

# Presbyopia Treatment by Monocular Peripheral PresbyLASIK

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## ABSTRACT

**PURPOSE:** To investigate monocular peripheral presbyLASIK on the non-dominant eye with distance-directed monofocal refractive surgery on the dominant eye in treating presbyopia.

**METHODS:** One hundred three patients underwent treatment with a VISX S4 system and follow-up from 1.1 to 3.9 years (mean 27.4 months). Average patient age was 53.3 years. Preoperative refraction ranged from  $-9.75$  to  $+2.75$  diopters (D). Non-dominant eyes underwent peripheral presbyLASIK—an aspheric, pupil-size dependent LASIK to induce central corneal relative flattening and peripheral corneal relative steepening. Dominant eyes underwent monofocal refraction-based LASIK (75.8%), wavefront-guided LASIK, limbal relaxing incisions, or no treatment to optimize distance vision.

**RESULTS:** At final follow-up, 91.3% (94/103) of all patients, 89% (25/28) of hyperopes, and 92% (69/75) of myopes reported complete spectacle independence and 7.8% (8/103) used spectacles for less than 1 hour per week. Distance unaided visual acuity was at least 20/20 in 67.9% (19/28) of hyperopes and 70.7% (53/75) of myopes, at least 20/20 at 80 cm in 85.7% (24/28) of hyperopes and 84% (63/75) of myopes, and at least 20/20 at 40 cm in 71.4% (20/28) of hyperopes and 65.3% (49/75) of myopes. PresbyLASIK increased overall higher order aberrations similarly to refraction-based LASIK for myopes but to a greater extent in hyperopic cases. PresbyLASIK WaveScan spherical equivalent refraction was stable in myopes but migrated an average  $+0.31$  D in hyperopes over the follow-up period.

**CONCLUSIONS:** Monocular peripheral presbyLASIK is a valuable option for presbyopic patients considering refractive surgery. [*J Refract Surg.* 2009;25:516-523.] doi:10.3928/1081597X-20090512-05

**A**spheric corneal LASIK laser ablation to produce a relatively more highly curved central cornea and a relatively flat midperipheral cornea has been termed “central presbyLASIK” by Alió et al,<sup>1</sup> who reported their surgical results using a proprietary ablation profile with 6-month follow-up. Another proprietary central presbyLASIK technique was described and patented by Ruiz<sup>2</sup> and independently tested by Jackson<sup>3</sup> in Canada.

Peripheral presbyLASIK with a relatively flatter central cornea and more highly curved corneal midperiphery was described by Avalos<sup>4</sup> (PARM technique), and a proprietary peripheral presbyLASIK algorithm was described and patented by Tamayo.<sup>5</sup> Telandro<sup>6</sup> reported 3-month follow-up results on a different peripheral presbyLASIK algorithm.

McDonnell et al<sup>7</sup> first described improved visual acuity from a multifocal effect after radial keratotomy. Moreira et al<sup>8</sup> was the first to report the use of laser refractive surgery to reduce symptoms of presbyopia.

Monovision is a well-established optical correction technique that employs the use of contact lenses and LASIK.<sup>9-12</sup> It works best for people who are only mildly presbyopic, but vision at reading distance or at intermediate distance diminishes with increasing age.

The goal of the present multi-year clinical study was to determine the outcome of the combination of monofocal distance vision correction on the dominant eye and peripheral presbyLASIK on the non-dominant eye. PresbyLASIK ablations were set to optimize acuity for reading and intermediate distance, and the ablation was designed to be potentially easily reducible to monofocal distance correction in case of patient dissatisfaction. Ablations were designed to produce equal

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The authors have no financial interest in the materials presented herein.

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Received: July 4, 2007; Accepted: June 18, 2008

Posted online: July 31, 2008

vision between eyes at midrange working distance. A related goal was for patients to attain unaided stereoacuity at intermediate distance that was comparable to the preoperative spectacle-corrected stereoacuity at reading distance.

## PATIENTS AND METHODS

### STUDY DESIGN

This study was an open-label, interventional, prospective, non-comparative evaluation. Institutional Review Board approval was obtained. All patients were informed and signed consent in accordance with the tenets of the World Medical Association Declaration of Helsinki. All patients had follow-up of at least 1 year. Follow-up ranging from 1.1 to 3.9 years (average 27.4 months) on 103 patients (47 men and 56 women) is reported. All patients who had retreatment were followed for at least 1 year beyond retreatment.

### DEMOGRAPHICS

Inclusion criteria were age 45 to 66 years, desire for spectacle independence, distance best spectacle-corrected visual acuity (BSCVA) of at least 0.8 in each eye, central corneal thickness of at least 500  $\mu\text{m}$ , spherical equivalent refraction between  $-10.00$  and  $+2.75$  diopters (D), normal corneal topography patterns, significant presbyopic symptoms, and no sign of cataract based on slit-lamp examination, no history of radial keratotomy, pupil center within 2 mm of the corneal apex light reflex, sufficient corneal thickness for residual corneal bed thickness to exceed 275  $\mu\text{m}$ , and no US Food and Drug Administration (FDA) exclusions for LASIK. Patients were classified as either myopes or hyperopes according to the spherical equivalent refraction of the eye that received presbyLASIK ablation.

The study comprised 75 myopes with a mean preoperative spherical equivalent refraction of  $-3.72 \pm 2.41$  D (range:  $-9.75$  to  $-0.12$  D) and 28 hyperopes with a mean preoperative spherical equivalent refraction of  $+0.99 \pm 0.70$  D (range:  $+0.12$  to  $+2.75$  D). At final postoperative follow-up, mean patient age among myopes was  $52.3 \pm 33.7$  years (range: 46.3 to 63.9 years) and  $56.1 \pm 4.3$  years (range: 47.9 to 65.4 years) among hyperopes. Scotopic pupil diameter at the time of surgery ranged from 3.5 to 7.2 mm by Colvard pupillometer (Oasis Medical, Glendora, Calif) and 3.65 to 8.55 mm by WaveScan pupillometry (VISX, Santa Clara, Calif). All patients had a corneal curvature between 39.00 and 47.50 D.

Peripheral presbyLASIK was applied to each patient's non-dominant eye. In the dominant eyes of the hyperopic group, 6 eyes had no surgery, 2 eyes had limbal relaxing incisions, and the remaining 20 eyes

had refraction-based LASIK. In the dominant eyes of the myopic group, 4 eyes had no surgery, 1 eye had limbal relaxing incisions, and the remainder had LASIK of which 10 eyes had a wavefront-guided procedure and 60 had a refraction-based procedure. Dominance was determined by history and the Miles test. Patient acceptance of monovision was determined by history, the application of  $+1.00$  lenses over the patient's distance correction in the non-dominant eye, and in 2 cases, by the application and multi-day testing of a  $+1.00$ -D soft contact lens over the non-dominant eye worn along with the regular distance spectacle correction.

All patients underwent initial procedures between March 27, 2003, and December 9, 2004, with follow-up until March 3, 2008. Our goal, which was achieved, was to have 100% follow-up for  $>1$  year. Some patients, initially lost to follow-up, were telephoned, called back to the office, and returned (sometimes from out of state) for a final visit. All but one patient follow-up occurred at our institute. Follow-up of patients was performed by the authors (R.L.E., M.A.G.) and also by Barbara J. Tazioli, COT, and Jung M. Rhee, MD, of Mercy Health System and Bruce H. Brumm, MD, in practice in Omaha, Nebraska.

### MAIN OUTCOME MEASURES OF STUDY

Measures of the effectiveness of surgery included the following: 1) patient reporting of the number of hours per week that any form of spectacles was needed; 2) scotopic distance vision measured with standardized scotopic projection charts; 3) photopic unaided vision at 80 cm and 40 cm on ETDRS charts; 4) photopic and scotopic near point acuity with distance correction; 5) mesopic vision at 40 cm; and 6) wavefront-derived refraction, manifest and cycloplegic refractions.

Measures of safety included: 1) patient reporting of difficulty with vision; 2) aberrometry; 3) Titmus stereoacuity at working distance; and 4) postoperative contrast sensitivity comparison between monofocally treated and multifocally treated eyes.

Pre- and postoperative WaveScan scotopic pupil size and total higher order aberrations, spherical aberration, coma, and trefoil were also analyzed.

### SURGICAL TECHNIQUE, SOFTWARE, ABLATION PROFILE, AND LASIK TECHNIQUE

In this study of our earliest series of patients who had procedures performed during 2003 and 2004, the ablation was divided into two parts to accomplish the presbyLASIK ablation on the non-dominant eye. The parts were 1) a myopic central ablation that was halted at a pupil size-dependent ablation diameter, and 2) a second ablation that was completed and set so that the

algebraic sum of the dioptric power of the second ablation plus the dioptric power of the first ablation was equal to the refraction being corrected. The method for reversal of presbyLASIK, if necessary, consisted of completion of the halted ablation.

All ablations took place using a VISX S4 laser operated with standard temperature and humidity controls. All ablations were centered over the pupil. Laser in situ keratomileusis flaps were created using a BD K-4000 microkeratome (Becton Dickinson, Franklin Lakes, NJ) targeting a 10.0-mm flap and 4-mm nasal hinge, with keratome ring and plate variations based on the preoperative keratometry, corneal diameter, and microkeratome manufacturer's guide. Flap thickness was set at 130  $\mu\text{m}$  or, in the case of thicker corneas, at 160  $\mu\text{m}$ , so the remaining corneal bed would be at least 275  $\mu\text{m}$ . During the year 2003, an automatic corneal shaper (ACS; Bausch & Lomb Surgical, Miami, Fla) was used for creating LASIK flaps.

To obtain the maximum patient spectacle independence in these presbyopic patients, we expected to perform fine-tuning second ablations for patients who had even the slightest perceptible ametropia causing any degree of spectacle dependence or perceived suboptimal vision, and patients agreed to that process. Retreatment was performed no less than 10 weeks postoperatively, and in one case, retreatment was delayed for 2 years for symptoms of ametropia to develop before retreating. Retreatments included refraction-based LASIK, wavefront-guided LASIK, and limbal relaxing incisions.

#### **FOLLOW-UP AND DATA ANALYSIS**

Follow-up examinations included refraction, wavefront mapping, measurements of stereoacuity, photopic and mesopic uncorrected visual acuity (UCVA), distance corrected near point acuity, and pupillometry. A comparison of the postoperative contrast sensitivity between monofocally and multifocally treated eyes was performed.

Statistical analysis was performed with SPSS/15.0 for Windows (SPSS, Chicago, Ill). The Student *t* test was applied to compare data sample means, and differences were considered statistically significant when  $P \leq .05$ .

### **RESULTS**

#### **SAFETY**

The monocular safety index ratio is the mean over individual eyes of the ratio of final postoperative distance BSCVA/preoperative distance BSCVA.

In the hyperopic group of distance LASIK eyes, two eyes gained one line of vision and one eye lost one line of vision. In addition, the distance LASIK eye of one

hyperopic patient lost no lines of vision by 1 year postoperative but lost two lines of vision in the second year of follow-up due to an evolving lens nuclear opacity. In the hyperopic group, the monocular safety index ratio for distance LASIK was 1.0067. One distance eye in the hyperopic group gained one line from a punctal plug but had no surgery.

In the hyperopic group of 28 presbyLASIK eyes, the monocular safety ratio was 0.9952. Two eyes gained one line and 4 eyes lost one line of correctable vision.

In the myopic group, the ratio for distance LASIK eyes was 1.0093. Four eyes gained one line and 3 eyes lost one line of vision. For the 75 presbyLASIK eyes in the myopic group, the monocular safety ratio was 0.9909, with 3 eyes gaining one line and 8 eyes losing one line of BSCVA. No patient lost lines of BSCVA in both eyes.

#### **EFFICACY**

Preoperatively, all patients used spectacle correction. At the end of follow-up, 91.3% (94/103) reported no spectacle use, 7.8% (8/103) used spectacles for less than 1 hour per week, and 1 (0.97%) patient reported using spectacles 20 hours a week.

Of the 28 hyperopes, 25 (89%) became completely spectacle free, 2 (7%) wore spectacles  $\leq 1$  hour per week, and 1 (4%) patient with late-onset nuclear sclerosis wore spectacles 20 hours a week. At final measurement, 67.9% (19/28) achieved distance visual acuity of at least 20/20, 85.7% (24/28) achieved at least 20/20 at 80 cm, and 71.4% (20/28) achieved at least 20/20 at 40 cm.

Of the 75 myopes, 69 (92%) became completely spectacle free and 6 (8%) wore spectacles for  $\leq 1$  hour per week. At final follow-up, binocular vision was as follows: 70.7% (53/75) achieved at least 20/20 at distance, 84% (63/75) achieved 20/20 at 80 cm, and 65.3% (49/75) achieved at least 20/20 at 40 cm.

Overall, 73.3% (55/75) myopes and 75% (21/28) hyperopes achieved a combination of binocular UCVA of at least 20/25 at distance, 40 cm, and 80 cm. A total of 44.0% (33/75) of myopes and 39.3% (11/28) hyperopes achieved a binocular UCVA of at least 20/20 at all three distances.

Average logMAR UCVA for all presbyLASIK treated eyes was 20/22.6 at 40 cm and 20/21.8 at 80 cm at 180  $\text{cd}/\text{m}^2$  lighting, and 20/63.9 at distance as measured by projection charts. Results of the hyperopic and myopic groups were similar. Average UCVA in the hyperopic group was 20/24.0 at 40 cm, 20/22.6 at 80 cm, and 20/57.3 at distance. For the myopic presbyLASIK treated eyes, average UCVA was 20/22.1 at 40 cm, 20/22.5 at 80 cm, and 20/65.2 at distance.

For eyes treated with distance LASIK, the distance efficacy index (ratio of the mean postoperative distance UCVA/preoperative distance BSCVA) was 0.94 in the hyperopic eyes treated with refraction-based LASIK and 0.96 in that same group when the patient whose distance eye developed a nuclear cataract is excluded. For myopes, the ratio was 0.93 overall, 0.97 for those receiving wavefront-guided LASIK, and 0.92 for those receiving refraction-based LASIK.

Peripheral presbyLASIK produced an advantage for near point vision at 40 cm as compared to monofocal distance LASIK when testing both eyes using spectacle correction for distance. The relative advantage of presbyLASIK over monofocal LASIK at near was more pronounced in low light. In the hyperopic group, in room light, the logMAR average vision of presbyLASIK eyes was 20/37.2 but monofocal eyes averaged only 20/75.2, and in 10 cd/m<sup>2</sup> light the presbyLASIK eyes averaged 20/39.5 compared to only 20/139.4 for monofocal eyes. In the myopic group, in room light, the presbyLASIK eyes averaged vision of 20/37.6 but monofocal eyes averaged only 20/76.9, and in the low light, the vision of presbyLASIK eyes averaged 20/43.6 whereas the monofocal average vision was only 20/138.4.

Postoperative distance UCVA using an ETDRS chart was compared to distance UCVA obtained using standardized projection chart testing in 23 monofocal LASIK eyes and 30 presbyLASIK eyes. ETDRS visual acuity values were generally more favorable than acuity values on the same eyes taken with the projection chart. The average ratio of acuity taken with the ETDRS chart to that taken with the projection chart was 1.04 for monofocal distance eyes and 1.22 for presbyLASIK eyes.

In the hyperopic group, the resultant refractive spherical equivalent averaged  $+0.21 \pm 0.43$  D in the distance eyes and  $-0.86 \pm 0.68$  D in the presbyLASIK group. The average refractive cylinder was  $+0.39 \pm 0.38$  D in the distance eyes and  $+0.58 \pm 0.57$  D in the presbyLASIK eyes.

In the myopic group, the resultant refractive spherical equivalent averaged  $-0.04 \pm 0.39$  D in the distance eyes and  $-1.24 \pm 0.63$  D in presbyLASIK eyes. The average refractive cylinder was  $+0.30 \pm 0.29$  D in distance eyes and  $+0.37 \pm 0.37$  D in presbyLASIK eyes.

#### ABERRATIONS

Ideally, aberration measurements are compared with equally sized pupils (eg, 6 mm). In the current study, WaveScan aberrometry readings were taken under identical lighting conditions in the same room, but pupil sizes were randomly distributed, not all 6 mm. Furthermore, a statistically significant decrease

was noted in the average pupil size between the preoperative average of 5.95 mm and the average of 5.69 mm at the end of the study ( $P < .0001$ ), which might cause an understatement of increases in acquired aberrations compared to what might have occurred if the lights in the WaveScan room had been individually adjusted to cause equal pupil sizes.

In monofocally treated eyes, average total higher order aberrations decreased in the few wavefront-guided cases, all myopes, taken as a group (from  $0.36 \mu\text{m}$  preoperatively to  $0.32 \mu\text{m}$  postoperatively). Total average higher order aberrations increased in the refraction-based cases (for myopes from  $0.30 \mu\text{m}$  preoperatively to  $0.42 \mu\text{m}$  postoperatively and for hyperopes from  $0.30 \mu\text{m}$  preoperatively to  $0.38 \mu\text{m}$  postoperatively). Average spherical aberration increased in myopes (from  $0.12 \mu\text{m}$  preoperatively to  $0.17 \mu\text{m}$  postoperatively) but decreased in hyperopes (from  $0.09 \mu\text{m}$  preoperatively to  $0.04 \mu\text{m}$  at postoperatively).

PresbyLASIK eyes had statistically significant increases in total higher order aberrations between preoperatively and the end of the study in all categories in myopic ( $0.32 \mu\text{m}$  to  $0.49 \mu\text{m}$ ) and hyperopic eyes ( $0.34 \mu\text{m}$  to  $0.52 \mu\text{m}$ ). Also, higher order aberration components generally increased in trefoil (for myopes from  $0.14$  to  $0.18 \mu\text{m}$  and for hyperopes from  $0.17$  to  $0.25 \mu\text{m}$ ) and coma (for myopes from  $0.18 \mu\text{m}$  to  $0.21 \mu\text{m}$  and for hyperopes from  $0.20$  to  $0.30 \mu\text{m}$ ). Spherical aberration increased from  $0.15$  to  $0.25 \mu\text{m}$  in myopic eyes but decreased from  $0.09 \mu\text{m}$  to  $-0.01 \mu\text{m}$  for hyperopes.

#### STABILITY

The refractive results were generally stable over time. Statistical analysis of stability was performed only on eyes that had experienced a single operation and only on those that had undergone LASIK or presbyLASIK but not limbal relaxing incisions. Spherical equivalent refractions derived from manifest refraction and wavefront mapping were examined. Data from the final follow-up examination were compared to values taken at the midpoint in the study, occurring at an average of 12.9 months postoperatively for these patients. Paired sample *t* testing was performed.

In preoperative myopic eyes, the average spherical equivalent refraction did not change noticeably among the monofocal or presbyLASIK eyes between mid-study and final measurements as measured by manifest refraction or from wavefront mapping.

In preoperative hyperopic eyes, the change in wavefront mapping spherical equivalent refraction between mid-study and final follow-up was insignificant for monofocal eyes, but for presbyLASIK eyes a hyperopic shift of  $+0.31$  D ( $P = .24$ ) occurred.

### ADVERSE SYMPTOMS

Bothersome anisometropia was experienced by a 46-year-old man whose unaided near point vision in his distance monofocal eye was also unexpectedly excellent. The patient elected to have reversal of the presbyLASIK correction to match the monofocal eye, which was successful. After the conversion of presbyLASIK to pure distance correction, the patient was spectacle-free.

Night halo/glare from the non-dominant, myopic presbyLASIK eye was the most common symptom and was present in 55% of patients at 1 week postoperative. Nighttime halo from the presbyLASIK eye was noted in 14.6% (15/103) of all patients at 90 days postoperative including 14% (4/28) of hyperopes and 15% (11/75) myopes. Nighttime halo was present at 6 months postoperatively in 7.8% (8/103) of all patients, 7.1% (2/28) of hyperopes, and 8% (6/75) of myopes. Inadequate unaided night vision in the presbyLASIK eye led 2 patients (1 myope and 1 hyperope) to the occasional use of spectacles for night driving, which eliminated the night halo.

No patient reported halo, glare, or starburst during daylight after 90 days postoperatively.

### CONTRAST SENSITIVITY

Photopic and scotopic contrast sensitivity were compared among monofocally treated eyes and presbyLASIK eyes. With distance BSCVA, no statistical difference was noted between monofocal LASIK eyes and presbyLASIK eyes on the VectorVision GSV-1000 device (VectorVision, Greenville, Ohio). Similarly, uncorrected presbyLASIK eyes did not statistically differ from monofocal LASIK eyes with near point spectacle correction at 40 cm on the Vistech contrast test (Vistech Consultants Inc, Dayton, Ohio) at 1.5, 3, 12, or 18 cycles per degree.

### STEREOACUITY

No significant change occurred in stereoacuity from monocular presbyLASIK. Titmus stereoacuity was tested preoperatively at 40 cm with near point correction and was tested without spectacle correction at 70 cm postoperatively. Stereoacuity readings at 70 cm were multiplied by the quantity (4/7) to be compared with the preoperative readings. This testing was performed in 40 consecutive postoperative patients at final follow-up. The preoperative logMAR average stereoacuity was 45.5 seconds and 30.4 seconds postoperatively. Thus, no diminution of stereoacuity occurred. Comparison of Titmus stereoacuity at different distances is reasonable because at the small angles of resolution, the arc and sine of the arc are inversely proportional to the

distance of the stereo test from the patient's eye.

Patient complaints of depth perception were scant. One patient, who usually worked threading wire under a magnifying glass, reported the need to change his method slightly but stated he was not inconvenienced.

### RETREATMENTS

Our goal was to maximize spectacle independence, and anyone needing spectacles for any purpose or who had complaints regarding visual quality after 10 weeks postoperatively became a possible candidate for retreatment. Limbal relaxing incisions were used to correct residual astigmatism of  $\leq 0.75$  D where there was no need to change spherical equivalent refraction. For cases requiring any change in spherical equivalent refraction, monofocal LASIK was performed. There were no second retreatments. At least 1-year follow-up beyond the time of retreatment was available in all cases.

Among the 150 eyes in the myopic group, 18 limbal relaxing incision retreatments were performed, of which 9 were in monofocal eyes and 9 were among presbyLASIK eyes. In the myopic group, 25 LASIK retreatments were performed, of which 14 were on monofocal distance eyes and 11 on presbyLASIK eyes. Thus, among myopic presbyLASIK eyes, 26.6% (20/75) were retreated with either limbal relaxing incisions or LASIK. Among the retreatments of distance LASIK eyes, no retreatments occurred in eyes initially corrected by wavefront-guided ablation.

Among the 56 eyes of the hyperopic group, 4 limbal relaxing incisions were performed, of which 2 were in presbyLASIK eyes. In the hyperopic group, 9 LASIK retreatments were performed, of which 3 were on monofocal distance eyes and 6 on presbyLASIK eyes. Thus, 28.6% (8/28) of hyperopic presbyLASIK eyes were retreated with either limbal relaxing incisions or LASIK.

### DISCUSSION

The results of monocular peripheral presbyLASIK analyzed herein, especially in the hyperopes, can be compared to the binocular central presbyLASIK series by Alió et al.<sup>1</sup> In their study, 6 (12%) of 50 eyes were retreated with standard LASIK for distance. After 6 months, 16 (64%) patients achieved a distance UCVA of at least 20/20 and 18 (72%) patients achieved a near UCVA of at least 20/40. They also reported 7 (28%) patients lost a maximum of 2 lines of BSCVA for distance.<sup>1</sup>

Our study and the study by Alió et al are not strictly comparable as their follow-up was only 6 months. We had 100% follow-up at 1.1 to 3.9 years postoperatively with at least 1-year additional follow-up in all cases that underwent retreatment. On the other hand, we did not have 100% follow-up at 6 months in all cases.

TABLE  
**Patient Outcome Summary of Monocular Peripheral PresbyLASIK Study**

	Hyperopic	Myopic
Average patient age at final eye exam (y)	56.1	52.3
No. patients	28	75
Average follow-up (mo)	27.9	27.1
No. patients spectacle-free (%)	25 (89)	69 (92)
No. patients who wore spectacles <1 h/wk (%)	2 (7)	6 (8)
Binocular UCVA of at least 20/20 (%)		
At distance	67.9	70.7
At 80 cm	85.7	84.0
At 40 cm	71.4	65.3
Binocular UCVA at distance AND at 80 cm AND at 40 cm of at least (%)		
20/25	75.0	73.3
20/20	39.3	44.0
Average UCVA in presbyLASIK eyes (logMAR)		
At distance	20/57.3	20/65.2
At 80 cm	20/22.6	20/22.5
At 40 cm	20/24.0	20/22.1
Average SE of presbyLASIK eyes	-0.86	-1.25
Monocular safety index (BSCVA postop/preop)		
All monofocal eyes	1.0067	1.0093
All presbyLASIK eyes	0.9952	0.9909
Nighttime halos in unaided presbyLASIK eyes* (%)		
At 90 days postoperative	14	15
At 6 months postoperative	7.1	8
Ratio of postoperative to preoperative total HOA		
Wavefront-guided monofocal LASIK	n/a	0.89
Refraction-based monofocal LASIK	1.40	1.27
PresbyLASIK	1.529	1.531
Monofocal eyes with wavefront-guided LASIK (%)	0	8
Vision in peripheral presbyLASIK eyes was maintained in low light		
Monofocal and PresbyLASIK vision at 40 cm	Photopic	Mesopic
With full distance correction	(180 cd/m <sup>2</sup> )	(10 cd/m <sup>2</sup> )
Monofocal	20/75.2	20/139.4
PresbyLASIK	20/37.2	20/39.5
No statistical difference in contrast sensitivity between monofocal LASIK-treated eyes and presbyLASIK-treated eyes		

UCVA = uncorrected visual acuity, SE = spherical equivalent refraction, BSCVA = best spectacle-corrected visual acuity, HOA = higher order aberrations  
 \*Two patients chose spectacles for some night driving. Halos were eliminated.

In the current study, 67.9% (19/28) of hyperopic patients achieved distance UCVA of at least 20/20 and 96.4% (27/28) achieved near UCVA of at least 20/40. Among 28 hyperopic presbyLASIK eyes in our study, 4 (14.3%) eyes lost one line of BSCVA for distance.

At final follow-up, 91.3% (94/103) of all patients, 89% (25/28) of hyperopes, and 92% (69/75) of myopes reported spectacle independence and 7.8% (8/103) used spectacles for <1 hour per week. Binocular distance UCVA was at least 20/20 in 67.9% (19/28) of hy-

peropes and 70.7% (53/75) of myopes, at least 20/20 at 80 cm in 85.7% (24/28) of hyperopes and 84% (63/75) of myopes, and at least 20/20 at 40 cm in 71.4% (20/28) of hyperopes and 65.3% (49/75) of myopes. Patient outcomes are summarized in the Table.

How does the vision of monocular peripheral presbyLASIK compare with that of monofocal monovision LASIK? A technology and patient-age matched study might answer the question best, but we can hypothesize. The presbyLASIK eyes in our study could read letters half the size of what the monofocal eyes could read in full room light and one-third the size under mesopic lighting when both eyes were fully corrected for distance. A significant number of our patients who, prior to surgery, had become unsuccessful with contact lens monovision, became successful monocular peripheral presbyLASIK patients. Also, with our experience of patients met subsequent to the current report, we successfully retreated previous monovision LASIK patients who either became visually compromised with increasing age or who were never satisfied with monovision LASIK.

The monovision LASIK study with the best visual acuities at the time of our current report was the FDA clinical study using VISX monovision wavefront-guided LASIK with iris registration.<sup>12</sup> This study included myopes with an average age of 50.2 years, in which 91.9% achieved near point acuity of 20/20 or better at 16 inches (48 cm) and 88.6% at 60 cm; however, no acuity data were offered for vision at a midrange of 80 cm. The monovision LASIK report of Braun et al<sup>11</sup> indicates that 7% of monovision patients elected to reverse the monovision and tolerate presbyopia. We have had no patient, including those in the current report, who elected reversal in favor of using reading glasses.

The optical results show good stability. Patients in our study have remained spectacle-free for as long as 3.9 years. Retreatments were performed as a result of optical issues that were detectable by cycloplegic refraction within the first 4 months although not immediately symptomatic. The one stability issue was a statistically significant regression back toward hyperopia of +0.31 D during the second half of the follow-up period in a small group of hyperopic presbyLASIK eyes.

The science of presbyLASIK is evolving and standards for studies on presbyLASIK also need to be developed much as ANSI Z80 12-2007 (American National Standards Institute, Washington, DC) has been developed for multifocal intraocular lenses. Our study suffers in the technology from the lack of wavefront-guided procedures in most patients, the lack of iris registration, and the need to have two separately cen-

tered ablations for the bifocal treatment, and in study design from the use of projection charts for distance (which also somewhat understated distance vision of the presbyLASIK eyes compared to vision taken with ETDRS backlit charts), the lack of preoperative contrast sensitivity testing (providing only the comparison of contrast sensitivity between postoperative monofocal LASIK and presbyLASIK), and the smaller size of the hyperopic group than the myopic group.

Initially, we chose to perform presbyLASIK on only the non-dominant eye for safety reasons in that the ablation could be converted to pure distance LASIK. As mentioned by Braun et al,<sup>11</sup> "The distance vision eye in the monovision patient may have a lower tolerance for residual refractive error and require a higher rate of enhancements than a standard laser vision correction patient." To achieve best distance correction and minimize retreatments, wavefront-guided distance LASIK is performed on the dominant eye, which we believe has been proven to provide best distance vision. Due to the good midrange vision attained with monocular peripheral presbyLASIK, we have found that it is much more tolerable than classical monovision in people of the same age. Furthermore, we have not yet seen a binocular presbyLASIK report in which the surgeon did not ultimately retreat some patients to produce a mild version of monovision to optimize acuity at distance and near.

Although monocular peripheral presbyLASIK produced high acceptance and spectacle independence rates, our retreatment rate was much higher than the rate reported by Alió et al,<sup>1</sup> which was in turn much higher than we normally see in young patients. None of the wavefront-guided distance eyes in this study needed retreatment. Subsequent to this study, our retreatment rates have fallen dramatically due to an improved presbyLASIK algorithm and the use of wavefront-guided distance LASIK. Also, we have found that many patients, both women and men in the presbyLASIK age group, benefit from punctal occlusion and reinstallation of plugs years later as the plugs disappear. Considering the results of this study and our more recent results, monocular peripheral presbyLASIK is a valuable alternative in the treatment of presbyopia and probably the preferred LASIK treatment for people aged 48 years and older.

### AUTHOR CONTRIBUTIONS

*Study concept and design (R.L.E.); data collection (R.L.E., M.A.G.); interpretation and analysis of data (R.L.E.); drafting of the manuscript (R.L.E.); critical revision of the manuscript (R.L.E., M.A.G.); statistical expertise (R.L.E.); obtained funding (R.L.E.); administrative, technical, or material support (R.L.E., M.A.G.)*

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