• Clinical Research •

Refractive outcomes and optical quality of PRESBYOND laser-blended vision for presbyopia correction

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Abstract

● **AIM:** To investigate the one-year refractive outcomes and optical quality following PRESBYOND laser-blended vision (LBV).

● **METHODS:** This retrospective study included 20 patients who underwent PRESBYOND treatment between Jan 2019 and Aug 2020. The patients were asked to attend a follow-up outpatient visit one year after surgery. Distance and near visual acuity as well as subjective refraction were examined. Optical quality was assessed using wavefront-supported custom ablation. A questionnaire evaluating optical quality and satisfaction was completed at the last visit.

● **RESULTS:** The average patient age was 48.1±7.4y (range, 41 to 58y). The mean preoperative spherical equivalent was -7.59±2.39 D. At the one-year follow-up, two eyes (both dominant eyes) lost one line of corrected distance visual acuity (CDVA), while the remaining eyes (38/40) maintained or gained lines of CDVA. The average binocular uncorrected distance visual acuity improved from 0.15±0.03 to 0.90±0.26 (decimal vision; P<0.001). The average binocular uncorrected near visual acuity increased from 0.34±0.28 to 0.97±0.07 (P<0.001). The spherical aberration was 0.04±0.06 μm in the nondominant eye and 0.09±0.09 μm in the dominant eye (P=0.02). All patients were satisfied with or accepted the outcomes of the surgery. The primary complaints were related to disturbances in night vision and relatively inferior near vision.

● **CONCLUSION:** Over the one-year observation period, PRESBYOND is a safe and effective option for presbyopia correction. The optical quality and near vision deserve further investigation.

● **KEYWORDS:** PRESBYOND; laser-blended vision; presbyopia; optical quality

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INTRODUCTION

Presbyopia is a common ocular aging-related disease. Its manifestations include impaired near vision, decreased optical quality, and frequent asthenopia[1-3]. The number of patients with an unmet need for presbyopia correction was 510 million globally in 2020, and this number is predicted to reach 866 million by 2050[4]. The mainstream correction methods available at present are pharmacology, spectacle usage, and surgery[5-6], with the latter method being preferred by patients seeking convenience in daily life.

Presbyopia surgeries involving the cornea include monovision approaches, presbyLASIK, and corneal inlays[7]. Monovision is probably the most mature, albeit still popular, approach in presbyopia correction. Several studies have demonstrated its successful application in laser *in situ* keratomileusis (LASIK) and small-incision lenticule extraction (SMILE)[8-9]. However, traditional monovision approaches may induce diminished contrast sensitivity and stereoacuity[10-11]. Laser-blended vision (LBV) was developed by importing preoperative spherical aberration to extend the depth of field in a micro-monovision protocol. This procedure has been applied in all types of ametropia and has yielded satisfactory results[12-14]

PRESBYOND, which was used in this study, is an advanced version of LBV using the MEL 90 excimer laser instead of the MEL 80 laser used previously. Ganesh *et al*[15] retrospectively analyzed the one-year results obtained with PRESBYOND and demonstrated satisfactory and fairly stable visual outcomes in both myopic and hyperopic individuals. However, studies evaluating optical quality, which is crucial for

patient satisfaction, are scarce[16]. For presbyopia correction, individual differences are more obvious due to adaption difficulties associated with aging[17]. The present study aimed to explore the refractive outcomes and optical quality after PRESBYOND.

SUBJECTS AND METHODS

Ethical Approval This study was approved by the Ethics Board of the Eye, Ear, Nose and Throat Hospital (EENT) of Fudan University. All enrolled patients were informed of the benefits and drawbacks of this surgery, and written informed consent was obtained from each patient. All study procedures were conducted in accordance with the Declaration of Helsinki.

Patients Selection From Jan 2019 to Aug 2020, patients seeking presbyopia correction were screened. The inclusion criteria were as follows: spherical diopter > -10.0 D or <+6.0 D and corrected distance visual acuity (CDVA) ≥ 20/25. The exclusion criteria were as follows: ocular surgery history, lens opacity or other retinal disease that may affect visual acuity, and abnormal corneal topography findings.

Preoperative Examinations Regular preoperative examinations included measurement of subjective refraction, corneal topography (Pentacam HR; Wetzlar, Germany), ocular aberration analysis using Wavefront Aberration Supported Customized Ablation (WASCA; Carl Zeiss Meditec), and fundus photography.

Eye dominance was initially evaluated by the "hole test"[12]. The results were confirmed only when the two consecutive measurements were consistent. Then, an anisometropia test using frame glasses was performed, targeting full correction in the dominant eye and a target of +1.5 D to the nondominant eye. Binocular uncorrected distance vision acuity (BUDVA) and near vision acuity (BUNVA) were tested while wearing such glasses. Distance-corrected near visual acuity (DCNVA) was also evaluated. After a period of adaption, patients were asked about their feelings when walking, reading, and taking stairs. If they experienced discomfort during the procedure, the target of the nondominant eye was reduced by +0.25 D intervals. If the patient could not tolerate +0.75 D anisometropia, which was recommended as the minimum level of monovision by the manufacturer, the patient was deemed as an unsuitable candidate. Once the target for the nondominant eye was determined, the specific data were entered into CRS-Master software platform. The generated aspheric ablation profile was then exported for treatment with the MEL 90 excimer laser.

Surgical Procedure VisuMax femtosecond laser (Carl Zeiss Meditec GmbH) and the MEL 90 excimer laser were used in the study. All surgeries were performed by the same surgeon (Zhou XT). Specific procedures were the same as previously reported[18]. The flap thickness was 100 μm with a width of 9.0 mm, and the ablation depth was dependent on the refraction error. The optical zone ranged from 6.0 mm to 6.5 mm. A bandage lens was applied to the cornea immediately after the operation.

Postoperative Follow-up The bandage lens was removed the day after the operation. The patients were asked to attend a follow-up visit one year after surgery. Regular examinations, including assessment of manifest refraction, monocular and binocular uncorrected distance visual acuity (UDVA; distance at 3 m), uncorrected near visual acuity (UNVA; 33 cm) and CDVA, were performed.

Ocular aberration was measured using WASCA. The analysis diameter was 6 mm. Parameters including spherical aberration (SA), coma, trefoil, and total higher-order aberrations (HOAs) were analyzed.

The patients also completed a questionnaire regarding optical quality at the last visit. Patients were asked to grade their eye symptoms from 1 to 4 according to the following scale: 1) no symptoms; 2) mild symptoms; 3) moderate symptoms; 4) severe symptoms. The symptoms were analyzed under outdoor activity, near vision, night vision, and depth vision. The presence of glare and blurred vision (yes/no) was also recorded. The patients' subjective satisfaction was also analyzed as follows: 1) extremely satisfied; 2) basically satisfied; 3) passable; 4) not satisfied.

Statistical Analysis All data were analyzed using SPSS Statistics (version 22.0, IBM Corp.). The paired *t*-test and the Mann-Whitney *U* test were used to compare data that were normally and non-normally distributed, respectively. Linear regression analysis was used to assess the predictability of correction. *P* values less than 0.05 were considered statistically significant.

RESULTS

A total of 20 patients (4 males) were enrolled in the study. The average patient age was 48.1±7.4y (range, 41-58y) with the average near add power being 1.14±0.69 D. Baseline and postoperative information are shown in Table 1.

Safety, Efficacy, and Predictability Overall, the safety index (postoperative CDVA/preoperative CDVA) of all eyes was 1.16±0.16. Two eyes (dominant eyes) lost one line of CDVA, while the remaining eyes (38/40) maintained or gained CDVA. Moreover, 70% (14/20) of the cases showed a BUDVA of 20/20 or better, and 70% (14/20) of the cases showed a BUNVA of 20/20. The average BUDVA improved from 0.15±0.03 to 0.90±0.26 after surgery (P<0.001). The average BUNVA increased from 0.34±0.28 to 0.97±0.07 after surgery (P<0.001). The DCNVA was not different between dominant and nondominant eyes. The mean binocular DCNVA was significantly worse than BUNVA (P<0.001).

The target refraction was plano and mild myopia in the dominant and nondominant eyes, respectively. Linear

Table 1 Refractive information before and after PRESBYOND

Parameters	Dominant eye	Nondominant eye	Mean/ binocular	Paired comparison
Spherical (D)				
Pre	-7.39±2.43	-6.89±2.30	-7.14±2.42	0.06
Post	-0.45±0.66	-1.08± 0.66	-0.77±0.72	<0.001
Cylinder (D)				
Pre	-0.86±0.52	-0.93±0.71	-0.89±0.62	0.43
Post	-0.31±0.29	-0.45±0.36	-0.38±0.33	0.32
SE (D)				
Pre	-7.82±2.40	-7.36±2.35	-7.59±2.39	0.54
Post	-0.61±0.65	-1.31±0.68	-0.96±0.75	<0.001
UDVA				
Pre	0.13±0.04	0.11±0.02	0.15±0.03	0.90
Post	0.88±0.30	0.52±0.25	0.90±0.26	<0.001
DCNVA				
Pre	/	/	/	/
Post	0.50±0.22	0.56±0.27	0.63±0.22	0.09
CDVA				
Pre	0.99±0.03	0.99±0.08	0.99±0.05	1.00
Post	1.15±0.16	1.11±0.13	1.13±0.14	0.15
UNVA				
Pre	0.34±0.30	0.30±0.24	0.34±0.28	0.33
Post	0.61±0.25	0.84±0.19	0.97±0.07	0.002

SE: Spherical equivalent; UDVA: Uncorrected distance visual acuity; DCNVA: Distance-corrected near visual acuity; CDVA: Corrected distance visual acuity; UNVA: Uncorrected near visual acuity.

Table 2 Ocular aberrations of dominant and nondominant eyes after PRESBYOND

Aberrations (μm)	Dominant eye	Nondominant eye	*P*
Coma	0.19±0.12	0.15±0.08	0.07
Trefoil	0.10±0.06	0.11±0.06	0.66
Spherical aberration	0.09±0.09	0.04±0.06	0.02
HOA	0.28±0.12	0.23±0.07	0.05

HOA: Higher-order aberration.

regression revealed that the fitness factor of both the dominant eye and the other eye were 0.94 (P<0.001), which implied that the regression relationship can explain 94% of the predictability in the achieved refraction (Figure 1).

Optical Quality After surgery, the coma, trefoil, and total HOA were not different between paired eyes (P>0.05). The SA was 0.04±0.06 μm in the nondominant eyes and 0.09±0.09 μm in the dominant eyes (P=0.02; Table 2).

Questionnaire As shown in Figure 2, all patients thought the surgery was acceptable. Mild, moderate, and severe night vision disturbances were observed in 50% (n=10), 20% (n=4), and 10% (n=2) of the patients, respectively, while 35% (n=7) of the patients had difficulties in near vision. Most patients did not experience difficulties in outdoor activities and depth judgment. Glare and blurred vision were reported in 25% (n=5) and 15% (n=3) of the cases, respectively. No patient wore distance glasses at the last visit, while 5 (25%) patients still relied on reading glasses occasionally.

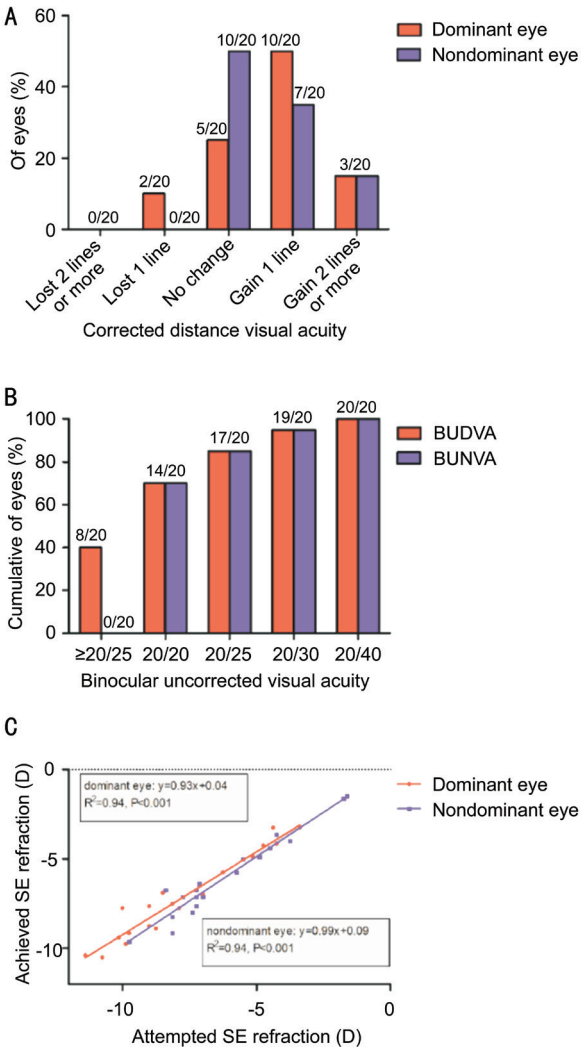

Figure 1 Refractive outcomes of PRESBYOND at the one-year visit A: Corrected distance visual acuity changes represent safety; B: Binocular distance/near visual acuity represents efficacy; C: Linear regression between attempted and achieved refraction represents predictability. BUDVA: Binocular uncorrected distance visual acuity; BUNVA: Binocular uncorrected near visual acuity.

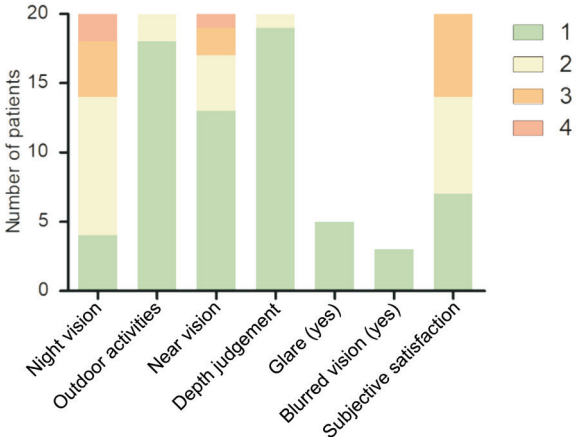

Figure 2 Questionnaire results for PRESBYOND at the one-year visit For symptom analysis, 1: No symptom, 2: Mild symptom, 3: Moderate symptoms, 4: Severe symptoms. Glare and blurred vision were judged by yes or no responses. For satisfaction assessment, 1: Extremely satisfied, 2: Basically satisfied, 3: Passable, 4: Not satisfied.

DISCUSSION

The study demonstrated that PRESBYOND is a safe and effective alternative for presbyopia correction through one-year observation. In the current study, both distance and near vision improved after surgery, and UNVA was significantly better than DCNVA.

One study that reported the findings for the first LBV-treated patients showed that LBV was an effective and stable presbyopia therapy[19]. The current study used the MEL 90 excimer laser instead of the MEL 80 laser used previously, further strengthening the evidence for the successful application of LBV. One characteristic difference between LBV and the simple monovision design was the blended vision achieved by SA induction[20]. In our study, 70% of the patients achieved 20/20 or better binocular distance vision as well as near vision, which was inferior than the monovision design[9]. We speculate that patients' baseline characteristics may partly explain the results. The spherical equivalent in the current study was over -7.0 D in both eyes, and high myopia may yield poorer visual acuity than low myopia[21]. The preoperative spherical equivalent in Ganesh *et al*[15] study was -3.36 D, and they reported that 97% of the patients were satisfied with their distance vision while 95% were satisfied with their near vision. Besides, our previous study found that age is a key factor determining monovision adaption[8]. The age range was wide in this study (41-58y), which may have increased the variability of the results. Nevertheless, 95% of the patients showed 20/30 binocular distance and near vision through LBV, which was defined as functional visual acuity[22] that can satisfying regular life needs.

This study showed that ocular aberrations except SA were identical between paired eyes, while SA was less in the nondominant eye than in the dominant eye. Our previous studies showed similar results for PresbyMAX, with nondominant eyes showing negative SA[23]. However, in a monovision-based SMILE, the SA was identical[8]. This was consistent with the surgical principle. The principle of LBV involves controlling alterations of SA to avoid degradation of optical quality while simultaneously increasing the focus depth[24]. A number of studies involving monovision LASIK and SMILE showed acceptable results and also identified the limitations of this approach, such as degraded stereopsis and contrast sensitivity[8,25-26], while LBV minimized such degradation through a precompensation factor to control the induction of SA. The association between SA and depth of focus has been well documented, with the depth of field increasing by 30% on average when adding 0.3 μm of SA[27]. Notably, inappropriate SA would diminish retinal image[28]. Unfortunately, one limitation of this retrospective study was that we could not obtain preoperative optical quality data. Thus, further quantitative analysis of SA changes can better reveal the underlying mechanisms.

All patients in this study were satisfied with the surgery or at least found the outcomes to be passable. The major optical disturbances were related to night vision, residual near vision difficulty, glare and blurred vision. Most symptoms were similar to those observed after regular LASIK[29]. Alarcon demonstrated that the monovision design diminishes contrast sensitivity, especially in the nondominant eyes[10]. This may account for blurred vision and night vision disturbances. Moreover, the patients' near vision was not as satisfactory as distance vision. We speculate that the relatively low residual refractive error in the nondominant eye cannot satisfy all near works. Hayashi *et al*[26] also found that modified monovision (0.75 D anisometropia) yielded worse near vision than traditional monovision (1.75 D anisometropia). Another possible mechanism proposed by Almutairi *et al*[30] was that the accommodative response reduced the image quality when the stimulus approached. Presbyopia correction cannot easily yield the best of both far and near vision. PRESBYOND combines monovision as well as controlled SA to provide optimized visual acuity. Thus, the surgery can be personalized on the basis of the patient's living habits.

One limitation of the current study is its small sample size. Thus, further studies with larger sample sizes are warranted to validate our findings. Moreover, some other factors affecting near vision are worth investigating, including pupil size, accommodation, and ocular surface condition[31]. These factors have inspired us to conduct further research to identify the principles of presbyopia correction.

In conclusion, PRESBYOND is an effective and safe presbyopia correction option. Further studies are required to explore the dose effect of SA and depth of field, which may improve the predictability of this surgery.

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