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# Predicted and Measured Changes in Posterior Corneal Astigmatism after Uncomplicated Femtosecond Assisted LASIK (FsLASIK) and Microkeratome LASIK Correction for Myopia and Low Astigmatism

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## ABSTRACT

**Purpose:** To compare predicted and measured changes in astigmatism at the posterior corneal surface (PCS) after FsLASIK or LASIK.

**Methods:** Astigmatism was measured at both corneal surfaces (Pentacam™) before and 3 months after unremarkable FFsLASIK (roup 1, n = 100) or LLASIK (roup 2, n = 100) for myopia (−7.25DS to −0.75DS) and low astigmatism ( $\leq 1.00$ DC). Photoablation was achieved using Schwind Amaris750S™ laser (Aberration Free profile, centered on corneal vertex). Pre- and postop astigmatic data, according to subjective refraction and estimates for the corneal surfaces (over the central 3.2 mm zone), were subjected to vector analysis to calculate surgically induced astigmatism (SIA) by refraction ( $SIA_R$ ), at the anterior ( $SIA_{Fact}$ ) and posterior corneal surfaces ( $SIA_{Bact}$ ). The difference vector between  $SIA_R$  and  $SIA_{Fact}$  was regarded as the predicted SIA at the PCS ( $SIA_{Best}$ ).

**Results:** Reporting key findings. Mean ( $\pm$ sd, 95%CI)  $SIA_{Best}$  and  $SIA_{Bact}$  powers in group 1 were  $-0.52$ DC ( $\pm 0.35$ ,  $-0.56$  to  $-0.45$ ) and  $-0.11$ DC ( $\pm 0.08$ ,  $-0.13$  to  $-0.10$ ) in group 1,  $-0.35$ DC ( $0.20$ ,  $-0.39$  to  $-0.32$ ) and  $-0.08$ DC ( $0.07$ ,  $-0.09$  to  $-0.06$ ) in group 2. Differences between  $SIA_{Best}$  and  $SIA_{Bact}$  were significant for powers but not axes. Significant correlations ( $p < .01$ ) were revealed between (I)  $SIA_R$  and  $SIA_{Fact}$  powers [Group 1,  $SIA_R = 0.370$ ,  $SIA_{Fact} = 0.292$ ,  $r = 0.299$ . Group 2,  $SIA_R = 0.484$ ,  $SIA_{Fact} = 0.394$ ,  $r = 0.519$ ] but not the axes and (II)  $\Delta C$  (difference between pre- $\times 1$ ) and postop measured PCS astigmatic powers) and  $\times 1$  [Group 1,  $\Delta C = 0.384 \times 1 + 0.119$ ,  $r = 0.423$ . Group 2,  $\Delta C = 0.135 \times 1 + 0.047$ ,  $r = 0.229$ ,  $p = .022$ ]. There was no correlation between  $SIA_{Best}$  and  $SIA_{Bact}$  powers or axes.

**Conclusion:** The changes in posterior corneal astigmatic powers according to Pentacam measurements are small and do not account for the deficit between  $SIA_R$  and  $SIA_{Fact}$  after FsLASIK or LASIK.

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LASIK; FsLASIK; astigmatism; vector analysis

## INTRODUCTION

Occasionally, an unexpected change in astigmatism occurs after refractive surgery. Some of the pioneers of LASIK encountered changes in refraction that did not completely match the changes in anterior corneal surface powers.<sup>1–4</sup> Could changes at the posterior corneal surface affect the difference between changes in refraction and anterior corneal surface powers? Some advocate the astigmatism at the posterior surface of the cornea should be considered when selecting toric IOL power.<sup>5–7</sup> Therefore, changes at this surface have the potential to influence the manifest astigmatism after corneal refractive surgery.

Changes at the posterior corneal surface do occur after LASIK, but these are small and of questionable importance.<sup>8–14</sup> A preliminary investigation revealed inconsistencies between measured and estimated changes at the posterior corneal surface after LASIK when the flap was created with either a femtosecond laser (FsLASIK) or manual microkeratome. This anecdotal evidence suggests the changes observed at the anterior and posterior corneal surfaces within the central region of the cornea do not completely match the corresponding surgically induced change in astigmatism observed by

refraction ( $SIA_R$ ). These discrepancies could be attributed to torsion at one corneal surface relative to the other alongside changes in other optical components of the cornea. On the other hand, the combined errors in measuring corneal surface powers and refraction could be the true source of such discrepancies. If any surgically induced changes of astigmatism at the posterior surface ( $SIA_{Bact}$ ) significantly contribute to any unexpected  $SIA_R$  then, estimated changes at this surface ( $SIA_{Best}$ ) should be supported by empirical evidence. The magnitude of  $SIA_{Bact}$  and  $SIA_{Best}$  should exceed, or at least be comparable with, the repeatability of the clinical measurement of corneal astigmatism. Values of, and differences between,  $SIA_{Bact}$  and  $SIA_{Best}$  less than the repeatability would be clinically irrelevant.

The aim of this study was to; firstly, compare the surgically induced change in astigmatism at the anterior corneal surface ( $SIA_{Fact}$ ) with  $SIA_R$ ; secondly, to calculate the  $SIA_{Best}$  that would account for any shortfall between  $SIA_{Fact}$  and  $SIA_R$  and finally, compare the  $SIA_{Best}$  with the actual surgically induced changes in posterior corneal surface astigmatism ( $SIA_{Bact}$ ) according to actual measurements of posterior corneal surface astigmatism.

## METHODS

### Study Design

This was a prospective, partially masked, semi-randomized, interventional, clinical study, performed at the Refractive Surgery Department of the Speciality Eye Hospital Svjetlost in Zagreb. The study was approved by the Ethics committee at the Speciality Eye Hospital Svjetlost. The tenets of the Helsinki agreement were respected throughout. Informed consent was obtained from all patients after details of the procedures, the risks and benefits were fully explained both verbally and in writing.

### Patient Selection

All patients underwent thorough preoperative ophthalmologic examinations prior to inclusion. Patients with stable refraction, myopia from  $-7.25\text{DS}$  to  $-0.75\text{DS}$  and astigmatism  $\leq 1.00\text{DC}$ , meeting the criteria normally adopted in refractive surgery were enrolled.<sup>15</sup> Patients with history of ocular surgery, abnormal corneal topography/tomography, preoperative corneal thickness  $< 500\ \mu\text{m}$ , calculated residual stromal bed thickness  $< 300\ \mu\text{m}$  or calculated percent tissue altered  $\geq 40\%$  were excluded from the study.

### Preoperative and Postoperative Assessment

Examination included uncorrected (UDVA) and corrected (CDVA) distance visual acuity, autorefractometry, manifest and cycloplegic refraction, full biomicroscopic examination, tonometry, dilated pupil fundus examination, aberrometry and corneal tomography. Where applicable, patients were asked to discontinue contact lens wear for up to 4 weeks, depending on the type of contact lenses, prior to the examination. All patients were examined 1 day, 1 week, 1 month and 3 months after the surgery. All postoperative visits included UDVA, CDVA, refraction, tonometry, and biomicroscopy. Additionally, corneal tomography, aberrometry and dilated fundus assessments were undertaken at the 3 months follow-up visit.

### Corneal Tomography

A single, factory calibrated, Pentacam HR<sup>TM</sup> (Oculus Optikgeräte GmbH, Wetzlar, Germany) instrument was used for the assessment of anterior and posterior corneal surface astigmatism. The Pentacam software averages the corneal surface powers over the central 3.2 mm of the cornea and generates pairs of SimK values (for power and axis). These SimK values were used to calculate any changes in astigmatism at the anterior and posterior corneal surfaces. The intra-observer variability of Pentacam for estimating anterior and posterior corneal astigmatic powers was assessed by asking an observer (1) to take 10 sequential measurements (each measurement separated by a single blink) from both eyes of 3 subjects (preop, post-FsLASIK and post-LASIK). After a short interval, a second observer (2) repeated the procedure on the same 3 subjects. The astigmatic values acquired by the two observers were evaluated using the

method of Bland and Altman<sup>16</sup> to determine the inter-observer variability of Pentacam.

### FsLASIK and LASIK Procedures

Both eyes were anesthetized with 2 drops of topical anesthetic (Novesin<sup>TM</sup>, OmniVision GmbH, Puchheim, Germany) instilled at two-minute intervals just before surgery. After standard cleaning with 2.5% povidone iodine and sterile draping, an eye lid speculum was used to keep the eye open. For FsLASIK, the patient was placed under a femtosecond laser (Intralase 150 Hz, Abbott Medical Optics, Santa Ana, California) and instructed to look at the central fixation target. The suction ring was placed on the eye, the vacuum was applied after proper alignment, the cone was inserted into the vacuum ring when an adequate vacuum level was confirmed. The pedal was pressed, and the femtosecond flap was created immediately after the final adjustments and alignment with the centre of the pupil. Flaps were preset at a nominal thickness of 100  $\mu\text{m}$  and diameter of 9.00 mm with a superior hinge. For LASIK, the patient was placed under excimer laser (Schwind Eye-Tech-Solutions, Kleinostheim, Germany) and instructed to look at the green fixation light. Two marks at 3 and 9 o'clock positions were placed on the cornea with a marker and the eye was rinsed with BSS. The suction ring was placed on the eye and the vacuum was applied. After confirmation of adequate vacuum level microkeratome (Moria M2, Anthony, France) was placed on the eye and the flap was cut. Size of the vacuum ring was chosen according to steeper K reading and the 90  $\mu\text{m}$  knife was used in order to create 100  $\mu\text{m}$  thick flap (range 86–164  $\mu\text{m}$ ) with superior hinge.

The flap was separated from the underlying stroma with a blunt spatula, lifted and folded back towards the superior fornix. After the flap was lifted, static cyclotorsion was assessed, and the excimer laser ablation was applied to the stroma. Static and dynamic cyclotorsion was compensated by the laser tracking system during ablation. Schwind Amaris 750S<sup>TM</sup> (Schwind Eye-Tech-Solutions, Kleinostheim, Germany) with the Aberration Free<sup>TM</sup> program was selected for all treatments. All ablations were centered on corneal vertex. Optical zones ranged from 7.0 to 7.2 mm while transition zone was automatically calculated by the laser software. For each case, the optical zone was chosen depending on scotopic pupil size and the depth of excimer laser ablation, the programmed treatment consisted of cycloplegic spherical correction with manifest astigmatic power and axis without any nomogram adjustment. Patients were instructed to concentrate on the fixation light throughout the ablation. When the ablation was completed, the flap was repositioned after the interface was irrigated with balanced salt solution to remove any debris.

### Postoperative Management

Postoperative therapy included a combination of topical antibiotic and steroid drops (Tobradex<sup>TM</sup>, Alcon, Forth Worth, Texas) 4 times daily for 2 weeks and preservative free artificial tears (Bepanthol<sup>TM</sup>, Bayer AG, Leverkusen, Germany) 6–8 times daily for at least 1 month.

## Data Collection and Analysis

Two hundred patients were enrolled in this study. One hundred underwent FsLASIK (group 1) and the remainder underwent LASIK (group 2). Data from one eye, right eyes in binocular treatments, were transported for analysis. All transported data were stored on an Excel spreadsheet (Microsoft, Redmond, WA).

To calculate surgically induced changes in astigmatism, all astigmatic results according to refraction and the SimK data were subjected to vector analysis using Alpins' method.<sup>17</sup> The difference between the axis of any astigmatism at the start of the study and the axis of the SIA was also calculated for each case. This would indicate any preferential direction (eg, clockwise or anti-clockwise rotation) in any pattern of change, or if the magnitude of the direction was skewed relative to the axis of any astigmatism before surgical correction.

For each case, the data were analyzed to determine the:

- (i) Surgically induced change in astigmatism according to refraction ( $SIA_R$ ), at the anterior ( $SIA_{Fact}$ ) and posterior ( $SIA_{Bact}$ ) corneal surfaces.
- (ii) Vectorial difference (DV) between  $SIA_R$  and  $SIA_{Fact}$  ( $\Delta 1$ ). If the sole determinate of  $SIA_R$  was  $SIA_{Fact}$  then the  $SIA_R$  should equal  $SIA_{Fact}$ . DV is the shortfall between  $SIA_R$  &  $SIA_{Fact}$  and is an estimate of  $SIA_{Best}$ .  $SIA_{Best}$  should equal  $SIA_{Bact}$  if the posterior corneal surface is the source of the discrepancy between  $SIA_R$  &  $SIA_{Fact}$ . If there is a substantial difference between  $SIA_{Best}$  and  $SIA_{Bact}$  then the vectorial difference between  $SIA_{Best}$  and  $SIA_{Bact}$  ( $\Delta 2$ ) would indicate the combined effect of other factors influencing astigmatism after FsLASIK.
- (iii) Vectorial difference (DV) between  $SIA_{Best}$  and  $SIA_{Bact}$ .

The repeatability of subjective refraction in the assessment of astigmatism is just below 0.50DC and this amount has a negligible effect on acuity.<sup>18,19</sup> Thus, a change in astigmatism from  $-0.50DC \times 160$  to  $-0.25DC \times 50$  could be regarded as insignificant. However, the vectorial difference between these two cases (i.e. the actual change from one time to the next) is  $-0.71DC \times 153$ . It would be reasonable to assume that changes in refractive astigmatism according to vector analysis of  $<0.50DC$  should be considered as clinically unimportant and those  $\geq 0.50DC$  should be considered as significant. It was decided, after initial analysis of the data, to extract subgroups in the FsLASIK and LASIK treated cases where the change in astigmatism by vector analysis was  $\geq 0.50DC$ .

The data were analyzed to determine the significance of any

- (a) difference between mean  $SIA_R$  and  $SIA_{Fact}$  powers and axes (paired t-test) and

correlation between  $SIA_R$  and  $SIA_{Fact}$  powers and axes (Pearson correlation r);

- (a) change in measured astigmatism at the posterior corneal surface (paired t-test), and

the correlation between the measured astigmatism at the posterior corneal surface before and after surgery (Pearson correlation r);

- (a) difference between mean  $SIA_{Best}$  and  $SIA_{Bact}$  powers and axes (paired t-test), and

correlation between  $SIA_{Best}$  and  $SIA_{Bact}$  powers and axes (Pearson correlation r);

- (a) correlation between the preop measured astigmatic powers at the posterior corneal surface and  $SIA_{Bact}$  (Pearson correlation r).

Appropriate non-parametric tests were planned for application when data were not normally distributed. The significance level was set at  $p < .05$ .

## RESULTS

The FsLASIK patients (group 1) consisted of 46 females and 54 males of mean age ( $\pm$ s.d, range) 31.8 ( $\pm 7.1, 20-46$ ) years. The LASIK patients (group 2) consisted of 59 females, 41 males of mean age ( $\pm$ s.d, range) 30.8 ( $\pm 6.1, 21-45$ ) years. The mean ( $\pm$ sd, range) preop spherical refractive errors were  $-3.12DS$  ( $\pm 1.44DS, -6.00DS$  to  $-1.75DS$ ) in group 1 and  $-2.87DS$  ( $\pm 1.47DS, -7.25DS$  to  $-0.50DS$ ) in group 2. At 3 months postop the mean ( $\pm$ s.d, 95%CI) spherical refractive errors were  $-0.18DS$  ( $\pm 0.51DS, -0.28DS$  to  $-0.08DS$ ) in group 1 and  $-0.15DS$  ( $\pm 0.37DS, -0.22DS$  to  $-0.08DS$ ) in group 2. The astigmatic errors are shown in Tables 1 and 2. In group 1 the  $SIA_R$  was zero in 21 cases and  $\geq 0.50DC$  in 56. In group 2 the  $SIA_R$  was zero in one case and  $\geq 0.50DC$  in 87. The main results are shown in Table 1-3, Figure 1-2.

### Intra- and Inter-Observer Variability for the Estimation of Anterior and Posterior Corneal Astigmatic Power

These data are presented in Table 1. The intra-observer repeatability for the estimation of anterior and posterior corneal astigmatic power ranged from  $\pm 0.06DC$  to  $\pm 0.14DC$  and zero to  $\pm 0.05DC$ . For the anterior corneal astigmatic power, the mean ( $\pm$ sd, 95% confidence limits) of the inter-observer error between pairs of measurements was  $0.10DC$  ( $\pm 0.09DC, 0.03DC$  to  $0.16DC$ ) and limits of agreement ( $\pm 1.96sd$ ) between the two operators was  $\pm 0.17DC$ . The corresponding values for the posterior corneal astigmatic power were  $0.01DC$  ( $\pm 0.03DC, 0.01DC$  to  $0.04DC$ ) and the limits of agreement was  $\pm 0.06DC$ . There were no significant correlations between the difference of values obtained by the two operators and the mean of each pair of values (anterior  $p = .792$ , posterior  $p = .723$ ).

### Difference between Mean $SIA_R$ and $SIA_{Fact}$

There was no significant difference between mean  $SIA_R$  and  $SIA_{Fact}$  powers (group 1  $p = .229$ , group 2  $p = .405$ ) or axes (group 1  $p = .115$ , group 2  $p = .135$ ). For the cases where  $SIA_R \geq 0.50DC$ , in group 1 there was no significant difference between mean  $SIA_R$  and  $SIA_{Fact}$  powers or axes ( $p = .055$  for powers,  $p = .148$  for axes,  $n = 56$ ), in group 2, there was a significant difference between  $SIA_R$  and  $SIA_{Fact}$  powers ( $p = .029$   $n = 87$ ) but not axes ( $p = .071$ ).

**Table 1.** Intra- and inter-observer variability for the estimation of anterior and posterior corneal astigmatic powers.

Subject	Observer 1		Observer 2	
	Anterior	Posterior	Anterior	Posterior
I,RE	-2.20(±0.11)	-0.40	-2.26(±0.10)	-0.39(±0.03)
I,LE	-2.19(±0.07)	-0.40	-2.21(±0.09)	-0.42(±0.04)
II,RE	-1.36(±0.14)	-0.87(±0.05)	-1.60(±0.14)	-0.87(±0.04)
II,LE	-1.35(±0.09)	-0.85(±0.05)	-1.40(±0.11)	-0.84(±0.05)
III,RE	-0.83(±0.07)	-0.20	-0.89(±0.06)	-0.20
III,LE	-1.20(±0.08)	-0.37(±0.05)	-1.24(±0.11)	-0.30

The mean (±sd) values of 10 sequential measurements obtained from both eyes of 3 subjects (I = preop, II = post-FsLASIK, III = post-LASIK) by observers 1 and 2. The sd values = zero are not included.

**Table 2.** Pre- and post op astigmatic powers and the surgically induced astigmatism (SIA) for all cases.

	Pre-op	Postop	SIA
Group 1 (FsLASIK, n = 100)			
R	-0.37DC (0.37,-0.44 to -0.30)	-0.19DC (0.36,-0.26to -0.12)	-0.48DC (0.41,-0.56 to -0.40)
Ant	-0.77(0.43,-0.86 to -0.70)	-0.62(0.30,-0.68 to -0.56)	-0.49(0.34,-0.55 to -0.42)
Post	-0.28(0.12,-0.30 to -0.25)	-0.29(0.12,-0.31 to -0.27)	-0.11(0.08,-0.13 to -0.10)
$\Delta 1 = -0.52$ (0.35,-0.56 to -0.45)			
$\Delta 2 = -0.53$ (0.35,-0.60 to -0.47)			
Group 2 (LASIK, n = 100)			
R	-0.73DC (0.22,-0.77 to -0.68)	-0.24DC (0.34,-0.30to -0.17)	-0.73DC (0.30,-0.79 to -0.68)
Ant	-1.12(0.40,-1.20 to -1.05)	-0.67(0.37,-0.74 to -0.59)	-0.71(0.32,-0.77 to -0.65)
Post	-0.33(0.12,-0.36 to -0.31)	-0.34(0.12,-0.36 to -0.31)	-0.08(0.07,-0.09 to -0.06)
$\Delta 1 = -0.35$ (0.20,-0.39 to -0.32)			
$\Delta 2 = -0.35$ (0.20,-0.39 to -0.32)			

The mean (±sd, 95% CI) values revealed by refraction (R), by Pentacam at the anterior (Ant) and posterior (Post) surfaces are shown.  $\Delta 1$  = Vectorial difference, for power, between SIA according to results of refraction ( $SIA_R$ ) and SIA according to Pentacam for the anterior corneal surface ( $SIA_{Fact}$  in the main text). This is the estimated SIA at the posterior corneal surface ( $SIA_{Best}$  in the main text).  $\Delta 2$  = Vectorial difference, for powers, between  $SIA_{Best}$  and SIA according to Pentacam for the posterior corneal surface ( $SIA_{Bact}$  in the main text).

### Correlation between $SIA_R$ and $SIA_{Fact}$

In group 1, linear regression revealed a significant association between  $SIA_R$  (y) and  $SIA_{Fact}$  (x) for powers ( $p < .01$ ) but not axes ( $p = .057$ ). The form of the significant association was

$$y = 0.370x - 0.292 \quad (r = 0.299, n = 100) \quad 1$$

There was no significant association between  $SIA_R$  and  $SIA_{Fact}$  powers and axes in the cases where  $SIA_R \geq 0.50DC$ .

In group 2, linear regression revealed significant associations ( $p < .01$ ) between  $SIA_R$  (y = power,  $y_1$  = axis) and  $SIA_{Fact}$

(x = power,  $x_1$  = axis) in all cases and those where  $SIA_R \geq 0.50DC$  (n = 87). The form of these associations were

$$y = 0.484x - 0.394 \quad (r = 0.519, n = 100) \quad 2.$$

$$y = 0.444x - 0.476 \quad (r = 0.559, n = 87) \quad 3.$$

$$y_1 = 0.641x_1 + 47.47 \quad (r = 0.636, n = 100) \quad 4.$$

$$y_1 = 0.624x_1 + 45.92 \quad (r = 0.609, n = 87) \quad 5.$$

**Table 3.** Pre- and post op astigmatic powers and the surgically induced astigmatism (SIA) where the change in astigmatism according to vector analysis of refraction was  $\geq 0.50DC$ .

	Pre-op	postop	SIA
Group 1 (FsLASIK, n = 56)			
R	-0.60DC (0.31,-0.68 to -0.52)	-0.27 DC (0.44,-0.39to -0.16)	-0.74 DC (0.36,-0.84 to -0.65)
Ant	-0.88 DC (0.47,-1.00 to -0.76)	-0.69 DC (0.33,-0.78 to -0.61)	-0.52 DC (0.36,-0.62 to -0.43)
Post	-0.28 DC (0.12,-0.31 to -0.25)	-0.30 DC (0.09,-0.33 to -0.27)	-0.11 DC (0.09,-0.13 to -0.09)
$\Delta 1 = -0.61$ (0.40,-0.72 to -0.51)			
$\Delta 2 = -0.63$ (0.37,-0.73 to -0.53)			
Group 2 (LASIK, n = 87)			
R	-0.74DC (0.22,-0.79 to -0.70)	-0.17DC (0.34,-0.25to -0.11)	-0.74 DC (0.21,-0.79 to -0.70)
Ant	-1.11DC(0.40,-1.2 to -1.03)	-0.62DC (0.36,-0.71 to -0.55)	-0.72DC (0.31,-0.78 to -0.65)
Post	-0.33DC (0.12,-0.35 to -0.30)	-0.33DC (0.13,-0.36 to -0.30)	-0.08DC (0.07,-0.09 to -0.06)
$\Delta 1 = -0.34$ (0.18,-0.38 to -0.31)			
$\Delta 2 = -0.34$ (0.18,-0.38 to -0.31)			

The mean (±sd, 95% CI) values revealed by refraction (R), by Pentacam at the anterior (Ant) and posterior (Post) surfaces are shown.  $\Delta 1$  = Vectorial difference, for power, between SIA according to results of refraction ( $SIA_R$ ) and SIA according to Pentacam for the anterior corneal surface ( $SIA_{Fact}$  in the main text). This is the estimated SIA at the posterior corneal surface ( $SIA_{Best}$  in the main text).  $\Delta 2$  = Vectorial difference, for powers, between  $SIA_{Best}$  and SIA according to Pentacam for the posterior corneal surface ( $SIA_{Bact}$  in the main text).



**Difference between SIA<sub>R</sub> and SIA<sub>Fact</sub> Axes**

Excluding the cases where SIA<sub>R</sub> was zero, in group 1 the mean (±sd,95% CI) difference between the SIA<sub>R</sub> and SIA<sub>Fact</sub> axes (Δα) was 10.6°(±39.8,1.8 to 19.4) and for the cases where SIA<sub>R</sub>≥0.50DC the mean Δα was 7.1°(±33.1,-1.5 to 15.8). Linear regression revealed a significant association between Δα and SIA<sub>R</sub> axis (x<sub>1</sub>) and the form of this association was

$$\Delta\alpha = 26.47 - 0.176x_1 (r = 0.269, p = 0.016, n = 79) \quad 6.$$

There was no significant association in those cases where SIA<sub>R</sub> ≥0.50DC (p = .123).

In group 2 the mean (±sd,95% CI) difference between the SIA<sub>R</sub> and SIA<sub>Fact</sub> axes (Δα) was 2.0°(±14.7,-0.9 to .4.9) and for the cases where SIA<sub>R</sub>≥0.50DC the mean Δα was 1.7°(±13.5,-1.2 to 4.6). There was no significant association between Δα and SIA<sub>R</sub> axis (p > .05 for all cases and those where SIA<sub>R</sub>≥0.50DC).

**Difference between Mean Pre- and Postop Measured Astigmatism at the Posterior Corneal Surface (PCS)**

There was no significant difference between the mean pre- and postop measured astigmatism at PCS for either powers or axes in either groups 1 or 2. This lack of significance was also encountered in the cases where SIA<sub>R</sub>≥0.50DC. The mean (±sd,95%CI) difference between the pre- and postop axes of astigmatism angles was 1.2°(±9.7,-0.7 to 3.1) in group 1 and 1.1°(±7.5,-0.4 to 2.5) in group 2.

**Correlation between Pre- and Postop Measured Astigmatism at PCS**

Linear regression revealed significant associations (p < .01, n = 100) between i) pre- and postop measured astigmatic powers (group 1 r = 0.600, group 2 r = 0.834), ii) preop measured astigmatic power (x) and the difference (ΔC) between pre- and postop measured astigmatic powers. The association ΔC and x was of the form

$$\text{Group 1, } \Delta C = 0.384x + 0.119 (r = 0.423, p < 0.01) \quad 7.$$

$$\text{Group 2, } \Delta C = 0.135x + 0.047 (r = 0.229, p = 0.022) \quad 8.$$

A significant association (p < .01, n = 100) was revealed between the pre-and postop axes of astigmatism (group 1 r = 0.589, group 2 r = 0.552). Significant associations were also found in those cases where SIA<sub>R</sub> ≥0.50DC.

**Difference between Mean SIA<sub>Best</sub> and SIA<sub>Bact</sub> Powers and Axes**

There was a significant difference between mean SIA<sub>Best</sub> and SIA<sub>Bact</sub> for powers in groups 1 (t = 11.00, p < .01) and 2 (t = 13.76, p < .01) but not axes (p > .05). Similar results were encountered where SIA<sub>R</sub>≥0.50DC. There was no significant association between SIA<sub>Best</sub> and SIA<sub>Bact</sub> powers or axes for all cases and those where SIA<sub>R</sub>≥0.50DC. The mean (±sd,95% CI) difference between the SIA<sub>Best</sub> and SIA<sub>Bact</sub> axes (Δθ) was -1.5°

(±53.1,-11.9 to 8.9) in group 1 and 3.5°(±48.5,-6.0 to 13.0) in group 2 .

There was no significant association between Δθ and SIA<sub>Best</sub> axis in group 1 (p = .223) or 2 (p = .308).

**Correlation between the Preop Measured Astigmatism at PCS and SIA<sub>Bact</sub>**

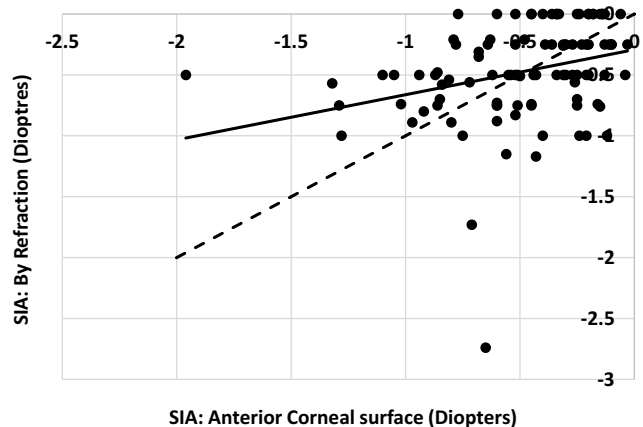
In both groups there was no significant association between posterior corneal surface astigmatism and SIA<sub>Bact</sub> for both powers and axes in either all or just the cases where SIA<sub>R</sub> ≥0.50DC.

**DISCUSSION**

The mean posterior corneal astigmatic power values at preop were respectively -0.28DC and -0.33DC in the FsLASIK and LASIK groups. These values support previous reports based on measurements obtained using Pentacam.<sup>7,20-25</sup> The mean values of SIA<sub>Bact</sub> were low and in keeping with previous findings.<sup>8-11</sup>

Glancing over Table 1-3, the differences between pairs of SIA<sub>R</sub> and SIA<sub>Fact</sub> powers were, in most instances, less than the repeatability for estimating anterior and posterior corneal astigmatism. If the root source of SIA<sub>R</sub> was just SIA<sub>Fact</sub> then the vectorial difference between SIA<sub>R</sub> and SIA<sub>Fact</sub> (Δ1) should be zero. This was not the case. The mean value of Δ1 was -0.35DC in LASIK, -0.52DC in FsLASIK group falling to -0.61DC when SIA<sub>R</sub> was ≥0.50DC. These values are meaningful in FsLASIK as they surpass the error in refraction.<sup>18,19</sup>

Turning to Figure 1, the correlation between SIA<sub>R</sub> and SIA<sub>Fact</sub> is significant, but there is a lack of cohesion between pairs of SIA<sub>R</sub> and SIA<sub>Fact</sub> powers. Turning to eqs.1-3, the gradients of the best fit lines linking SIA<sub>R</sub> and SIA<sub>Fact</sub> are just below 0.50 indicating that SIA<sub>Fact</sub> of 1DC is predicted to contribute to the SIA<sub>R</sub> by less than 0.50DC. In both groups the respective values of SIA<sub>Bact</sub> are small and on par with the reliability in the estimation of posterior corneal astigmatism.



**Figure 1.** Comparison between surgically induced astigmatism (SIA) at the anterior corneal surface (SIA<sub>Fact</sub>) and corresponding surgically induced astigmatism according to results by refraction (SIA<sub>R</sub>). The best fit (solid line) is represented by y = 0.370x - 0.292 (r = 0.299, p < .01, n = 100). The broken line represents the ideal scenario where SIA<sub>R</sub> = SIA<sub>Fact</sub>.

Therefore, other factors are responsible for the shortfall between  $SIA_R$  and  $SIA_{Fact}$  in both groups.

Eqs 4&5 describe the association between  $SIA_R$  and  $SIA_{Fact}$  axes in LASIK. This was an expected result, but a similar association was not found in FsLASIK. Furthermore, a significant association between  $SIA_R$  and  $SIA_{Fact}$  powers was not detected in FsLASIK when linear regression was restricted to those cases where  $SIA_R$  was  $\geq 0.50DC$ . Turning to Figure 2 and eq.6 for the FsLASIK cases, the difference between  $SIA_R$  and  $SIA_{Fact}$  axes ( $\Delta\alpha$ ) was relatively low when the  $SIA_R$  angle was near  $90^\circ$ , that is when the change in astigmatism was predominately ‘against-the-rule’. A similar result was not found in the LASIK group. The shortfall between  $SIA_R$  and  $SIA_{Fact}$  powers, and axes, in FsLASIK are mediated by factors other than those affecting any shortfall in LASIK.

The high levels of precision and sophistication of modern laser delivery systems are ruled out as potential factors contributing to any divergence between  $SIA_R$  and  $SIA_{Fact}$  powers and axes. Changes occurring during the postop healing phase, such as unexpected alterations in epithelial thickness distribution, adjustments in astigmatism at the epithelial-stromal boundary and/or modulation of stromal bulk distribution and hydration, have the potential to influence  $\Delta 1$ . If a change in the measured posterior corneal astigmatism is a major factor influencing  $\Delta 1$  then  $SIA_{Best}$  should equal  $\Delta 1$ , and equal  $SIA_{Bact}$ . There was neither a significant change in the mean measured value of posterior corneal astigmatism nor a correlation between  $SIA_{Best}$  and  $SIA_{Bact}$ . Once again, this suggests that other factors are responsible for  $\Delta 1$  in both groups.

During this study it was assumed that the SimK values generated by Pentacam were truly representative of the actual astigmatism at the corneal surfaces within the central pupillary region. The estimation of posterior corneal surface curvature is derived using an algorithm that depends on i) anterior corneal surface radius, or inclination, at multiple loci over the central cornea ii) the perpendicular distance separating the anterior and posterior surfaces at each one of the multiple loci and iii) the refractive index of the cornea along the antero-posterior direction of the cornea at each locus. The numerical uncertainty associated with every single independent variable will contribute

to the final error in the calculation of the radius of the posterior corneal surface at each one of the multiple loci. The cumulative errors in estimating each one of these radii will further contribute to the final error, hence the validity, in the computation of  $SIA_{Bact}$ .<sup>26</sup> The repeatability of anterior corneal astigmatic power fell within the range  $\pm 0.17DC$ . Therefore, the validity in the computation of  $SIA_{Bact}$  must fall outside this range. Dunne et al<sup>27</sup> described a procedure for estimating the astigmatism at the posterior corneal surface. The error in their procedure was  $\pm 0.27DC$  for power and  $\pm 6^\circ$  for the axis. These are representative of repeatability not validity. The  $\Delta 1$  values in LASIK are slightly higher than  $0.27DC$  and could be interpreted as indicative of repeatability. But this cannot be said for the  $\Delta 1$  values in FsLASIK group where the values are double this figure.

Feizi et al<sup>28</sup> used Pentacam and found a weak correlation between the measured posterior corneal astigmatism and the internal astigmatism derived from refraction in pseudophakic eyes. The outcome of their study questions the validity not the repeatability of Pentacam. There is reasonable agreement between different instruments for estimating the average radius of the posterior corneal surface.<sup>29</sup> However, inter-technique differences amount to  $\geq 0.50DC$  in upto 55% of cases and  $>10^\circ$  in 45% of cases regarding the measurement posterior corneal astigmatism.<sup>30,31</sup> The cumulative errors associated with estimating posterior corneal astigmatism, in a clinical setting, impact on the final calculation of  $SIA_{Bact}$ .

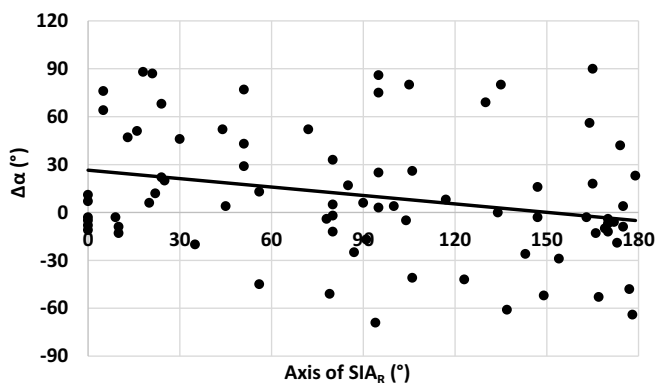
There were significant associations between pre-and postop measured values for posterior corneal astigmatic powers and axes. Predictions based on eqs 7 & 8 can be interpreted as indicators of repeatability, but not validity. A simple, straightforward, clinical mechanism for independently calibrating, and validating, the Pentacam facility to measure posterior corneal surface astigmatism would be welcome. Unfortunately, such a procedure is not readily available.  $SIA_{Best}$  does not match  $SIA_{Bact}$ , and there is no simple way of determining which is the chief factor influencing the difference.

## DECLARATION

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**Figure 2.** Difference ( $\Delta\alpha$ ) between the axis ( $^\circ$ ) of the surgically induced astigmatism ( $SIA$ ) at the anterior corneal surface ( $SIA_{Fact}$ ) and corresponding axis of the surgically induced astigmatism by refraction ( $SIA_R$ ) in relation to axis of  $SIA_R$  ( $x$ ). The best fit (solid line) is represented by  $\Delta\alpha = 26.472 - 0.176x$  ( $r = 0.269$ ,  $p = .016$ ,  $n = 79$ ).

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