Bilateral Implantation of Asymmetrical Diffractive Multifocal Intraocular Lenses

Felix K. Jacobi, MD; Jochen Kammann, MD; Karl W. Jacobi, MD; Ute Großkopf, MD; Karin Walden, MD

Objective: To evaluate visual results after bilateral implantation of multifocal intraocular lenses (IOLs) with asymmetrical light distribution for the far and near focus.

Methods: Twenty-nine patients underwent bilateral implantation of silicone-optic, foldable, diffractive IOLs in a prospective, 2-center, noncontrolled interventional study. Each patient had a distant-dominant multifocal IOL implanted in 1 eye and a near-dominant multifocal IOL implanted in the fellow eye. Refractive and visual results, including contrast acuity and binocular visual function, were determined. Patients were questioned for postoperative spectacle usage.

Results: Visual and contrast acuity in the dominant focus of either lens was superior to that in the nondominant focus at 3.5 to 12 months postoperatively, ie, performance was best at distance for the distant-dominant and at near for the near-dominant lens. In binocular viewing, the monocular maximal results added up to an improved binocular visual performance. Binocular visual function was within normal limits. Eighty percent of patients reported no use of spectacles at any time postoperatively.

Conclusions: Bilateral implantation of asymmetrical diffractive IOLs is an effective alternative for restoring simultaneous distance and near vision with a potential for improved contrast sensitivity compared with conventional multifocal IOLs.

PATIENTS AND METHODS

Twenty-nine patients with cataracts were enrolled in this prospective, nonrandomized clinical study that was performed at 2 surgical sites: Department of Ophthalmology, University of Giessen, Giessen, Germany (n = 14), and St Johannes Hospital, Dortmund, Germany (n = 15). To be eligible for the study, patients were required to have bilateral cataracts without any other significant eye disease or abnormalities of ocular motility, and 1.5 diopters (D) or less of preoperative astigmatism. Patients were required to understand the investigational nature of the study, have a motivation to be spectacle free, and provide informed consent. No institutional review board approval was required for this study. All surgery was performed by 2 experienced surgeons (F.K.J., J.K.) using a standardized technique of sutureless, clear-corneal phacoemulsification. Before IOL implantation, 2 holes measuring 1.2 to 1.4 mm were trephined into the lens’ disc haptic by means of Eliot trephines to facilitate viscoelastic aspiration from the capsular bag. The IOLs were implanted with either an injector device or implantation forceps. There were no surgical complications.

At 1 study center, all surgery was performed on both eyes in 1 procedure. At the other center, the mean interval between surgery was 91 days. Lens selection was handled differently at each site because of the difference in the timing of the surgery in both eyes. In bilateral simultaneous surgery, the distant-dominant lens was always implanted in the right eye and the near-dominant lens in the left eye. In sequential surgery, the distant-dominant lens was always implanted in the first eye and the near-dominant lens in the second eye. Thus, 8 patients (28%) of the total study population had a distant-dominant lens implanted in the left eye. Patients were unaware of which eye had a distant- or near-dominant multifocal IOL.

The multifocal IOL used in this study was a 1-piece bifocal diffractive silicone IOL. The near addition is 4.0 D, which corresponds to approximately 3.2 D in the spectacle plane. The lens was produced in a disc haptic design (Chiron-Adatomed, Munich, Germany). There are 2 versions of the lens that use the same design and diffractive principle but differ in light distribution for the far and near focus. By assigning the appropriate dimensions to the 16 concentric rings on the posterior lens surface, 70% of incident light is focused for distance vision and 30% for near vision in the distant-dominant lens, and vice versa for the near-dominant lens. In contrast to other types of diffractive IOLs with a symmetrical light distribution, the asymmetrical multifocal IOL has a lower loss of light at higher orders of diffraction (13% instead of 18%) that are out of focus. The clinical defocus curve determined by measuring distance acuities with −3.0 D to 3.0 D of overrefraction is demonstrated for a patient who underwent binocular implantation (Figure 2). The IOL has an optic diameter of 5.5 mm (≥22 D) to 6 mm (<22 D) and a total diameter of 10 mm (Figure 3). The lens optic is biconvex and aspheric, and has a diffractive zone of 4.5 mm in diameter. The lenses supplied for this study were available in the range from 19.0 to 25.0 D in 1.0-D increments. Postoperative target refraction was emmetropia.

Measurement of the modulation transfer function (MTF), a test to quantify the image quality in an optical system, of the multifocal lenses was performed in an optical laboratory before clinical use. Measured is the modulation, or contrast, of the image formed by the system for variously sized (spatial frequencies), high-contrast targets whose luminance can be described by sinusoidal functions. Changes of in vitro MTF measurements are expected to cause reciprocal proportional changes in clinically measured contrast sensitivity. The MTF has become a standard today for evaluation of multifocal IOLs, as indicated by the Food and Drug Administration guidelines for multifocal IOL studies. The MTF of a near-dominant diffractive IOL measured through the distance and near focus is shown in Figure 4. The spatial frequency on the abscissa has been converted into normalized frequency to facilitate comparison between the diffraction-limited lens and the multifocal lens. The normalized frequency fixes the cut of frequency of the diffraction-limited lens at unity irrespective of pupil diameter and wavelength. The curve of the theoretic diffraction-limited lens has been plotted to cross the ordinate at 0.7 and 0.3 values to account to the relative light distribution of 30% for the far and 70% for near focal point in the near-dominant lens. The MTF of the multifocal IOL closely approximates the MTF of the theoretical diffraction-limited lens, which demonstrates high image quality of the lens. The MTF for the dominant-dominant lenses (not shown) corresponds to that of the near-dominant lens but switched for the far and near focal point. This high image quality

be additive, thus allowing a binocular contrast sensitivity and distance and near visual acuity that are superior to the function in bilateral multifocal IOLs with symmetrical light distribution (Figure 1). The concept can be considered a combination of multifocal IOL implantation and monovision, but unlike monovision, asymmetrical bilateral multifocal IOL implantation does not induce anisometropic blur.

The objective of the study was to evaluate visual results after bilateral implantation of asymmetrical multifocal IOLs.

RESULTS

Distance and near visual acuity results are given in Table 1, Table 2, and Table 3. Distance visual acuity was better in eyes with the distant-dominant than the near-dominant multifocal IOL, both with and without distance correction. In near visual acuity testing, this tendency was reversed. We observed better near acuities more frequently in eyes with a near-dominant lens than in those with a distant-dominant lens. With distance correction, all patients achieved J1 binocularly. With near addition, we measured J1 in all eyes with a distant-dominant lens and in all but 1 eye (J2) in eyes with a near-dominant lens. Binocular distance visual acuity was improved compared with monocular distance visual acuity in eyes with the distant-dominant lens, both with and without correction. Eighteen (72%) of 25 patients were able to binocularly read 20/20 and J1 and 25 (100%), 20/25 and J2 or better with distance correction. Uncorrected, 14 (56%) of 25 patients achieved 20/25 and J2 or better.

TABLE 1

Measurement of the modulation transfer function (MTF), a test to quantify the image quality in an optical system, of the multifocal lenses was performed in an optical laboratory before clinical use. Measured is the modulation, or contrast, of the image formed by the system for variously sized (spatial frequencies), high-contrast targets whose luminance can be described by sinusoidal functions. Changes of in vitro MTF measurements are expected to cause reciprocal proportional changes in clinically measured contrast sensitivity. The MTF has become a standard today for evaluation of multifocal IOLs, as indicated by the Food and Drug Administration guidelines for multifocal IOL studies. The MTF of a near-dominant diffractive IOL measured through the distance and near focus is shown in Figure 4. The spatial frequency on the abscissa has been converted into normalized frequency to facilitate comparison between the diffraction-limited lens and the multifocal lens. The normalized frequency fixes the cut of frequency of the diffraction-limited lens at unity irrespective of pupil diameter and wavelength. The curve of the theoretic diffraction-limited lens has been plotted to cross the ordinate at 0.7 and 0.3 values to account to the relative light distribution of 30% for the far and 70% for near focal point in the near-dominant lens. The MTF of the multifocal IOL closely approximates the MTF of the theoretical diffraction-limited lens, which demonstrates high image quality of the lens. The MTF for the dominant-dominant lenses (not shown) corresponds to that of the near-dominant lens but switched for the far and near focal point. This high image quality...
The visual acuity results were echoed by our findings in contrast acuity testing. Eyes with a distant-dominant lens performed better when tested at far, and eyes with a near-dominant lens, when tested with a −3.0-D addition, ie, visual performance was optimal in the dominant focus of either lens. Binocular contrast acuity results again exceeded monocular results (Figure 5).

Mean ± SD stereoscopic acuity was 74.3 ± 41.1 minutes of arc (range, 25-200 minutes of arc), with 19 (76%) of 25 patients showing values of 80 minutes of arc or less. Mean ± SD convergence amplitudes of 9.2° ± 3.0° and divergence amplitudes of −4.0° ± 1.4° were measured.

The frequency of postoperative spectacle usage was 20% (5 patients) for distance vision. Eighty percent of patients (20/25) reported no spectacle use at any time, and no one required near addition.

Refractive results are given in Table 4. Twenty-three (92%) of 25 patients had less than 1 D of refractive error from target refraction in their eye with the distant-dominant lens, compared with 18 (72%) of 25 in the eye with the near-dominant lens. Seven (28%) of 25 patients had more than 1 D of difference in spherical equivalent between both eyes.

In this study, 2 new features in the field of multifocal IOL implantation were combined to achieve simultaneous distance and near vision with improved contrast sensitivity after bilateral surgery. We used 2 versions of a foldable silicone IOL with an aspheric, diffractive bifocal optic that provide an asymmetrical light distribution for the
far and near focus of either 70%:30% or 30%:70%. These lenses were bilaterally implanted in an asymmetrical fashion: each patient received a distant-dominant IOL in 1 eye and a near-dominant IOL in the fellow eye. Furthermore, this is the first report of clinical results after implantation of foldable diffractive multifocal IOLs. The concept of bilateral implantation of asymmetrical multifocal IOLs has been previously evaluated with refractive IOLs made of polymethylmethacrylate.

Our results demonstrate a pronounced effect of the asymmetrical light distribution with statistically significant differences in distance and near visual acuity between the distant- and near-dominant multifocal IOLs. We detected maximal visual acuity results in the dominant focus of either multifocal IOL, apparently at the expense of acuity loss in the nondominant focus. The contrast acuity results were analogous to the visual acuities and demonstrated an improved performance in the dominant focus of either lens. It is notable that contrast acuity with the Regan contrast chart improved in eyes with the near-dominant lens while overrefracting with −3.0 D. This implicates a safety margin in the presented concept. A slight loss in mean distance visual acuity in the eyes with the near-dominant lens can be restored by adding the proper correction, ie, −3.0-D addition. This would be indicated, for instance, when vision is lost in the distant-dominant eye because of macular degeneration.

Binocular summation in eyes with bilateral asymmetrical multifocal IOLs is clearly evidenced by improvement of binocular visual function over monocular viewing. The ideal outcome of bilateral multifocal IOLs with asymmetrical light distribution would have been an enhanced contrast sensitivity in the dominant focus without any effect on visual acuity in the nondominant focus.

Figure 1. Conceptual depiction of the principle of bilateral multifocal intraocular lens implantation with asymmetrical light distribution. Note a sharp-contoured image of objects at distance and at near, but image contrast is inverse between both eyes at the respective distances. In binocular viewing, image contrast in the dominant focus of both eyes adds up to improve binocular vision.

Figure 2. Monocular and binocular distance visual acuity in a 69-year-old woman, with defocus from emmetropia.

Figure 3. Scanning electron micrograph of the 1-piece silicone intraocular lens with a diffractive zone on the posterior surface, with an asymmetrical light distribution for the far and near focus.

Figure 4. Modulation transfer function of a near-dominant diffractive intraocular lens (IOL) measured through the near (top) and distance (bottom) focus.
was a realistic goal based on psychophysical data, which indicate less sensitivity of visual acuity to variation of stimulus luminance compared with contrast sensitivity.16

The asymmetrical diffractive multifocal lenses used in this study were designed after a number of earlier experimental and clinical studies were conducted.8,15 Light distributions of 70%:30% and 30%:70%, respectively, were considered the best choice on the basis of these results. Jacobi and Eisenmann8 introduced the concept of bilateral implantation of asymmetrical multifocal IOLs in 1993 with the use of all-poly(methyl methacrylate), 3-zone refractive multifocal IOLs at various light distributions (50%: 50%, 60%:40%, 40%:60%, 70%:30%, and 30%:70%). They performed experimental, psychophysical studies with the use of a specially designed optical system that simulates visual perception through any type of IOL under monocular and binocular viewing conditions.17 The optical system, which is similar to an astronomical telescope, projects a real image of an IOL into the normal phakic eye of a subject. This produces a virtual IOL in the sub-
focal IOL is theoretically superior to a truly multifocal IOL that spreads light over several focal points. In our lens optic design, in pupil diameters larger than 4.5 mm, relatively more light is refracted to the far than to the near focus compared with pupil diameters of 4.5 mm or less. This theoretically favors distance vision over near vision in large pupils, ie, it enhances distance dominance in the distant-dominant lens and lessens near dominance in the near-dominant lens. In our aged study population, this aspect is probably not relevant because of the already diminished pupil size in elderly patients. In young patients, who have better responsiveness to pupil reaction, enhancement of distance dominance may in fact prove advantageous under low illumination, such as at night. The significance of pupil size was not determined in our study. All tests were done with a pharmacologically unaffected pupil size.

The near addition in the foldable diffractive IOL is 4.0 D, which is adequate to provide good near vision as indicated by our results. This near addition is consistent with most other current multifocal IOL designs.

The advantage of the investigated multifocal IOL is that it can be folded and implanted through an approximately 3.5-mm-wide, self-sealing sutureless incision. The benefit of a low surgically induced astigmatism and quick visual rehabilitation in small-incision cataract surgery is well recognized with monofocal and multifocal IOL implantation.

The disc haptic design in the foldable diffractive lens has a track record with good clinical results from its monofocal counterpart (model 90D, Chiron-Adatomed).

One shortcoming of the multifocal lenses used in the present study was their availability in 1-D steps only. This accounts for the unsatisfactory refractive results with 1 D or more of refractive error from target refraction in some eyes. This was especially evident in eyes with a near-dominant lens (mean ± SD absolute error, 0.76 ± 0.66 D), while the results in eyes with a distant-dominant lens were within normal limits of refractive outcome data (mean ± SD absolute error, 0.57 ± 0.39 D). The former may reflect a difficulty in accurately refracting a near-dominant diffractive lens through the nondominant far focal point. To attain a higher accuracy, the multifocal IOLs will be produced in 0.5-D steps in the future, but this was not possible for technical reasons at the time the study was conducted.

It is inherent in the design of multifocal IOLs in general that they trade off a certain amount of image clarity for an increased depth of focus compared with monofocal IOLs. This is also true for both styles of the diffractive lenses.

### Table 4. Refractive Data

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<thead>
<tr>
<th></th>
<th>Distant-Dominant MIOL (n = 25)</th>
<th>Near-Dominant MIOL (n = 25)</th>
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</thead>
<tbody>
<tr>
<td><strong>Target refraction, D</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean ± SD</td>
<td>−0.13 ± 0.22</td>
<td>−0.12 ± 0.34</td>
</tr>
<tr>
<td>Range</td>
<td>−0.64 to 0.25</td>
<td>−0.68 to 0.46</td>
</tr>
<tr>
<td><strong>Postoperative refraction</strong></td>
<td></td>
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<tr>
<td>(spherical equivalent), D</td>
<td>0.14 ± 0.72</td>
<td>−0.14 ± 0.88</td>
</tr>
<tr>
<td>Mean ± SD</td>
<td>−1.25 to 1.25</td>
<td>−2.5 to 0.75</td>
</tr>
<tr>
<td>Range</td>
<td>0 to 1.21</td>
<td>0 to 2.02</td>
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<tr>
<td><strong>Absolute refractive error, D</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean ± SD</td>
<td>0.57 ± 0.39</td>
<td>0.76 ± 0.66</td>
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*MIOL indicates multifocal intraocular lens; D, diopters.*
used in the present study. In combination, however, they gain an improvement in contrast sensitivity as well as distance and near visual acuity under binocular viewing conditions. Ultimately, one may assume that this gain is only at the expense of another visual modality, namely, binocular visual function. This could not be substantiated by means of clinical tests in our study. The results of stereoscopic acuity and fusional amplitude measurements suggest intact binocular vision in the majority of patients. The advanced mean age of our study population must be considered when the results are compared with normal data. The difference in image contrast between the 2 eyes does not appear to affect binocular vision to a degree that is clinically relevant. It may require more refined testing to detect subclinical deficits in binocular visual function, such as testing under low-luminance conditions. In experimental studies, a negative influence of dissimilar image contrast on stereoscopic acuity has been described.\(^5\)

The postoperative survey of spectacle usage demonstrates a high success rate with regard to spectacle independence in our study population. This is most evident for near vision, with no patient requiring near addition. The need for glasses is greatly influenced by the postoperative refractive status, which is determined by the accuracy of biometry, the A-constant, and the available lens powers. The high degree of spectacle independence in our study population compares well with previous clinical studies using different styles of multifocal lenses.\(^6,7\)

Eye dominance has potential importance in the concept of bilateral implantation of asymmetrical multifocal IOLs. In monovision it is well established that correcting the dominant-dominant eye for distance vision and the non-dominant eye for near vision has a higher success rate in terms of patient acceptance.\(^8\) In our study, however, we were unable to define the population in terms of ocular dominance and establish an accurate assignment of the dominant-dominant lens to the dominant-dominant eye and the near-dominant lens to the non-dominant eye, because to our knowledge there is no approved method to unerringly determine ocular dominance in patients with bilateral cataracts. Our study results are therefore potentially biased by our strategy to arbitrarily assign the dominant-dominant lens to right eyes in cases of bilateral simultaneous surgery and to the first eye to be operated on in sequential surgery. The majority of our study population received the distant-dominant lens in the right eye. In the general population, the percentage of right-eye dominance is approximately 80%.\(^9\)

The purpose of the reported study was to validate the feasibility of the concept of bilateral implantation of asymmetrical diffractive IOLs. It is an effective alternative to provide good simultaneous distance and near vision with improved contrast sensitivity and intact binocular vision after bilateral cataract surgery. Randomized clinical trials that compare the performance of the asymmetrical diffractive IOLs with conventional and monofocal IOLs will further elucidate the usefulness of this concept.

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Reprints: Felix K. Jacobi, MD, Department of Ophthalmology, University of Giessen, Friedrichstr 18, 35392 Giessen, Germany (e-mail: felix.k.jacobi@uni-giessen.de).

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