

Presbyopic LASIK using hybrid bi-aspheric micro-monovision ablation profile for presbyopic corneal treatments

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Running head: Hybrid bi-aspheric micro-monovision profiles in presbyopia

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PURPOSE: To evaluate distance and near image quality after hybrid bi-aspheric multifocal central presbyLASIK treatments.

DESIGN: Consecutive case series

Methods: Sixty-four eyes of 32 patients consecutively treated with central presbyLASIK were assessed. The mean age of the patients was 51 ± 3 years with a mean spherical equivalent refraction of -1.08 ± 2.62 D and mean astigmatism of 0.52 ± 0.42 D. Monocular corrected distance visual acuity (CDVA), corrected near visual acuity (CNVA) and distance corrected near visual acuity (DCNVA) of non-dominant eyes; binocular uncorrected distance visual acuity (UDVA), uncorrected intermediate visual acuity (UIVA), distance corrected intermediate visual acuity (DCIVA) and uncorrected near visual acuity (UNVA) were assessed pre- and post-operatively. Subjective quality of vision and near vision was assessed using the 10-item, Rasch-scaled, Quality of Vision and Near Activity Visual Questionnaire respectively.

RESULTS: At one year post-operatively, 93% of patients achieved 20/20 or better binocular UDVA; 90% and 97% of patients had J2 or better UNVA and UIVA respectively; 7% lost 2 Snellen lines of CDVA; Strehl ratio reduced by $\sim -4 \pm 14\%$. Defocus curves revealed a loss of half a Snellen line at best focus, with no change for intermediate vergence (-1.25 D) and a mean gain of 2 lines for near vergence (-3 D).

CONCLUSIONS: Presbyopic treatment using a hybrid bi-aspheric micro-monovision ablation profile is safe and efficacious. The post-operative outcomes indicate improvements in binocular vision at far, intermediate and near distances with improved contrast sensitivity. A 19% retreatment rate should be considered to increase satisfaction levels, besides a 3% reversal rate.

Introduction

Presbyopia is an age related condition characterized by the gradual loss of the eye's ability to focus actively on nearby objects. This condition is mainly attributed to a loss of elasticity of the crystalline lens, accompanied by a change in the ciliary muscle strength and lens curvature¹. Refractive surgeons have faced challenges in effectively combining the treatment of refractive errors and presbyopia. Surgical presbyopia corrections have seen several developments from the monovision and multifocal ablation techniques, to the modern hybrid methods combining the benefits of several techniques. Corneal inlays and intraocular lenses have also been a popular alternative treatment for presbyopia². Monovision techniques³ usually involve correcting the dominant eye for distance as opposed to crossed monovision⁴ where the dominant eye is corrected for near vision.

Charman⁵ proposed that the main aim of presbyopia treatments was to extend the binocular depth-of-focus to yield adequate distance- and near vision with good retinal contrast at lower spatial frequencies. Dai⁶ first proposed the use of rigorous methodologies to theoretically optimize vision over the entire target range from near to distance. Multifocal ablations are designed to achieve these characteristics. These result in a pseudo-accommodative cornea realized in the form of either a peripheral near zone (concentric ring for near vision)⁷ or in the form of a central near zone (central disc for near vision)⁸.

PresbyLASIK is one such robust technique based on traditional Laser-Assisted in situ Keratomileusis (LASIK) to correct the visual defect for distance while simultaneously reducing the near spectacle dependency in presbyopic patients^{9,10}. PresbyLASIK has been stated as a promising technology, but lacking the level of maturity of monovision¹¹. For achieving maximum patient satisfaction, good near vision should be accompanied with no detrimental effect in the distance vision. A hybrid method combining micro-monovision and multifocal ablation could potentially achieve full range of vision.

In this work, a Hybrid bi-aspheric micro-monovision technique is presented and the outcomes are retrospectively analyzed in 64 consecutive eyes (of 32 patients) treated using this method.

METHODS

PATIENTS

This cohort study was based on a consecutive case series of patients treated by a single surgeon (MHAL), with the hybrid bi-aspheric micro-monovision technique to correct presbyopia, at VisionClinics, Utrecht, the Netherlands. Proper informed consent was obtained from each patient, for both the treatment and use of their de-identified clinical data for publication. The Independent Review Board Nijmegen (IRBN) evaluated the study and stated that the investigation in this form is not subject to Medical Research Involving Human Subjects Act (WMO). The outcomes of performing presbyLASIK in 64 consecutive eyes (32 patients) were retrospectively analyzed. The average age of the 32 patients (17 male and 15 female; 17 Hyperopes and 15 Myopes) was 51 ± 3 years (range 45 to 55 years). The mean preoperative spherical equivalent was -1.08 ± 2.62 D (-6.75 to 2.00 D), with mean preoperative astigmatism 0.54 ± 0.50 D (0.00 to 2.10 D), and mean spectacle near addition 1.75 ± 0.36 D (1.00 to 2.50 D).

To categorize the candidate as presbyopic, the monocular corrected near visual acuity (CNVA) at 40cm had to be at least two logRAD lines better than the distance corrected near visual acuity (DCNVA) at 40cm in each eye. Inclusion criteria were patients older than 45 years, medically suitable for LASIK, presbyopic with corrected distance visual acuity (CDVA) no worse than 20/32 in either eye (with at least 20/25 in the best eye), stable refraction (<0.5 D change in mean spherical equivalent) for 1 year prior to the study, discontinued usage of contact lenses for at least 2 to 4 weeks (depending on contact lens type) prior to the preoperative evaluation and photopic pupil diameter smaller than 3.0 mm. The pupil diameters were obtained from the topographic measurements. Patients were required to have normal keratometry and topography (visually no suspect or form fruste keratoconus). Patients who suffered from systemic illness, had a calculated corneal bed thickness less than 300 μ m after ablation, had preoperative central corneal thickness of less than 470 μ m, had previous ocular surgery or had abnormal corneal topography were excluded from the study. Additional exclusion criteria were clinically-relevant lens opacity, a pupil offset of 0.7mm or more and any signs of binocular vision anomalies at distance and near.

PREOPERATIVE ASSESSMENT

A full ophthalmologic examination was performed on all the patients prior to surgery including manifest refraction, cycloplegic refraction, slit-lamp microscopy of the anterior segment, handheld ultrasound pachymetry (Corneo-Gage Plus; Sonogage, Cleveland, Ohio), dilated funduscopy, and Goldmann intraocular pressure measurement. CDVA and uncorrected distance visual acuity (UDVA) were assessed with Early Treatment Diabetic Retinopathy Study (ETDRS) charts. Near and intermediate acuity was assessed unaided and distance corrected (Uncorrected near visual acuity (UNVA), DCNVA, uncorrected intermediate visual acuity (UIVA) and distance corrected intermediate visual acuity (DCIVA)), with the Dutch version of the Radner Reading Charts at 40cm. All the tests were performed binocularly. The selection of the distance and near eye was based on a protocol described by Durrie et al¹².

The corrected visual acuity was always assessed with trial frames and not contact lenses. Binocular defocus curves were measured (with both eyes corrected for distance, i.e. eliminating the effect of the micro-monovision component) with induced lens blur from +1.5D to -4.0D in 0.5D randomized spherical steps, using distance ETDRS charts with the letters randomized between presentations and magnification effects being accounted for¹³.

Contrast sensitivity with and without glare, was measured using the Contrast Glare Tester CGT-1000 (Takagi Seiko Co Ltd, Nagano-Ken, Japan) at six target sizes (6.3°, 4.0°, 2.5°, 1.6°, 1.0°, and 0.7°) after correcting the refractive error with spectacles. Log values of the contrast sensitivity scores were used for statistical analysis. Corneal and ocular aberrometry was performed with the OPD Scan II (Nidek, Gamagori, Japan) over a 6mm diameter. Root mean square (RMS) higher order aberrations, Strehl ratio and corneal asphericity were extracted.

Subjective, patient reported outcomes were assessed using two questionnaires: the Quality of Vision questionnaire and the Near Activity Visual Questionnaire. The Quality of Vision questionnaire was developed by McAlinden et al.^{14,15} to assess symptoms such as glare, halos, starbursts etc. with the use of simulation photographs. Symptoms are scored based on their frequency, severity and bothersome. The questionnaire is valid for use with spectacle wearers, contact lens wearers, and those having had laser refractive surgery, intraocular refractive surgery, or eye disease including cataract^{16,17,18}. The Near Activity Visual Questionnaire was used to assess patient satisfaction with near functional vision¹⁹. For both questionnaires the raw response scores were converted to a 0-100 Rasch scale with higher scores indicating worse quality of vision.

The Quality of Vision and Near Activity Visual Questionnaire were administered preoperatively, and at 3 months, 6 months and one-year postoperatively. Patients were instructed to answer the questionnaires at each follow-up visit to account their subjective impression in unaided bright and dim lighting conditions.

SURGICAL PROCEDURE

All the treatments were prepared using the SCHWIND PresbyMAX treatment planning module in aspheric mode (SCHWIND eye-tech-solutions GmbH and Co. KG, Kleinostheim, Germany). The devices used in this study bear the standards of European conformity (Conformité Européene or CE marking) but are not approved by the U.S. Food and Drug Administration (FDA). The hybrid surgical technique involved treating the dominant eye (also referred to as the distant eye) more towards distance vision (target refraction -0.1D) and the non-dominant eye (also referred to as the near eye) slightly towards near vision (target refraction -0.9 D) for achieving micro-monovision. Multifocality^{20,21,22,11} increases the range of intermediate vision with a different depth of focus between the distant eye (+1.1D) and the near eye (+2.2D).

For each treatment, the planning software calculated the size of the optimal transition zone, depending on the preoperative refraction and optical treatment zone. Drops of topical anaesthetic were instilled in the upper and lower fornices. Flaps were made using Intralase iFS 150 KHz femtosecond laser (AMO, Chicago, Illinois, USA) with a 100 µm nominal flap thickness.

Additional drops of topical anaesthetics were instilled; the lid margins and periocular region were disinfected using diluted povidone. A sterile drape covering eye lashes and face was used to isolate the surgical field. A lid speculum was inserted to allow maximum exposure of the globe.

Proper alignment of the eye with the laser was achieved with a 1050 Hz infrared eye tracker with simultaneous limbus, pupil, and torsion tracking integrated into the laser system and centered on the corneal vertex. The eye tracker had a typical response time of 1.7 milliseconds with a system total latency time of 2.9 milliseconds. The flap was lifted and the excimer laser ablation was delivered to the stroma. Aspheric non-wavefront-guided treatments were performed. The ablation profile was centered on the corneal vertex determined by the topographer (taking 70% of the pupil offset value), which closely approximates the visual axis^{23,24}. Further, the topographic keratometry readings at 3mm diameter were used for the compensation of the loss of efficiency when ablating the cornea at non-normal incidences. Patients were requested to look at a pulsing green fixation light throughout the ablation.

The flap was repositioned and the interface was irrigated with balanced salt solution, for removing any debris. Patients received topical antibiotic drops QID for 1 week; corticosteroid drops QID tapering off in 1 week and ocular lubricants as needed.

POSTOPERATIVE EVALUATION

Patients were reviewed at six weeks, three months, six months, and one year post operatively. All postoperative follow-up visits included measurement of monocular and binocular UDVA, UNVA, UIVA, manifest refraction, CDVA, DCNVA, DCIVA and defocus curves. The response to Quality of Vision and Near Activity Visual Questionnaire, topography and aberrometry, and contrast sensitivity was recorded at every follow up visit except 6-weeks post operatively.

STATISTICAL ANALYSIS

Data were assessed for normality using the Shapiro-Wilk test. Analysis of variance and t-tests were performed on normally distributed data and Friedman tests and *post-hoc* Wilcoxon signed-ranks tests when the data was not normally distributed.

Distance visual acuity was evaluated in logMAR but converted to equivalent Snellen fractions for reporting comparability. Similarly, near visual acuity was evaluated in logRAD but converted to Jaeger scale for reporting comparability. Manifest refraction was used for pre to postoperative comparison. Uncorrected and corrected visual acuity, contrast sensitivity, spherical equivalent refraction and refractive astigmatism were individually analyzed for myopes and hyperopes.

RESULTS

The mean optical treatment zone diameter was 6.58 ± 0.26 mm (6.0 to 7.0 mm, median 6.5 mm). The total ablation zone ranged from 6.8 mm to 8.9 mm.

EFFICACY

The distribution of binocular UDVA, UIVA and UNVA are presented in figure 1. At one year follow up, 93% myopic patients and 94% hyperopic patients achieved 20/20 or better binocular UDVA; 100% myopic patients and 94% hyperopic patients achieved Jaeger level J2 or better UIVA; while 93% myopic patients and 88% hyperopic patients achieved Jaeger level J2 or better UNVA.

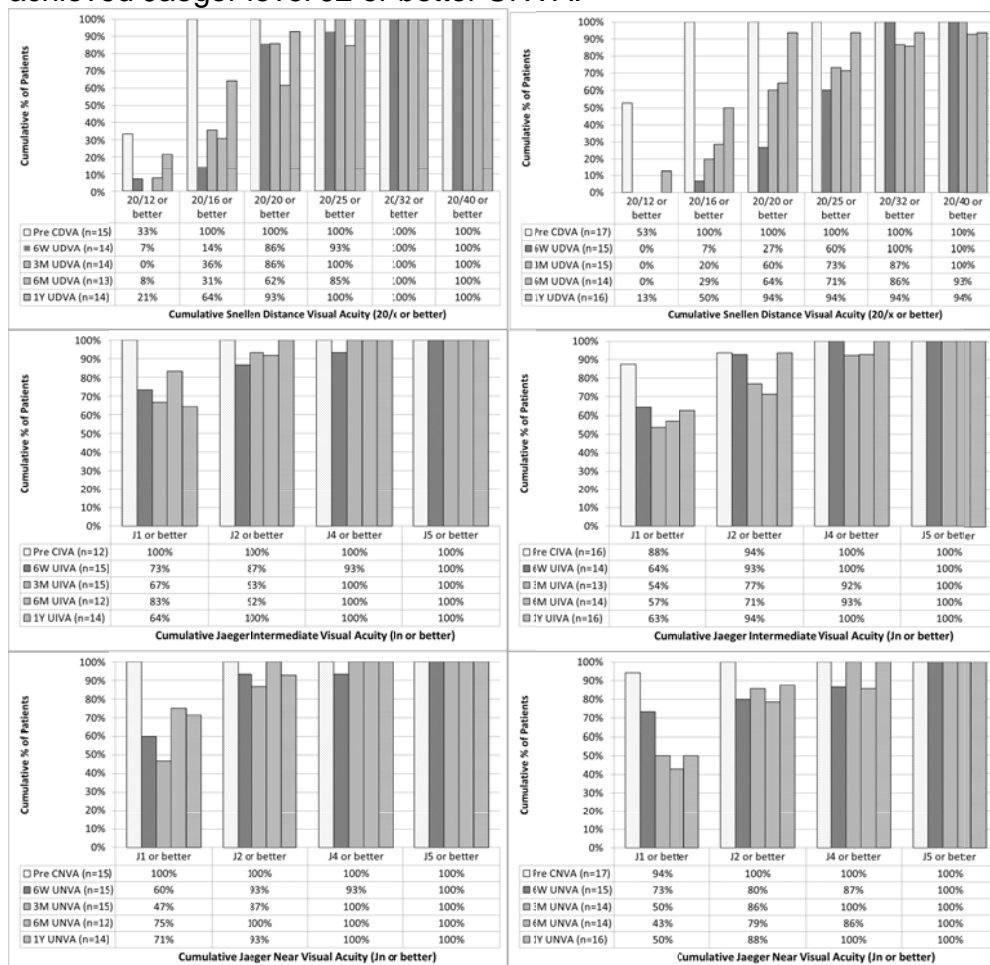


Fig. 1. Changes in binocular uncorrected visual acuity at one year follow up after treating with Hybrid bi-aspheric micro-monovision ablation profile for presbyopic corneal treatments. Myopic patients are presented in the left panel and hyperopic patients are presented in the right panel. Top left) 93% of the myopic patients achieved 20/20 or better binocular uncorrected distance visual acuity (UDVA). Top right) 94% hyperopic patients achieved 20/20 or better binocular UDVA. Middle left) 100% myopic patients achieved Jaeger level J2 or better binocular uncorrected intermediate visual acuity (UIVA). Middle right) 94% hyperopic patients achieved Jaeger level J2 or better UIVA. Bottom left) 93 % myopic patients achieved Jaeger level J2 or better uncorrected near visual acuity (UNVA). Bottom right) 88 % hyperopic patients achieved Jaeger level J2 or better UNVA.

Changes in contrast sensitivity scores were assessed with and without the disability glare (Figure 2). At the 3 and 6 months follow up, the contrast sensitivity scores remained similar to the respective preoperative scores in both tests (with and without the disability glare), but improved respectively at the 1 year follow up ($p < 0.005$ at all sizes).

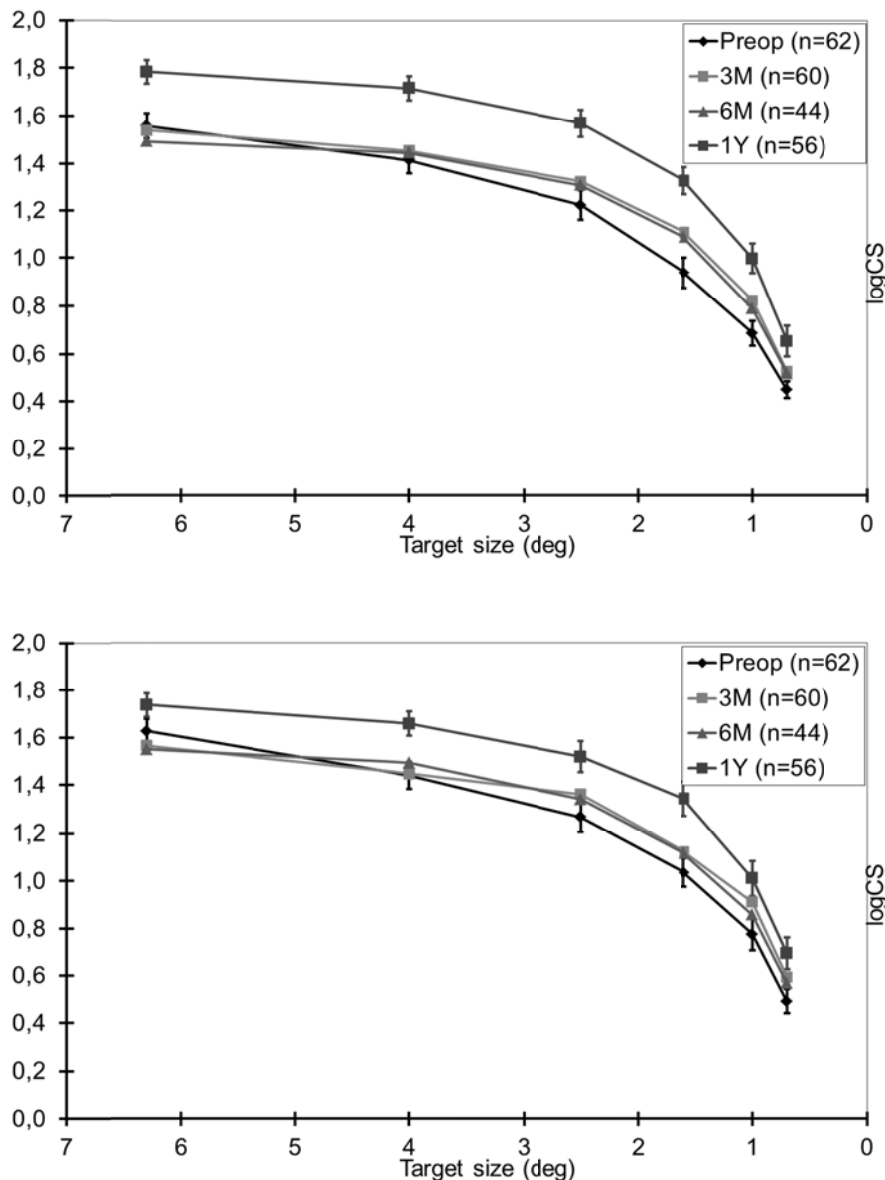


Fig. 2. Contrast sensitivity scores assessed preoperatively, 3 months, 6 months and one year after treating with Hybrid bi-aspheric micro-monovision ablation profile for presbyopic corneal treatments. The contrast sensitivity scores were assessed with (Top) and without (Bottom) disability glare. Here M and Y represent months and years respectively. At 3 and 6 months follow up, the contrast sensitivity scores remained similar to the respective preoperative scores in both tests (with and without the disability glare), but improved respectively at 1 year follow up ($p < 0.005$ at all sizes). The error bars represent the upper and lower 95% confidence limits of the mean of measurements, preoperatively and one year postoperatively.

SAFETY

The change in binocular DCIVA and DCNVA is presented in figure 3. At one year follow up, 85% myopic patients and 94% hyperopic patients achieved a Jaeger level J2 or better binocular DCIVA; while 57% myopic patients and 63% hyperopic patients achieved a Jaeger level J4 or better binocular DCNVA. A loss of 2 Snellen lines of binocular CDVA (figure 4) was observed in 7% myopic patients and 6% hyperopic patients, at one year follow up.

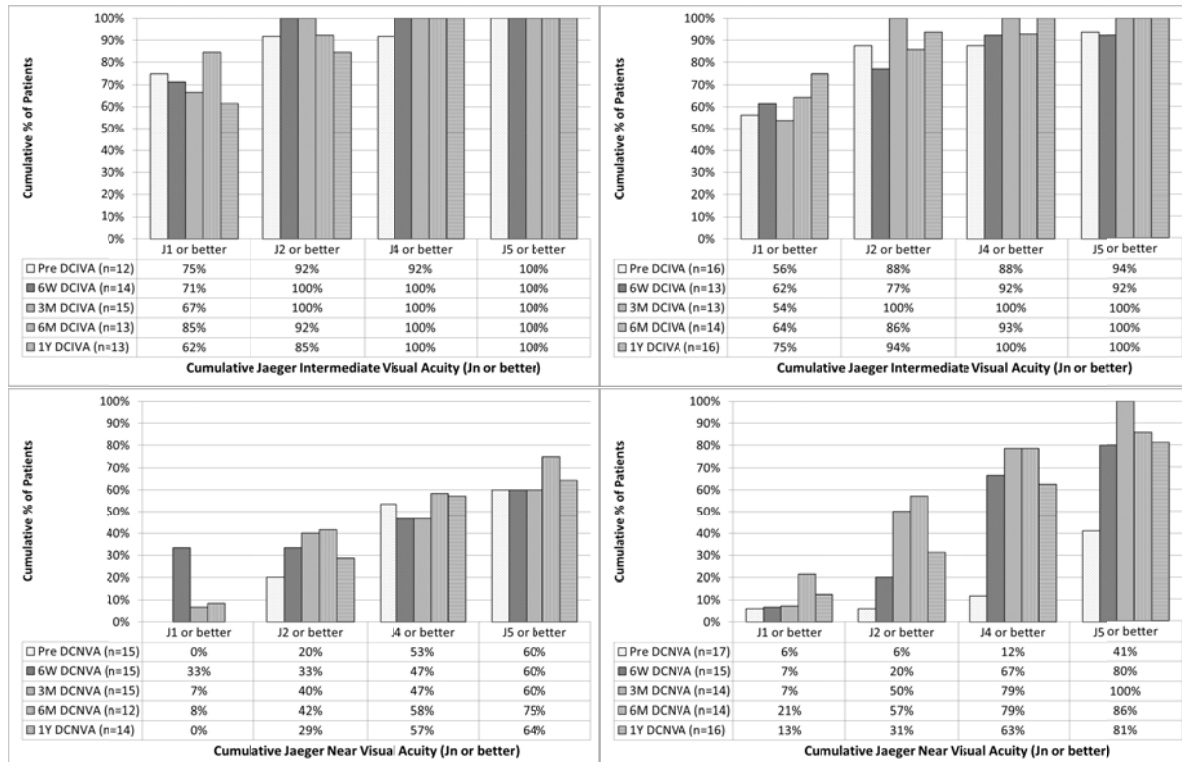


Fig. 3. Changes in binocular distance corrected visual acuity at one year follow up after treating with Hybrid bi-aspheric micro-monovision ablation profile for presbyopic corneal treatments. Myopic patients are presented in the left panel and hyperopic patients are presented in the right panel. Top left) At one year follow up, 85% myopic patients achieved a Jaeger level J2 or better binocular distance corrected intermediate visual acuity (DCIVA). Top right) At one year follow up, 94% hyperopic patients achieved a Jaeger level J2 or better binocular DCIVA. Bottom left) At one year follow up, 57% myopic patients achieved a Jaeger level J4 or better binocular distance corrected near visual acuity (DCNVA). Bottom right) At one year follow up, 63% hyperopic patients achieved a Jaeger level J4 or better binocular DCNVA.

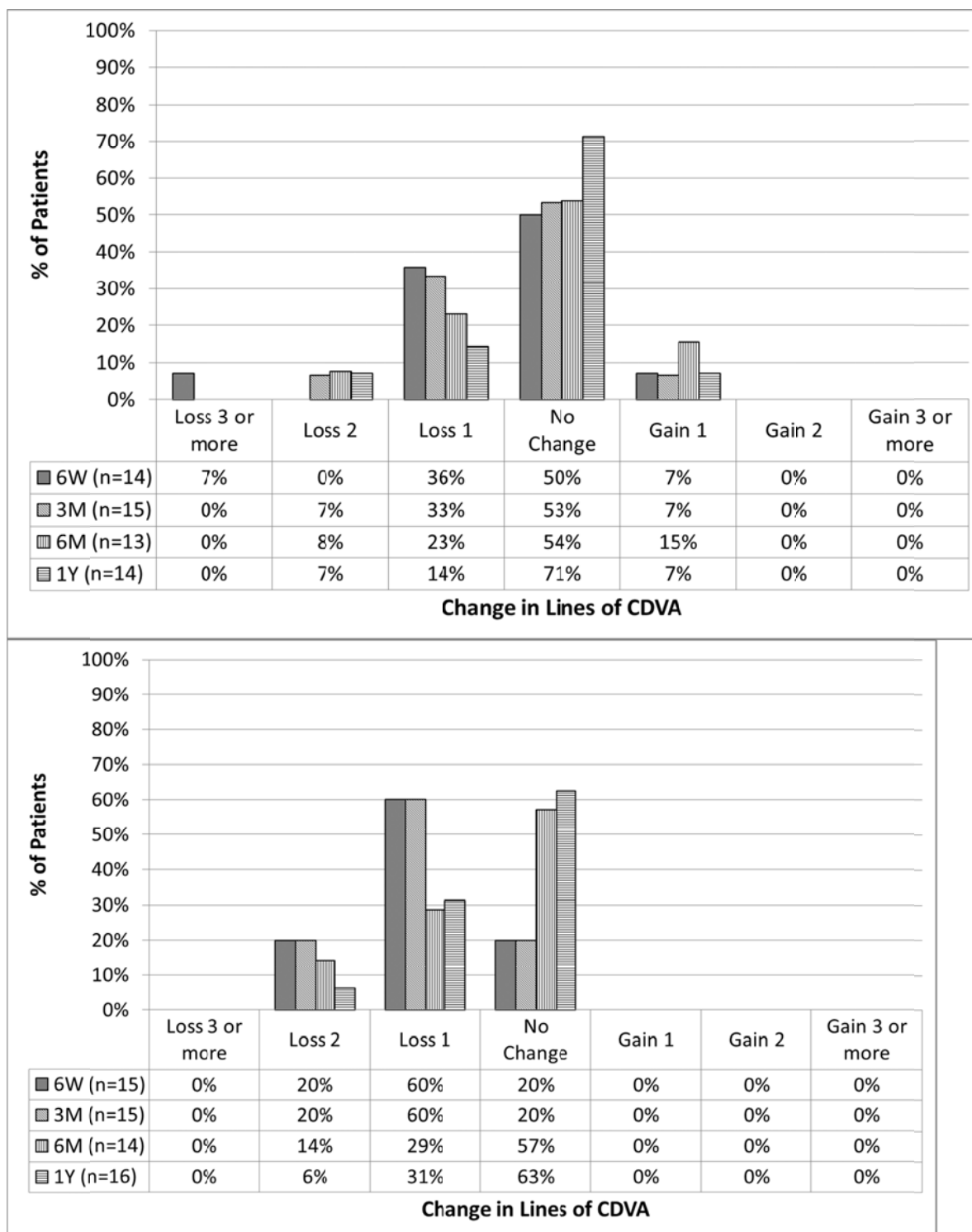


Fig. 4. Changes in binocular corrected distance visual acuity (CDVA) at one year follow up after treating with Hybrid bi-aspheric micro-monovision ablation profile for presbyopic corneal treatments. Top) Myopic patients: A loss of 2 Snellen lines of CDVA was observed in 7% myopic patients at one year follow up. Bottom) Hyperopic patients: A loss of 2 Snellen lines of CDVA was observed in 6% hyperopic patients at one year follow up.

ACCURACY

For Myopic and hyperopic patients, a good separation was observed between the dominant and non-dominant eye, for refractive deviation from target spherical equivalent refraction and astigmatism (figure 5). In myopic patients, 100% distance eyes were within 0.5D of emmetropia while 67% near eyes were within 0.6D of micro-monovision target (-0.9D); in hyperopic patients, 76% distance eyes were within 0.5D of emmetropia while 59% near eyes were within 0.6D of micro-monovision target (-0.9D). For myopic patients, 100% distance eyes and 73% near eyes were within 0.5D of astigmatism; in hyperopic patients, 100% distance eyes and 59% near eyes were within 0.5D of astigmatism. Refractive stability was achieved for both dominant (DE) and non-dominant eye (NE) in myopic and hyperopic patients, from 6 weeks postoperatively (figure 6). A nearly linear (coefficient of determination $r^2 = 0.97$, $p < .00001$) relationship between the laser attempted and achieved spherical equivalent refraction was observed (Figure 7).

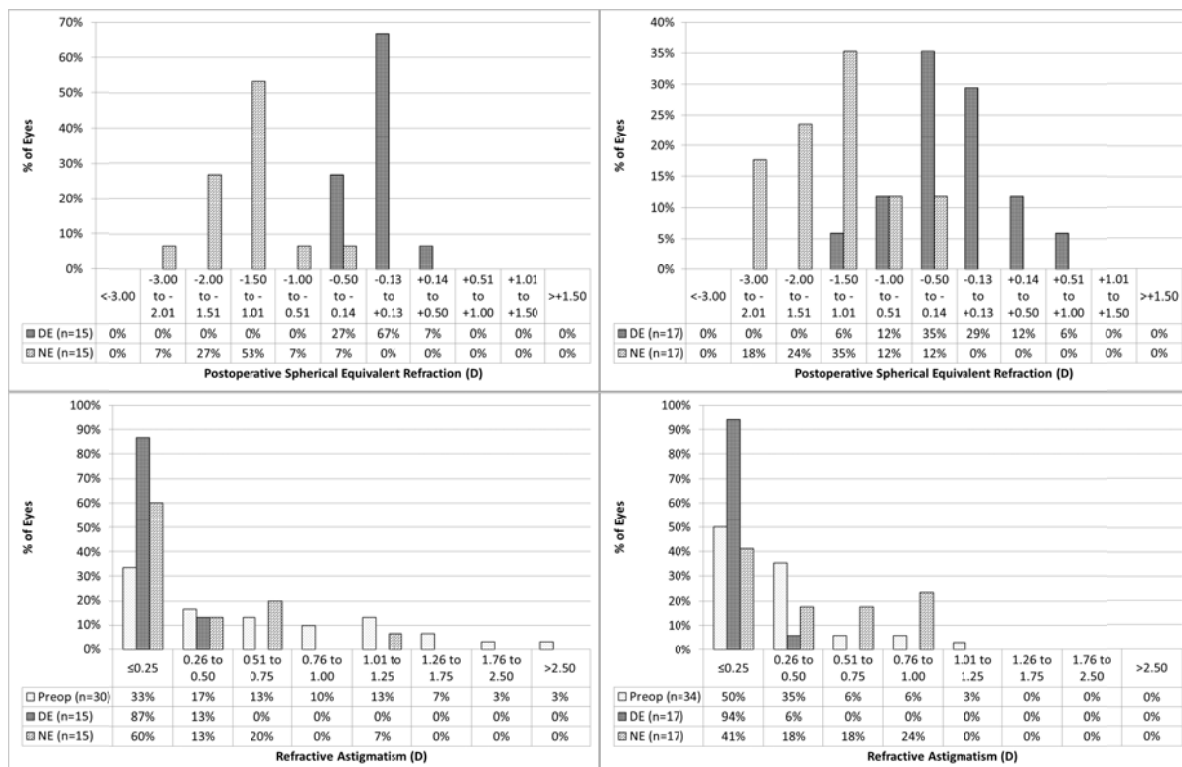


Fig. 5. Spherical equivalent refraction and refractive astigmatism one year after treating with Hybrid bi-aspheric micro-monovision ablation profile for presbyopic corneal treatments. Here DE and NE represent distance and near eye respectively. Myopic patients are presented in the left panel and hyperopic patients are presented in the right panel. Top) Post-operative spherical equivalent refraction. Top left) In myopic patients, 100% distance eyes were within 0.5D of emmetropia while 67% near eyes were within 0.6D of micro-monovision target (-0.9D). Top right) In hyperopic patients, 76% distance eyes were within 0.5D of emmetropia while 59% near eyes were within 0.6D of micro-monovision target (-0.9D). Bottom) Post-operative refractive astigmatism. Bottom left) In myopic patients, 100% distance eyes and 73% near eyes were within 0.5D of astigmatism. Bottom Right) In hyperopic patients, 100% distance eyes and 59% near eyes were within 0.5D of astigmatism.

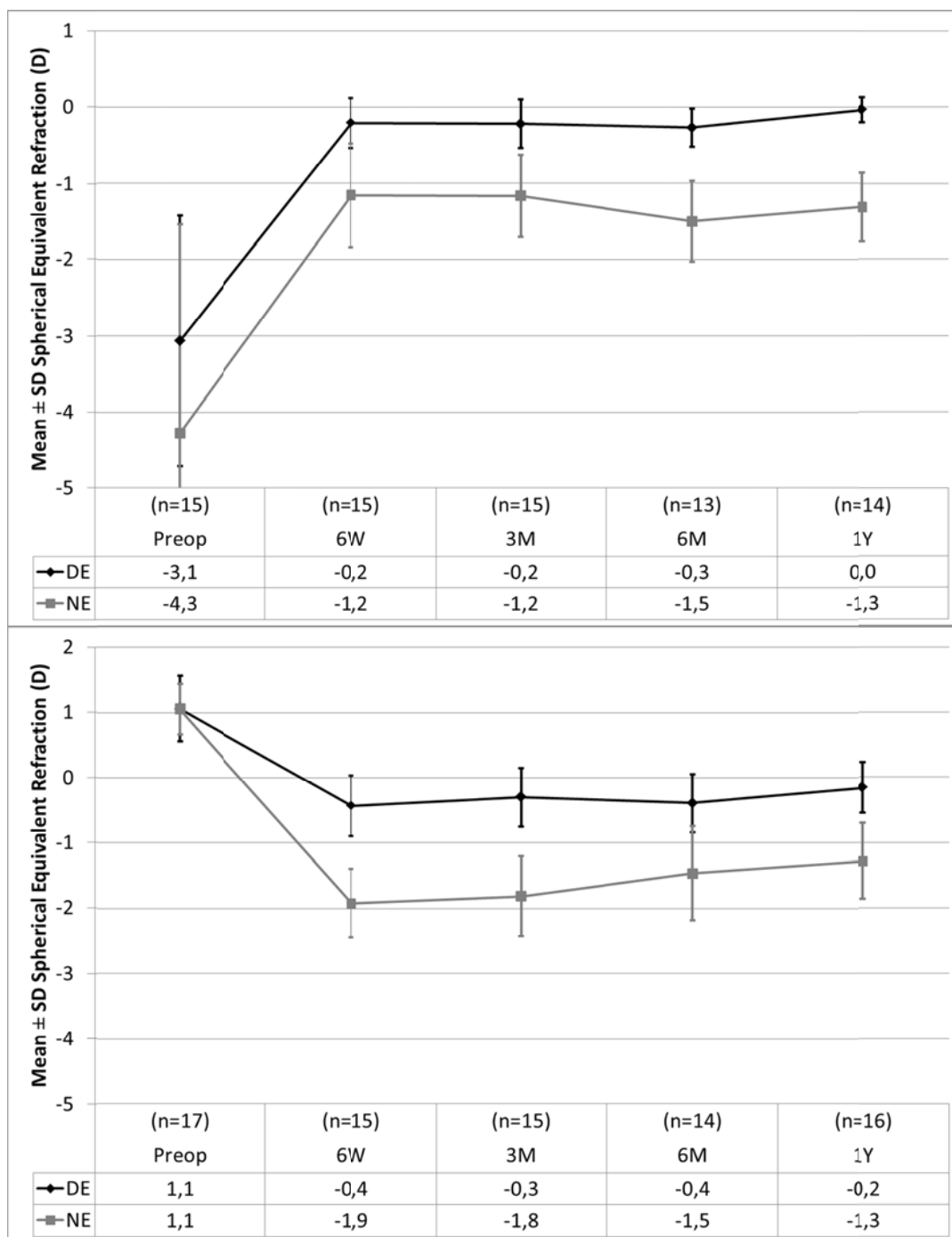


Fig. 6. Mean spherical equivalent refraction assessed preoperatively, and at one year follow up after treating with Hybrid bi-aspheric micro-monovision ablation profile for presbyopic corneal treatments. Top) Myopic patients. Bottom) Hyperopic patients. Here W, M and Y represent weeks, months and years respectively. Refractive stability was achieved for both distance (DE) and near eye (NE) in myopic and hyperopic patients, from 6 weeks postoperatively.

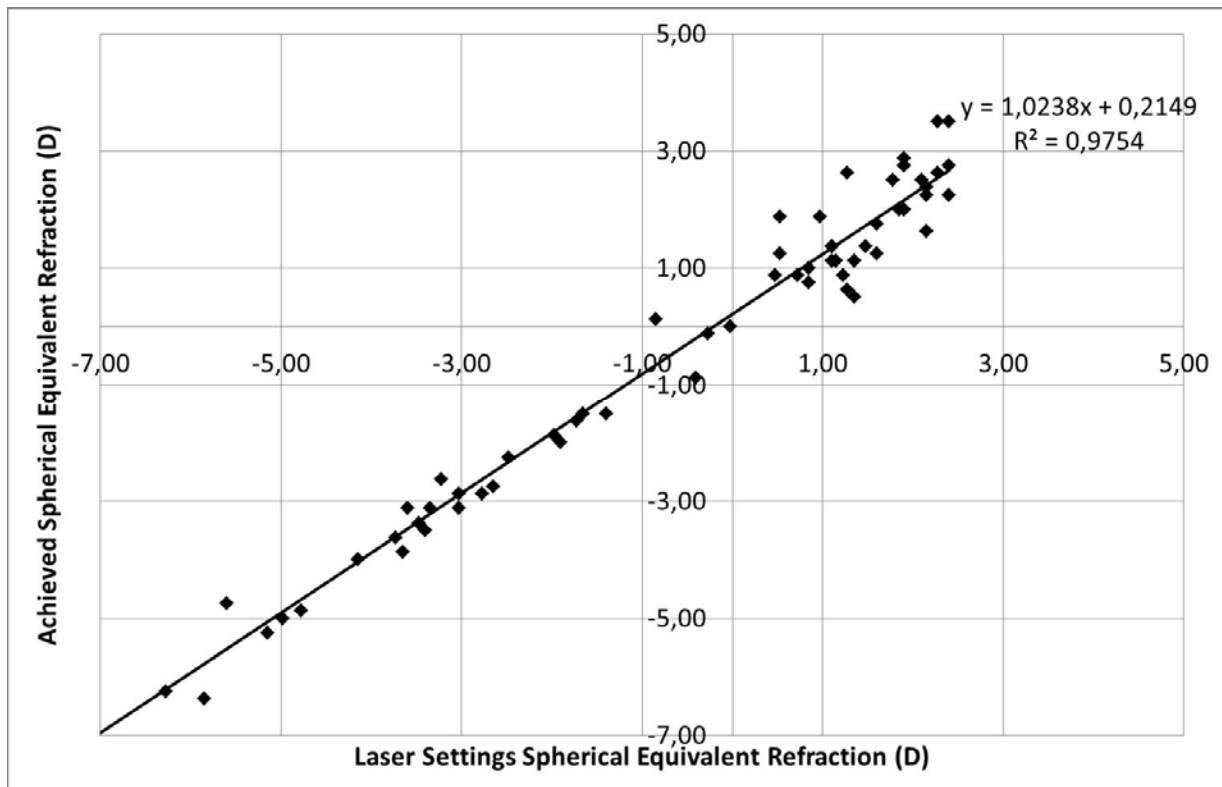


Fig. 7. The relationship between laser setting spherical equivalent refraction and the achieved spherical equivalent refraction one year after treating with Hybrid bi-aspheric micro-monovision ablation profile for presbyopic corneal treatments. A linear trend can be observed between the attempted and achieved refraction in our cohort ($R^2=0.9754$).

SUBJECTIVE RATING

Quality of Vision scores assessing symptoms based on their frequency, severity and bothersome, are presented in figure 8. Compared to the corrected pre-operative scores, the Quality of Vision worsened postoperatively ($p = 0.02$) mainly with an increase in patients seeing haloes ($p = 0.002$), blurred vision ($p = 0.02$) and double vision ($p = 0.01$).

Near Activity Visual Questionnaire (NAVQ) scores assessing patient satisfaction with near functional vision and overall satisfaction, are presented in figure 9. The Near Activity Visual Questionnaire scores improved from little to very high satisfaction level ($p < 0.00001$), with an improvement in Rasch scores ($p < 0.0001$). Stability was observed in Near Activity Visual Questionnaire scores from 3 months follow up time.

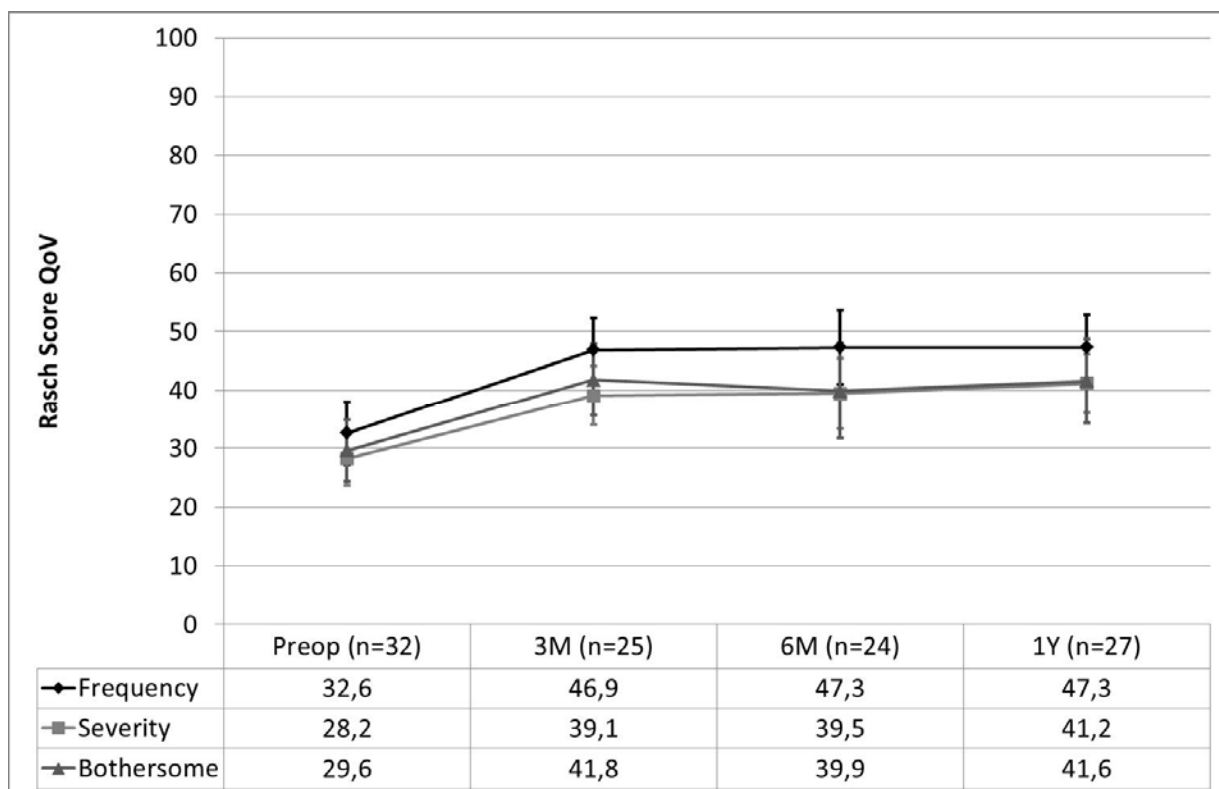


Fig. 8. Quality of Vision (QoV) questionnaire scores assessing symptoms based on their frequency, severity and bothersome, on each follow up visit after presbyLASIK treatment. The raw response scores were converted to a 0-100 Rasch scale with higher scores indicating worse quality of vision. A minor decline is observed in the Rasch scores post-operatively compared to the corrected pre-operative scores. Here M and Y represent months and years respectively.

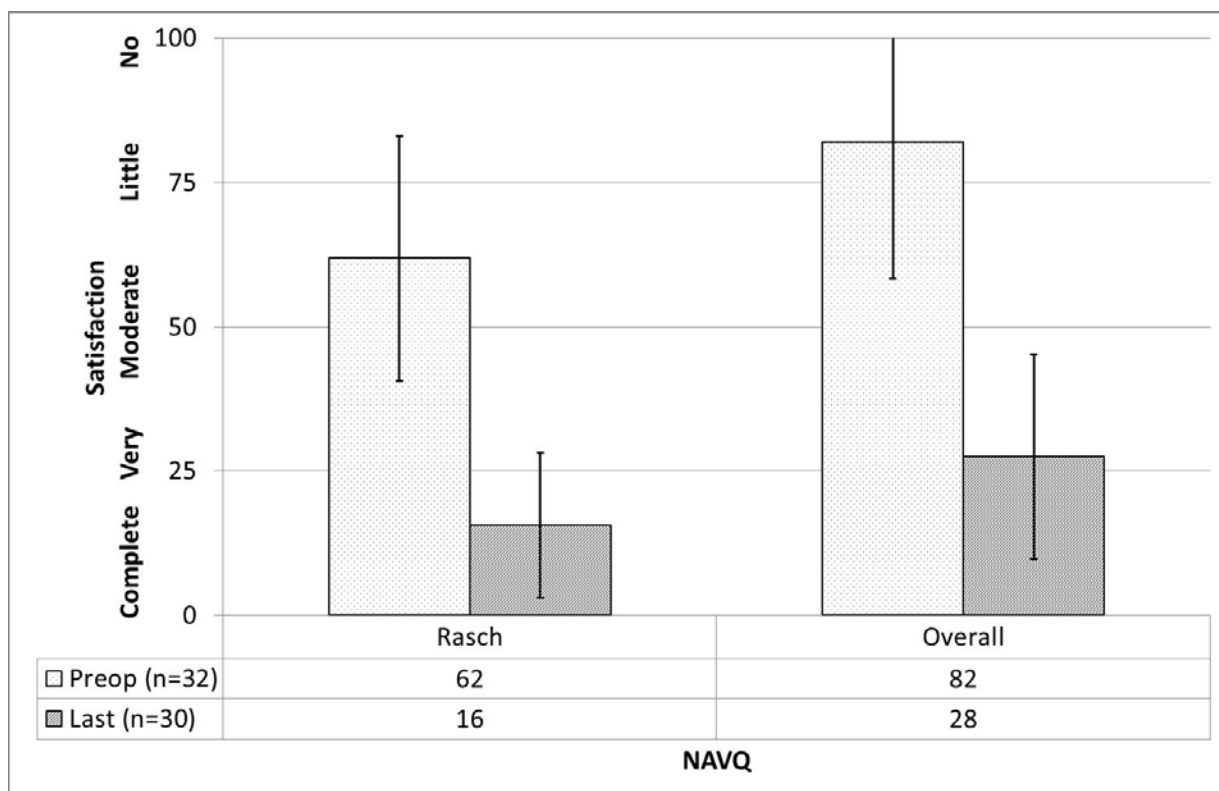


Fig. 9. Near Activity Visual Questionnaire (NAVQ) scores assessing patient satisfaction with near functional vision and overall satisfaction level, preoperatively and at the last post-operative visit after treating with Hybrid bi-aspheric micro-monovision ablation profile for presbyopic corneal treatments.. The raw response scores were converted to a 0-100 Rasch scale with higher scores indicating worse quality of vision. NAVQ improved from little to very high satisfaction level, with an improvement in Rasch scores. Here 'Last' represents the Rasch scores at the last follow up (at 6 months or 1 year postoperatively).

ABERRATIONS

Change in corneal asphericity (Q value) at 3mm diameter, Strehl ratio, Root mean square (RMS) of higher order aberrations (at 6mm diameter), corneal and ocular spherical aberrations, are presented in figure 10. Asphericity was more prolate after surgery indicating a central myopia (within 3mm diameter, $p < 0.00001$). Compared to the preoperative status, one year post-operatively the Strehl ratio reduced by $\sim 4 \pm 14\%$ ($p = 0.00007$), the corneal and ocular spherical aberrations (at 6 mm diameter) decreased by $-0.38 \pm 0.33 \mu\text{m}$ and $-0.28 \pm 0.35 \mu\text{m}$ respectively ($p < 0.00001$), with an increase in RMS higher order aberrations (at 6 mm diameter) by $0.15 \pm 0.24 \mu\text{m}$ ($p = 0.00002$). All these metrics indicated good stability from 3 months onwards.

Binocular defocus curves and the change between defocus curves (preoperatively and at 1 year follow up) are presented in figures 11 and 12 respectively. Defocus curves indicate stability from 6 weeks follow up. The difference in defocus curves shows a decrease of 0.05 logMAR at best focus (-0.35 ± 0.57 lines, $p = 0.0009$), with no change for intermediate vergence (-1.00D and -1.50D) and a mean gain of 2 lines for near vergence (-2.00D and closer, $p = 0.00400$) at one year follow up. A slightly better distance vision was observed preoperatively, but the near and intermediate vision (at $2.00\text{D}/50\text{ cm}$ and $2.50\text{D}/40\text{ cm}$) improved post-operatively.

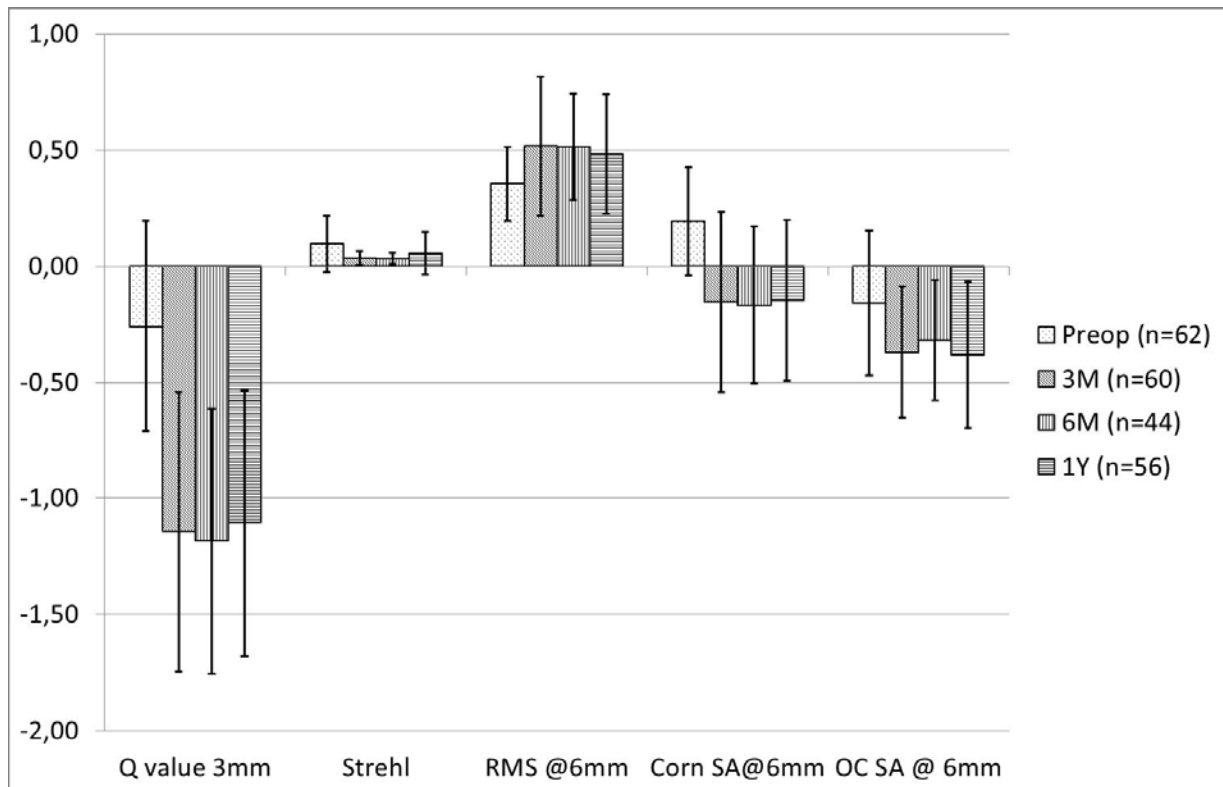


Fig. 10. Change in corneal asphericity (Q value) at 3mm diameter, Strehl ratio (Strehl), Root mean square (RMS) of higher order aberrations (at 6mm diameter), corneal and ocular spherical aberrations (Corn SA and OC SA respectively, at 6mm diameter) preoperatively, and at one year follow up after treating with Hybrid bi-aspheric micro-monovision ablation profile for presbyopic corneal treatments. Here M and Y represent months and years respectively. One year post-operatively, the Strehl ratio reduced by $\sim 4 \pm 14\%$, the corneal and ocular spherical aberrations (at 6mm diameter) decreased by $-0.38 \pm 0.33 \mu\text{m}$ and $-0.28 \pm 0.35 \mu\text{m}$ respectively, with an increase in RMS higher order aberrations (at 6mm diameter) by $0.15 \pm 0.24 \mu\text{m}$. All these metrics indicated good stability from 3 months onwards.

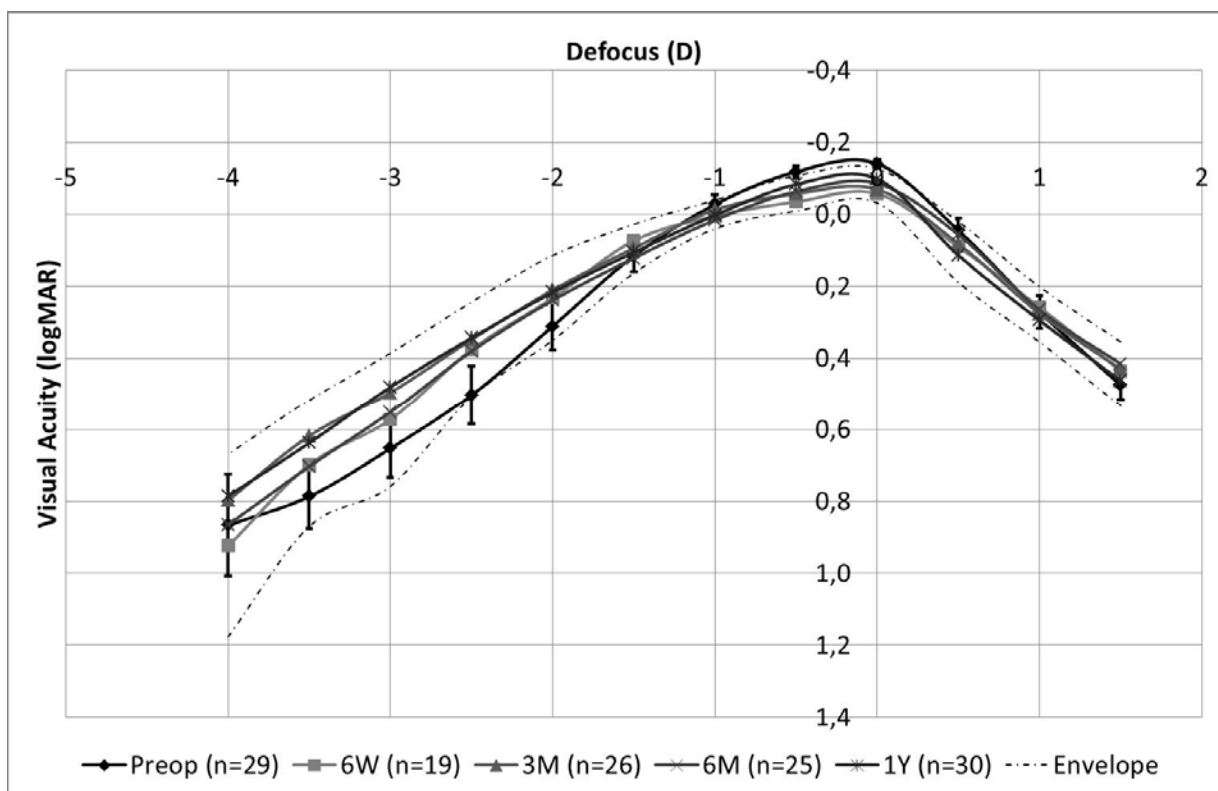


Fig. 11. Binocular defocus curves from uncorrected vision asymmetrically to longer (+1.5D) and shorter vergences (-4.0D), assessed preoperatively and at one year follow up after treating with Hybrid bi-aspheric micro-monovision ablation profile for presbyopic corneal treatments. The error bars represent the upper and lower 95% confidence limits of the mean of measurements, preoperatively. The upper and lower envelop represents respectively, the maximum and minimum values of the confidence limits of postoperative measurements (irrespective of the follow up time) with respect to vergence. Here W, M and Y represent weeks, months and years respectively.

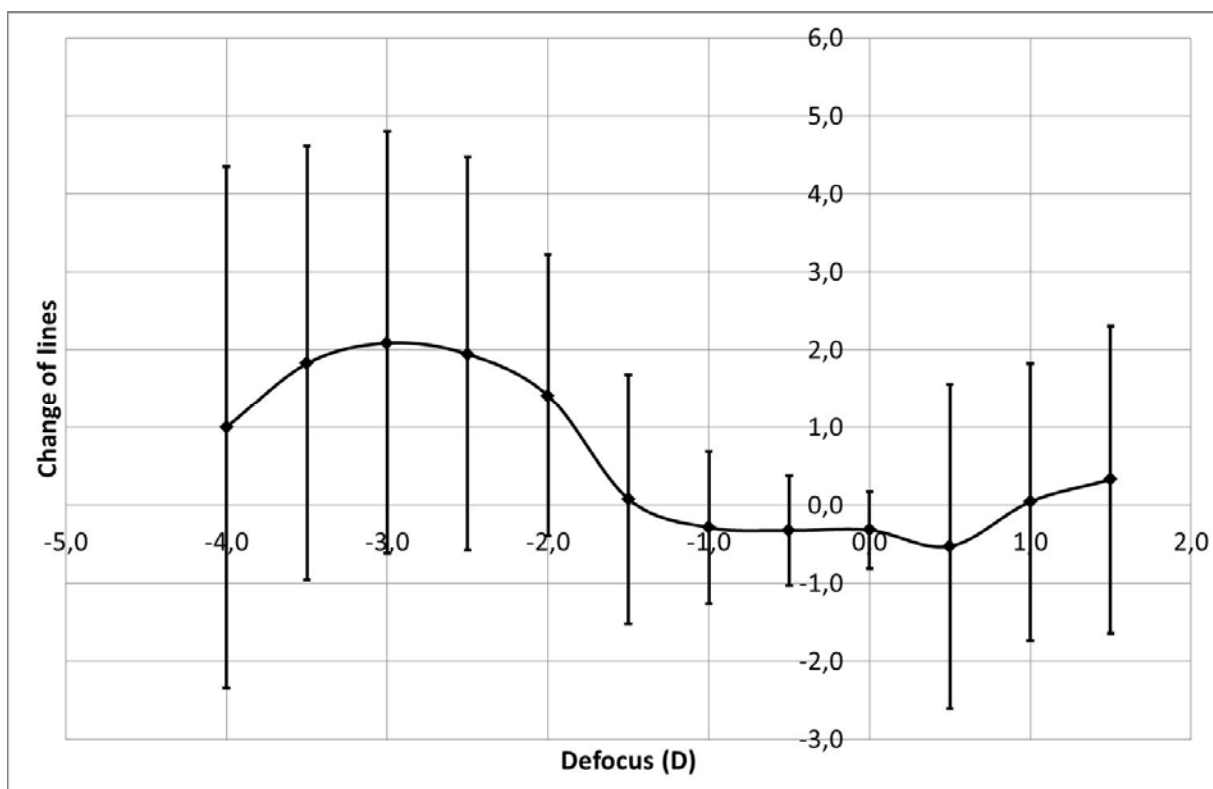


Fig. 12. Change in Defocus curves with respect to vergence, assessed preoperatively and at last follow up after treating with Hybrid bi-aspheric micro-monovision ablation profile for presbyopic corneal treatments. At one year follow up, a loss of half a logMAR was observed at best focus for distance, with no change for intermediate vergence (-1.25D) and a mean gain of 2 lines for near vergence (-3D).

RETREATMENTS

Secondary treatment was performed in 12 eyes (11 patients: 19% from the 64 eyes; 7 eyes in Myopic group (of 6 patients) and 5 eyes in Hyperopic group (of 5 patients) to improve distance (9 eyes) or near (3 eyes) outcomes. The secondary treatments were performed using a non-wavefront guided aspheric treatment to tune distance refraction to the desired value. All retreatments were performed at least 6-months follow-up after the initial treatment. Figure 13 presents the pre-operative CDVA (pre-PresbyMAX) and the post-operative UDVA (pre and post-retreatment) and spherical equivalent refraction in the eyes that underwent a secondary treatment. At one year follow up from the initial treatment (i.e. up to 6-months post-retreatment), 83% of myopic patients and 100% of hyperopic patients undergoing secondary treatment achieved a 20/20 or better binocular UDVA. Compared to the outcomes at 6 months follow up pre-retreatment, significant improvements were observed post-retreatment (only 20% myopic and 60% hyperopic patients achieved 20/20 or better binocular UDVA six months post-operatively after the initial treatment). Binocular UIVA and UNVA remained relatively stable in these eyes through the post-operative follow ups.

Two eyes (3% from the 64 eyes) underwent a partial presby reversal treatment to reduce the effects of the primary treatment, due to the patient's perceived intolerance (mainly loss of CDVA) to the induced multifocality. The details about the reversal of this

technique and corresponding aberrations and topography changes have been published elsewhere²⁵.

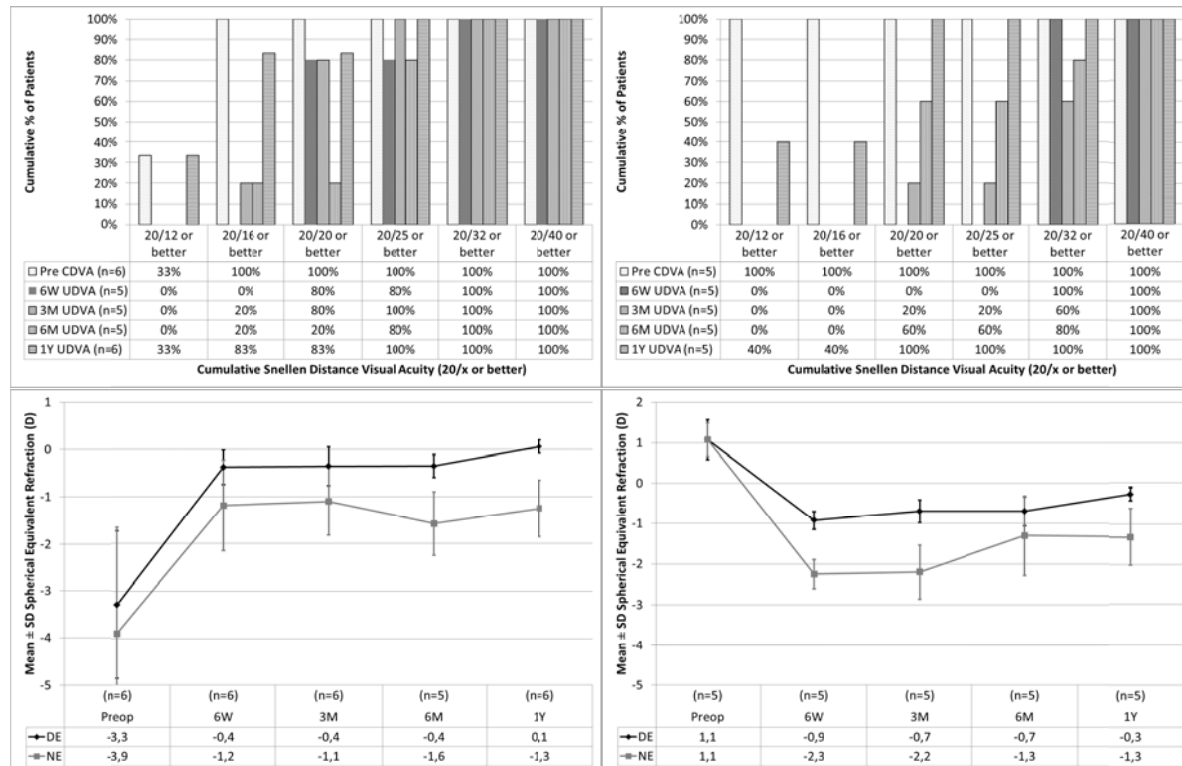


Figure 13. Change in binocular uncorrected distance visual acuity (UDVA) and spherical equivalent refraction after a secondary treatment (in 12 eyes, 11 patients), to improve distance (9 eyes) or near (3 eyes) outcomes in eyes that underwent an initial treatment with Hybrid bi-aspheric micro-monovision ablation profile for presbyopic corneal treatments. All retreatments were performed after the 6-months follow-up. All follow up times presented here are from the initial treatments (i.e up to 6-months post-retreatment). Myopic patients are presented in the left panel and hyperopic patients are presented in the right panel. Top left) 83% of myopic patients achieved a 20/20 or better binocular UDVA at one year follow up, compared to only 20% at 6 months follow up. Top right) 100% of hyperopic patients achieved a 20/20 or better binocular UDVA at one year follow up, compared to only 60% at 6 months follow up. Bottom) Mean spherical equivalent refraction at one year follow in distance eye was 0.1D for myopic patients (left) and -0.3D for hyperopic eyes (right); whereas for near eye was -1.3D for both myopic and hyperopic patients.

DISCUSSION

This consecutive case series analyzed the efficacy and safety of presbyopic treatments using a hybrid bi-aspheric micro-monovision ablation profile. This technique was expected to combine the benefits of multifocal ablations and micro-monovision with enhanced depth of focus and a wider range of intermediate vision. Our independent analysis of myopic and hyperopic patients revealed very comparable long term results after the treatment. The binocular vision was expected to improve overall, with the non-dominant eye imparting an improvement in Near Activity Visual Questionnaire scores

and the dominant eye imparting an improvement in Quality of Vision scores. Most of the outcome measures showed significant improvement compared to the pre-op status. The improvement in corrected and uncorrected distance and near visual acuity was significant post operatively. Improvements in refraction and visual acuity were also seen in patients undergoing secondary treatments. In addition, analyzing the Near Activity Visual Questionnaire responses revealed an improvement in all the topics and the Rasch scores indicated improvements from little (pre-op) to high (post-op) satisfaction. Although, it would be interesting to know the profile of the defocus curves monocularly for the presbyopic eyes, this was not possible due to the retrospective nature of this study. However, the defocus curves with both eyes corrected for distance, i.e. eliminating the effect of the micro-monovision component, revealed a loss of half a Snellen line at the best focus for distance, but a gain of 2 lines at the near vergence. Monocularly, it would be expected that the defocus curves would be shallower, with separation between the dominant and non-dominant eye. The metric area under the defocus curves demonstrates a slight drop at distance vision postoperatively, but not a gain at near or intermediate vision. This could be due to the curves crossing at near (-2.00D to -4.00D) and intermediate (-0.50D to -2.00D) vision boundary; and missing data points in this range.

Corneal topography and aberrometry revealed a decrease in corneal and ocular spherical aberrations, associated with an increase in the RMS higher order aberrations. Furthermore, Quality of Vision responses revealed minor decline in terms of blurred vision, haloes and double vision post operatively compared to the patient responses preoperatively (using correction glasses). Stability in the Near Activity Visual Questionnaire rating and refraction was reached after 3 months and 6 weeks postoperatively. The presented clinical outcomes are based on 1 year of clinical follow up, which is considered adequate in refractive surgery. However, presbyopia increases with age. Therefore, longer follow up could shed light on the durability of performance during further degradation of accommodation. As a recommendation from the manufacturer of the laser system, patients were required to have pupil diameters smaller than 3.0mm in photopic (for effectively using the central near disk of the profile) and larger than 4.5mm in mesopic light conditions (for getting enough light in the distance focus using the pericentral distance annulus of the profile; however, pupil diameters were obtained from the topography, and eyes with pupil diameter smaller than 3.0 mm in photopic conditions are currently included for surgery by the clinic.

Many clinical studies have evaluated various surgical techniques to treat presbyopia; however the current developments throughout the corneal presbyopic correction spectrum indicate a converging trend towards hybrid techniques. These hybrid modifications include: Supracor™ (TECHNOLAS Perfect Vision GmbH), PresbyMAX (reduced multifocality in distance eye combined with full multifocality and monovision in the near eye), Intracor (full correction in distance eye combined with Intracor multifocality and monovision in the near eye), KAMRA™ (AcuFocus, Inc.) (full correction in distance eye combined with pinhole based extended depth-of-focus and monovision in the near eye), Presbyond™ (Carl Zeiss Meditec AG) laser blended vision (moderate multifocality in both eyes combined with monovision in the near eye) and refractive corneal inlays (e.g. raindrop™ from ReVision Optics, USA).

A brief summary and comparison of the clinical studies with different methods to treat presbyopia is presented in Table 1, although intermediate visual acuity is not

included due to the unavailability of this metric in most studies. However, Seyeddain et al.²⁶ reported in their cohort, 71.9% treatments achieving 20/20 or better UIVA compared to the 63% reported in our cohort.

Table 1. A comparison of clinical outcomes using different techniques for laser presbyopia corrections¹.

Study	n	Follow Up	Group/Sub group	UDVA better 20/20 or	UNVA J2 or better	CDVA Loss 2 or more lines	Ret	Rev
Presby LASIK								
Alio et al ⁸	50	6 M	Presb	64%	72% (20/40 or better)	14%	12%	-
Luger et at. ¹¹	66	1 Y	Hyp and myo with/without astig	48%	94%	3%	-	-
Luger et al ²⁰	48	3 M	Hyp and myo with/without astig	25%	50%	-	0%	0%
Iribarne et al. ²¹	50	6 M	Hyp and myo with/without astig	41%	91%	5%	-	-
Bauda et al ²²	716	6 M	Myo	43%	98%	26%	19%	1%
			Hyp	45%	90%	25%	(Overall)	(Over all)
Monovision								
Wright et al. ³	42	7 M (3-15)	Myo presb treated with PRK induced monovision	76.2%	100% (20/30 or better)	-	26.2%	-
	32	11 M (3-17)	Emm treated with PRK	62.5%	25% (20/30 or better)	-	37.5%	-
Alarcon et al ²⁸	50	3 M		90%	90% (J1 or better)	-	12%	-
Conductive keratoplasty								
Stahl. ²⁹	10	1 Y	1 Y follow up	89% (20/20 and J1)	89%	-	0% (overall)	0% (over all)
	9	3 Y	3 Y follow up	22% (20/20 and J1)	33%	-		
Supracor								
Ryan et al. ³⁰	46	6 M	Hyp	48%	73.9% (J5 or better)	4%	21.7%	-
Intracor								
Holzer et al. ³¹	25	3 M		48%	8% (20/20 or better)	8%	-	-
Intracorneal Inlay								
Yilmaz et al. ³²	22	4 Y	Emm or post LASIK presb	73%	96% (J3 or better)	5%	22.7% (Cataract extraction)	18.2%
Seyedd ain et al. ³³	32	2 Y	Emm presb	74 %	65.6% (J1 or better)	6%	6.3%	0%
Tomita et al. ³⁴	223	6 M	Presb patients with previous LASIK	100%	77%	0%	-	-
Multifocal IOL								
McAlin din et al. ²	44	3 M	-	68.2%	-	0%	13.6%	0%
Biaspheric cornea modulation								
Uthoff et al. ³⁵	20	6 M	Emm	80% (0.1 logMar)	40% (0.1 logRad)	10%	6.6% to 10% (may require overall)	
	20	6 M	Hyp	100% (0.1 logMar)	30% (0.1 logRad)	10%		
	20	6 M	Myo	70% (0.1 logMar)	60% (0.1 logRad)	20%		
Presented study								
Current	64	1 Y		93%	90%	7%	19%	3%

¹ Here M is months, Y is year, Myo is myopia, Hyp is hyperopia, Emm is emetropia, presb is presbyopia, astig is astigmatism, n is number of eyes, CDVA is corrected distance visual acuity, UDVA is uncorrected distance visual acuity, UNVA is uncorrected near visual acuity, Ret is retreatments and Rev is reversals.

Methods depending only on the depth of focus might face difficulty to create more than 1.5D of near vision independence. In contrast, with the models based on multifocal ablations one can gain a higher near vision independence. Since, presbyopia increases with age, a wide range of near vision shall be an asset in such cases. In addition, the difference in the depth of focus between the near and far eye provides the patient with a wider binocular range of focus for an enhanced intermediate vision.

The depth of focus acts as a useful marker, however, some studies consider acuity at a typical near vision distances as a more suitable metric that is closely related to patients' real expectations and concerns²⁷. Our analysis and results indicate significant success in presbyopic treatments using the hybrid bi-aspheric micro-monovision ablation profiles. We evaluated the subjective perception of patients for distant (Quality of Vision) and near visual quality (Near Activity Visual Questionnaire scores) and found significant improvements in the Near Activity Visual Questionnaire scores with improved uncorrected and corrected near and distance visual acuity and contrast sensitivity. Presbyopic treatment using a hybrid bi-aspheric micro-monovision ablation profile is safe and efficacious. The post-operative outcomes indicate improvements in binocular vision at far, intermediate and near distances with improved contrast sensitivity. A 19% retreatment rate should be considered to increase satisfaction levels, besides a 3% reversal rate.

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