Functional Outcome and Patient Satisfaction After Artisan Phakic Intraocular Lens Implantation for the Correction of Myopia

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• PURPOSE: To determine patient satisfaction after Artisan phakic intraocular lens (PIOL) implantation to correct myopia.

• DESIGN: Non-comparative prospective case series.

• METHODS: One hundred twenty eyes of 60 patients who had undergone Artisan PIOL implantation to correct myopia were analyzed. A validated questionnaire that consisted of 66 satisfaction items were self-administered by patients 12 months after surgery. Clinical parameters (PIOL decentration, the difference between pupil size and PIOL optical zone, and optical aberrations) were measured. Main outcome measures of satisfaction scale scores (global satisfaction, quality of uncorrected and corrected vision, night vision, glare, day and night driving) were analyzed. Correlations with clinical parameters were obtained.

• RESULTS: After surgery, 98.3% of patients were satisfied, and 73.3% of patients considered their night vision to be the same or better; 44.1% of patients reported more bothersome glare. The night vision score correlated with spheric aberration ($r = -0.303$; $P = .020$). The glare score correlated with the difference between scotopic pupil size and PIOL optical zone ($r = -0.280$; $P = .030$) and vertical coma ($r = -0.337$; $P = .009$). The night driving score correlated with postoperative spheric equivalent ($r = 0.375$; $P = .009$), total root mean square aberrations ($r = -0.337$; $P = .017$), higher order root mean square aberrations ($r = -0.313$; $P = .027$), and vertical coma ($r = -0.297$; $P = .036$).

• CONCLUSION: Overall satisfaction after Artisan PIOL implantation for myopia is excellent. The quality of night vision and night driving were related to scotopic pupil size, individual higher order aberrations, and residual refractive error. (Am J Ophthalmol 2006;142:31–39. © 2006 by Elsevier Inc. All rights reserved.)

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IN GENERAL, HIGH LEVELS OF PATIENT SATISFACTION are reported after refractive surgery, which includes photorefractive keratectomy, laser-assisted in situ keratomileusis (LASIK),[1–8] and phakic intraocular lens implantation (PIOL).[9,10] However, numerous studies have outlined a decreased quality of vision after refractive surgery that may be attributed to contrast sensitivity loss and subsequent night vision complaints (NVCs). Proposed mechanisms for this decrease in quality of vision have been the use of small optical zones in patients with large preoperative scotopic pupil sizes and highly oblate corneal profiles after laser surgery.[2,11–14] After corneal laser surgery, it may be difficult to determine the exact effective optical zone size because of variations in the transition zones of current excimer lasers. Therefore, it is often difficult to establish the disparity between the optical zone size and the scotopic pupil size. In addition, in contrast to previous assumptions, several recent reports show that a large pupil size is probably not a major risk factor for NVCs after LASIK surgery.[4,5,14,15]

The purpose of this study was to assess patient satisfaction and to determine possible risk factors for the development of NVCs after Artisan PIOL implantation. The Artisan PIOL is a lens with a fixed optical zone of 5 or 6 mm, depending on the dioptric power of the lens, and is used for the correction of moderate-to-severe myopia. The risk factors that were investigated included the preoperative pupil size under dim light conditions, the disparity between the pupil size and the optical zone of the PIOL, and the decentration of the PIOL. The presence of postoperative higher-order aberrations (HOAs) was also assessed.

METHODS

• QUESTIONNAIRE AND STUDY DESIGN: The study and data accumulation were carried out with approval from the

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Institutional Review Board from the Academic Hospital Maastricht, The Netherlands.

The questionnaire that was used in our study was developed and validated by Brunette and associates[1,16] and has been used previously for the evaluation of patient satisfaction after photorefractive keratectomy and to assess postoperative visual symptoms. The questionnaire was translated into the Dutch language from the original English without changes to the contents and construction of the original questionnaire. Later it was translated back into English, after which original and back-translated versions were compared, and minor inconsistencies were corrected. The instrument has proved to be reliable by a high level of internal consistency with Cronbach's alpha coefficients of ≥ 0.83.[5,16] In the questionnaire, 66 items were self-administered by the patients 12 months after the PIOL implantation procedure. For analysis purposes, these items were reformulated by applying factor analysis into seven distinct scales.[16] Scale scores increased with satisfaction, ranging from 1 (very dissatisfied) to 5 (very satisfied). Each of the seven scales covered a specific aspect of quality of vision that included global satisfaction, quality of uncorrected and corrected vision, quality of night vision, glare, daytime driving, and night driving.

Before the routine examination, the questionnaire was provided to the patient by an independent employee who had no interest or involvement with the patient and who requested the patient to fill in the questionnaire. Patients were informed about the study procedure and provided informed consent.

• SURGICAL PROCEDURE: All treatments were performed by a single surgeon (R.M.M.A.N.) at the Academic Center for Refractive Surgery, University Eye Clinic of Maastricht.

Exclusion criteria were a preoperative best-corrected visual acuity (BCVA) of <20/50, an anterior chamber depth of <3.0 mm (determined by immersion A-scan biometry method), an endothelial cell count of <2000 cells/mm^2 (Noncon ROBO Pachy SP-9000; Konan Medical Inc, Tokyo, Japan), glaucoma. and retinal disease.

The Artisan iris claw-fixated PIOL has a convex-concave polymethyl methacrylate optic with either a 6-mm (for intraocular lens powers up to –15.5 diopters [D]) or a 5-mm (for intraocular lens powers from –16.0 D up to –24.0 D) diameter and is available in 0.50-D steps (Ophtec BV, Groningen, The Netherlands). Refractive error, refractive cylinder power, anterior chamber depth, and topographically derived keratometric dioptric values (Orbtek Orbscan II, version 3.10.31; Bausch & Lomb, Munich, Germany) were inserted into the van der Heijde formula to calculate the dioptric power of the lens.[17] The power of the lens was chosen to obtain emmetropia. When the emmetropic lens was not available, the power of the lens was estimated for a slight residual myopia.

Surgery was performed with general anesthesia. A two-plane 6.3- or 5.3-mm corneoscleral incision was centered at 12 o'clock. Two stab incisions were performed at 2 o'clock and 10 o'clock and directed towards the enclavation sites. After an intracameral injection of acetylcholine and the insertion of a viscoelastic substance (Healon GV; Pharmacia, Uppsala, Sweden), the lens was introduced with a Budo forceps (Duckworth and Kent, Ltd, Baldock Herts, United Kingdom). After subtle rotation of the lens, it was fixated in the horizontal axis with the use of a disposable enclavation needle (Ophtec BV). A slit iridotomy was performed at 12 o'clock to avoid pupillary block glaucoma. The viscoelastic substance was exchanged for balanced salt solution (Alcon, Fort Worth, Texas, USA). The wound was sutured with three to five interrupted 10-0 nylon sutures (Alcon). After the operation, topical tobramycin 0.3% combined with dexamethasone 0.1% (Tobradex, Alcon, Couvreur, Belgium) and ketorolactrometamol 0.5% (Acular; Westport Co, Mayo, Ireland) were used four times daily for three weeks in a tapered schedule and three times daily for one week, respectively. Selective suture removal was performed, depending on the subjective refraction.

A surgical delay of one month between both eyes was established for all patients. Patients who were included showed a stable postoperative refraction and were examined before the operation and at day one, week one, month one, month three, and month six and from then at six-month intervals. The routine examination consisted of the measurement of the Snellen uncorrected visual acuity (UCVA) and BCVA with subjective and manifest refraction, corneal topography, and intraocular pressure measurement with Goldmann applanation tonometry. Because no binocular visual acuity measurement was available, the UCVA and BCVA of the best eye were used for all calculations. When scales such as night vision, glare, and night driving were assessed, the UCVA and BCVA of the worst eye were used.

• PUPIL AND WAVEFRONT MEASUREMENTS: The scotopic and mesopic-low pupil size was measured with a digital infrared pupillometer (P2000 SA pupillometer; Procyon Instruments Ltd, London, United Kingdom). This device performs binocular simultaneous measurements of the pupil diameter at 3 illuminance levels (scotopic [0.04 lux], low mesopic [0.4 lux], and high mesopic [4.0 lux]). At each illuminance level, a sequence of 10 images is acquired within two seconds and stored in a portable computer.[18]

Wavefront measurements were performed with a Hartmann-Shack wavefront sensor (Zywave aberrometer, software version 3.21; Bausch & Lomb-Technolas, Munich, Germany). The Zywave aberrometer uses a wavelength of 780 nm and an array of approximately 70 to 75 lenslets. Three Zywave measurements were taken under standardized mesopic light conditions after installation of phenylephrine 5% (Bournonville Pharma BV, The Hague, The Netherlands) and were analyzed with the use of the provided software. To avoid instrument accommodation,

TABLE 1. Characteristics of Patient Population Who Received Artisan Phakic Intraocular Lens Implantation for the Correction of Myopia

Characteristic	Measure	Median	Range
Age (y)	44.3 ± 8.7	45.0	26 to 63
Female (%)	65.0		
Before surgery (n = 120 eyes of 60 patients)			
Mean sphere (D)	−11.14 ± 3.99	−10.50	−24.50 to −4.75
Mean cylinder (D)	−0.97 ± 0.89	−0.75	−4.25 to 0.75
Mean SE (D)	−12.09 ± 4.09	−10.88	−5.63 to −27.25
−12.00 ≤ SE < −5.63 (%)	61.7		
−18.00 ≤ SE < −12.00 (%)	30.0		
−27.25 ≤ SE < −18.00 (%)	8.3		
BCVA 20/20 or better (%)	44.0		
BCVA between 20/20 and 20/40 (%)	39.9		
BCVA 20/40 or worse (%)	16.1		
Mean pupil diameter (mm) (scotopic)	6.2 ± 0.79	6.2	4.6 to 7.6
At 12 months FU (n = 120 eyes of 60 patients) (%)			
UCVA 20/20 or better	25.8		
UCVA between 20/20 and 20/40	42.5		
UCVA 20/40 or worse	31.7		
Loss of 1 Snellen line of BCVA	5.8		
Loss of 2 Snellen lines of BCVA	0.8		
Gain of 2 Snellen lines or more of BCVA	23.3		
At 12 months FU (n = 120 eyes of 60 patients)			
Refractive outcome			
Mean SE (D)	−0.60 ± 0.78	−0.50	−3.50 to 0.75
Mean SE ± 0.50 D of emmetropia (%)	62.4		
Mean SE ± 1.00 D of emmetropia (%)	81.5		

BCVA = best-corrected visual acuity; D = diopters; FU = follow-up; SE = spherical equivalent; UCVA = uncorrected visual acuity.

the eye is fogged approximately 1.0 D (D) during measurements. Wavefront errors were described with Zernike polynomials for a virtual pupil diameter of 6 mm that resembles pupil size under mesopic conditions. The Zywave measurements allow a Zernike approximation from second order to fifth order for 6-mm pupils. The aberrations that were used in this study are classified in terms of total root mean square aberrations (total RMS) of the wavefront error and HOAs, which included total higher-order root mean square (total HO-RMS) of the wavefront error, horizontal coma (Z_3^1), vertical coma (Z_3^{-1}), trefoil-x (Z_3^3), trefoil-y (Z_3^{-3}) and spherical aberration (SA; Z_4^0).[19–21]

• DATA ANALYSIS: Logarithm of minimal angle of resolution (logMAR) values of the UCVA and the BCVA of the best eye were used for calculations.

The amount of decentration of the PIOL was determined by measuring the deviation of the center of the PIOL from the center of the pupil with the digital photography mode within the Zywave aberrometer. The pupil-optical zone disparity, which is defined as the disparity between the pupil size and the optical zone of the PIOL, was calculated by subtracting the optical zone of the PIOL from the scotopic and mesopic-low pupil size as measured by the Procyon pupillometer. For parameters that were expected to have an adverse effect in relation to glare and NVCs (such as preoperative pupil size, the pupil-optical zone disparity, and the decentration of the PIOL), the greatest value of both eyes were taken for analysis. Wavefront analysis was performed for pupil diameters of 6.0 mm. Zernike coefficients up to the 4th order are included currently in the measurements. Calculations were performed with total RMS, total HO-RMS, horizontal coma, vertical coma, trefoil-x, trefoil-y, and SA. Changes in the quality of vision scale scores were determined by defining correlations with total HOAs and individual HOAs.

For statistical analyses, results from the wavefront examinations were transformed into absolute values, and Snellen visual acuities were transformed to logMAR values.

Correlations between the scale scores and clinical parameters were performed for data that were obtained at the 12-month follow-up examination and assessed with the Pearson r coefficient of correlation and the Spearman rank correlation (SPSS for Windows; SPSS Inc, Chicago, Illinois, USA). The Mann-Whitney test was used to compare satisfaction score differences between spectacle and non-spectacle or contact lens wearers before or after surgery.

TABLE 2. Scale Scores Descriptives After Artisan Phakic Intraocular Lens Implantation for the Correction of Myopia

Scale	Mean ± SD*	Range
Global satisfaction	4.2 ± 0.56	1.9–5.0
Uncorrected daytime vision	3.2 ± 0.87	1.6–5.0
Corrected daytime vision	3.5 ± 0.90	2.0–5.0
Night vision	3.2 ± 0.65	1.6–4.4
Glare	3.0 ± 0.84	1.4–5.0
Daytime driving	4.7 ± 0.87	1.0–5.0
Night driving	3.2 ± 1.31	1.0–5.0

SD = standard deviation.
*Scores 0–5 (5 meaning totally satisfied).

The analysis of variance test was used to compare differences between patient age and the satisfaction scales. All values in the text are mean ± SD.

RESULTS

A TOTAL OF ONE HUNDRED TWENTY EYES OF 60 CONSECUtive patients were included in this study. The patient group consisted of 39 female patients (65%) and 21 male patients (35%). Population characteristics and scale scores are listed in Tables 1 and 2. Data were provided only for patients who were subjected to the particular condition.

• PATIENT SATISFACTION AND SELF-PERCEIVED OUTCOME: Before surgery, 71.7% of patients wore contact lenses on a regular basis. The most frequently reported motivations for desiring surgical correction were a general dislike of handling glasses (33.9%), intolerance to contact lens wear (18.6%), to be less dependent on glasses (15.3%), and a dislike of handling contact lenses (6.8%).

• GLOBAL SATISFACTION: The mean overall satisfaction score was 4.22 ± 0.56 (5 being totally satisfied). Most patients (96.7%) reported that their main goal of surgery had been achieved; 98.3% of patients were satisfied or very satisfied with the result of surgery; 98.3% of patients reported that the surgery had been a good choice for them; 93.3% of patients experienced a quality of vision as they had expected after the operation; and for 70.0% of patients, the best consequence of surgery was that they no longer felt dependent on their glasses or contact lenses. After surgery, no significant difference in global satisfaction was shown between patients who wore spectacles or contact lenses for distance vision (4.12 ± 0.64; n = 36) and those who did not wear any type of correction (4.35 ± 0.44; n = 24) before surgery.

• QUALITY OF DAYTIME VISION WITHOUT CORRECTION: The mean score was 3.20 ± 0.87; 50.0% of patients reported that, after surgery, their self-perceived uncorrected vision for distance was slightly or much better than their preoperative corrected vision; 21.7% of patients considered it to be the same, and 28.3% of patients reported it as being slightly or much worse.

Uncorrected near vision was characterized as slightly or much better than the preoperative corrected near vision by 28.3% of patients, to be the same by 37.3% of patients, and to be slightly or much worse by 35.0% of patients.

• QUALITY OF DAYTIME VISION WITH CORRECTION: Most patients (73.3%) wore contact lenses before surgery; 26.7% of patients wore spectacles. After surgery, the regular use of glasses for distance vision and near vision and of contact lenses was reported by 38.3% (n = 23), 38.3% (n = 23), and 1.7% (n = 1) of patients, respectively. The mean score for patients who were wearing glasses for quality of daytime vision was 3.47 ± 0.90. There was no correlation between the corrected vision score and patient age ($r = -0.289$; $P = .087$).

• QUALITY OF NIGHT VISION: The mean night vision score was 3.16 ± 0.65. After surgery, 58.4% of patients were satisfied with their night vision. In comparison with before surgery, 73.3% of patients considered their night vision after surgery to be the same or better; 26.7% of patients considered it to be worse or much worse. NVCs after surgery included perception of stars around lights (41.7%), halos, fog, or haze around street lights (48.4%), double outline of images (6.7%), ghost images (8.3%), and distortion of details (33.3%). Patients recalled such symptoms before surgery in 33.3%, 35.0%, 6.6%, 6.7%, and 21.6% of cases, respectively.

• GLARE: The mean glare score was 3.02 ± 0.84. Only one patient (1.7%) showed a score of 5 for the glare scale (totally satisfied). Patients reported glare or light sensitivity on sunny days, snowy weather conditions, foggy conditions, or when going from dim to bright light conditions in 50.8%, 42.6%, 12.5%, and 35.0%, respectively. After surgery, daytime glare and glare from lights at night were considered more bothersome than before surgery by 32.8% and 44.1% of patients, respectively. Glare from oncoming car headlights was reported by 68.4% of patients and believed to be more bothersome for night driving than before surgery by 55.8% of patients.

• DRIVING: A total of 51 patients (85.0%) reported driving a car. The mean daytime driving score was 4.66 ± 0.87. The mean night driving score was 3.22 ± 1.31. A daytime and night driving score of 5 was reported by 80.4% and 15.7% of patients, respectively.

After surgery, 51% of patients reported experiencing night driving problems; 39.2% of patients reported having

TABLE 3. Correlation Coefficients Between Clinical Parameters and Satisfaction Scales After Artisan Phakic Intraocular Lens Implantation for the Correction of Myopia

Clinical Parameter	Overall Satisfaction	Uncorrected Vision	Corrected Vision	Night Vision	Glare	Daytime Driving	Night Driving
Visual acuity of best eye (logMAR)							
UCVA at 12 months FU	−0.119	−0.346†	0.130	−0.053	−0.027	−0.165	−0.178
Difference UCVA at 12 months FU and BCVA pre-op	−0.245	−0.419†	−0.038	0.024	0.069	−0.077	−0.023
BCVA at 12 months FU	0.091	0.003	0.076	0.031	−0.069	−0.082	−0.169
BCVA Snellen line loss	−0.098	−0.113	−0.285	0.220	0.192	0.072	0.117
Spherical equivalent (D)							
Mean SE at 12 months FU	0.019	0.148	−0.217	−0.030	−0.006	0.119	0.375†
Difference in SE between eyes	−0.336*	−0.194	−0.164	−0.083	−0.173	−0.233	−0.351†
PIOL decentration and pupil size (mm)							
Decentration amount	0.023	0.124	0.091	0.025	0.168	0.188	0.118
Scotopic pupil size	0.155	0.273*	0.286	−0.132	−0.256*	0.219	0.044
Mesopic-low pupil size	0.201	0.276*	0.336*	−0.054	−0.178	0.092	−0.088
Scotopic PIOL-disparity	0.192	0.340†	0.362*	−0.154	−0.280*	0.154	0.024
Mesopic-low PIOL disparity	0.229	0.325*	0.389*	−0.085	−0.204	0.048	−0.083
Age (yrs)	2.04	1.89	0.32	2.36	1.28	0.49	1.36

BCVA = best-corrected visual acuity; D = diopters; FU = follow-up; PIOL = phakic intraocular lens; SE = spherical equivalent; UCVA = uncorrected visual acuity.
*$P < 0.05$ level; †$P < 0.01$ level.

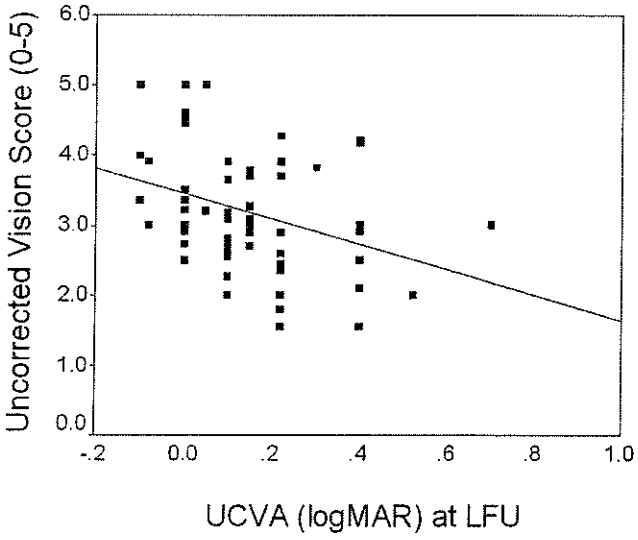

FIGURE 1. Uncorrected vision score vs uncorrected visual acuity (UCVA; logarithm of minimal angle of resolution [logMAR]) at 12 months follow-up (LFU) after Artisan phakic intraocular lens (PIOL) implantation ($r = -0.346$; $P = .007$).

more difficulty during night driving than before surgery, and 56.9% of patients reported having less difficulty.

• CORRELATION BETWEEN SATISFACTION SCALES AND CLINICAL PARAMETERS: *Visual Acuity.* At the 12-month follow-up visit, 25.8% of eyes had a UCVA of 20/20 or better, and 76.6% of eyes had a UCVA of 20/40 or better (Table 1). Before the operation, 44.0% of eyes had a BCVA of better than 20/20, and 90.6% of eyes had a BCVA of 20/40 or better. There was a loss of 1 Snellen line of BCVA in 5.0% of eyes and a loss of 2 Snellen lines of BCVA in 0.8% of eyes. In addition, there was a gain of at least 2 Snellen lines of BCVA in 23.3% of eyes.

The mean logMAR UCVA of the best eye at the time of the questionnaire was 0.14 ± 0.17 and showed a correlation with the uncorrected vision score ($r = -0.346$; $P = .007$; Table 3; Figure 1). The mean preoperative logMAR BCVA of the best eye was 0.07 ± 0.12 and did not correlate with any of the satisfaction scales. The mean difference between the preoperative logMAR BCVA and the postoperative logMAR UCVA was 0.07 ± 0.15 and showed a negative correlation with the uncorrected vision score ($r = -0.419$, $P = .001$). The mean difference between the pre- and postoperative logMAR BCVA was −0.09 ± 0.09.

Refraction. Surgery was aimed at the correction of myopia. Preoperatively, the mean spherical equivalent (SE) was −12.09 ± 4.09 D. After surgery, the mean SE was −0.60 ± 0.78 D. In the population, 62.4% was within ±0.5 D, and 81.5% was within ±1.0 D from emmetropia, respectively. The postoperative sphere and SE showed a positive correlation with night driving ($r = 0.309$; $P = .034$; and $r = 0.375$; $P = .009$), respectively). The postoperative cylinder showed a positive correlation with the uncorrected vision score ($r = 0.417$; $P = .001$). The difference in the postoperative SE between eyes was 0.08 ± 0.63 D and showed a negative correlation with global satisfaction and night driving ($r = -0.336$; $P = .009$; and $r = -0.351$; $P = .012$, respec-

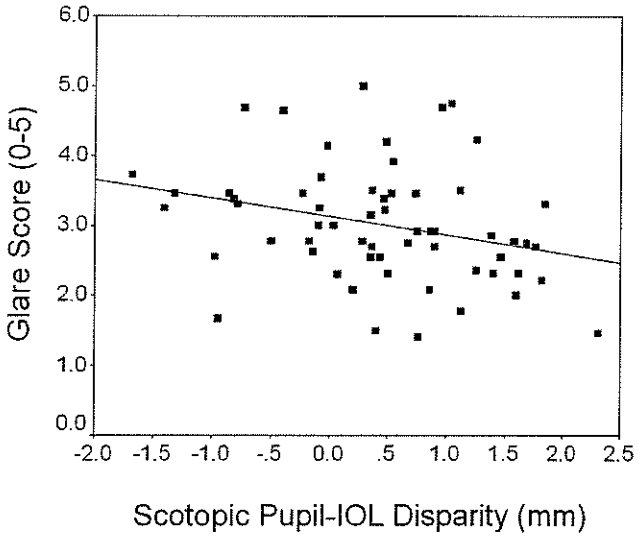

FIGURE 2. Glare score vs scotopic pupil-optical zone disparity after Artisan phakic intraocular lens (PIOL) implantation ($r = -0.280$; $P = .030$).

TABLE 4. Aberration Descriptives After Artisan Phakic Intraocular Lens Implantation for the Correction of Myopia

Type (μm)	Mean ± SD	Range
Total RMS	3.73 ± 1.73	1.32–7.77
Total HO-RMS	1.05 ± 0.52	0.35–3.34
Horizontal coma (Z_3^{1})	0.48 ± 0.34	0.01–2.30
Vertical coma (Z_3^{-1})	0.36 ± 0.36	0.00–2.45
Trefoil-x (Z_3^{3})	0.29 ± 0.19	0.02–0.89
Trefoil-y (Z_3^{-3})	0.28 ± 0.26	0.01–0.82
SA (Z_4^{0})	0.64 ± 0.33	0.13–1.89

HO-RMS = higher order root mean square of the wavefront error; RMS = root mean square of the wavefront error; SA = spherical aberration; SD = standard deviation.

tively). There was no correlation between night vision and the preoperative dioptric power ($r = 0.060$; $P = .659$) or the PIOL optical zone size ($r = -0.041$; $P = .754$).

Lens Decentration. The mean ± SD amount of decentration of the PIOL was 0.36 ± 0.14 mm (range, 0.14 to 0.74 mm). Considering the centration of the PIOL on the center of the pupil, 86.4% was placed within 0.5 mm, and 100% was placed within 0.75 mm from the center, respectively. The amount of PIOL decentration showed a weak positive correlation with glare ($r = 0.267$; $P = .041$). There was no correlation between HOAs and the amount of decentration of the PIOL.

Pupil Size and Pupil-IOL Optical Zone Disparity. Mean scotopic and mesopic-low pupil sizes for all eyes were 6.2 ± 0.79 mm (range, 4.6 to 7.6 mm) and 5.2 ± 0.79 mm (range, 3.5 to 7.2 mm), respectively. The scotopic and the mesopic-low pupil size showed a positive correlation with the uncorrected vision score ($r = 0.273$; $P = .035$; and $r = 0.276$; $P = .033$, respectively). The scotopic and mesopic-low pupil-optical zone disparity showed a positive correlation with the uncorrected vision score ($r = 0.340$; $P = .008$; and $r = 0.325$; $P = .011$, respectively) and the corrected vision score ($r = 0.362$; $P = .030$; and $r = 0.389$; $P = .019$, respectively). The scotopic pupil size and the scotopic pupil-optical zone disparity showed a weak negative correlation with glare ($r = -0.256$; $P = .049$; and $r = -0.280$; $P = .030$, respectively; Figure 2). There was no correlation between pupil size and night vision or night driving scores (Table 3).

Aberrations. All aberration measurements for the eye with the best UCVA and quality of vision scale scores are shown in Tables 4 and 5. The night vision score showed a positive correlation with SA (Z_4^{0}; $r = 0.303$; $P = .020$). The glare score showed a negative correlation with total HO-RMS and vertical coma ($r = -0.284$; $P = .029$; $r = -0.337$; $P = .009$; Figure 3). The night driving score showed a negative correlation with total RMS, HO-RMS, and vertical coma ($r = -0.337$; $P = .017$; $r = -0.313$; $P = .027$; $r = -0.297$; $P = .036$, respectively; Figure 4). The mesopic-low pupil size showed a positive correlation with vertical coma ($r = 0.274$; $P = .036$). The amount of PIOL decentration showed a positive correlation with horizontal coma ($r = 0.298$; $P = .022$).

DISCUSSION

IN THIS STUDY, WE ANALYZED PATIENT SATISFACTION AND self-perceived quality of vision after Artisan PIOL implantation for the correction of moderate-to-high myopia.

For this purpose, a self-administered validated questionnaire was applied that represented the quantification of perceived quality of vision after refractive surgery. The study demonstrated that overall patient satisfaction after the Artisan PIOL implantation procedure was excellent and showed comparable results to previous PIOL studies.[9,10,22] The results were also comparable with laser refractive surgery studies,[1,3–5,10,22] which was unexpected, because it is well-known that the predictability of satisfaction after refractive surgery decreases when higher levels of myopia are treated.[3]

Functional outcome results that considered UCVA, SE, and the amount of decentration of the PIOL (86.4% had a decentration <0.5 mm) were comparable with previous reports regarding anterior chamber PIOLs for the correction of myopia (Table 6).[10,22–25]

Our results showed a negative correlation between the quality of vision without correction and the difference between the postoperative logMAR UCVA and the pre-

TABLE 5. Correlation Coefficients Between Aberrations and Night Vision, Glare, Night Driving, and Clinical Parameters After Artisan Phakic Intraocular Lens Implantation for the Correction of Myopia

Variable	Total RMS	HO-RMS	Z_3^1	Z_3^{-1}	Z_3^3	Z_3^{-3}	Z_4^0
Night vision‡	−0.208	−0.189	0.003	−0.179	0.067	0.013	−0.303*
Glare‡	−0.180	−0.284*	−0.029	−0.337†	−0.060	−0.285*	−0.228
Night driving‡	−0.337*	−0.313*	−0.211	−0.297*	−0.073	−0.186	−0.257
Scotopic pupil (mm)	0.049	0.058	−0.033	0.181	−0.033	0.125	0.048
Mesopic-low pupil (mm)	0.071	0.068	−0.066	0.274*	−0.057	0.124	−0.016
Scotopic PIOL disparity (mm)	0.097	−0.010	−0.112	−0.132	0.074	0.088	−0.066
Mesopic-low PIOL disparity (mm)	0.110	−0.007	−0.140	0.203	0.043	0.079	−0.121
Decentration PIOL (mm)	−0.057	0.103	0.298*	−0.014	0.130	−0.053	0.035

HO-RMS = higher order root mean square; RMS = root mean square; Z_3^1 = horizontal coma; Z_3^{-1} = vertical coma; Z_3^3 = trefoil-x; Z_3^{-3} = trefoil-y; Z_4^0 = spherical aberration; PIOL = phakic intraocular lens.
*$P < .05$; †$P < .01$ level; ‡1 (very dissatisfied) to 5 (very satisfied).

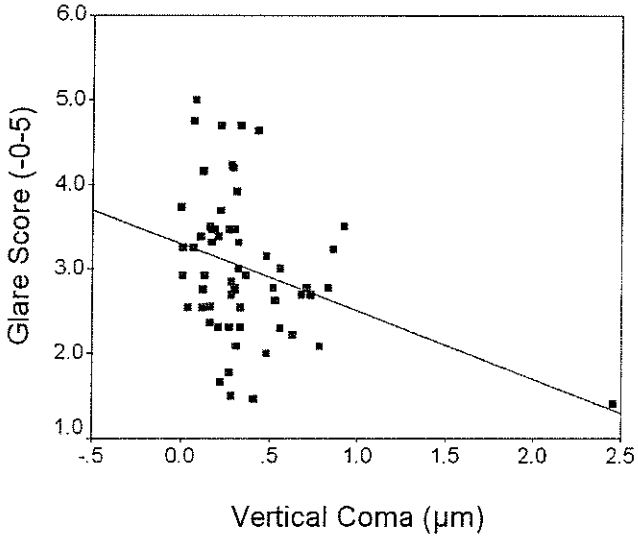

FIGURE 3. Glare score vs vertical coma (Z_3^{-1}) after Artisan phakic intraocular lens (PIOL) implantation ($r = -0.337$; $P = .009$).

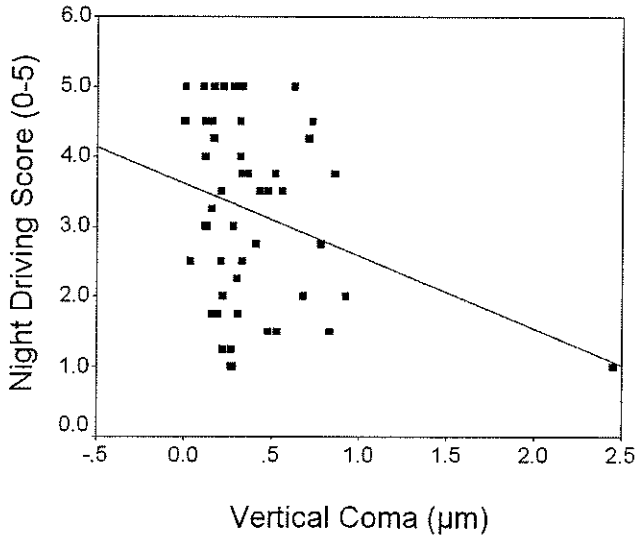

FIGURE 4. Night driving score vs vertical coma (Z_3^{-1}) after Artisan phakic intraocular lens (PIOL) implantation ($r = -0.297$, $P = .036$).

operative logMAR BCVA. In addition, better scores for quality of vision without correction were correlated to higher postoperative UCVA values. Similar findings have also been reported in two recent patient satisfaction studies after LASIK surgery for the correction of myopia.[4,5]

We report that, after surgery, 23 patients (38.3%) regularly wore glasses for distance vision. We do not believe that this finding is a suboptimal result, because most patients aimed to be less dependent on their high-power spectacles instead of being totally spectacle-free.

Secondary effects such as decreased night vision and glare remain the main downsides after refractive surgery. Our study showed that, after surgery, night vision decreased and glare increased in 26.7% and 44.1% of patients. Despite these complaints, overall patient satisfaction remained high, with >90% of patients reporting that they generally were satisfied after surgery. This value is consistent with several other published reports on satisfaction levels after refractive surgery techniques.[2,4–6,11–15,24,26]

Recently, NVCs that occurred after laser refractive surgery have been correlated with the scotopic and/or mesopic-low pupil-optical zone disparity. Presumably, a wider optical zone or a transition zone would decrease the incidence of NVCs.[27,28] The disparity between the pupil size and the optical zone is considered to be the main source of halos, starbursts, and glare. This study demonstrated a weak negative correlation between the scotopic pupil–optical zone disparity and the glare score, but not with the "real-life" mesopic-low pupil size. Our study also showed that the scotopic and mesopic-low pupil-optical zone disparity correlated with the uncorrected and corrected vision score. These correlations may be explained by the fact that, in eyes with a larger pupil size, more light energy was directed through the corrected optical zone of the PIOL.

TABLE 6. Comparison of Clinical Outcome Measures Between This Study and Previous Studies on Artisan Phakic Intraocular Lens Implantation for the Correction of Myopia

Clinical Outcome	Study			
	El Danasoury et al[10] (2002)	Maloney et al[25] (2002)	Malecaze et al[22] (2002)	Our Study
Eyes (n)	90	155	25	120
Mean preoperative SE (D)*	−13.93 ± 2.9	−12.69 ± 3.80	−10.19 ± 1.56	−12.09 ± 4.09
FU (mo)	12	6	12	12
UCVA ≥ 20/40 (%)	88.4	85.0	60	76.6
Mean SE ± 1.0 D of emmetropia (%)	65.1	90.0	60.0	81.7
Mean SE ± 0.5 D of emmetropia (%)	25.6	48.0	n/a	62.4

D = diopters; FU = follow-up; SE = spherical equivalent; UCVA = uncorrected visual acuity.
*Data are given as mean ± SE.

This finding could indicate a possible beneficial consequence of larger pupils in reference to postoperative vision after refractive surgery.[4,15,29] In addition, the Stiles-Crawford effect probably protects patients with a pupil-optical zone disparity from increased levels of glare after Artisan PIOL implantation.[30] These issues emphasize the importance of standardized preoperative pupil size measurement.

The average PIOL decentration value was 0.36 ± 0.14 mm. In contrast to expectations, higher levels of PIOL decentration did not lead to increased glare, which showed that PIOL centration on the pupil center was not a significant predictor of postoperative glare levels. This might be related to the fact that the pupillary axis is known not to coincide with the visual axis in eyes with high myopia.[31]

Wavefront aberrations can measure the optical quality after corneal laser surgery objectively. Several studies have reported on induced aberrations after corneal laser surgery.[21,28,32–34] A recent case series demonstrated no tendency towards deterioration of the optical performance after the insertion of an Artisan lens for the treatment of high myopia.[35]

Our study demonstrated a correlation between the three satisfaction scales night vision, glare, and night driving and the total RMS, higher-order RMS, vertical coma, trefoil-y, and SA.

Correlations were also seen between the mesopic low pupil size and vertical coma and between the amount of PIOL decentration and horizontal coma. However, this did not lead to increased glare complaints in our patient population. These findings are explained most probably by the proposed change in pupil dynamics after PIOL implantation, which results in a larger vertical than horizontal pupil diameter after pupil dilation,[36] thereby increasing the amount of vertical coma and other aberrations. A limitation in our study was the lack of preoperative wavefront measurement data, which would have enabled us to determine objectively the effect of PIOL implantation on wavefront aberrations. However, the wavefront aberrometer that was used in this study cannot accurately measure aberrations in eyes with a myopic SE of >-12.0 D; the average SE in our patient group was -12.09 D (range, -5.63 to -27.25 D).

In conclusion, patient satisfaction after Artisan PIOL implantation for myopia is excellent, despite the occurrence of NVCs. We believe that accurate measurements of the "real-life" pupil size under dim light conditions remain vital when selecting suitable refractive surgery candidates. Future research and PIOL design modifications should aim to limit HOAs and PIOL decentration effects to optimize night vision and to minimize glare. Until the outcome of refractive surgery is fully predictable, patients should be educated on the potential side-effects of PIOL implantation.

REFERENCES

1. Brunette I, Gresset J, Boivin JF, et al. Functional outcome and satisfaction after photorefractive keratectomy: part 2, survey of 690 patients. Ophthalmology 2000;107:1790–1796.
2. Hadden OB, Ring CP, Morris AT, Elder MJ. Visual, refractive, and subjective outcomes after photorefractive keratectomy for myopia of 6 to 10 diopters using the Nidek laser. J Cataract Refract Surg 1999;25:936–942.
3. Knorz MC, Wiesinger B, Liermann A, Seiberth V, Liesenhoff H. Laser in situ keratomileusis for moderate and high myopia and myopic astigmatism. Ophthalmology 1998;105:932–940.
4. Bailey MD, Mitchell GL, Dhaliwal DK, Boxer Wachler BS, Zadnik K. Patient satisfaction and visual symptoms after laser in situ keratomileusis. Ophthalmology 2003;110:1371–1378.
5. Tahzib NG, Bootsma SJ, Eggink FA, Nabar VA, Nuijts RM. Functional outcomes and patient satisfaction after laser in situ keratomileusis for correction of myopia. J Cataract Refract Surg 2005;31:1943–1951.
6. Hammond SD Jr, Puri AK, Ambati BK. Quality of vision and patient satisfaction after LASIK. Curr Opin Ophthalmol 2004;15:328–332.
7. McGhee CN, Craig JP, Sachdev N, Weed KH, Brown AD. Functional, psychological, and satisfaction outcomes of laser in situ keratomileusis for high myopia. J Cataract Refract Surg 2000;26:497–509.

8. McDonald MB, Carr JD, Frantz JM, et al. Laser in situ keratomileusis for myopia up to −11 diopters with up to −5 diopters of astigmatism with the summit autonomous LADARVision excimer laser system. Ophthalmology 2001;108:309–316.
9. Dick HB, Aliyeva S, Tehrani M. Change in pupil size after implantation of an iris-fixated toric phakic intraocular lens. J Cataract Refract Surg 2005;31:302–307.
10. El Danasoury MA, El Maghraby A, Gamali TO. Comparison of iris-fixed Artisan lens implantation with excimer laser in situ keratomileusis in correcting myopia between −9.00 and −19.50 diopters: a randomized study. Ophthalmology 2002; 109:955–964.
11. Ghaith AA, Daniel J, Stulting RD, Thompson KP, Lynn M. Contrast sensitivity and glare disability after radial keratotomy and photorefractive keratectomy. Arch Ophthalmol 1998;116:12–18.
12. Hersh PS, Brint SF, Maloney RK, et al. Photorefractive keratectomy versus laser in situ keratomileusis for moderate to high myopia: a randomized prospective study. Ophthalmology 1998;105:1512–1523.
13. Waring GO 3rd. Quality of vision and freedom from optical correction after refractive surgery. J Refract Surg 1997;13: 213–215.
14. Schallhorn SC, Kaupp SE, Tanzer DJ, Tidwell J, Laurent J, Bourque LB. Pupil size and quality of vision after LASIK. Ophthalmology 2003;110:1606–1614.
15. Pop M, Payette Y. Risk factors for night vision complaints after LASIK for myopia. Ophthalmology 2004;111:3–10.
16. Brunette I, Gresset J, Boivin JF, Boisjoly H, Makni H. Functional outcome and satisfaction after photorefractive keratectomy: part 1, development and validation of a survey questionnaire. Ophthalmology 2000;107:1783–1789.
17. van der Heijde GL, Fechner PU, Worst JG. [Optical consequences of implantation of a negative intraocular lens in myopic patients]. Klin Monatsbl Augenheilkd 1988;193:99–102.
18. Kohnen T, Terzi E, Kasper T, Kohnen EM, Buhren J. Correlation of infrared pupillometers and CCD-camera imaging from aberrometry and videokeratography for determining scotopic pupil size. J Cataract Refract Surg 2004;30: 2116–2123.
19. Hament WJ, Nabar VA, Nuijts RM. Repeatability and validity of Zywave aberrometer measurements. J Cataract Refract Surg 2002;28:2135–2141.
20. Mirshahi A, Buhren J, Gerhardt D, Kohnen T. In vivo and in vitro repeatability of Hartmann-Shack aberrometry. J Cataract Refract Surg 2003;29:2295–2301.
21. Porter J, MacRae S, Yoon G, Roberts C, Cox IG, Williams DR. Separate effects of the microkeratome incision and laser ablation on the eye's wave aberration. Am J Ophthalmol 2003;136:327–337.
22. Malecaze FJ, Hulin H, Bierer P, et al. A randomized paired eye comparison of two techniques for treating moderately high myopia: LASIK and Artisan phakic lens. Ophthalmology 2002;109:1622–1630.
23. Budo C, Hessloehl JC, Izak M, et al. Multicenter study of the Artisan phakic intraocular lens. J Cataract Refract Surg 2000;26:1163–1171.
24. Benedetti S, Casamenti V, Marcaccio L, Brogioni C, Assetto V. Correction of myopia of 7 to 24 diopters with the Artisan phakic intraocular lens: two-year follow-up. J Refract Surg 2005;21:116–126.
25. Maloney RK, Nguyen LH, John ME. Artisan phakic intraocular lens for myopia: short-term results of a prospective, multicenter study. Ophthalmology 2002;109:1631–1641.
26. Rajan MS, Jaycock P, O'Brart D, Nystrom HH, Marshall J. A long-term study of photorefractive keratectomy; 12-year follow-up. Ophthalmology 2004;111:1813–1824.
27. Fan-Paul NI, Li J, Miller JS, Florakis GJ. Night vision disturbances after corneal refractive surgery. Surv Ophthalmol 2002;47:533–546.
28. Boxer Wachler BS, Huynh VN, El-Shiaty AF, Goldberg D. Evaluation of corneal functional optical zone after laser in situ keratomileusis. J Cataract Refract Surg 2002;28:948–953.
29. Klyce SD. Night vision after LASIK: the pupil proclaims innocence. Ophthalmology 2004;111:1–2.
30. Atchison DA, Scott DH. The Stiles-Crawford effect and subjective measurement of aberrations. Vision Res 2002;42: 1089–1102.
31. Mandell RB. Locating the corneal sighting center from videokeratography. J Refract Surg 1995;11:253–259.
32. Hiatt JA, Grant CN, Boxer Wachler BS. Establishing analysis parameters for spherical aberration after wavefront LASIK. Ophthalmology 2005;112:998–1002.
33. Mrochen M, Jankov M, Bueeler M, Seiler T. Correlation between corneal and total wavefront aberrations in myopic eyes. J Refract Surg 2003;19:104–112.
34. Kohnen T, Buhren J, Kuhne C, Mirshahi A. Wavefront-guided LASIK with the Zyoptix 3.1 system for the correction of myopia and compound myopic astigmatism with 1-year follow-up: clinical outcome and change in higher order aberrations. Ophthalmology 2004;111:2175–2185.
35. Brunette I, Bueno JM, Harissi-Dagher M, Parent M, Podtetenev M, Hamam H. Optical quality of the eye with the Artisan phakic lens for the correction of high myopia. Optom Vis Sci 2003;80:167–174.
36. Bootsma SJ, Tahzib NG, Eggink FAGJ, Brabander de J, Nuijts RMMA. Evaluation of pupil dynamics after implantation of Artisan phakic intraocular lenses. J Refract Surg [Forthcoming].

Biosketch

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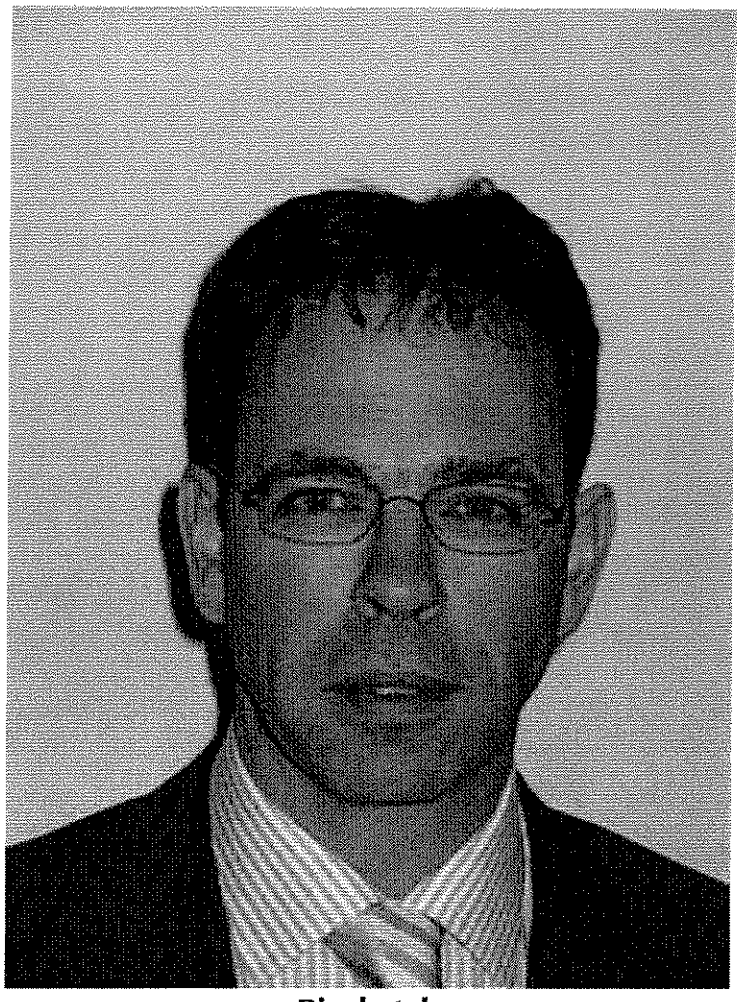

Biosketch

Rudy M. M. A. Nuijts, MD, PhD, is experienced in corneal transplantation surgery and cataract and refractive surgery. He completed a PhD on Toxicity of Intraocularly Used Drugs and Solutions at Emory Eye Center, Atlanta. Dr Nuijts researches corneal disease and patient satisfaction after cataract and refractive surgery. Dr Nuijts is the treasurer of the Dutch Corneal Society, secretary of The Netherlands Intraocular Implant Society, and board member of The Netherlands Transplantation Society, and the European Society of Cataract and Refractive Surgeons.