Pyramidal aberrometry in wavefront-guided myopic LASIK

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Abstract

Purpose Pyramidal aberrometry has greater sampling density and a higher dynamic range than Hartman Shack aberrometry. We set out to evaluate measurement repeatability and clinical results for pyramidal aberrometry in routine myopic WF LASIK.

Methods We reviewed results from 265 consecutive eyes treated with myopic wavefront-guided LASIK using the Amaris 1050RS Excimer Laser and Peramis pyramidal aberrometer (Schwind Eye-Tech Solutions GmbH, Kleinostheim, Germany). We calculated limits of repeatability for the aberrometric refraction spherical equivalent and higher order aberrations for the Peramis aberrometer using results from 3 consecutive scans acquired preoperatively and postoperatively for the first 100 eyes treated.

Results To one decimal place, we found 95% limits of repeatability for sphere, cylinder, and spherical equivalent values for 3rd and 4th order aberration indices at 0.3D, 0.2D and 0.1D respectively. 95% of eyes were within ±0.5D of the manifest refraction spherical equivalent target postoperatively. Unaided distance visual acuity (UDVA) in 96% of 232 eyes with a plano refraction target outcome was ≥20/20. 97% of eyes had ≤0.5D refraction cylinder. No eyes lost ≥2~~1~~ lines of corrected distance visual acuity (CDVA).

Conclusions These data demonstrate good measurement repeatability, safety and efficacy for pyramidal aberrometry in routine myopic LASIK.

Introduction

Routine myopic LASIK treatment using contemporary excimer laser systems is normally based on either manifest refraction, with modifications to the ablation profile designed to neutralize mean induced aberrations (conventional LASIK), or aberrometric refraction, with compensation for both mean induced aberrations and the individual preoperative aberration profile for the eye to be treated (wavefront-guided LASIK). Theoretical advantages for wavefront-guided LASIK are better measurement repeatability for aberrometry versus manifest refraction[1,2], protection from data entry errors in treatment planning, and lower postoperative higher order aberration (HOA) scores. Differences in results are small, and most studies have failed to demonstrate a clear advantage for wavefront-guided over conventional LASIK in normal eyes with low to moderate myopia and myopic astigmatism.[3,4] But wavefront-guided treatment may produce superior results in eyes with a root mean square total HOA (RMS-HOA) > 0.30µm preoperatively.[5]

Until recently, most wavefront-guided excimer laser treatments have been driven by Hartmann Shack aberrometry. Hartmann Shack aberrometry works by reflecting a ray of infrared laser light off the retina and sampling the emerging beam over the pupillary zone with a grid array of lenslets. Aberrometric data is then derived from a function of the difference between the measured position of the emergent beam and its reference position based on a neutral wavefront at each point sampled. Measurement fidelity for Hartmann Shack systems is limited by the density of the sampling array, and the measurement range is limited by spot-crossover. Spot cross-over is a term used to describe the situation in which the emergent beam is deviated beyond the sampling area of the reference sensor and into the sampling area of the neighboring

Commented [BA1]: Add: a) Pesudovs K, Parker KE, Cheng H, Applegate RA. The precision of wavefront refraction compared to subjective refraction and auto refraction. Optom Vis Sci 2007: May (5): 387-92.
b) Thibos LN, Hong X, Bradley A, Applegate RA. Accuracy and precision of objective refraction from wavefront aberrations. J Vis 2004: 4; 329-51.

sensor, resulting in a failed scan acquisition. This limits the application of Hartmann Shack systems in the highly aberrated eyes that would benefit most from wavefront-guided treatment.

Ragazzoni et al.[6] described a pyramidal aberrometry in 1996. Pyramidal aberrometry in the eye is also based on sampling the emergent beam from infrared light reflected off the retina over the pupillary zone. An oscillating pyramidic optical component, placed at the focal plane splits emergent light into four images of the pupil. These images are captured through relay optics by a charged coupled device (CCD) camera. Differences in light intensity between corresponding loci on these four images are used to derive aberrometric information. Measurement fidelity is only limited by the pixel density of the CCD camera, and spot cross-over does not occur. Theoretical advantages for pyramidal aberrometry include greater sampling density and a higher dynamic range than Hartman Shack aberrometry.

Here we set out to evaluate measurement repeatability in routine clinical use and clinical results in myopic wavefront-guided LASIK using the first commercially available pyramidal aberrometry based system. To the best of our knowledge, this is the first published data on pyramidal aberrometry guided treatment.

Patients and Methods

We conducted a retrospective analysis of anonymized data from consecutive cases of myopic wavefront-guided LASIK (≤10D sphere; ≤4D cylinder) performed by a single surgeon (BA) at Moorfields Eye Hospital between November 2017 and January 2019.

We extracted additional data from consecutive wavefront scans acquired during pre- and postoperative examination for the first 100 eyes treated for measurement repeatability analysis.

We studied data collected electronically in the course of routine clinical practice as part of a continuous review of laser vision correction accuracy approved by the Clinical Audit and Effectiveness Committee at Moorfields Eye Hospital NHS Foundation Trust. The study and consent procedures adhered to the tenets of the Declaration of Helsinki.

Aberrometry

We performed Peramis (Schwind Eye-Tech-Solutions GmbH, Kleinostheim, Germany) pyramidal aberrometry as a first step in preoperative and postoperative examinations. We uncoupled aberrometry from topography measurement, selecting aberrometry only rather than combined aberrometry and topography measurement, and performed aberrometry before any other scans or manifest refraction in order to minimize acquisition time and the possible influence of fatigue on measurement repeatability. Three consecutive scans were acquired in mesopic lighting conditions for the right then the left eyes by a single optometrist (HH) according to a standardised operating procedure, including standardised oral instructions to each patient. We instructed patients to keep their forehead and chin in contact with the rests, to avoid head tilt, keep their focus relaxed – looking through rather than at the fixation target, and to blink whenever they felt like doing so, but to keep the eyes wide open in between blinks.

Treatment

We determined eligibility for LASIK using standard criteria.[7,8] We selected patients for wavefront-guided treatment if the aberrometric acquisition diameter was greater than 5.0mm on all scans, and greater than 5.5mm on the scan selected for treatment planning in each eye. Eyes not meeting these criteria were treated with conventional myopic LASIK and were excluded from analysis. We exported the scan with the largest acquisition diameter and a green light quality indicator for the iris cyclotorsional registration image for treatment planning in Schwind CAM software. We used a 6.5mm optical zone throughout.

After importing aberrometry and topographic data, we performed nomogram adjustments to the target sphere in treatment planning software with reference to the manifest refraction spherical equivalent as previously described.[9] No adjustments were entered for the target cylindrical correction.

Throughout the study period, we performed wavefront-guided LASIK using Intralase iFS (J&J vision, Irvine, CA) femtosecond laser flap creation, 8.5mm flap diameter, 100-110µm flap thickness, and the Schwind Amaris® 1050RS excimer laser.

Data archiving and analysis

We archived anonymised data extracts on an Excel (Microsoft Corp, Seattle) spreadsheet for analysis and filtered outlying values using plausibility limits to screen for data entry errors.

In the subset of 100 eyes studied for measurement repeatability, we calculated 95% limits of repeatability (95%LoR) from the standard deviation within measures (Sw) derived from a random effects ANOVA applying the formula: 95%LoR = 1.96*SQRT(2)*Sw.[1] We calculated

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~~limits of agreement~~95%LoR for spherical equivalent values normalized to a 5mm pupil for the following variables pre and postoperatively: sphere, cylinder, coma, trefoil, spherical aberration, and root mean square total higher order aberrations (RMS-HOA).

We compared pupil diameters throughout the aberrometry scan acquisition sequence as a surrogate measure of accommodation control and measurement fatigue during scanning.

For the first 100 eyes, we derived limits of agreement (LoA) and bias, or mean difference, values for measured aberrometric and manifest refraction spherical equivalent values pre and postoperatively using Bland Altman plots.[10]

Aberration terms~~s~~ were reported as equivalent defocus~~in~~ (D) ~~as there is~~ using a linear conversion between root mean square (RMS) wavefront variance (µm) and equivalent defocus (D)~~µm and D, with no averaging or assumptions, using the formula~~[11]:

$$D = 16.\mathrm{SQRT}(3).\mu/P^2$$

Where D = dioptric spherical equivalent; µ = ~~wavefront RMS~~RMS wavefront variance in microns; P = analysis diameter.

We summarized treatment results for myopic wavefront-guided LASIK using standard outcome reporting.[12]

Results

81% of eyes eligible for myopic LASIK had a mesopic pupil size and aberrometry scan acquisition diameter >5.5mm, and were treated with wavefront-guided LASIK. Mean pre and postoperative values for aberrometric indices and 95% LoR for the first 100 eyes are tabulated (Table 1). To one decimal place, we found 95% LoA for sphere, cylinder, and HoA indices at 0.3D, 0.2D and 0.1D respectively, implying that differences between 19 out of 20 consecutive measures would not exceed this value.

There was a trend towards a reduction in pupil size at the end of the measurement sequence (Figure 1) but this was not reflected in any trend to changes in the mean measured sphere (Table 1).

On average, the preoperative aberrometric refraction spherical equivalent was approximately 0.2D less myopic than manifest refraction spherical equivalent. Again, this implies good control over accommodation during pyramidal aberrometry (Fig 2a). We observed a~~a~~ trend (R2 = 0.2; Kendall's Tau = -0.22; p=0.001) towards overestimation of ~~both hyperopic and~~ myopic outcomes versus manifest refraction values in postoperative examination (Fig 2b).

Outcomes for 265 consecutive eyes (133 patients; age 36.2±8.9 years) treated with myopic wavefront-guided LASIK using pyramidal aberrometry are summarized in Figure 3. Three months after surgery, 95% of eyes were within ±0.5D of the intended refraction spherical equivalent (SE) target. Unaided distance visual acuity (UDVA) in 96% of 232 eyes with a plano refraction target outcome was ≥20/20. 97% of eyes had ≤0.5D refraction cylinder after surgery. No eyes lost ≥1 line of corrected distance visual acuity (CDVA).

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Discussion

This study was initiated to investigate measurement repeatability data and treatment results for a pyramidal aberrometer in routine myopic LASIK. Our results show good SE measurement repeatability in pyramidal aberrometry. Treatment results of wavefront-guided myopic LASIK using this pyramidal aberrometry system demonstrate efficient, safe and predictable refractive outcomes in routine clinical practice.

Although data were analyzed ~~prospectively~~ retrospectively ~~reviewed~~, these data were archived prospectively in a well-structured clinical database based on United Kingdom national recommendations.[13] Data acquisition, and aberrometry in particular was also based on standard operating procedures. Our aberrometric results are reported as spherical equivalent dioptric values (D) at a standardised 5mm pupil diameter. As described by Thibos et al, ~~We believe~~ this format is more clinically intuitive than aberrometric results expressed in microns (µm), and has the advantage of normalizing root mean square (RMS) expressions of wavefront variance in µm by pupil area. ~~.~~

> **Commented [BA3]:** Add reference 11 Thibos et al J Opt Soc Am 2002 here

Against these strengths, this study is non-comparative, and references the existing literature to evaluate results in relation to measurement repeatability versus manifest refraction and treatment outcomes. We also did not use a patient reported outcome measure in addition to standard reporting in routine clinical practice. We are therefore unable to comment on possible benefits of wavefront-guided versus conventional treatment for subjective visual outcomes.

The existing literature on measurement repeatability for aberrometers in routine clinical practice is limited by variations in methodology and expression of aberration terms. But our data suggest measurement precision (repeatability) for the pyramidal aberrometer used here is similar to that for Hartman Shack aberrometers used in leading contemporary wavefront-guided LASIK systems (Table 2). Pyramidal aberrometry avoids problems with spot crossover inherent in Hartmann-Shack systems when imaging more irregular corneas, and may therefore have advantages for therapeutic treatment of irregular astigmatism. This is an important area for further study.

There are more than 300 publications on wavefront-guided laser surgery in the scientific literature. This is a technology in evolution, and existing studies report variable and conflicting outcomes and conclusions.[5] Studies of earlier systems[3,4] have failed to demonstrate a clear advantage of wavefront-guided over conventional treatment for low to moderate myopia and myopic astigmatism. No statistically significant differences were observed regarding safety, efficacy, or predictability among groups.[3,4] To define patient groups for whom wavefront-guided laser surgery may offer an advantage, other studies are stratified eyes by RMS-HOA scores. Results for wavefront-guided and conventional LASIK were similar for eyes with <0.30µm preoperative RMS-HOA at same pupil sizes. For eyes with a preoperative RMS-HOA >0.30µm, wavefront-guided treatment resulted in lower aberration scores postoperatively.[14,15] Correction of HOAs could lead to an improvement in contrast sensitivity and visual acuity.[16,17], and a reduction in visual quality problems including glare and halos after treatment.[18,19] These side effects have been attributed to the increased HOAs, induction of positive spherical aberration, and decreased corneal asphericity that are associated with the ablation profile of traditional LASIK refractive surgery, with some studies reporting superior night vision performance and a reduction of glare symptoms after wavefront-guided LASIK. [20,21] Schallhorn et al.[20] observed a significant improvement of night driving visual performance after wavefront-guided correction compared to conventional treatment, but aberration

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compensation in conventional LASIK treatment based on mean induced aberrations has improved in later laser systems since these results were published. Our findings (Table 1), and work by Thibos et al, suggest that equivalent defocus for spherical equivalent RMS HOAtotal HOA values in normal corneas eyes standardised to a 5mm pupil areis <0.3D. If they exist, differences between results for contemporary wavefront-guided systems and conventional LASIK are small, and may not be picked up in analyses restricted to visual acuity or spherical equivalent refraction data.

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Both our data and previous results for Hartmann Shack aberrometers[2,5] suggest better measurement repeatability for aberrometric sphere and cylindrical refraction than for manifest refraction data. Aberrometric precision for cylinder terms in particular is superior to manifest refraction. Our good astigmatic outcomes (Figure 3) in particular indicate that enhanced measurement precision for astigmatismthis may confer some advantages for wavefront-guided treatment in routine clinical practice.

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b) Thibos LN, Hong X, Bradley A, Applegate RA. Accuracy and precision of objective refraction from wavefront aberrations. J Vis 2004: 4; 329-51.

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Commented [BA8]: Again insert a) Pesudovs K, Parker KE, Cheng H, Applegate RA. The precision of wavefront refraction compared to subjective refraction and auto refraction. Optom Vis Sci 2007: May (5): 387-92.
b) Thibos LN, Hong X, Bradley A, Applegate RA. Accuracy and precision of objective refraction from wavefront aberrations. J Vis 2004: 4; 329-51.

The core piece of the pyramidal aberrometer used here is an oscillating pyramidic optical component, placed at the focal plane. The pyramid splits the light in four beams, which are imaged by a relay optics onto an observation plane, producing four images of the pupil. These four intensity patterns provide information on the gradients of the aberrated wavefront. Measurement resolution is only limited by the pixel density of the CCD camera, and spot cross-over does not occur. Pyramidal aberrometry may therefore be able to obtain wavefront information on more irregular corneas and facilitating the treatment of irregular astigmatism.W Besides, wavefront-guided treatment does not require data transcription other than for nomogram adjustments, protecting from human error during treatment programming. This may also be an important advantage in routine clinical practice, particularly in high volume treatment settings.

The standard measurement for refractive outcomes, including those for investigations of wavefront-guided LASIK, remains subjective manifest refraction. Previous investigators have highlighted the difference between measurement repeatability (precision) and accuracy – aligning defocus measurements correctly with visual acuity. Both refraction modalities are likely to have some bias (systematic under or overcorrection versus the true value). Nomograms derived from regression analysis applying a modification to the target sphere based on a weighted difference between the manifest and aberrometric refraction have previously been shown to improve spherical equivalent manifest refraction results, and were used in this study. Our analyses suggest a small (0.2D) uniform trend to underestimation of manifest refraction spherical equivalent myopia by pyramidal aberrometry in preoperative patients (Fig 2a). In postoperative pyramidal aberrometry, we observed a weak but statistically significant trend ($R2 = 0.2$; Kendall's Tau = 0.22; $p = 0.001$) towards over-estimation of myopia in comparison with manifest refraction spherical equivalent (Fig 2b). It is important to consider this in relation to wavefront-guided enhancement LASIK treatments using this system, and to modulate the refraction target sphere with reference to the pre-enhancement manifest refraction spherical equivalent.

Our data demonstrate that pyramidal aberrometry can be applied safely and effectively as a basis for treatment programming in routine myopic LASIK. Pyramidal aberrometry systems may have advantages over Hartmann Shack aberrometry including a higher dynamic range and greater measurement fidelity. Differences between results for wavefront-guided and conventional LASIK normal eyes are small, but incremental gains are important in the quest

Commented [BA9]: Add reference 12 – Waring et al Standard outcome reporting

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a) Thibos LN, Hong X, Bradley A, Applegate RA. Accuracy and precision of objective refraction from wavefront aberrations. J Vis 2004: 4; 329-51.
b) Pesudovs K, Parker KE, Cheng H, Applegate RA. The precision of wavefront refraction compared to subjective refraction and auto refraction. Optom Vis Sci 2007: May (5): 387-92.
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Commented [BA11]: Add reference 9 Allan et al JCRS for optimized outcomes. Future research will determine whether pyramidal aberrometry is superior to Hartmann Shack systems for the measurement and treatment of irregular astigmatism and eyes with higher starting levels of HOAs.

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Legends for Tables and Figures

Table 1. Measurement repeatability in pyramidal aberrometry before and after myopic wavefront-guided LASIK (N= 100 eyes). LoR = limits of repeatability, SA= spherical aberration, SE= spherical equivalent, HOA = higher-order aberrations. Dioptric spherical equivalent values standardised for a 5mm pupil were applied throughout.

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Table 2. Comparison of 95% limits of Repeatability (LoR) for aberrometers used in leading contemporary wavefront-guided LASIK platforms. Orthogonal terms for coma and trefoil were combined using the square root of the sum of the squares. Equivalent defocus (D) values were derived from root mean square (RMS) wavefront variance (μm) values and normalised for analysis diameter using the formula: $D = 16.\mathrm{SQRT}(3)\mu/P^2$ where: D = equivalent defocus; μ = RMS wavefront variance; and P = analysis diameter.

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Figure 1. Mesopic pupil diameter through the pyramidal aberrometry scan acquisition sequence.

Figure 2. Bland Altman Plots. Differences between preoperative (a) and postoperative (b) measured values for manifest (M) and wavefront (WF) refraction spherical equivalent. For better illustration, altered x-axis scales were used. Figure B includes target emmetropia only.

Figure 3. Standard graphs for refractive outcomes of 265 myopic eyes prior to and 3 months after wavefront-guided LASIK.

Acknowledgments

The authors would like to thank Mr. Samuel Arba-Mosquera for his valuable advice during manuscript preparation.

Table 1.

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Variable	Measurement 1 Mean	Measurement 1 SD	Measurement 2 Mean	Measurement 2 SD	Measurement 3 Mean	Measurement 3 SD	95% LoR
Preoperative							
SE	-4.625	2.087	-4.582	2.102	-4.566	2.110	0.325
Cylinder	0.533	0.466	0.531	0.492	0.543	0.477	0.183
Coma	0.109	0.069	0.117	0.079	0.116	0.081	0.079
Trefoil	0.084	0.070	0.096	0.076	0.100	0.080	0.085
SA	0.063	0.068	0.063	0.063	0.066	0.069	0.059
RMS-HOA	0.218	0.063	0.230	0.076	0.240	0.072	0.094
Postoperative							
SE	-0.530	0.529	-0.505	0.546	-0.487	0.566	0.273
Cylinder	0.266	0.337	0.268	0.327	0.275	0.373	0.159
Coma	0.153	0.102	0.158	0.110	0.169	0.117	0.100
Trefoil	0.065	0.085	0.066	0.089	0.060	0.089	0.092
SA	0.055	0.072	0.055	0.079	0.049	0.085	0.069
Total HOA	0.256	0.098	0.275	0.108	0.279	0.119	0.113

Table 2.

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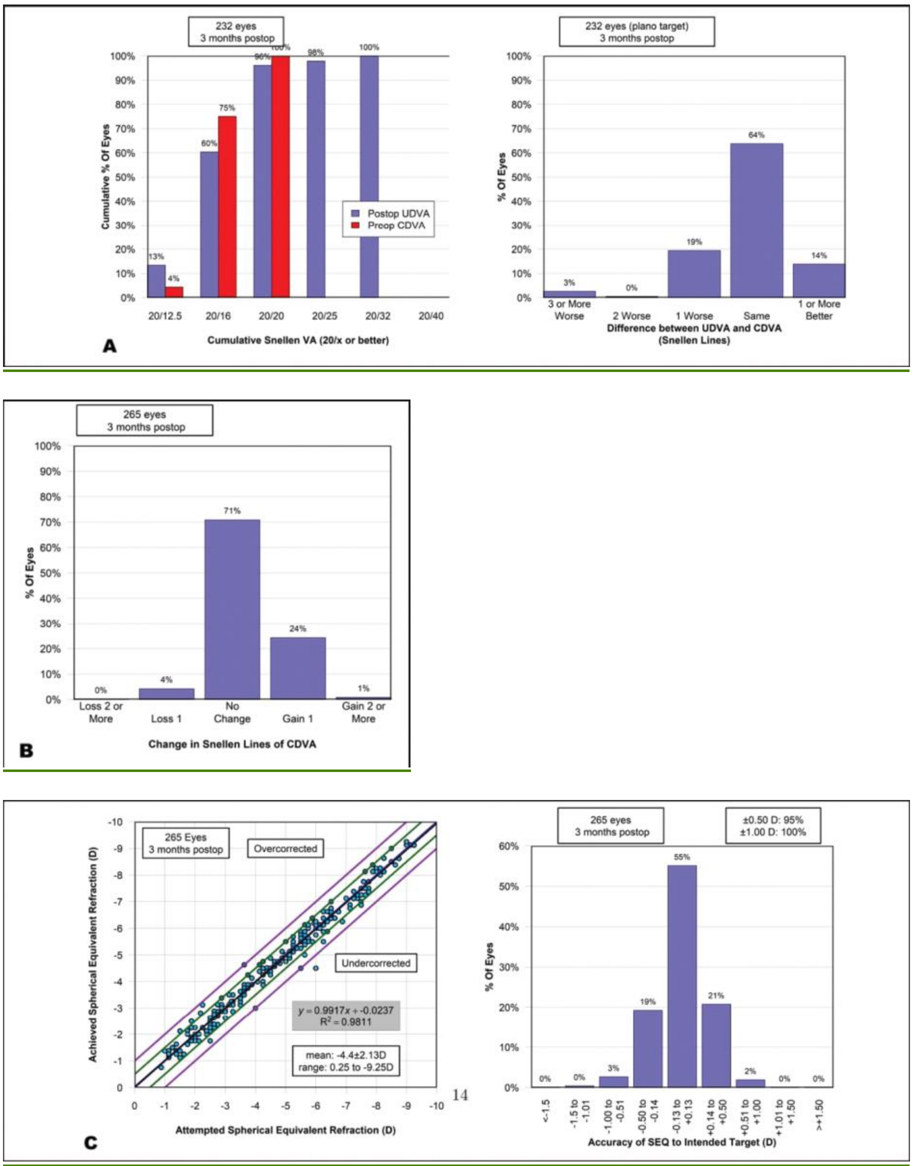
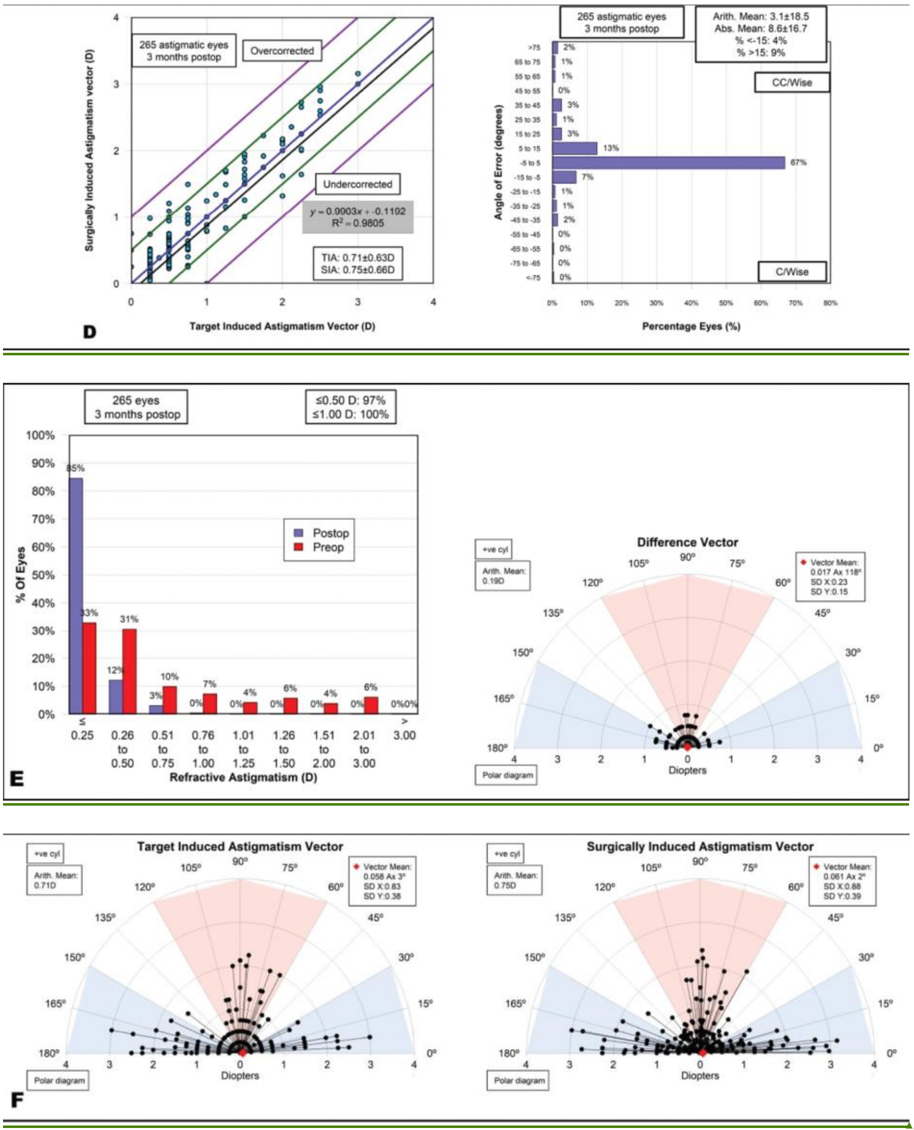
	Peramis	iDesign	Zywave
Sphere	0.33	0.7	0.33
Cyl	0.18	0.21	0.28
Coma	0.08	0.06	0.10
Trefoil	0.09	0.07	0.11

SA	0.06	0.05	0.06
TotalHOA	0.09	0.07	0.11

Fig





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