fulfill the P_{10} criterion.

Figure 5 shows 4 statistically relevant functions $f(\Delta\gamma)$ for 7.0 mm pupils when correction of the 2nd to 6th orders is planned. Ninety-nine percent of the treated eyes can be expected to end up with RMS residual aberrations (2nd to 6th orders) below the uppermost curve after refractive treatments with torsional misalignments up to 45 degrees in magnitude. Fifty percent of the examined eyes are expected to have RMS residual wavefront aberrations that lie below the median

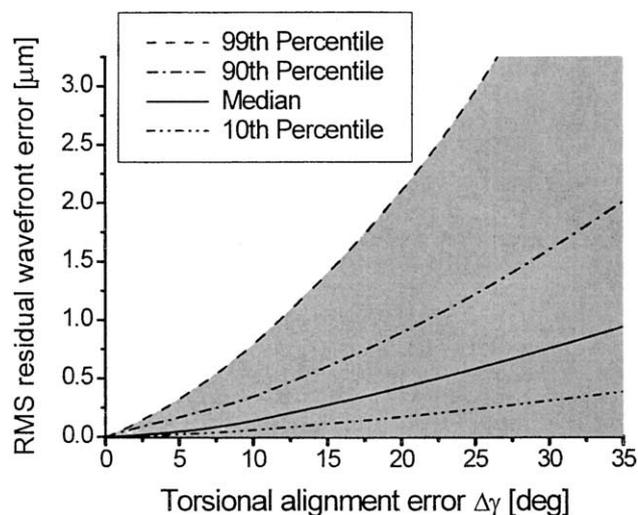


Figure 5. (Bueeler) Root-mean-square residual wavefront error (2nd to 6th Zernike orders) as a function of the torsional alignment error (7.0 mm pupil data). Ninety-nine percent of treated eyes can be expected to end up with RMS residual aberrations (2nd to 6th orders) below the uppermost curve after refractive treatments with torsional misalignments up to 35 degrees in magnitude. Fifty percent of the examined eyes are expected to have RMS residual wavefront aberrations below the median curve and so on.

curve. The functions $f(\Delta\gamma)$ of 80% of the sampled normal eyes are located between the 10th percentile curve and the 90th percentile curve. Intersecting these functions with the rating criteria provides the data that were statistically evaluated in Figure 6.

Figure 6 shows the percentage of normal eyes expected to meet the different image-quality criteria MA (Figure 6, *A*), P_{10} (Figure 6, *B*), and OT (Figure 6, *C*) at a certain amount of torsional misalignment with the 3 pupil sizes. These results were obtained for treatments designed to correct spherocylindrical errors and HOAs. In general, alignment becomes less critical with smaller pupil sizes as the influence of the HOAs decreases. Assuming a misalignment of 5 degrees, the diffraction limit could be achieved in only 15% of the measured eyes with a 7.0 mm pupil but in 85% with a 3.0 mm pupil (Figure 6, *A*). If the torsional alignment error were increased to 10 degrees, the MA criterion would not have been fulfilled in any eye with a 7.0 mm pupil. However, the goal would have been reached in 45% of eyes with a 3.0 mm pupil. In Figure 6, *B*, with a 10-degree alignment error, the P_{10} criterion would be met in 45% of eyes with 7.0 mm pupils and in 85% of eyes with 3.0 mm pupils. If the torsional alignment error could be kept below 15 degrees, none of the examined eyes with a 7.0 mm pupil would experience a loss of optical quality after surgery as the OT criterion is met by all of them (Figure 6, *C*).

The alignment accuracies required to fulfill the 3 criteria in 95% of the examined eyes are summarized in Table 3.

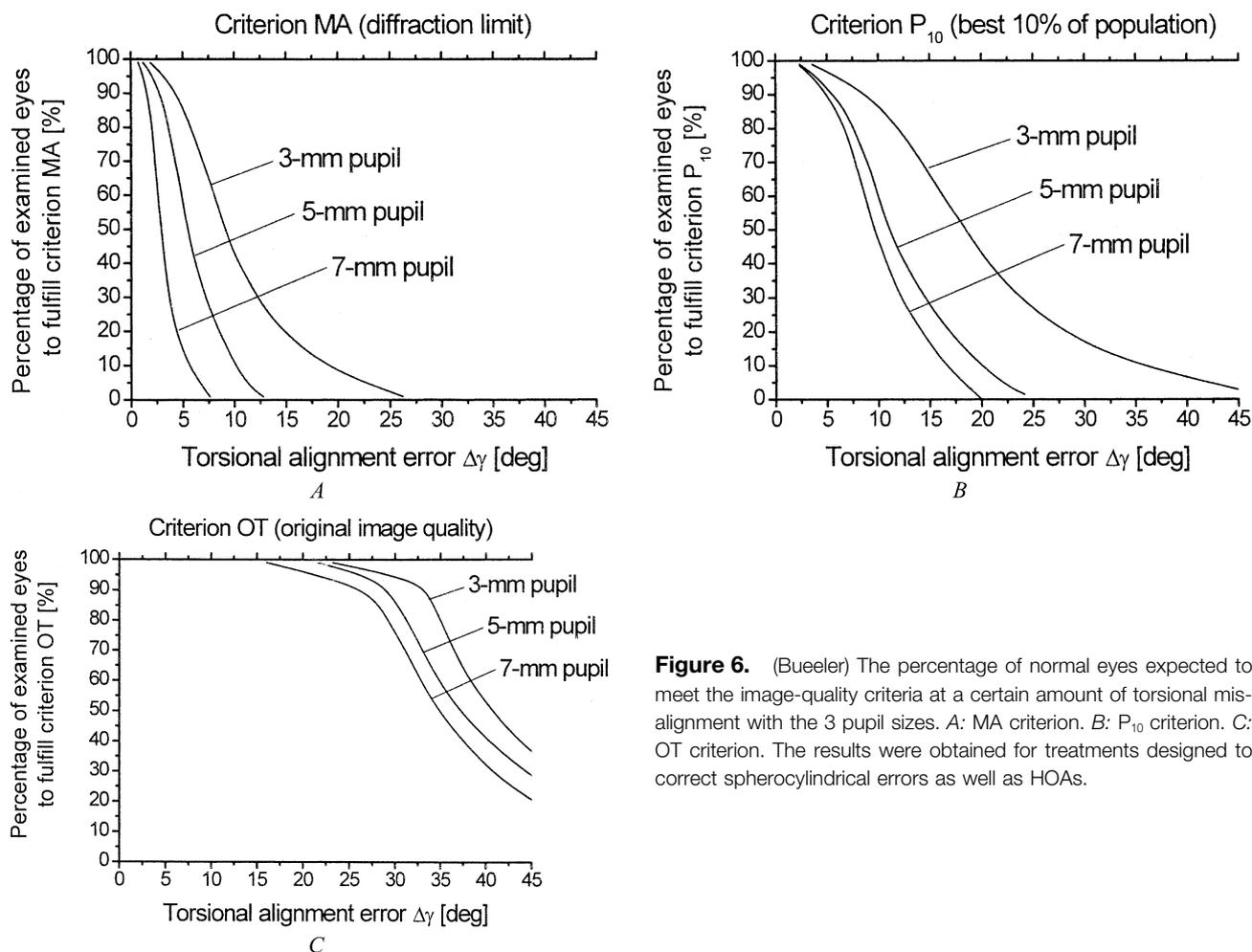


Figure 6. (Bueeler) The percentage of normal eyes expected to meet the image-quality criteria at a certain amount of torsional misalignment with the 3 pupil sizes. A: MA criterion. B: P₁₀ criterion. C: OT criterion. The results were obtained for treatments designed to correct spherocylindrical errors as well as HOAs.

Discussion

This study investigated the effect of torsional misalignments of the ablation on the postoperative optical outcome. The aim was to determine the torsional alignment accuracy needed in wavefront-guided refractive surgery to improve the ocular optics to a specific level in a certain percentage of normally aberrated eyes.

Comparison of wavefront-guided treatments with classic spherocylindrical procedures with a 7.0 mm pupil demonstrated stricter requirements for torsional alignment when trying to correct HOAs, especially in eyes with a small original cylinder. The data points in Figure

Table 3. Required alignment accuracies to fulfill the 3 criteria in 95% of the examined eyes.

Pupil Diameter (mm)	Accuracy Required (deg) for Criteria		
	MA	P ₁₀	OT
3	3	6	29
7	1	4	21

4, which are located on the solid line for pure spherocylindrical corrections, move downward to smaller alignment tolerances when wavefront-guided surgery is simulated. In some cases (Figure 4, right), the torsional alignment tolerance decreased by 25 degrees (points moved downward in diagram) if correction of not only the spherocylindrical errors but also the HOAs is planned. To achieve the diffraction limit in 95% of the measured normal eyes with a 7.0 mm pupil, alignment of wavefront-guided treatments would have to be performed with a torsional precision of approximately 1 degree or better (Figure 6, A). As alignment becomes less critical in smaller pupils, the same optical quality would result in 95% of the 3.0 mm pupils providing an accuracy of 3 degrees or better.

Holladay and coauthors²⁰ studied the tolerable angular error to achieve certain absolute levels of precision for different magnitudes of cylindrical errors. Calculations were done for spherocylindrical treatments only. The authors found that with an angular error of 30

degrees, the achieved precision is always equal to the magnitude of the measured cylinder.

One major difficulty in centering any ophthalmic procedure is that the alignment cannot be completely controlled by the physician. He or she relies on the cooperation of the patient, who is asked to fixate on a target during the measurement and the surgical procedure. Alignment errors can happen systematically or randomly. In the first case, an initial displacement of the treatment relative to the reference coordinate system is maintained as a constant offset error. Precise alignment techniques linking the measurement and the treatment are required to avoid this type of centration error. Random decentrations are due to eye movements such as drifts and tremors and might be practically avoided by active intraoperative eye tracking.

Grossly decentered ablation zones can lead to serious disabling side effects such as halos, glare, and diplopia.^{21–25} The loss in mesopic vision is also correlated with the amount of decentration¹⁰ observable after laser in situ keratomileusis and photorefractive keratectomy.^{26,27} Recently, our group theoretically investigated the effect of constant lateral decentrations based on measured wavefront aberration data from the cohort of eyes used in this study.¹³ Simulations were done for wavefront-guided treatments, trying to correct sphere, cylinder, and HOAs. To achieve the diffraction limit (MA criterion) in 95% of the eyes with a 7.0 mm pupil, the lateral displacements should not exceed 0.07 mm, whereas an accuracy of 0.50 mm was enough to guarantee that none of the treated subjects will experience a degraded optical performance compared to the preoperative state.

Several reports have dealt with the topic of misalignment in refractive surgery, analyzing cases of displaced ablations.^{10,23–25} Most focused on lateral translations away from the entrance pupil center; they did not consider any type of rotational misalignment. Guirao and coauthors¹² discuss the effect of cyclorotations and translations of an ideal correction pattern on the ocular modulation transfer function and the RMS of the residual wavefront error based on 6.0 mm pupil data from 10 eyes. The mean value and standard deviation of the RMS wavefront aberrations including defocus and astigmatism was $0.97 \mu\text{m} \pm 0.47$ (SD). The image quality did not fall below the Rayleigh limit for toler-

ances (measure of the diffraction limit) until the rotation angle was 3 degrees, which is consistent with our results obtained for a cohort of eyes with mean RMS wavefront aberrations including defocus and astigmatism of $1.22 \pm 1.05 \mu\text{m}$ with 6.0 mm pupils. Furthermore, they found that the benefit of also correcting HOAs decreases when the misalignment increases. These results, however, were based on a small number of eyes.

Torsional alignment errors can result from a slight lateral tilt of the patient's head between the measurement and the treatment as well as from ocular cyclotorsion between the seated and the supine positions. However, Smith and Talamo²⁸ did not find a statistically significant difference between the 2 measurements in the seated and the supine positions, although they observed cyclotorsion up to 16 degrees in some patients. Clinical trials presented by SMI (Sensomotoric Instruments GmbH) show a mean and standard deviation for ocular torsion of 2.8 ± 3.6 degrees, with a maximum of 9.4 degrees. Further clinical trials are needed to clarify the amount of ocular cyclotorsion and lateral head tilt to be expected in refractive surgery.

Together with the Strehl ratio (defined as the ratio between the maximum intensity of the aberrated eye and the intensity of the corresponding diffraction-limited eye), the RMS value is a common measure to describe the optical quality of a system. Reports^{4,29} show a significant but weak correlation between determined RMS values and high- and low-contrast visual acuity. Today, the representation of wavefront data by single values such as the RMS wavefront error is not standardized. However, rating the retinal image quality by the RMS value is a prevalent method that was suitable for our purposes. Several concepts for rating visual performance such as "visual benefit" by Williams et al.³⁰ and the concept presented by Ballentine et al.³¹ have recently been introduced.

Referring to our results for wavefront-guided treatments with 7.0 mm pupils, it seems unlikely that an eye's optical quality would be degraded compared to the preoperative state (OT criterion) if the torsional alignment error did not exceed 15 degrees. In 90% of the examined eyes, an accuracy of 25 degrees or better would have been sufficient to achieve the same goal. However, a torsional precision of approximately 1 degree or better would be necessary to achieve a diffraction-

tion-limited retinal image in 95% of the normal eyes with a 7.0 mm pupil (MA criterion).

Our results demonstrate that precise torsional alignment is more important in wavefront-guided treatments than in conventional spherocylindrical treatments as far as the relative improvement in image quality is concerned.

Procedures ensuring that the initial placement of the coordinate system used in the treatment coincides exactly with the reference system set up in the measurement must be elaborated. Rough centration based on the operator's judgment might not be accurate enough to achieve improved optical quality in a high percentage of treated eyes.

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