3 Years Clinical Outcomes of Aspheric Micro-monovision LASIK for Correction of Presbyopia and Myopic Astigmatism

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Research article

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Abstract

Background: To investigate long term safety and efficacy of aspheric micro-monovision LASIK for correction of presbyopia and myop ic astigmatism.

Methods: One hundred and fourteen eyes of 57 patients with a mean age 48 ± 4.05 years (range: 43 to 62 years) undergoing aspheric micro-monovision LASIK treatment using the MEL 80 excimer laser (Carl Zeiss Meditec AG, Jena, Germany) were enrolled. Visual acuity, manifest refraction, amplitude of accommodation and patients' subjective rating was evaluated from 1 day to 3 years postoperatively.

Results: There were no eyes in which spherical equivalent changed by over 0.75D between 1 day and 3 years. Ninety five percent of eyes were within ±0.50 D of target correction of spherical equivalent. The percentage of monocular uncorrected distance visual acuity ≧20/20 was 95%,and all eyes achieved 20/25 or better. The percentage of binocular uncorrected near visual acuity ≧J2 was 93%,and all patients achieved J4 or better. Ninety one percent of the patients could see uncorrected both 20/20 and J2 or better binocularly. Six percent (6/108) eyes lost 1 line and no eyes lost 2 lines of corrected distance visual acuity. The overall satisfaction score for surgery was 93±6.

Conclusions: The aspheric micro-monovision LASIK using the Carl Zeiss Meditec MEL 80 Platform was an efficacious option for older myopia patients with presbyopia. Three years postoperative outcomes in Chinese population indicated improvements in uncorrected binocular vision at far and near distances with high satisfaction.

Background

Presbyopia is a universal disorder in people older than 40 years of age. [1] Restoration of loss of accommodation and achieving complete spectacle independence in presbyopic patients remains a challenge for refractive surgeons. [2] In fact, monovsion is still a regular and effective choice for presbyopia correction, which can be archived by IOLs, contact lens or laser ablations. [3–5] But the anisometropia induced by monovision is hard to adapt for some patients and the myopic target chosen for nondominant eyes in traditional monovision strategy empirically depends on age of patients. [6]

LASIK with a non-linear aspheric ablation profile and micro-monovision which can increase the spherical aberration in both eyes was created in 2009,and this treatment also be known as laser blended vision(LBV) [7] This aspheric ablation profile was calculated using CRS-master platform and final treatment profile outputs depending on preoperative refractive diopter, costumed aspheric aberration induced and functional age which depends on patient's residual accommodation rather than real age. As traditional monovision, targeted for exactly plano in dominant eyes. However, the non-dominant eye was targeted for slight myopia with an ideal target of −1.50 D in most cases.

Dr. Dan Z. Reinstein detailed reported the efficacy, safety and predictability of LBV in several studies. [7] [8] [9] According to 3-month outcomes in a Chinese population, it was safe and well-tolerated method of

simultaneous correction of myopia and presbyopia with a measurable increase in accommodative amplitude. [10] In 2015, 3 years postoperative visual outcomes and patient satisfaction after LBV were evaluated retrospectively. [11] However, there is no prospective study of long-term outcomes in an age-stratified population. Therefore, the purpose of this study was to evaluate the long-term safety and efficacy of LBV to treat myopic astigmatism and presbyopia using the MEL80 and CRS-Master platform.

Methods

This study was a non-comparative case series and was approved by the Medical Ethics Committee of Zhongshan Ophthalmic Center, Sun Yat-Sen University, People's Republic of China. The study followed the tenets of Declaration of Helsinki. A total of 57 patients undergoing LBV treatment were enrolled. All patients signed the informed consent before surgery. The mean age of the 57 patients (22 male and 35 female) was 48 ± 4.05 years (range: 43 to 62 years). Patients in this study had a mean preoperative spherical equivalent of −5.59 ±1.85 D (range: −1.25D to −11.10D), cylinder of −0.62 ±0.43 D (range: −2.25D to 0.00D) and spectacle near addition of 1.75±0.26D (0.75 to 2.50 D). Patients were enrolled in this study if they were presbyopic, had corrected distance visual acuity (CDVA) of 20/25 or better in both eyes, were medically suitable for LASIK, can tolerate at least −0.75D anisometropia during the tolerance test. Patients suffering from systemic illness, had clinically relevant lens opacity, had previous ocular surgery, or had abnormal binocular vision were excluded from the study.

Baseline data included measurement of monocular and binocular uncorrected distance visual acuity(UDVA), uncorrected near visual acuity(UNVA), corrected distance visual acuity(CDVA), corrected near visual acuity(CNVA), distance corrected near visual acuity(DCNVA), manifest refraction, cycloplegic refraction, presbyopic add, slit-lamp examination, dilated fundus examination, corneal topography (Pentacam, Oculus Optikgerate,Wetzlar,Germany), ocular wavefront (WASCA wavefront analyzer, Carl Zeiss Meditec, Jena, Germany) and subjective rating questionnaires. Ocular dominance was determined use the "hole test". [8] The patient's tolerance was measured by simulating the intended postoperative refraction using a phoroptor, and the patient's acceptance was confirmed through wearing the trial frame which simulated the intended postoperative refraction at least 5 minutes. The subjective questionnaire included 6 items about satisfaction of (1)near vision, (2)distance vision, (3)intermediate vision, (4)night vision,(5)dependence on glasses and (6)overall satisfaction with correction. Each scale ranged from 0 to 100, where 0 indicated not at all satisfied and 100 indicated completely satisfied. Near acuity was measured under the same lighting conditions in one optometry room using the Sloan Letter Near Vision Card–729000(GOOD-LITE®, IL, USA) which was designed such that the card is 40 cm away from the patient's eye when a bead on a 40-cm cord is placed at the patient's lateral canthus. The minus-lens–stimulated measurement was used to measure the amplitude of accommodation of patients as previous study described. [12]

All aspheric ablation treatments were prepared using the CRS-Master software platform (Carl Zeiss Meditec, Jena, Germany).The sphere and cylinder values entered into the laser were based on the manifest refraction without any nomogram adjustment. A target of −1.50 D was used for most non-

dominant eyes but manually adjusted according to patient's tolerance of anisometropia. Figure 1 is the scatterplot which shows the distribution of intended spherical equivalent refraction in the near eye plotted against the patient's age.

The same surgeon (Q. L.) performed all operations using the VisuMax femtosecond laser and MEL 80 excimer laser (both Carl Zeiss Meditec AG, Jena, Germany). Surgical parameters were listed as below: 1)100-μm thickness flap,2)mean optical zone was 6.32±0.24mm (range: 6.00 to 7.00),3)mean transition zone was 2.2±0.12 mm (range: 1.30 to 2.30),4)total ablation zone was 6.89±0.17mm (range: 6.50 to 8.30).

At 3 years after surgery, 54 patients (108 eyes, 95%) were still available for follow-up and all of them completed 3 years follow-up. Three patients classified as lost to follow-up and were excluded from the analysis. Postoperative follow-up examinations included manifest refraction, monocular and binocular UDVA, UNVA, CDVA, DCNVA and CNVA. Manifest refraction and visual acuity measurements were performed at 1 day, 1 week, 1 month, 3 months, 6 months, 1 year and 3 years postoperatively. Subjective questionnaire and minus-lens–stimulated accommodative amplitude were performed at the last visit.

Data were recorded in an Excel software database (2013, Microsoft Corp.).SPSS version 16.0 (SPSS, Inc., Chicago, IL) was used for statistical analysis. For normally distributed data, student paired t tests were used. For non-normally distributed data, Friedman tests were performed. A P value less than.05 was considered statistically significant.

Results

The baseline characteristics were summarized in Table 1.Postoperative visual acuity and refractive outcomes shown in Table 2.

Postoperatively, the distribution of monocular and binocular UDVA and UNVA are presented in Figure 2. The percentage of UDVA ≥20/20 and ≥20/40 were 75% and 95% in the dominant eyes and nondominant eyes, respectively. 90% of the nondominant eyes achieved UNVA ≥J2, while 75% of the dominant eyes achieved UNVA ≥J5. Binocular near visual acuity ≥J4 was achieved in all patients. All eyes achieved CDVA of 0.0 logMAR (20/25) or better postoperatively. 91% of the patients could see uncorrected both 20/20 and J2 or better binocularly.

Change in lines of CDVA at all follow-up visits shown in the Figure 3. No eyes lost 2 lines of CDVA after treatment. At 3 years postoperatively, there was a loss of one line corrected distance visual acuity in 6% (6 out of 108) eyes and no eyes lost 2 lines.

Refractive outcomes are presented in Figure 4. There were no eyes in which spherical equivalent changed by over 0.75D between 1 day and 36 months. At 3 years postoperatively, the mean spherical equivalent in distance eyes and near eyes were −0.05± 0.23 D (range:−1.00 to 0.75) and −1.34±1.67 D (range −0.75 to −2.75 D), respectively (Table 2). Ninety-five percent of the eyes were within 0.50 D of target refraction,

and all of the eyes were within 1.00D. Ninety-four percent (51 out of 54) of distance eyes were within 0.5 D of emmetropia while 96% (52 out of 54) of near eyes were within 0.5 D of micro-monovision target (–1.50D); all eyes were within 0.5 D of target astigmatism refraction.

Accommodative amplitude increased from 4.42 ± 1.26D (range 0 to 4.5) to 4.91 ± 1.43 D (range 0.50 to 4.75) (P <.05) (Table 3). In different age groups, accommodation amplitude increased after surgery. However, only patients older than 46 years showed a significant increase in amplitude (P <.05).

Table 4 shows the subjective rating after LBV. The mean satisfaction scores was 93±6 (range 80 to 100).The satisfaction scores for both near vision and distance vision improved significantly after surgery. After 3 years, 94% patients achieved completely “glasses-off”. No patient used spectacles for distance vision, even while driving at night.

Discussion

This consecutive case series analyzed the long term safety and efficacy of presbyopic treatments using LBV. After 3 years, there was a loss of one line on corrected distance visual acuity after surgery in only 6% (6 out of 108) of the eyes and no patients lost 2 lines in this study. Compared to the nomogram of near addition in traditional LASIK-induced monovision, the age of the patient was not a consideration when choosing target refraction for the nondominant eye. [8, 10] In the current study, the mean attempted and achieved spherical equivalent in the near eye was –1.51 ± 0.29 and –1.34 ± 1.67 D, respectively. In earlier studies, mean refraction of the near eyes was –1.31D at 3 months and –1.3D at 1 year. [8, 10] Micro-monovision myopic target of nondominant eyes were stable during the 3 year follow up.

Using this aspheric micro-monovision LASIK for presbyopia correction, the non-dominant eye was targeted for slight myopia with a target of –1.50 D in most cases. In the current study, no patients reported difficulty in adaptation during the 3 year follow-up period. However, the efficacy of near vision could be a concern due to the decrease of anisometropia. At 3 years follow-up, still 93% (50 out of 54) of patients achieved 0.1 logRAD or better binocular uncorrected near visual acuity. The satisfaction questionnaire scores improved significantly after surgery. These present results showed that DCNVA and amplitude of accommodation both improved significantly after surgery. Thus, the induced spherical aberration increased the depth of field and the measured amplitude of accommodation. More importantly, accommodation amplitude increased after LBV in different age groups. The significantly increased pseudo-accommodation was useful, [13] especially in patients older than 46 years of age and suffering from severe presbyopia syndrome.

After three years, visual acuity and refraction results were stable. The results of this present study match those reported by other studies which using LBV and presbyLASIK. [8] [11] [10] [14] [15] The excellent results with respect to visual acuity could be due to moderate myopia with low astigmatism in most eyes. However, these study outcomes confirmed that LBV was safe and effective for presbyopia correction.

The limitation of this study was that the average age of patients in this study was 48 years with a mean spectacle near addition of 1.75D (range: 0.75 to 2.50 D). This is generally regarded as a low to moderate presbyopia. The study lacked a significantly older population. Nevertheless, patients under 50 years of age formed the majority of patients willing to undergo LBV. There aren't enough older patients with refractive errors and clear lens, devoid of cataract, in this study. Analyzing the long term efficacy and safety of LBV in older presbyopic treatments could have more clinical value. Similar to earlier studies on LBV, this study didn't have a control group. However, pupil diameter become naturally smaller with age and the aspherical ablation design with negative spherical aberrations would induce myopic refraction during accommodation mitosis. [16] Both these effects were beneficial for improving presbyopia symptoms. However, a patient with emmetropic refraction and significant positive ocular spherical aberration, e.g. after regular myopic LASIK treatments or small incision lenticule extraction (SMILE) treatments, could have a fluctuating refraction depending on the pupil diameter. In other words, the disappearance of SA upon pupil contraction would cause a hyperopic shift in the refractive state of the eye and require compensatory accommodation (accommodative lag). This would further alleviate the presbyopia symptoms.

Conclusion

In conclusion, to our knowledge, this is the first 3 years long term prospective study to analyze the efficacy and safety of LBV LASIK for correction of presbyopia and myopic astigmatism using the Carl Zeiss Meditec MEL 80 Platform. This protocol was safe and effective for treating presbyopia and myopic astigmatism over a long term. Three years postoperative outcomes in Chinese population indicated improvements in uncorrected binocular vision at far and near distances with high satisfaction. Careful patient selection and information was necessary.

Abbreviations

LBV: laser blended vision; LASIK: Laser-assisted in situ keratomileusis;CDVA: Corrected distance visual acuity; UDVA: Uncorrected distance visualacuity; UNVA: Uncorrected near visual acuity; LogMAR:Log minimum angle resolution;LogRAD:Log reading acuity determination,the reading equivalent of logMAR

Declarations

Ethics approval and consent to participate

The study was approved by the Medical Ethics Committee of Zhongshan Ophthalmic Center, Sun Yat-Sen University, People's Republic of China. The study followed the tenets of Declaration of Helsinki. Written informed consent was obtained from all subjects after the aims and nature of the study were explained to the participants.

Consent for publication

Not applicable.

Availability of data and materials

The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.

Competing interests

The authors declare that they have no competing interests.

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Authors' contributions

LF drafted the manuscript and performed the literature. ZT participated in information gathering and editing. LQ conceived the idea and supervised writing of this paper. All authors read and approved the final manuscript.

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Tables

Table 1.Summary of the Preoperative findings

Preoperative	Monocular Eyes	Binocular Patients
No.	114	57
Age(years)	-	48 ± 4.05 (43 to 62)
Gender ratio(M:F)	-	0.63(22:35)
UDVA(LogMAR)	1.06±0.57(1 to 2)	1.02±0.48(1 to 2)
CDVA(LogMAR)	-0.05±0.07(-0.18 to 0.10)	-0.08±0.04(-0.20 to 0.10)
UNVA(LogRAD)	0.75±0.32(0.4 to 1.0)	0.62±0.43(0.3 to 1.0)
DCNVA(LogRAD)	0.80±0.34(0.5 to 2.0)	0.75±0.32(0.5 to 2.0)
CNVA(LogRAD)	0.07±0.08(0.0 to 0.2)	0.00±0.05(-0.1 to 0.18)
Spherical equivalent(D)	-5.59 ±1.85 D(-1.25 to -11.10)	-
Astigmatism(D)	-0.62 ±0.43 D (-2.25 to 0.00)	-
Spectacle near addition(D)	1.75±0.26 (0.75–2.50)	-
Target SE refraction (D)		
Dominant eye	Plano	-
Non-Dominant eye	-1.51 ± 0.29(-0.75 to -2.25)	-
Optical zone(mm)	6.32±0.24(6.00 to 7.00)	-
Total ablation zone(mm)	6.89±0.17(6.50 to 8.30)	-

All values are presented as mean ± standard deviation (range); UDVA=Uncorrected Distance Visual Acuity; CDVA: Corrected Distance Visual Acuity; UNVA=Uncorrected Near Visual Acuity; DCNVA=Distance Corrected Near Visual Acuity, represents distance corrected without spectacle near addition; CNVA=Corrected Near Visual Acuity, represents distance corrected with spectacle near addition for best near visual acuity; D=Diopter

Table2.Summary of the postoperative data after treatment

3 Year Postoperative	Monocular Eyes	Binocular Patients
No.	108	54
UDVA(LogMAR)		0.00±0.07(-0.18 to 0.00)
Dominant eyes	0.00±0.21(-0.18 to 0.70)	-
Non-dominant eyes	0.27±0.13(0.18 to 0.60)	-
CDVA(LogMAR)		-0.05±0.05(-0.18 to 0.00)
Dominant eyes	0.00±0.14(-0.18 to 0.00)	-
Non-dominant eyes	0.00±0.12(-0.18 to 0.00)	-
UNVA(LogRAD)		0.07±0.04(0.00 to 0.40)
Dominant eyes	0.43±0.18(0.20 to 0.50)	-
Non-dominant eyes	0.08±0.14(0.00 to 0.50)	-
DCNVA(LogRAD)		0.20±0.25(0.01 to 0.40)
Dominant eyes	0.32±0.18(0.18 to 0.40)	-
Non-dominant eyes	0.21±0.11(0.18 to 0.40)	-
CNVA(LogRAD)		0.08±0.14(-0.18 to 0.10)
Dominant eyes	0.08±0.04(-0.10 to 0.10)	-
Non-dominant eyes	0.08±0.09(-0.10 to 0.10)	-
Spherical equivalent(D)		-
Dominant eyes	-0.05±0.23(-1.00 to 0.75)	-
Non-dominant eyes	-1.34±1.67(-0.75 to -2.75)	-
Astigmatism(D)		-
Dominant eyes	-0.18±0.15(-0.75 to 0.00)	-
Non-dominant eyes	-0.27±0.12(-1.00 to 0.25)	-

All values are presented as mean ± standard deviation (range); UDVA=Uncorrected Distance Visual Acuity; CDVA: Corrected Distance Visual Acuity; UNVA=Uncorrected Near Visual Acuity; DCNVA=Distance Corrected Near Visual Acuity, represents distance corrected without spectacle near addition; CNVA=Corrected Near Visual Acuity, represents distance corrected with spectacle near addition for best near visual acuity; D=Diopter

Table3. Minus-lens–stimulated accommodative amplitude

Groups(Age,Y)	Preoperative (D)	Postoperative (D)	P*value
Pre-op	Pre-op	Post-3y	
41-45(n=22)	4.26±0.27(2.75 to 4.50)	4.59±0.30(3.75 to 4.50)	0.32
46-50(n=27)	3.50±0.16(0.75 to 3.75)	4.33±0.20(0.75 to 4.75)	**0.01**
>50(n=5)	1.79±0.97(0 to 2.00)	2.50±0.85(0.50 to 3.00)	**0.00**
Total(n=54)	4.42±1.26(0 to 4.50)	4.91±1.43(0.50 to 4.75)	**0.02**

All values are presented as mean ± standard deviation (range); Y=Years old; D=Diopters*P value less than 0.05 was considered statistically significant using paired student's t tests.

Table4: Postoperative Patient Satisfaction Scores

Scale	Preoperative	Postoperative	P**
Near vision	44±20(0 to 50)	90±5(80 to 100)	**0.00**
Distance vision	49±17(0 to 50)	90±3(80 to 100)	**0.00**
Intermediate vision	65±14(0 to 80)	91±6(80 to 100)	0.46
Night vision	80±5(60 to 100)	87±6(70 to 100)	0.32
Dependence on glasses	0	94±6(80 to 100)	**0.00**
Satisfaction with correction	37±14(0 to 50)	93±6(80 to 100)	**0.00**

Questionnaire included scales ranging from 0 to 100,where 0 induced not at all satisfied and 100 indicated completely satisfied.**P value less than 0.05 was considered statistically significant using paired student's t tests; All values are presented as mean ± standard deviation (range)

Figures

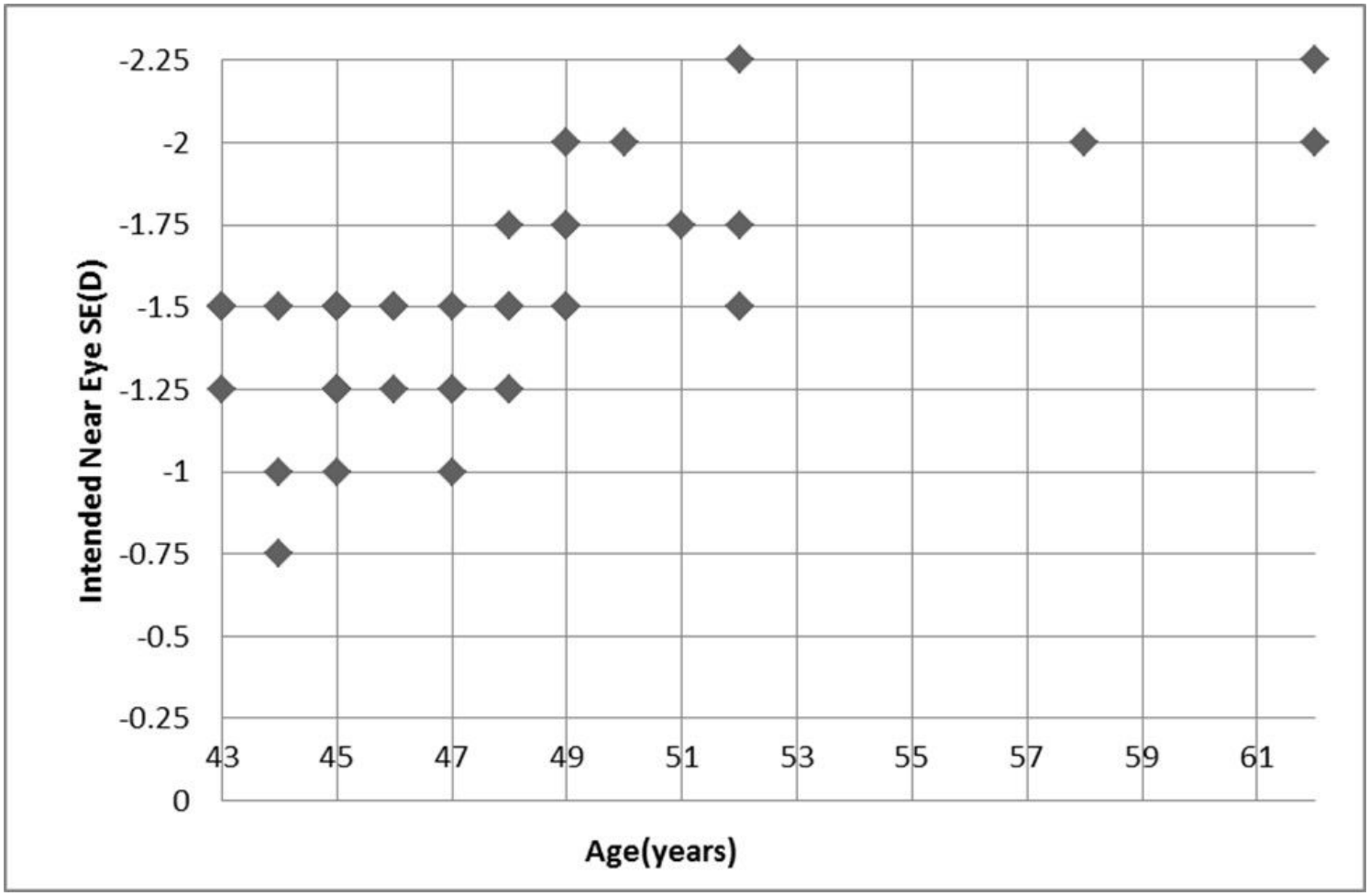


Figure 1

the scatterplot shows the distribution of intended spherical equivalent (SE) refraction in the near eye plotted against the patient's age. D: Diopter

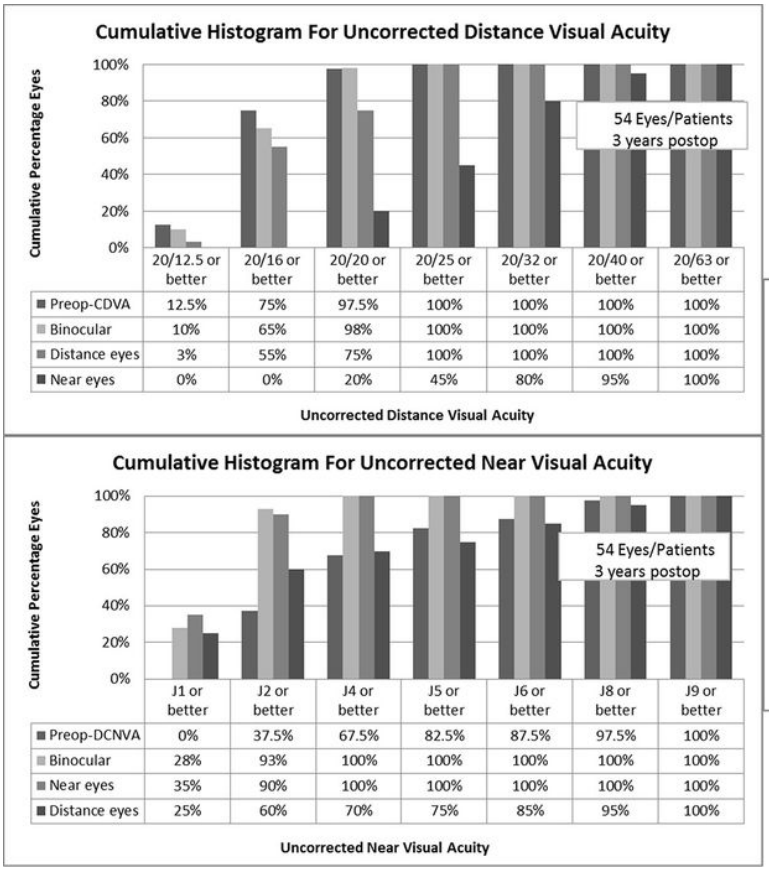
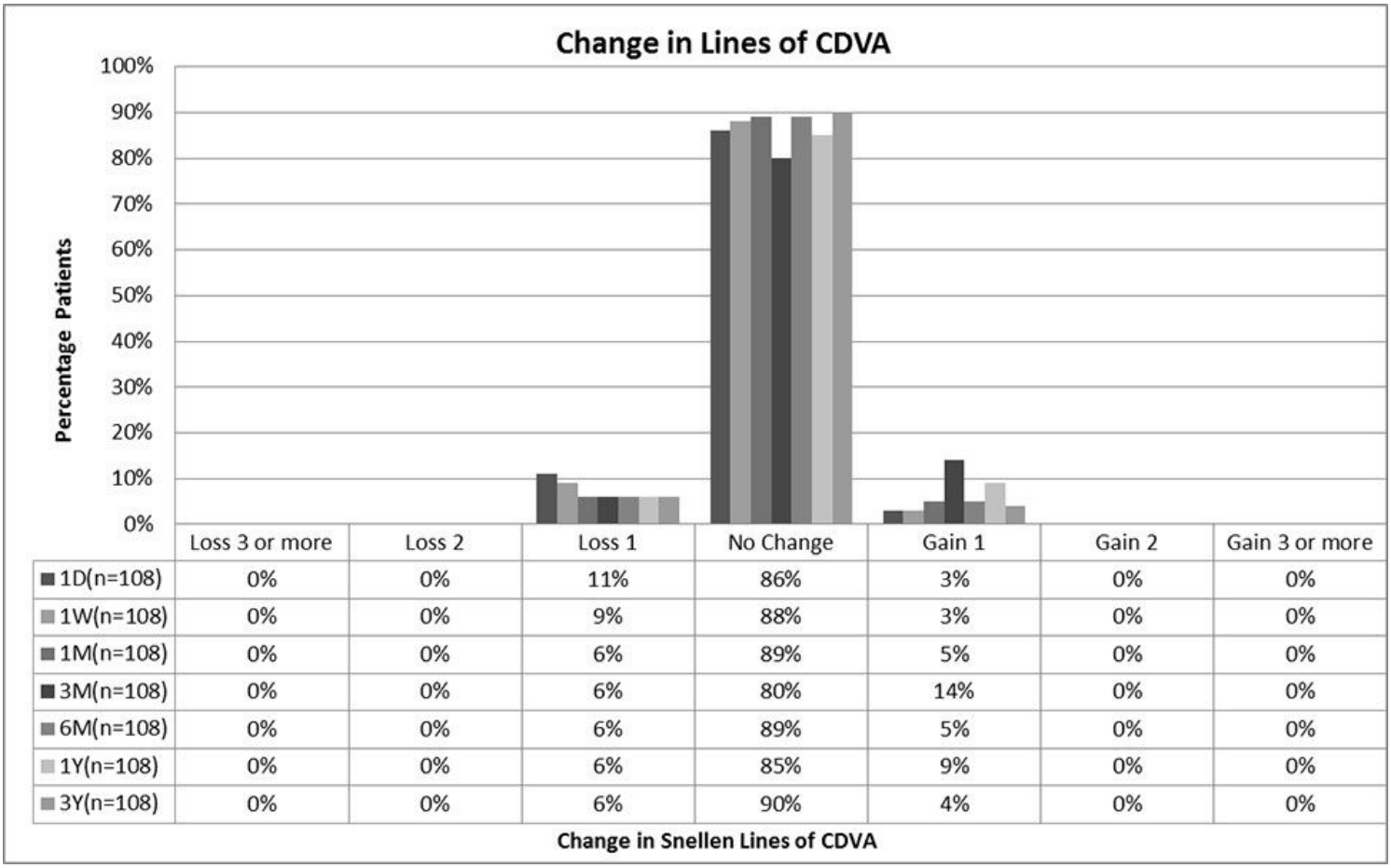


Figure 2

Changes in binocular uncorrected visual acuity at 3 year after treating with aspheric micro-monovison LASIK. Preop-CDVA=Preoperative corrected distance visual acuity; Preop-DCNVA=Preoperative distance corrected near visual acuity.



	Loss 3 or more	Loss 2	Loss 1	No Change	Gain 1	Gain 2	Gain 3 or more
1D(n=108)	0%	0%	11%	86%	3%	0%	0%
1W(n=108)	0%	0%	9%	88%	3%	0%	0%
1M(n=108)	0%	0%	6%	89%	5%	0%	0%
3M(n=108)	0%	0%	6%	80%	14%	0%	0%
6M(n=108)	0%	0%	6%	89%	5%	0%	0%
1Y(n=108)	0%	0%	6%	85%	9%	0%	0%
3Y(n=108)	0%	0%	6%	90%	4%	0%	0%

Figure 3

Changes in lines of corrected distance visual acuity (CDVA) at 3 years after treating with aspheric micro-monovison LASIK. D, W, M, and Y represent day, week, month, and year, respectively.

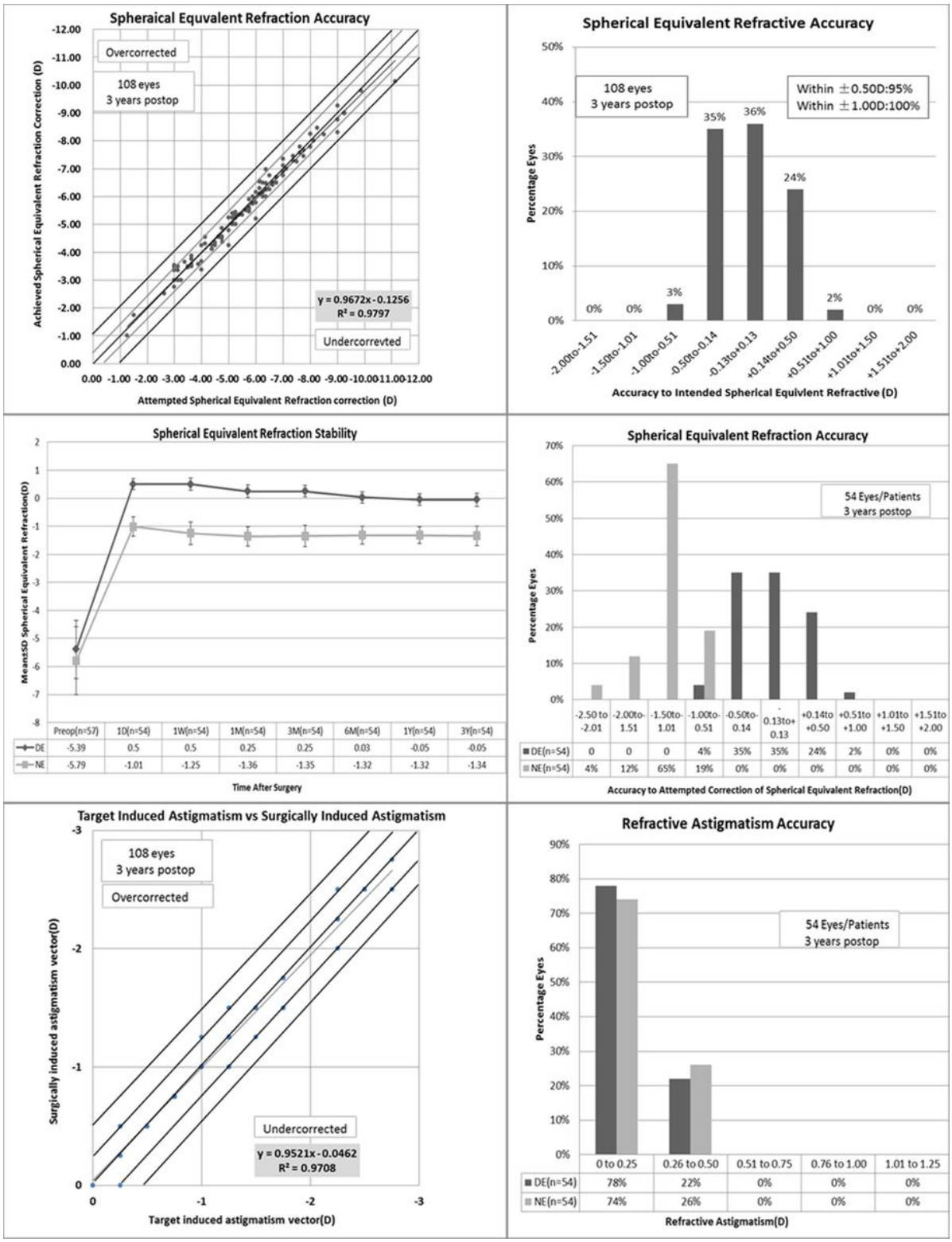


Figure 4

Refractive outcomes of the patients. W, M, and Y represent week, month, and year, respectively. D in 1D (middle left) represents day, and in others figures D = diopters.DE: distance eyes, NE: near eyes.