Objective: To evaluate the theoretical effect of decentration of aspherical intraocular lenses (IOLs) and wavefront-corrected IOLs up to the sixth order on higher-order aberrations (HOAs) (third through sixth order) of the eye.

Methods: An aspherical IOL with HOAs of fourth-order spherical aberrations only (−0.287 μm with a 6-mm pupil) and a wavefront-corrected IOL with HOAs of equal magnitude and opposite from the corneal HOAs were created and laterally shifted up to 1 mm to simulate decentred IOLs. The residual HOAs for pupils of 3 to 6 mm were calculated by combining the HOAs from the cornea and the centered IOL. Based on the residual HOAs, optical quality was rated by 3 criteria: the Marechal criterion, a diffraction-limited optical system with an aberration less than 1/14; P10, the lower 10th percentile of the corneal HOAs in this study group; and decreased HOA, residual ocular HOAs less than the corresponding corneal HOAs.

Results: Simulated implantation of the aspherical IOLs and wavefront-corrected IOLs was performed in 154 eyes of 94 patients aged 40 to 80 years. For a centered aspherical IOL and a 6-mm pupil, no eyes met the Marechal criterion, and the P10 and decreased-HOA criteria were met by 46% and 93% of eyes, respectively. For a 6-mm pupil, the required centration was 0.47 mm to meet the decreased-HOA criterion in 50% of eyes. With a wavefront-corrected IOL and a 6-mm pupil, the centraions required to meet the criteria for 90% of eyes were 0.04 mm for the Marechal criterion, 0.36 mm for P10, and 0.48 mm for the decreased-HOA criterion.

Conclusion: Excellent centration is required to maximize the visual outcome of wavefront-corrected IOLs.

Clinical Relevance: With current surgical techniques, implantation of aspherical IOLs and wavefront-corrected IOLs will reduce total ocular HOAs below corneal HOAs in approximately 45% and 86% of eyes (6-mm pupil), respectively.

Arch Ophthalmol. 2005;123:1226-1230

METHODS

PATIENT SELECTION

The subjects were selected from our refractive-surgery candidates and cataract patients. Inclusion criteria were the following: (1) manifest refractive sphere of −3 to +3 diopters (D) and cylinder of less than 2 D; (2) age of 40 to 80 years; (3) no previous ocular or corneal surgery; (4) no corneal scar or other corneal pathology; (5) no contact-lens wear or contact lens wear discontinued for 8 weeks for rigid gas-permeable lenses, 4
RESIDUAL WAVEFRONT ABERRATION

Assuming implantation of the AIOL and WIOL in patients' eyes, the combination of the wavefront aberrations from the AIOL (W_{AIOL}) or WIOL (W_{WIOL}) and from the patient's cornea (W_{COR}) would produce the residual ocular aberration (W_{RES}):

\[ W_{RES} = W_{COR} + W_{AIOL} = W_{COR} + W_{WIOL} \]

If the AIOL was perfectly centered, the \( W_{RES} \) would equal the \( W_{COR} \) for all Zernike terms except the fourth-order SA, which would decrease or increase depending on the patient's corneal SA. If the WIOL was perfectly centered, the \( W_{RES} \) would be 0.

We computed \( W_{COR} \) from Humphrey Atlas corneal elevation data using the CTView program, which uses the standards for calculating and reporting the optical aberrations of eyes as proposed by Thibos et al. The topographic maps were recentered around the entrance pupil, and wavefront aberrations from the cornea were calculated using a corneal refractive index of 1.38.

Lateral shifts of the lens to 0.05, 0.10, 0.15, 0.20, 0.25, 0.50, 0.75, and 1.00 mm were performed to simulate a decentered AIOL or WIOL. We calculated \( W_{RES} \) for eyes with centered and decentered lenses for 3-, 4-, 5-, and 6-mm pupils.

DATA ANALYSIS

Rating of Optical Quality

The root-mean-square (RMS) of \( W_{RES} \) resulting from a decentered IOL was used to evaluate the optical quality of the eye and rated by 3 image-quality criteria as used in Bueeler et al's study (Table 1):

1. Marechal (MA) criterion: The MA criterion states that a well-corrected, diffraction-limited optical system has an RMS wavefront error not exceeding \( 1/4 \) wave. For a wavelength of 555 nm, the MA criterion was 0.04 µm. This strict criterion is difficult to achieve, especially in eyes with large pupils.
2. Lower 10th percentile (P_{10}). The P_{10} criterion represents the lower 10th percentile of the preoperative corneal HOAs (third- to sixth-order) RMS in the examined eyes. It was 0.06 µm for a 3-mm pupil and increased to 0.38 µm for a 6-mm pupil. If an eye meets this criterion, its optical quality is within the top 10% of this study group.
3. Decreased HOA (D_{HOA}): This criterion is the least strict of the 3 and compares the residual aberrations with the corneal aberrations before surgery. The rationale of this criterion is that if an aberration-free IOL is implanted, the \( W_{RES} \) would be caused only by the preexisting corneal aberrations, assuming that the corneal HOAs within the 6-mm zone do not change following the cataract incision. This criterion is fulfilled when the \( W_{RES} \) is equal to or less than the corneal HOAs.

RESULTS

The mean \( \pm \) SD age of the 154 eyes of 94 patients was 61 ± 12 years (range, 40-80 years). For a 6-mm pupil, the mean \( \pm \) SD corneal total HOA was 0.51 ± 0.13 µm (range, 0.23-0.86 µm), and fourth-order SA was +0.29 ± 0.09 µm (range, 0.08-0.54 µm).

ASPERHICAL IOL

Coma was the main aberration induced by the decentered AIOL. Figure 1. Figure 2 shows the \( W_{COR} \) and \( W_{RES} \) with the centered and decentered AIOL for a 6-mm pupil. On average, the \( W_{RES} \) was less than the \( W_{COR} \) if the AIOL was decentered less than 0.5 mm.

When the AIOL was perfectly centered, 1% of eyes met the MA criterion for the 3-mm pupil and none for the 4- to 6-mm pupils; 9%, 19%, 28%, and 46% of eyes met the P_{10} criterion (Figure 3A); and 51%, 77%, 92%, and 93% of eyes met the D_{HOA} criterion for 3-, 4-, 5-, and 6-mm pupils, respectively (Figure 3B).

With increasing amounts of decentration, the percentages of eyes meeting the criteria decreased (Figure 3). For 6-mm pupils, centration accuracies of 0.10 and 0.47 mm were required to meet the D_{HOA} criterion in 90% and 50% of eyes, respectively (Table 2).
Figure 1. An example of an aspherical intraocular lens (AIOL) decentered 0.5 mm along the 180° meridian for a 6-mm pupil. The coefficient of fourth-order spherical aberration ($Z_4$) in the AIOL is −0.29 µm, and the coefficient of the induced third-order horizontal coma ($Z_3$) is −0.30 µm.

Figure 2. Corneal higher-order aberrations (HOAs) and residual HOAs with centered and decentered aspherical intraocular lenses for a 6-mm pupil. Vertical bars indicate 2 SDs.

WAVEFRONT-CORRECTED IOL

Figure 4 shows the percentages of eyes that met the MA, $P_{10}$, and $D_{HOA}$ criteria at a specific decentration with the 4 pupil sizes. Decentration of less than 0.1 mm was required for most eyes to meet the MA criterion. A higher percentage of eyes met the MA criterion with smaller pupils at a specific decentration of the WIOL. For example, with a decentration of 0.1 mm, 69%, 57%, 21%, and 2% of eyes met the MA criterion for 3-, 4-, 5-, and 6-mm pupils, respectively (Figure 4A).

Less critical centration was required to meet the $P_{10}$ and $D_{HOA}$ criteria, and the alignment became less critical with larger pupils (Figure 4B and C). For example, for 3-, 4-, 5-, and 6-mm pupils, and a decentration of 0.3 mm, 16%, 48%, 75%, and 92% of eyes met the $P_{10}$ criterion, and 38%, 75%, 88%, and 98% of eyes met the $D_{HOA}$ criterion, respectively.

For 6-mm pupils, centration accuracies required to meet the MA, $P_{10}$, and $D_{HOA}$ criteria in 90% of eyes were 0.04, 0.36, and 0.48 mm, respectively (Table 3).

Clinical studies have shown that an aspherical IOL can improve visual performance, particularly contrast sensitivity and mesopic vision. An obvious concern of this lens is the effect of decentration on the optical outcome. Holladay et al reported that the modulation transfer function of an eye with an AIOL would exceed that of the spherical IOL if the AIOL is decentered less than 0.4 mm or tilted less than 7°. The purpose of this study was to more fully explore the anticipated effect on ocular HOAs of decentration of an AIOL and to extend this investigation to WIOLs.

Because the AIOL compensates only for fourth-order SAs of the cornea, even with the perfectly centered lens, the ocular residual HOAs were 0.09 µm lower on aver-
age than the corneal HOAs. In the eyes measured in our study, it was not possible to meet the MA criterion with an AIOL, and only 9% to 46% of eyes met the $P_{10}$ criterion with a perfectly centered AIOL. To ensure that 50% of eyes have ocular residual HOAs less than their corneal HOAs, the decentration could not exceed 0.27 mm for a 4-mm pupil or 0.37 mm for a 6-mm pupil. The allowed decentration of 0.47 mm is inconsistent with the findings of Holladay et al that the modulation transfer function for a 6-mm pupil would be improved if 20-D and 30-D AIOLs were not decentered more than 0.4 and 0.5 mm, respectively.

With a WIOL, the residual HOAs would be 0 if it is centered perfectly. To meet the MA criterion in 90% of the eyes, the lens has to be centered within 0.10 mm for a 3-mm pupil, and even more accurate centration is required as pupil size increases. To ensure that 90% of eyes have residual ocular HOAs within the $P_{10}$ of normal corneal HOAs, WIOL decentration has to be less than 0.13 mm for a 3-mm pupil and 0.36 mm for a 6-mm pupil. If an aberration-free IOL is implanted, the residual ocular HOAs would be equal to the corneal HOAs. In the worst-case scenario, we probably do not want to induce more aberrations than the corneal HOAs. For ocular HOAs not to exceed corneal HOAs in 90% of eyes, our results show that the lens decentration has to be less than 0.20 mm for a 3-mm pupil and 0.48 mm for a 6-mm pupil.

In wavefront-guided corneal ablation, Bueeler et al reported that to achieve the diffraction-limited MA criterion in 95% of the eyes, lateral alignment accuracies of 0.21 and 0.07 mm or better were required for 3- and 7-mm pupils, respectively; to meet the $P_{10}$ criterion, accuracies within 0.41 and 0.22 mm were required for 3- and 7-mm pupils, respectively. We found that more critical centration was required for the WIOL to meet the MA criterion and the alignment became less critical with larger pupils; this may be explained by the fact that corneal HOAs are larger than ocular HOAs, and corneal HOAs increase dramatically with increasing pupil size compared with ocular HOAs. In the study by Bueeler et al, a criterion of each eye's total (second- to sixth-order) preoperative RMS wavefront aberration was used to rate the residual aberration; in contrast, we used the corneal HOAs of each eye.

What can surgeons expect with regard to the accuracy of IOL centration? With continuous curvilinear capsulorhexis and in-the-bag IOL placement, mean IOL centration has been reported to be within 0.1 to 0.3 mm.

Referring to Table 1, we see that with a 6.0-mm pupil and decentration of 0.47 mm, 50% of eyes will experience a reduction in the HOAs compared with HOAs that are present in their corneas. One can therefore conclude that less than half of all patients implanted with AIOLs will have postoperative ocular HOAs that are lower than the HOAs in their corneas. With regard to WIOLs (Table 3) with a 6.0-mm pupil and a decentration of 0.48 mm, total ocular HOAs were less than those present in the cornea in 90% of eyes. One can therefore conclude that the majority of eyes implanted with WIOLs will experience postoperative HOAs that are less than those present in the cornea preoperatively. Obviously, clinical evaluation is required to determine the visual impact of these changes on patients' quality of vision.

Table 3. Required Centration Accuracies to Fulfill the MA, $P_{10}$, and $D_{HOA}$ Criteria in 90% of Eyes Implanted With Wavefront-Corrected Intraocular Lenses

<table>
<thead>
<tr>
<th>Pupil Size, mm</th>
<th>MA</th>
<th>$P_{10}$</th>
<th>$D_{HOA}$</th>
</tr>
</thead>
<tbody>
<tr>
<td>3</td>
<td>0.10</td>
<td>0.13</td>
<td>0.20</td>
</tr>
<tr>
<td>4</td>
<td>0.08</td>
<td>0.18</td>
<td>0.28</td>
</tr>
<tr>
<td>5</td>
<td>0.06</td>
<td>0.26</td>
<td>0.37</td>
</tr>
<tr>
<td>6</td>
<td>0.04</td>
<td>0.36</td>
<td>0.48</td>
</tr>
</tbody>
</table>

Abbreviations: $D_{HOA}$, decreased higher-order aberration; MA, Marechal; $P_{10}$, lower 10th percentile.
A major limitation of this study is that the RMS of the residual wavefront aberration was used as a representation of the optical quality of the eye. Although reports show a significant but weak correlation between determined RMS values and high- and low-contrast visual acuity,10,11 Applegate et al12 reported that different Zernike terms with the equivalent RMS values can interact to improve or reduce visual performance. Further studies are required to define parameters that correlate well with visual performance.

Other limitations of this study include that it is a theoretical analysis, clinical studies investigating the required alignment of the lens based on visual performance are obviously required, and we did not model the effect of torsional misalignment of the IOL on the change in ocular HOAs.

In conclusion, our results demonstrate that excellent centration is required to maximize the reduction of HOAs following implantation of wavefront-modified IOLs.

Submitted for Publication: October 7, 2004; final revision received February 7, 2005; accepted February 8, 2005.

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Financial Disclosure: None.

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