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Long-term results of excimer laser procedure to correct astigmatic refractive errors

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Statistical Analysis C
Data Interpretation D
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Background: The aim of this study was to evaluate long-term efficacy, safety, stability, and predictability of photorefractive keratectomy (PRK) as treatment of astigmatism.

Material/Methods: Ninety-four eyes of 52 patients, treated with PRK for compound myopic astigmatism, compound hyperopic astigmatism, and mixed astigmatism were studied during a 36-month period. Main outcome measures were uncorrected and best-corrected visual acuity (UCVA, BCVA), refraction, and corneal transparency. Astigmatism correction was analyzed by a power vector method.

Results: In myopic astigmatism group (42 eyes), postoperative UCVA was 20/40 or better in 100% of eyes, 20/25 or better in 38 eyes out of 42 (90.5%), and 20/20 or better in 25/42 eyes (59.5%). No eye lost lines of the BCVA, 40/42 (95.2%) eyes had refraction within $\pm 1D$ and 37/42 (88.1%) within $\pm 0.50 D$. In the hyperopic astigmatism group (28 eyes), the UCVA was 20/40 or better in 100% of eyes, 20/25 or better in 26/28 eyes (92.8%), and 20/20 or better in 24/28 eyes (85.7%); 1/28 eyes (3.6%) lost 1 line of the BCVA, 23/28 eyes (82.1%) were within $\pm 1D$, and 21/28 (75%) were within $\pm 0.50D$. In the mixed astigmatism group (24 eyes), the UCVA was 20/40 or better in 100% of eyes, 20/25 or better in 22/24 eyes (91.7%) and 20/20 in 15/24 (62.5%) eyes. No eye lost lines of BCVA, 23/24 eyes (95.8%) were within 1.0 D, and 20/24 eyes (83.3%) were within 0.50 D of defocus refraction. Power vector analysis showed a significant reduction of blurring strength in all examined groups.

Conclusions: PRK is a safe and effective procedure for correction of all types of astigmatism, with good stability and efficacy at 3-year follow-up.

Key words: **astigmatism • excimer laser • refractive surgery • photorefractive keratectomy • long term outcome**

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Background

The challenge for the laser refractive surgery in treatment of astigmatism is to obtain a satisfactory and stable visual outcome with good safety and efficacy. Several papers reported results about myopic astigmatism correction, but only a small number of studies relating to hyperopic and mixed astigmatism treatment are available [1–9]. Moreover, the majority of existing reports include rather short follow-up and the long-term outcome studies are quite sporadic. Long-term results of refractive procedures are useful for assessing the long-term stability and safety of the treatment and to detect late onset of eventual complications.

In the present study we report a long-term evaluation of safety, efficacy, predictability, and stability of the photo-astigmatic keratectomy (PARK) in myopic, hyperopic, and mixed astigmatism with moderate and high cylinder magnitude. The study followed the tenets of the Declaration of Helsinki and we obtained approval from our Institutional Review Board.

Material and Methods

In this retrospective study, 94 eyes of 52 patients (23 M and 28 F) who had undergone astigmatism correction were evaluated. Only subjects who underwent all postoperative controls at 1, 3, 6, and 12 months and three years and whose data were available for analysis were enrolled. Patient age ranged from 23 to 50 years (mean 34.2 ± 10.3) at time of surgery. The eyes were divided into 3 groups according to astigmatism. Group 1 was composed of 42 eyes with compound myopic astigmatism. Sphere ranged from -1.25 to -6.60 D (mean -3.22 ± 1.76 D), cylinder magnitude ranged from -1.25 to -4.25 D (mean -2.01 ± 0.72 D), and spherical equivalent refraction (SE) ranged from -2.00 to -7.25 D (mean -4.19 ± 1.65 D). Group 2 was composed of 28 eyes with compound hyperopic astigmatism. Sphere ranged from $+0.50$ to $+5.50$ (mean $+2.94 \pm 2.07$ D), cylinder magnitude ranged from $+1.50$ to $+3.50$ D (mean $+2.11 \pm 0.59$ D), and SE refraction ranged from $+1.25$ to $+6.50$ D (mean $+4.0 \pm 2.04$). Group 3 included 24 eyes with mixed astigmatism. Sphere ranged from $+0.50$ to $+3.50$ (mean $+1.43 \pm 0.94$ D), cylinder magnitude ranged from -2.00 to -4.50 D (mean -3.05 ± 0.82 D), and defocus equivalent refraction (DE) ranged from 1.50 to 5.75 D (mean 2.95 ± 1.16 D). Preoperative assessment included visual acuity, both uncorrected (UCVA) and best spectacle corrected (BCVA), corneal topography, tonometry, corneal thickness, refraction, retinoscopy, pupillometry, and tears secretion test. Exclusion criteria were change in refraction within the last year, corneal pathologies, and general diseases such as diabetes or immunological disorders. Photorefractive keratectomy was performed by 1 operator (AR) with a Mel 70 G-Scan excimer laser (Carl Zeiss, Jena, Germany) provided with flying spot with Gaussian

profile with diameter of 1.8 mm. Ablation zone varied from 6.5 mm to 7 mm with extension of 1.8 mm for transition in myopic astigmatism; it was of 6 mm in hyperopic and mixed astigmatism with transition zone extended for 1.8 mm. The sphere-cylindrical algorithm was used to perform ablations. A contact lens was applied after the treatment and all patients received drops of antibiotics, non-steroidal anti-inflammatory drugs, and artificial tears 4 times daily until epithelium healed and contact lens was removed; than the corticosteroid drops started. All subjects were examined before the laser procedure and after 1, 3, 6, 12, and 36 months after the treatment. Main outcome measures were UCVA, BCVA, refraction, refractive cylinder magnitude, and corneal transparency. The astigmatism correction results were analyzed with power vectors method as described by Thibos [10]. In this method, power vectors are a geometrical representation of spherocylindrical refractive errors in 3 fundamental dioptric components: spherical equivalent and Jackson crossed cylinders (M, J_0, J_{45}). Calculated power vector length is a measure of the overall blurring strength (B), expressed in diopters, of refractive error. Graphs were created following JRS instructions using Excel 2007 software (Microsoft Corporation) [11,12]. MedCalc 11.4.1.0 software was used for statistical analysis. Linear regression analysis was used to analyze attempted vs. achieved spherical equivalent refraction and the t test to evaluate change in blur strength (B) vector, which is a measure of overall blurring strength of a spherocylindrical lens or refractive error. A p values less than 0.05 were considered as statistically significant.

Results

Myopic astigmatism

The UCVA before the treatment was 20/100 or better in 4.8% of eyes (2/42), it was less than 20/100 and 20/200 or better in 21.4% of eyes (9/42), and it was less than 20/200 in 73.8% (31/42). Three years after treatment, UCVA achieved 20/40 or better in 100% of eyes (42/42), 20/25 or better in 90.5% of eyes (38/42), and 20/20 in 59.5% of eyes (25/42) (Figure 1A). The BCVA was 20/25 or better in 100% of eyes preoperatively and 20/20 or better in 69% (29/42). No eye lost lines of BCVA, in 71.4% of eyes (30/42) BCVA was unvaried, and 28.6% (12/42) gained 1 line (Figure 1B). Achieved vs. attempted correction showed a high value of coefficient of determination $r^2=0.97$ (Figure 1C). Stability was very good during 3 years period (Figure 1D). Predictability was very satisfying – 95.2% of eyes had refraction within ± 1 D, 88.1% had refraction within ± 0.50 D, and 45.2% were plano of target refraction (Figure 1E). Spherical equivalent changed from -4.19 ± 1.65 D to -0.05 ± 0.31 D and refractive cylinder magnitude decreased 95.5%, from -2.01 ± 0.71 D to -0.09 ± 0.20 D at 3 years. Mean sphere changed from -3.22 ± 1.76 D to -0.02 ± 0.26 D at 3-year control. Hyperopic shift

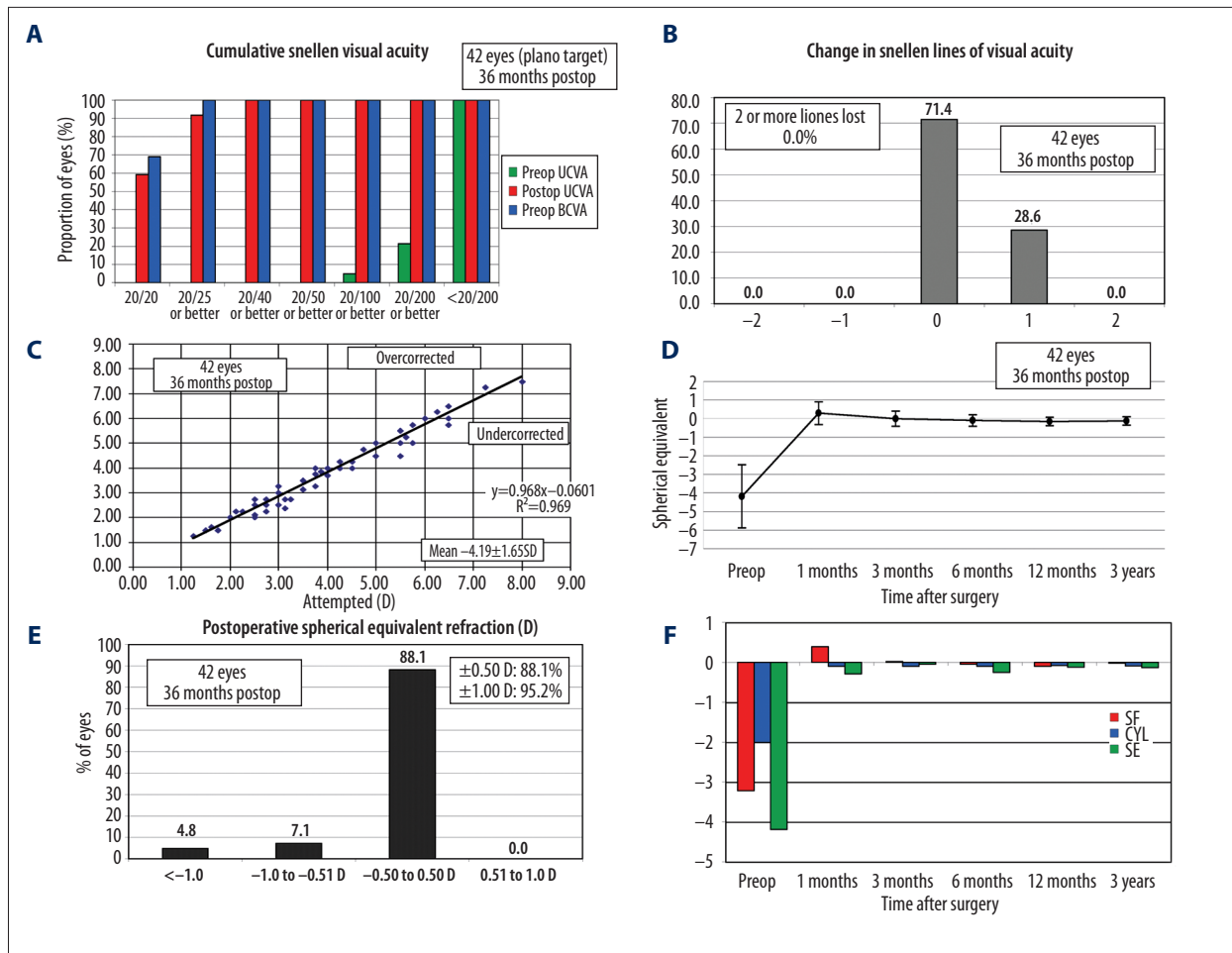


Figure 1. Cumulative plate for myopic astigmatism results. (A) Visual acuity bar graph. (B) Change in corrected distance visual acuity. (C) Spherical equivalent (SE) attempted vs. achieved. (D) Stability of SE refraction. (E) SE refractive accuracy. (F) Sphere, cylinder and SE outcome.

Table 1. Statistical summary of the distribution of manifest refractive errors before and after refractive surgery in myopic astigmatism group.

	M	J_0	J_{45}	B
Before surgery (mean \pm SD)	-4.375 ± 1.547	0.713 ± 0.452	0.192 ± 0.603	4.513 ± 1.493
After surgery (mean \pm SD)	-0.347 ± 0.440	0.075 ± 0.174	0.0196 ± 0.102	0.468 ± 0.377

M – spherical power; J_0 and J_{45} – Jackson crossed cylinders; B – blur strenght.

of sphere was measured at 1 month and it regressed at the third month (Figure 1F). Power vector analysis showed reduction of all components, with significant change of blur strength from 4.513 ± 1.493 to 0.468 ± 0.377 ($p < 0.0001$) (Table 1).

Hyperopic astigmatism

UCVA before the treatment was 20/25 or better in 28.6% of eyes (8/28) and it was 20/40 or better in 53.6% of eyes (15/28),

20/50 or better in 64.3% (18/28), 20/100 or better in 75% (21/28), and 20/200 or better in 92.8% (26/28). It was inferior to 20/200 in 7.2%. Three years after treatment, the UCVA achieved 20/40 or better in 100% of eyes, 20/25 or better in 92.8% of eyes (26/28), and 20/20 in 85.7% of eyes (24/28). The preoperative BCVA was 20/40 or better in 100% of eyes, 20/25 or better in 89.3% (25/28), and 20/20 in 71.4% (20/28) (Figure 2A). There were 3.6% of eyes (1/28) that lost 1 line of BCVA, 64.3% (18/28) were unvaried, 21.4% (6/28) gained 1 line,

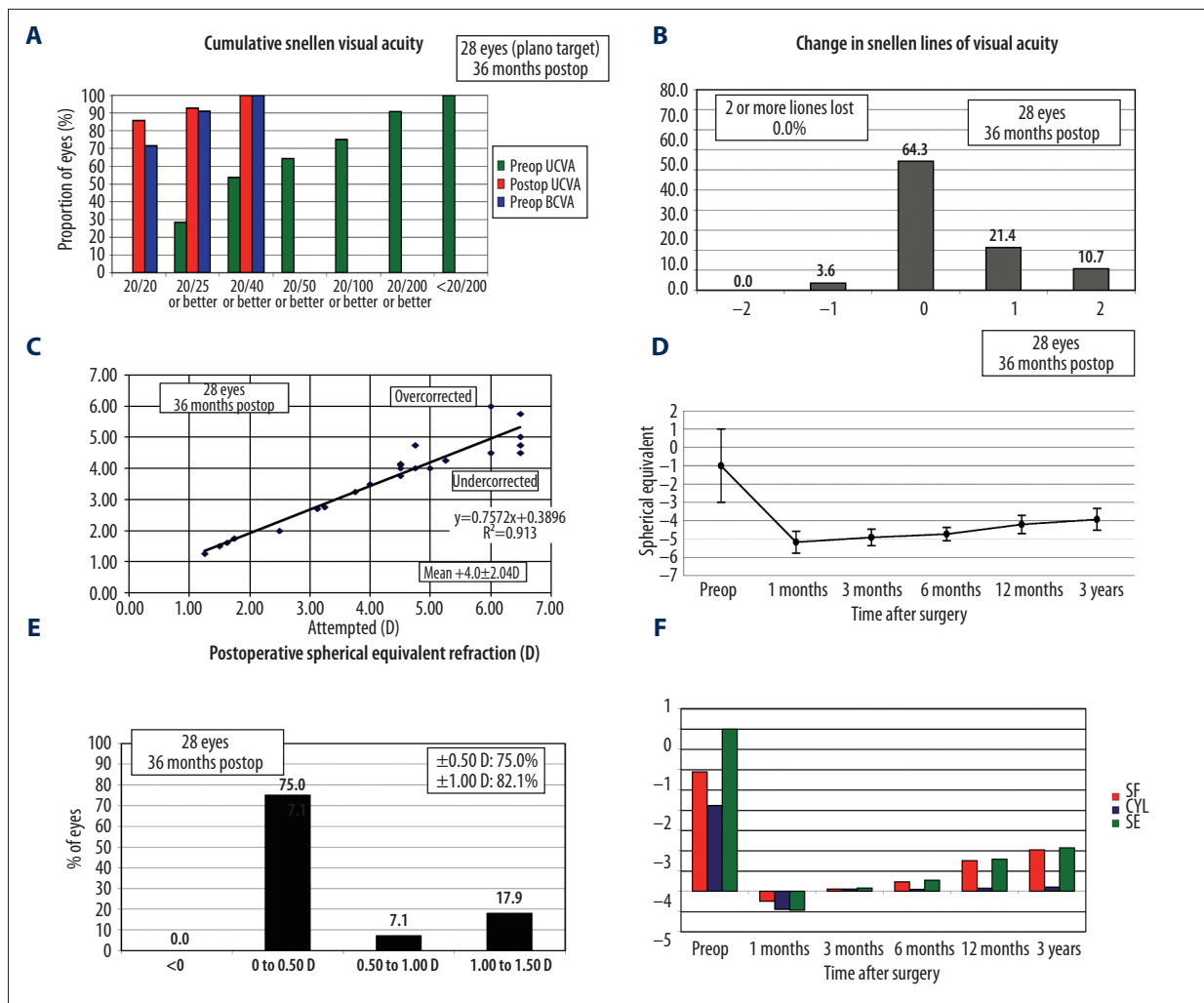


Figure 2. Cumulative plate for hyperopic astigmatism results. (A) Visual acuity bar graph. (B) Change in corrected distance visual acuity. (C) Spherical equivalent (SE) attempted vs. achieved. (D) Stability of SE refraction. (E) SE refractive accuracy. (F) Sphere, cylinder and SE outcome.

Table 2. Statistical summary of the distribution of manifest refractive errors before and after refractive surgery in hyperopic astigmatism group.

	M	J ₀	J ₄₅	B
Before surgery (mean ±SD)	4.068±1.747	0.203±0.863	-0.099±0.563	4.323±1.675
After surgery (mean ±SD)	1.341±0.546	0.023±0.072	-9.1E-05±0.001	1.336±0.543

M – spherical power; J₀ and J₄₅ – Jackson crossed cylinders; B – blur strenght.

and 10.7% (3/28) gained 2 lines of BCVA (Figure 2B). Achieved vs. attempted correction analysis showed high values of coefficient of determination $r^2=0.91$ (Figure 2C). Stability of results was present between the third and sixth month. Successively, a slight hyperopic shift was evidenced (Figure 2D). Predictability was very satisfying, with 82.1% of eyes (23/28) within ±1D and 75% (21/28) within ±0.50D; 32.1% (9/28) of eyes were plano of

target refraction (Figure 2E). Spherical equivalent changed from +4.0±2.04 D to +0.22±0.36 D and refractive cylinder magnitude changed 97.9%, from +2.11±0.59D to +0.045±0.15 D. Myopic shift of sphere was measured at 1 month (Figure 2F). Table 2 shows statistical data of power vector analysis with reduction of all components and significant change of final blur strength, from 4.323±1.675 to 1.336±0.543 ($p<0.0001$).

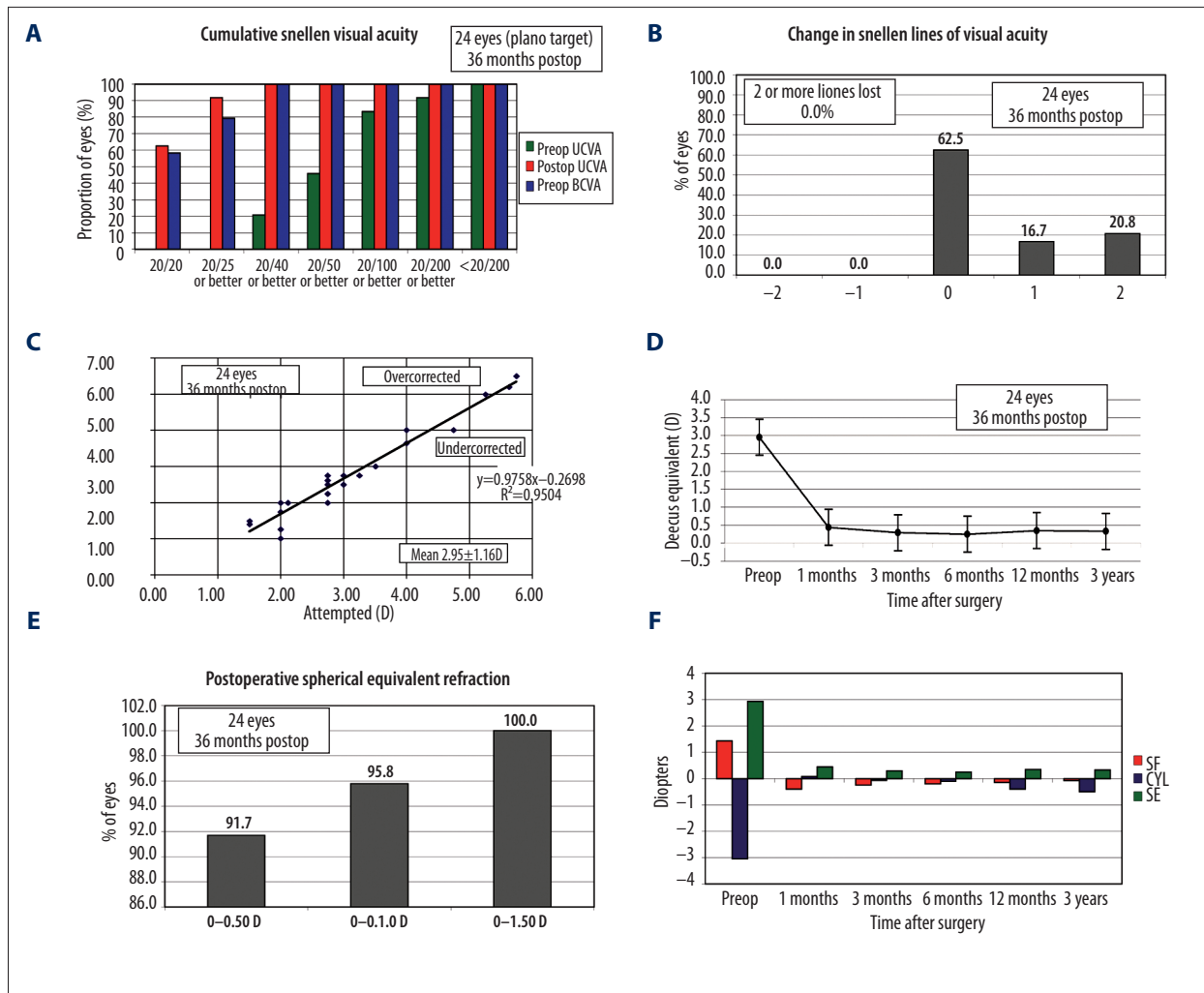


Figure 3. Cumulative plate for mixed astigmatism results. (A) Visual acuity bar graph. (B) Change in corrected distance visual acuity. (C) Defocus equivalent (DE) attempted vs. achieved. (D) Stability of DE refraction. (E) DE refractive accuracy. (F) Sphere, cylinder and DE outcome.

Table 3. Statistical summary of the distribution of manifest refractive errors before and after refractive surgery in mixed astigmatism group.

	M	J ₀	J ₄₅	B
Before surgery (mean ±SD)	-0.11 ± 0.829	1.046 ± 0.844	0.3889 ± 0.705	1.712 ± 0.496
After surgery (mean ±SD)	0 ± 0.3913	0.0484 ± 0.1937	-0.0089 ± 0.0257	0.319 ± 0.303

M – spherical power; J₀ and J₄₅ – Jackson crossed cylinders; B – blur strenght.

Mixed astigmatism

The UCVA before the laser procedure was less than 20/25 in all eyes. It was 20/40 in 20.8% (5/24) of eyes, it was 20/50 or better in 45.8% of eyes (11/24), it was 20/100 or better in 83.3%, and 20/200 or better in 91.7% (22/24). It was less than 20/200 in 8.3% (2/24).

Three years after treatment, the UCVA achieved 20/40 or better in 100% of eyes, it was 20/25 or better in 91.7% of eyes (22/24), and it dropped to 20/20 in 62.5% of eyes (15/24). The preoperative BCVA was 20/40 or better in 100% of eyes, 20/25 or better in 79.2% (19/24), and 20/20 in 58.3% (14/24) (Figure 3A). No eye lost lines of BCVA. In 62.5% of eyes (15/24) it was unvaried and 16.7% (4/24) gained 1 line, and 20.8%

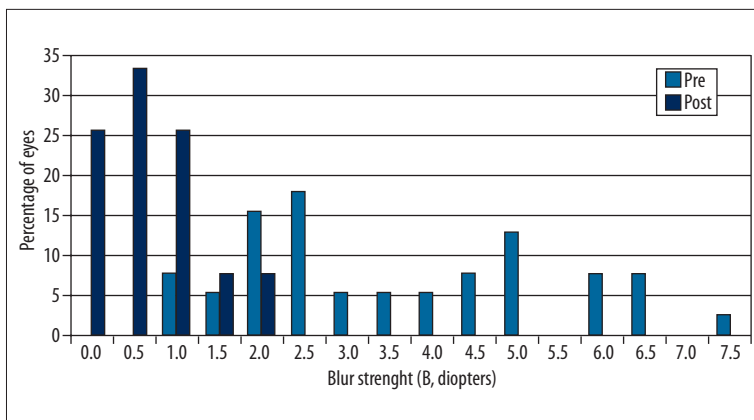


Figure 4. Overall frequency distribution of blur strength of manifest refractive error as a result of refractive surgery.

(5/24) gained 2 lines (Figure 3B). Linear regression analysis for attempted vs.achieved correction showed high values of coefficient of determination $r^2=0.95$ (Figure 3C). Stability of results was present since the third month after the treatment and it was unvaried among the whole follow-up period (Figure 3D). Predictability was satisfying, with 95.8% of eyes between 0 to 1.0 D of defocus refraction and 91.7% had refraction within 0 to 0.50 D; 45.8% were plano of target refraction (Figure 3E). Defocus equivalent changed from 2.95 ± 0.87 D to 0.25 ± 0.23 D and refractive cylinder magnitude changed 98.4%, from -3.05 ± 0.82 D to -0.05 ± 0.37 D (Figure 3F). Power vector analyses results are reported in Table 3. A significant change of final blur strength from 1.712 ± 0.496 to 0.319 ± 0.303 was present ($p<0.0001$). Overall analysis of frequency distribution of blur strength (B) shown in Figure 4 demonstrates the effectiveness of laser treatment. Overall cylinder correction analyzed with the power vector method is reported in Figure 5 and represents reduction of both JCC components after the laser procedure. As to corneal clarity, a transient mild-to-moderate haze was present at 1 month and 3 months control in 23.4% of eyes. Three years after treatment, all eyes exhibited clear corneas.

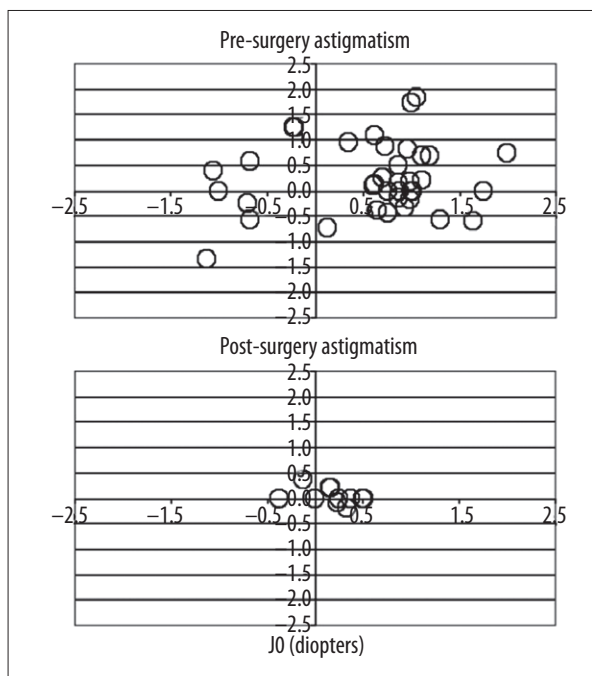


Figure 5. Manifest astigmatism before (A) and after surgery (B). Each data point represents the astigmatism component of a power vector for one eye.

Discussion

Laser refractive surgery for astigmatism has been widely performed for more than 20 years, but until now there have only been a few scientific reports considering the long-term results. Additionally, there are no reports on the correction of different astigmatic errors treated with the same laser platform with follow-up longer than 12 to 18 months [13,14].

This situation can be attributed to the continuous technological improvement of laser platforms, which has produced a great number of short-term reports on new devices and algorithms for refractive correction [1,3,4,7,15,16]. Existing studies, with follow-up ranging from 12 to 18 months, have reported a refractive outcome for myopic astigmatism ranging from 69.8% to 85% of eyes within ± 0.50 D and from 77% to 97% within

± 1 D. The UCVA of 20/40 or better was achieved in 84% to 93% and 20/20 or better in 42.6% to 58% of eyes treated [6,17–19]. In correction of hyperopic astigmatism, 52% to 64.7% of eyes were within ± 0.50 D and 82% to 90.3% within ± 1 D, and visual outcome with UCVA of 20/40 or better was obtained in 84% to 99% and 20/20 in 46% to 61% of eyes [19–21]. Mixed astigmatism results indicate 72.7% of eyes were within ± 0.50 D and 90.9% of eyes were within ± 1.0 D, while 83% of eyes with UCVA of 20/40 or better and 32% with 20/20 were demonstrated [20,21]. In our study, we report 3-year results of PRK for myopic, hyperopic, and mixed astigmatism with moderate to high refractive cylinder magnitude, treated with the sphere-cylindrical algorithm of the MEL 70 G-Scan excimer laser. As compared to existing reports, the results of myopic astigmatism

treatment are similar, but in hyperopic and mixed astigmatism we obtained better results. This outcome is undoubtedly attributable to technological improvement associated with the introduction of the flying spot and wider ablation zones. The results obtained confirm that good predictability and stability of correction can be expected for the 3-year long follow-up period. All types of astigmatism were corrected with good safety and efficacy. Treatment was effective and stable in both myopic and mixed astigmatism. In the hyperopic astigmatism group, a slight regression of sphere was observed between 6 and 36 months, with stability of the cylinder magnitude. This finding confirms the difficulties in treating hyperopic refractive error, due to both the corneal regression and the residual latent hyperopia that becomes manifest over time. The correction of refractive cylinder was stable starting from the first month after treatment in all groups. Power vector analysis showed postoperative changes of all components of the analyzed refractive errors, with significant reduction of the principal parameter such as blur strength (B). The overall distribution of blurring strength before and after the laser procedure indicates significant decrease in blurring after the treatment. The overall representation of the JCC components before and after the PRK permits immediate evaluation of astigmatic changes obtained after the treatment.

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Conclusions

We conclude that PARK procedure with the MEL 70 excimer laser achieved satisfactory correction of all types of astigmatism with moderate and high cylinder magnitude, satisfying refractive and visual results with good safety, efficacy and stability, after 3 years of follow-up. We believe that reporting long-term results of PRK for astigmatism may help to better understand the stability, efficacy, and predictability of this surgical procedure and can further improve the laser characteristics and surgical approach, thereby improving the achievable clinical outcome.

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