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# Presbyopic LASIK Using Hybrid Bi-Aspheric Micro-Monovision Ablation Profile for Presbyopic Corneal Treatments



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- PURPOSE: To evaluate distance and near image quality after hybrid bi-aspheric multifocal central presbyLASIK treatments.
- DESIGN: Consecutive case series.
- METHODS: Sixty-four eyes of 32 patients consecutively treated with central presbyLASIK were assessed. The mean age of the patients was  $51 \pm 3$  years with a mean spherical equivalent refraction of  $-1.08 \pm 2.62$  diopters (D) and mean astigmatism of  $0.52 \pm 0.42$  D. Monocular corrected distance visual acuity (CDVA), corrected near visual acuity (CNVA), and distance corrected near visual acuity (DCNVA) of nondominant eyes; binocular uncorrected distance visual acuity (UDVA); uncorrected intermediate visual acuity (UIVA); distance corrected intermediate visual acuity (DCIVA); and uncorrected near visual acuity (UNVA) were assessed pre- and postoperatively. Subjective quality of vision and near vision was assessed using the 10-item Rasch-scaled Quality of Vision and Near Activity Visual Questionnaire, respectively.
- RESULTS: At 1 year postoperatively, 93% of patients achieved 20/20 or better binocular UDVA; 90% and 97% of patients had J2 or better UNVA and UIVA, respectively; 7% lost 2 Snellen lines of CDVA; Strehl ratio reduced by  $\sim -4\% \pm 14\%$ . Defocus curves revealed a loss of half a Snellen line at best focus, with no change for intermediate vergence ( $-1.25$  D) and a mean gain of 2 lines for near vergence ( $-3$  D).
- CONCLUSIONS: Presbyopic treatment using a hybrid bi-aspheric micro-monovision ablation profile is safe and efficacious. The postoperative outcomes indicate improvements in binocular vision at far, intermediate, and near distances with improved contrast sensitivity. A 19% retreatment rate should be considered to increase satisfaction levels, besides a 3% reversal rate. (Am J Ophthalmol 2015;160(3):493–505. © 2015 by Elsevier Inc. All rights reserved.)

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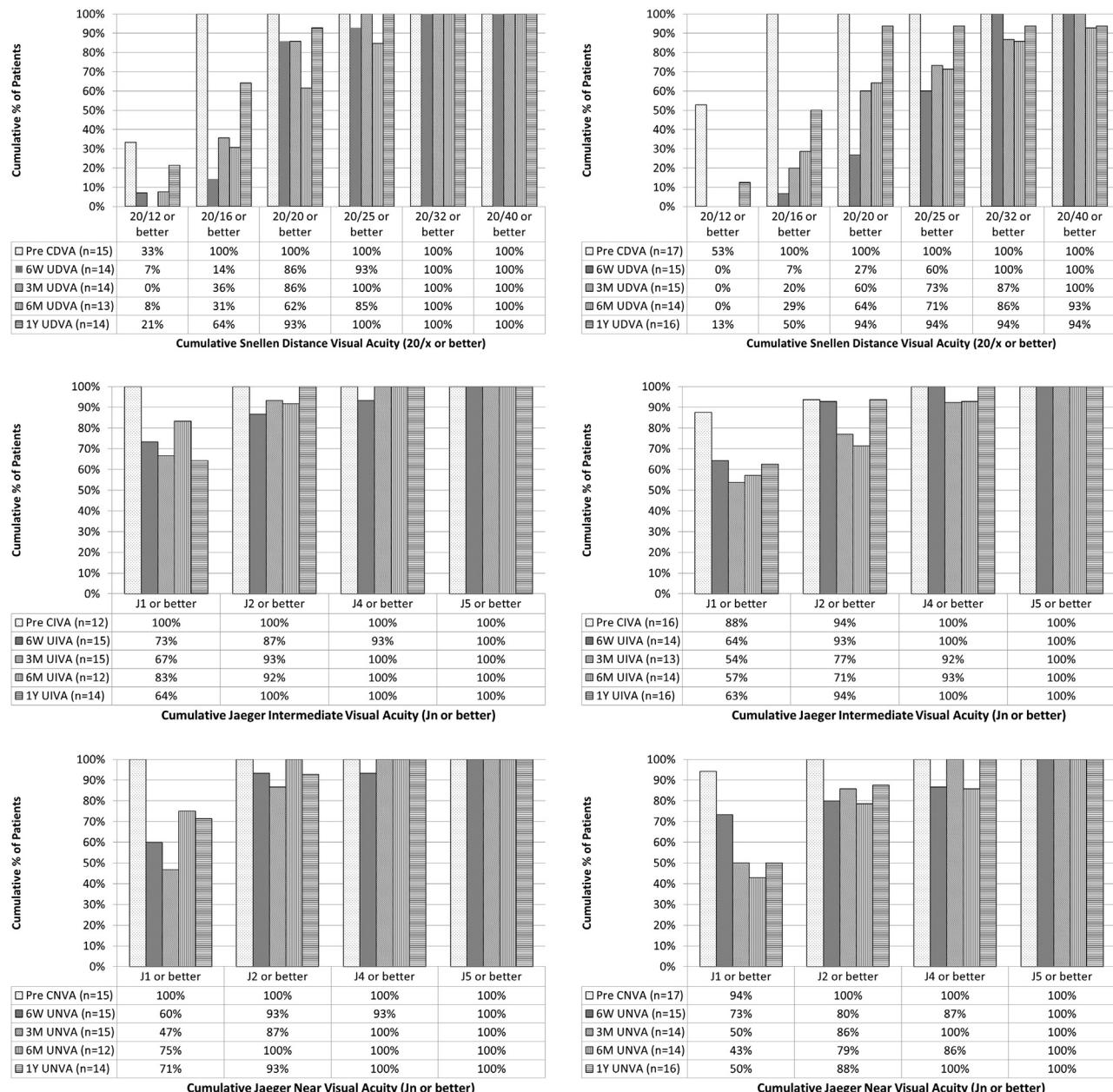
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**P**RESBYOPIA IS AN AGE-RELATED CONDITION characterized by the gradual loss of the eye's ability to focus actively on nearby objects. This condition is mainly attributed to a loss of elasticity of the crystalline lens, accompanied by a change in the ciliary muscle strength and lens curvature.<sup>1</sup> Refractive surgeons have faced challenges in effectively combining the treatment of refractive errors and presbyopia. Surgical presbyopia corrections have seen several developments, from the monovision and multifocal ablation techniques to the modern hybrid methods combining the benefits of several techniques. Corneal inlays and intraocular lenses have also been a popular alternative treatment for presbyopia.<sup>2</sup> Monovision techniques<sup>3</sup> usually involve correcting the dominant eye for distance, as opposed to crossed monovision,<sup>4</sup> where the dominant eye is corrected for near vision.

Charman<sup>5</sup> proposed that the main aim of presbyopia treatments was to extend the binocular depth of focus to yield adequate distance and near vision with good retinal contrast at lower spatial frequencies. Dai<sup>6</sup> first proposed the use of rigorous methodologies to theoretically optimize vision over the entire target range from near to distance. Multifocal ablations are designed to achieve these characteristics. These result in a pseudo-accommodative cornea realized either in the form of a peripheral near zone (concentric ring for near vision)<sup>7</sup> or in the form of a central near zone (central disc for near vision).<sup>8</sup>

PresbyLASIK is one such robust technique based on traditional laser-assisted in situ keratomileusis (LASIK) to correct the visual defect for distance while simultaneously reducing the near spectacle dependency in presbyopic patients.<sup>9,10</sup> PresbyLASIK has been stated as a promising technology, but lacking the level of maturity of monovision.<sup>11</sup> For achieving maximum patient satisfaction, good near vision should be accompanied with no detrimental effect in the distance vision. A hybrid method combining micro-monovision and multifocal ablation could potentially achieve full range of vision.

In this work, a hybrid bi-aspheric micro-monovision technique is presented and the outcomes are retrospectively analyzed in 64 consecutive eyes (of 32 patients) treated using this method.

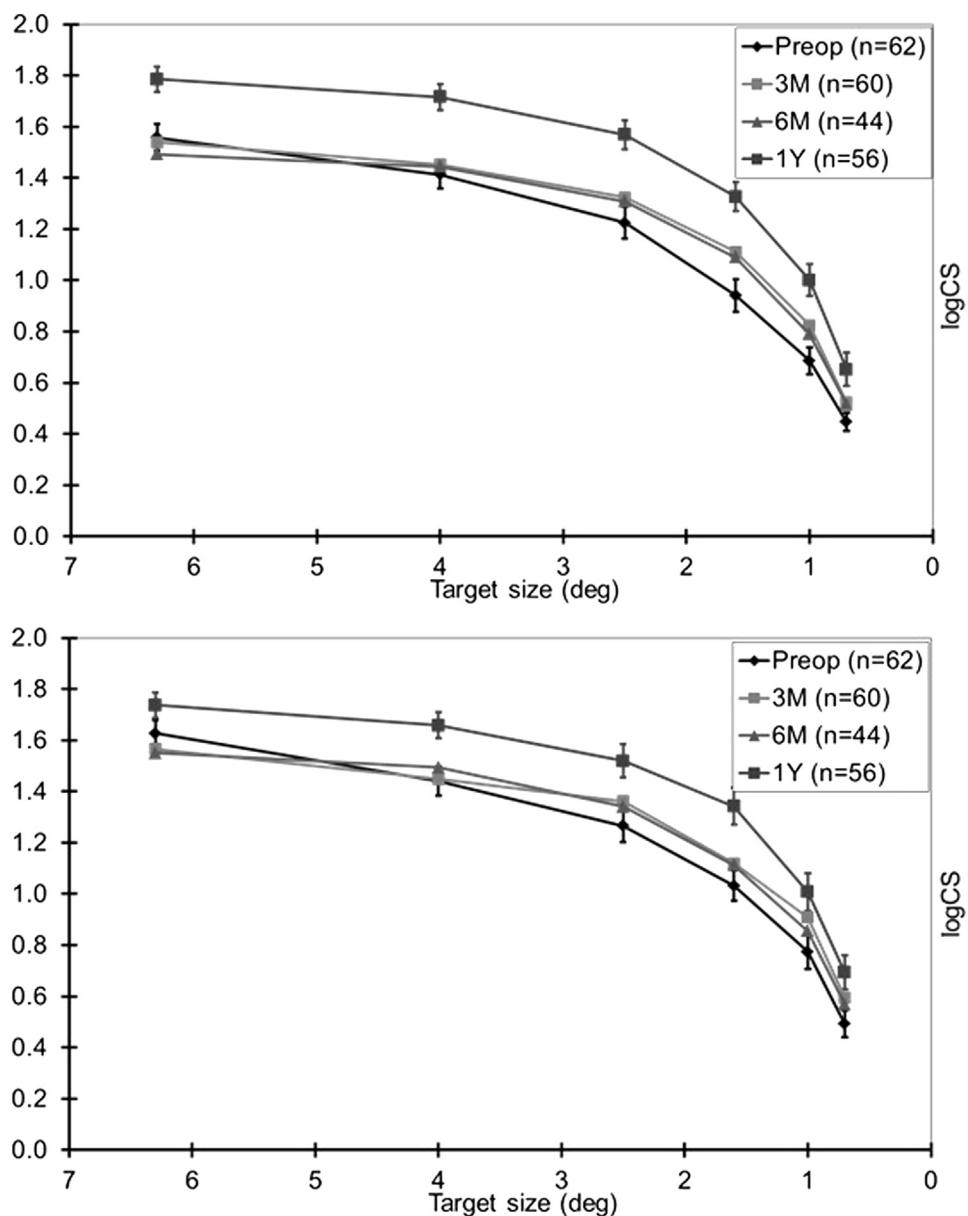


**FIGURE 1.** Changes in binocular uncorrected visual acuity at 1 year follow-up after treating with hybrid bi-aspheric micro-monovision ablation profile for presbyopic corneal treatments. Myopic patients are presented in the left panels and hyperopic patients are presented in the right panels. (Top left) Ninety-three percent of the myopic patients achieved 20/20 or better binocular uncorrected distance visual acuity (UDVA); (Top right) 94% of hyperopic patients achieved 20/20 or better binocular UDVA; (Middle left) 100% of myopic patients achieved Jaeger level J2 or better binocular uncorrected intermediate visual acuity (UIVA); (Middle right) 94% of hyperopic patients achieved Jaeger level J2 or better UIVA; (Bottom left) 93% of myopic patients achieved Jaeger level J2 or better uncorrected near visual acuity (UNVA); (Bottom right) 88% of hyperopic patients achieved Jaeger level J2 or better UNVA.

## METHODS

- PATIENTS:** This cohort study was based on a consecutive case series of patients treated by a single surgeon (M.H.A.L.) with the hybrid bi-aspheric micro-monovision technique to correct presbyopia, at

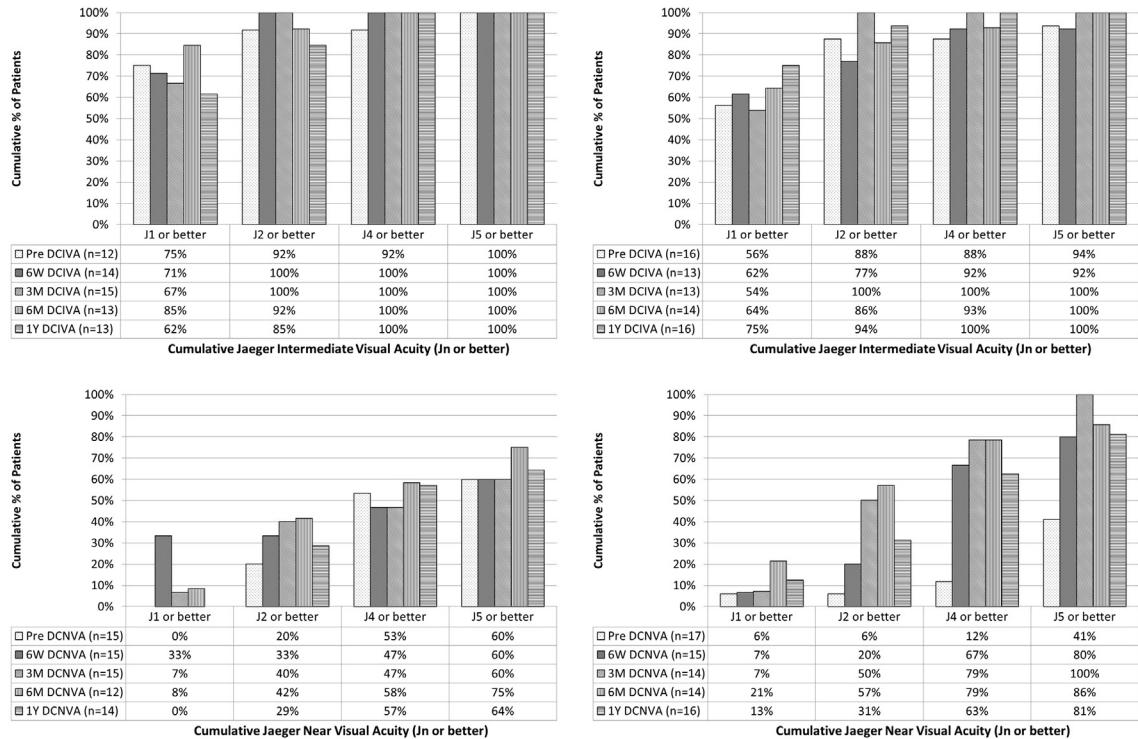
VisionClinics, Utrecht, Netherlands. Proper informed consent was obtained from each patient, for both the treatment and use of their de-identified clinical data for publication. The Independent Review Board Nijmegen (IRBN) evaluated the study and stated that the investigation in this form is not subject to the Medical Research Involving



**FIGURE 2.** Contrast sensitivity scores assessed preoperatively and 3 months (3M), 6 months (6M), and 1 year (1Y) after treating with hybrid bi-aspHERIC micro-monovision ablation profile for presbyopic corneal treatments. The contrast sensitivity scores were assessed with (Top) and without (Bottom) disability glare. At 3 and 6 months follow-up, the contrast sensitivity scores remained similar to the respective preoperative scores in both tests (with and without the disability glare), but improved, respectively, at 1 year follow-up ( $P < .005$  at all sizes). The error bars represent the upper and lower 95% confidence limits of the mean of measurements, preoperatively and 1 year postoperatively.

Human Subjects Act (WMO). The outcomes of performing presbyLASIK in 64 consecutive eyes (32 patients) were retrospectively analyzed. The average age of the 32 patients (17 male and 15 female; 17 hyperopic and 15 myopic) was  $51 \pm 3$  years (range 45–55 years). The mean preoperative spherical equivalent was  $-1.08 \pm 2.62$  D (−6.75 to 2.00 D), with mean preoperative astigmatism  $0.54 \pm 0.50$  D (0.00–2.10 D) and mean spectacle near addition  $1.75 \pm 0.36$  D (1.00–2.50 D).

To categorize the candidate as presbyopic, the monocular corrected near visual acuity (CNVA) at 40 cm had to be at least 2 logRAD lines better than the distance corrected near visual acuity (DCNVA) at 40 cm in each eye. Inclusion criteria were patients older than 45 years, medically suitable for LASIK, presbyopic, with corrected distance visual acuity (CDVA) no worse than 20/32 in either eye (with at least 20/25 in the best eye), stable refraction (<0.5 D change in mean spherical equivalent) for 1



**FIGURE 3.** Changes in binocular distance corrected visual acuity at 1 year follow-up after treating with hybrid bi-aspheric micro-monovision ablation profile for presbyopic corneal treatments. Myopic patients are presented in the left panels and hyperopic patients are presented in the right panels. (Top left) At 1 year follow-up, 85% of myopic patients achieved a Jaeger level J2 or better binocular distance corrected intermediate visual acuity (DCIVA). (Top right) At 1 year follow-up, 94% of hyperopic patients achieved a Jaeger level J2 or better binocular DCIVA. (Bottom left) At 1 year follow-up, 57% of myopic patients achieved a Jaeger level J4 or better binocular distance corrected near visual acuity (DCNVA). (Bottom right) At 1 year follow-up, 63% of hyperopic patients achieved a Jaeger level J4 or better binocular DCNVA.

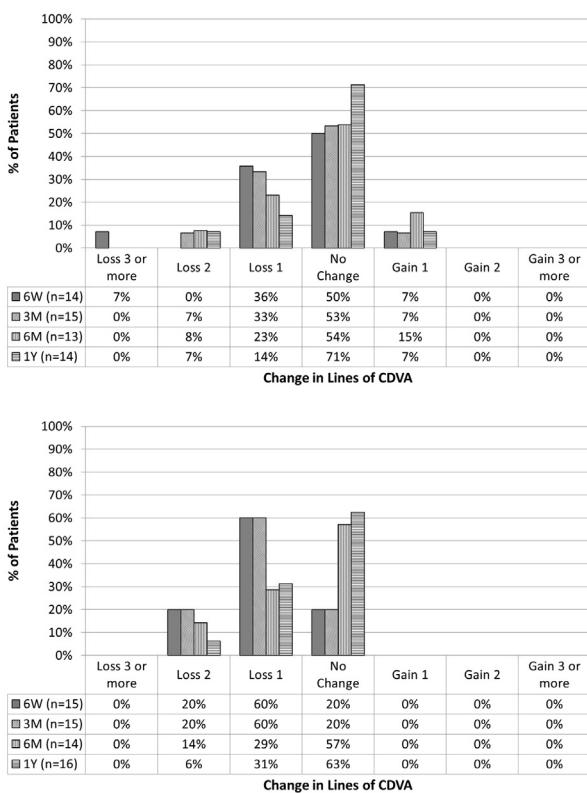
year prior to the study, discontinued usage of contact lenses for at least 2–4 weeks (depending on contact lens type) prior to the preoperative evaluation, and photopic pupil diameter smaller than 3.0 mm. The pupil diameters were obtained from the topographic measurements. Patients were required to have normal keratometry and topography (visually no suspect or form fruste keratoconus). Patients who suffered from systemic illness, had a calculated corneal bed thickness less than 300 µm after ablation, had preoperative central corneal thickness of less than 470 µm, had previous ocular surgery, or had abnormal corneal topography were excluded from the study. Additional exclusion criteria were clinically relevant lens opacity, a pupil offset of 0.7 mm or more, and any signs of binocular vision anomalies at distance and near.

- PREOPERATIVE ASSESSMENT:** A full ophthalmologic examination was performed on all the patients prior to surgery including manifest refraction, cycloplegic refraction, slit-lamp microscopy of the anterior segment, handheld ultrasound pachymetry (Corneo-Gage Plus; Sonogage, Cleveland, Ohio, USA), dilated funduscopic, and Goldmann intraocular pressure measurement. CDVA and uncorrected

distance visual acuity (UDVA) were assessed with Early Treatment Diabetic Retinopathy Study (ETDRS) charts. Near and intermediate acuity was assessed unaided and distance corrected (uncorrected near visual acuity [UNVA], DCNVA, uncorrected intermediate visual acuity [UIVA], and distance corrected intermediate visual acuity [DCIVA]), with the Dutch version of the Radner Reading Charts at 40 cm. All the tests were performed binocularly. The selection of the distance and near eye was based on a protocol described by Durrie.<sup>12</sup>

The corrected visual acuity was always assessed with trial frames and not contact lenses. Binocular defocus curves were measured (with both eyes corrected for distance, ie, eliminating the effect of the micro-monovision component) with induced lens blur from +1.5 D to -4.0 D in 0.5 D randomized spherical steps, using distance ETDRS charts with the letters randomized between presentations and magnification effects being accounted for.<sup>13</sup>

Contrast sensitivity with and without glare was measured using the Contrast Glare Tester CGT-1000 (Takagi Seiko Co Ltd, Nagano-Ken, Japan) at 6 target sizes (6.3 degrees, 4.0 degrees, 2.5 degrees, 1.6 degrees, 1.0 degrees, and 0.7 degrees) after correcting the refractive error



**FIGURE 4.** Changes in binocular corrected distance visual acuity (CDVA) at 1 year follow-up after treating with hybrid bi-aspheric micro-monovision ablation profile for presbyopic corneal treatments. (Top) Myopic patients: A loss of 2 Snellen lines of CDVA was observed in 7% of myopic patients at 1 year follow-up. (Bottom) Hyperopic patients: A loss of 2 Snellen lines of CDVA was observed in 6% hyperopic patients at 1 year follow-up. W, M, and Y represent weeks, months, and years, respectively.

with spectacles. Log values of the contrast sensitivity scores were used for statistical analysis.

Corneal and ocular aberrometry was performed with the OPD Scan II (Nidek, Gamagori, Japan) over a 6 mm diameter. Root mean square (RMS) higher-order aberrations, Strehl ratio, and corneal asphericity were extracted.

Subjective patient-reported outcomes were assessed using 2 questionnaires: the Quality of Vision Questionnaire and the Near Activity Visual Questionnaire. The Quality of Vision Questionnaire was developed by McAlinden and associates<sup>14,15</sup> to assess symptoms such as glare, halos, and starbursts with the use of simulation photographs. Symptoms are scored based on their frequency, severity, and bothersomeness. The questionnaire is valid for use with spectacle wearers, contact lens wearers, and those having had laser refractive surgery, intraocular refractive surgery, or eye disease including cataract.<sup>16-18</sup> The Near Activity Visual Questionnaire was used to assess patient satisfaction with near functional vision.<sup>19</sup> For both

questionnaires the raw response scores were converted to a 0–100 Rasch scale, with higher scores indicating worse quality of vision.

The Quality of Vision and Near Activity Visual Questionnaires were administered preoperatively and at 3 months, 6 months, and 1 year postoperatively. Patients were instructed to answer the questionnaires at each follow-up visit to recount their subjective impression in unaided bright and dim lighting conditions.

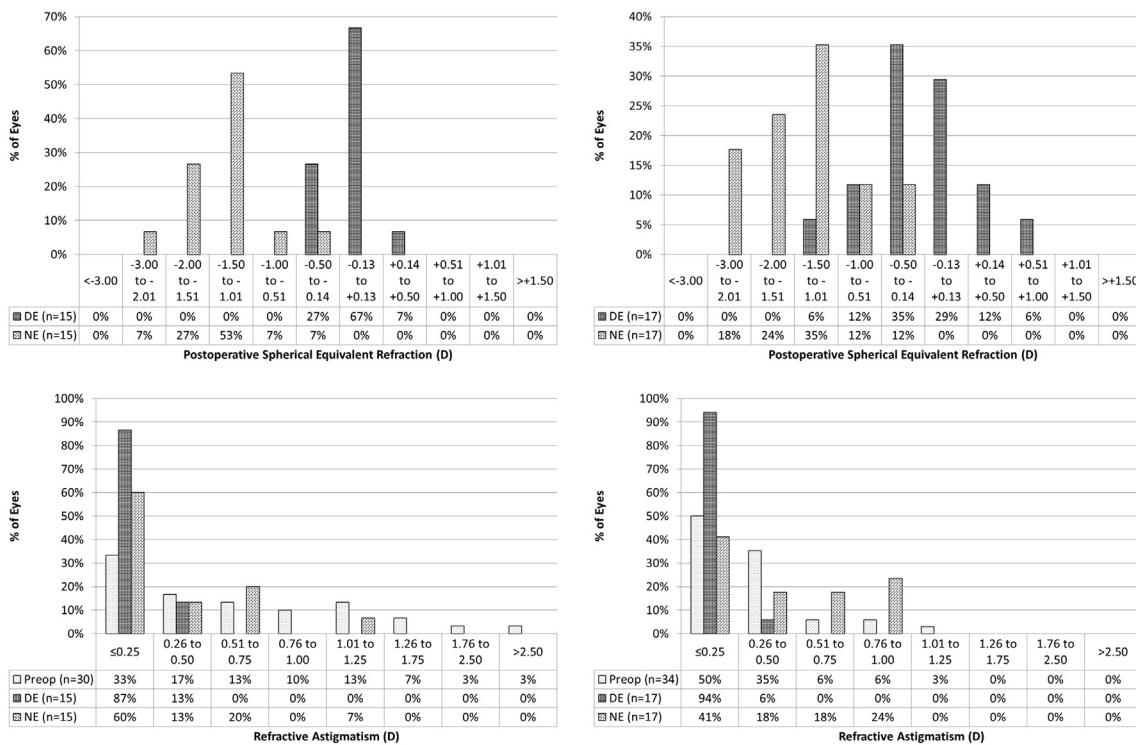
• **SURGICAL PROCEDURE:** All the treatments were prepared using the SCHWIND PresbyMAX treatment planning module in aspheric mode (SCHWIND eye-tech-solutions GmbH and Co KG, Kleinostheim, Germany). The devices used in this study bear the standards of European conformity (Conformité Européene or CE marking) but are not approved by the US Food and Drug Administration (FDA). The hybrid surgical technique involved treating the dominant eye (also referred to as the distant eye) more toward distance vision (target refraction -0.1 D) and the nondominant eye (also referred to as the near eye) slightly toward near vision (target refraction -0.9 D) for achieving micro-monovision. Multifocality<sup>11,20-22</sup> increases the range of intermediate vision with a different depth of focus between the distant eye (+1.1 D) and the near eye (+2.2 D).

For each treatment, the planning software calculated the size of the optimal transition zone, depending on the preoperative refraction and optical treatment zone. Drops of topical anaesthetic were instilled in the upper and lower fornices. Flaps were made using Intralase iFS 150 KHz femtosecond laser (AMO, Chicago, Illinois, USA) with a 100 µm nominal flap thickness.

Additional drops of topical anesthetics were instilled; the lid margins and periocular region were disinfected using diluted povidone. A sterile drape covering eye lashes and face 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 torsion tracking integrated into the laser system and centered on the corneal vertex. 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. Aspheric non-wavefront-guided treatments were performed. The ablation profile was centered on the corneal vertex determined by the topographer (taking 70% of the pupil offset value), which closely approximates the visual axis.<sup>23,24</sup> Further, the topographic keratometry readings at 3 mm diameter were used for the compensation of the loss of efficiency when ablating the cornea at non-normal incidences. 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 for removing any debris.



**FIGURE 5.** Spherical equivalent refraction and refractive astigmatism 1 year after treating with hybrid bi-aspheric micro-monovision ablation profile for presbyopic corneal treatments. Myopic patients are presented in the left panels and hyperopic patients are presented in the right panels. (Top) Postoperative spherical equivalent refraction. (Top left) In myopic patients, 100% of distance eyes were within 0.5 diopter (D) of emmetropia while 67% of near eyes were within 0.6 D of micro-monovision target (-0.9 D). (Top right) In hyperopic patients, 76% of distance eyes were within 0.5 D of emmetropia while 59% of near eyes were within 0.6 D of micro-monovision target (-0.9 D). (Bottom) Postoperative refractive astigmatism. (Bottom left) In myopic patients, 100% of distance eyes and 73% of near eyes were within 0.5 D of astigmatism. (Bottom right) In hyperopic patients, 100% of distance eyes and 59% of near eyes were within 0.5 D of astigmatism. DE = distance eye; NE = near eye.

Patients received topical antibiotic drops 4 times a day for 1 week; corticosteroid drops 4 times a day tapering off in 1 week, and ocular lubricants as needed.

- POSTOPERATIVE EVALUATION:** Patients were reviewed at 6 weeks, 3 months, 6 months, and 1 year postoperatively. All postoperative follow-up visits included measurement of monocular and binocular UDVA, UNVA, UIVA, manifest refraction, CDVA, DCNVA, DCIVA, and defocus curves. The response to Quality of Vision and Near Activity Visual Questionnaires, topography and aberrometry, and contrast sensitivity were recorded at every follow-up visit except 6 weeks postoperatively.

- STATISTICAL ANALYSIS:** Data were assessed for normality using the Shapiro-Wilk test. Analysis of variance and t tests were performed on normally distributed data and Friedman tests and post hoc Wilcoxon signed rank tests when the data were not normally distributed.

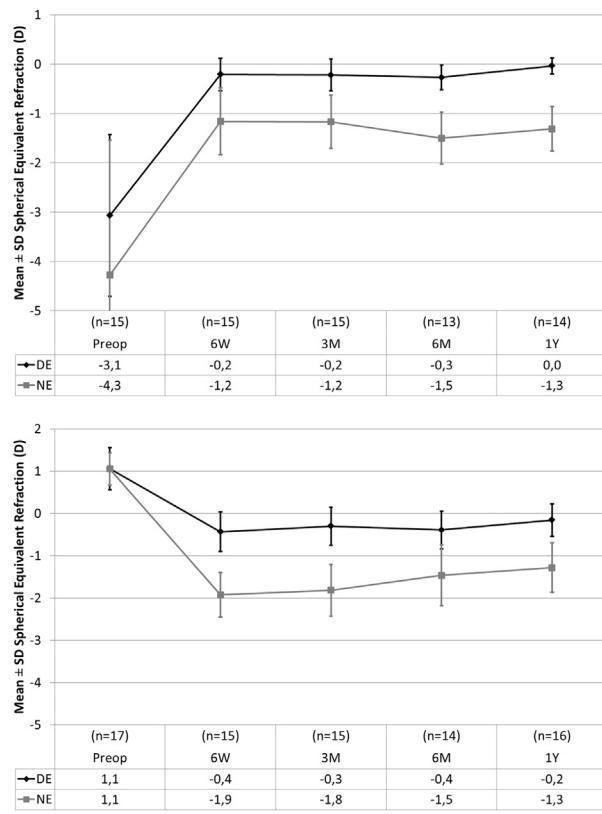
Distance visual acuity was evaluated in logMAR but converted to equivalent Snellen fractions for reporting comparability. Similarly, near visual acuity was evaluated

in logRAD but converted to Jaeger scale for reporting comparability. Manifest refraction was used for preoperative to postoperative comparison. Uncorrected and corrected visual acuity, contrast sensitivity, spherical equivalent refraction, and refractive astigmatism were individually analyzed for myopic and hyperopic patients.

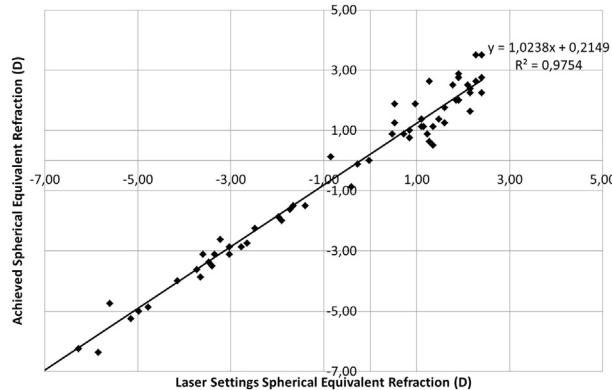
## RESULTS

THE MEAN OPTICAL TREATMENT ZONE DIAMETER WAS  $6.58 \pm 0.26$  mm (6.0–7.0 mm, median 6.5 mm). The total ablation zone ranged from 6.8 mm to 8.9 mm.

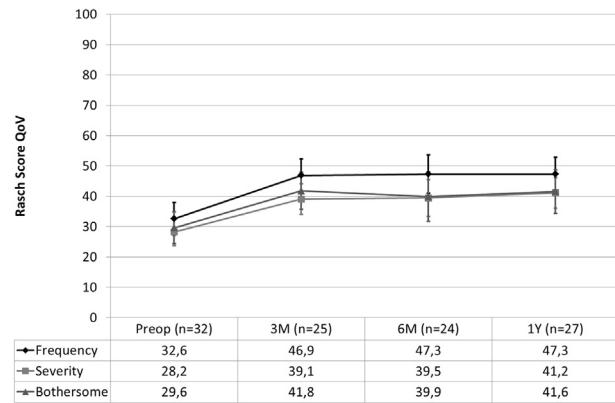
- EFFICACY:** The distribution of binocular UDVA, UIVA, and UNVA are presented in Figure 1. At 1 year follow-up, 93% (13 out of 14) of myopic patients and 94% (15 out of 16) of hyperopic patients achieved 20/20 or better binocular UDVA; 100% (14 out of 14) of myopic patients and 94% (15 out of 16) of hyperopic patients achieved Jaeger level J2 or better UIVA; while 93% (13 out of 14) of



**FIGURE 6.** Mean spherical equivalent refraction assessed preoperatively and at 1 year follow-up after treating with hybrid bi-aspheric micro-monovision ablation profile for presbyopic corneal treatments. (Top) Myopic patients. (Bottom) Hyperopic patients. Refractive stability was achieved for both distance (DE) and near eye (NE) in myopic and hyperopic patients, from 6 weeks postoperatively. W, M, and Y represent weeks, months, and years, respectively.



**FIGURE 7.** The relationship between laser setting spherical equivalent refraction and the achieved spherical equivalent refraction 1 year after treating with hybrid bi-aspheric micro-monovision ablation profile for presbyopic corneal treatments. A linear trend can be observed between the attempted and achieved refraction in our cohort ( $R^2 = 0,9754$ ).



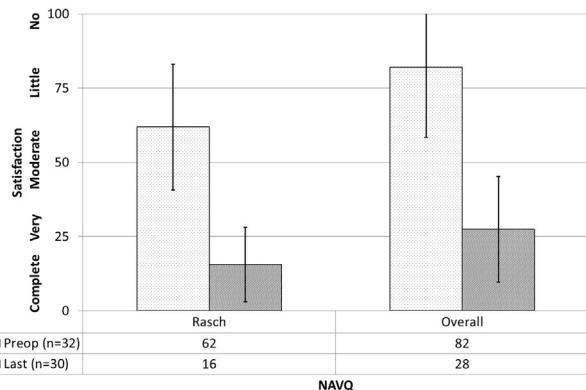
**FIGURE 8.** Quality of Vision (QoV) Questionnaire scores assessing symptoms based on their frequency, severity, and bothersomeness, on each follow-up visit after presbyLASIK treatment. The raw response scores were converted to a 0–100 Rasch scale with higher scores indicating worse quality of vision. A minor decline is observed in the Rasch scores post-operatively compared to the corrected preoperative scores. M and Y represent months and years, respectively.

myopic patients and 88% (14 out of 16) of hyperopic patients achieved Jaeger level J2 or better UNVA.

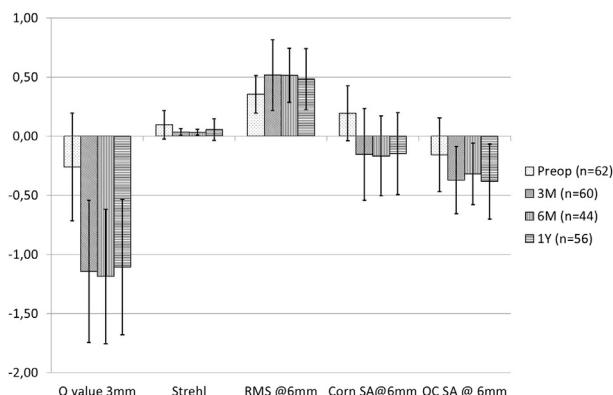
Changes in contrast sensitivity scores were assessed with and without the disability glare (Figure 2). At 3 and 6 months follow-up, the contrast sensitivity scores remained similar to the respective preoperative scores in both tests (with and without the disability glare), but improved, respectively, at the 1 year follow up ( $P < .005$  at all sizes).

- SAFETY:** The change in binocular DCIVA and DCNVA is presented in Figure 3. At 1 year follow-up, 85% (11 out of 13) of myopic patients and 94% (15 out of 16) of hyperopic patients achieved a Jaeger level J2 or better binocular DCIVA, while 57% (8 out of 14) of myopic patients and 63% (10 out of 16) of hyperopic patients achieved a Jaeger level J4 or better binocular DCNVA. A loss of 2 Snellen lines of binocular CDVA (Figure 4) was observed in 7% (1 out of 14) of myopic patients and 6% (1 out of 16) of hyperopic patients at 1 year follow-up.

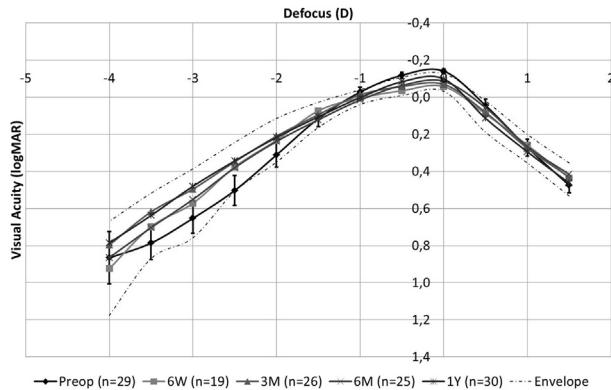
- ACCURACY:** For myopic and hyperopic patients, a good separation was observed between the dominant and nondominant eye for refractive deviation from target spherical equivalent refraction and astigmatism (Figure 5). In myopic patients, 100% (15 out of 15) of distance eyes were within 0.5 D of emmetropia while 67% (10 out of 15) of near eyes were within 0.6 D of micro-monovision target (-0.9 D); in hyperopic patients, 76% (13 out of 17) of distance eyes were within 0.5 D of emmetropia while 59% (10 out of 17) of near eyes were within 0.6 D of micro-monovision target (-0.9 D). For myopic patients, 100% (15 out of 15) of distance eyes and 73% (11 out of 15) of near eyes were within 0.5 D of astigmatism; in hyperopic patients, 100% (17 out of 17) of distance eyes and 59% (10 out of 17) of near eyes were within 0.5



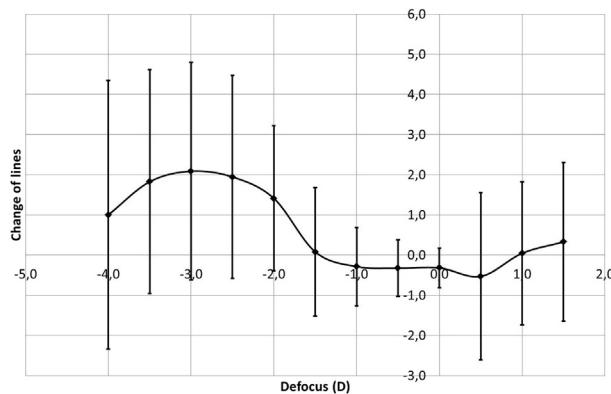
**FIGURE 9.** Near Activity Visual Questionnaire (NAVQ) scores assessing patient satisfaction with near functional vision and overall satisfaction level, preoperatively and at the last post-operative visit after treating with hybrid bi-aspheric micro-monovision ablation profile for presbyopic corneal treatments. The raw response scores were converted to a 0–100 Rasch scale with higher scores indicating worse quality of vision. NAVQ improved from little to very high satisfaction level, with an improvement in Rasch scores. “Last” represents the Rasch scores at the last follow-up (at 6 months or 1 year postoperatively).



**FIGURE 10.** Change in corneal asphericity (Q value) at 3 mm diameter, Strehl ratio (Strehl), root mean square (RMS) of higher-order aberrations (at 6 mm diameter), corneal and ocular spherical aberrations (Corn SA and OC SA, respectively, at 6 mm diameter) preoperatively and at 1 year follow-up after treating with hybrid bi-aspheric micro-monovision ablation profile for presbyopic corneal treatments. M and Y represent months and years, respectively. One year postoperatively, the Strehl ratio reduced by  $\sim -4\% \pm 14\%$  and the corneal and ocular spherical aberrations (at 6 mm diameter) decreased by  $-0.38 \pm 0.33 \mu\text{m}$  and  $-0.28 \pm 0.35 \mu\text{m}$ , respectively, with an increase in RMS higher-order aberrations (at 6 mm diameter) by  $0.15 \pm 0.24 \mu\text{m}$ . All these metrics indicated good stability from 3 months onward.

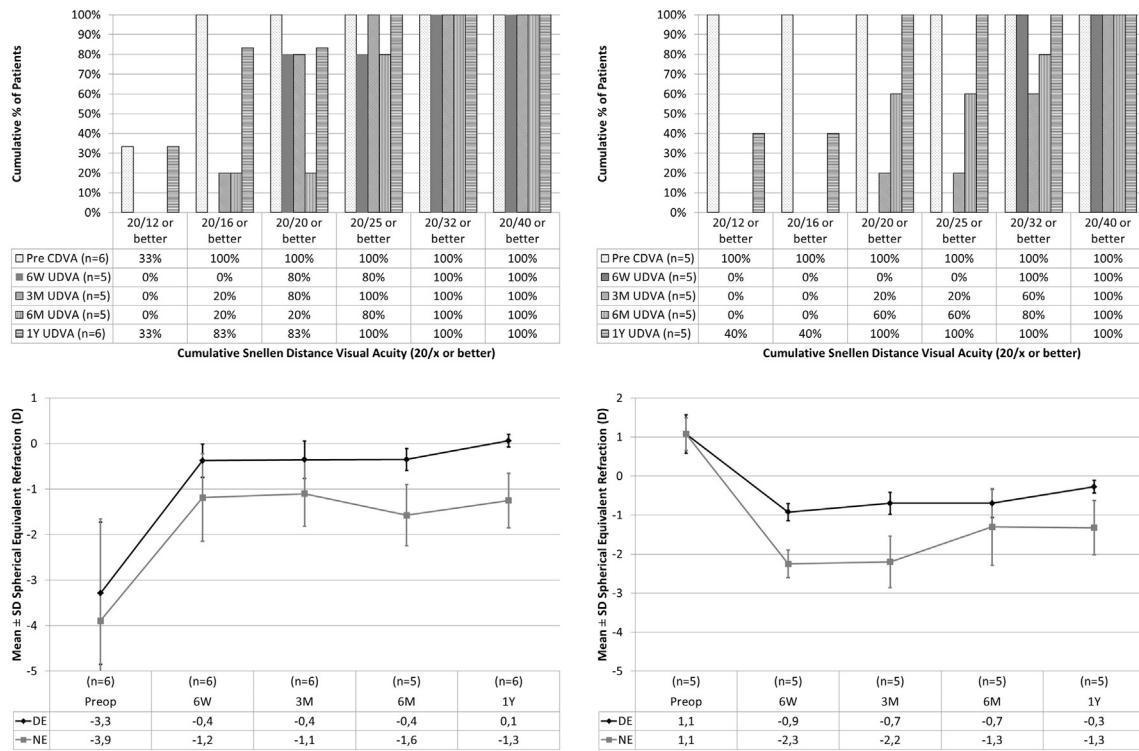


**FIGURE 11.** Binocular defocus curves from uncorrected vision asymmetrically to longer ( $+1.5$  diopter [D]) and shorter vergences ( $-4.0$  D), assessed preoperatively and at 1 year follow-up after treating with hybrid bi-aspheric micro-monovision ablation profile for presbyopic corneal treatments. The error bars represent the upper and lower 95% confidence limits of the mean of measurements, preoperatively. The upper and lower envelope represents, respectively, the maximum and minimum values of the confidence limits of postoperative measurements (irrespective of the follow-up time) with respect to vergence. W, M, and Y represent weeks, months, and years, respectively.



**FIGURE 12.** Change in defocus curves with respect to vergence, assessed preoperatively and at last follow-up after treating with hybrid bi-aspheric micro-monovision ablation profile for presbyopic corneal treatments. At 1 year follow-up, a loss of half a logMAR was observed at best focus for distance, with no change for intermediate vergence ( $-1.25$  diopter [D]) and a mean gain of 2 lines for near vergence ( $-3$  D).

D of astigmatism. Refractive stability was achieved for both dominant (DE) and non-dominant eye (NE) in myopic and hyperopic patients, from 6 weeks postoperatively (Figure 6). A nearly linear (coefficient of determination  $r^2 = 0.97$ ,  $P < .00001$ ) relationship between the laser attempted and achieved spherical equivalent refraction was observed (Figure 7).



**FIGURE 13.** Change in binocular uncorrected distance visual acuity (UDVA) and spherical equivalent refraction after a secondary treatment (in 12 eyes, 11 patients), to improve distance (9 eyes) or near (3 eyes) outcomes in eyes that underwent an initial treatment with hybrid bi-aspHERIC micro-monovision ablation profile for presbyopic corneal treatments. All retreatments were performed after the 6-month follow-up. All follow-up times presented here are from the initial treatments (ie, up to 6 months post-retreatment). Myopic patients are presented in the left panels and hyperopic patients are presented in the right panels. (Top left) Eighty-three percent of myopic patients achieved a 20/20 or better binocular UDVA at 1 year follow-up, compared to only 20% at 6 months follow-up; (Top right) 100% of hyperopic patients achieved a 20/20 or better binocular UDVA at 1 year follow-up, compared to only 60% at 6 months follow-up; (Bottom) Mean spherical equivalent refraction at 1 year follow-up in distance eye was 0.1 diopter (D) for myopic patients (left) and  $-0.3$  D for hyperopic eyes (right), whereas for near eye it was  $-1.3$  D for both myopic and hyperopic patients.

- SUBJECTIVE RATING:** Quality of Vision scores assessing symptoms based on their frequency, severity, and bothersomeness are presented in Figure 8. Compared to the corrected preoperative scores, the Quality of Vision score worsened postoperatively ( $P = .02$ ), mainly with an increase in patients seeing haloes ( $P = .002$ ), blurred vision ( $P = .02$ ), and double vision ( $P = .01$ ).

Near Activity Visual Questionnaire (NAVQ) scores assessing patient satisfaction with near functional vision and overall satisfaction are presented in Figure 9. The Near Activity Visual Questionnaire scores improved from little satisfaction to very high satisfaction level ( $P < .00001$ ), with an improvement in Rasch scores ( $P < .0001$ ). Stability was observed in Near Activity Visual Questionnaire scores from 3 months follow-up time.

- ABERRATIONS:** Change in corneal asphericity (Q value) at 3 mm diameter, Strehl ratio, RMS of higher-order aberrations (at 6 mm diameter), and corneal and ocular spherical aberrations are presented in Figure 10. Asphericity was

more prolate after surgery, indicating a central myopia (within 3 mm diameter,  $P < .00001$ ). Compared to the preoperative status, 1 year postoperatively the Strehl ratio reduced by  $\sim -4\% \pm 14\%$  ( $P = .00007$ ) and the corneal and ocular spherical aberrations (at 6 mm diameter) decreased by  $-0.38 \pm 0.33 \mu\text{m}$  and  $-0.28 \pm 0.35 \mu\text{m}$ , respectively ( $P < .00001$ ), with an increase in RMS higher-order aberrations (at 6 mm diameter) by  $0.15 \pm 0.24 \mu\text{m}$  ( $P = .00002$ ). All these metrics indicated good stability from 3 months onward.

Binocular defocus curves and the change between defocus curves (preoperatively and at 1 year follow-up) are presented in Figures 11 and 12, respectively. Defocus curves indicate stability from 6 weeks follow-up. The difference in defocus curves shows a decrease of 0.05 logMAR at best focus ( $-0.35 \pm 0.57$  lines,  $P = .0009$ ), with no change for intermediate vergence ( $-1.00$  D and  $-1.50$  D) and a mean gain of 2 lines for near vergence ( $-2.00$  D and closer,  $P = .00400$ ) at 1 year follow-up. A slightly better distance vision was observed preoperatively, but the near and

**TABLE.** A Comparison of Clinical Outcomes Using Different Techniques for Laser Presbyopia Corrections

Study	n	Follow-up	Group/Subgroup	UDVA 20/20 or Better	UNVA J2 or Better	CDVA Loss 2 or More Lines	Ret	Rev
<b>PresbyLASIK</b>								
Alio et al <sup>8</sup>	50	6 M	Presb	64%	72% (20/40 or better)	14%	12%	-
Luger et al <sup>11</sup>	66	1 Y	Hyp and myo with/without astig	48%	94%	3%	-	-
Luger et al <sup>20</sup>	48	3 M	Hyp and myo with/without astig	25%	50%	-	0%	0%
Iribarne et al <sup>21</sup>	50	6 M	Hyp and myo with/without astig	41%	91%	5%	-	-
Baudu et al <sup>22</sup>	716	6 M	Myo	43%	98%	26%	19% (overall)	1% (overall)
			Hyp	45%	90%	25%		
<b>Monovision</b>								
Wright et al <sup>3</sup>	42	7 M (3–15)	Myo presb treated with PRK induced monovision	76.2%	100% (20/30 or better)	-	26.2%	-
	32	11 M (3–17)	Emm treated with PRK	62.5%	25% (20/30 or better)	-	37.5%	-
Alarcón et al <sup>28</sup>	50	3 M		90%	90% (J1 or better)	-	12%	-
<b>Conductive keratoplasty</b>								
Stahl <sup>29</sup>	10	1 Y	1 Y follow up	89% (20/20 and J1)	89%	-	0% (overall)	0% (overall)
	9	3 Y	3 Y follow up	22% (20/20 and J1)	33%	-		
<b>Supracor</b>								
Ryan et al <sup>30</sup>	46	6 M	Hyp	48%	73.9% (J5 or better)	4%	21.7%	-
<b>Intracor</b>								
Holzer et al <sup>31</sup>	25	3 M		48%	8% (20/20 or better)	8%	-	-
<b>Intracorneal inlay</b>								
Yilmaz et al <sup>32</sup>	22	4 Y	Emm or post LASIK presb	73%	96% (J3 or better)	5%	22.7% (cataract extraction)	18.2%
Seyeddain et al <sup>26</sup>	32	2 Y	Emm presb	74%	65.6% (J1 or better)	6%	6.3%	0%
Tomita et al <sup>33</sup>	223	6 M	Presb patients with previous LASIK	100%	77%	0%	-	-
<b>Multifocal IOL</b>								
McAlindin et al <sup>2</sup>	44	3 M		-	68.2%	-	0%	13.6%
<b>Biaspheric cornea modulation</b>								
Uthoff et al <sup>34</sup>	20	6 M	Emm	80% (0.1 logMAR)	40% (0.1 logRAD)	10%	6.6%–10% (may require overall)	
	20	6 M	Hyp	100% (0.1 logMAR)	30% (0.1 logRAD)	10%		
	20	6 M	Myo	70% (0.1 logMAR)	60% (0.1 logRAD)	20%		
<b>Presented study</b>								
Current	64	1 Y		93%	90%	7%	19%	3%

Astig = astigmatism; CDVA = corrected distance visual acuity; Emm = emmetropia; Hyp = hyperopia; IOL = intraocular lens; M = months; Myo = myopia; n = number of eyes; Presb = presbyopia; Ret = retreatments; Rev = reversals; UDVA = uncorrected distance visual acuity; UNVA = uncorrected near visual acuity; Y = year.

intermediate vision (at 2.00 D//50 cm and 2.50 D//40 cm) improved postoperatively.

• **RETREATMENTS:** Secondary treatment was performed in 12 eyes (11 patients: 19% from the 64 eyes; 7 eyes in Myopic group [of 6 patients] and 5 eyes in Hyperopic group [of 5 patients]) to improve distance (9 eyes) or near (3 eyes) outcomes. The secondary treatments were performed using a non-wavefront-guided aspheric treatment to tune distance refraction to the desired value. All retreatments were performed after at least 6 months follow-up after the initial treatment. Figure 13 presents the preoperative CDVA (pre-PresbyMAX) and the postoperative UDVA (pre- and post-retreatment) and spherical equivalent refraction in the eyes that underwent a secondary treatment. At 1 year follow-up from the initial treatment (ie, up to 6 months post-retreatment), 83% (5 out of 6) of myopic patients and 100% (5 out of 5) of hyperopic patients undergoing secondary treatment achieved a 20/20 or better binocular UDVA. Compared to the outcomes at 6 months follow-up pre-retreatment, significant improvements were observed post-retreatment (only 20% [1 out of 5] of myopic and 60% [3 out of 5] of hyperopic patients achieved 20/20 or better binocular UDVA 6 months postoperatively after the initial treatment). Binocular UIVA and UNVA remained relatively stable in these eyes through the postoperative follow-ups.

Two eyes (3% from the 64 eyes) underwent a partial Presby reversal treatment to reduce the effects of the primary treatment, owing to the patient's perceived intolerance (mainly loss of CDVA) to the induced multifocality. The details about the reversal of this technique and corresponding aberrations and topography changes have been published elsewhere.<sup>25</sup>

## DISCUSSION

THIS CONSECUTIVE CASE SERIES ANALYZED THE EFFICACY and safety of presbyopic treatments using a hybrid bi-aspheric micro-monovision ablation profile. This technique was expected to combine the benefits of multifocal ablations and micro-monovision with enhanced depth of focus and a wider range of intermediate vision. Our independent analysis of myopic and hyperopic patients revealed very comparable long-term results after the treatment. The binocular vision was expected to improve overall, with the nondominant eye imparting an improvement in Near Activity Visual Questionnaire scores and the dominant eye imparting an improvement in Quality of Vision scores. Most of the outcome measures showed significant improvement compared to the preoperative status. The improvement in corrected and uncorrected distance and near visual acuity was significant postoperatively. Improvements in refraction and visual acuity were also seen in patients undergoing secondary treatments. In addition, analyzing the

Near Activity Visual Questionnaire responses revealed an improvement in all the topics and the Rasch scores indicated improvements from little (preoperative) to high (postoperative) satisfaction. Although it would be interesting to know the profile of the defocus curves monocularly for the presbyopic eyes, this was not possible owing to the retrospective nature of this study. However, the defocus curves with both eyes corrected for distance (ie, eliminating the effect of the micro-monovision component) revealed a loss of half a Snellen line at the best focus for distance but a gain of 2 lines at the near vergence. Monocularly, it would be expected that the defocus curves would be shallower, with separation between the dominant and nondominant eye. The metric area under the defocus curves demonstrates a slight drop at distance vision postoperatively, but not a gain at near or intermediate vision. This could be due to the curves crossing at near (-2.00 D to -4.00 D) and intermediate (-0.50 D to -2.00 D) vision boundary and missing data points in this range.

Corneal topography and aberrometry revealed a decrease in corneal and ocular spherical aberrations, associated with an increase in the RMS higher-order aberrations. Furthermore, Quality of Vision responses revealed minor decline in terms of blurred vision, haloes, and double vision postoperatively compared to the patient responses preoperatively (using correction glasses). Stability in the Near Activity Visual Questionnaire rating and refraction was reached after 3 months and 6 weeks postoperatively. The presented clinical outcomes are based on 1 year of clinical follow-up, which is considered adequate in refractive surgery. However, presbyopia increases with age. Therefore, longer follow-up could shed light on the durability of performance during further degradation of accommodation. As a recommendation from the manufacturer of the laser system, patients were required to have pupil diameters smaller than 3.0 mm in photopic (for effectively using the central near disk of the profile) and larger than 4.5 mm in mesopic light conditions (for getting enough light in the distance focus using the pericentral distance annulus of the profile; however, pupil diameters were obtained from the topography, and eyes with pupil diameter smaller than 3.0 mm in photopic conditions are currently included for surgery by the clinic).

Many clinical studies have evaluated various surgical techniques to treat presbyopia; however, the current developments throughout the corneal presbyopic correction spectrum indicate a converging trend toward hybrid techniques. These hybrid modifications include Supracor (TECHNOLAS Perfect Vision GmbH), PresbyMAX (reduced multifocality in distance eye combined with full multifocality and monovision in the near eye), Intracor (full correction in distance eye combined with Intracor multifocality and monovision in the near eye), KAMRA (AcuFocus, Inc) (full correction in distance eye combined with pinhole-based extended depth of focus and monovision in the near eye), Presbyond (Carl Zeiss Meditec AG)

laser blended vision (moderate multifocality in both eyes combined with monovision in the near eye), and refractive corneal inlays (eg, raindrop from ReVision Optics, USA).

A brief summary and comparison of the clinical studies with different methods to treat presbyopia is presented in the Table, although intermediate visual acuity is not included owing to the unavailability of this metric in most studies. However, Seyeddain and associates<sup>26</sup> reported in their cohort 71.9% of treatments achieving 20/20 or better UIVA compared to the 63% reported in our cohort.

Methods depending only on the depth of focus might face difficulty to create more than 1.5 D of near vision independence. In contrast, with the models based on multifocal ablations one can gain a higher near vision independence. Since presbyopia increases with age, a wide range of near vision shall be an asset in such cases. In addition, the difference in the depth of focus between the near and far eye provides the patient with a wider binocular range of focus for an enhanced intermediate vision.

The depth of focus acts as a useful marker; however, some studies consider acuity at a typical near vision distance as a more suitable metric that is closely related to patients' real expectations and concerns.<sup>27</sup> Our analysis and results indicate significant success in presbyopic treatments using the hybrid bi-aspheric micro-monovision ablation profiles. We evaluated the subjective perception of patients for distance (Quality of Vision) and near visual quality (Near Activity Visual Questionnaire scores) and found significant improvements in the Near Activity Visual Questionnaire scores with improved uncorrected and corrected near and distance visual acuity and contrast sensitivity. Presbyopic treatment using a hybrid bi-aspheric micro-monovision ablation profile is safe and efficacious. The postoperative outcomes indicate improvements in binocular vision at far, intermediate, and near distances with improved contrast sensitivity. A 19% retreatment rate should be considered to increase satisfaction levels, besides a 3% reversal rate.

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