Monovision LASIK Versus Presbyopia-Correcting IOLs: Comparison of Clinical and Patient-Reported Outcomes

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ABSTRACT

PURPOSE: To compare clinical and quality of life outcomes between patients who underwent monovision LASIK and refractive lens exchange.

METHODS: The study comprised 590 patients with refractive lens exchange and 608 patients with monovision LASIK available for 3-month postoperative clinical visits. All patients with refractive lens exchange had a Tecnis Symfony lens (Johnson & Johnson Vision Care, Inc., Santa Ana, CA) in at least one eye. Patients were divided into four refractive categories: moderate to high myopia, low myopia, plano presbyopia, and hyperopia. Three-month postoperative data were compared between monovision LASIK and refractive lens exchange for each group.

RESULTS: Postoperatively, the percentage of patients with binocular uncorrected distance visual acuity of 20/20 or better, for monovision LASIK and refractive lens exchange, respectively, was as follows: moderate to high myopia: 84.7% vs 90.7% (*P* = .31), low myopia: 89.4% vs 85.2% (P = .45), plano presbyopia: 90.5% vs 89.9% (*P* = .90), and hyperopia: 77.5% vs 84.2% (*P* = .03). For near vision, the percentage with binocular near visual acuity of 20/40 or better (J5) at 40 cm was as follows: moderate to high myopia: 98.9% vs 90.7% (P < .01), low myopia: 100% vs 98.1% (P = .17), plano presbyopia: 96.8% vs 95.8% (P = .34), and hyperopia: 95.6% vs 95.7% (P = .96). There was a statistically significant difference in patient satisfaction in favor of monovision LASIK for moderate to high myopia (94.3% for monovision LASIK vs 79.1% for refractive lens exchange, P < .01). For all other refractive categories, there was no significant difference in patient satisfaction. All myopic patients with refractive lens exchange experienced more postoperative visual phenomena than patients with monovision LASIK. The plano presbyopia group had comparable visual phenomena between the two procedures.

CONCLUSIONS: Monovision LASIK and refractive lens exchange are both reasonable options for presbyopic patients.

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he two most commonly used surgical presbyopia correction techniques are monovision induced by excimer laser¹⁻¹⁰ and crystalline lens removal with either monovision using monofocal intraocular lenses (IOLs) or bilateral implantation of multifocal IOLs.¹¹⁻¹³ With monovision, the dominant eye is corrected for distance vision and the other eye is intentionally myopic to aid near vision. The success of this technique depends on the patient's ability to tolerate anisometropia and to suppress the unwanted blurred image (interocular blur suppression).^{1,3,14} Multifocal lenses simultaneously correct distance and near vision, whereas the refractive target in both eyes is emmetropia.¹¹⁻¹³ However, these lenses have been associated with unwanted visual side effects, night vision problems, and loss of contrast sensitivity.^{13,15} Ongoing modifications in multifocal lens designs aim to reduce unwanted photic phenomena while preserving a good range of functional vision for distance and near.¹³ One of the latest developments in lens designs is the introduction of an extended range of vision IOL (Tecnis Symfony; Johnson & Johnson Vision Care, Inc., Santa Ana, CA). This IOL is supposed to provide one elongated focal area rather than various individual focal points, thus reducing the incidence of visual phenomena.¹⁶

Both surgical methods (excimer laser monovision and refractive lens exchange) have their advantages and shortcomings. Despite being the two most commonly performed surgical corrections for presbyopia,^{14,17} few studies have directly compared the outcomes of the two techniques.¹⁸ The aim of

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this study was to evaluate visual outcomes, patient satisfaction, and optical side effects in patients who underwent monovision with LASIK and refractive lens exchange with the Tecnis Symfony IOL in at least one eye.

PATIENTS AND METHODS

This retrospective study was deemed exempt from full review by the Committee of Human Research at the University of California–San Francisco because it used only retrospective, de-identified patient data. Informed consent to undergo refractive lens exchange or monovision LASIK was obtained from all patients prior to surgery. As part of informed consent, all patients agreed to the use of their de-identified data for research purposes and statistical analysis.

De-identified data of patients who underwent primary LASIK for monovision or refractive lens exchange between July 2013 and June 2016 and met inclusion criteria were exported from the electronic database. The inclusion criteria were: age between 45 and 60 years, preoperative manifest sphere between -10.00 and +3.00 diopters (D), preoperative corrected distance visual acuity (CDVA) of 20/25 or better in each eye, attended the 3-month postoperative clinical examination, and completed a patient experience questionnaire at the 3-month visit. In the refractive lens exchange group, we excluded all patients who did not have a Tecnis Symfony IOL implanted in at least one eye. This requirement was necessary to achieve better uniformity in the refractive lens exchange group and avoid combinations of too many IOL types. Patients with previous ocular surgery or any ocular pathology (other than refractive error) were excluded from this study. The decision to proceed with monovision LASIK or refractive lens exchange was primarily based on patient preference and tolerance of monovision. All patients who elected monovision LASIK had a monovision trial with a phoropter/trial frame in the consultation room. If there was any doubt about monovision tolerance or the correct amount of anisometropia, a multiple-day contact lens trial was conducted. The amount of myopia in the monovision eye was based on the patient's requirements for binocular near/distance vision.

Preoperative examination included detailed ophthalmic examination with manifest and cycloplegic refraction, uncorrected distance visual acuity (UDVA), CDVA, uncorrected near visual acuity (UNVA), slitlamp evaluation, dilated funduscopy, autorefraction and tonometry (Tonoref II; Nidek Co. Ltd., Gamagori, Japan), corneal topography (Pentacam; Oculus Optikgeräte, Wetzlar, Germany), wavefront aberration measurement (iDesign; Johnson & Johnson Vision Care, Inc.), endothelial cell count (SP 2000P specular microscope; Topcon Europe BV, Capelle aan den Ijssel, Netherlands), biometry (IOLMaster; Carl Zeiss Meditec AG, Jena, Germany), and retinal optical coherence tomography (Cirrus 4000 OCT; Carl Zeiss Meditec AG).

Visual acuity was measured at distance with a Snellen visual acuity chart and at near with a logarithmic near visual acuity chart (Early Treatment of Diabetic Retinopathy Study [ETDRS]) at 40 cm. Near visual acuity was recorded in Snellen distance equivalent (meters).

Postoperatively, patients were evaluated at 1 day, 1 week, 1 month, and 3 months. At each visit, refraction, CDVA, UDVA, and UNVA were measured. At all follow-up visits, patients completed a purpose-developed satisfaction questionnaire (Table A, available in the online version of this article). It was self-administered by the patient using a password-protected and secure computer terminal in a private area of the clinic. The questionnaire responses were stored in the secured central database, which is compliant with ISO 27001 for information security management systems. All response fields used a Likert scale to obtain the patient's preferences or degree of agreement. The 3-month postoperative questionnaire was completed by all patients and used for analysis. Of all patients with refractive lens exchange or monovision LASIK, 79.8% (956 patients) also completed a preoperative questionnaire, which allowed comparison of the change in preoperative to postoperative visual phenomena/dry eyes and difficulties in night driving and near and distance vision.

SURGICAL TECHNIQUE

All surgeries were performed in 37 surgical centers by 27 experienced ophthalmologists. LASIK procedures were performed with the VISX STAR S4 IR excimer laser (Johnson & Johnson Vision Care, Inc.) using a wavefront-guided ablation profile (Advanced CustomVue; Johnson & Johnson Vision Care, Inc.). Corneal flaps were created by a femtosecond laser (iFS; Johnson & Johnson Vision Care, Inc.). For myopic treatments, the optical zone diameter was 6 mm; for myopic astigmatism, the minor axis of the elliptical optical zone was 6 mm. The transition zone was 8 mm. Hyperopic treatments had a 6-mm optical zone and 9-mm transition zone. Standard postoperative treatment was administered to all patients, consisting of topical levofloxacin 0.5% and topical prednisolone acetate 1% four times a day for 1 week and preservative-free artificial tear drops.

Refractive lens exchange surgeries were performed with the use of a femtosecond laser (Catalys Precision Laser System; Johnson & Johnson Vision Care, Inc.). Corneal incisions were typically made on the steepest meridian, and the IOLs were implanted in the capsular bag using the Unfolder Platinum 1 series inserter

	Monovision LASIK	vs Refractive	Lens Exchange/S	challhorn et a
	TABLE 1			
Refractive Lens E	xchange: Lens Type	es and Con	nbinations	
Types/Combinations	Moderate to High Myopia	Low Myopia	Plano Presbyopia	Hyperopia
s Symfony/Tecnis +3.25 add	20.9% (9)	16.7% (9)	22.7% (27)	17.9% (67)
ral Tecnis Symfony (micromonovision target ^a)	18.6% (8)	27.8% (15)	23.5% (28)	24.1% (90)
ral Tecnis Symfony (emmetropic target)	60.5% (26)	55.6% (30)	53.8% (64)	58% (217)
nant eye targeted for emmetropia, non-dominant eye				

The Tecnis Symfony Model ZXR00 or Model ZXT 100 to 370 (toric) (Tecnis Symfony) and Tecnis Multifocal model ZLB00 (Tecnis +3.25 add) intraocular lenses are manufactured by Johnson & Johnson VIsion Care, Inc., Santa Ana, CA.

(Johnson & Johnson Vision Care, Inc.). When the corneal astigmatism was between 0.50 and 1.50 D, incisions were placed on the steepest corneal meridian. A toric lens was used in patients with corneal astigmatism greater than 1.50 D. Postoperatively, patients were instructed to instill one drop of levofloxacin 0.5% four times daily for 2 weeks, one drop of dexamethasone 0.1% four times daily for 2 weeks, and one drop of ketorolac trometamol 0.5% four times daily for 1 month.

All patients with refractive lens exchange had a Tecnis Symfony (model ZXR00) or Tecnis Symfony toric (models ZXT 100 to 370) IOL implanted in their dominant eye. Of all patients with refractive lens exchange, 57.1% (337 patients) had bilateral Tecnis Symfony IOLs with emmetropic target in each eye, 23.9% (141 patients) had bilateral Tecnis Symphony with micromonovision aim (non-dominant eye aimed for -0.50 to -1.00 D), and the remaining 19% (112 patients) had a combination of a Tecnis Symfony IOL in the dominant eye and a diffractive Tecnis multifocal IOL with +3.25 near addition in their non-dominant eye (model ZLB00). The proportion of patients with each IOL combination is shown in Table 1. There was no statistically significant difference in the proportion of patients with each lens combination in the four refractive categories (P =.86). The decision about lens selection was based on the patient's lifestyle, expectations, and visual requirements. In most of the cases, the selection of lenses for both eyes was determined ahead of the first eye surgery.

STATISTICAL ANALYSIS

Lens 1 Tecnis Bilater Bilater ^aDomini

For statistical analysis, all patients were divided into categories according to their preoperative refractive error/visual acuity. First, all patients with UDVA of 20/25 or better in each eye, regardless of preoperative refractive error, were considered to have "plano presbyopia." The remaining patients were divided based on the sphere in the most ametropic eye into the following categories: moderate to high myopia (sphere of -3.25 D or less), low myopia (sphere between -0.25 to -3.00

D), and hyperopia (sphere between +0.25 and +3.00 D). Refractive/visual outcomes and quality of life outcomes were compared between refractive lens exchange and monovision LASIK for each refractive category. For continuous data, a normality of data sample was first assessed by a Kolmogorov–Smirnov test and then data samples were compared with either the independent t test or Mann–Whitney U test, depending on the normality assumption. The chi-square test was used to compare percentages. Binocular UDVA, binocular UNVA, and patient questionnaire outcomes were analyzed on a per-patient basis. Postoperative CDVA and refractive predictability were calculated on a per-eye basis. All data were analyzed using the Microsoft Office Excel 2011 program (Microsoft Corporation, Redmond, WA) and STATISTICA (StatSoft Inc., Palo Alto, CA). A P value of .05 was considered statistically significant.

RESULTS

Table 2 shows the number of patients and preoperative clinical data for each refractive category for monovision LASIK and refractive lens exchange. The mean age was 51.9 ± 3.8 years for the monovision LASIK group and 54.0 \pm 3.7 years for the refractive lens exchange group (P < .01). The male-to-female ratio was 38.5% and 61.5% for the monovision LASIK group and 50.7% and 49.3% for the refractive lens exchange group, respectively (P < .01). In patients with monovision LASIK, the refractive target in the eye with monovision was between -1.00 and -2.00 D in 77.3% (470) of patients and between -1.25 and -1.75 D in 59.2% (360) of patients.

Table 3 shows the 3-month postoperative clinical outcomes. All refractive categories had comparable mean binocular UDVA between monovision LASIK and refractive lens exchange, apart from hyperopia, where refractive lens exchange slightly outperformed monovision LASIK (mean binocular UDVA $-0.04 \pm 0.10 \log$ MAR refractive lens exchange vs -0.01 ± 0.12 logMAR monovision LASIK, P < .01). Figure 1 shows the percentage of patients achieving 20/20 or better binocular UDVA. Similarly, the only category that showed a statistically

	TABLE 2 Preoperative Cli		
Category	M-LASIK	RLE	Р
Moderate to high myopia ^b			
Sphere (D)	-5.06 ± 1.43 (-9.00 to -3.25)	-5.02 ± 1.45 (-9.75 to -3.25)	.88
Cylinder (D)	-0.77 ± 0.66 (-5.25 to 0.00)	-0.71 \pm 0.55 (-2.00 to 0.00)	.58
CDVA (logMAR)	-0.06 \pm 0.05 (-0.18 to 0.10)	-0.04 \pm 0.07 (-0.18 to 0.10)	.01
Low myopia ^c			
Sphere (D)	-2.11 ± 0.84 (-3.00 to -0.25)	-1.77 ± 0.88 (-3.00 to -0.25)	.02
Cylinder (D)	-0.95 ± 0.89 (-3.75 to 0.00)	-0.61 \pm 0.53 (-2.50 to 0.00)	.01
CDVA (logMAR)	-0.07 \pm 0.05 (-0.18 to 0.10)	-0.06 \pm 0.05 (-0.18 to 0.10)	.67
Plano presbyopia ^d			
Sphere (D)	+1.04 ± 0.53 (-0.75 to +1.75)	+0.91 ± 0.50 (-0.50 to +1.75)	.12
Cylinder (D)	-0.52 ± 0.41 (-1.50 to 0.00)	-0.43 ± 0.33 (-2.00 to 0.00)	.11
CDVA (logMAR)	-0.07 \pm 0.04 (-0.18 to 0.00)	-0.07 \pm 0.05 (-0.18 to 0.10)	.56
Hyperopia ^e			
Sphere (D)	+1.76 ± 0.50 (0.50 to +3.00)	+1.92 ± 0.61 (+0.25 to +3.00)	< .01
Cylinder (D)	-0.51 \pm 0.48 (-4.00 to 0.00)	-0.52 \pm 0.43 (-2.75 to 0.00)	.92
CDVA (logMAR)	-0.06 ± 0.05 (-0.18 to 0.10)	-0.06 ± 0.05 (-0.18 to 0.10)	.11

^bM-LASIK group = 176 patients (352 eyes); RLE group = 43 patients (86 eyes).

^cM-LASIK group = 94 patients (188 eyes); RLE group = 54 patients (108 eyes).

^dM-LASIK group = 63 patients (126 eyes); RLE group = 119 patients (238 eyes).

eM-LASIK group = 275 patients (550 eyes); RLE group = 374 patients (748 eyes).

significant difference was hyperopia, where 77.5% of patients with monovision LASIK achieved binocular UDVA of 20/20 or better compared to 84.2% of patients with refractive lens exchange (P = .03).

The mean postoperative binocular UNVA was worse for patients with refractive lens exchange in each refractive category (Table 3). The mean binocular UNVA was 0.18 ± 0.13 logMAR (approximately J3) for all patients with monovision LASIK and 0.23 ± 0.13 logMAR (approximately J4) for patients with refractive lens exchange. However, the percentage of patients who achieved binocular UNVA of J5 or better was comparable between monovision LASIK and refractive lens exchange for all four refractive categories, except for moderate to high myopia, where monovision LASIK significantly outperformed refractive lens exchange (Figure 2).

Patients with plano presbyopia and hyperopia with refractive lens exchange had significantly better mean CDVA (Table 3), although the difference in the mean CDVA between monovision LASIK and refractive lens exchange was minimal (less than one letter on the Snellen chart). Postoperative loss of two or more lines of CDVA for monovision LASIK and refractive lens exchange at 3 months was as follows: high to moderate myopia 0.0% vs 2.3% (*P* < .01), low myopia: 0.0% vs

0.9% (P = .18), plano presbyopia: 2.4% vs 2.1% (P = .87), and hyperopia: 4.2% vs 1.3% (*P* < .01).

The reasons for CDVA loss for the monovision LASIK eyes (26 eyes) were ocular surface issues (20 eyes) and corneal haze (2 eyes); in 4 eyes, the reason for CDVA loss was unclear. Seventeen of 26 eyes that lost two or more lines of CDVA at 3 months had 20/20 or better CDVA on the last available follow-up and no eve had CDVA worse than 20/30.

A total of 18 eyes lost two or more lines of CDVA in the refractive lens exchange group for the following reasons: posterior capsular opacification (7 eyes), unknown cause (8 eves), cystoid macular edema (1 eve), anterior uveitis (1 eye), and ocular surface issues (1 eye). Of all 18 eyes that lost two or more lines of CDVA at 3 months, 12 had CDVA of 20/20 or better at the last available follow-up and no eye had CDVA worse than 20/25.

Table 3 shows the mean postoperative sphere and cylinder for each refractive category. Of all eyes targeted for distance vision, the percentage of eyes with spherical equivalent within 0.50 D of emmetropia for monovision LASIK and refractive lens exchange, respectively, was as follows: moderate to high myopia: 83.5% vs 85.9% (P = .63), low myopia: 90.4% vs 80.6% (P = .06), plano presbyopia: 90.5% vs 86.7% (P = .42), and hyperopia:

	TABLE 3 3-Month Postoperative	Clinical Data ^a	
Category	M-LASIK	RLE	Р
Moderate to high myopia ^b			
Sphere (D)	Near eye: -1.41 ± 0.40 ; Distance eye: $+0.05 \pm 0.44$	Near eye: -0.88 ± 0.27 ; Distance eye: $+0.04 \pm 0.43$	-
Cylinder (D)	-0.25 \pm 0.28 (-1.50 to 0.00)	-0.37 ± 0.35 (-1.50 to 0.00)	< .01
Binocular UDVA (logMAR)	-0.03 \pm 0.12 (-0.18 to 0.80)	-0.05 \pm 0.07 (-0.18 to 0.10)	.51
Binocular UNVA (logMAR)	0.16 \pm 0.11 (0.00 to 0.50)	0.27 ± 0.15 (0.00 to 0.60)	< .01
CDVA (logMAR)	-0.07 \pm 0.05 (-0.18 to 0.10)	-0.06 ± 0.05 (-0.18 to 0.10)	.10
Low myopia ^c			
Sphere (D)	Near eye: -1.35 ± 0.47 ; Distance eye: $+0.21 \pm 0.34$	Near eye: -0.65 \pm 0.30; Distance eye: +0.03 \pm 0.50	-
Cylinder (D)	-0.26 ± 0.29 (-1.25 to 0.00)	-0.41 ± 0.38 (-1.50 to 0.00)	< .01
Binocular UDVA (logMAR)	-0.04 \pm 0.09 (-0.18 to 0.22)	-0.04 ± 0.10 (-0.18 to 0.30)	.50
Binocular UNVA (logMAR)	0.16 ± 0.14 (-0.08 to 0.40)	0.25 \pm 0.13 (-0.08 to 0.60)	< .01
CDVA (logMAR)	-0.07 ± 0.06 (-0.18 to 0.22)	-0.06 ± 0.05 (-0.18 to 0.10)	.73
Plano presbyopiad			
Sphere (D)	Near eye: -1.75 \pm 0.64; Distance eye: +0.03 \pm 0.30	Near eye: -0.74 ± 0.32 ; Distance eye: -0.02 ± 0.44	-
Cylinder (D)	-0.34 \pm 0.34 (-1.50 to 0.00)	-0.32 ± 0.34 (-1.50 to 0.00)	.74
Binocular UDVA (logMAR)	-0.06 ± 0.08 (-0.18 to 0.22)	-0.06 ± 0.09 (-0.18 to 0.22)	.26
Binocular UNVA (logMAR)	0.16 ± 0.13 (-0.08 to 0.60)	0.22 \pm 0.13 (-0.08 to 0.60)	< .01
CDVA (logMAR)	-0.06 ± 0.05 (-0.18 to 0.10)	-0.07 ± 0.05 (-0.18 to 0.10)	< .01
Hyperopia ^e			
Sphere (D)	Near eye: -1.81 ± 0.74 ; Distance eye: -0.03 ± 0.39	Near eye: -0.93 \pm 0.37; Distance eye: -0.07 \pm 0.50	-
Cylinder (D)	-0.41 ± 0.45 (-2.50 to 0.00)	-0.38 ± 0.36 (-1.75 to 0.00)	.18
Binocular UDVA (logMAR)	-0.01 \pm 0.12 (-0.18 to 0.90)	-0.04 ± 0.10 (-0.18 to 0.60)	< .01
Binocular UNVA (logMAR)	0.20 ± 0.13 (-0.08 to 0.60)	0.22 ± 0.12 (-0.08 to 0.70)	.05
CDVA (logMAR)	-0.05 ± 0.06 (-0.18 to 0.22)	-0.06 ± 0.06 (-0.18 to 0.22)	< .01

M-LASIK = monovision LASIK; RLE = refractive lens exchange; D = diopters; UDVA = uncorrected distance visual acuity; CDVA = corrected distance visual acuity; UNVA = uncorrected near visual acuity

^aValues are listed as mean ± standard deviation (range). "Near eye" refers to all eyes where postoperative refractive target was myopic, whereas "Distance eye" refers to all eyes with emmetropic refractive target. RLE "near eye" category only contains near eyes from the Tecnis Symfony micromonovision group. All remaining lens combinations are included in the "Distance eye" category.

^bM-LASIK group = 176 patients (352 eyes); RLE group = 43 patients (86 eyes).

^cM-LASIK group = 94 patients (188 eyes); RLE group = 54 patients (108 eyes).

^dM-LASIK group = 63 patients (126 eyes); RLE group = 119 patients (238 eyes).

^eM-LASIK group = 275 patients (550 eyes); RLE group = 374 patients (748 eyes).

86.5% vs 83.3% (P = .21). The mean sphere in the near vision eye for monovision LASIK was -1.62 ± 0.64 D. Postoperative mean sphere in the near eye for the Tecnis Symfony micromonovision was -0.86 ± 0.36 D.

PATIENT-REPORTED OUTCOMES

Preoperatively, there was no statistically significant difference in dry eyes, visual phenomena, night driving, or distance and near activities between monovision LASIK and refractive lens exchange in any of the four refractive categories. The mean mesopic pupil diameter was slightly larger in the monovision LASIK group, but the difference was not statistically significant (mean pupil size monovision LASIK: 5.65 ± 0.94 mm, refractive lens exchange: 5.56 ± 0.84 mm, P = .09). However, no correlation was found between postoperative visual phenomena symptoms and pupil size in both the refractive lens exchange and monovision LASIK datasets.

Postoperatively, patients were asked about their overall satisfaction with their vision (Figure 3). There

Monovision LASIK vs Refractive Lens Exchange/Schallhorn et al

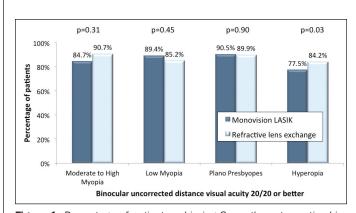


Figure 1. Percentage of patients achieving 3-month postoperative binocular uncorrected distance visual acuity of 20/20 or better, stratified according to the preoperative refractive error.

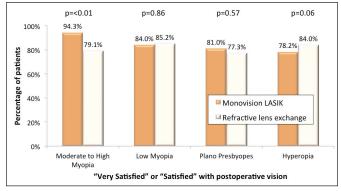


Figure 3. Three-month postoperative satisfaction with vision, stratified according to the preoperative refractive error.

was a statistically significant difference in patient satisfaction in favor of monovision LASIK for moderate to high myopia (94.3% for monovision LASIK vs 79.1% for refractive lens exchange, P < .01). For all other refractive categories, there was no statistically significant difference in patient satisfaction. Although there was a slight difference in age between refractive lens exchange and monovision LASIK when combining all patients, no correlation between age and postoperative satisfaction was found in this dataset (P = .21). A separate analysis was also performed to compare postoperative satisfaction between refractive lens exchange lens combinations in each refractive category, and no statistically significant difference was found.

Similar outcomes were seen in the percentage of patients who would recommend the procedure to their friends or relatives. Of all patients in the moderate to high myopia group, 98.9% of patients with monovision LASIK and 90.7% of patients with refractive lens exchange responded affirmative (**Figure 4**). For the remaining refractive categories, there was no statistically significant difference in the percentage of patients who would recommend the procedure to their friends and relatives.

Table B (available in the online version of this article)

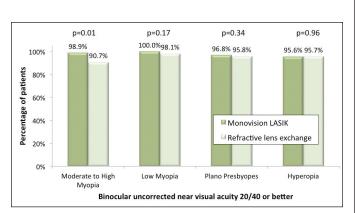


Figure 2. Percentage of patients achieving 3-month postoperative binocular uncorrected near visual acuity 20/40 (J5) or better, stratified according to the preoperative refractive error.

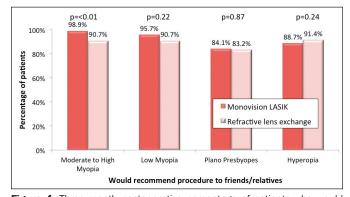


Figure 4. Three-month postoperative percentage of patients who would recommend the procedure to their friends or relatives, stratified according to the preoperative refractive error.

shows the summary of patient experience questionnaire outcomes. There was no statistically significant difference between monovision LASIK and refractive lens exchange in percentage of patients having significant difficulty with dry eyes or significant increase in dry eyes symptoms in any refractive category.

Patients with refractive lens exchange in the moderate to high myopia group were more likely to have significant postoperative visual phenomena. For example, less than 1% of patients with monovision LASIK moderate to high myopia had significant postoperative difficulty with glare/halo/starburst, whereas the percentage of patients with refractive lens exchange with significant difficulty ranged between 9.3% and 14% for the different phenomena. The same applies to the increase in visual phenomena: less than 8% of patients had an increase in visual phenomena in the monovision LASIK group, whereas 24.4% of patients had an increase in visual phenomena in the refractive lens exchange group. Interestingly, there was no statistically significant difference in night driving difficulty between monovision LASIK and refractive lens exchange. Patients with moderate to high myopia monovision LASIK also reported greater ease than patients with refractive lens exchange in near vision activities, but there was no statistically significant difference in distance activities (**Table B**).

In the low myopia group, there was also higher incidence of visual phenomena in patients with refractive lens exchange compared to monovision LASIK. The percentage of patients with significant glare/halo/starburst was 1.1% or less for monovision LASIK, whereas 7.4% to 9.3% of patients with refractive lens exchange experienced significant postoperative difficulties with visual phenomena. The increase in visual phenomena ranged between 9.3% and 12% for monovision LASIK and between 20.9% and 30.2% for refractive lens exchange (**Table B**). However, there was no statistically significant difference in ghosting or double vision. There was also no statistically significant difference in night driving difficulty or near or distance activities in the low myopia group.

There was no significant difference in postoperative visual phenomena or increase in visual phenomena between monovision LASIK and refractive lens exchange in the plano presbyopia group, except for ghosting and double vision, which was significantly worse for the monovision LASIK group (9.5% with monovision LASIK vs 2.5% with refractive lens exchange had postoperative significant difficulty with ghosting/double vision, P = .04). In the plano presbyopia group, 8.4% to 12.7% of patients (regardless of the procedure type) had significant difficulty with postoperative glare/ halo/starburst and 20.9% to 33.7% had an increase in glare/halo/starburst. There was no statistically significant difference in night driving and near and distance activities between the two procedures.

Patients with hyperopia had similar postoperative scores for significant visual phenomena, but patients with refractive lens exchange had a higher increase in visual phenomena postoperatively. Of all patients with monovision LASIK and hyperopia, 14.5% to 17.1% had a significant increase in glare/halo/starburst, whereas the increase in visual phenomena ranged from 24.8% to 27.0% for patients with refractive lens exchange (**Table B**). Incidence of significant ghosting/double vision between monovision LASIK and refractive lens exchange was comparable in this group. There was no statistically significant difference in difficulties with night driving or near and distance activities.

POSTOPERATIVE COMPLICATIONS

The complication rate was 2% in the monovision LASIK group and 1.5% in the refractive lens exchange group, increasing to 6.4% with inclusion of posterior capsular opacification cases.

MONOVISION LASIK

There were two cases (0.16%) of unilateral retinal detachment. The first was in a 58-year-old woman, 1 year after uneventful LASIK for -6.50 D of myopia. Unfortunately, the patient was referred for management externally and the outcomes of retinal detachment repair are not known. The second patient was a 51-year-old man who underwent LASIK for -6.00 D of myopia and developed retinal detachment 6 months after laser vision correction. The last available CDVA following retinal detachment repair was 20/25. One eye (0.08%) developed significant diffuse lamellar keratitis (grade 3) that required flap lift and irrigation, and the CDVA returned to 20/16 following surgical intervention.

One patient developed unilateral peripheral epithelial ingrowth that stabilized and did not affect CDVA or the patient's refraction. Five eyes (0.41%) of 4 patients had flap striae, of which 2 eyes required flap lift and smoothing. All cases of flap striae had CDVA of 20/20 or better at the last examination.

Three eyes (0.25%) of 2 patients were treated for presumed microbial keratitis in the early postoperative stage. All cases responded to treatment with topical antibiotics and resolved within 2 weeks. There was also a case of a sterile infiltrate (1 eye of 1 patient) that resolved within the first postoperative week. All 4 eyes had a final CDVA of 20/16.

Other complications included 5 eyes (0.41%) of 3 patients with interface haze that required management with topical steroids for longer than 1 month, but the final CDVA was 20/20 or better in all cases. There were 3 patients (6 eyes, 0.49%) with bilateral transient light sensitivity syndrome that also resolved without any issues.

PRESBYOPIA-CORRECTING IOL

In one patient, a dislocated IOL in the right eye (inferior haptic of IOL in anterior chamber) significantly raised intraocular pressure and corneal edema was noted on the first postoperative day. Following IOL repositioning, the patient's CDVA eventually recovered to 20/20, but the postoperative complications resulted in a non-reactive pupil. This did not cause any cosmetic or visual problems for the patient.

Two eyes (0.17%) of two patients developed postoperative cystoid macular edema that responded to treatment with topical steroids/nonsteroidal antiinflammatory drops. Last available CDVA was 20/25 in the first case and 20/16 in the second case. Seven eyes (0.59%) of 5 patients had elevated intraocular pressure that required management for longer than 1 week, but eventually resolved within the first postoperative month in all cases. Final CDVA in all eyes was 20/20 or better. There were 8 eyes (0.68%) of 5 patients with postoperative anterior uveitis that either persisted for longer than 1 week postoperatively (4 eyes) or recurred two to three times (4 eyes). In all cases, anterior uveitis resolved within 6 months. All eyes had CDVA of 20/20 or better at the last available examination.

Of all patients with refractive lens exchange, 57 eyes (4.8%) developed posterior capsular opacification, of which 26 required Nd:YAG laser capsulotomy. Following capsulotomy, 23 eyes had CDVA of 20/20 or better and all eyes had CDVA of 20/25 or better.

DISCUSSION

This study compared two surgical options of presbyopia correction. Both surgical methods achieved comparable binocular uncorrected distance visual acuity except for the hyperopia group, where patients with refractive lens exchange achieved significantly better outcomes. The mean binocular UDVA approached 20/20 for all refractive subcategories (Table 3). There was also no significant difference in the number of patients with significant difficulty with distance vision tasks (Table B). Monovision LASIK had slightly better near visual acuity (Table 3), which was more apparent in the moderate to high myopia group, where the percentage of patients achieving J5 or better binocular UNVA was higher (Figure 2). In eyes targeted for emmetropia, the mean sphere was close to plano in all refractive categories (Table 3). Although monovision LASIK had slightly better predictability in terms of percentage of eyes within 0.50 D of emmetropia, the difference between refractive lens exchange and monovision LASIK was not statistically significant. Of all refractive categories, patients with hyperopia who had monovision LASIK had the highest CDVA loss of two or more lines at 3 months (4.2%), which was mainly associated with ocular surface/dry eye issues, but CDVA eventually recovered to 20/20 in most monovision LASIK cases and no eye had CDVA worse than 20/30.

Generally, patients with refractive lens exchange experienced more photic phenomena despite the use of the latest extended range of vision IOL optical principle (Tecnis Symfony) in the majority of eyes.¹⁶ An exception was the plano presbyopia group, where visual phenomena seemed to be comparable between monovision LASIK and refractive lens exchange (**Table B**). Visual phenomena in the plano presbyopia group was higher than in other refractive groups, which agrees with the literature. It has been previously reported that patients with plano presbyopia have higher expectations and are more likely to experience visual side effects after presbyopia correction surgery.¹⁹ Interestingly, there was no significant difference in the proportion of patients having significant difficulty with night driving between monovision LASIK and refractive lens exchange in any refractive category.

In 2010, Barisic et al.¹⁸ compared refractive lens exchange with monovision LASIK in a prospective randomized study of 50 patients in each category. To our knowledge, this is the only study directly comparing monovision LASIK and refractive lens exchange. Comparable to our outcomes, there was no significant difference in binocular distance vision between the two techniques. However, the near visual acuity was better for refractive lens exchange. This is understandable because the near target in the monovision eye in this study was only -0.50 to -1.25 D and the authors used a multifocal lens with much stronger near addition (Tecnis ZMA00, +4.00 D add; Johnson & Johnson Vision Care, Inc.) in the refractive lens exchange group. Similar to our outcomes, patients with refractive lens exchange experienced more visual phenomena (12% severe symptoms at 6 months), whereas patients with monovision LASIK experienced none. Despite the differences in optical side effects and near vision in Barisic et al.'s study,¹⁸ both groups were equally satisfied with the outcomes of the procedure, and 94% of patients in the refractive lens exchange group and 96% of patients in the monovision LASIK group would undergo the same procedure again. Satisfaction scores in our study were also similar between monovision LASIK and refractive lens exchange, except for patients with moderate to high myopia, where monovision LASIK had higher satisfaction rates.

Monovision is a viable option only to those patients who are able to adapt to it.^{14,17,20-22} Patient selection, preoperative demonstration, and determining the correct amount of myopia to target in the near eye that best meets the needs of the patient are crucial.²³ The reported tolerance to monovision induced by contact lenses is between 50% and 86%,²⁴⁻²⁸ whereas satisfaction with surgically induced monovision ranges from 72% to 97.6%.¹⁻⁶ Monovision has been reported to be well tolerated by patients with myopia,^{2,8,9} but the reported satisfaction rates with monovision in patients with hyperopia are often contradictory.^{6,29,30} For example, Goldberg²⁹ compared outcomes of monovision LASIK between myopia and hyperopia with a followup between 6 to 24 months. Patients with hyperopia were more likely to have surgical enhancement, had slightly lower satisfaction rates, and were more likely to experience optical side effects postoperatively. However, there were only 29 patients with hyperopic monovision included in this study. On the other hand, Braun et al.⁶ found similar acceptance rates for monovision LASIK in hyperopia (90.9%) and myopia (93.3%) in a retrospective analysis of patients with a minimum of 1 month of follow-up. Again, the subset of patients with hyperopic monovision was small (22 patients). A larger study³⁰ of 129 patients with hyperopia monovision with a follow-up of up to 1 year postoperatively showed excellent results in terms of binocular visual acuity (95% of patients had binocular UDVA 20/20 or better and UNVA J5 or better), although the enhancement rate for the mean follow-up of 12.5 months was high (22%). Direct comparison to patients with myopia was not included in this study. To our knowledge, this study presents the largest cohort of patients with hyperopia with surgically induced monovision (275 patients).

Refractive lens exchange is a surgically more invasive option than LASIK. However, it may be preferred in presbyopia with early crystalline lens changes or those who are unable to tolerate the anisometropia induced by monovision. The near visual acuity achieved in patients with refractive lens exchange ranged between 0.25 and 0.27 logMAR in patients with myopia and was slightly better (0.22 logMAR) in patients with plano presbyopia and hyperopia (**Table 3**). This is comparable to previous findings of binocular UNVA of a large study evaluating outcomes of extended depth of focus IOLs (0.21 \pm 0.16 logMAR).¹⁶

The incidence of significant visual phenomena in the current study was somewhat higher than previously reported with this type of IOL. For example, in a large study by Cochener et al.,¹⁶ the incidence of severe halo with the Tecnis Symfony lens was only 3.1%, as opposed to our outcomes of 9.3% to 14.0%. The higher incidence could be due to shorter follow-up (3 months, compared to 6 months in Cochener's study) and perhaps because 19% of patients in our study had a diffractive multifocal lens with +3.25 near add (Tecnis Multifocal ZLB00) in the second eye. Another explanation for higher visual phenomena in our study could be the use of a different questionnaire and different scaling of symptoms. Despite the higher incidence of optical side effects, the satisfaction rates (except for the moderate to high myopia group) were comparable between monovision LASIK and refractive lens exchange (Figure 3).

Our study had several limitations. First, it was retrospective and the two study groups were not matched by age, resulting in patients with refractive lens exchange being slightly older than patients with monovision LASIK. However, the difference was minimal (mean difference 2.1 years), the age range in this study was narrow (45 to 60 years), and we found no correlation between patient's age and satisfaction. Therefore, it is unlikely that the age difference would adversely affect the comparison of the two groups. There also may be a component of follow-up bias because patients who had no complaints may have been less likely to

attend the 3-month postoperative visit. Patients with monovision LASIK were also more likely to be female, whereas refractive lens exchange had an almost equal portion of male and female patients. It has been previously reported that women are more likely to select surgical monovision.^{1,6} However, when evaluating patient satisfaction with refractive surgery, gender is not usually considered as an independent factor affecting postoperative satisfaction.^{4,31}

Another potential source of bias is the selection process of the surgical procedure. Refractive lens exchange was preferred by patients who were intolerant to monovision. It is possible that patients who are not able to adapt to monovision may selectively be more sensitive to visual side effects and might be less satisfied with the visual results of multifocal IOLs. To reduce potential bias and ensure the two groups were comparable, we only included patients who requested surgery for refractive reasons (CDVA 20/25 or better) and had a refractive error in the range treatable with LASIK.

Another limitation of this study is a relatively short follow-up (3 months). Additional regression may occur, particularly in hyperopic LASIK, which could potentially affect satisfaction rates at later follow-up visits.³² Comparison of intermediate vision outcomes in each refractive category would also be beneficial, but it was not possible in this retrospective study.

Despite these limitations, this study is not only the largest study comparing monovision LASIK to refractive lens exchange, but also shows the difference between the two techniques separately for different refractive categories. Going forward, it would be useful to monitor the rates of reported visual symptoms over a longer period of time to see whether the difference between the two groups abates.

Monovision LASIK and refractive lens exchange are both feasible options for patients with presbyopia. In this study, monovision LASIK was found to induce less visual phenomena, especially in higher myopia. Patients with higher myopia tended to have worse clinical outcomes and were less satisfied with refractive lens exchange. Monovision LASIK may be a better option in this population, but additional studies are needed to confirm this finding. In the other refractive error categories, patients with refractive lens exchange had more visual phenomena, but visual outcomes and patient satisfaction with their vision were equivalent. As with any refractive surgery, understanding the needs of the patient is paramount in surgical planning. Refractive surgeons may find the information from this study useful in helping to select the best procedure for their patients and aid in informing them about the expected outcomes.

AUTHOR CONTRIBUTIONS

Study concept and design (SCS, DT, JAV, JMS, SJH, MP); data collection (KAH); analysis and interpretation of data (SCS, JMS, KAH, MP); writing the manuscript (SCS, MP); critical revision of the manuscript (SCS, DT, JAV, JMS, KAH, SJH); statistical expertise (SCS, JMS, KAH, MP); supervision (SCS, DT, JAV, JMS, SJH)

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TABLE A

Patient Experience Questionnaire

Question 1: Thinking about your vision during the last week, how satisfied are you with your vision? (without the use of glasses or contact lenses)?

(1 = Very satisfied, 2 = Satisfied, 3 = Neither, 4 = Dissatisfied, 5 = Very dissatisfied)

Question 2: Would you recommend vision correction surgery to your friends and relatives? (1 = Yes, 2 = No)

Question 3: Think about your vision during the last week. Please rate the degree of difficulty you experienced with:

- * Dry eyes
- * Glare
- * Halo
- * Starburst
- * Ghosting/double vision

(Measured on discrete scale from 1 = No difficulty to 7 = Severe difficulty).

Question 4: Because of your eyesight, how much difficulty do you have with driving at night?

(1 = No difficulty, 2 = A little difficulty, 3 = Moderate difficulty, 4 = A lot of difficulty, 5 = Never try to do this because of my vision, 6 = Never do this for other reasons)

Question 5: Because of your eyesight, how much difficulty do you have doing work or hobbies that require you to see well up close, such as cooking, fixing things around the house, sewing, using hand tools, or working with a computer? $(1 = No \text{ difficulty}, 2 = A \text{ little difficulty}, 3 = Moderate difficulty}, 4 = A \text{ lot of difficulty}, 5 = Never try to do this because of my vision, 6 = Never do this for other reasons}$

Question 6: Because of your eyesight, how much difficulty do you have taking part in active sports or other outdoor activities that you enjoy (like hiking, swimming, aerobics, team sports, or jogging)?

(1 = No difficulty, 2 = A little difficulty, 3 = Moderate difficulty, 4 = A lot of difficulty, 5 = Never try to do this because of my vision, 6 = Never do this for other reasons)

Questions 3 to 6 were part of both the preoperative and postoperative questionnaire. Preoperatively, patients rated the degree of difficulty with spectacles/contact lens correction; postoperatively, patients rated the degree of difficulty without correction.

QuestionM-LASIKRLEPM-LASIKRLEPPostoperative significant difficulty with dry eyes 1.7% 7.0% $.06$ 3.2% 7.4% $.24$ Postoperative significant difficulty with dry eyes 1.7% 17.5% $.24$ 11.0% 16.7% $.38$ Preoperative to postoperative increase in dry eyes 10.7% 17.5% $.24$ 11.0% 16.7% $.38$ Preoperative to postoperative increase in glare 7.1% 24.4% $< .01$ 9.3% $.00$ Preoperative significant difficulty with halo 0.6% 14.0% $< .01$ 12.0% 23.3% $.11$ Preoperative significant difficulty with halo 0.6% 24.4% $< .01$ 12.0% 23.3% $.11$					пурегоріа	
1.7% $7.0%$.06 $3.2%$ $7.4%$. $10.7%$ $17.5%$.24 $11.0%$ $16.7%$. $0.0%$ $9.3%$ < .01 $1.1%$ $7.4%$. $0.1%$ $9.3%$ < .01 $1.1%$ $7.4%$. $0.1%$ $24.4%$ < .01 $9.3%$ 20.9% . $0.6%$ $14.0%$ < .01 $1.1%$ $9.3%$. $5.0%$ $24.4%$ < .01 $12.0%$ $23.3%$.	P M-LASIK	RLE	Р	M-LASIK	RLE	٩
10.7% 17.5% .24 11.0% 16.7% 0.0% 9.3% < .01	24 4.8%	2.5%	.42	1.8%	2.4%	.61
$\begin{array}{rrrrrrrrrrrrrrrrrrrrrrrrrrrrrrrrrrrr$	38 11.4%	16.9%	.45	14.9%	11.5%	.25
$7.1\% 24.4\% < .01 9.3\% 20.9\% \\ 0.6\% 14.0\% < .01 1.1\% 9.3\% \\ 5.0\% 24.4\% < .01 12.0\% 23.3\% \\ \end{array}$	04 11.1%	9.2%	.49	5.8%	8.0%	.28
0.6% 14.0% < .01 1.1% 9.3% 5.0% 24.4% < .01 12.0% 23.3%	38 20.9%	28.1%	.38	16.4%	26.1%	< .01
5.0% $24.4%$ < 01 $12.0%$ $23.3%$	01 12.7%	12.6%	.98	5.1%	9.4%	.04
	11 23.3%	33.7%	.22	14.5%	27.0%	< .01
Postoperative significant difficulty with star- 0.6% 11.6% < .01 0.0% 9.3% < .01 burst	.01 12.7%	8.4%	.36	8.4%	8.3%	76.
Preoperative to postoperative increase in 7.7% 24.4% < .01 9.3% 30.2% < .01 starburst	.01 25.0%	25.8%	.92	17.1%	24.8%	.04
Postoperative significant difficulty with 0.0% 2.3% .04 0.0% 0.0% NA ghosting/double vision	JA 9.5%	2.5%	.04	2.2%	2.9%	.55
Preoperative to postoperative increase in 2.1% 7.3% .10 6.7% 10.0% .53 ghosting/double vision	53 23.3%	14.6%	.22	11.0%	7.8%	.21
Postoperative significant difficulty with night 5.3% 9.8% .28 6.6% 1.1.5% .31 driving	31 14.0%	9.4%	.36	10.1%	10.2%	.95
Preoperative to postoperative increase in 1.5% 5.1% .18 2.8% 4.9% .57 night driving difficulties	57 11.9%	8.3%	.51	3.6%	5.8%	.25
Postoperative significant difficulty with near 2.9% 18.6% < .01 4.3% 11.3% .10 activities	10 4.9%	2.5%	.39	2.2%	3.2%	.43
Preoperative to postoperative increase in 2.1% 9.5% .03 2.7% 9.1% .13 near activities difficulties	.13 2.1%	1.0%	.58	0.9%	1.6%	.48
Postoperative significant difficulty with 0.6% 0.0% .63 0.0% 0.0% NA distance activities	JA 3.4%	2.6%	.76	2.3%	1.9%	77.
Preoperative to postoperative increase in 0.7% 0.0% .60 0.0% 0.0% NA distance activities difficulties	JA 0.0%	2.1%	.32	0.9%	1.3%	.71