

ORIGINAL ARTICLE

3-Month experience in presbyopic correction with bi-aspheric multifocal central presbyLASIK treatments for hyperopia and myopia with or without astigmatism

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LogRAD

Abstract

Purpose: To analyze simultaneous vision (distance and near) 3-month after bi-aspheric multifocal central presbyLASIK treatments for hyperopia and myopia with or without astigmatism.

Methods: Retrospective study analyzing patients that had been treated for correcting distance ametropiae and alleviating presbyopic symptoms simultaneously. All patients had been treated in Presby Aspheric mode using FemtoLASIK. No eye had previous corneal refractive surgery. Preoperative corneal curvature ranged between 40 D and 48 D, with pachymetry thicker than 500 μm . Preoperative best distance corrected visual acuity (CDVA) was 0.1 LogMAR or better, with best corrected near vision (CNVA) of 0.2 LogRAD or better.

Results: 66 patients treated using PresbyMAX software (SCHWIND eye-tech-solutions GmbH and Co. KG, Kleinostheim, Germany) were reviewed. For 24 patients, 3-month follow-up was completed. At 3 months, 71% of patients achieved UDVA 0.1 LogMAR or better, 79% patients obtained UNVA 0.1 LogRAD or better, and 83% of eyes were within 0.75 diopters (D) of defocus. Postoperative mean spherical equivalent refraction was -0.15 ± 0.50 D. Stability was achieved from the 6-week follow-up. 92% of patients achieved UDVA 0.2 LogMAR or better and UNVA 0.2 LogRAD or better. No statistical differences between myopes/hyperopes or between males/females were found.

Conclusions: Patient selection and expectation management are essential to achieve patient satisfaction. Even though optically the results are quite predictable, some patients find it difficult to adapt to the compromise between far and near vision, and others are dissatisfied by the minor loss of distance VA.

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PALABRAS CLAVE

Visión simultánea;
 Visión lejana y
 cercana;
 esférico;
 Multifocal;
 Presbylasik;
 Presbicia;
 adición;
 LogRAD

Experiencia de 3 meses tras la corrección de la presbicia con tratamientos presbyLASIK centrales multifocales biasféricos para la hipermetropía y la miopía con o sin astigmatismo

Resumen

Objetivo: analizar la visión simultánea (de lejos y de cerca) 3 meses después de tratamientos presbyLASIK centrales multifocales biasféricos para la hipermetropía y la miopía con o sin astigmatismo.

Métodos: Estudio retrospectivo que incluye pacientes que habían sido tratados para corregir ametropías de lejos y a la vez aliviar los síntomas de la presbicia. Todos los pacientes habían sido tratados en modo *Presby Aspheric* utilizando FemtoLASIK. Ningún ojo se había sometido a cirugía refractiva corneal anteriormente. La curvatura corneal preoperatoria se encontraba entre 40 D y 48 D, con una paquimetría mayor de 500 μm . La agudeza visual de lejos mejor corregida preoperatoria (AVLC) era de 0,1 logMAR o mejor, con una visión de cerca mejor corregida (AVCC) de 0,2 logRAD o mejor.

Resultados: se revisaron 66 pacientes tratados con el software PresbyMAX (SCHWIND eye-tech-solutions GmbH and Co. KG, Kleinostheim, Germany). Se completó el seguimiento de 3 meses para 24 pacientes. Al cabo de 3 meses, el 71% de los pacientes había alcanzado una agudeza visual de lejos sin corregir (UDVA) de 0,1 logMAR o mejor, el 79% una agudeza visual de cerca sin corregir (UNVA) de 0,1 logRAD o mejor y el 83% de los ojos tenían hasta 0,75 dioptrías (D) de desenfoque. El equivalente esférico medio postoperatorio fue de $-0,15 \pm 0,50$ D. A partir del seguimiento de 6 semanas se alcanzó la estabilidad. El 92% de los pacientes alcanzó una UDVA de 0,2 logMAR o mejor y una UNVA de 0,2 logRAD o mejor. No se detectaron diferencias estadísticas entre miopes e hipermétropes ni entre hombres y mujeres.

Conclusiones: la selección de pacientes y la gestión de las expectativas son clave para lograr la satisfacción del paciente. Aunque desde el punto de vista óptico los resultados son bastante predecibles, algunos pacientes tienen dificultades para tolerar el compromiso entre visión de lejos y de cerca y otros están descontentos por la mínima pérdida de AV de lejos.

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Refractive corrections for presbyopia by means of excimer laser systems are as old as laser refractive surgery itself.¹ Moreira et al. stated in 1993¹: "After multifocal ablations, a greater spread of surface powers is observed, often with a bimodal distribution, indicative of an apparent multifocal effect. These observations suggest that in some patients undergoing photorefractive keratectomy for myopia, it may be possible to reduce symptoms of presbyopia".

Vinciguerra et al.² proposed a 10–17 μm deep semilunar-shaped zone immediately below the pupillary centre, steepening the corneal curvature in that area and reported promising results with this technique.³

Monovision is another extended technique⁴ usually in the form of dominant eye corrected for distance opposed to crossed monovision⁵ (dominant eye corrected for near) offering better near vision than control patients, with minimal compromise in stereo acuity and overall high patient satisfaction.

Attempts for pseudo-accommodative cornea opened new concepts for correction of presbyopia; basically in the form of a peripheral near zone (concentric ring for near vision)⁶ or in the form of a central near zone (central disc for near vision).⁷

Charman⁸ concluded that the main requirement in presbyopia is extended binocular depth-of-focus to yield adequate distance and near vision with good retinal

contrast at lower spatial frequencies, rather than the highest levels of acuity and modulation transfer function at a single distance. He further suggested that, for many presbyopes, this can be achieved by aiming residual high-order aberrations.

Artola et al.⁹ found evidence for delayed presbyopia after photorefractive keratectomy for myopia due to the corneal aberrations induced, which may reduce the quality of the retinal image for distance but enhance near acuity by way of a multifocal effect that can delay the onset of age-related near vision symptoms.

Dai¹⁰ was one of the first to propose the use of rigorous methodologies to theoretically optimize vision over the entire target range from near to distance.

Ortiz et al.¹¹ characterized the optical quality by the Strehl ratio, the spot size on the retina, and objective decimal visual acuity calculated based on measured corneal topography using Fresnel propagation algorithm based on a realistic eye model. They found that with a complete characterization of the eye and a complete propagation algorithm (that takes into account all refractive surfaces in the eye at the same time), it is possible to evaluate the optical quality in eyes of patients who have undergone central presbyLASIK treatment.

Reinstein et al.¹² successfully combined extended depth of focus with monovision in a micro-monovision protocol, whereas Epstein and Gurgos¹³ combined monocular

peripheral presbyLASIK on the non-dominant eye with monofocal distance correction on the dominant eye.

From the coexistence of so many different and opposing techniques for approaching the same presbyopic problem, it can be inferred that a satisfying corneal laser correction is yet to be found.

Methods

Patient population and examinations

This study followed the tenets of the Declaration of Helsinki.

48 eyes of 24 patients undergoing bilateral LASIK for refractive presbyopic corrections were enrolled. The average age was 58 ± 4 years (range, 49 years to 66 years). Patients included in the study had manifest spherical refractive error ranging from -7.00 D to $+3.25$ D with up to 3.00 D of astigmatism,¹⁴ with presbyopic adds of up to $+2.75$ D. Patients were enrolled in the study if they had best corrected distance visual acuity (CDVA) of 20/25 or better using the Early Treatment of Diabetic Retinopathy Study (ETDRS) chart, stable refraction for 1 year prior to the study and discontinued contact lenses for at least 2 to 4 weeks (depending on contact lens type) prior to the preoperative evaluation. Patients were required to have normal keratometry and topography. For comparative analyses, all aberrations were analyzed for a diameter of 6 mm.

Patients who suffered from systemic illness, had a calculated postoperative corneal bed thickness less than $300 \mu\text{m}$ after ablation, had preoperative central corneal thickness of less than $500 \mu\text{m}$, had previous ocular surgery, or had abnormal corneal topography were excluded from the study.

Baseline examinations included measurement of uncorrected distance and near visual acuity (UDVA and UNVA respectively), CDVA, manifest refraction, distance corrected near visual acuity (DCNVA), corrected near visual acuity (CNVA), presbyopic add, contrast and glare sensitivity, corneal topography, corneal wavefront, ultrasound corneal pachymetry, pupillometry, slit lamp examination of the anterior segment and a dilated fundus examination.

Preoperative and postoperative contrast sensitivities with and without glare, using Takagi Contrast Glare Tester CGT-1000 (Takagi Seiko Co Ltd, Nagano-Ken, Japan), were measured at six target sizes: 6.3° , 4.0° , 2.5° , 1.6° , 1.0° , and 0.7° after correcting the refractive error with spectacles. Log values of the contrast sensitivity scores were used for statistical analysis.

At one day postoperatively, UDVA and UNVA were measured and the patient underwent a slit lamp examination of the anterior segment. The same measurements as the baseline examination (with the exception of dilated funduscopy and pupillometry unless warranted and contrast sensitivity at 3 months only) were performed at 1 week, 6 weeks, and 3 months postoperatively.

Treatment plan

All treatments^{15,16} were prepared using the SCHWIND PresbyMAX treatment planning module in Aspheric mode^{17,18} (SCHWIND eye-tech-solutions GmbH and Co. KG, Kleinostheim, Germany). This module integrates bi-aspheric

multifocal ablation profiles combining two focus-shifted aspheric profiles with different asphericities that compensate as well for the peripheral loss of energy due to an increased angle of incidence on the cornea^{19,20} and for biomechanical changes induced during LASIK (Fig. 1). The treatment of ocular or corneal wavefront aberrations was not intended in this study.

The sphere and cylinder values entered into the laser were based on the manifest refraction without nomogram adjustment, with both eyes attempting the same goal. Further, the flat and steep keratometry readings at 3 mm diameter as measured by the topographer were used for the compensation of the loss of ablation efficiency when the laser hits the cornea in non-normal incidence.¹⁹ All eyes underwent the refractive treatment using 6.2 to 7.0 mm diameter optical zones based on the preoperative scotopic pupil diameter and based on the kind of refractive error. For each treatment, the planning software calculated the size of the optimal transition zone, depending on the preoperative refraction and optical zone. The total ablation zone ranged from 6.5 mm to 9.0 mm.

Retreatments were not permitted during the course of this study. Once finalized, the treatment plan was directly entered or transferred via Secure Digital memory card to the SCHWIND AMARIS excimer laser.²¹

Surgery

Drops of topical anesthetic were instilled in the upper and lower fornices. Flaps were made using Intralase 60 KHz femtosecond laser (AMO, Chicago, Illinois, USA) using 105 nominal flap thickness.

Additional drops of topical anesthetic were instilled, the lid margins and periocular region were disinfected using diluted povidone. A sterile drape was used to isolate the surgical field. A lid speculum was inserted to allow maximum exposure of the globe.

Proper alignment of the eye with the laser was achieved with a 1050 Hz infrared eye tracker with simultaneous limbus, pupil, and torsion²² tracking integrated into the laser system and centred on the corneal vertex.²³ The eye tracker had a typical response time of 1.7 ms with a system total latency time of 2.9 ms. The flap was lifted and the excimer laser ablation was delivered to the stroma. Patients were requested to look at a pulsing green fixation light throughout the ablation. The flap was repositioned and the interface was irrigated with balanced salt solution, removing any debris. Patients received topical antibiotic drops QID for 1 week and corticosteroid drops QID tapering off in 1 week and ocular lubricants as needed.

Excimer laser

The laser ablation algorithm used a flying spot laser delivery system that operates at 500 Hz with a super-Gaussian beam profile of 0.54 mm Full Width Half Maximum.²⁴ Depending on the planned refractive correction, approximately 80% of the corneal ablation is performed with a high fluence level ($>400 \text{ mJ/cm}^2$), thus decreasing treatment times.²⁴ Fine correction is performed for the remaining $\sim 20\%$ of the treatment using a low fluence level ($<200 \text{ mJ/cm}^2$) which reduces

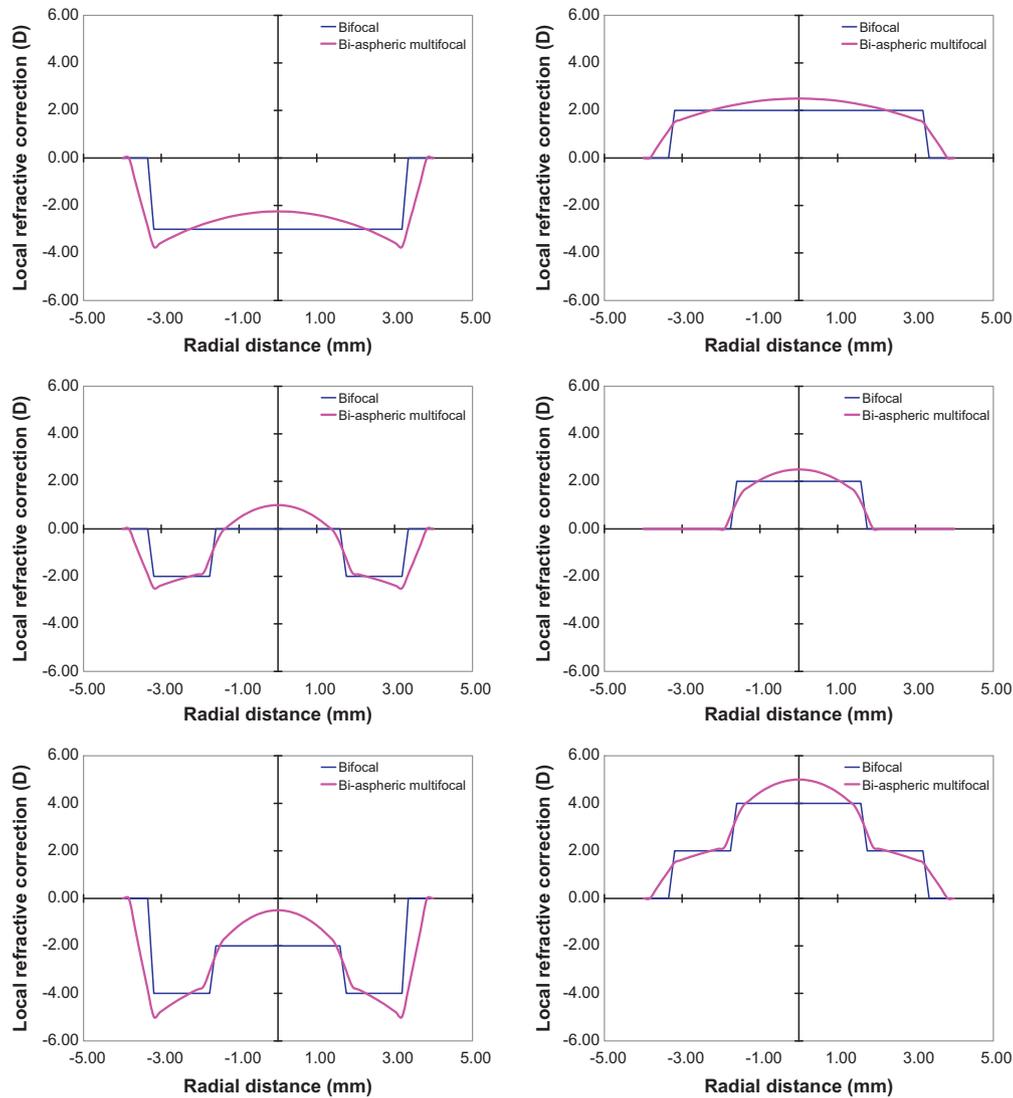


Figure 1 The SCHWIND PresbyMAX module integrates bi-aspheric multifocal ablation profiles combining two focus-shifted aspheric profiles with different asphericities. Top-left: Aspheric refractive correction compared to monofocal refractive correction for -3 D of myopia. Top-right: Aspheric refractive correction compared to monofocal refractive correction for $+2$ D of hyperopia. Middle-Left: Bi-aspheric refractive correction compared to bifocal refractive correction for -2 D of myopia combined with $+2$ D of presbyopic add. Middle-Right: Bi-aspheric refractive correction compared to bifocal refractive correction for emmetropia combined with $+2$ D of presbyopic add. Bottom-left: Bi-aspheric refractive correction compared to bifocal refractive correction for -4 D of myopia combined with $+2$ D of presbyopic add. Bottom-right: Bi-aspheric refractive correction compared to bifocal refractive correction for $+2$ D of hyperopia combined with $+2$ D of presbyopic add.

the ablation volume per pulse delivered in order to smooth out the ablated area.²⁴ Spot placement is randomized in order to prevent heat buildup between laser pulses.²⁵⁻²⁷ Additionally, an aspiration system with laminar flow dynamics is incorporated to reduce debris and heat buildup.

Data analysis

Refractive and visual outcomes, changes in high-order aberrations and contrast and glare sensitivities were analyzed using Microsoft Excel software (Microsoft, Redmond, Washington, USA). LogMAR and LogRAD visual acuities was converted to Snellen or revised Jaeger acuities for data reporting purposes.

Box and whisker plots are reported in the form: the central line represents the median value, the box represents the percentile range 25% to 75% (1st and 3rd quartiles), and the whiskers represent the minimum and maximum values.

The paired single sided *t*-test was used to determine statistically significant changes. A *p* value less than 0.05 was considered statistically significant. Data for 6 weeks and 3 months after LASIK are reported here.

Results

Fig. 2 shows the preoperative distributions for spherical equivalent and astigmatism.

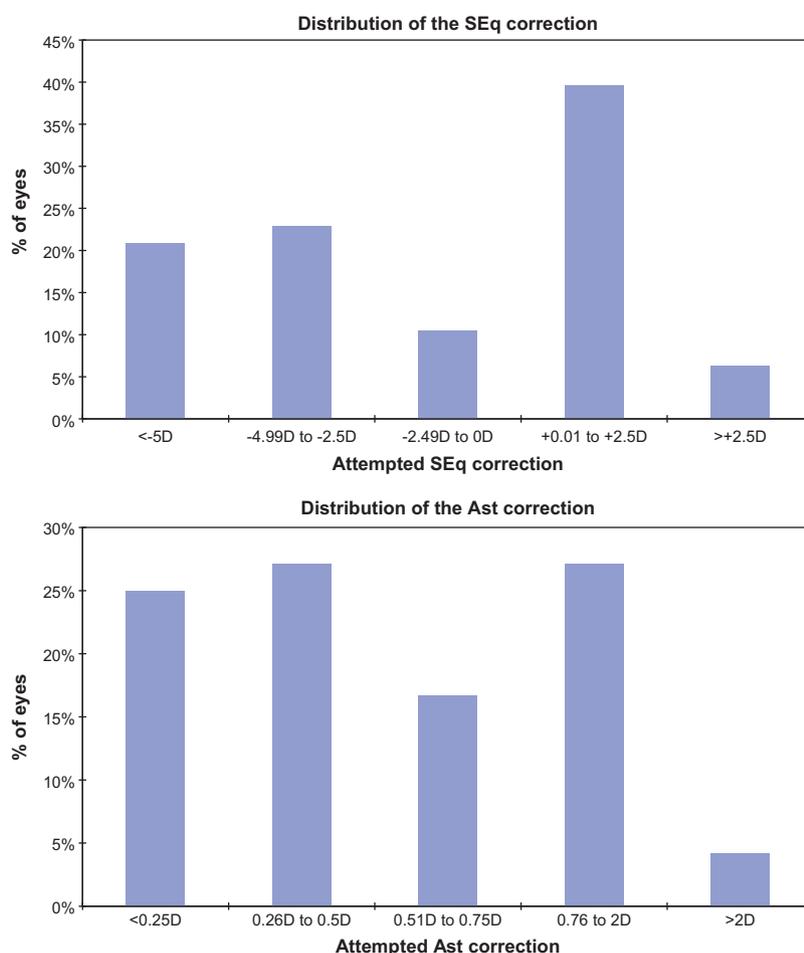


Figure 2 Distribution of the preoperative refraction.

Visual acuities

Preoperative

UDVA ranged from -0.2 LogMAR to $+2.0$ LogMAR (20/12 to 20/2000), whereas CDVA ranged from -0.4 LogMAR to 0.0 LogMAR (20/8 to 20/20). DCNVA ranged from $+0.1$ LogRAD to $+0.8$ LogRAD (J1–J10), whereas UNVA ranged from -0.2 LogRAD to $+1.5$ LogRAD ($>J1$ to $<J14$), and CNVA ranged from -0.2 LogRAD to $+0.2$ LogRAD ($>J1$ – $J2$).

6-Week postoperative

Figure 3 shows values of UDVA at 6-week postoperative visit that ranged from -0.1 LogMAR to $+1.0$ LogMAR monocularly (20/16 to 20/200), and from -0.2 LogMAR to $+0.5$ LogMAR binocularly²⁸ (20/12 to 20/63), whereas CDVA ranged from -0.1 LogMAR to $+0.4$ LogMAR monocularly (20/16 to 20/50). The loss in monocular CDVA was statistically significant ($p < 0.0001$). DCNVA ranged from 0.0 LogRAD to $+0.6$ LogRAD monocularly and binocularly ($>J1$ – $J8$), whereas UNVA ranged from -0.1 LogRAD to $+0.6$ LogRAD monocularly ($>J1$ – $J8$), and from -0.1 LogRAD to $+0.4$ LogRAD binocularly ($>J1$ – $J6$). The improvement in monocular DCNVA was statistically significant ($p < 0.0001$).

At 6-week postoperatively, 54% of the eyes could see uncorrected both 0.2 LogMAR and 0.2 LogRAD or better (20/32 and J2), and 88% of the patients could see

uncorrected both 0.2 LogMAR and 0.2 LogRAD or better binocularly (20/32 and J2) (Fig. 4).

3-Month postoperative

Figure 3 shows values of UDVA at 3-month postoperative visit that ranged from -0.1 LogMAR to $+1.0$ LogMAR monocularly (20/16 to 20/200), and from -0.2 LogMAR to $+0.5$ LogMAR binocularly (20/12 to 20/63), whereas CDVA ranged from -0.2 LogMAR to $+0.2$ LogMAR monocularly (20/12 to 20/32). The loss in monocular CDVA was statistically significant ($p < 0.0001$) but no change in this parameter was noticed between 6-weeks and 3-months ($p = 0.2$). DCNVA ranged from 0.0 LogRAD to $+0.6$ LogRAD monocularly ($>J1$ – $J8$), and from -0.1 LogRAD to $+0.5$ LogRAD binocularly ($>J1$ – $J6$), whereas UNVA ranged from -0.1 LogRAD to $+0.5$ LogRAD monocularly ($>J1$ – $J6$), and from -0.2 LogRAD to $+0.3$ LogRAD binocularly ($>J1$ – $J4$). The improvement in monocular DCNVA was statistically significant ($p < 0.0001$) and there were further improvements in this parameter between 6-weeks and 3-months ($p = 0.02$).

At 3-month postoperatively, 79% of the eyes could see uncorrected both 0.3 LogMAR and 0.3 LogRAD or better (20/40 and J4), and 63% of the patients could see uncorrected both 0.1 LogMAR and 0.1 LogRAD or better binocularly (Fig. 4) (20/25 and J1).

Fig. 5 shows the scattergram of uncorrected visual acuities for far and near.

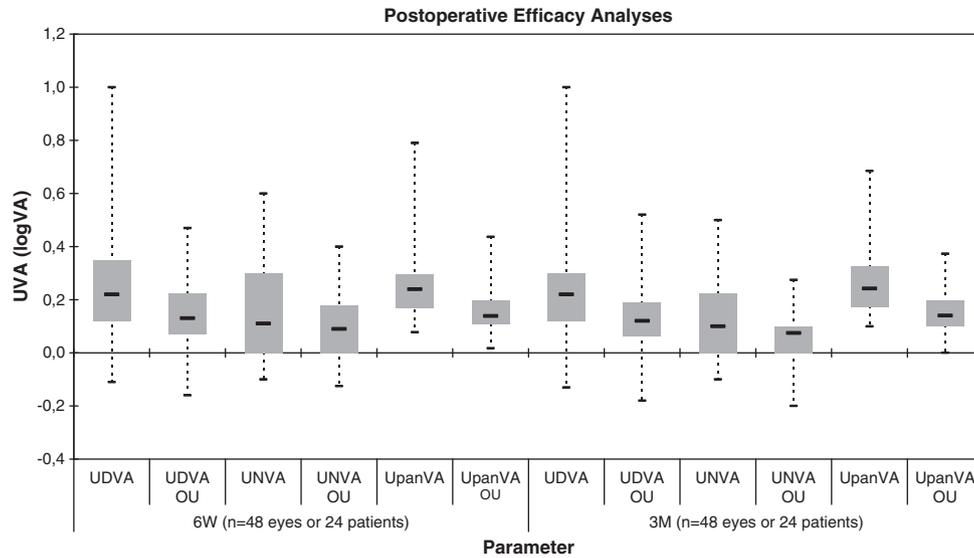


Figure 3 Postoperative efficacy analyses for 6-weeks and 3-months postoperatively. UDVA averaged +0.2 LogMAR monocularly, and +0.1 LogMAR binocularly. No change in DVA was noticed between 6-weeks and 3-months ($p=0.2$). UNVA averaged +0.1 LogRAD monocularly and binocularly. There were minor improvements in NVA between 6-weeks and 3-months ($p < 0.05$). UpanVA, uncorrected pan visual acuity.

Refractive outcomes

Scattergram of the achieved versus attempted refractive corrections show only -5% an undercorrection rate of 5% for SEq and an undercorrection of 6% for manifest astigmatism at 3M postop (Fig. 6). The global refractive deviation from target refraction was -0.2 ± 0.5 D for SEq, 0.3 ± 0.3 D for Ast, and 0.5 ± 0.3 D for the norm of the U-Vector (Fig. 7).

70% of the eyes were within 0.50D of target refraction already at 6W postop (Fig. 8).

Pseudoaccommodation

The change in DCNVA was taken as metric for the achieved pseudo-accommodation. The change in DCNVA from preop to 3-month postop ranged from 1 line loss to 6 lines gained. This change correlated to the planned addition (Fig. 9).

OPD-scan II aberrations

Preoperative

Table 1 shows the OPD-scan II aberrations for 6 mm pupil. Root mean square (RMS) of the high-order-aberrations (HOA) of the OW for 6 mm pupil ranged from 0.14 μm to 1.03 μm . Corneal SphAb for 6 mm pupil ranged from 0.00 μm to +0.49 μm , whereas ocular SphAb for 6 mm pupil ranged from -1.45 μm to +0.15 μm .

6-Week postoperative

RMS of the HOA of the OW for 6 mm pupil ranged from 0.19 μm to 1.21 μm (change $p < 0.0001$). Corneal SphAb for 6 mm pupil ranged from -0.64 μm to +1.22 μm (change $p < 0.0001$), whereas ocular SphAb for 6 mm pupil ranged from -0.61 μm to +0.05 μm (change $p < 0.0005$).

Table 1 Summary of the wavefront aberrations.

@6 mm	Pre op			6 W			3 M		
	RMS	Corn SA	Oc SA	RMS	Corn SA	Oc SA	RMS	Corn SA	Oc SA
<i>n</i>	46	46	46	46	46	44	48	48	48
Mean	0.3672	0.241	-0.225	0.5116	-0.082	-0.344	0.5005	-0.115	-0.334
StdDev	0.1931	0.093	0.324	0.2150	0.376	0.154	0.1873	0.317	0.371
Median	0.337	0.24	-0.16	0.500	-0.12	-0.33	0.461	-0.07	-0.35
1st quartil	0.207	0.18	-0.30	0.344	-0.38	-0.45	0.391	-0.42	-0.47
Min	0.135	0.00	-1.45	0.191	-0.64	-0.61	0.134	-0.95	-1.47
Max	1.033	0.49	0.15	1.206	1.22	0.05	1.104	0.35	0.81
3rd Quartil	0.444	0.29	-0.02	0.628	0.13	-0.25	0.613	0.14	-0.15
<i>p</i> -Val pre-post				<0.0001	<0.0001	0.0001	<0.0001	<0.0001	0.036
<i>p</i> -Val post-post							0.244	0.093	0.255

@6 mm, at 6 mm analysis diameter; pre op, preoperatively; 6 W, at 6 week follow-up; 3 M, at 3 month follow-up; RMS, root mean square; Corn SA, corneal spherical aberration; Oc SA, ocular spherical aberration; n, number; StdDev, standard deviation.

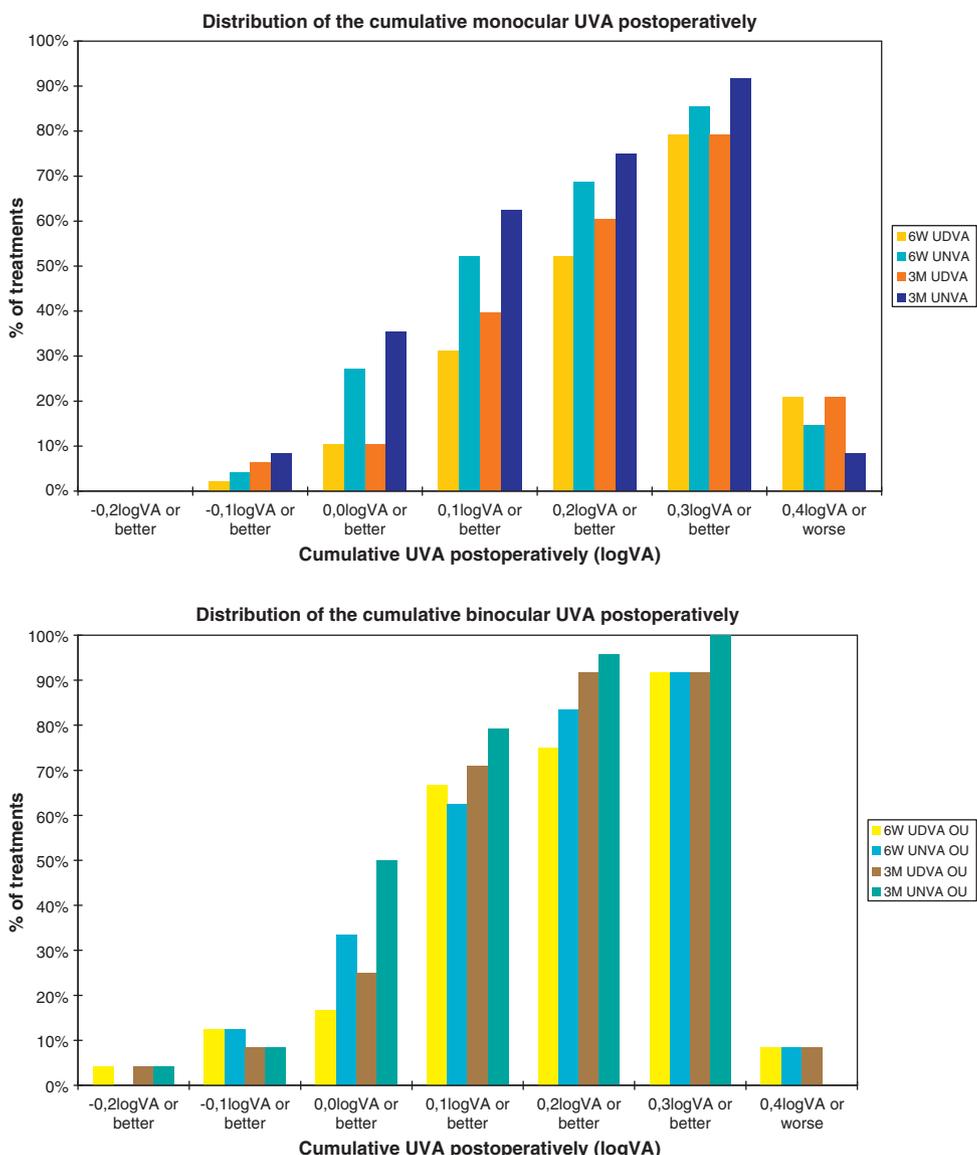


Figure 4 Histograms for the cumulative uncorrected visual acuities postoperatively. At 6-week postoperatively, 54% of the eyes could see uncorrected both 0.2 LogMAR and 0.2 LogRAD or better, and 88% of the patients could see uncorrected both 0.2 LogMAR and 0.2 LogRAD or better binocularly. At 3-month postoperatively, 79% of the eyes could see uncorrected both 0.3 LogMAR and 0.3 LogRAD or better, and 63% of the patients could see uncorrected both 0.1 LogMAR and 0.1 LogRAD or better binocularly.

3-Month postoperative

RMS of the HOA of the OW for 6 mm pupil ranged from 0.13 μm to 1.10 μm (change $p < 0.0001$). Corneal SphAb for 6 mm pupil ranged from -0.95 μm to +0.35 μm (change $p < 0.0001$), whereas ocular SphAb for 6 mm pupil ranged from -1.47 μm to +0.81 μm (change $p < 0.05$). The change in aberrations from 6-week to 3-month was not statistically significant ($p = 0.2$).

as reported by Pentacam ranged from -0.56 to +0.23, whereas Q-value reported by OPD-Scan ranged from -0.42 to +0.26.

6-Week postoperative

Q-value reported by OPD-Scan ranged from -2.05 to -0.24 (change $p < 0.0001$).

Asphericity

Table 2 shows the asphericity values before surgery, 6 week and 3 months after surgery.

3-Month postoperative

Q-value as reported by Pentacam ranged from -1.19 to +0.86 (change $p = 0.4$), whereas Q-value reported by OPD-Scan ranged from -2.32 to -0.30 (change $p < 0.0001$). The change in Q-value reported by OPD-Scan from 6-week to 3-month was statistically significant ($p = 0.03$).

Preoperative

The quotient of asphericity (Q) represents how fast the corneal surface deviates from a spherical surface. Q-value¹⁵⁻¹⁷

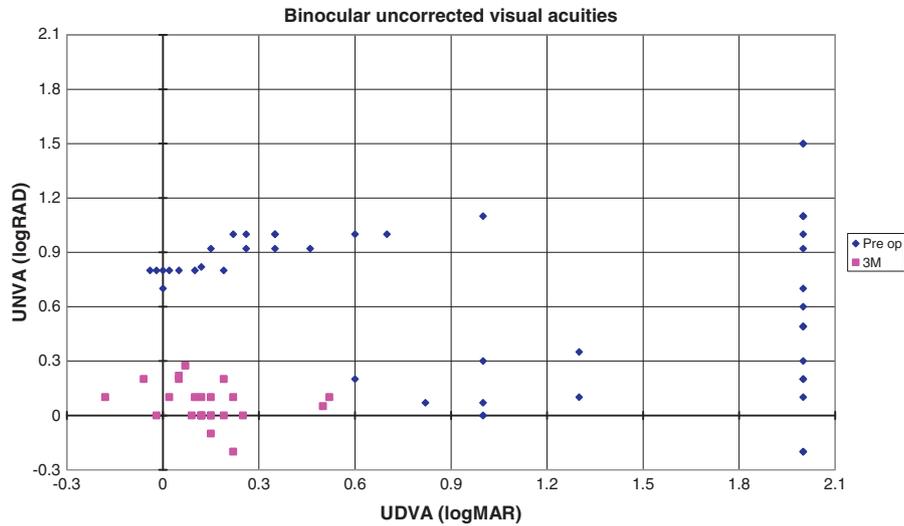


Figure 5 Uncorrected visual acuities scattergram.

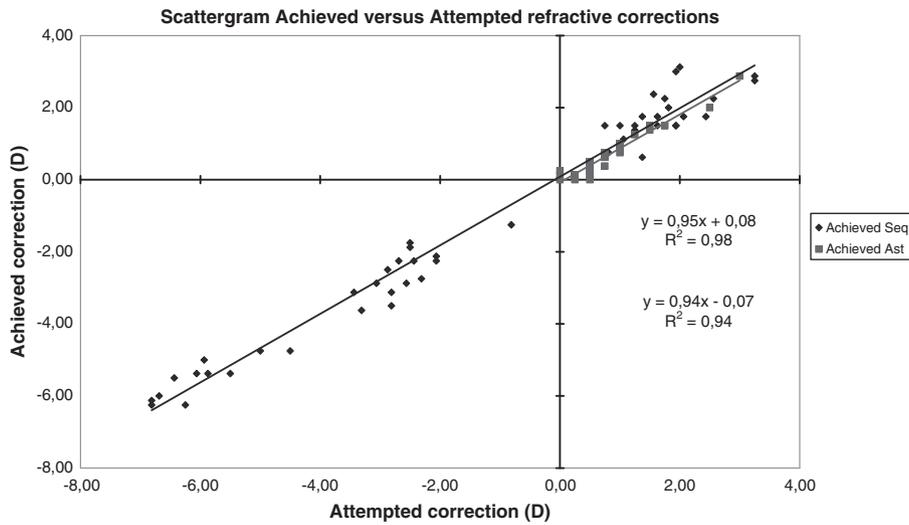


Figure 6 Scattergram of the achieved versus attempted refractive corrections for the spherical equivalent (Seq) and the manifest astigmatism (Ast).

Table 2 Summary of the corneal asphericities.

3 mm	Pre op		6 W	3 M	
	Q value Pentacam	Q value OPD		Q value Pentacam	Q value OPD
<i>n</i>	48	46	46	43	48
Mean	-0.162	-0.142	-1.165	-0.156	-1.240
StdDev	0.163	0.148	0.487	0.621	0.468
Median	-0.17	-0.14	-1.14	-0.18	-1.15
1st quartil	-0.24	-0.23	-1.49	-0.67	-1.60
Min	-0.56	-0.42	-2.32	-1.19	-2.32
Max	0.23	0.26	-0.24	0.86	-0.30
3rd quartil	-0.09	-0.07	-0.89	0.30	-0.94
<i>p</i> -Val pre-post			<0.0001	0.406	<0.0001
<i>p</i> -Val post-post					0.033

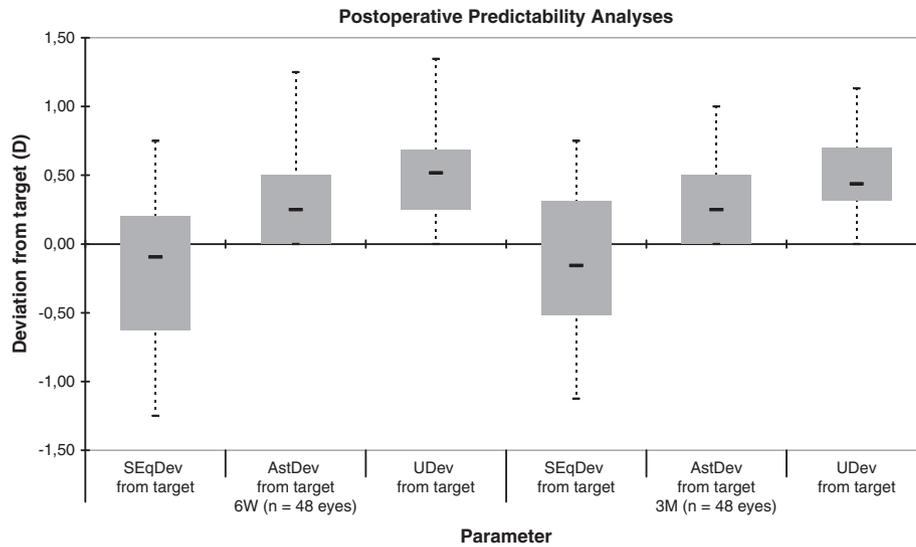


Figure 7 Postoperative predictability analyses. The global refractive deviation from target refraction was -0.2 ± 0.5 D for SEq, 0.3 ± 0.3 D for Ast, and 0.5 ± 0.3 D for the norm of the U-Vector. SEq, Spherical equivalent; Ast, Astigmatism; U, U-vector; Dev, Deviation line.

Contrast sensitivity

Figs. 10 and 11 compare in logarithmic scale the contrast sensitivity without and with glare. Contrast measurements were slightly reduced post than pre ones. Glare measurements were always less scored than non-glare ones. Glare measurements were not reduced from pre to post. No significant differences in Contrast or Glare between 6W and 3M were detected.

Discussion

The main goal of a surgical procedure to correct presbyopia is to enhance not only distance but also near visual acuity and the range of relatively clear vision. The surgical

techniques to correct presbyopia can be broadly categorized as follows: systems that mimic the crystalline lens and bi- or multifocal techniques that enhance depth of focus and monovision. The use of artificial aperture stops has been also established for increasing depth of focus. Patients may rate an intervention highly even though essential features of normal visual perception are degraded. For example, monovision is highly rated by patients even though binocular vision is compromised.²⁹ Measuring the depth of focus is a useful marker but measuring acuity at typical near vision distances may be closer related to patients' real expectations and concerns.³⁰

Monovision LASIK has been found to produce high levels of patient satisfaction, with Goldberg³¹ reporting 96% satisfaction and Miranda³² 92%.

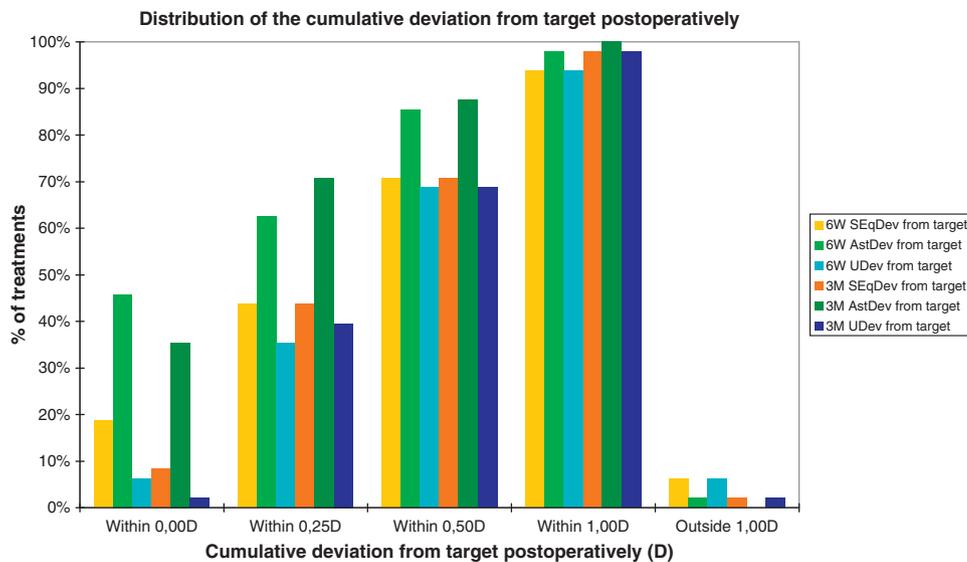


Figure 8 Postoperative distribution of the refractive outcomes. 70% eyes were within 0.50D of target refraction already at 6W postop.

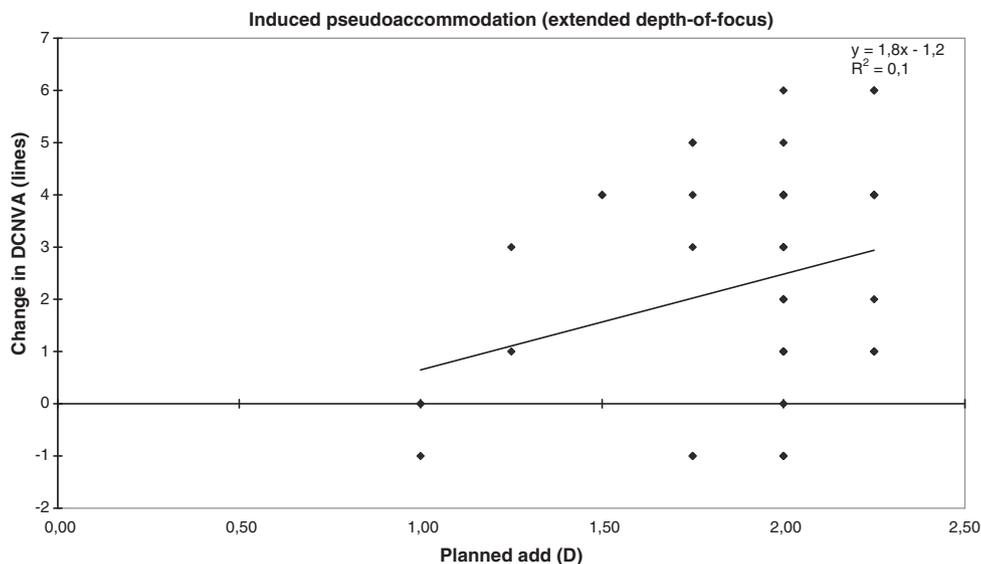


Figure 9 Postoperative pseudoaccommodation analysis. 70% eyes were within 0.50D of target refraction already at 6 W postop. The change in DCNVA was taken as metric for the achieved pseudo-accommodation. The change in DCNVA from preop to 3-month postop ranged from 1 line loss to 6 lines gained. This change correlated to the planned addition.

Contact lens monovision and LASIK-induced monovision traditionally use a nomogram for near addition, with the degree of anisometropia increasing from approximately -1.50D for a 45-year-old patient up to -2.50D for a 65-year-old patient.³³ Tolerance for monovision reduces with the value of induced anisometropia and is no longer tolerated when it is larger than 2.50D.

The performance of different types of IOLs (refractive, diffractive, pseudo-accommodating, and multifocal) is constantly being improved,^{34,35} but the IOLs cause a decrease in near vision contrast sensitivity.³⁶

PresbyLASIK treatment uses the principles of LASIK surgery to create a multifocal corneal surface aimed at reducing near vision spectacle dependence in presbyopic patients. This treatment constitutes the next step in the correction of presbyopia after monovision LASIK.^{37,38}

The term presbyLASIK indicates a corneal surgical procedure based on traditional LASIK to create a multifocal surface able to correct any visual defect for distance while simultaneously reducing the near spectacle dependency in presbyopic patients.^{39,40}

Using a micro-monovision protocol, Reinstein et al.¹² recently succeeded with an intended postoperative refraction of plano to low myopia for the dominant eye and in the range of -1.00 to -1.50D for the non-dominant eye, irrespective of the patient's age, and determined that the near eye had a beneficial effect on binocular UDVA when compared to the monocular UDVA of the dominant (distance) eye.

Pinelli et al.⁴¹ investigated the outcome of the correction of presbyopic patients with hyperopia using a peripheral presbyLASIK algorithm called Peripheral Multifocal LASIK (PML). This treatment creates a multifocal corneal profile in a 6.5-mm diameter zone by the combination of a positive ablation performed over a 6.5-mm zone and a negative ablation performed over an optical zone no smaller than 5 mm. The hypothesis is that the ring between the 5- and 6.5-mm optical zones provides multifocality.

In several reports,^{7,30,42,43} Alió et al. demonstrated the efficiency, predictability, stability, safety, and visual quality of central presbyLASIK in presbyopic patients with hyperopia.

In another study,¹¹ they reported the correlation of the clinical results of this presbyLASIK method with a theoretical predictive model, showing the adjustment of both.

Concerning pseudo-accommodation and multifocality, these methods can neither correct presbyopia, nor restore accommodation, nor stop the progress of presbyopia, nor slow down the progress of presbyopia. If the lens cannot accommodate, after any pseudo-accommodative or multifocal approach, the lens will still not accommodate. Using presbyLASIK techniques it is possible to benefit from pseudo-accommodation and multifocality, reducing dependency on reading-spectacles by providing controlled extended depth-of-focus. Treatments can be prescribed for preventing latent presbyopic symptoms, delaying reading-spectacles demands while presbyopia progresses and treatments may be repeated with minimum risk if reading-spectacles demands renew.

If no cataracts are present, but refractive defects exist, presbyLASIK techniques offer the potential to correct far-distance refraction and to alleviate the presbyopic symptoms, with the goal of spectacle-free vision at all distances.

The specific planning software platform allows using WaveFront diagnostic data together with Presbyopic compensation combining the advantages of both techniques (improved visual outcome through WaveFront guided correction^{44,45} and enhanced pseudo-accommodation). Finally, a Controlled Multifocal Vision is expected and the profile meets the requirements:

- Multifocally, the centre is corrected for near and the periphery for far vision.
- Optimized bi-aspheric profile.
- Adding a pre-calculated amount of different high order spherical aberrations.

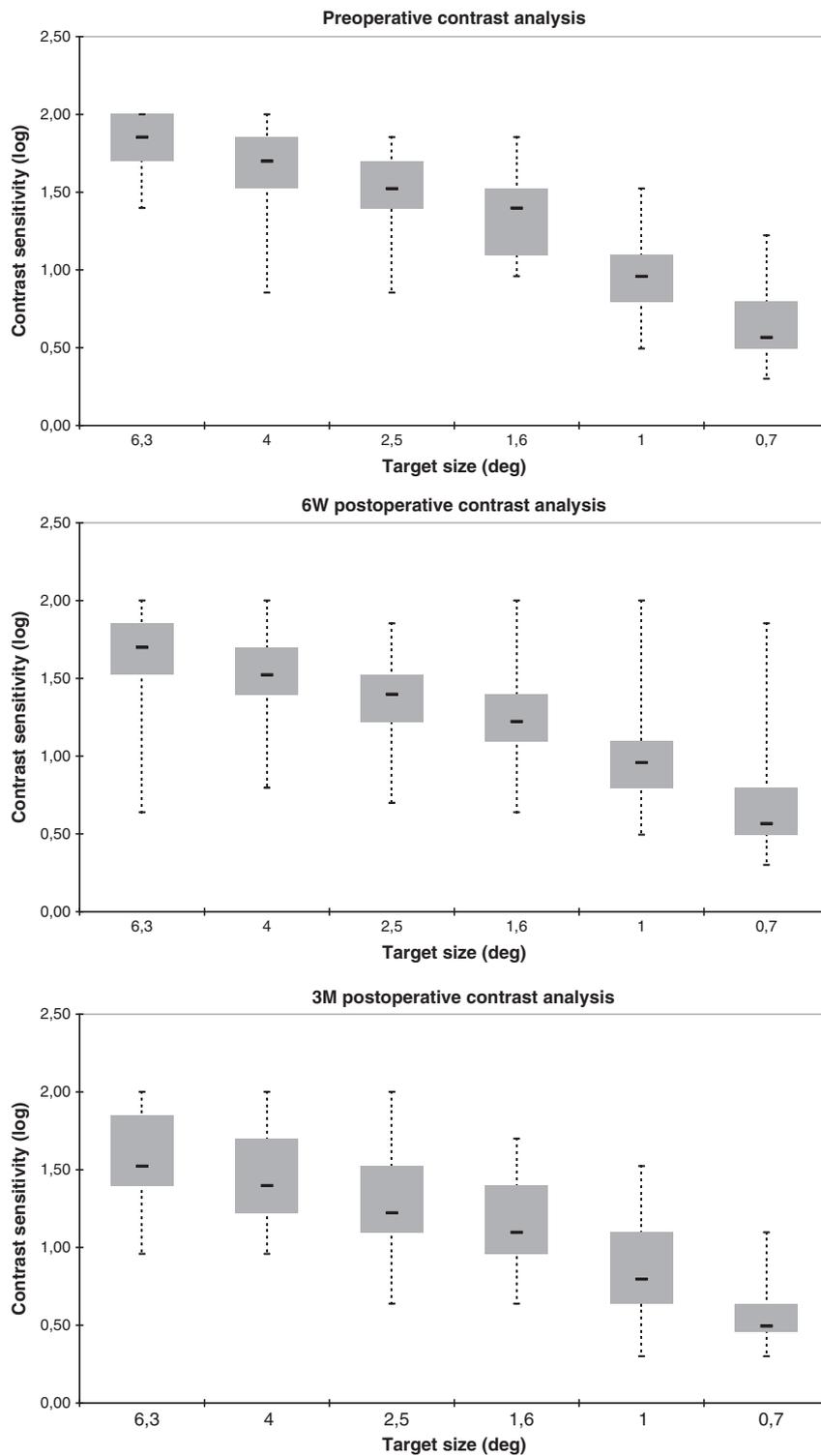


Figure 10 Logarithmic scale of the contrast sensitivity without glare. Contrast measurements were slightly reduced post than pre ones. No significant differences in Contrast between 6 W and 3 M. Top: Preoperative contrast sensitivity without glare. Middle: 6-week postoperative contrast sensitivity without glare. Bottom: 3-month postoperative contrast sensitivity without glare.

In our cohort, patients have got (both objectively and subjectively) good distance vision, very good vision at the intermediate region, and excellent near vision. Combined, it offers a possible compromise for the whole distance range.

We have performed some permutations with the available data now based on the change of DCNVA as a metric for induced multifocality, and we have only observed statistically significant univariate correlations between DCNVA and preoperative SEq (higher hyperopic treatment implies

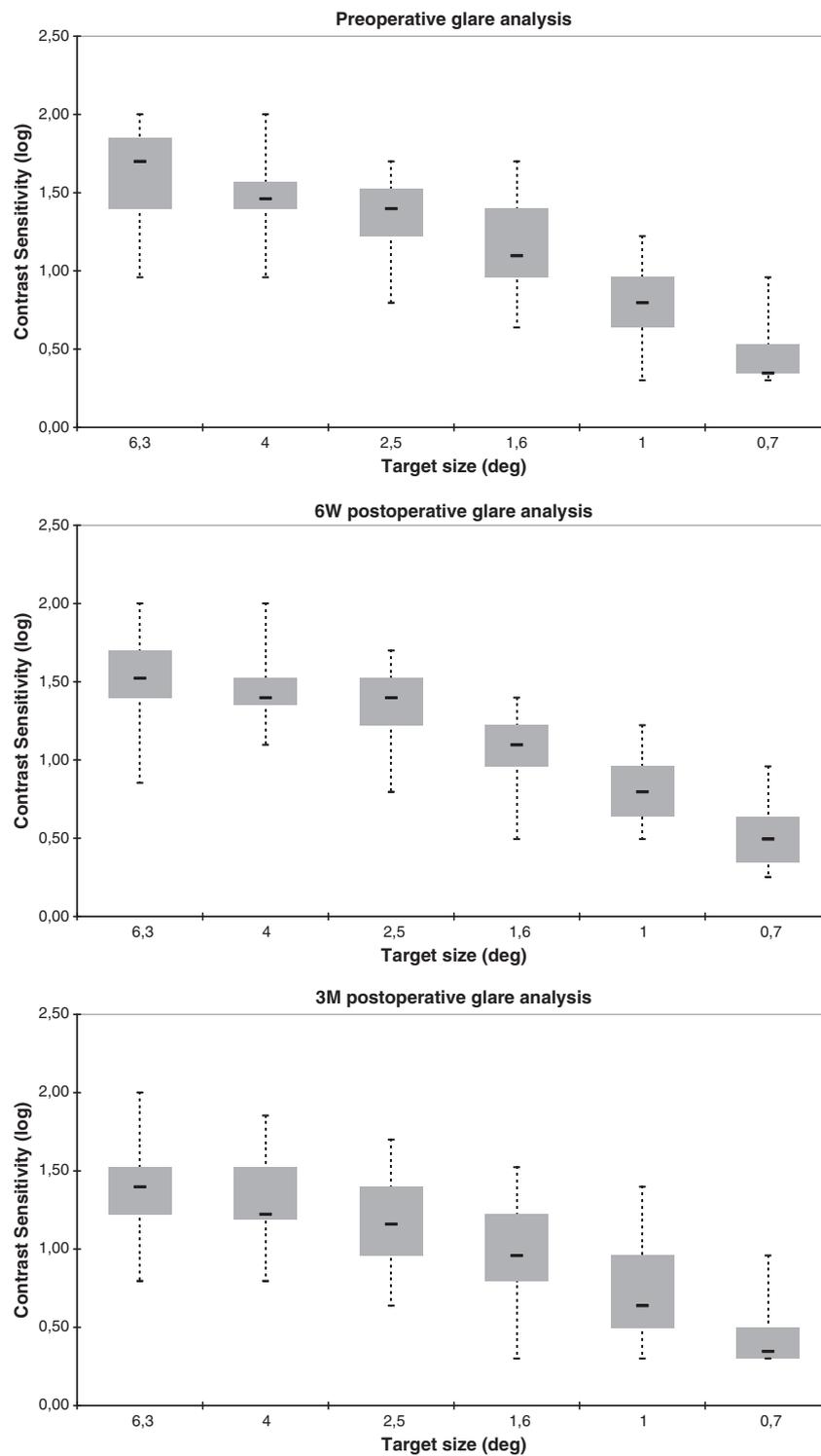


Figure 11 Logarithmic scale of the contrast sensitivity with glare. Glare measurements were always less scored than non-glare ones. Glare measurements were not reduced from pre to post. No significant differences in Glare between 6W and 3M. Top: Preoperative contrast sensitivity with glare. Middle: 6-week postoperative contrast sensitivity with glare. Bottom: 3-month postoperative contrast sensitivity with glare.

higher gain in DCNVA), preoperative ast (lower astigmatism preop implies higher gain in DCNVA), OZ (larger OZ planned implies higher gain in DCNVA), offset (larger offset implies higher gain in DCNVA).

There was a wide range for the postoperative DCNVA (0.3 ± 0.1 LogRAD ($\sim J4.6$), 0.0 LogRAD to +0.6 LogRAD monocularly (>J1–J8), and 0.2 ± 0.1 LogRAD ($\sim J3.5$), -0.1 LogRAD to +0.5 LogRAD binocularly (>J1–J6)), whereas the

outcome for near was excellent (0.1 ± 0.2 LogRAD ($\sim J2.7$), -0.1 LogRAD to $+0.5$ LogRAD monocularly ($>J1-J6$), and 0.1 ± 0.1 LogRAD ($\sim J1.8$), -0.2 LogRAD to $+0.3$ LogRAD binocularly ($>J1-J4$)). This apparent contradiction can be explained at the light of the slightly myopic spherical equivalent postoperative (-0.4 ± 0.5 D, -1.38 D to $+0.50$ D) further improving UNVA at the cost of slightly diminishing UDVA (0.2 ± 0.2 LogMAR ($\sim 20/35$), -0.1 LogMAR to $+1.0$ LogMAR monocularly (20/16 to 20/200), and 0.1 ± 0.1 LogMAR ($\sim 20/27$), -0.2 LogMAR to $+0.5$ LogMAR binocularly (20/12 to 20/63)).

Nonetheless, it is really important to individually check whether a patient is a PresbyMAX candidate or not. The patients shall be asked for their profession, hobbies, and expectations comparing whether the postoperative visual performance provided with the ablation profile can comply with patient's needs. A trial with adequate multifocal contact lenses or just providing slightly defocused images (via trial frame) to the retina simulates postoperative visual impressions in a way and verifies for patient's acceptance.

The aim of this approach is a spectacle-free vision in usual day-life-situations but with possibly need of additives, i.e. spectacles for reading or distance, in case of special demands while focussing. Well-lit conditions provide best near performance, dimmed conditions are optimal for distance – patients profit wearing sunglasses for distance. Centring on corneal vertex²³ is essential and helps to reduce the induction of unwanted high-order aberrations, especially disturbing asymmetrical aberrations like coma.

Controversy remains regarding where to centre corneal refractive procedures to maximize the visual outcomes. A misplaced refractive ablation might result in undercorrection and other undesirable side effects. The coaxial light reflex seems to lie nearer to the corneal intercept of the visual axis than the pupil centre (PC) and is, thus, recommended that the corneal coaxial light reflex be centred during refractive surgery. Boxer Wachler et al.⁴⁶ identified the coaxial light reflex and used it as the centre of the ablation. De Ortueta and Arba Mosquera⁴⁷ used the corneal vertex (CV) measured by videokeratometry as the morphologic reference to centre corneal refractive procedures.

The centre of the pupil considered for a patient who fixates properly is the locus where the line-of-sight passes through, which is the reference axis recommended by the OSA for representing the wavefront aberration.⁴⁸

Nevertheless, because the pupil centre is unstable, a morphologic reference is more advisable.^{23,49,50} It is well known that the pupil centre shifts with changes in the pupil size, moreover, because the entrance pupil we see is a virtual image of the real one.

Due to the smaller angle kappa associated with myopes compared with hyperopes,^{51,52} centration issues are less apparent. However, angle kappa in myopes may be sufficiently large to show differences in results.²³

A pupillary offset of 0.25 mm seems to be sufficiently large to be responsible for differences in ocular aberrations,²³ however, not large enough to correlate this difference in ocular aberrations with functional vision.

Nowadays, technology has evolved significantly and uses sophisticated algorithms, optimized tools in the planning,

and proposes the challenge of improving surgery outcomes in terms of visual acuity and night vision. At the same time, patients have a better understanding and are better informed with regard to the potential of laser refractive surgery, raising quality requirements demanded to clinical staff and equipment.

In discussing visual benefit, although VA data are helpful, there may be patients with 20/20 vision who are unhappy with their visual outcomes due to poor mesopic and low-contrast VA.

Human vision is a binocular process. Having two eyes gives binocular summation in which the ability to detect faint objects is enhanced. It can give stereopsis in which parallax provided by the two eyes' different positions on the head give precise depth perception. Such binocular vision is usually accompanied by binocular fusion, in which a single image is seen despite each eye is having its own image of any object.

Literature suggests that marked anisometropia is uncommon,^{53,54} either in the magnitude of sphere or astigmatism, with few notable exceptions concluding that the axis of astigmatism does not follow any particular rule (mirror or direct symmetry) across right and left eyes.

Porter et al.⁵³ confirmed in a large population that although the pattern of aberrations varies from subject to subject, aberrations, including irregular ones, are correlated in left and right eyes of the same subject, indicating that they are not random defects.

Wang et al.⁵⁴ found that anterior corneal wave aberrations varied greatly among subjects, but a moderate to high degree of mirror symmetry existed between right and left eyes.

Our analysis suggests, that bi-aspheric multifocal central presbyLASIK treatments for hyperopia and myopia with or without astigmatism provides fair but sufficient simultaneous vision (distance and near) 3-month after surgery.

Conclusions

In our cohort, at 3 months, 71% of patients achieved UDVA 0.1 logMAR or better, 79% patients obtained UNVA 0.1 logRAD or better, and 83% of eyes were within 0.75 diopters (D) of defocus. Postoperative mean spherical equivalent refraction was -0.15 ± 0.50 D. Stability was achieved from the 6-week follow-up. 92% of patients achieved UDVA 0.2 logMAR or better AND UNVA 0.2 logRAD or better. No significant differences among myopes, hyperopes, emmetropes or between males and females were found.

Patient selection and expectation management are essential to achieve patient satisfaction. Even though optically the results are quite predictable, some patients find it difficult to adapt to the compromise, and others are dissatisfied by the minor loss of distance VA. Certain individuals are best suited for PresbyMAX. A trial with multifocal contact lenses or trial frames that creates slightly defocused images to the retina can be used to simulate postoperative visual impressions and verify patient acceptance. Asking patients about their profession, hobbies, and expectations helps to understand whether the postoperative visual performance can meet their individual needs.

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