

# Presbyopic Correction Using Monocular Bi-aspheric Ablation Profile (PresbyMAX) in Hyperopic Eyes: 1-Year Outcomes

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## ABSTRACT

**PURPOSE:** To present the 1-year outcomes of combining monocular bi-aspheric ablation profile and contralateral monofocal LASIK in hyperopic patients with presbyopia.

**METHODS:** In this retrospective case series, 36 consecutive patients (72 eyes) who underwent simultaneous bi-aspheric ablation (PresbyMAX: SCHWIND Eye-Tech-Solutions GmbH and Co KG, Kleinostheim, Germany) in the non-dominant eye and monofocal regular LASIK in the dominant eye for correction of hyperopia and presbyopia were reviewed for 1 year. Binocular uncorrected distance (UDVA), near (UNVA), corrected distance (CDVA), and distance corrected near (DCNVA) visual acuity and manifest refraction were analyzed postoperatively.

**RESULTS:** At 1 year, the mean binocular UDVA improved significantly from  $0.26 \pm 0.25$  to  $0.039 \pm 0.088$  logMAR ( $P < .001$ ). Binocular UNVA also improved from  $0.73 \pm 0.30$  to  $0.10 \pm 0.22$  logRAD ( $P < .001$ ). Eighty-seven percent of patients achieved UDVA of 20/25 or better and 90% had UNVA of J3 or better. Simultaneous binocular distance and near vision of 20/25 and J2 or better was achieved in 70%. Only 17% of patients had a binocular DCNVA of J2 or better. No patient suffered from a loss of 2 lines of CDVA. Refractive stability was achieved for both eyes from 1 month postoperatively. The re-treatment rate was 14% for improvement of near vision within 6 months to 1 year.

**CONCLUSIONS:** Presbyopic correction using monocular PresbyMAX combined with monofocal regular LASIK in the fellow eye is safe and acceptable in hyperopic patients.

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Presbyopia is an age-related condition associated with a decrease in accommodation leading to difficulty in focusing for near objects. Over the years, corneal presbyopia corrections have evolved from the monovision and multifocal ablation techniques to hybrid methods combining the benefits of several techniques.<sup>1</sup> Monovision is a well-established presbyopic correction technique by inducing intentional anisometropia.<sup>2</sup> Presbyopic LASIK (presbyLASIK) is another approach aiming to compensate the effect of presbyopia by creating a multifocal cornea using special ablation profiles.<sup>3</sup> PresbyMAX (SCHWIND Eye-Tech-Solutions GmbH and Co KG, Kleinostheim, Germany) is a central multifocal presbyLASIK approach based on the creation of a bi-aspheric multifocal corneal surface with a central hyperpositive area to achieve near correction, surrounded by an area for distance correction. It has demonstrated good binocular near vision but reduced far vision, which translates to a compromised safety of the procedure.<sup>4</sup> Several hybrid methods to correct presbyopia reported good uncorrected near and distance vision, including a combined extended depth of field with micro-monovision, also known as laser blended vision,<sup>5-7</sup> and a combined peripheral presbyLASIK procedure in the non-dominant eye with monofocal distance correction in the dominant eye.<sup>8</sup> A recent study on a hybrid method combining micro-monovision and PresbyMAX also reported excellent outcomes in achieving full range of vision.<sup>9</sup>

The current study presents the 1-year results of combining monocular bi-aspheric ablation profile (PresbyMAX) and contralateral monofocal distance correction in patients with bilateral hyperopia and presbyopia.

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## PATIENTS AND METHODS

### PARTICIPANTS

In this study, we retrospectively analyzed the case records of all consecutive patients who underwent simultaneous bi-aspheric ablation in one eye and monofocal regular LASIK in the fellow eye to correct hyperopia and presbyopia between May 2013 and December 2014 at Hong Kong Laser Eye Center. The study adhered to the tenets of the Declaration of Helsinki and was approved by the institutional review board at New Territory East Cluster, Hong Kong.

Inclusion criteria were age 45 years or older, presbyopia, medically suitable for LASIK, corrected distance visual acuity (CDVA) of 20/25 or better in either eye, stable refraction for 1 year, discontinued use of contact lenses for at least 4 weeks prior to preoperative evaluation, and photopic pupil diameter smaller than 3 mm and larger than 4.5 mm in scotopic condition. Exclusion criteria included abnormal topography, estimated residual bed thickness of 300  $\mu\text{m}$  or less, history of previous ocular surgery, systemic illness, ocular diseases, and any signs of unilateral or bilateral visual anomalies at distance and near, except refractive errors or presbyopia.

### PREOPERATIVE ASSESSMENT

Preoperative assessment included slit-lamp and fundus examination by an ophthalmologist. Monocular and binocular CDVA, uncorrected distance (UDVA), corrected near (CNVA), uncorrected near (UNVA), and distance corrected near (DCNVA) visual acuity were assessed. Near vision was assessed using the Jaeger eye chart at 35 cm. Corrected visual acuity was always assessed with trial frame and not contact lenses. Additional examination included manifest refraction, corneal topography, and aberrometry (Keratron: Optikon 2000 SpA, Rome, Italy).

### SURGICAL TECHNIQUE

The same surgeon (PSKK) performed all procedures. All treatments were prepared using the SCHWIND PresbyMAX treatment planning module in aspheric mode. The dominant eye was treated with regular monofocal LASIK toward distance vision. The non-dominant eye was treated with PresbyMAX. The addition was planned and selected within the range of +1.50 to +2.50 diopters (D). For each treatment, the planning software calculated the size of the treatment optimal transition zone and target refraction, depending on the age, preoperative refraction, and optical treatment zone.

LASIK flaps were created using the 150-kHz IntraLase femtosecond laser (Abbott Medical Optics, Abbott Park, IL). Stromal ablation was performed with AMARIS (SCHWIND Eye-Tech-Solutions GmbH and Co KG) us-

ing a 6.5-mm optical zone. Alignment of the eye with the laser was maintained with an infrared eye tracker with simultaneous limbus, pupil, and torsion tracking integrated into the laser system and centered on the corneal vertex. Aspheric non-wavefront-guided treatments were performed. The ablation profile was centered on the corneal vertex using pupillary offset measured with the topographer, which approximates the visual axis.<sup>10</sup> Patients were asked to look in the direction of the fixation light throughout the ablation. Following laser ablation of the stromal tissue, the flap was replaced and the stromal bed was washed with balanced salt solution.

Postoperatively, all patients received topical moxifloxacin 0.5% ophthalmic solution three times a day for 1 week. Preservative-free artificial tears were used for 3 months postoperatively.

### POSTOPERATIVE EVALUATION

Patients were reviewed at 1 day, 1 week, 1, 3, and 6 months, and 1 year postoperatively. Examinations included slit-lamp biomicroscopy, measurement of monocular and binocular UDVA, UNVA, CDVA, CNVA, DCNVA, and manifest refraction. Corneal aberrations at a 6-mm diameter were measured at 6 months. Overall patient satisfaction was assessed, including subjective visual performance in a highly illuminated environment and mid- and low-illuminated environments.

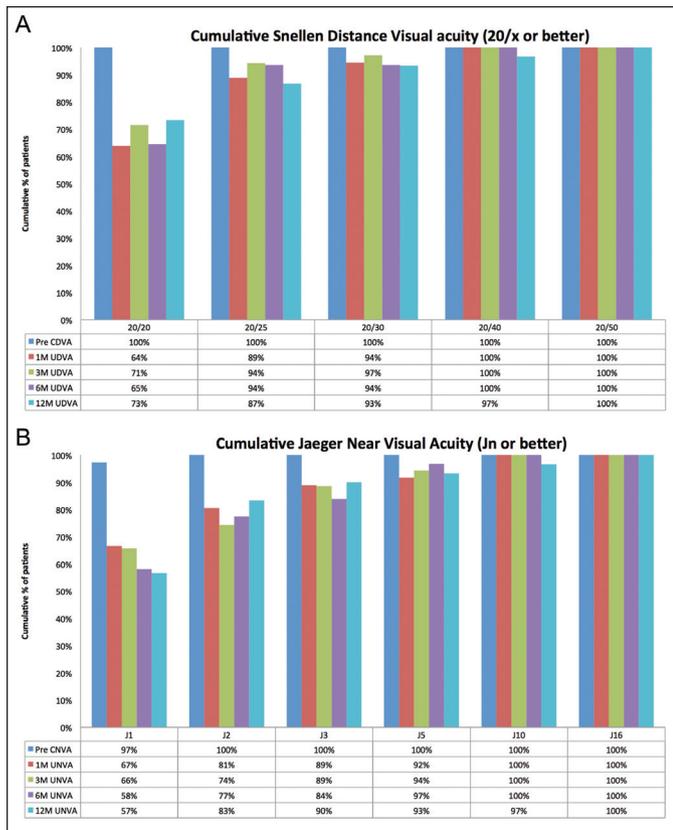
### STATISTICAL ANALYSIS

Statistical analyses were performed using IBM/SPSS software (version 21; SPSS, Inc., Chicago, IL). Descriptive statistics was reported. The Wilcoxon signed rank test was performed for preoperative and postoperative changes. The Mann-Whitney test was used for comparison between dominant and non-dominant eyes. Distance visual acuity was reported in logMAR and Snellen fractions, whereas near visual acuity was reported in logRAD and Jaeger scale. A *P* value of less than .05 was considered statistically significant.

### RESULTS

The outcomes 36 patients (72 eyes) were analyzed over 1 year. The mean age was  $53.1 \pm 4.0$  years. The mean binocular UDVA was  $0.26 \pm 0.25$  logMAR, which improved significantly to  $0.032 \pm 0.075$  logMAR at 6 months and  $0.039 \pm 0.088$  logMAR at 1 year ( $P < .001$ ). The mean binocular UNVA also improved significantly from  $0.73 \pm 0.30$  to  $0.079 \pm 0.12$  and  $0.10 \pm 0.22$  logRAD at 6 months and 1 year, respectively ( $P < .001$ ) (Figure 1).

At 6 months, 94% of patients achieved 20/25 or better binocular UDVA, and 77% achieved Jaeger level J2 or better binocular UNVA. The corresponding values

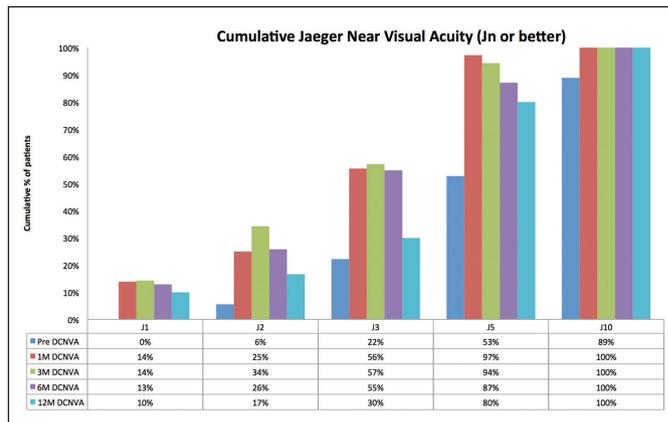


**Figure 1.** Changes in binocular (A) distance and (B) near uncorrected visual acuity at 1, 3, 6, and 12 months (M) after presbyopic corneal treatment. CDVA = corrected distance visual acuity; CNVA = corrected near visual acuity; UDVA = uncorrected distance visual acuity; UNVA = uncorrected near visual acuity

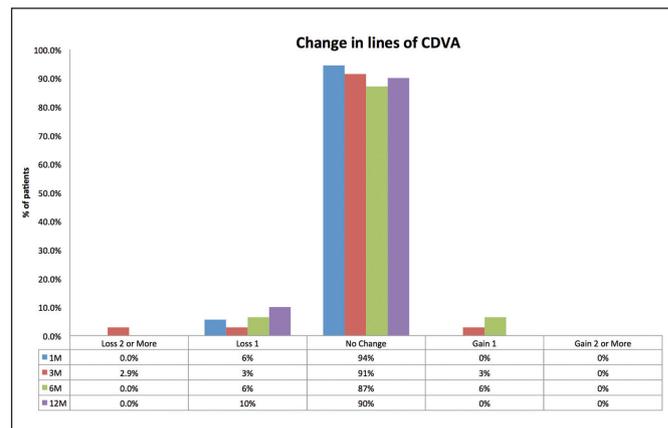
at 1 year were 87% and 83%, respectively. Simultaneous binocular distance and near vision of 20/25 and J2 or better was achieved in 71% at 6 months and 70% at 1 year postoperatively. At 6 months and 1 year, 77% of patients achieved simultaneous binocular distance and near vision of 20/25 and J3 or better.

The change in binocular DCNVA is shown in **Figure 2**. At 6 months, 26% of patients achieved Jaeger level J2 or better binocular DCNVA. At 1 year, only 17% of patients attained the same level. At 6 months, 93% of patients had no change or gain in Snellen lines of binocular CDVA. The corresponding value was 90% at 1 year. No patient suffered from a loss of two Snellen lines of binocular CDVA at 6 months and 1 year postoperatively (**Figure 3**).

The mean preoperative manifest refraction spherical equivalent was  $1.24 \pm 0.79$  and  $1.29 \pm 0.85$  D for dominant and non-dominant eyes, respectively ( $P = .804$ ). Target refraction was 0.00 D for the dominant eye receiving monofocal LASIK and  $-0.62 \pm 0.06$  D for the non-dominant eye receiving PresbyMAX. A good separation was observed between the dominant and non-dominant eye for postop-



**Figure 2.** Changes in binocular distance corrected near visual acuity (DCNVA) at 1, 3, 6, and 12 months (M) after presbyopic corneal treatment.

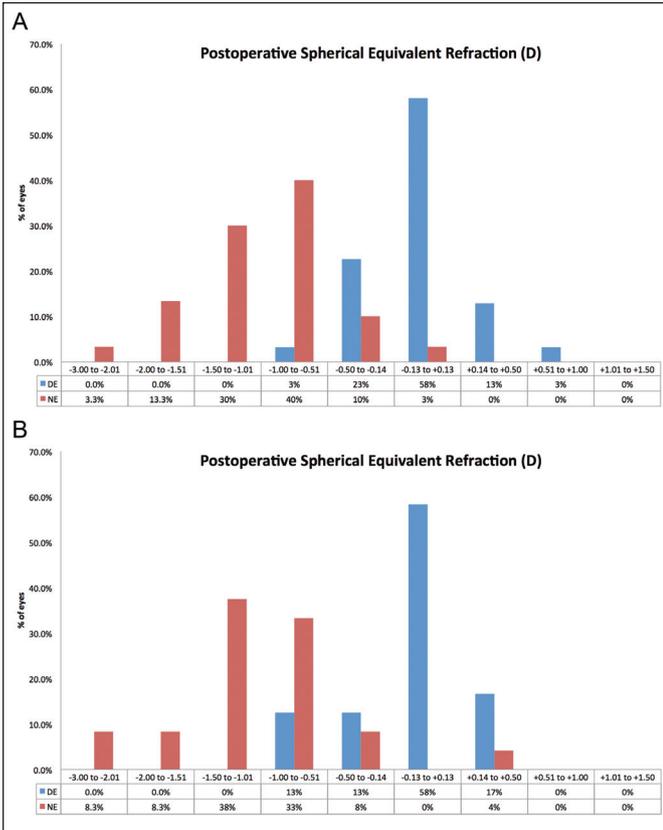


**Figure 3.** Changes in binocular corrected distance visual acuity (CDVA) at 1, 3, 6, and 12 months (M) after presbyopic corneal treatment.

erative refraction at 6 months and 1 year (**Figure 4**). The postoperative refraction was  $-0.030 \pm 0.33$  and  $-1.12 \pm 0.56$  D for dominant and non-dominant eyes at 6 months ( $P < .001$ ). At 1 year, it was  $-0.10 \pm 0.33$  and  $-1.15 \pm 0.64$  D, respectively ( $P < .001$ ), respectively. Refractive stability was achieved in both eyes from 1 month postoperatively (**Figure 5**). Corneal topography of the dominant eye and non-dominant eye of patients receiving this multifocal cornea-monovision approach is shown in **Figure A** (available in the online version of this article).

At 6 months, there was a statistically significant induction of negative spherical aberration after PresbyMAX and hyperopic LASIK ( $P < .001$ ), but greater in magnitude after PresbyMAX ( $P < .001$ ). The postoperative change in coma, trefoil, and total higher order aberrations did not reach statistical significance after either procedure ( $P < .061$ ). However, the change in total higher order aberrations was significantly different between fellow eyes ( $P = .019$ ) (**Table 1**).

Re-treatment was performed in 5 (14%) patients to improve near vision within postoperative 6 months to

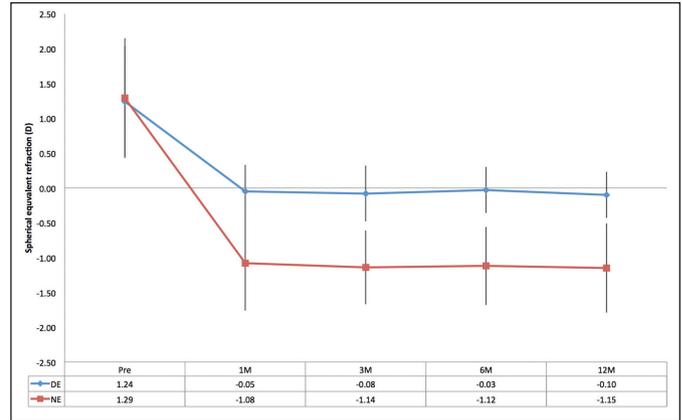


**Figure 4.** Spherical equivalent refraction at (A) 6-month and (B) 1-year follow-up visits after presbyopic corneal treatment for dominant (DE) and non-dominant (NE) eyes. D = diopters

1 year. The re-treatment included a non-wavefront-guided aspheric ablation to tune near refraction of the non-dominant eye to the desired value. No eye required reversal treatment over 1 year. The visual outcomes were satisfactory for 34 (94.4%) patients. All patients found this procedure acceptable in performing daily tasks under high illumination. Seven (9.6%) and 19 (26.0%) patients reported difficulty in visual performance in mid- and low-illuminated environments, respectively.

**DISCUSSION**

The current study used PresbyMAX for near vision in the non-dominant eye and monofocal LASIK in the dominant eye for distance vision. We aimed to preserve a better far vision because presbyLASIK has been shown to offer less optimal distance vision compared to a modified micro-monovision termed laser blended vision by Reinstein et al.<sup>5</sup> This technique induces a certain amount of spherical aberration to each eye to increase the depth of field and makes the non-dominant eye slightly myopic. After the primary procedure, 99% of hyperopic patients achieved binocular UDVA of 20/25 or better and 87% had binocular UNVA of J3 or better at



**Figure 5.** Mean spherical equivalent refraction measured preoperatively (Pre) and at 1, 3, 6, and 12 months (M) after presbyopic corneal treatment for dominant (DE) and non-dominant (NE) eyes. D = diopters

1 year. Loss of two lines or more was only seen in 0.5%. A re-treatment rate of 22% with equal distribution between distance and near eye was reported. We observed that 87% of our patients achieved binocular UDVA of 20/25 or better and 90% had J3 or better binocularly. Simultaneous binocular distance and near vision of 20/25 and J2 or better was achieved in 70% at 1 year.

PresbyLASIK is an attempt to replace the dynamic process of accommodation with a static modification of the corneal surface. This discrepancy between dynamic and static is the reason why presbyLASIK must be a compromise and cannot restore accommodative functionality together with high visual acuity and quality at all distances.<sup>3</sup> There are two different approaches for presbyLASIK treatment, termed central and peripheral presbyLASIK. Central presbyLASIK is a procedure in which the central corneal area is created for near vision and the mid-peripheral area is for distance vision. Alió et al. reported the results from a central presbyLASIK procedure in 25 patients to correct hyperopia and presbyopia.<sup>11</sup> At 6 months, 88% achieved binocular UDVA of 20/25 or better and 92% achieved binocular UNVA of J3 or better. Loss of two lines or more in binocular CDVA occurred in 14% patients, and the re-treatment rate for distance vision was 12%. Jackson et al. also evaluated central presbyLASIK in 25 presbyopic patients with hyperopia for up to 1 year postoperatively.<sup>12</sup> All patients achieved binocular UDVA of 20/25 or better and 86% had J2 or better. All patients had simultaneous binocular UDVA of 20/25 or greater and UNVA of J3 or better. Loss of two lines or more was reported in 10% of patients.

Peripheral presbyLASIK is a procedure in which the central cornea is shaped for far vision and the mid-peripheral cornea for near vision. Uy and Go reported that a UDVA of 20/30 or better and J3 or better was attained independently in 87% of eyes with hyperopic or emmetropic presbyopia at 3 months.<sup>13</sup> Epstein and

TABLE 1  
**Comparison of the Preoperative and Postoperative  
 Corneal Aberrations Analyzed at 6-mm Diameter**

Variable	Preoperative	Postoperative	P <sup>a</sup>	P <sup>b</sup>
Coma aberration ( $\mu\text{m}$ )				
PresbyMAX	0.363 $\pm$ 0.151	0.443 $\pm$ 0.243	.092	.175
Hyperopic LASIK	0.323 $\pm$ 0.160	0.309 $\pm$ 0.129	.939	
Trefoil aberration ( $\mu\text{m}$ )				
PresbyMAX	0.159 $\pm$ 0.091	0.181 $\pm$ 0.116	.545	.842
Hyperopic LASIK	0.182 $\pm$ 0.169	0.188 $\pm$ 0.144	.157	
Spherical aberration ( $\mu\text{m}$ )				
PresbyMAX	0.314 $\pm$ 0.129	-0.185 $\pm$ 0.223	< .001	< .001
Hyperopic LASIK	0.322 $\pm$ 0.141	0.081 $\pm$ 0.174	< .001	
Total HOA ( $\mu\text{m}$ )				
PresbyMAX	0.549 $\pm$ 0.171	0.624 $\pm$ 0.257	.076	.019
Hyperopic LASIK	0.537 $\pm$ 0.266	0.509 $\pm$ 0.235	.061	

HOA = higher order aberrations

<sup>a</sup>Comparison between postoperative and preoperative aberrations using Wilcoxon signed rank test. P < .05 represents statistical significance.

<sup>b</sup>Comparison between change in aberrations between eyes receiving PresbyMAX (SCHWIND Eye-Tech-Solutions GmbH and Co KG, Kleinostheim, Germany) and hyperopic LASIK using Mann-Whitney test. P < .05 represents statistical significance.

Gurgos described the results of using monocular peripheral presbyLASIK in the non-dominant eye and regular LASIK in the dominant eye for distance vision.<sup>8</sup> In 28 hyperopic patients, 68% had binocular UDVA of 20/20 or better and 71% had binocular UNVA of J2 or better, with a re-treatment rate of 28% at 1 year postoperatively. Seventy-five percent of patients with hyperopia reached a combined binocular UCVA of 20/25 or better and UNVA of J2 or better.

The PresbyMAX method uses biphase multifocal ablation profiles, which can be combined with correction of ametropia. It is a central presbyLASIK in which target refraction for far distance is combined with the induction of central steepening associated with increased pseudoaccommodation. Uthoff et al. performed PresbyMAX on both eyes and reported improvement of bilateral UDVA to -0.04 logMAR and UNVA to 0.24 logRAD in 20 patients with hyperopia at 6 months.<sup>14</sup> All patients with hyperopia achieved binocular UDVA of 20/25 or better and 30% reached UNVA of J2 or better. Loss of two lines or more in binocular CDVA was seen in 10% of patients. Luger et al. applied bilateral PresbyMAX to a group of myopic and hyperopic patients and reported that 70% of them obtained binocular UDVA of 20/25 or better and 84% achieved binocular UNVA of J2 or better at 1 year.<sup>15</sup> Loss of two lines or more was seen in 3%. Baudu et al. reported one of the largest groups of patients receiving bilateral PresbyMAX.<sup>4</sup> In patients with hyperopia, 74% achieved binocular UDVA of 20/25 or better and

90% had binocular UNVA of J2 or better at 6 months. Simultaneous binocular distance and near vision of 20/25 and J2 or better was achieved in 65%.

Hyperopic LASIK has also been reported to induce negative spherical aberrations, greater coma, and total higher order aberrations of the cornea.<sup>16-18</sup> PresbyMAX also tends to induce similar changes.<sup>9,14,15</sup> We observed a negative shift in corneal spherical aberration but a nonsignificant change in total higher order aberrations postoperatively. This could be due to the small amounts of refractive correction (1.29 D), as suggested by Wang and Koch.<sup>19</sup> The greater induction of negative spherical aberration after PresbyMAX compared to hyperopic LASIK could be due to the near add of the PresbyMAX ablation profile, which makes the cornea more prolate. Alió et al. demonstrated that a greater hyperopic correction makes spherical aberration and asphericity more negative.<sup>16</sup> Apart from ablation profiles, treatment centration could explain the induction of corneal coma after LASIK, especially in hyperopic eyes with large angle kappa.<sup>20</sup> Recently, it was shown that hyperopic LASIK centering on corneal vertex reduced the induction of coma in correcting low to moderate hyperopia.<sup>21</sup> This could explain the lower induction of coma in our series. Discussion of using pupil center, corneal vertex, or corneal light reflex as a centration reference is beyond the scope of this article, and this topic has been reviewed extensively.<sup>22</sup>

Satisfaction of treatment was reported in the majority of patients. None of our patients requested reversal

of treatment. Our patients requested enhancement because of insufficient near vision over time rather than a compromised distance vision. This is important because the distance vision eye in a patient with monovision has a lower tolerance for residual refractive error and requires a higher rate of enhancements than in a patient with standard laser vision correction.<sup>23</sup> Corneal epithelial remodeling could be responsible for the reduced effectiveness of PresbyMAX over time, which has been demonstrated following treatment regression in LASIK.<sup>24</sup>

Similarly, Luger et al. attempted to achieve maximum patient satisfaction by combining PresbyMAX with the micro-monovision technique to provide good near vision accompanied with no detrimental effect in the distance vision.<sup>9</sup> PresbyMAX was performed in both eyes with a target refraction of -0.10 D in the dominant eye for distance vision and -0.90 D in the non-dominant eye for near vision. In 16 hyperopic patients, 94% reached binocular UDVA of 20/25 or better and 88% had binocular UNVA of J2 or better at 1 year postoperatively. There were 6% of patients who lost two lines of binocular CDVA. Refractive outcomes and satisfaction of presbyopic patients with hyperopia treated with another type of central presbyLASIK (Supracor) with micro-monovision were also encouraging.<sup>25</sup> The current study demonstrated a safer procedure despite its decreased efficiency in providing near vision. Only 17% of our patients had binocular DCNVA of J2 or better at 1 year, compared to 31% observed by Luger et al.<sup>9</sup> The overcorrection toward myopia in some of our cases should be responsible for the improved near performance apart from central steepening in PresbyMAX.

The current study was limited by a small sample size and retrospective study design. Lack of sufficient sample size could render comparative analysis of aberrations difficult. Using the change in total higher order aberrations following PresbyMAX, our sample size could only achieve a power of 0.33. Unfortunately, we did not measure intermediate visual acuity or the contrast sensitivity of our patients. Most patients were satisfied with visual performance under sufficient illumination. The age of our patients ranged from 46 to 64 years. Some physiological accommodation might still be present as a reason for improved near visual acuity. The current study investigated the effect of a multifocal cornea monovision approach in patients with hyperopia. It has been shown that patients with myopia and hyperopia responded differently to presbyLASIK.<sup>4,8,9,14</sup> In addition, the level of satisfaction with the presbyopic procedure was different between myopic and hyperopic patients.<sup>26</sup> Patients with presbyopia and myopia are less likely to be satisfied because they have experienced

excellent near vision prior to the procedure and likely expect the same postoperatively. On the other hand, patients with presbyopia and hyperopia are more forgiving because both hyperopia and presbyopia are corrected at the same time. It should be stressed that good expectation management is as important as postoperative visual outcomes.

Presbyopic correction using monocular PresbyMAX combined with monofocal regular LASIK in the fellow eye is safe and acceptable in hyperopic patients. Near vision improves and distance vision is well maintained over 1 year.

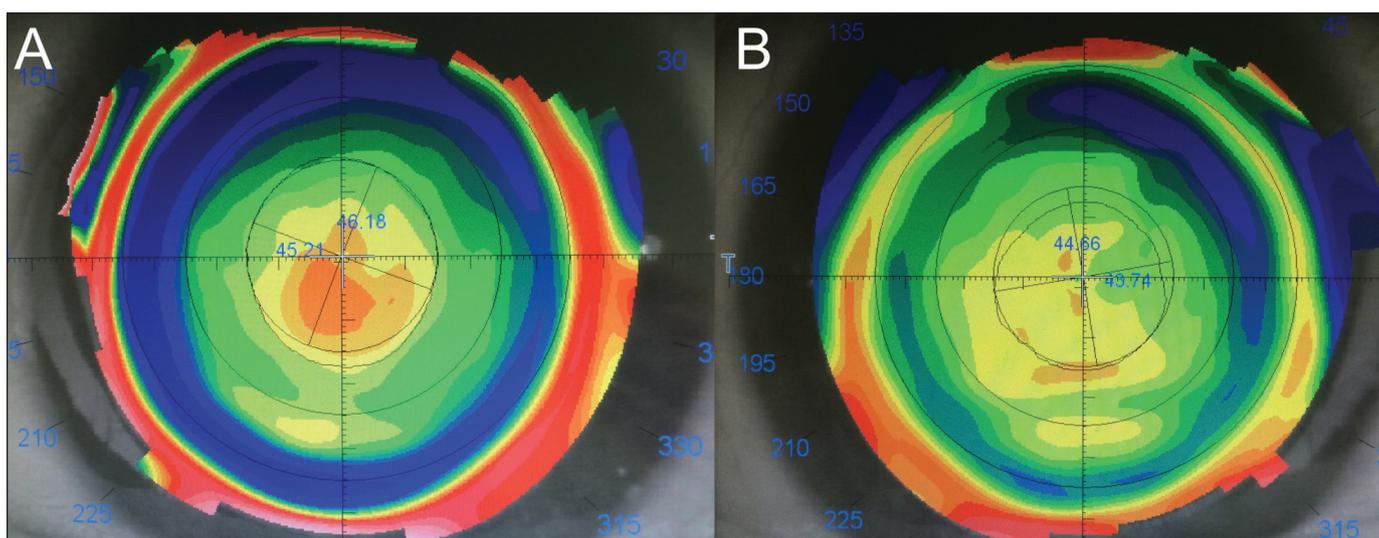
#### AUTHOR CONTRIBUTIONS

*Study concept and design (TCYC, PSKK); data collection (PSKK); analysis and interpretation of data (TCYC, PSKK, VJ, VCPW, ALKN); writing the manuscript (TCYC, ALKN); critical revision of the manuscript (TCYC, PSKK, VJ, VCPW, ALKN); statistical expertise (TCYC, PSKK); administrative, technical, or material support (ALKN); supervision (PSKK, VJ, VCPW)*

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**Figure A.** Corneal topography of the (A) non-dominant eye (PresbyMAX; SCHWIND Eye-Tech-Solutions GmbH and Co KG, Kleinostheim, Germany) and (B) dominant eye (hyperopic LASIK) of one patient.