Int Ophthalmol
https://doi.org/10.1007/s10792-020-01554-7

ORIGINAL PAPER

Correction of pseudophakic presbyopia using Lasik with aspheric ablation profiles and a micro-monovision protocol

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Received: 15 May 2020 / Accepted: 16 August 2020

Abstract

Purpose To evaluate the outcomes of Lasik with aspheric ablation profiles and a micro-monovision protocol for correction of presbyopia in pseudophakic patients.

Patients and methods This study included 50 pseudophakic eyes of 25 patients. Full ophthalmic examination, dominant eye tests and tests for tolerance of anisometropia (1 or 2 diopters) were done preoperatively. All cases were treated by Lasik with laser-blended vision technique. The dominant eye corrected to plano, and the nondominant eye corrected with near add in the range from 1.50 to 2.00 diopters. Excimer laser ablation was done using the MEL90 with a 250-Hz pulse rate (Carl Zeiss Meditec, Jena, Germany, Triple-A profile, Lasik mode). The follow-up period was 6 months with visits at 1, 3 and 6 months postoperatively.

Results The mean postoperative uncorrected distant visual acuity at 1 month (0.74 ± 0.11) was significantly lower than the preoperative level (0.84 ± 0.14) ($p < 0.001$). But it improved at the 3rd (0.80 ± 0.09) and 6th months (0.82 ± 0.10) with no significant difference with the preoperative level ($p = 0.344$). The mean uncorrected near visual acuity was significantly higher at the 1st (2.94 ± 1.63 J), 3rd (2.95 ± 1.82 J) and 6th (2.92 ± 1.83 J) postoperative months than the preoperative level (2.26 ± 1.48 J) ($p < 0.001$). Insignificant change in stereopsis was found after surgery ($p = 0.849$). The micro-monovision was well tolerated (95.8%).

Conclusion Lasik with aspheric ablation profiles and a micro-monovision protocol is an effective option for presbyopia correction in pseudophakic patients.

Introduction

Presbyopia, a Greek word means "old eyes," refers to the age-related deterioration of the accommodative ability of the crystalline lens. This leads to recession of the near point of accommodation around the age of 40 years [1, 2]. Not all presbyopic eyes are "old eyes," some ocular conditions like traumatic cataract, panretinal laser photocoagulation, and pseudophakia instigate to presbyopia. Systemic diseases as diabetes mellitus, cardiovascular accidents, multiple sclerosis, myasthenia gravis and anemia are considered independent risk factors for early presbyopia. Drugs like antidepressants, diuretics, antihistaminics and antipsychotics may cause considerable loss of accommodation as a side effect [3, 4].

Proper treatment of presbyopia turned out to be a priority because people stay active and inevitably continue to work longer than ever before. The

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Published online: 09 September 2020

presbyopic population at the time of writing this work (2020) are 1.4 billion, and the number is candidate to increase up to 1.8 billion by 2050 [5, 6]. Although there are many modalities to reasonably manage the visual impairment associated with presbyopia, all the available approaches are compensatory not corrective. The static methods for presbyopia correction aim to increase the depth of focus and include: monovision, presbyLASIK, corneal inlays, corneal shrinking techniques and multifocal intraocular lenses (IOLs). The dynamic methods include scleral implants and accommodative IOLs [7]. Corneal approaches appear to be safer, as they are less invasive procedure [8].

A few studies have been concerned with the use of Lasik monovision in hypermetropes, myopes and emmetropes; however, they reported promising results regarding the effectiveness and patient satisfaction [9, 10]. We noticed that some pseudophakic patients, especially younger patients, complain from difficulty in reading and are not compliant to the reading glasses. In this study, we aimed to evaluate the outcomes of Lasik with aspheric ablation profiles and a micro-monovision protocol for presbyopia correction in pseudophakic patients.

Patients and methods

This is a prospective noncomparative single-armed study including 25 patients with 50 pseudophakic eyes. The study protocol was approved by the Institutional Ethical Committee in Benha University, Egypt (22-06-18). All procedures were done according to the Declaration of Helsinki and its updates. Every patient signed an informed consent before enrollment.

This study included cases of bilateral pseudophakia with stable refraction for at least 1 year, and this means that all cases underwent phacoemulsification and IOL implantation at least 1 year earlier. Cases with history of ocular surgery other than phacoemulsification and intraocular lens implantation were excluded from the study. Those suffering from other ocular diseases were also excluded.

All patients underwent bilateral Lasik for correction of myopia, hypermetropia and astigmatism with correction of presbyopia using aspheric ablation profiles and a micro-monovision protocol. Surgical procedures were done in El Masa eye center, Benha, Egypt, by the same surgeon (MNE) between August 2018 and September 2019.

Preoperative assessment

A complete ophthalmologic examination was performed to every patient before surgery. It included slit-lamp microscopy of the anterior segment, manifest and cycloplegic refraction, dilated fundus examination and Goldmann applanation intraocular pressure measurement. Corrected and uncorrected distant visual acuity (CDVA, UDVA) was determined. Furthermore, we did keratometry and topography (Pentacam version 1.20, Oculus, Germany).

The TNO stereo test (Lameris Ootech BV) was used to determine stereopsis. The test was made binocularly with the patient's best correction preoperatively and without correction at 6 months postoperatively. The dominant eye was assessed utilizing many methods; the hole test, pointing method and stating which eye was used for capturing photographs by a camera.

Contrast Sensitivity Contrast sensitivity was assessed using the digital chart HDC-9000N/PF (Huvitz, Republic of Korea). The scale of the test extents from 0.10 to 1.35. A value of 1.00 shows the patient enjoys normal contrast sensitivity. A value more than 1.00 signifies the contrast sensitivity is better than normal. A value below 1.00 suggests lower than normal contrast sensitivity. The test was performed binocularly with the best distance correction preoperatively and without correction at the end of the follow-up.

Tolerance to anisometropia was tested with the dominant eye fully corrected and the other eye corrected with near add in the range 1.50–2.00 D. The intended postoperative refraction of the nondominant eye was determined according to the extent of cross-blurring reported by the patients in preoperative assessment. By cross-blurring, we mean to describe reduction of interocular blur suppression. The patient's tolerance to cross-blurring was determined by simulating the intended postoperative refraction. If the patient said that he was completely unaware of this, the patient was considered tolerant of a + 2.00 D "add." Those with mild to moderate cross-blurring mention that their vision was blurred or "odd." In these patients the "add" in the nondominant eye was decreased in 0.25 D increments until they observe

minimal or no cross-blurring. The age of the patient was not a matter when choosing the "add" to be used for the nondominant eye, as all eyes were pseudophakic. An "add" of 2.00 D was used whenever possible, and this was decreased only if necessary, according to the repetition of the "add" needed for minimal to no cross-blur. Those who could not withstand at least 1.00 D of "add" were reported as exclusions from the study.

Surgical procedure

Lasik was done by Laser Blended Vision technique. Excimer laser ablation was done using the MEL90 with a 250-Hz pulse rate (Carl Zeiss Meditec, Jena, Germany, Triple-A profile, Lasik mode). The MEL90 exhibits a precise tracking system. The CRS-Master software assisted to produce the ablation profile. Nonlinear aspheric ablation profiles were applied for both distance and near correction, which diminish the generation of spherical aberration to a range that grants an enhanced depth of field. Proprietary nonlinear aspheric ablation profiles were used for all eyes (both distance and near), which integrate a precompensation factor for the production of spherical aberration; the profiles were planned to lessen the induction of spherical aberration so that postoperative spherical aberration was within a range that grants an increased depth of field, but without altering contrast sensitivity. The spherical aberration precompensation factor was concluded based on the awaited induction of spherical aberration given the intended correction, the level of naturally occurring preoperative spherical aberration, the age of the patient and the tolerance of accuracy depending on the manifest refraction.

Optical zone diameters used were 6.00 mm, 6.25 mm and 6.50 mm. The CRS-Master created a file on a USB storage device, which was conveyed to the laser and imported for treatment. The Moria microkeratome was used in all cases after choosing the suction ring according to Moria M2 nomogram based on the keratometric value K1. The planned flap thickness was 100 μm.

Postoperative care

Tobradex and Vigamox (Alcon Laboratories Inc, Ft Worth, Tex) eye drops were applied four times daily for the first 2 weeks and various types of tear substitutes according to the condition of the patient. The follow-up period extended up to 6 months with visits at 1, 3 and 6 months postoperatively.

Statistical analysis

Raw data were analyzed by SPSS statistical package version 23 (SPSS Inc. Released 2015. IBM SPSS statistics for windows, version 23.0, Armonk, NY: IBM Corp) and presented as number (No), percentage (%) mean and standard deviation (SD). Repeated-measures ANOVA (with or without Bonferroni correction) with Mauchly test for sphericity test was used for comparison among three or more consecutive measures in the same group of quantitative variables. Assumed sphericity was employed for normally distributed data, while Greenhouse–Geisser was used for not normally distributed data. P value of 0.05 or less was considered statistically significant.

Results

This study included 50 pseudophakic eyes of 25 patients. All cases underwent Lasik with aspheric ablation profile and a micro-monovision protocol to ametropia and presbyopia. Two patients were excluded from the statistical analysis. One missed the follow-up. The other showed intolerance of 1.5 D anisometropia, and she requested distant correction in both eyes to achieve optimal distant vision. The net result was that 23 patients with 46 eyes were included in analysis.

The preoperative characteristics of our patients are shown in Table 1. The mean age was 39.34 ± 13.08 years ranging from 19 to 60 years. About 52% were males and the right eye was dominant in 73.9% of patients. The mean preoperative spherical equivalent (SE) was -1.00 ± 1.59 D ranging from -4.0 to $+1.50$ D. The amount of tolerated anisometropia in preoperative evaluation was 2 D in six cases, 1.75 D in seven cases, 1.5 D in seven cases and 1.25 D in three cases. The mean keratometry was 43.27 ± 2.05 D for K1 and 45.06 ± 1.87 D for K2. The mean preoperative pupillary diameter was 2.4 ± 1.02 mm (photopic) and 3.7 ± 1.46 mm (mesopic).

The mean postoperative UCDVA at 1 month decreased significantly than the preoperative level

Table 1 Patients' characteristics

Variables	No. (%)
Age in y (mean ± SD, range)	39.34 ± 13.08, 19.0–60.0
Preop. SE in D (mean ± SD, range)	− 1.00 ± 1.59, − 4.0 to + 1.50
Gender	
Male	12 (52.2)
Female	11 (47.8)
Dominant eye	
Right	17 (73.9)
Left	6 (26.1)
K readings in D (mean ± SD)	
K1	43.27 ± 2.05
K2	45.06 ± 1.87
Pupil diameter in mm	
Photopic	2.4 ± 1.02
Mesopic	3.7 ± 1.46

SE spherical equivalent, *D* diopter, *mm* millimeter

($p < 0.001$); however, it began to improve starting at the 3rd month with no significant difference with the preoperative level ($p = 0.344$) but significantly higher than the 1st postoperative month ($p < 0.001$). The mean UCDVA was stabilized through the 6th postoperative month with no significant difference between the 3rd and 6th postoperative months (Fig. 1).

The mean UCNVA significantly improved at the 1st, 3rd and 6th postoperative months than the preoperative level ($p < 0.001$). The mean UCNVA started to stabilize starting at the 1st postoperative month and stayed at the same level throughout the 3rd and 6th postoperative months (Fig. 2).

A statistically insignificant change in stereopsis was found after surgery. The mean stereopsis was

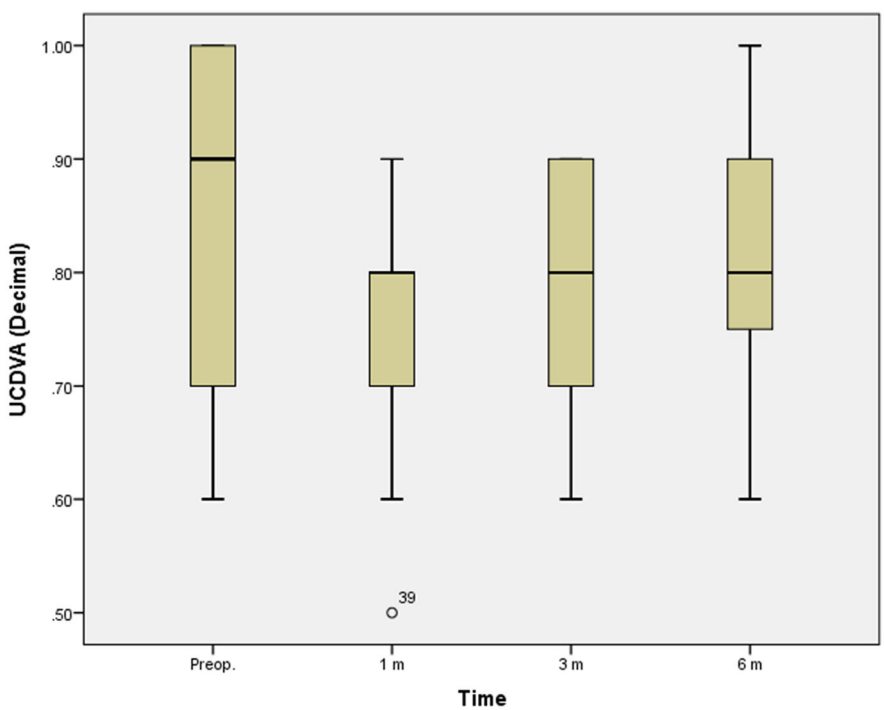

Fig. 1 Uncorrected distant visual acuity (UCDVA) in preoperative evaluation and postoperative follow-up visits

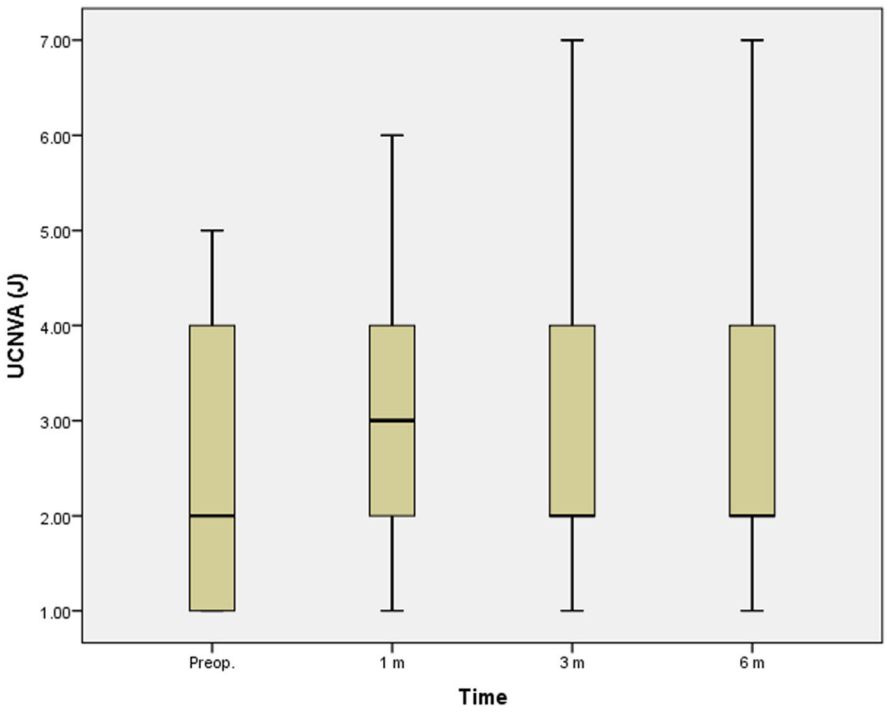

Fig. 2 Uncorrected near visual acuity (UCNVA) in preoperative evaluation and postoperative follow-up visits

184.71 ± 81.28 arcsec (range 60–40 arcsec) preoperatively and 189.17 ± 77.58 arcsec (range 60–40 arcsec) 6 months postoperatively ($p = 0.849$). There was no statistically significant change in photopic and mesopic pupillary diameter. There was no statistically significant reduction in contrast sensitivity, as the mean was 1.07 preoperatively and 0.98 postoperatively at the end of the follow-up ($p = 0.347$).

Discussion

Proper treatment of presbyopia typically represents an encouraging cause of enthusiastic research. The expectations and the number of patients with presbyopia are progressively increasing. During the previous decades, a substantial effort has been exerted to improve surgical methods for management of presbyopia [11].

Available strategies of presbyopia correction, based on static or dynamic surgical methods, include intracorneal inlays, corneal multifocality, lens-based treatment and combined approaches. Every single method has its particular advantages and drawbacks. Corneal inlays lead to distinct improvement on UCDVA but may cause haze formation and corneal scarring. Bifocal lens-based correction of presbyopia improves UCDVA and UCNVA though may carry an increased risk of blurred vision and glaring [12–14].

Corneal correction of presbyopia using an excimer laser could be in the form of monovision, alteration of corneal asphericity and producing corneal multifocality [15, 16]. Kanellopoulos et al. tried a new treatment modality using topographically customized CXL aiming to obtain a predictable, hyperopic and presbyopic refractive change. Annular section mid-peripherally was used to benefit from differential response and biomechanical alterations to obtain asphericity changes and central corneal steepening [17, 18].

We used the Laser Blended Vision (Carl Zeiss Meditec, Jena, Germany) technique to correct presbyopia in pseudophakic eyes. This technique combines control of spherical aberration to enhance depth of field with micro-monovision (anisometropia approaching 2 D in the nondominant eye). The aspheric micro-monovision protocol was well tolerated (95.8%). One (4.2%) patients who did not tolerate anisometropia of 1.5 D. This patient requested both eyes be corrected for far vision after the primary treatment. The tolerance was comparable to that noted in emmetropic [19] and hyperopic [20] cases but higher than that reported in a myopic [21] eyes (88%).

This may be because of the degree of presbyopia. It was reported that patients with mild presbyopia are less tolerant to anisometropia than patients with marked presbyopia as cases of myopia were younger [19]. In our study, although our cases are younger, all cases were pseudophakics with complete loss of accommodation (marked presbyopia) and this explains the high tolerance.

In this study we had a wide range of age from 19 to 60 years with mean age of 39.34 ± 13.08 years. In all previous studies the age was above 40 years as this is the normal age of presbyopia [18–23]. Pseudophakia also explains the variability of refractive states, with mean SE of preoperative distant visual acuity 0.84 ± 0.14. Others studied micro-monovision in emmetropic, myopic or hypertropic patients separately [19–22].

The postoperative UCDVA at 1 month decreased significantly than the preoperative level. This is noteworthy because most of the presbyopia patients expect to retain distant vision after surgery as good as or even better than spectacle distant vision. This can be returned to ordinary LAISK complications as glaring and dry eye which improves by time and suitable tear substitutes. Dry eye may be more in our cases as the previous studies offered corneal procedure in virgin eyes. But in our study, we did laser corneal procedure in eyes previously operated for cataract. Both Lasik [24] and phacoemulsification [25] can lead to dry eye. Furthermore, this decrease in UCDVA in the first postoperative month may be a matter of initial intolerance to anisometropia between the two eyes. This decrement was stated in two publications. They stated that this procedure results in a loss of lines of CDVA at 6 months after surgery [22, 23]. Other studies stated that uncorrected binocular visual acuity of 20/20 at distance and J3 at near was achieved in 99% of patients with no loss of CDVA [20, 21]. However, the UCDVA began to improve at the 3rd month with no significant difference with the preoperative level, but significantly higher than the 1st postoperative month. The UCDVA was stabilized through the 6th postoperative month with no significant difference between 3rd and 6th postoperative months.

The preoperative UCNVA was significantly lower than the UCNVA at the 1st, 3rd and 6th postoperative months. No significant differences were recorded among the UCNVA at the 1st, 3rd or 6th postoperative months. This improvement in both near and distant vision seems to express a slight increase in depth of field even with a minor asphericity utilized in the ablation profile.

Femtosecond Lasik monovision was described formerly using the EC-5000 excimer laser (NIDEK Co Ltd, Gamagori, Japan) and IntraLase FS30 (Abbott Medical Optics, Santa Ana, California). The nondominant eyes were treated with target refraction of 1.50 D. Mean UNVA was J3 nearly the same as in our study [26]. Ayoubi et al. [26] also reported outcomes of monovision via conductive keratoplasty; mean UNVA was J5.5. Studies on multifocal ablation profiles showed a decrease in quality of vision [27–30]. Refractive intracorneal inlays were also studied as an option for treatment of presbyopia. Some corneal inlays were associated with poor refractive predictability and loss of CDVA [12], and more recent inlays resulted in better outcomes [31, 32]. Huseynova T and associates evaluated the NVA after KAMRA corneal inlay (AcuFocus, Inc., Irvine, CA) implantation in patients with pseudophakia. They found that the implantation of a small aperture corneal inlay improved UCNVA while maintaining UCDVA [33].

In our cases there was a statistically insignificant decrease in stereopsis after surgery. A significant decrease in stereopsis after monovision LASIK treatments has been reported [34, 35]. The micro-monovision influences stereopsis but less than the conventional monovision technique [36]. This may be due to the small degree of anisometropia, and the induced spherical aberration did not considerably alter stereopsis. In our cases, no statistically significant change in contrast sensitivity was found postoperatively. In a study by Reinstein et al. [21] of myopic presbyopic eyes, there were no changes in contrast sensitivity. In a different study Reinstein et al. [20] found no reduction in the mean contrast sensitivity.

Our study was limited by the small number of patients and the lack of information about the previously implanted intraocular lens (IOL). The small number of subjects may affect the statistical results. The type of IOL may affect the induced spherical aberrations. Also, the lack of aberrometer may limit our study results.

We concluded that Lasik with aspheric ablation profiles and a micro-monovision protocol is an effective option for presbyopia correction in pseudophakic patients who are incompliant with reading

glasses. More studies with larger sample size and longer follow-up duration are recommended.

Funding This study was funded by the authors.

Compliance with ethical standards

Conflict of interest The authors declare that they have no conflict of interest.

Ethical approval All procedures in this study were approved by the Benha University Research Ethics Committee and with the 1964 Declaration of Helsinki and its later revisions or equivalent ethical standards.

Informed consent Informed consent was obtained from all participants included in this study.

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