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Retrospective observational study of micro-monovision small incision lenticule extraction (SMILE) for the correction of presbyopia and myopia

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Abstract

This study was aimed to evaluate refractive and visual outcomes after micro-monovision small incision lenticule extraction (SMILE) in patients with presbyopia and myopia. In total, 72 patients (144 eyes) with a mean age of 46.0 ± 4.9 years were included in this study. The dominant eye was treated for distance vision and the nondominant eye for near vision by targeting between −0.50 and −1.75 diopters (D). Treatment efficacy, safety, and refractive stability were calculated from postoperative data including refraction, binocular uncorrected distance visual acuity (UDVA), binocular uncorrected near visual acuity, monocular uncorrected distance visual acuity, and monocular corrected distance visual acuity (CDVA). Six months post-surgery, binocular UDVA was better than or equal to 20/20 in 88% of patients. No loss in 2 or more lines was observed in the Snellen lines of corrected distance visual acuity. Mean spherical equivalent (SE) for the distance eye was −0.18 ± 0.37 D, whereas the attempted and achieved SE in the near eye were −0.90 ± 0.44 and −0.99 ± 0.54 D, respectively. In total, 79% of eyes were within ±0.50 D, and 98% within ±1.00 D, of the intended refraction. A UDVA of 0.0 logMAR (20/20) or better, and an uncorrected near visual acuity of Jaeger (J) of 3 (20/32) or better, were observed in 83% of patients. Micromonovision refractive surgery using SMILE enhanced functional near vision in presbyopic patients.

Abbreviations: CDVA = corrected distance visual acuity, D = diopter, J = Jaeger, LASIK = laser-assisted in situ keratomileusis, SE = spherical equivalent, SMILE = small-incision lenticule extraction, UDVA = uncorrected distance visual acuity.

Keywords: corneal surgery, laser, monovision, myopia, presbyopia, small incision lenticule extraction

1. Introduction

Presbyopia is an age-related loss of accommodation in the crystalline lens. This refractive error typically affects people older than 40 years of age and can decrease the quality of life considerably.[1] It is estimated that approximately 2.1 billion people will be affected by presbyopia in 2020.[2,3] Furthermore, recent changes in society, whereby daily activities require computer work and use of "smartphones," have increased the need for spectacle independence. Current treatment options for presbyopia include monovision, corneal multifocal ablation, corneal inlays, and clear lens exchange with multifocal intraocular lenses.

Monovision is a technique that corrects the dominant eye to emmetropia for distance vision and the nondominant eye to myopia for near vision.[4] The purpose of this treatment is to provide presbyopic patients with functional distance and near vision to avoid the need to wear glasses. Correction options for monovision include contact lenses or refractive surgery, such as laser-assisted in situ keratomileusis (LASIK) or laser assisted sub-epithelial keratomileusis.[4–6]

Recent advances in refractive surgery led to the introduction of small-incision lenticule extraction (SMILE) for the treatment of myopic astigmatism.[7,8] It is believed that SMILE preserves more corneal nerves, and better maintains biomechanical strength, compared to flap-based procedures.[9,10] Therefore, it has several advantages including early visual recovery and reduced eye dryness compared to other refractive surgeries. To the best of our knowledge, no clinical results have been reported for monovision using SMILE.

The purpose of this study was to evaluate refractive and visual outcomes following micro-monovision SMILE in patients with presbyopia and myopia.

2. Patients and methods

This study was a retrospective, noncomparative case series that included 72 myopic presbyopic patients that underwent SMILE between September 7, 2012 and June 10, 2016, at the B and Viit Eye Center, Seoul, Republic of Korea. Patients were included in this study if they were suitable for myopic SMILE surgery, aged

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above 40 years of age, had <6 diopters (D) of myopia, and <3 D of astigmatism. We excluded patients who had undergone ocular surgery previously, or who had visually significant cataracts or suspected ocular diseases including keratoconus, glaucoma, corneal epithelial pathology, and posterior segment pathology.

2.1. Preoperative examination

A full preoperative ophthalmologic examination was performed. Measurements of uncorrected distance visual acuity (UDVA), best spectacle-corrected visual acuity (CDVA), corneal topography, mesopic infrared pupillometry (Colvard pupilometer; Oasis Medical Inc., Glendora, CA), slit-lamp biomicroscopy, tonometry (NT-500; Nidek, Aichi,Japan), pachymetry (US-500 Echoscan; Nidek), and funduscopy were performed.

2.2. Micro-monovision assessment

The dominant eye was determined using the Porta test.[11] In the test, the patient extends one arm out superimposing the thumb of that hand with a distance target. The testee closes one eye alternatively to determine the dominant eye. The patient was then corrected to monovision using glasses for 30 minutes. Full correction was attempted for the dominant eye. The initial addition for the nondominant eye was 1.50 D, which was then reduced until the patient reported no cross-blur. In the event that the patient could not read Jaeger (J) 2, addition was increased. Subsequently, patients were asked if they could tolerate the anisometropia; patients who reported no visual discomfort or disturbances were considered suitable candidates for the micro-monovision treatment.

2.3. Surgical procedure

All surgical procedures were performed using the 500-kHz VisuMax femtosecond laser system (Carl Zeiss Meditec AG, Jena, Germany) and topical anesthesia with proparacaine hydrochloride (Alcaine; Alcon, Fort Worth, TX). Four cleavage planes were constructed to produce anterior and posterior surfaces of the refractive lenticule, the lenticule border, and a superior incision opening 2 mm in length. Cap thickness ranged from 110 to 120 μm and the lenticule diameter was 6.0 or 6.6 mm. The residual stromal bed was > 280 μm. Following the cutting procedure, the refractive lenticule was extracted through the superior incision using surgical forceps.

2.4. Postoperative follow-up

Patients were instructed to instill topical steroids (fluorometholone 0.1%; Samil, Seoul, Korea) 6 times a day, and to gradually reduce this number over a period of 14 days. Topical antibiotics (moxifloxacin 0.5%; Alcon Novartis, New York, NY) were administered 4 times a day for 14 days.

All patients were followed up at 1 day and 1 week, as well as 1, 3, and 6 months, after surgery. Each visit included slit-lamp, binocular uncorrected near visual acuity, binocular UDVA, monocular UDVA and CDVA measurements.

2.5. Statistical analysis

Outcome data were analyzed and displayed in accordance with standardized guidelines described previously by Waring.[12] Outcome parameters were calculated as described below:[7]

1. Treatment efficacy was evaluated for distance-corrected eyes by comparing UDVA at 6 months after surgery to CDVA prior to surgery.
2. Safety was assessed by comparing CDVA prior to surgery to CDVA at 3 months after surgery.
3. Refractive predictability was the percentage of eyes within ±0.50 D and ±1.00 D of the attempted refraction.

Statistical analyses were performed using the SPSS software (version 18; SPSS Inc., Chicago, IL). The independent-samples *t* test was used to compare the preoperative and postoperative data between distance-corrected eyes and near-corrected eyes. Paired-samples *t* test was used to compare the spherical equivalent (SE) between 1 day and 6 months post-surgery for both distance-corrected eyes and near-corrected eyes, respectively. *P* value <.05 was considered statistically significant.

2.6. Ethics

The study adhered to the tenets of the Declaration of Helsinki and was conducted in compliance with the regulations of the Institutional Review Board of Daejeon St. Mary's Hospital, Daejeon, Korea.

3. Results

In total, 144 eyes from 72 myopic patients with presbyopia (33% male, 67% female) were included in this study. The average patient age was 46 years (range: 40–57 years). The right eye was dominant in 65% of patients. Table 1 presents the descriptive characteristics of the preoperative and treatment-attempted refractive error, central corneal thickness, intended cap/lenticule thickness and residual stromal bed thickness for each distance and near target treatment group. The preoperative refractive error and corneal thickness showed no difference between the 2 groups. Significant difference was found for sphere treatment attempt, SE treatment attempt, and intended lenticule thickness. Near-corrected group received less amount of refractive correction. The intended lenticule thickness was thinner in the near-corrected group.

Table 2 shows the postoperative refractive results of distance-corrected eyes and near-corrected eyes. Significant difference was evident for the achieved change in SE and resultant SE between the 2 groups. Table 3 displays the distribution of target SE in nondominant eyes. Generally, more myopic target was planned for the older presbyopes.

3.1. Visual acuity

Treatment efficacy is illustrated in Figure 1A and B. The cumulative histogram shows that 99% of dominant eyes had a UDVA of 20/25 or better after 6 months. Binocular UDVA was better than or equal to 20/20 in 88% of patients. Figure 1B shows data for dominant eyes with distance correction. In total, 51 dominant eyes (71%) had a UDVA at 6 months after surgery that was the same or better than CDVA before surgery, and 68 eyes (94%) had a UDVA within one line of CDVA before surgery. Safety is shown in Figure 1C. Nine eyes (6%) had lost one line of CDVA, and no eyes lost 2 or more lines at 6 months post-surgery.

3.2. Refraction

Refractive predictability is displayed in Figure 1D and E. Refractive astigmatism prior to surgery and at 6 months post-surgery is shown in Figure 1F. A strong correlation was observed

Table 1

The preoperative baseline characteristics of distance-corrected eyes and near-corrected eyes.

Parameter	Distance-corrected eyes		Near-corrected eyes		*P* value
	Mean ± SD	Range	Mean ± SD	Range	
Preoperative sphere, D	−3.77 ± 1.47	−8.50 to −1.00	−3.95 ± 1.46	−8.00 to −1.50	.478
Preoperative cylinder, D	−0.63 ± 0.53	−2.75–0.00	−0.67 ± 0.56	−2.25–0.00	.649
Preoperative spherical Equivalent refraction, D	−4.09 ± 1.50	−8.50 to −1.25	−4.28 ± 1.51	−8.13 to −1.50	.438
Sphere treatment attempt, D	−3.77 ± 1.47	−8.50 to −1.00	−3.02 ± 1.47	−7.00 to −0.50	.002*
Cylinder treatment attempt, D	−0.60 ± 0.51	−2.25–0.00	−0.67 ± 0.56	−2.25–0.00	.441
Spherical equivalent treatment attempt, D	−4.08 ± 1.47	−8.50 to −1.25	−3.35 ± 1.51	−7.13 to −1.00	.004*
Central corneal thickness, μm	538.6 ± 28.9	469–600	537.6 ± 28.2	470–596	.841
Intended cap thickness, μm	110.0 ± 0.0	110–110	110.1 ± 1.2	110–120	.319
Intended lenticule thickness, μm	86.5 ± 21.3	40–131	74.5 ± 22.9	34–136	.001*
Residual stroma bed thickness, μm	342.1 ± 33.5	281–419	353.0 ± 35.0	296–427	.059

D = diopters.
* *P*-value < .05.

Table 2

The postoperative refractive results of distance-corrected eyes and near-corrected eyes 6 months after treatment.

Parameter	Distance-corrected eyes		Near-corrected eyes		*P* value
	Mean ± SD	Range	Mean ± SD	Range	
Achieved change in Spherical equivalent, D	3.91 ± 1.44	1.38 ~ 7.63	3.30 ± 1.55	0.63 ~ 7.13	.015*
Spherical equivalent refraction, D	−0.18 ± 0.37	−1.125 ~ +1.00	−0.99 ± 0.54	−2.0 ~ +0.375	<.001*

D = diopters.
* *P*-value < 0.05.

between attempted and achieved SE refraction at 6 months post-surgery ($r^2 = 0.98$). The mean difference between attempted and achieved SE refraction at 6 months post-surgery was 0.11 ± 0.41 D (range: −1.25–1.25 D). In total, 79% and 98% of eyes were within ±0.50 D and ±1.00 D of the attempted refraction, respectively. The percentage of eyes having <0.50 D of astigmatism increased from 59% before surgery to 78% at 3 months post-surgery.

3.3. Stability

Stability is shown in Figure 1G. The mean SE for the dominant eye changed from −4.09 ± 1.50 D preoperatively to −0.19 ± 0.40 D 1 day after surgery, −0.23 ± 0.39 D after 1 month, and −0.18 ± 0.37 D after 6 months. The mean SE for the nondominant eye changed from −4.28 ± 1.51 D preoperatively to −1.04 ± 0.48 D 1 day following surgery, −0.94 ± 0.56 D after 1 month, and −0.99 ± 0.54 D after 6 months. We observed no difference in SE between 1 day and 6 months post-surgery for both dominant and nondominant eyes, respectively ($P = .713$ for dominant eyes and $P = .199$ for nondominant eyes).

Table 3

Target spherical equivalent refraction in the near eye.

Target SE, D	Number of patients, %	Age, years	Preoperative SE, D
−0.50	30 (41.7)	42.1 ± 2.51	−3.83 ± 1.59
−0.75	13 (18.1)	44.8 ± 3.03	−5.01 ± 1.33
−1.00	6 (8.3)	47.7 ± 2.16	−4.92 ± 1.87
−1.25	7 (9.7)	48.6 ± 2.57	−3.81 ± 0.77
−1.50	11 (15.3)	52.9 ± 3.33	−4.53 ± 1.40
−1.75	5 (6.9)	51.2 ± 2.17	−4.55 ± 1.38

D = diopters, SE = spherical equivalent.

3.4. Near visual acuity

Combined distance and near binocular uncorrected vision is shown in Figure 2. Uncorrected binocular near visual acuity measurements revealed that 38% of patients (n = 27) achieved J1 and 94% (n = 68) achieved over J3 near vision. In addition, 4 patients achieved J4 near visual acuity. A UDVA of 0.0 logMAR (20/20) or better, and an uncorrected near visual acuity of J3 (20/32) or better, were observed in 83% of patients.

4. Discussion

Presbyopia is a refractive problem in the elderly that has not been solved satisfactorily. It is characterized by decreased accommodation for near objects. One possible treatment option is monovision laser therapy, which corrects the dominant eye for distance and the nondominant eye for near vision.[4] Previous studies have investigated the clinical outcomes of monovision using LASIK.[6,13]

To the best of our knowledge, this is the first report on modified monovision using SMILE. This retrospective study included 72 patients who have completed 6 months of follow-up. Our results showed that binocular uncorrected near visual acuity was over J3 in 94% of patients at 6 months post-surgery. Overall, our findings showed that this approach was effective in correcting presbyopia.

Our results can be considered from 2 points of view; namely, SMILE and monovision. With respect to SMILE, our data were comparable to findings from previous studies.[7,14,15] With regard to the refractive predictability, Hansen et al showed that 88% of eyes were within ±0.50 D and 98% were within ±1.00 D of the intended refraction at 3 months post-surgery. Similarly, our findings showed that 79% and 98% of eyes were within ± 0.50 D and ± 1.00 D of the attempted refraction, respectively. However,

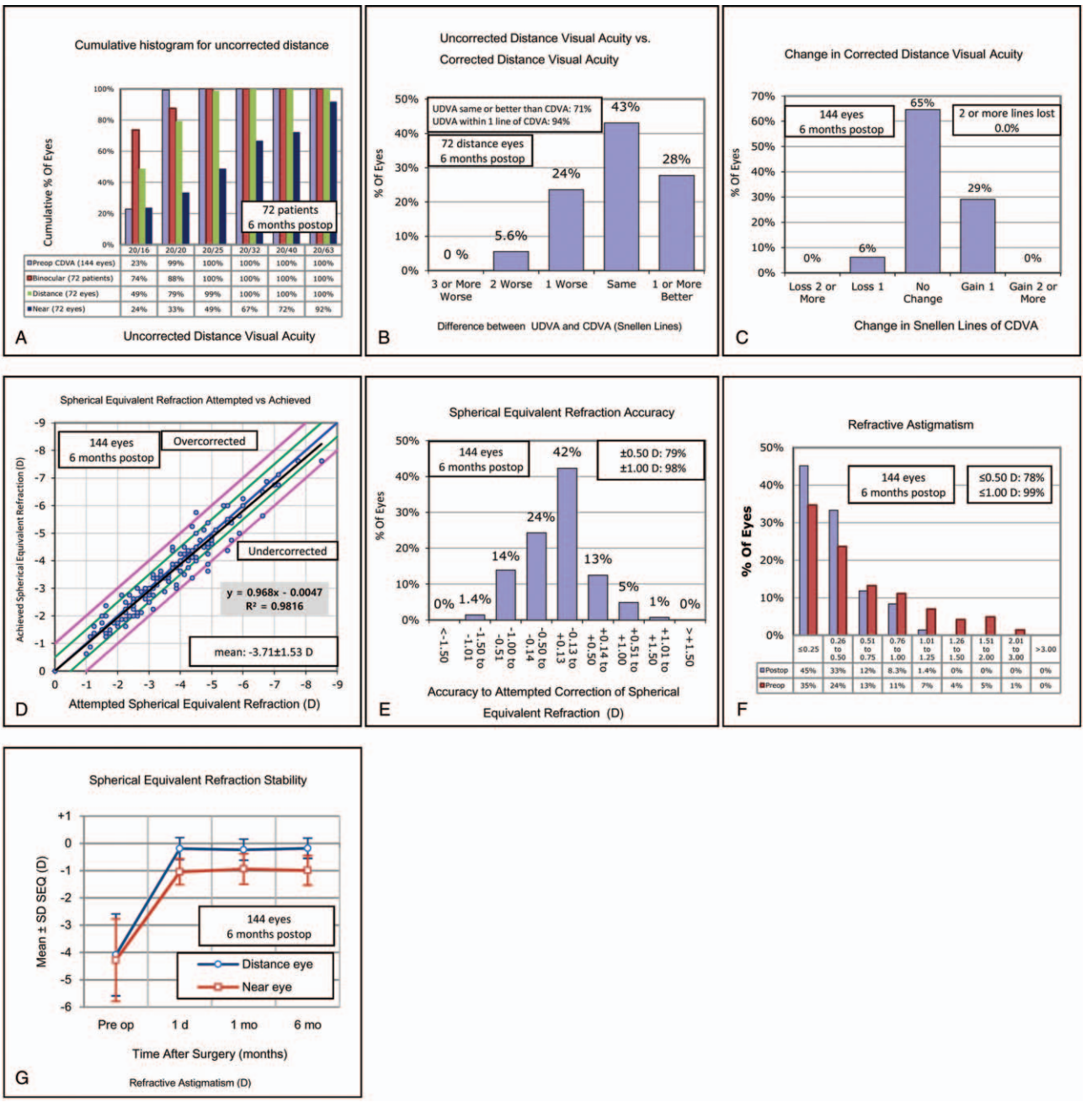

Figure 1. Refractive outcomes at 6 months post-small incision lenticule extraction for 144 eyes with myopic presbyopia. CDVA = corrected distance visual acuity, D = diopters, Postop = postoperative, Preop = preoperative, UDVA = uncorrected distance visual acuity.

3 eyes were not within ± 1.00 D of the target refraction. One eye that was to be corrected for near vision was over-corrected, resulting in near emmetropia. However, the patient had good distance vision and was satisfied with the results; therefore, no further treatment was planned. In addition, 2 eyes in 1 patient were under-corrected. However, the patient achieved 20/20 distance vision and J1 binocular near vision. Since the patient was pleased with the clinical results, no re-treatment was performed. Considering the efficacy of the treatment in this study, 99% of eyes achieved a UDVA of 20/25 or better for the dominant eye, which was treated for emmetropia. Our outcomes are comparable to those of previous reports.[7,15] Collectively, our results reflect previous findings that SMILE is a predictable and efficient method.

The other important aspect of our study was monovision treatment for presbyopic correction. The mean SE was −0.99 ± 0.54 D for the nondominant eye after surgery, and 54 patients (75%) gained a mean binocular uncorrected visual acuity over J2. SE refraction stability was also stable for near-corrected eyes (Fig. 1F). Previous studies have reported clinical results for myopic presbyopic patients after LASIK-induced monovision.[6,13] Garcia-Gonzalez et al[6] observed that the induced myopic diopter was −0.97 D in the nondominant eye, with a mean near binocular uncorrected visual acuity of 0.74. Taking

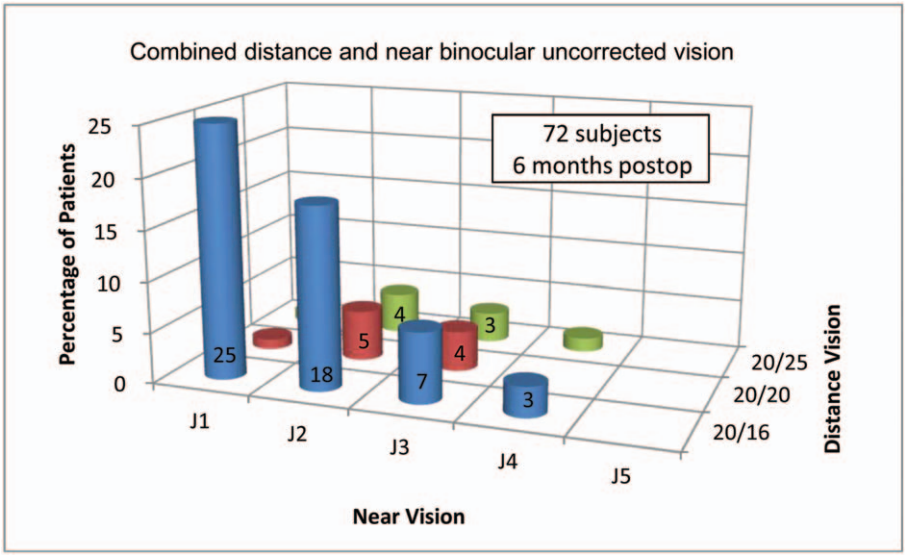

Figure 2. Distribution of combined distance and near binocular uncorrected vision.

into consideration the visual acuity conversion from decimal to Jaeger standard, the visual outcomes of their study were similar to our results.

The SMILE procedure offers several advantages compared to LASIK. First, SMILE is known to result in greater biochemical stability. This increased biochemical stability has been attributed to the absence of a flap and a decreased inflammatory response.[16–18] As mentioned previously, the absence of a flap can decrease dry eye symptoms. One concern with LASIK is damage to the corneal nerves, which leads to dry eye syndrome. Considering that presbyopic patients are within the age range prone to dry eye syndrome, the SMILE procedure, which decreases nerve damage, might be preferable. Previous reports have shown few changes in postoperative corneal sensitivity following SMILE surgery in comparison to femtosecond LASIK.[9,19] A previous meta-analysis reported the superiority of SMILE versus femtosecond LASIK in terms of tear breakup time, ocular surface disease index scores, corneal sensitivity, and corneal sub-basal nerve density.[20]

This study only included myopic presbyopic patients for 2 reasons. First, ablation patterns differ between myopic and hyperopic corrections. Hyperopic correction typically results in hyperprolate cornea, which has some multifocality.[21,22] Therefore, even distance-corrected-hyperopic eyes may simulate presbyopic correction due to the induced multifocality, complicating the interpretation of the results. Second, SMILE surgery is only suitable for myopic eyes. When the indication is broadened to include hyperopic eyes, a separate clinical study is required to evaluate the application of SMLE to hyperopic presbyopia.

Limitations of monovision include decreases in contrast sensitivity, stereopsis, and depth of perception, which result in poor adaptation. In this study, to avoid unsatisfactory results, the patients completed reading tests to determine the amount of spherical power to add to the nondominant eye. However, despite such efforts, problems can still arise. First, the pretest to select patients suitable for monovision is not error-free. Second, as the patient ages, the "add amount" may be insufficient. The average age of our participants was 46 years (range: 40–57 years), at which there may be some residual accommodation power.

A limitation of our study was that contrast sensitivity was not evaluated. The degree of change in contrast sensitivity according to monovision differs among reports. Levinger et al[13] reported that contrast sensitivity and glare decreased significantly in 40 presbyopic patients after excimer laser monovision correction. The mean refraction of near eyes was -1.74 ± 0.59 D. Meanwhile, a study by Garcia-Gonzalez and colleagues, which used LASIK monovision, showed that the distance binocular contrast sensitivity decreased slightly with versus without monovision.[6] However, the mean value was still within the normal limits for the patient's age, at all spatial frequencies. Another limitation was the relative short follow-up duration

This study evaluated the clinical outcomes of modified monovision using SMILE in myopic presbyopic patients up to 6 months post-surgery. Our findings showed that binocular uncorrected near visual acuity was over J3 in 94% of participants and the refractive predictability was acceptable. Overall, the results showed that this approach was effective in relieving presbyopic symptoms when patients were screened appropriately. Thus, SMILE monovision should be considered for patients with myopia and presbyopia.

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