23 Multifocal Intraocular Lenses: Fyodorov Gradiol

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23.1 Introduction

Currently diffractive and refractive multifocal intraocular lenses (MIOLs) are often used for refractive lens exchange and presbyopia correction [1–12]. The principle of MIOLs involves subdividing incoming light into at least two components that form focal zones of specific depths. MIOLs represent an optical compromise between high-quality visual function in variable luminance conditions and the ability to see at various distances. Fundamentally, multifocal correction is a correlation between depth of focus and modulation transfer functions (MTFs) of the optical system. The MIOL design providing the best quality of vision and independence from spectacle correction is still under debate.

Presently, the lenticular theory is the dominant theory of presbyopia. This theory proposes that the main causes of presbyopia are the changes over time in optical and biomechanical parameters of the physiologic lens [13–21]. This theory incorporates well-established data including annual growth rate of the crystalline lens (0.02 mm/year), changes in mean equivalent refractive index (1.427 ÷ 1.418), and surface refractive index (1.386 ÷ 1.394) [22–26].

Change in the physiologic lens is a result of a decrease of negative spherical aberration toward positive spherical aberration in individuals of presbyopic age. This change in spherical aberrations and magnitude of the spherical aberration can have a number of optical consequences including changing the depth of focus. If depth of focus increases, it can result in a "passive" ability of the eye to see at various distances without an active change of lens power during accommodation [27]. We tried to emulate this physiologic process that can be modeled by gradient optics while developing a MIOL.

Currently available MIOLs have variable refractive power due to the complex shape of anterior and/or posterior surfaces; however, gradient refractive index multifocal lens (GRIN lens) is characterized by varying refractive power due to a change of refractive index in the inner structure of the IOL.

GRIN lenses are widely used in in a variety of optical systems, such as slide projectors, cameras, binoculars, telescope, and many other imaging devices and telecommunications applications.

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There are two gradient index (GRIN) lenses types: axial gradient and radial/cylindrical gradient. In the axial gradient, the refractive index varies in a continuous way along the optical axis of the inhomogeneous medium. In the axial gradient, the surfaces of constant index are planes perpendicular to the optical axis. In the radial/cylindrical, the index profile varies continuously from the optical axis to the periphery along the transverse direction in such a way that the surfaces of constant index are concentric cylinders about the optical axis.

The multifocal IOL with variable refractive index design is a lens that has an index of refraction profile that varies in two directions simultaneously: from the optical axis to the periphery and along the optical axis.

This feature results in a number of optical and structural advantages. This design will likely improve functional results and diminish optical side effects in patients who undergo MIOL implantation.

In addition to mimicking normal physiology, there are other potential benefits of gradient IOLs compared to other MIOL design including:

- A smooth optical surface that decreases the possibility of mechanical damage to the lens optic during implantation.
- Postoperative functional vision is achieved over a wide range, including near and intermediate distances which is of utmost important for computer work and driving.
- Good visual functions under varying light conditions (photopic, mesopic, and scotopic).
- Better retinal image quality postoperatively.

The purpose of the current study was to use theoretical, laboratory research to develop and clinically evaluate a MIOL with gradient refractive index optics. We tried to emulate this physiologic process that can be modeled by gradient optics while developing a MIOL. The goal of our study was to create an IOL with sufficient pseudoaccommodation (up to 5.00 D), which corresponds to the normal accommodation values of 40–45-year-old subjects [28].

23.2 Computer Modeling of Human Eye Optics with Implanted Multifocal Gradient Intraocular Lens

Original mathematical modeling software was developed based on fundamental optical principles. This software was used to optimize gradient IOL parameters in order to simulate the highest image quality possible. The software performs calculations for the optics of the human eye. This software can construct and analyze test object images by ray tracing in the axial and transverse planes, to model and visualize the color images projected on the retina. Additionally, comparative quantitative analysis can be performed of the optical characteristics of the IOL (modulation transfer and scattering functions) while changing varying parameters (diameter, surface curvature radius, and refractive index).

23.2.1 Theoretical Basis and Software Algorithm

The software is based on the calculation of light rays, each of which is incident to the lens surface at arbitrary point under variable angles. The only simplifying assumption fully fulfilled in all designs is the lens axial symmetry. The IOL surface can be modeled as spheric, ellipsoid, hyperbolic, or parabolic. The software calculates convex, concave, convex–concave, and concave–convex lenses. Calculation of each ray is performed according to the laws of geometric optics in a three-dimensional space.

To simulate an image of a point source of light, it is necessary to calculate the light ray data emitting from the given source and passing through the lens at different locations in a transverse fashion. Visualization of software simulation allows an understanding of the emission pattern and image type formed by the light rays. Mean focal distance calculation results in plotting a focal distance–principal optical axis distance diagram, which provides information on spherical aberration of the lens. This information is also garnered from the value of the standard deviation of the focal distance. Spherical and

higher-order aberrations are calculated according to the software algorithm. The algorithm is easily extrapolated to the system of lenses and can be modified for calculation of lenses with complex surface structure including gradient optic lenses.

23.3 Software Windows

23.3.1 Determination of Optimal Optical Parameters for a Gradient Multifocal Intraocular Lens

The calculations were performed by software consisting of visual programming environment Borland C++ Builder (version 6) with the Windows XP operating system (Microsoft Corp., Redmond, WA, USA). The program operating window is presented in Fig. 23.1 that demonstrates a software version for a particular gradient lens calculation, which consists of outer and inner components. The latter has a smaller diameter differing from the outer component by external surface radii and refraction index. The software accounts for a considerable number of optical system parameters including cornea, aqueous humor, artificial lens, vitreous body, and retina. IOL parameters are set either as optical components diameter, curvature radius, refraction index, IOL thickness, lens sphericity in relation to the optical axis, and diaphragm diameter (i.e., pupil).

The human eye optical parameters include radius of curvature of the outer corneal surface (7.7 mm), inner corneal surface (6.8 mm), outer corneal surface–retina distance (24.0 mm), retinal curvature radius (12.0 mm), cornea refraction index (1.376), aqueous humor (1.336), and vitreous body (1.337).

Computer modeling software allowed analysis of the distribution of rays and ray patterns in the principal focus neighborhood and types of aberrations. Figure 23.2 demonstrates the ray transmission near multifocal gradient lens focus reflecting correlation to optimal lens parameters. The software plots focal distance–ray position to lens optical axis diagram (if the source is positioned at the principal optical axis and sufficiently distant from the lens) (Fig. 23.3). The diagram provides

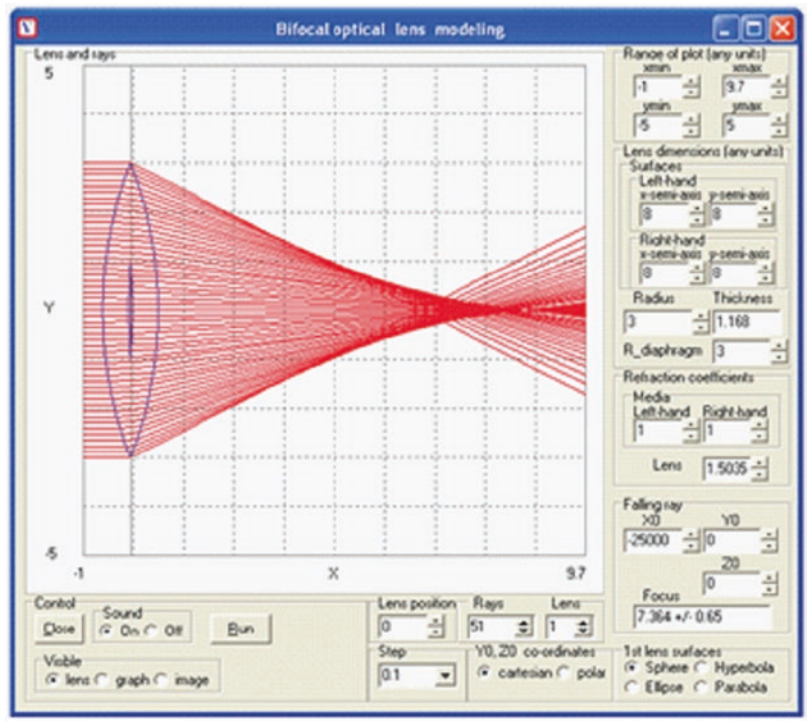

Fig. 23.1 Software window. Modeling ray passes through gradient lens, thus determining focal zone parameters

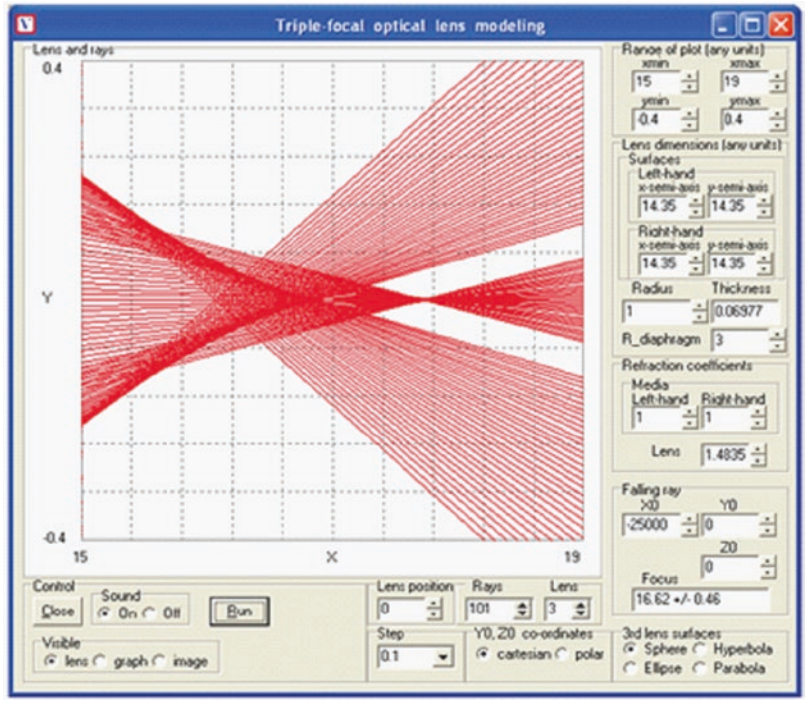

Fig. 23.2 Rays transmission nearby multifocal gradient lens focus. Outer lens component refraction index (RI) is 1.5035, inner component RI – 1.4835

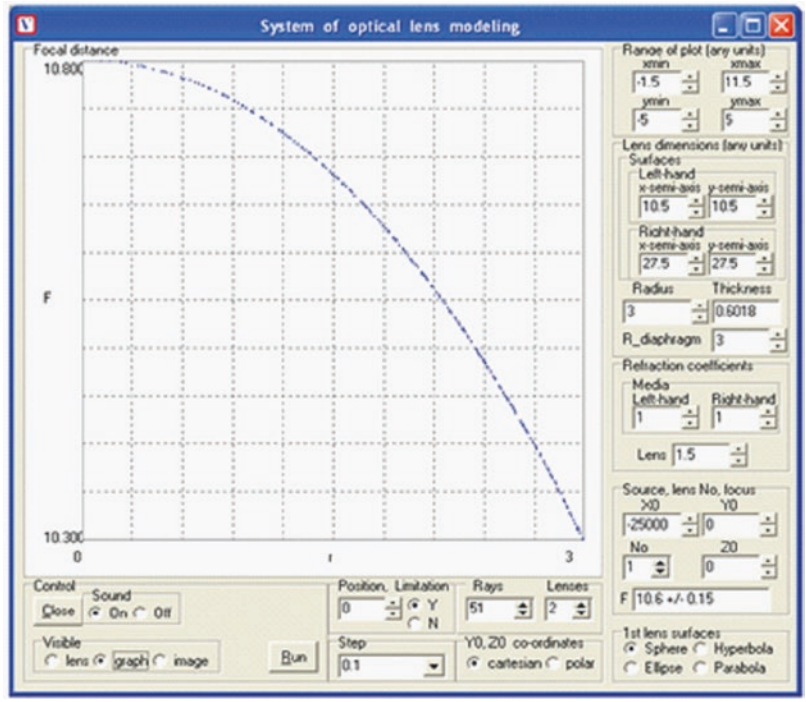

Fig. 23.3 Focal distance–ray radial coordinate diagram

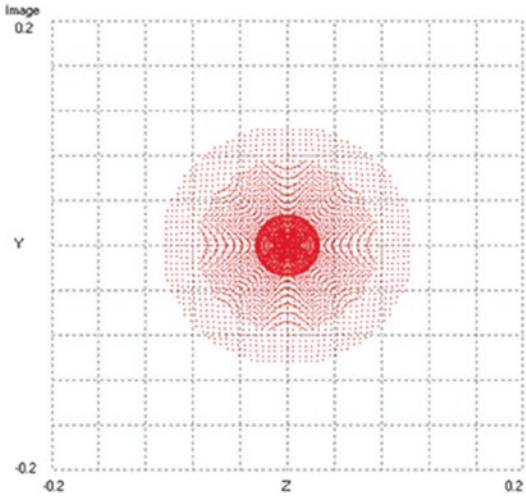

Fig. 23.4 Point light source image formed by multifocal lens

information on the spherical aberrations of a given lens. The focal distance standard deviation value provides information on spherical aberration. All other lens aberrations are calculated according to the software algorithm.

The software enables simulation and analysis of point light sources located at various distances from principal optical axis of the lens. Figure 23.4 demonstrates the light scattering sources around the maximum concentration zone of the light beam that is attributed to one of the multifocal lens foci.

Simultaneous analysis and visualization of spherical and chromatic aberrations by the software allows simulation of color images of test objects formed on the retina of a pseudophakic eye. To obtain image quantitative estimation, the computer modeling software calculates MTF and scattering function.

In order to calculate and select multifocal gradient IOL optimal parameters, we performed comprehensive computer modeling data evaluation. Additional optical power (difference in refractive power between zones for far and near) was specified by optimal distance for near vision (30/33 cm) and was determined by a refraction index (1.520 and 1.4795 for outer and inner components correspondingly) and by components curvature radius (15.11 mm outer lens component, 13.66 mm inner). Optimal calculated value of refractive power difference for far and near (outer and inner components of the lens) was 3.0 D.

For the retinal image computer modeling data, priority was place on distance vision for pseudophakic patients, safe driving (especially for acute miosis under bright light), and the possibility of senile miosis. Hence, the central optical zone was designed for far vision. The diameter of the inner component was calculated with consideration of optimal redistribution of light rays under varying light conditions (variable pupil diameters) (Figs. 23.1, 23.2, 23.3, and 23.4).

The optimal calculated value of the inner component diameter was modeled for 2.0 mm (3.0 mm pupil diameter). Under photopic conditions, the distribution of light rays between far and near zones was 45 and 55%, respectively (inner component diameter 2.0 mm). Under bright light and 2.5 mm miosis, the redistribution of light rays occurs at 65 and 35%, respectively. Under mesopic conditions and 3.5–4.0 mm pupil diameter, the distribution of light rays for far and near zones was 30 and 70%, respectively. The overall diameter of the optical zone is 6.0 mm. The inner component is placed in the center of outer component on radius and thickness. The overall IOL thickness is 1.0 mm, and its central component is 0.4 mm.

A variety of methods have been developed for producing materials with a variation in the index of refraction that is suitable for GRIN optics. Polymer GRIN lenses are often fabricated by copolymerization of two different monomers undergoing diffusion.

A single piece foldable multifocal gradient IOL was manufactured with step-by-step polymerization technology in transfer molds of photohardening material (ultraviolet light) with various refraction indexes (oligouretanmethacrylate). This technology can produce multifocal artificial lenses with gradient optics. The relative simplicity is an advantage of the manufacturing process; hence, it is possible to combine stages of material polymerization with lens manufacturing concurrently. Additionally, polymerization in the mold determines better optical characteristics of the lens in comparison to lens milling by achieving better surface quality and minimizing optical aberrations in the IOL.

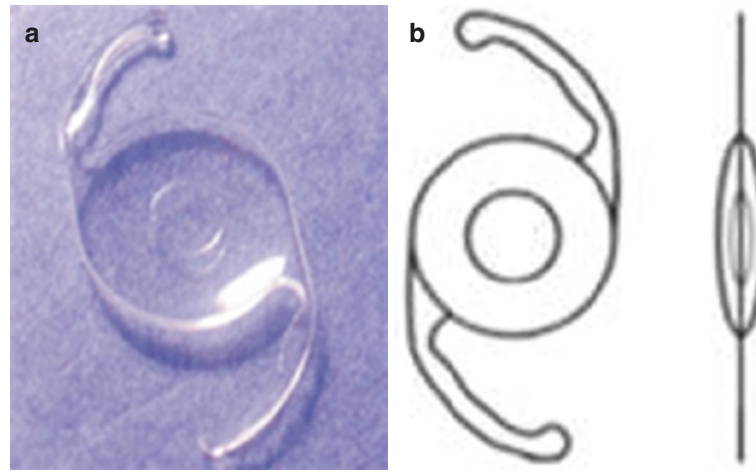

Fig. 23.5 Gradiol MIOL with visible border between components ((**a**) – photo, (**b**) – scheme)

The Gradiol IOL is a joint invention and the result of collaboration between the S. Fyodorov Eye Microsurgery Complex (B. Malyugin, T. Morozova) and REPER–NN (V. Treushnikov, E. Viktorova), a lens manufacturing company.

We have been developing our concept of the gradient optic in the multifocal intraocular correction for the past 15 years. The multifocal IOLs with variable refractive index have undergone certain evolution. It was the way from rigid model to foldable one, from optics with visible border between components (Fig. 23.5 a, b) to optics without transition zone (Fig. 23.6 a, b).

Figure 23.7 (a, b) demonstrates new generation Gradiol MIOL without transition zone. The optical part is compound and contains inner and outer components. The optical part of the gradient intraocular lens contains the combination of one photohardening optical material which is hydrophobic oligouretanmethacrylate with various refraction index 1.4795, 1.520.

The inner component is designed for far vision. Haptic part of lenses and exterior component are performed from one optically transparent material. The multifocal lens has a biconvex design with 6.0 mm optic and a 12.5 mm overall length. The optical part of the gradient intraocular lens has smooth surfaces. Power difference between components is 3.5 diopters.

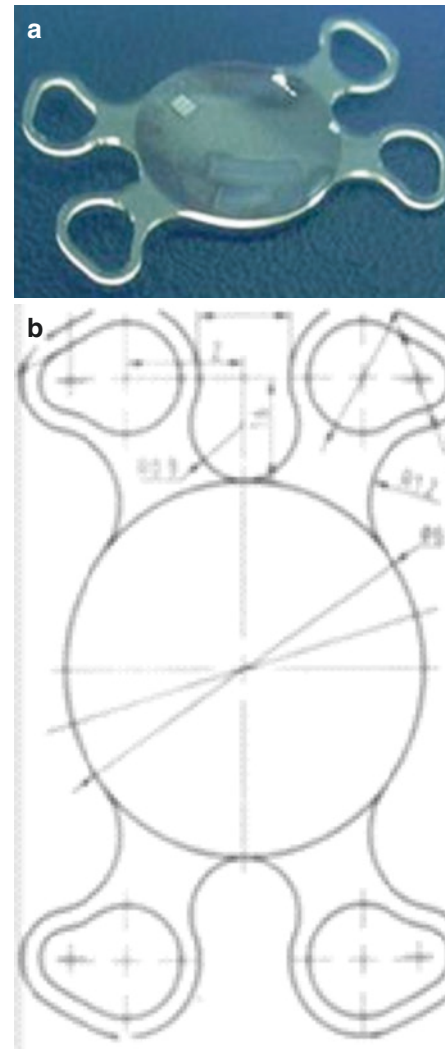

Fig. 23.6 Gradiol MIOL without transition zone between components ((**a**) – photo, (**b**) – scheme)

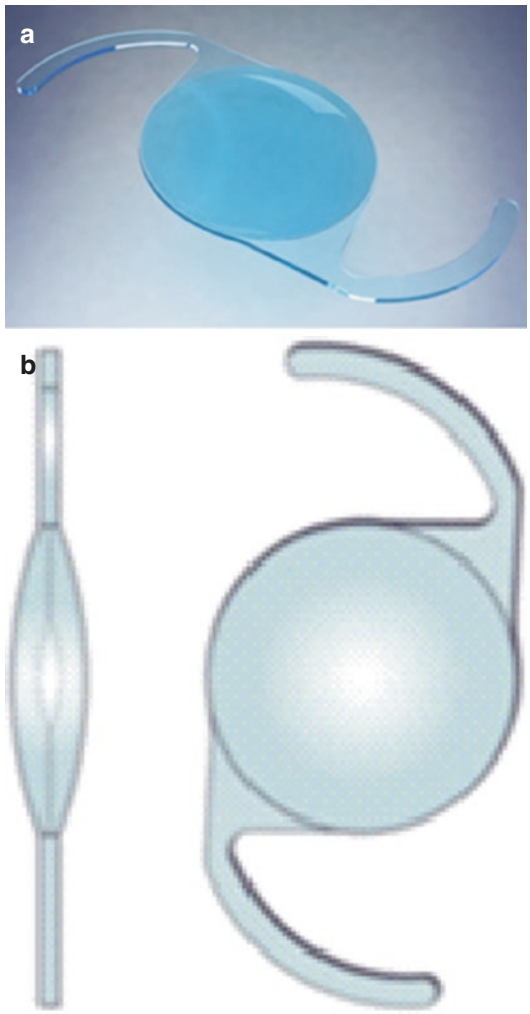

Fig. 23.7 Latest generation Gradiol MIOL without transition zone ((**a**) – photo, (**b**) – scheme)

23.4 New Generation Gradient Multifocal IOLs Laboratory Research (Also Viejo Testing Lab and Optical Research Lab, USA)

23.4.1 Methods

23.4.1.1 Back Focal Length (BFL) Bench EQ-113 Is Used to Measure the Lenses in Air

The BFL Bench measures the back focal length (BFL) of the IOL, and then the optical power is determined from a chart correlating the BFL to the optical power.

Resolution is a measure of image quality and is read as the finest (smallest) group – element that is visible in the image of the standard Air Force bar target. (Fine detail bars correspond to higher numbers of G–E.) Monofocal IOLs typical require the designation 4–3 or better, but there is no specification for Multifocal IOLs, so they could be 4–2 or worse, in air.

23.4.1.2 IOL Magnification Bench EQ-111 Is Used to Measure the Lenses in a Liquid-Filled Cell

Optical Power is measured in Line Pair Separation (LPS) of two lines in the image, which is converted to Diopter (D) using IOL Power Charts, specifically calculated per IOL design and the test medium, in this case water.

Resolution is a measure of image quality and is read as the finest (smallest) group – element that is visible in the image of the standard Air Force bar target. (Fine detail bars correspond to higher numbers of G– E.) For monofocal IOLs, the pass/fail may be based on the specification of passing for 4–5 (Group 4 – Element 5), or higher, sequentially called 4–6, then 5–1.

23.4.1.3 CrystalWave IOL Measurement System Is Used to Evaluate Diopter and Wavefront

Aperture size is set by software commands and is easily changed. An obscuration mask can also be applied to the lens to block rays through the center of the lens, unlike the other instruments This is the instrument that can produce any kind of map of the light or the lens, because the other instruments only integrate and average all light passing though the circular aperture of the chosen diameter.

23.5 Results

23.5.1 BFL Bench Measurements in Air

For the BFL bench, the aperture is typically 3 mm, but 4 mm and 5 mm are also available. For Lens L, the measurements were made with 2

apertures, at 3 and 5 mm. Table 23.1 shows the data of this study. The resolution for the near image improved for the larger aperture, suggesting that the center of the lens is devoted to the far (distance) image. This effect was verified with lens R, which also seemed to show that 4 mm was the best aperture size for the near image.

For the data on Lens L above, a simulation was conducted using Zemax to determine what index of refraction would make the 21D IOL (labeled for the eye) produce the far BFL that was measured in air. (This also assumed about 0.33 mm of difference between the EFL and BFL, based on about 1 mm center thickness of the lens. That itself was confirmed by the "optical thickness" of about 0.66 mm measured on the BFL Bench between the anterior and posterior surface reflections.) Similarly, the near BFL measurement was simulated to calculate the near diopter. These calculations lead to the conclusions of an add power of about 3.5 D and an index difference of about 0.025, as seen in Table 23.2.

Also, later using that information to simply scale the optical powers for Lens R (specifically that Optical Power 1 ≈ Focal Length) produced an estimate of the add power of about 3.1D.

23.5.2 IOL Magnification Bench Measurements in Water

For Lens L, the Mag Bench measurements were made only for the for 3 mm aperture. Two power charts are available for IOLs of 1.459 and 1.540 refractive index. Averaging values in these charts at the nominal IOL diopters produced LPS values that would be approximately correct for an index of 1.4995 (which is very close to the average GRIN of 1.4975 calculated in the previous study). Table 23.3 shows that the mismatch of the Mag Bench measured data and the BFL Bench results is only about 1% at +21D and +24.5 D for both multifocal optical power calculations.

For Lens L, the image quality in water is typically specified when inside a full simulated eye model. The Mag Bench test setup only has a wet cell with parallel flat glass windows, but pictures can be recorded. The titles show the approximate

Table 23.1 Results of the BFL measurements (in air)

Lens ID	Aperture diameter (mm)	Far BFL (mm)	Far resolution	Near BFL (mm)	Near resolution
L	3	14.444	4–2	13.712	4–1
L	5	14.469	4–2	13.715	4–3
L	Average	14.457	Same all apertures	13.714	Better for 5 mm
R	3	14.433	4–3	13.748	4–1
R	4	14.421	4–3	13.754	4–5
R	5	14.409	4–3	13.760	4–4
R	Average	14.421	Same all apertures	13.754	Best for 4 mm

Table 23.2 Results of the Zemax simulations to estimate IOL characteristics

Lens ID	Calculated add power (D)	Assumed far diopter (D)	Calculated far index of refraction	Calculated near diopter (D)	Calculated near index of refraction
L	3.5	21.00	1.485	24.49	1.510
R	3.1	Lens L assumed 21	–	Scaled from Lens L	–

resolution values seen, at about 4–1 for the far image (Fig. 23.8) and about 4–5 for the near image (Fig. 23.9).

23.5.3 CrystalWave Diopter Maps and Wavefront Data for Future Analysis

For Lens L, the CrystalWave was used at various aperture sizes to map the optical power, and data suggests that the central zone has the lower diopter by as much as about 3.4 D (over a zone of about 1.5 mm diameter). The size of the zone is most easily seen in the two following figures of slope maps (Figs. 23.10 and 23.11).

The uniformity of the different zones of the multifocal IOL can be estimated in Figs. 23.12 and 23.13 and Tables 23.4 and 23.5. The diameters and diopter are shown in the titles. The difference in the directly measured diopter values of 1.5 mm vs 2.0 mm is about 0.25 D, and the mask of the central area improves the diop-

Table 23.3 Results of the Mag Bench estimates of LPS to diopter conversions

Lens ID	Calculated far LPS (mm)	Measured far LPS (mm)	Far percentage error	Calculated near LPS (mm)	Measured near LPS (mm)	Near percentage error
L	3.50	3.55	1 0.4%	3.00	3.04	1.1%

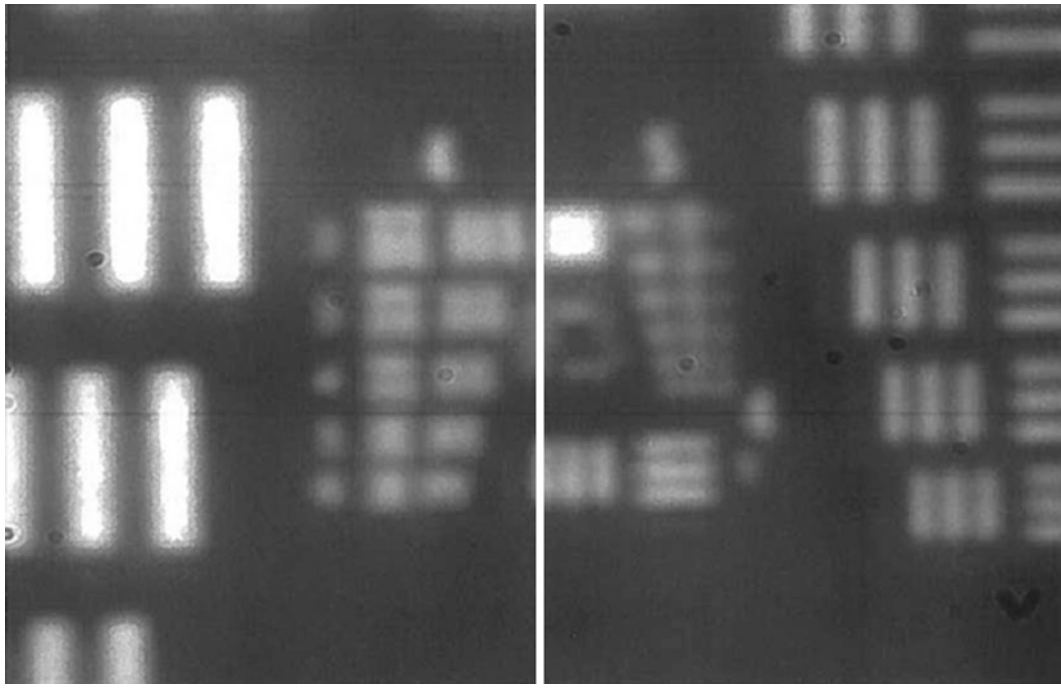

Fig. 23.8 Mag Bench far image with resolution approximately 4–1

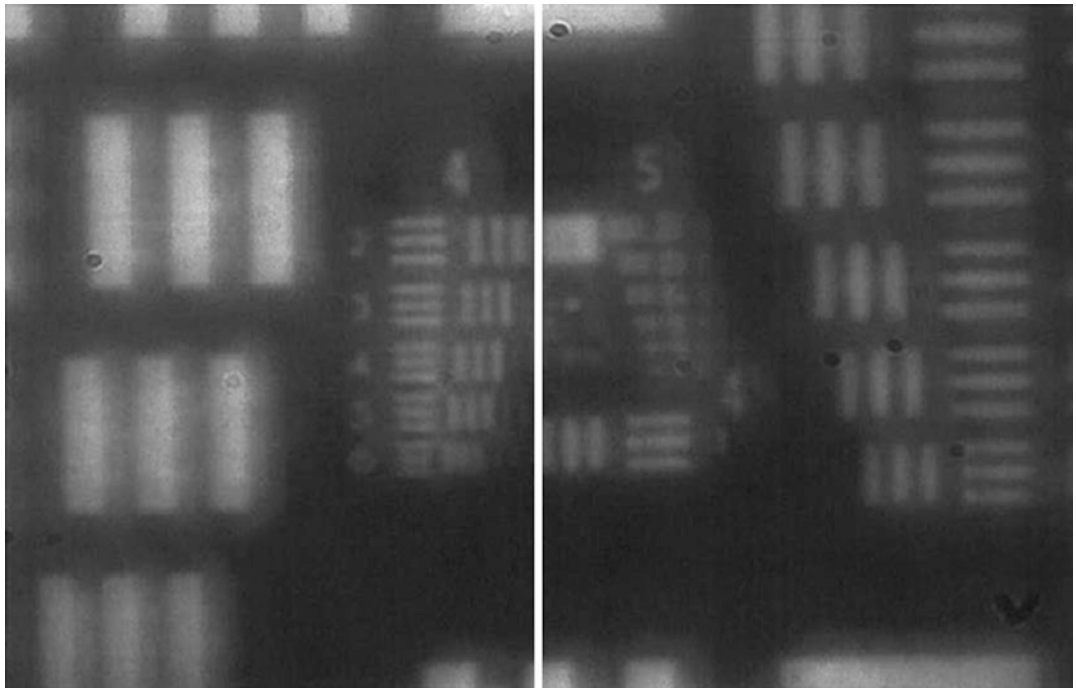

Fig. 23.9 Mag Bench near image with resolution approximately 4–5

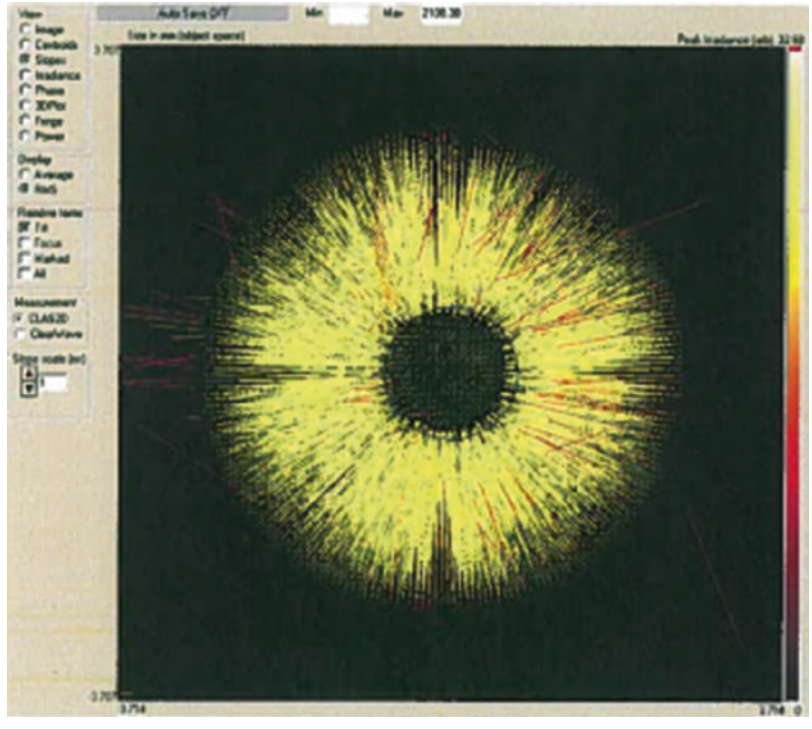

Fig. 23.10 CrystalWave slopes at 1.5 mm aperture (blue circle) at 21.17 D

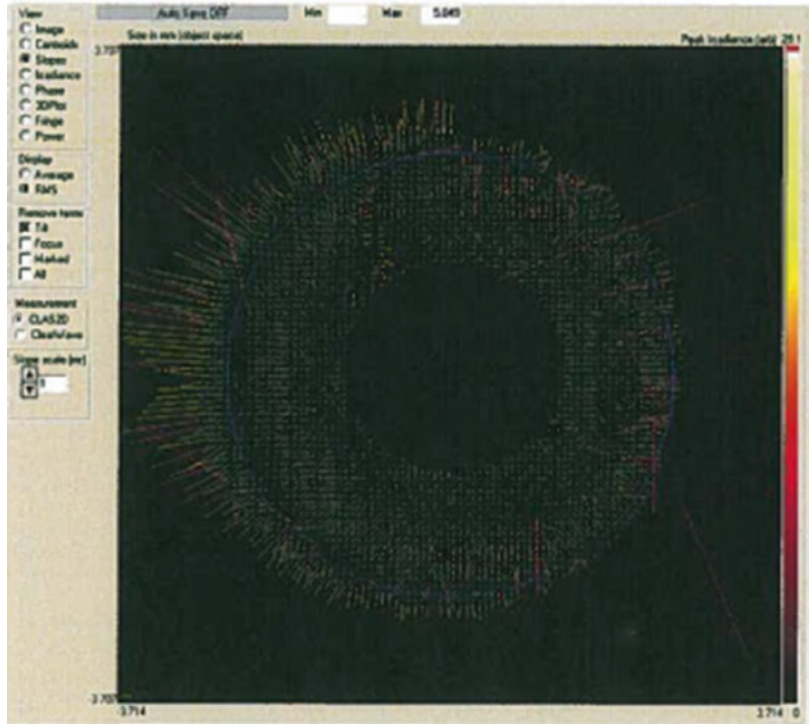

Fig. 23.11 CrystalWave slopes with 5 mm annular aperture (blue circle) at 24.33 D

ter purity of the annular zone, changing the average by about 0.2 D.

The gradient multifocal IOLs laboratory research confirms that there is no mismatch of the measured data and the data of IOLs labeling. The near back focal length (BFL) measurement and next calculations lead to the conclusions of an add power of about 3.5 D and index difference of about 0.025.

The CrystalWave test at various aperture sizes suggests that the central zone has the lower diopter by as much as about −3.4 D. Also the multifocal IOLs with gradient optic have good resolution for the near image (4–5) and far (distance) image (4–1).

We have performed a lot of theoretical, laboratory, and clinical research of multifocal IOL with gradient optic different design and additional power including multicentral clinical study (150 clinical cases) of Gradiol without transition zone. However, in this review we introduce clinical study of the earliest generation Gradiol with visible border between components and clinical study of new generation Gradiol without transition zone.

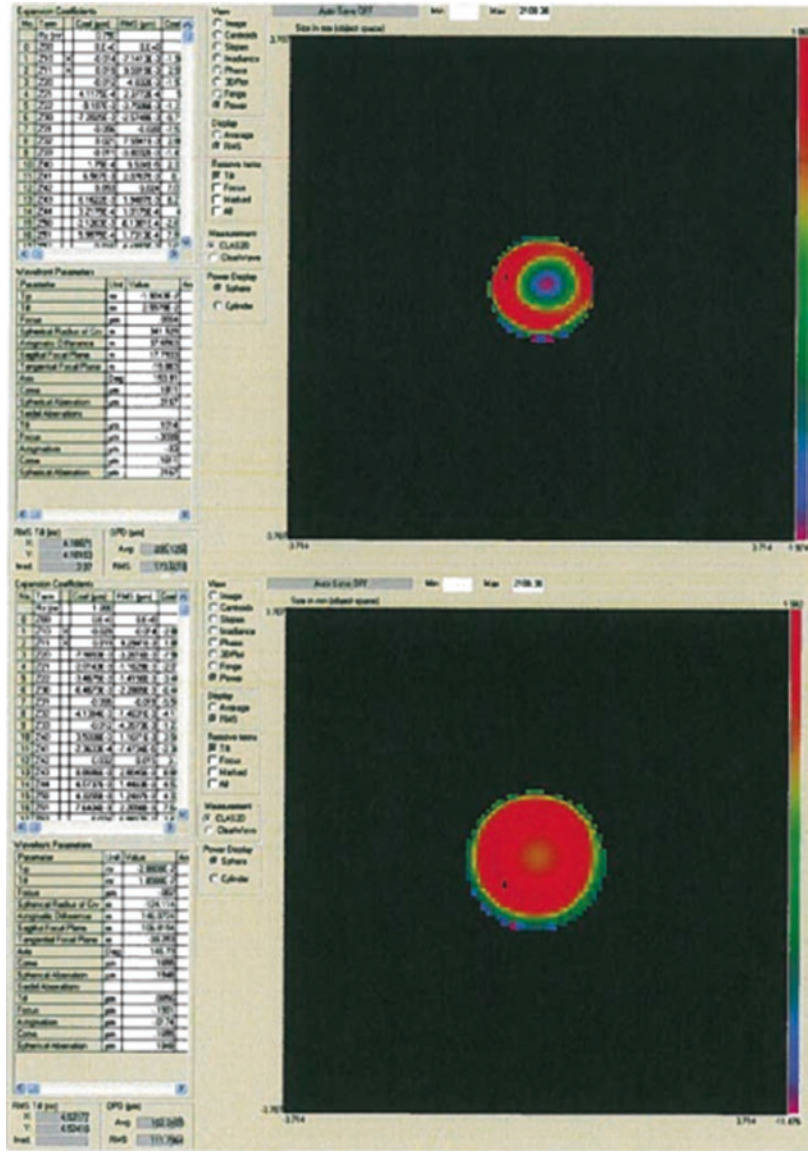

Fig. 23.12 CrystalWave power maps with 1.5 and 2 mm apertures (2 mm is 20.94 D)

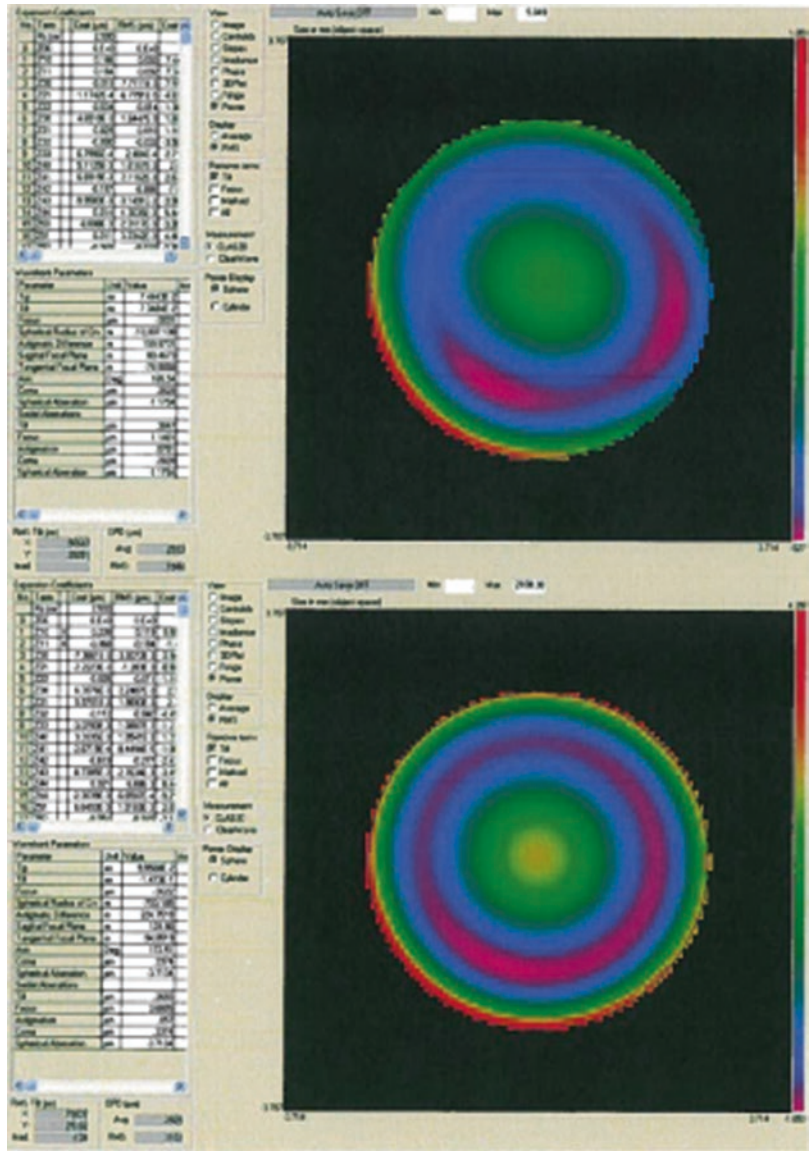

Fig. 23.13 Power maps with 5 mm annular and full apertures (full 5 mm is 24.14 D)

Table 23.4 Representative CrystalWave test reports at 1.5 mm aperture (Zernike table)

Analysis diameter (mm)		1.5		
Power (D)		21.219		
WFE RMS (μm)		0.134		
WFE RMS HO (μm)		NA		
WFE PV (μm)		0.619		
Spherical aberration Z42 (μm)		0.054064		
No.	**Term**	**Coeff** (μm)	**Polar coord**	**Description**
0	Z00	0	1	Piston or constant term
1	Z10	−0.029822	rsinQ	Tilt about y-axis
2	Z11	0.13439	rcosQ	Tilt about x-axis
3	Z20	−0.009329	r^2sin2Q	Astigmatism with axis at + − pi/4
4	Z21	−0.000545	2r^2–1	Focus shift
5	Z22	−0.010016	r^2cos2Q	Astigmatism with axis at 0 or pi/2

Table 23.4 (continued)

6	Z30	−0.007258	r^3sin3Q	Triangular astigmatism with base on x-axis
7	Z31	−0.055202	(3r^3–2r)sinQ	Third-order coma along x-axis
8	Z32	0.015886	(3r^3–2r)cosQ	Third-order coma along y-axis
9	Z33	−0.01343	r^3cos3Q	Triangular astigmatism with base on y-axis
10	Z40	0.002538	r^4sin4Q	Tetrafoil
11	Z41	0.006904	(4r^4–3r^2)sin2Q	
12	Z42	0.054064	6r^4–6r^2 + 1	Third-order spherical aberration
13	Z43	0.005473	(4r^4–3r^2)cos2Q	
14	Z44	−0.003816	rA^cos4Q	Tetrafoil

Table 23.5 Representative CrystalWave test reports at 4.5 mm aperture (Zernike Table)

Analysis diameter (mm)		4.5		
Power (D)		23.961		
WFE RMS (μm)		0.326		
WFE RMS HO (μm)		NA		
WFE PV (μm)		1.411		
Spherical aberration Z42 (μm)		−0.646205		
No.	**Term**	**Coeff** (μm)	**Polar coord**	**Description**
0	Z00	0	1	Piston or constant term
1	Z10	0.073944	rsinQ	Tilt about y-axis
2	Z11	0.164457	rcosQ	Tilt about x-axis
3	Z20	−0.005239	r^2sin2Q	Astigmatism with axis at + − pi/4
4	Z21	−0.001505	2r^2–1	Focus shift
5	Z22	−0.018499	r^2cos2Q	Astigmatism with axis at 0 or pi/2
6	Z30	−0.002194	r^3sin3Q	Triangular astigmatism with base on x-axis
7	Z31	0.027622	(3r^3–2r)sinQ	Third-order coma along x-axis
8	Z32	−0.104378	(3r^3–2r)cosQ	Third-order coma along y-axis
9	Z33	0.000366	r^3cos3Q	Triangular astigmatism with base on y-axis
10	Z40	0.002812	r^4sin4Q	Tetrafoil
11	Z41	0.010195	(4r^4–3r^2)sin2Q	
12	Z42	−0.646205	6r^4–6r^2 + 1	Third-order spherical aberration
13	Z43	−0.017548	(4r^4–3r^2)cos2Q	
14	Z44	0.008115	rA^cos4Q	Tetrafoil

23.6 Clinical Studies

All clinical studies were conducted according to the principles of the Declaration of Helsinki and were approved by the local ethical committee. All patients were adequately informed and signed a consent form.

Inclusion criteria were incipient or moderate cataract (Lens Opacity Classification System III, N01, C1, P1, or more severity) causing a significant reduction in visual quality, patient motivation (desire to no longer wear spectacles or contact lenses for distance or near vision).

Exclusion criteria were astigmatism greater than 1.0 diopter, anterior and posterior segment pathology such as chronic uveitis, zonular dialysis, pseudoexfoliation syndrome, glaucoma, diabetic retinopathy, age-related macular degeneration, and neuro-ophthalmic disease. Patients with previous anterior and posterior segment surgery or ocular trauma, abnormal iris, pupil deformation, and intraoperative or postoperative complications were also excluded. All eyes were targeted for emmetropia postoperatively using the SRK/T formula.

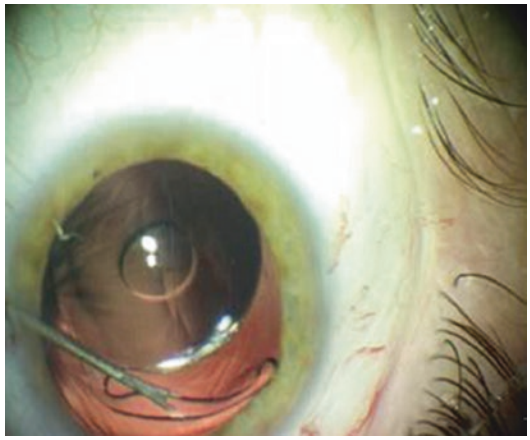

Fig. 23.14 Implantation of Gradiol trailing haptic element into the capsular bag

The surgical procedure included phacoemulsification through a 2.2 mm clear corneal incision under topical anesthesia. The IOL was implanted in the capsular bag with an injector (Fig. 23.14). At the end of the surgery, the incisions were hydrated.

All patients were discharged 1 h after surgery. Postoperative medications included topical moxifloxacin and dexamethasone 0.1% QID for 3 weeks.

Patients were scheduled for clinical evaluation preoperatively and 1 day, 1 week, 1 month, 3 months, and 6 months postoperatively. Additional visits were scheduled if necessary.

23.7 Clinical Study of Gradiol with Visible Border between Components

23.7.1 Patients and Method

Twenty-six patients (29 eyes) were prospectively enrolled with age ranging from 27 to 82 years. This non-comparative study included 11 males and 15 females. All patients had cataracts mean visual acuity deterioration of 0.11 ± 0.09.

No major complications were observed during the early or late postoperative periods.

Outcome Measures.

A standard comprehensive ophthalmic examination, including manifest refraction, biomicroscopy, intraocular pressure measurement, and funduscopy, was performed at all visits.

Uncorrected and best-corrected distance visual acuities were measured with decimal charts. Uncorrected and best-corrected near visual acuities were measured with reading charts (Russian validated version). Uncorrected and best-corrected distance visual acuities, monocular uncorrected and best-corrected near visual acuities, and best distance-corrected near visual acuity (NVA) were recorded at 5 m for distance measurements and 33 cm for near measurements in all patients. All visual acuity measurements were performed monocularly.

Refraction was measured with an autorefractor and retested subjectively.

Methods used for pseudoaccommodation testing included:

- Sphere addition-assisted defocusing with 1.0 D step at corrected visual acuity (VA) for far 0.8 using an accommodometer.
- Sphere addition-assisted defocusing with 0.5 D step at corrected VA 0.5 using conventional optotypes.
- Contrast sensitivity (CS) was measured with Optec 3000 (Stereo Optical Company, Inc. Chicago, IL, USA).

To perform a quantitative analysis of visual dysfunctions, we employed the VF-14 patient questionnaire (VF-14) [29]. To further assess functional needs and specific characteristics of multifocal correction, we included additional questions on the ability to use a computer without spectacle correction (to evaluate vision at intermediate distances) and details of optical disturbances (type and level).

23.8 Clinical Results

23.8.1 Distances Visual Acuity

Distance VA improved in all cases after phacoemulsification after implantation of gradient MIOL. Analysis of data on distance uncorrected and corrected visual acuity at various follow-up periods (1, 3, and 6 months) proves stability and good functional visual acuity (Table 23.6).

Better functional results were obtained in patients with slight hyperopia of ±0.5 D sphere, ±0.5 D of against-the-rule corneal astigmatism, and 1.0 D with-the-rule corneal astigmatism. Mean spherical equivalent was +0.09 D.

23.8.2 Near Visual Acuity

Data on uncorrected and best-corrected visual acuity for near at various follow-up periods (1, 3, and 6 months) also proved stability and good functional visual acuity (Table 23.7). These data indicate full visual rehabilitation and high scores on the subjective evaluation postoperatively. Near VA outcomes indicated that reading could be performed without additional spectacle correction.

Evaluation of near VA with full distance correction is presented in Table 23.8. This measure assesses visual function specific to MIOLs. Additional distance correction in cases of residual myopic refraction decreases NVA compared to uncorrected near VA. Additional correction for far in cases of residual hyperopic refraction either increases or has no effect on near VA compared to near VA without correction. The latter determines residual hyperopic refraction postoperatively, which is more preferable.

Table 23.6 Mean far visual acuity post-op

Mean VA	1 month	3 months	6 months
Uncorrected	0.73 ± 0.16	0.72 ± 0.20	0.73 ± 0.18
With correction	0.77 ± 0.19	0.88 ± 0.13	0.89 ± 0.15

Table 23.7 Mean near visual acuity post-op

Mean VA	1 month	3 months	6 months
Uncorrected	0.62 ± 0.16	0.60 ± 0.21	0.57 ± 0.19
With correction	0.70 ± 0.20	0.76 ± 0.18	0.84 ± 0.07

23.8.3 Pseudoaccommodation Amplitude

The difference in power between optical zones should provide calculated pseudoaccommodation amplitude of at least 3.00 D. The pseudoaccommodation after gradient IOL implantation was 4.75 ± 0.50 D (Fig. 23.15).

Table 23.8 Best distance-corrected near visual acuity (VA; 16 cases) and patient's post-op refraction

VA for near without correction	VA for near with correction for far	Refraction
0.5	0.4	M
0.8	1	H
0.7	0.7–0.8	H
0.8	0/4	M
0.8	0.4	M
0.5	0.8	H
0.6	0.8	H
0.7	0.3	M
0.4	0.5	H
0.5	0.3	M
0.9	0.6	M
0.3	0.5	H
0.4	0.2	M
0.3	0.8	H
0.3	0.1	M
0.5	0.3	M
M: Myopia, H: Hyperopia		

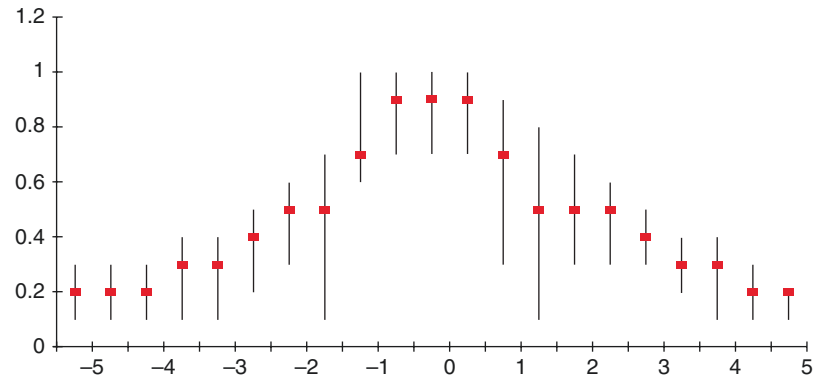

Fig. 23.15 Defocus curve after Gradiol implantation

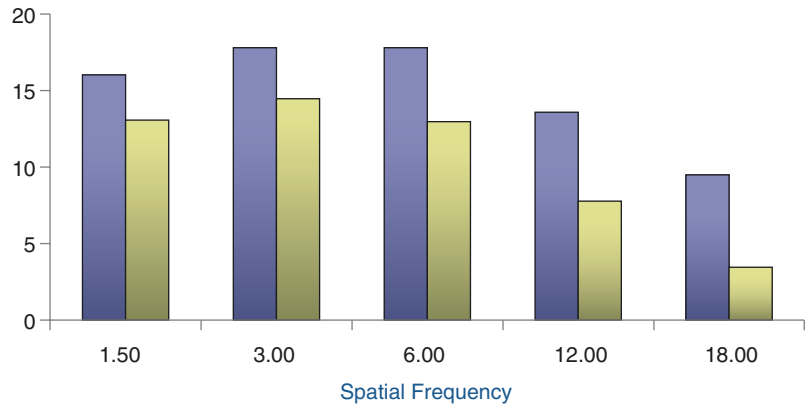

Fig. 23.16 Data on spatial contrast sensitivity testing after Gradiol implantation. Three months post-op

There was an even distribution of light energy among all optical zones (for far, near, and intermediate distances). The defocus curve was smooth with peak at the point of maximum corrected distance VA.

23.8.4 Contrast Sensitivity Testing

CS testing is one of the basic components of comprehensive clinical evaluation of postoperative visual outcomes. Previous studies have confirmed that CS and mesopic visual acuity (with/without glare) are diminished after MIOL implantation compared to normal values.

In the current study, there was no change in CS compared to normal values across all spatial frequencies after multifocal gradient IOLs implantation (Fig. 23.16).

23.8.5 Optical Disturbances

Optical disturbances included light streaks, halos, flare, flashes, and glare [30]. Halos and glare were the most frequent complaints.

The grades varied from subtle to pronounce (Table 23.9). There was no tendency for these optical disturbances to decrease over long-term follow-up.

The cause of the optical disturbances is likely the separation of light at the focal zones as well as the presence of distinct borders between the inner and outer optics. The majority of patients (57.1%) noted optical disturbances during history taking, and only 10.7% of cases were functionally significant.

Table 23.9 Optical phenomena

Type	Total (abs)	Total (%)
Pronounced (halos only)	3	10.7
Moderate	–	–
Subtle (halos, glare)	13	46.4
Total	16	57.1
Halos	13	46.4
Glare	3	10.7

Mostly patients complained of halos under scotopic conditions and a “blinding” effect from oncoming headlights while driving at night. None of the patients required MIOL explanation due to night vision disturbances.

Of all the patients with optical disturbances postoperatively, 81.3% had residual myopic refraction. Residual myopia increases light scatter resulting in an increase of the optical disturbance and decreasing patient’s quality of life.

23.8.6 Subjective Questionnaire

The mean VF-14 score was equivalent to 100 indicating high subjective satisfaction after Gradiol implantation. Postoperatively, 86% of patients were able to perform near tasks without spectacle correction, including prolonged work at near, small print text reading, as well computer work under varying light conditions (bright and dim light).

23.9 Clinical Study of New Generation Gradiol without Transition Zone

23.9.1 Patients and Method

Twenty-three patients (25 eyes) were prospectively enrolled with mean age 67, 5 years. All patients had cataracts mean visual acuity deterioration of 0.15 ± 0.08.

No major complications were observed during the early or late postoperative periods.

Patients were scheduled for clinical evaluation preoperatively and 1 day, 1 week, 1 month, 3 months, and 1 year postoperatively. Additional visits were scheduled if necessary.

23.9.2 Outcome Measures

A standard comprehensive ophthalmic examination, including manifest refraction, biomicroscopy, intraocular pressure measurement, and funduscopy, was performed at all visits.

Uncorrected and best-corrected distance visual acuities were measured with decimal charts. Uncorrected and best-corrected near visual acuities were measured with reading charts (Russian validated version). Uncorrected and best-corrected distance visual acuities, uncorrected and best-corrected near visual acuities, and uncorrected and best-corrected intermediate visual acuities were recorded at 5 m for distance measurements, 33 cm for near measurements, and 66 cm for intermediate measurements in all patients. All visual acuity measurements were performed monocularly.

Refraction was measured with an autorefractor and retested subjectively.

Methods used for pseudoaccommodation testing included:

- Sphere addition-assisted defocusing with 1.0 D step at corrected visual acuity (VA) for far 0.8 using an accommodometer.
- Sphere addition-assisted defocusing with 0.5 D step at corrected VA = 20/32 using conventional optotypes.
- Contrast sensitivity (CS) was measured with Functional Image Analyzer Optec 6500 (Stereo Optical Company, Inc. Chicago, IL, USA).

To perform a quantitative analysis of visual dysfunctions, we employed the VF-14 patient questionnaire (VF-14) [29]. To further assess functional needs and specific characteristics of multifocal correction, we included additional questions on the ability to use a computer without spectacle correction (to evaluate vision at intermediate distances) and details of optical disturbances (type and level).

23.10 Clinical Results

23.10.1 Visual Acuity

In the prospective clinical trial, patients have achieved good objective results with the multifocal gradient lens new generation.

Analysis of data on distance uncorrected and corrected visual acuity at various follow-up periods (1 and 3 months and 1 year) proves stability and good functional visual acuity.

Near VA outcomes indicated that reading could be performed without additional spectacle correction.

Visual acuity improved in all distances after phacoemulsification and implantation of gradient MIOL.

One week after implantation, mean uncorrected distance VA was 0.81 ± 0.09, mean uncorrected near VA 0.51 ± 0.11, mean uncorrected intermediate VA 0.55 ± 0.07, mean corrected distance VA 0.88 ± 0.06, mean corrected near VA 0.73 ± 0.08, and mean corrected intermediate VA 0.71 ± 0.06 (Fig. 23.17).

One month after implantation, mean uncorrected distance VA was 0.87 ± 0.07, mean uncorrected near VA 0.58 ± 0.11, mean uncorrected intermediate VA 0.55 ± 0.09, mean corrected distance VA 0.98 ± 0.08, mean corrected near VA 0.78 ± 0.06, and mean corrected intermediate VA 0.72 ± 0.08 (Fig. 23.18).

Three months after implantation, mean uncorrected distance VA was 0.9 ± 0.08, mean uncorrected near VA 0.65 ± 0.09, mean uncorrected intermediate VA 0.58 ± 0.11, mean corrected distance VA 0.98 ± 0.07, mean corrected near VA 0.84 ± 0.09, and mean corrected intermediate VA 0.78 ± 0.08 (Fig. 23.19).

One year after implantation, mean uncorrected distance VA was 0.9 ± 0.06, mean uncorrected near VA 0.66 ± 0.07, mean uncorrected intermediate VA 0.63 ± 0.09, mean corrected distance VA 0.98 ± 0.08, mean corrected near VA 0.84 ± 0.09, and mean corrected intermediate VA 0.78 ± 0.06 (Fig. 23.20).

Mean spherical equivalent was −0.43 D.

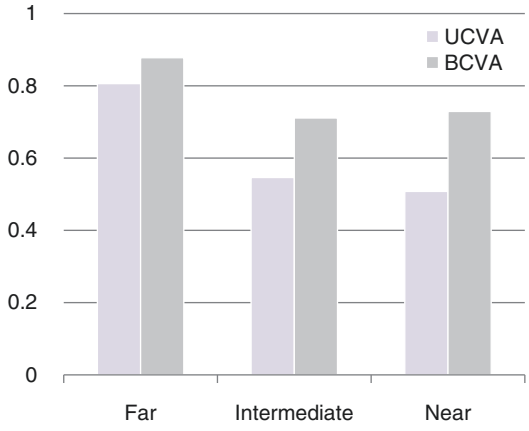

Fig. 23.17 Visual acuity 1 week post-op

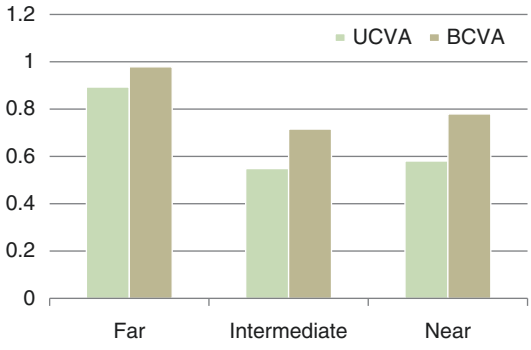

Fig. 23.18 Visual acuity 1 month post-op

23.10.2 Pseudoaccommodation Amplitude

The difference in power between optical zones should provide calculated pseudoaccommodation amplitude of at least 3.00 D. The pseudoaccommodation after gradient IOL implantation was 4.75 ± 0.50 D (VA = 20/32) (Fig. 23.21).

The defocus curve has had two peaks at the point of maximum corrected distance VA and − 2.5D.

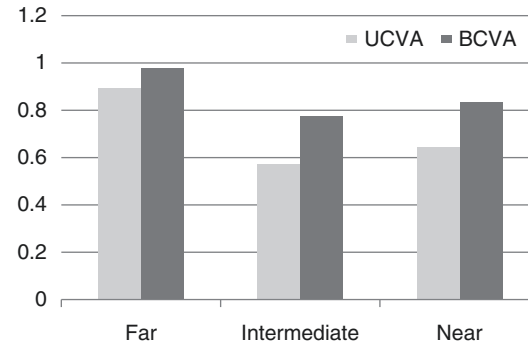

Fig. 23.19 Visual acuity 3 months post-op

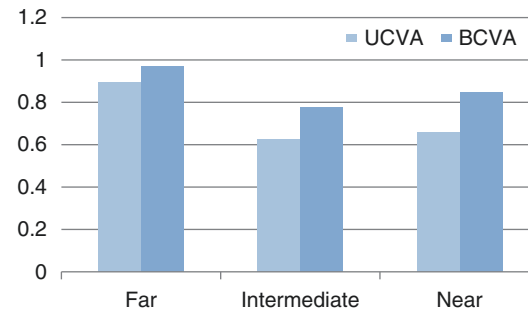

Fig. 23.20 Visual acuity 1 year post-op

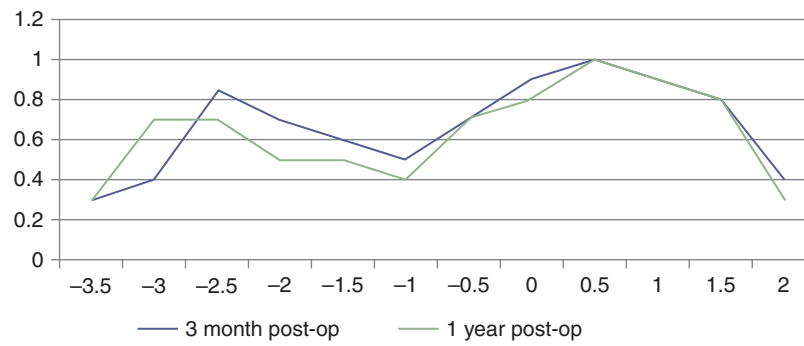

Fig. 23.21 Pseudoaccommodation curve 3 months and 1 year post-op

23.10.3 Contrast Sensitivity Testing

We have done research of contrast sensitivity in daytime condition (85°cd/m^2) with and without glare and mesopic condition (3°cd/m) 3 months and 1 year post-op. Cs data decreased mildly in high spatial frequencies (Fig. 23.22) especially with glare and mesopic condition (3°cd/m^2) (Figs. 23.23 and 23.25) with improvements for some spatial frequencies at 1 year after surgery (Figs. 23.22, 23.24, 23.25, and 23.26). Patients were completely satisfied at daytime conditions and mostly satisfied at night.

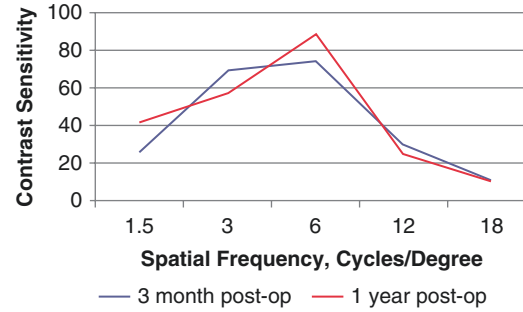

Fig. 23.22 Contrast sensitivity, Functional Image Analyzer Optec 6500 monocular testing, daytime condition (85°cd/m²), 3 months and 1 year post-op

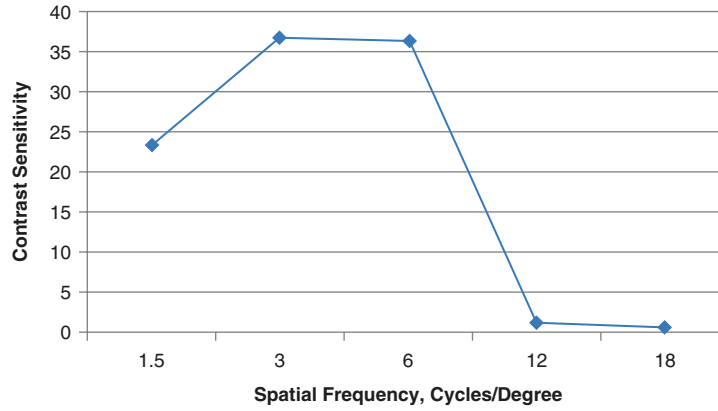

Fig. 23.23 Contrast sensitivity, Functional Image Analyzer Optec 650 monocular testing, mesopic condition (3 cd/m²) 3 months post-op

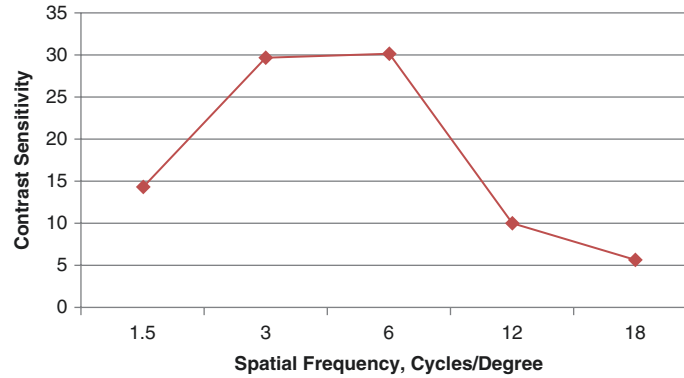

Fig. 23.24 Contrast sensitivity, Functional Image Analyzer Optec 6500 monocular testing, mesopic condition (3°cd/m²) 1 year post-op

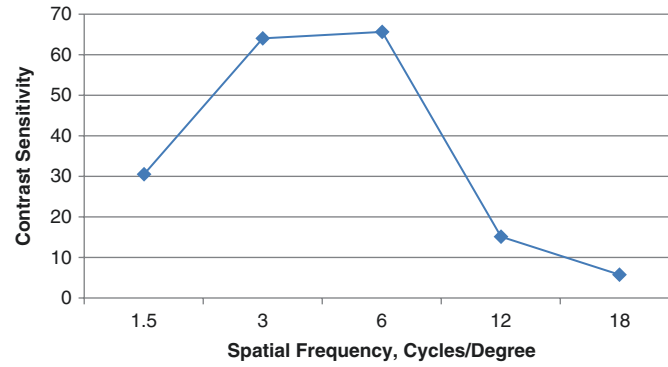

Fig. 23.25 Contrast sensitivity, Functional Image Analyzer Optec 6500 monocular testing, daytime condition (85°cd/m²) level 1 + glare 3 months post-op

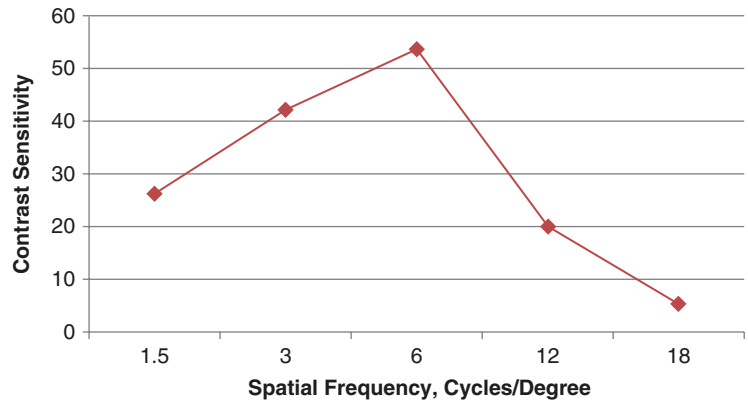

Fig. 23.26 Contrast sensitivity, Functional Image Analyzer Optec 6500 monocular testing, daytime condition (85°cd/m²) level 1 + glare 1 year post-op

In the current study, there was no change in CS compared to normal age values after multifocal gradient IOLs implantation.

23.10.4 Optical Disturbances

Questionnaire revealed optical phenomena only in 5% in post-op.

Patients complained of halos under scotopic conditions and a "blinding" effect from oncoming headlights while driving at night. None of the patients required MIOL explantation due to night vision disturbances.

23.11 Subjective Questionnaire

The mean VF-14 score was equivalent to 100 indicating high subjective satisfaction after Gradiol implantation. Eighty-six percent of patients postoperatively were able to perform near tasks without spectacle correction, including prolonged work at near, small print text reading, as well computer work under varying light conditions (bright and dim light).

Fig. 23.27 PSF (point spread function) and Strehl ratio data 3 months post-op

23.11.1 OPD Scan Aberrometry

The Wavefront study found very impressive PSF (point spread function) data and Strehl ratio of the multifocal gradient IOL without transition zone (Fig. 23.27).

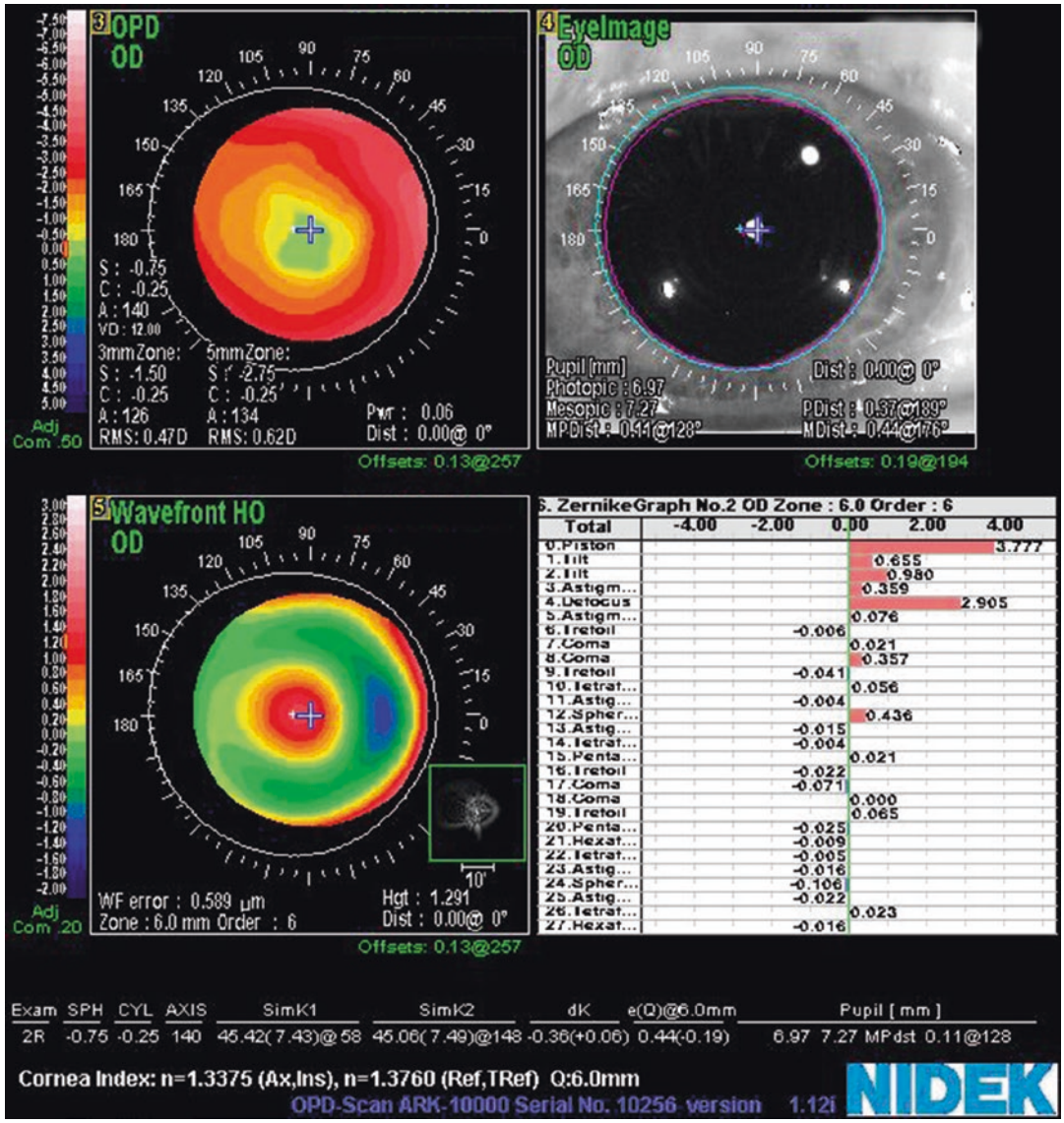

Fig. 23.28 OPD scan aberrometry data 3 months post-op

Defocus data in the OPD scan aberrometry demonstrated constructive characteristics of the IOLs with variable refractive index (Fig. 23.28).

23.12 Discussion

It is possible to theoretically calculate the light beam distribution in optical models of the human eye, including the modulation transfer and scattering functions, and perform retinal image quality modeling. However, simulation of the effect of neural processing on visual functions after MIOL is not possible. Hence, the final conclusion on the efficacy of a specific MIOL can only be reached after clinical trials. The functional outcomes for far and near vision and pseudoaccommodative amplitude indicate the Gradiol is efficacious.

The outcomes for distance visual acuity after implantation of Gradiol with visible border

between components were comparable to diffractive and refractive MIOLs previous generation. For example, after ReSTOR® IOL implantation (diffractive/refractive; Alcon Inc., Fort Worth, TX, USA), the uncorrected distance VA was 0.8 in 54% cases, and uncorrected near VA of 0.5 was achieved in 100% of the cases and 0.8 was achieved in 52% of the cases [31, 32]. A multicenter trial of the AMO Array® (refractive IOL) reported distance uncorrected VA of 0.7 or better was achieved by 73% of cases and near VA of 0.5 or better was achieved by 85% of cases. Another study [33] reported mean binocular uncorrected distance VA after ReZoom® refractive MIOL implantation was equal to 1.0 and 0.5 for near.

Patients, who have undergone refractive and gradient IOL previous generation implantation, have had better intermediate vision (from 40 cm to 1.0 m) compared to patients who have undergone diffractive bifocal IOL implantation. Intermediate vision is important for driving (dashboard control) and computer work.

Currently there are some new approaches in the multifocal IOL's assessment.

First of them is visual acuity measurement with ETDRS charts. Researchers report on excellent functional results after modern multifocal IOL implantation.

Rosen E., Alio J.L., Dick H.B. et al. performed a meta-analysis of peer-reviewed studies involving implantation of a multifocal intraocular lenses (IOLs) different design in presbyopic patients with cataract or having refractive lens exchange (RLE) [1]. The mean percentage of multifocal IOL implanted eyes achieving a monocular UDVA of 0.30 LogMAR (20/40) or better was 95.7% based on 31 studies that reported this outcome for 3826 eyes. The mean percentage of eyes achieving a monocular UDVA of 0.00 LogMAR (20/20) or better was 58.1% based on 19 studies of 1810 eyes [1].

Kretz F.T.A. et al. evaluated the clinical outcomes after cataract surgery with implantation of a new diffractive multifocal intraocular lens (IOL) with a lower near addition (+2.75 D) [2]. In this study 143 eyes of 85 patients aged between 40 years and 83 years that underwent cataract surgery with implantation of the multifocal IOL (MIOL) TECNIS ZKB00 (Abbott Medical Optics, Santa Ana, California, USA) were evaluated. Postoperative mean monocular uncorrected distance visual acuity, uncorrected near visual acuity, and uncorrected intermediate visual acuity was 0.20 LogMAR or better in 73.7%, 81.1%, and 83.9% of eyes, respectively [2].

Attia M.S. et al. reported on functional results after implantation of an AcrySof IQ ReSTOR C3.0 diopter (D) multifocal IOL [3]. Forty eyes (20 patients) were enrolled. Monocularly, the medians were UDVA, 0.00 LogMAR (range 0.26 to −0.14 logMAR); 40 cm UNVA, 0.04 LogMAR (range 0.24 to −0.10 logMAR); and 80 cm UIVA, 0.15 LogMAR (range 0.40 to −0.18 logMAR) [3].

Cochener B. compared the visual results and patient satisfaction after bilateral implantation between a bifocal and a trifocal intraocular lens (IOL) [4]. Fifteen patients (30 eyes) were implanted with the FineVision IOL (PhysIOL, Liége, Belgium) and 12 patients (24 eyes) received the TECNIS ZMB00 IOL (Abbott Medical Optics, Santa Ana, CA). The mean binocular uncorrected visual acuity was 0.02 ± 0.04 LogMAR in the FineVision group and 0.04 ± 0.05 LogMAR in the TECNIS group, and the mean binocular uncorrected near visual acuity was 0.01 ± 0.00 LogMAR in both groups [4].

In Russia decimal chart for visual acuity's measurement is a standard for clinical and scientific research. It was special project to create new ETDRS charts with Russian letters. We have initiated this project especially for Gradiol new generation assessment. There are various methods for assessing visual acuity, though the most widely used are charts; different countries traditionally use their own tables. It is long since standard for testing visual acuity in Russia was decimal chart (with 12 rows of uppercase letters and seven letters of the Russian alphabet used – Ш, Б, М, Н, К, Ы) and chart contains 12 rows of Landolt rings (four versions with different gap locations: top, bottom, right, and left).

Collaborative work between the S. Fyodorov Eye Microsurgery Complex State Institution, the Research Center of the University of Crete (UoC), and the company "Precision Vision"

Table 23.10 Visual acuity at different distances (4 m, 66 cm, and 33 cm) after implantation of multifocal Gradient IOL 1 day, 1 month, and 3 months post-op

Visual acuity in post-op	Measurement system	Post-op period					
		1 day	*p*	1 month	*p*	3 months	*p*
UCDVA	LogMAR	0.162 ± 0.06	$p < 0.175$	0.106 ± 0.04	$p < 0.327$	0.151 ± 0.05	$p < 0.002$
	Decimal	0.750 ± 0.18		0.800 ± 0.10		0.740 ± 0.19	
	Converted value	0.140 ± 0.11		0.100 ± 0.05		0.150 ± 0.12	
BCDVA	LogMAR	0.081 ± 0.04	$p < 0.298$	0.088 ± 0.04	$p < 0.922$	0.058 ± 0.05	$p < 0.000$
	Decimal	0.830 ± 0.11		0.850 ± 0.08		0.900 ± 0.12	
	Converted value	0.080 ± 0.06		0.080 ± 0.04		0.050 ± 0.06	
UCIVA	LogMAR	0.217 ± 0.07	$p < 0.412$	0.291 ± 0.04	$p < 0.882$	0.230 ± 0.08	$p < 0.047$
	Decimal	0.670 ± 0.23		0.560 ± 0.11		0.660 ± 0.19	
	Converted value	0.200 ± 0.13		0.270 ± 0.08		0.220 ± 0.10	
UCNVA	LogMAR	0.400 ± 0.04	$p < 0.64$	0.330 ± 0.04	$p < 0.825$	0.266 ± 0.05	$p < 0.001$
	Decimal	0.430 ± 0.09		0.500 ± 0.10		0.560 ± 0.12	
	Converted value	0.380 ± 0.09		0.310 ± 0.09		0.260 ± 0.08	
BCNVA	LogMAR	0.290 ± 0.06	$p < 0.104$	0.226 ± 0.05	$p < 0$	0.082 ± 0.04	$p < 0.000$
	Decimal	0.570 ± 0.18		0.700 ± 0.13		0.860 ± 0.09	
	Converted value	0.270 ± 0.16		0.220 ± 0.09		0.070 ± 0.04	

Note: p for the significance of differences calculated between data obtained in the LogMAR system and the decimal scale (after conversion of VD to VL using a conversion table) for different distances

led to the creation of modified ETDRS charts with specially developed optotypes based on the Cyrillic alphabet. The introduction of analogs of ETDRS tables with letters from the Russian alphabet will not only avoid the hindrances to comparing results from clinical and statistical studies performed in different countries but will also provide for exchange of databases between ophthalmologists in different centers.

Forty-one eyes (41 patients – 12 men, 29 women, mean age 66.4 ± 5.15 years), with monocular implantation of multifocal gradient IOL new generation, were enrolled in comparative clinical study of visual acuity using a variety of measurement methods (Table 23.10).

The outcomes for visual acuity at different distances after implantation of Gradiol without transition zone were comparable to modern multifocal IOLs.

CS testing is one of the basic components of comprehensive clinical evaluation of postoperative visual outcomes. Previous studies have confirmed that mesopic visual acuity and CS at low and high spatial frequencies especially in mesopic condition (3°cd/m^2) are diminished after MIOL implantation compared to monofocal IOL implantation.

Recently it was shown that CS data of modern multifocal IOL (bifocal and trifocal) is comparable to the normal age-related values.

CS testing of Gradiol with visible borders between components was comparable with previous outcomes from diffractive MIOLs and refractive AMO array [34]. In previous studies, CS in both groups at low and high spatial frequencies was identical to the normal values. Compared to refractive MIOLs, CS in patients with diffractive MIOLs was lower at mid-spatial frequencies. Glare testing CS in the first group was significantly lower than normal values [34].

The comparison of CS in our study showed that gradient MIOLs has advantages over diffractive MIOLs as the latter result in more impairment of CS and increased glare.

Lubiński W. et al. evaluated visual contrast sensitivity in prospective study of 40 eyes of 20 patients with an age range from 48 to 67 years and undergoing cataract surgery with implantation of the diffractive one-piece IOL TECNIS ZMB00 (Abbott Medical Optics) in one eye and

3 weeks later in the other eye [35]. Contrast sensitivity under different conditions (1.5, 3, 6, 12, and 18 cycles/degree, CSV-1000, FACT) was within normal age-matched limits, with significant improvements for some spatial frequencies at 3 and 6 months after surgery ($p < 0.04$) [35].

Rosen E., Alio J. L., Dick H.B. et al. analyzed 132 studies that included contrast sensitivity data [1]. Of the 132 studies, 31 compared the outcomes in a multifocal IOL group with those in a control group with a monofocal IOL. One-third of these studies (11) concluded there was no difference in contrast sensitivity between patients with multifocal and monofocal IOLs. The remaining two-thirds (22) found reduced contrast sensitivity at the highest spatial frequencies for multifocal IOLs compared with monofocal controls, although contrast sensitivity outcomes generally remained within the age-matched normal range [1].

CS data of the latest generation of Gradiol demonstrated contrast sensitivity decreasing in high spatial frequencies and mesopic condition (3°cd/m^2) with improvements for some spatial frequencies at 1 year after surgery. Patients were completely satisfied at daytime conditions and mostly satisfied at night.

In the current study, there was no change in CS compared to normal age values after multifocal gradient IOLs implantation.

The main problem in our previous study was photic phenomena which were not noticed before cataract surgery.

Postoperative optical disturbances are important for functional assessment of the MIOL implantation. In clinical study after implantation of Gradiol with visible borders between components, we found clinically significant disturbances in 10.7% of cases. There was no regression of symptoms with long-term follow-up. Often neural processing adapts to these disturbances, ignoring them over time. Therefore, most of the patients noted optical disturbances only after meticulous discussion (57%). These disturbances can be explained by light reflection from the transition zone and IOL surface and light diffraction at the border of the optical components.

Comparative analysis of our data to other previous studies of optical disturbances indicated similar outcomes for different types of MIOLs. Haring G. et al. [30] reported optical side effects in 9% of patients after monofocal IOL implantation and in 41% of cases after refractive multifocals. Halos and glare are the most frequent complaints in patients after MIOL implantation compared to monofocal IOLs. Haring G et al. compared the incidence and severity of photic phenomena after the implantation of the Array (Allergan) refractive multifocal intraocular lens (MIOL) and a monofocal IOL [30]. The study comprised 231 randomly selected patients from 4 study centers. The patients had had uneventful phacoemulsification with implantation of a refractive MIOL ($n = 138$) or a monofocal IOL ($n = 93$). Overall, 9% of patients with a monofocal IOL and 41% of those with an MIOL reported photic phenomena that had not been noticed before cataract surgery [30].

Takhtayev and Balashevich [31] studied symptoms after AcrySof ReSTOR (Alcon Inc., Fort Worth, TX, USA) implantation and observed visual impairment in twilight conditions in 8% cases, optical side effects near point sources of light in 11% of cases, and impairment on glare testing in 14% of cases. The symptoms were of moderate severity [31].

Recently there are new approaches to understanding and analysis of photic phenomena (dysphotopsia).

Currently approximately 20% of patients who receive polymethyl methacrylate intraocular lenses (IOLs) may experience some degree of transient glare, streaks, arcs, or halos after surgery. This is independent of optic style. These photic phenomena have been referred to as edge glare, undesired light images, or pseudophakic dysphotopsia (R.J. Olson, MD, "Pseudophakic Dysphotopsia," presented at the 16th Congress of the European Society of Cataract and Refractive Surgeons, Nice, France, September 1998) [30, 36, 37, 38]. Patients described they experienced light sensations postoperatively (light streaks, halos, flare, flashes, or glare) that had not been noticed preoperatively [30].

The term dysphotopsia has been used to describe a variety of unwanted visual phenomena encountered by pseudophakic patients. There are positive and negative phenomenon. Positive dysphotopsia may include halos, ghost images, starburst, and arcs, rings, or flashes of light that may ultimately interfere with vision function. The most common negative dysphotopsia is manifest as dark crescent or curved shadows that can appear similar to a scotoma in the peripheral temporal field of vision [30, 36, 37].

Researchers investigate possible etiologies of negative dysphotopsia. Proposed etiologies include edge design, edge smoothness, edge thickness, index of refraction of the IOL, pupil size, amount of functional nasal retina, edema from the clear corneal incision, distance between the iris and IOL, amount of pigmentation of the eye, corneal shape, prominent globe and shallow orbit, and interaction between the anterior capsulorhexis and IOL [38–41].

The commonly used term dysphotopsia is not in Stedman's Medical Dictionary or Webster's Dictionary; it has been adopted in the ophthalmology literature to mean a positive phenomenon or a negative phenomenon with no attributable retinal or cerebral findings that is most likely related to an implanted IOL [41].

Rosen E. et al. reported that visual symptoms, disabling glare and halos, in patients with multifocal IOL can be found in the range of 0% to 10% [1].

In clinical study by Baykara M. et al., quality of life was evaluated by Visual Function-14 (VF-14) questionnaire [42]. Two hundred eyes of 100 patients with the Acriva UD Reviol MFB 625 (VSY Biotechnology, Istanbul, Turkey), were evaluated. Only 5 (2.3%) patients reported halo and glare at postoperative 12 months [42].

Akaishi L. et al. investigated 942 patients with multifocal correction [43]. After an average follow-up of 13.6 months, for glare after the second implant, of the 942 patients who answered the question, 6.1% ($n = 58$) rated their observation as severe in effect, 26.2% ($n = 247$) rated it as moderate, and 67.7% ($n = 637$) rated it as none or mild. Halos were reported as severe by 2.12% of patients ($n = 20$), moderate by 16.45% ($n = 155$), and absent or mild by 81.43% ($n = 767$). No other complaints were reported [43]. Modern multifocal IOLs including Gradiol new generation without transition zone demonstrate low incidence of dysphotopsia.

Conventional visual acuity testing is the most widely used test for evaluation of functional outcomes. However, this test does not reflect patient satisfaction and does not provide information on the effects on work or quality of life. Subjective testing in all MIOLs groups demonstrated high patient satisfaction postoperatively. Previous reports of patient satisfaction vary considerably indicating a range of 32–81% of patients who did not require additional spectacle correction [44–49]. In our studies – previous and latest – 86% of patients did not use spectacle correction for work at distance and near including during prolonged activity and driving [50].

In modern study by Rosen E., Alio J.L., Dick H.B. et al., spectacle independence was reported by 63 studies with different design of multifocal IOL (4066 patients) with a mean value of 80.1% [1].

Kim J.S. et al. note that complete spectacle independence after diffractive multifocal IOL implantation with additional add power of D2.75 diopters (D) (Group 1, TECNIS ZKB00 23 eyes), D3.25 D (Group 2, TECNIS ZLB00 21 eyes), or D4.00 D (Group 3, TECNIS ZMB00 21 eyes) was in 87.0% (20 of 23) of Group 1, 85.7% (18 of 21) of Group 2, and 76.9% (16 of 21) of Group 3. These slight differences were not statistically significant [6].

In clinical study of 188 patients undergoing bilateral sequential cataract surgery or bilateral refractive lens exchange, patients were preoperatively randomized (allocation ratio 1:1) to bilateral implantation with the AT LISA 809 M IOL (n = 94) or ReSTOR SN6AD1 IOL ($n = 94$). Complete spectacle independence was achieved in 69 of 84 (82.1%) AT LISA 809 M recipients and 66 of 85 (77.6%) ReSTOR SN6AD1 recipients [7].

There are interesting national features in investigating multifocal intraocular correction in the study by Yamauchi T. et al. [9] that included patients implanted with either TECNIS monofo-

cal IOLs (ZA9003 or ZCB00) or TECNIS multifocal IOLs (ZMA00 or ZMB00) bilaterally. All of the subjects in this study were Japanese patients. In general, Japanese persons, especially those who select the implantation of monofocal IOLs, have less psychological resistance against glasses. They do not feel inconvenienced if they must read books or newspapers with glasses. Researchers consider this phenomenon to explain why the near vision VFQ-25 scores of the monofocal group were not inferior to those of the multifocal group, although the mean UNVA was worse and the rate of spectacle dependency was higher in the monofocal group. Approximately 85% of multifocal patients were spectacle independent in our study, a rate consistent with the findings of previous reports of TECNIS multifocal IOLs in which the percentage ranges from 82.6% to 92.8% [9].

Rosen E., Alio J.L., Dick H.B. et al. analyzed overall patient satisfaction after multifocal and monofocal IOLs implantation and noted that it was good with both multifocal and monofocal IOLs, with ratings ranging from 61.8% to 100% [1].

Akaishi L., Vaz R., Vilella G. et al. concluded that 88% (829 of 942 patients) of the patients after multifocal intraocular correction were totally satisfied with their quality of vision [43].

In our studies we applied VF-14 for patient satisfaction's measurement [29]. The VF-14 has high internal consistency and correlates more strongly with the overall self-rating of the amount of trouble and satisfaction patients have with their vision than do several measures of visual acuity or the Sickness Impact Profile score. The VF-14 score is moderately correlated with visual acuity in the better eye. VF-14 is developed by the Cataract Patient Outcomes Research Team. The VF-14 is a reliable and valid measure of functional impairment caused by cataract and provides information not conveyed by visual acuity or a general measure of health status [29].

The mean VF-14 score was equivalent to 100 indicating high subjective satisfaction after Gradiol implantation, including prolonged work at near, small print text reading, as well computer work under varying light conditions.

Based on these results, the current clinical trial proved safety, efficacy, and stability of results determining adequate visual rehabilitation and high patient satisfaction. These results are encouraging and provide the impetus for further design enhancements to existing MIOLs or the creation of new models.

23.13 What Are the Advantages of this Intraocular Lens

- The only multifocal intraocular lens based on change of index of refraction of the inner optical structure of the lens.
- Good outcomes with very little photic phenomena.
- Good defocus curve for far and near distances.
- Good contrast sensitivity function in low mesopic conditions.

23.14 What Are the Disadvantages of this Intraocular Lens

- This lens is pupil dependent and should be used only in patients with expected good pupillary function after surgery.
- More clinical studies are necessary, multicentrically designed, to validate its results.
- The defocus curve shows a limitation in intermediate vision.

Conflict of Interest Boris Malyugin, Tatiana Morozova, and Valentin Cherednik have no conflict of interest.

Informed Consent All procedures followed were in accordance with the ethical standards of the responsible committee on human experimentation (institutional and national) and with the Helsinki Declaration of 1975, as revised in 2000. Informed consent was obtained from all patients for being included in the study.

No animal studies were carried out by the authors for this chapter.

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