• Clinical Research •

Objective optical quality and visual outcomes after the PresbyMAX monocular ablation profile

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Abstract

● **AIM:** To assess objective visual quality after presbyopia correction using the PresbyMAX monocular mode.

● **METHODS:** This prospective, nonrandomized study included 28 eyes from 18 patients (mean age 50.4±5.6y) who underwent presbyopia correction with the PresbyMAX monocular mode. Monocular and binocular visual acuities were evaluated preoperatively, 1d, 1wk, 1, 3mo, and 1y after surgery. Optical quality was analyzed by Hartmann-Shack wavefront aberration supported cornea ablation. Modulation transfer function (MTF) cutoff frequency, Strehl ratio, and objective scattering index (OSI) were analyzed using an optical quality analysis system.

● **RESULTS:** One year after surgery, 100% and 94.4% of patients achieved binocular uncorrected distance and near visual acuity of 20/25, respectively. At the last visit Spherical aberration and total higher aberration were higher than the corresponding preoperative levels (P<0.001); however, no significant difference was found in MTF, OSI, or Strehl ratio. Transient decreases in OSI and MTF mainly occurred in the nondominant eyes. There was no significant difference in optical quality between the dominant and nondominant eyes, except for spherical aberration and horizontal coma (P<0.05).

● **CONCLUSION:** The PresbyMAX monocular mode is safe and effective for presbyopia correction. It has little effect on optical quality, though short-term degraded optical quality occurred mainly in the bi-aspheric ablated eyes.

● **KEYWORDS:** presbyopia; monovision; optical quality; PresbyMAX

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INTRODUCTION

Presbyopia is an issue for the elderly population. Owing to decreased accommodation, people with presbyopia experience difficulty completing work activities, frequent eye fatigue, and impaired optical quality. This also leads to lower quality of life. To date, several presbyopia correction methods have been applied to restore near vision[1]. Approaches have included use of intraocular lens, aperture corneal inlay, and corneal refractive surgeries. The major mechanisms of these surgeries are monovision and multifocal design[2-5].

PresbyLASIK is the most commonly used method for presbyopia correction. This surgery provides spectacle-free near vision by creating an aspherical corneal surface, and includes central PresbyLASIK[6] (a central hyperpositive area for near vision) and peripheral PresbyLASIK[7] (a mid-peripheral area for near vision). PresbyLASIK improves functional near vision, but does not improve the level of maturity of monovision[8]. Monovision correction, in which one eye is refracted for near vision while the other is refracted for distance vision, provides good acuity for both distance and near vision. However, binocular vision is compromised, and stereopsis is often impaired[9].

By inducing a micro-monovision portal, Saib *et al*[10] found that central PresbyLASIK improved functional near, intermediate, and distance vision in hyperopic patients with presbyopia. Luger *et al*[11] demonstrated the efficacy and safety of the hybrid bi-aspheric micro-monovision ablation profile. Baudu *et al*[12] found using traditional monovision, both intermediate and near vision, is better when spherical aberration is increased in the nondominant eye. PresbyMAX is widely used with the monocular ablation profile being the most recent one[11-13]. It creates a bi-aspherical surface in the nondominant eye and facilitates full correction in the dominant eye. To our knowledge, optical quality after correction using the PresbyMAX monocular mode has rarely been reported.

The purpose of this study was to assess objective visual quality after PresbyMAX monovision ablation. Hope to contribute to the body of evidence regarding surgical presbyopia correction.

SUBJECTS AND METHODS

Ethical Approval All procedures mentioned below were approved by the review board of Eye, Ear, Nose and Throat (EENT) Hospital, and the study adhered to the tenets of the Declaration of Helsinki. Written informed consent was obtained from all participants before surgery as a standard protocol.

Subjects Participants were recruited from Refractive Center of the EENT Hospital of Fudan University from July 2017 to November 2017. The inclusion criteria were as follows: >40 years of age, corrected distance visual acuity (CDVA) ≥20/25, and uncorrected near visual acuity (UNVA) <20/40 that could increase at least 1 line with adding power. The exclusion criteria were as follows: other eye diseases except ametropia, history of ocular surgery, systemic diseases, and intolerance for 1 D of anisometropia.

Measurements The dominant eye was determined using the "hole test"[14]. Frame glasses were applied to test patients' tolerance for anisometropia (the dominant eye was fully corrected and the nondominant eye was undercorrected) according to their vision requirements. In some patients, only one eye was operated, as the other eye was mild myopia or hyperopia and could already meet the near or distance vision need.

Regular preoperative examinations, including subjective refraction, intraocular pressure measurement, and binocular and monocular visual acuity (Sellen Chart, 4 m for distance vision, 33 cm for near vision) were conducted preoperatively and at 1d, 1wk, 1, 3mo, and 1y after surgery. Objective optical quality was analyzed using Hartmann-Shack wavefront aberration supported cornea ablation (WASCA; Carl Zeiss Meditec AG) and a double-pass optical quality analysis system (OQASII; Visiometrics, Terrassa, Spain)[15]. Both devices used an artificial diameter of 4 mm, which mimics the physiological size. All data were processed preoperatively and at 1, 3mo, and 1y after surgery. All 18 patients completed the one year visit.

Surgical Mode The monocular ablation profile was designed through a topographer (Keratron Scout, Optikon, Rome, Italy), which approximateed the visual axis and induces an addition ranging from 1.25 D to 2.5 D to increase the depth of field in the non-dominant eye. For each operated eye, two steps were performed: flap creation using the Visumax femtosecond laser (Carl Zeiss Meditec AG, Jena, Germany) and stromal ablation using Schwind Amaris 1050RS with Smart Pulse Technology (Schwind eye-tech-solutions GmbH, Kleinostheim, Germany). The dominant eye was fully corrected using standard femtosecond laser-assisted *in situ* keratomileusis (FS-LASIK). The intended flap thickness was 110-120 μm, the hinge was set at the 12 o'clock position with an angle of 90°, and the diameter of the flap was 8 mm. After flap creation, the patient was transferred to the Schwind Amaris platform. A normal aspheric FS-LASIK ablation profile was performed on the dominant eye, and a bi-aspheric PresbyMAX ablation profile was performed on the non-dominant eye. The optical zone was set between 6.2 and 6.8 mm, centered on the corneal reflex point. After regular ablation, the central 3-mm cornea of the non-dominant eye was reshaped to a hyperpositive area for near correction, which was decided by the amount of presbyopia addition. Laser ablation was performed using a 193-nm flying spot laser system with a super-Gaussian beam profile of 0.54-mm full width at half maximum. Spot placement adopted an intellectual thermal effect control mechanism to prevent heat buildup.

Patients were instructed to wear bandage contact lenses for 1d; 0.1% fluorometholone eye drops and artificial tears were applied successively for 3wk.

Statistical Analysis Results are presented as the mean±standard deviation. All data processing was performed using SPSS (IBM Corporation, Armonk, NY, USA). A linear mixed model was used to compare values at different time points. The least significant difference (LSD) method was adopted for multiple comparisons. The Mann-Whitney *U* test was used in subgroup comparison. In all analyses, *P*-values less than 0.05 were considered statistically significant.

RESULTS

Patient Characteristics Twenty-eight eyes of 18 patients (7 men, 11 women) with a mean age of 50.4±5.6y (range: 42-61y) were included in this study. Eight patients underwent monocular surgery on the nondominant eye because the other eye satisfied the distance vision (UDVA ≥20/20) requirement; the other 10 patients underwent binocular surgery. The mean spherical equivalent (SE) was -1.96±4.59 D (range: -9.88 to 6.88 D). The average adding power was 1.58±0.66 D. Among them, 16 myopic eyes had a mean SE of -5.40±2.42 D and 12 hyperopic eyes had an SE of 2.61±1.90 D. The cylinder power was -0.45±0.28 D on average (range: -1.00 to 0.00 D).

Refractive Outcomes All surgeries were uneventful, without any intraoperative or postoperative complications. The safety index was 1.02±0.14 at postoperative 1y. In total, 85.8% of the treated eyes achieved CDVA equal to or better than preoperative CDVA; among them, 67.9% (19/28) of eyes maintained the preoperative level of CDVA at 1y after surgery, with 14.3% (4 eyes) gaining 1 line and 3.6% (1 eye) gaining 2 lines. No eyes lost 2 lines or more of CDVA, and 14.3% (4/28) of eyes lost 1 line.

The binocular uncorrected distance visual acuity (BUDVA) and near visual acuity (BUNVA) 1y after surgery are shown in Figure 1. All patients achieved a BUDVA of 20/20, and 94.4% patients achieved a BUNVA of 20/25, both of which significantly improved from the corresponding preoperative

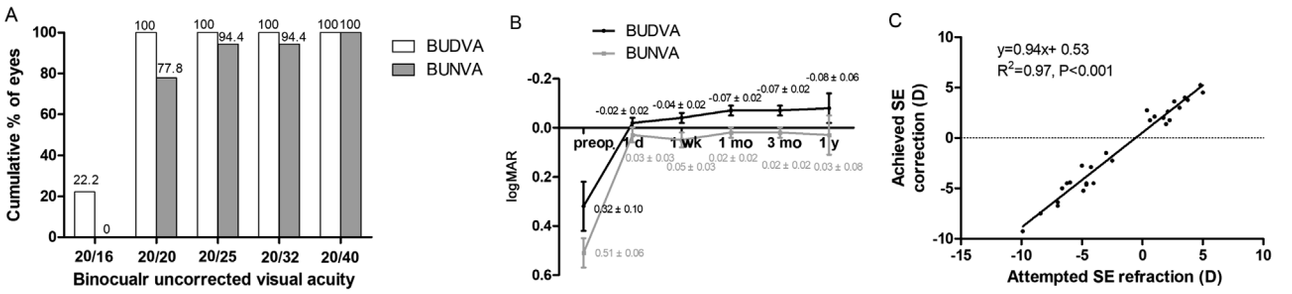

Figure 1 One year refractive outcomes of PresbyMAX.

Table 1 Ocular aberration in the treated eyes μm

Aberration	Preop.	1mo	3mo	1y	*P*
SA	0.05±0.04	-0.03±0.08[a]	-0.03±0.07[a]	-0.02±0.06[a]	<0.001
Vertical coma	-0.02±0.07	-0.05±0.14	-0.03±0.13	-0.03±0.13	0.56
Horizontal coma	0.00±0.06	0.01±0.08	0.00±0.08	-0.01±0.07	0.61
Trefoil	0.07±0.03	0.08±0.05	0.08±0.05	0.08±0.06	0.56
HOA	0.17± 0.09	0.29±0.14[a]	0.29±0.23[a]	0.28±0.23[a]	0.003

SA: Spherical aberration; HOA: Higher order aberration. [a]Statistally different compared with preoperative values in pairwise comparison.

Table 2 Comparison of ocular aberration in subgroups μm

Aberration	Preop.		1mo		3mo		1y		Δ	
	DG	NDG	DG	NDG	DG	NDG	DG	NDG	DG	NDG
SA	0.06±0.03	0.05±0.04	0.05±0.05[a]	-0.08±0.05[b]	0.01±0.04[a,b]	-0.05±0.04[b,c]	0.02±0.04[a]	-0.05±0.04[b,c]	-0.03±0.05[a]	-0.10±0.04
Vertical coma	-0.05±0.07	-0.02±0.08	-0.06±0.09	-0.05±0.16	-0.06±0.10	-0.03±0.15	-0.05 ±0.09	-0.03±0.14	-0.01±0.06	-0.01±0.15
Horizontal coma	-0.01±0.06	0.00±0.06	-0.05±0.06[a]	0.03±0.07	-0.06±0.07[a]	0.02±0.07	-0.07±0.05[a]	0.02±0.07	-0.07±0.09[a]	0.02±0.08
Trefoil	0.06±0.03	0.07±0.03	0.08±0.05	0.07±0.05	0.09±0.05	0.07 ±0.06	0.09±0.06	0.07±0.06	0.03±0.05	0.00±0.05
HOA	0.18±0.02	0.16±0.11	0.27±0.14	0.31±0.15[b]	0.25±0.14	0.32±0.28[b]	0.22±0.08	0.31±0.28[b]	0.05±0.07	0.15±0.24

SA: Spherical aberration; HOA: Higher order aberration; DG: Dominant eye group; NDG: Non dominant eye group. Δ: Values at 1y postoperatively minus preoperative values; [a]Statistically different between DG and NDG, $P<0.01$; [b]Statistically different compared with preoperative value; [c]Statistically different compared with 1mo after surgery.

values and maintained stable since 1mo after surgery. None of the eyes underwent enhancement surgery until 1y after surgery.

Objective Visual Quality Ocular aberration measured *via* WASCA is shown in Table 1. Positive spherical aberration was transferred to negative values after surgery ($P<0.001$). The total higher order aberration (HOA) was higher than that of the preoperative value and remained stable 1mo after surgery (1mo *vs* 3mo, $P>0.05$; 3mo *vs* 1y, $P>0.05$). HOA increased by 0.11±0.20 μm 1y after surgery. Spherical aberration decreased significantly toward negative values ($P<0.001$). Trefoil, vertical coma, and horizontal coma were unchanged during the follow-up period.

The treated eyes were divided into the dominant eye group (standard FS-LASIK; DG, $n=10$) and the non-dominant eye group (bi-aspheric PresbyMAX ablation; NDG, $n=18$). The mean preoperative SEs of the two groups were -2.03±5.43 D and -1.92±4.13 D ($P=0.95$). No significant difference was found in ocular aberration between the two groups, except for spherical aberration (0.02±0.04 μm in DG *vs* -0.05±0.04 μm in NDG) and horizontal coma (-0.07±0.05 in DG *vs* 0.02±0.07 in NDG). The changes (values at 1y after surgery minus preoperative values) in HOAs of paired eyes are shown in Table 2.

Intraocular image quality is shown in Table 3. At 3mo postoperatively, all image-quality parameters were comparable with the corresponding preoperative values and remained stable 3mo after surgery. A decrease in the Strehl ratio occurred at 1mo after surgery. In the subgroup analysis, no significant differences were found between the DG and NDG groups. Decreased vision quality was found in the NDG 1mo after surgery (Table 4).

DISCUSSION

Creation of monovision or multifocal is a common way to restore refractive power in eyes with presbyopia. Previous studies have reported the efficacy and safety of surgical correction for presbyopia[1]. In the present study, we focused on the most recent ablation file of PresbyMAX-monocular ablation and assessed objective optical quality after this surgery for presbyopia.

Our results demonstrated that PresbyMAX significantly increased both distance and near visual acuities 1y after

Table 3 Intraocular image quality in treated eyes

Parameters	Preop.	1mo	3mo	1y	*P*
OSI	0.71±0.40	0.89±0.37	0.76±0.35	0.89±0.44	0.15
MTF_{cutoff} (cpd)	34.41±7.20	30.84±10.13	34.55±10.13[b]	32.33±10.39	0.37
SR	0.20±0.04	0.16±0.04[a]	0.17± 0.04	0.16±0.05	0.04
OV100%	1.15±0.24	1.06±0.35	1.15±0.33[b]	1.09±0.33	0.46
OV20%	0.82±0.2	0.72±0.26	0.81±0.27	0.78±0.28	0.63
OV9%	0.51±0.13	0.42±0.14	0.45±0.14	0.45±0.16	0.26

OSI: Ocular scattering index; MTF_{cutoff}: Modulated transfer function cutoff frequency; cpd: Cycles per degree; SR: Strel ratio. [a]Statistically different compared with preoperative values in pairwise comparison; [b]Statistically different compared with 1mo after surgery in pairwise comparison.

Table 4 Comparison of intraocular image quality in subgroups

Parameters	Preop.		1mo		3mo		1y		Δ	
	DG	NDG	DG	NDG	DG	NDG	DG	NDG	DG	NDG
OSI	0.76±0.28	0.68±0.46	0.82±0.33	0.94±0.40[a]	0.88±0.38	0.74±0.34[b]	0.79±0.34	0.87±0.44	0.00±0.43	0.37±0.62
MTF_{cutoff} (cpd)	33.88±6.21	34.71±7.88	34.67±9.84	27.98±9.55[a]	33.55±10.25	34.28±10.12[b]	35.67±10.08	32.49±8.85	1.81±8.80	-5.01±13.23
SR	0.19±0.03	0.20±0.05	0.18±0.04	0.16±0.04[a]	0.17±0.05	0.17±0.04	0.19±0.06	0.16±0.04	0.00±0.07	-0.04±0.06
OV100%	1.13±0.20	1.16±0.27	1.16±0.32	0.94±0.32[a]	1.12±0.33	1.14±0.33[b]	1.19±0.32	1.04±0.33	0.06±0.27	-0.17±0.45
OV20%	0.79±0.15	0.84±0.23	0.82±0.28	0.65±0.22[a]	0.77±0.29	0.80±0.26[b]	0.86±0.30	0.73±0.24	0.08±0.35	-0.15±0.36
OV9%	0.49±0.12	0.52±0.14	0.45±0.13	0.39±0.14[a]	0.44±0.14	0.44±0.13	0.48±0.19	0.41±0.13	0.01±0.24	-0.13±0.19

OSI: Ocular scattering index; MTF_{cutoff}: Modulated transfer function cutoff frequency; cpd: Cycles per degree; SR: Strel ratio; DG: Dominant eye group; NDG: Non dominant eye group; Δ: Values at 1y postoperatively–preoperative values. [a]Statistically different compared with preoperative values in pairwise comparison; [b]Statistically different compared with 1mo after surgery in pairwise comparison.

surgery. With 85.8% of eyes showing no loss of CDVA, the safety of PresbyMAX was comparable to that of PresbyLASIK. When functional visual acuity was defined as 20/30, as described by Uy and Go[16], the success rates for improving distance and near vision qualities were 100% and 94.4%, respectively. These are higher than the results obtained in the study by Uy and Go[16]. Chan *et al*[13] retrospectively reviewed the long-term results of the monovision mode and found that a BUDVA and BUNVA of 20/25 were achieved in 70% (36 patients), and no loss of 2 lines of CDVA occurred. Luger *et al*[11] also reported the long-term results of PresbyMAX (32 patients); they reported that 93% of patients achieved 20/20 or better binocular BUDVA, and 90% of patients had J2 BUNVA 1y after surgery.

In addition to time, different surgical modes also account for the postoperative results. The PresbyMAX symmetric mode was initially used to make the two eyes contribute equally to visual acuity at all distances, thereby resulting in excellent stereoscopic and near vision[12]. Results of the study by Luger *et al*[11] showed that better distance vision was achieved with a hybrid technique that creates multifocality in both eyes with micro-monovision. They found great improvements in binocular vision at far, intermediate, and near distance with improved contrast sensitivity. As for the monocular mode applied in the present study, depth of field was only induced in the nondominant eye, which provides faster recovery and better distance vision than the symmetric mode does; this is preferred over the hybrid mode for individuals who mainly need distance vision correction.

HOA increased at 1y after surgery, which was similar to the results of a previous study[17]. Furthermore, we found that more induced aberrations were present in the nondominant eye than in the dominant eye, especially spherical aberration. Remarkably decreased spherical aberration in the nondominant eye does help improve near vision, because negative change in spherical aberration tends to increase depth of focus[18]. To bring about a pseudo-accommodative effect, PresbyMAX creates a central hyper-positive area, which makes the eye more myopic by shifting the center of focus and increasing the depth of focus. This is in agreement with Gifford *et al*[19], who, after comparing multifocal and single-vision soft contact lenses, concluded that a multifocal lens creates greater negative aberration. This makes the eye more myopic and increases the depth of focus. Moreover, a less smooth interface may also contribute to higher HOAs, as pointed out by Medeiros *et al*[20]. In the present study, though coma variants showed no change after surgery, subgroup analysis revealed that horizontal comas increased more in the dominant eye than in the nondominant eye, while vertical comas remained the same between them. First, the direction and magnitude of the change in coma varied greatly among individuals[21]. Besides, Karimian *et al*[22] found that spherical refractive error was significantly correlated

with primary horizontal coma. Based on this theory, greater negative coma in the dominant eye can be explained by less residual refraction error in the monovision design. In cornea surgery, it is known that comas reflect characteristics such as asymmetry, regularity, tilt, and decentration[23]. Our results showed that neither monofocal ablation nor bi-aspherical aberration increased the risk of decentration, and both had little effect on the overall coma. This is also concordant with the OQAS values.

Multifocality provides an advantage in the range of focus, however, it also results in aberration-induced loss of image clarity. The present study revealed a significant increase in SR at 1mo after surgery, especially in the nondominant eye. Despite this, all parameters recovered to the corresponding preoperative levels within 3mo. A previous study reported that 11.75% of eyes showed a decrease in Mtf 3mo after LASIK[24]. Miao *et al*[25] also found unchanged OQAS values 3mo after small incision lenticule extraction. Similar results were reported by Lim *et al*[26]; no differences in optical quality parameters were noted between the presbyopia treatment group and the age-matched control group. The fluctuation in the current study can be explained by the blurred vision in the transition period after surgery. Older age in the present study made the results incomparable with other study[27]. However, this study did reveal that there was little effect on retinal image quality after PresbyMAX, and the recovery after surgery was fast.

The major limitation of the current study was the relatively small sample size, as the inclusion criteria were strict. We believe that a thorough preoperative assessment and anisometropia test are critical to meet patients' expectations, because there would be transient impaired visual quality in early stage, especially in the nondominant eye. Further studies are needed to explore the long-term effects of the PresbyMAX monocular mode.

In conclusion, the PresbyMAX monocular mode is safe and effective for presbyopia correction and can improve both distance and near vision. The surgery has little effect on optical quality; though degraded optical quality occurs in the bi-aspheric ablated eyes in the early stage, it can gradually recover to the preoperative level.

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