Pyramidal Aberrometry in Wavefront-Guided Myopic LASIK

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ABSTRACT

PURPOSE: To evaluate measurement repeatability and clinical results for pyramidal aberrometry in routine myopic wavefront-guided laser in situ keratomileusis (LASIK).

METHODS: 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) were reviewed. Limits of repeatability were calculated for the aberrometric refraction spherical equivalent and higher order aberrations for the Peramis aberrometer using results from three consecutive scans acquired preoperatively and postoperatively for the first 100 eyes treated.

RESULTS: The 95% limits of repeatability for pyramidal aberrometric measurement were: 0.3 diopters (D) for sphere, 0.2 D for cylinder, and 0.1 D (dioptric equivalent) for 3rd and 4th order aberration indices. A total of 95% of eyes were within ±0.50 D of the manifest refraction spherical equivalent target postoperatively. Uncorrected distance visual acuity was 20/20 or better in 96% of 232 eyes with a plano refraction target outcome. A total of 97% of eyes had a refraction cylinder of 0.50 D or less. No eyes lost one or more line of corrected distance visual acuity.

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

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ntil 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 of the retina and sampling the emerging beam over the pupillary zone with a grid array of lenslets. Aberrometric data are 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 cross-over. 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 neighbor-

ing 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.

Ragazzoni¹ described pyramidal aberrometry in 1996. Pyramidal aberrometry in the eye is also based on sampling the emergent beam from infrared light reflected off of 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 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 charged coupled device camera, and spot cross-over does not oc-

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cur. Theoretical advantages for pyramidal aberrometry include greater sampling density and a higher dynamic range than Hartmann-Shack aberrometry.

We set out to evaluate measurement repeatability in routine clinical use and clinical results in myopic wavefront-guided laser in situ keratomileusis (LASIK) using the first commercially available system based on pyramidal aberrometry. To the best of our knowledge, this article is the first published data on treatment guided by pyramidal aberrometry.

PATIENTS AND METHODS

We conducted a retrospective analysis of anonymized data from consecutive cases of myopic wavefront-guided LASIK (\leq 10.00 diopters [D] sphere; \leq 4.00 D cylinder) performed by a single surgeon (BDA) at Moorfields Eye Hospital between November 2017 and January 2019.

We extracted additional data from consecutive wavefront scans acquired during preoperative 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) 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 to minimize acquisition time and the possible influence of fatigue on measurement repeatability. Three consecutive scans were acquired in mesopic lighting conditions for first the right and then the left eyes by a single optometrist (HH) according to a standardized operating procedure, including standardized oral instructions to each patient. We instructed patients to keep their forehead and chin in contact with the rests, avoid head tilt, keep their focus relaxed (looking through rather than at the fixation target), and blink whenever they felt like doing so, but to keep their eyes wide open between blinks.

TREATMENT

We determined eligibility for LASIK using standard criteria.^{2,3} We selected patients for wavefront-guided treatment if the aberrometric acquisition diameter was

greater than 5 mm on all scans and greater than 5.5 mm 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 6.5-mm optical zone throughout.

After importing aberrometric 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.⁴ No adjustments were entered for the target cylindrical correction.

Throughout the study period, we performed wavefront-guided LASIK using Intralase iFS femtosecond laser (J&J Vision) flap creation, 8.5-mm flap diameter, 100 to 110 μ m flap thickness, and the SCHWIND Amaris 1050RS excimer laser.

DATA ARCHIVING AND ANALYSIS

We archived anonymized data extracts on an Excel (Microsoft Corporation) 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 analysis of variance applying the formula: 95% LoR = 1.96*SQRT(2)*Sw.⁵ We calculated 95% LoR for spherical equivalent values normalized to a 5-mm pupil for the following variables preoperatively and postoperatively: sphere, cylinder, coma, trefoil, spherical aberration, and 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 preoperatively and postoperatively using Bland-Altman plots.⁶

Aberration terms were reported as equivalent defocus (D) using a linear conversion between RMS wavefront variance (μ m) and equivalent defocus (D)⁷: D = 16.SQRT(3). μ /P², where D = dioptric spherical equivalent; μ = RMS wavefront variance in microns; and P = analysis diameter.

We summarized treatment results for myopic wavefront-guided LASIK using standard outcome reporting.⁸

TABLE 1 Measurement Repeatability in Pyramidal Aberrometry Before and After Myopic Wavefront-Guided LASIK (N = 100 Eyes)ª						
Variable	Measurement 1, Mean ± SD	Measurement 2, Mean ± SD	Measurement 3, Mean ± 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		
Total 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		

LASIK = laser in situ keratomileusis; SD = standard deviation; LoR = limits of repeatability; SE = spherical equivalent; SA = spherical aberration; HOA = higher order aberrations

^aValues are presented as mean ± SD. Dioptric spherical equivalent values standardized for a 5-mm pupil were applied throughout.

RESULTS

A total of 81% of eyes eligible for myopic LASIK had a mesopic pupil size and aberrometry scan acquisition diameter of greater than 5.5 mm, and were treated with wavefront-guided LASIK.

Mean preoperative and postoperative values for aberrometric indices and 95% LoR for the first 100 eyes were tabulated (**Table 1**). To one decimal place, we found 95% LoA for sphere, cylinder, and HoA indices at 0.3 D, 0.2 D, and 0.1 D, respectively, implying that differences between 19 of 20 consecutive measures would not exceed this value.

There was a trend toward a reduction in pupil size at the end of the measurement sequence (**Figure A**, available in the online version of this article) 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 0.2 D less myopic than manifest refraction spherical equivalent. Again, this implies good control over accommodation during pyramidal aberrometry (**Figure BA**, available in the online version of this article). We observed a trend $(R^2 = 0.2;$ Kendall's Tau = -0.22; P = .001) toward overestimation of myopic outcomes versus manifest refraction values in postoperative examination (**Figure BB**).

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 1**. Three months after surgery, 95% of eyes were within ± 0.50 D of the intended refraction spherical equivalent target. Uncorrected distance visual acuity in 96% of 232 eyes with a plano refraction target outcome was 20/20 or better. A total of 97% of eyes had refraction cylinder of 0.50 D or less after surgery. No eyes lost one or more lines of corrected distance visual acuity.

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 spherical equivalent measurement repeatability in pyramidal aberrometry. Treatment results of wavefront-guided myopic LASIK using this pyramidal aberrometry system demonstrated efficient, safe, and predictable refractive outcomes in routine clinical practice.

Although data were analyzed retrospectively, these data were archived prospectively in a well-structured clinical database based on United Kingdom national recommendations.⁹ Data acquisition and aberrometry in particular were also based on standard operating procedures. Our aberrometric results are reported as spherical equivalent dioptric values (D) at a standardized 5-mm pupil diameter. As described by Thibos et



Figure 1. Standard graphs for refractive outcomes of 265 myopic eyes prior to and 3 months after wavefront-guided laser in situ keratomileusis. (A) Difference in uncorrected (UDVA) and corrected (CDVA) visual acuity. (B) Change in CDVA. (C) Attempted vs achieved spherical equivalent refraction (SEQ). (D) Target induced astigmatism (TIA). (E) Difference vector for refractive astigmatism. (F) Difference vectors for TIA and surgically induced astigmatism (SIA). D = diopters



Figure 1 (cont'd). Standard graphs for refractive outcomes of 265 myopic eyes prior to and 3 months after wavefront-guided laser in situ keratomileusis. (A) Difference in uncorrected (UDVA) and corrected (CDVA) visual acuity. (B) Change in CDVA. (C) Attempted vs achieved spherical equivalent refraction (SEQ). (D) attempted versus achieved astigmatic change. (E) Difference vector for refractive astigmatism. (F) Difference vectors for target induced astigmatism (TIA) and surgically induced astigmatism (SIA). D = diopters

al,⁷ this format is more clinically intuitive than aberrometric results expressed in microns, and has the advantage of normalizing RMS expressions of wavefront variance in microns by pupil area.

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 Hartmann-Shack aberrometers^{10,11} used in leading contemporary wavefront-guided LASIK systems (**Table A**, available in the online version of this article). Pyramidal aberrometry avoids problems with spot cross-over 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 wavefrontguided laser surgery in the scientific literature. This is a technology in evolution, and existing studies report variable and conflicting outcomes and conclusions.¹² Studies of earlier systems^{13,14} 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.^{13,14} 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 eves with less than 0.30 µm preoperative RMS-HOA at the same pupil sizes. For eyes with a preoperative RMS-HOA greater than 0.30 µm, wavefront-guided treatment resulted in lower aberration scores postoperatively.^{15,16}

Correction of HOAs could lead to an improvement in contrast sensitivity and visual acuity^{17,18} and a reduction in visual quality problems including glare and halos after treatment.^{19,20} 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.^{16,17} Schallhorn et al²¹ observed a significant improvement of night driving visual performance after wavefrontguided correction compared to conventional treatment, but aberration compensation in conventional LASIK treatment based on mean induced aberrations has improved in later laser systems since these results were published. Our findings and work by Thibos et al⁷ suggest that equivalent defocus for total HOAs in normal eyes is less than 0.30 D. 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.

Both our data and previous results for Hartmann-Shack aberrometers^{12,23-26} 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.^{23,24} Our good astigmatic outcomes (**Figure 1**) indicate that enhanced measurement precision for astigmatism may confer some advantages for wavefront-guided treatment in routine clinical practice.

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,⁸ including those for investigations of wavefront-guided LASIK, remains subjective manifest refraction. Previous investigators^{223,24} 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 undercorrection 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 results⁴ and were used in this study. Our analyses suggest a small (0.2 D) uniform trend to underestimation of manifest refraction spherical equivalent myopia by pyramidal aberrometry in preoperative patients (Figure BA). In postoperative pyramidal aberrometry, we observed a weak but statistically significant trend toward overestimation of myopia in comparison with manifest refraction spherical equivalent (Figure BB). 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 normal eyes undergoing wavefront-guided and conventional LASIK are small, but incremental gains are important in the quest 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.

AUTHOR CONTRIBUTIONS

Study concept and design (AF, HH, BDA); data collection (AF, HH, BDA); analysis and interpretation of data (AF, BDA); writing the manuscript (AF, BDA); critical revision of the manuscript (HH, BDA); statistical expertise (AF, BDA); supervision (BDA)

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Figure A. Mesopic pupil diameter through the pyramidal aberrometry scan acquisition sequence. OD = right eye; OS = left eye



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

TABLE A Comparison of LoR for Aberrometers Used in Leading Contemporary Wavefront-Guided LASIK Platforms ^{a,b}					
Parameter	Peramis	iDesign	Zywave		
Sphere	0.33	0.7	0.33		
Cylinder	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		
Total HOA	0.09	0.07	0.11		

LoR = 95% limits of repeatability; LASIK = laser in situ keratomileusis; SA = spherical aberration; HOA = higher order aberrations.

^aOrthogonal 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 (μ m) values and normalized for analysis diameter using the formula: D = 16.SQRT(3) μ /P² where: D = equivalent defocus; μ = RMS wavefront variance; and P = analysis diameter.

^bCreated using data from references 17 and 18.

The Peramis is manufactured by SCHWIND eye-tech-solutions GmbH; the iDesign is manufactured by Johnson & Johnson Surgical Vision, Inc; and the Zywave is manufactured by Bausch & Lomb GmbH.

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