ORIGINAL ARTICLE

Mesopic Pupillometry in Pre-LASIK Patients by a Placido-Disc Topographer and Hartmann-Shack Aberrometer

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ABSTRACT

Introduction: Precise pupillometry is crucial to determine ablation optical zone (OZ) size selection in LASIK. Significant difference in the selection induces unwanted postoperative night visual disturbance. Placido-disc topographer and Hartmann-Shack aberrometer are commonly used in LASIK preoperative assessment. However, little is known on the precision and agreement of these devices in pupillometry. Hence, this study aimed to evaluate the precision (repeatability and reproducibility) and inter-device agreement of a Placido-disc topographer and Hartmann-Shack aberrometer in measuring mesopic pupil size in pre-LASIK patients. **Methods:** Mesopic pupillometry on 38 pre-LASIK patients were performed using both devices by two masked operators, on two separate sessions. Intra-session repeatability, inter-operator reproducibility and inter-device agreement were analysed. A disagreement value of ±0.5 mm and 95% limits of agreement (LoA) were determined. **Results:** Hartmann-Shack aberrometer demonstrated higher repeatability and reproducibility than Placido-disc topographer in mesopic pupillometry. Ninety-seven percent and all of Hartmann-Shack wavefront aberrometer pupillometry were within ±0.5 mm in repeated sessions and between the operators, respectively. The mesopic pupil size obtained from Placido-disc topographer was significantly larger than Hartmann-Shack aberrometer results ($P = 0.02$). The agreement between devices was low (LoA > ±1 mm) and only 53% of Placido-disc topographer pupillometry were within ±0.5 mm of Hartmann-Shack aberrometer pupillometry. **Conclusion:** Hartmann-Shack aberrometer has higher precision within sessions and between operators, and it provides smaller mesopic pupillometry than Placido-disc topographer. Precise mesopic pupillometry could assist refractive surgeons in choosing a correct ablation OZ size during LASIK surgery to improve postoperative outcome.

Keywords: Agreement, Hartmann-Shack aberrometer, Mesopic pupillometry, Placido-disc topographer, Precision

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INTRODUCTION

A comprehensive eye assessment is important for laser-assisted *in-situ* keratomileusis (LASIK) to ensure the suitability and outcome of the procedure. Preoperative assessment for LASIK involves various ocular biometric measurements using multiple diagnostic devices. Pupil size is one of the essential parameters which determines the optical zone (OZ) size (1). Visual disturbance symptoms at night during the early postoperative period still reported in patients with small OZ and large pupil size even with the most advanced LASIK machine (1,2). Precise evaluation of pupil size in dim illumination (mesopic) is an important step during LASIK preoperative assessment (2).

Mesopic is defined as illumination ranges between 0.05 to 50 lux (3). Scotopic and photopic refer to the illumination level of lower than 0.05 lux and higher than 50 lux, respectively (3). Low mesopic represents real driving ambient which affects most patient's visual performance at night (4). The pupil is a dynamic structure and its size is influenced by illumination level, accommodation and psychological status during the measurement (5,6). Medications, refractive errors and age may also affect the pupillary size (5,6). There is a significant amount of pupillary hippus and anisocoria which can occur at any illumination levels (7,8). These physiological characteristics of the pupil may impose difficulty in the determination of pupil size. A good pupillometry device should be replicable (7,8) during each session with acceptable inter-operator reproducibility (9).

Pupillometry function has been incorporated in most anterior segment diagnostic technologies (10–12). These include topography, aberrometry, tomography and optical biometry. However, studies to address the precision and agreement on the pupillary function between all these technologies were not verified. The precision and agreement of Placido-disc based topographer and Hartmann-Shack wavefront aberrometer in measuring ocular biometric parameters, aberrations and refractions have been well-documented (13–17). Nevertheless, the repeatability and reproducibility of both devices in measuring mesopic pupil size are still inconclusive. To address this gap, this study objective was to evaluate the repeatability, reproducibility, and inter-device agreement of a Placido-disc topographer and Hartmann-Shack aberrometer in measuring mesopic pupil size during LASIK preoperative assessment.

MATERIALS AND METHODS

A comparative study was conducted involving 38 myopic subjects who were candidates for LASIK. Written informed consent was obtained from all subjects. This study received approval from the IIUM Research Ethics Committee (IREC 2019-161), and it adhered to the institutional guidelines and the Declaration of Helsinki for human research.

The sample size was determined using the Power and Sample Size Calculations (PS) software, version 3.1.6 (Vanderbilt University, Tennessee, United States). The pooled standard deviation (SD) of the differences between pupillometry devices retrieved from the previous study was 0.64 mm (10). Power of study was determined at 80%, 95% confidence interval (CI) with a significance level (*P*) of 0.05 and a detectable difference of 0.5 mm between pupillometry devices (12). The minimum sample of 33 subjects was required.

The subjects were selected during a comprehensive LASIK preoperative assessment between June and September 2019 using convenience sampling. Subjects with best-corrected visual acuity better than 6/9 were selected. Those with pre-existing ocular pathologies such as glaucoma, systemic diseases including diabetes mellitus, and had history of ocular trauma and surgery were excluded as previously described (18).

Automated mesopic pupillometry was performed using the Atlas 9000 topographer (Carl Zeiss Meditec AG, Jena, Germany) and the wavefront aberration supported corneal ablation (WASCA) analyser (Carl Zeiss Meditec AG, Jena, Germany). These devices are incorporated to the customised refractive surgery treatment planning station; CRS-Master (Carl Zeiss Meditec AG, Jena, Germany). The Atlas 9000 uses 22-concentric Placido-disc rings principle for topographic measurement. The distance of the light-emitting diode (LED) target to subject's corneal plane during the measurement was about 11 to 12 cm depending on the subject's face. Topographic imaging included pupil size measurements were obtained with internal illumination of 16.8 lux. The WASCA is an objective aberrometer that applies a 210 μm resolution sensor of Hartmann-Shack wavefront system with 1425 measuring points. The working distance of the measurement was 5 to 6 cm relying on the subject's face. The device internal illumination during measurement was 4.8 lux.

The measurement was conducted between 0900 and 1100 AM to avoid potential diurnal variation effect (19). All subjects were given two minutes of dark adaptation (4,12,20). All the pupil size measurements were performed in the same room at mesopic illumination of 1 lux (4,12,21) which may mimic night driving ambient (4). The illumination level was monitored using MS6612 digital light meter (Mastech Group, North Carolina, United States) throughout the study. Only one eye of each subject (22) was chosen randomly using Research Randomiser software (23). The fellow eye was occluded using an opaque eye shield to prevent induced convergence-miotic reflex (4).

The pupillary size measurement was done by two single-blinded operators who were masked to each other. In the first session, the primary operator (M.A.S.) performed two sets of repeated pupil size measurements using both devices for intra-session repeatability analysis. The same measurements were repeated in the second session by another operator (U.H.S.), a week apart at the same interval time and protocol for inter-operator reproducibility. The operators instructed the subjects to completely blink just prior to each measurement and to sit back after each repeated measurement. The operators also realigned the devices between each repeated measurement. The mean average of two sets repeated measurements in the first session were used for inter-device agreement assessment.

Statistical Analysis

Data analysis was employed using Statistical Package for the Social Sciences (SPSS) software for Windows version 25.0 (SPSS Inc., Chicago, Illinois, United States) and MedCalc statistical software version 17.2 (MedCalc Software Inc., Mariakerke, Belgium). Normality distribution of the data was verified using the Kolmogorov-Smirnov test with $P > 0.05$. Paired *t*-tests were employed to identify significant differences in intra-session, inter-operator, and inter-device in determining pupil size. A *P*-value of less than 0.05 was set as the level of significance. Increment of 0.5 mm in pupillary size is considered significant in making a refractive surgical decision (12). Hence, the pupillometry difference within ±0.5 mm between two measurements was set as a cut-off for agreement assessments (4,12,20).

Intra-Session Repeatability and Inter-Operator Reproducibility

In assessing a device's precision, the repeatability precision (S_r), reproducibility precision (S_R), repeatability precision limit (r), reproducibility precision limit (R), coefficient of variation (CoV) and intraclass correlation coefficient (ICC) were evaluated (22,24). The S_r and S_R are intra-session repeatability and inter-operator reproducibility of within-subject standard deviations, respectively (24). The r and R were calculated as $1.96\sqrt{2} \times S_r$ and $1.96\sqrt{2} \times S_R$, respectively, which are the differences between measurements should be within 95% interval (24). The CoV was determined as the S_r or S_R was divided to the overall mean. Higher repeatability or reproducibility is indicated by lower CoV. The two-way mixed model and consistency type, and the two-way random model and absolute agreement type of ICCs were carried out to assess the repeatability and reproducibility, respectively. Better repeatability and reproducibility for the clinical setting were considered for ICC value closer to 1.

Inter-Device Agreement

The agreement between devices was assessed using Bland-Altman analysis. The 95% limits of agreement (LoA) were determined as the mean difference ± 1.96 SD of the difference. Superior agreement between devices is indicated by a narrower 95% LoA (25,26).

RESULTS

Thirty-eight eyes (19 right eyes; 19 left eyes) of 38 subjects (19 males; 19 females) were involved with the mean age of 30.8 ± 5.9 years (range 20 to 40 years). Their mean spherical equivalent was 6.09 ± 1.61 D (range -3.25 to -9.25 D).

Intra-Session Repeatability and Inter-Operator Reproducibility

Both devices revealed insignificant differences in intra-session and inter-operator ($P > 0.05$). Mesopic pupillometry by Placido-disc topographer in first measure (5.57 mm) was not significantly different from second measure (5.65 mm), $P = 0.07$, and also was not statistically significant between first operator (5.57 mm) and second operator (5.51 mm), $P = 0.27$. Mesopic pupillometry by Hartmann-Shack aberrometer also showed no statistically significant differences between first measure (5.34 mm) and second measure (5.33 mm), $P = 0.71$, and between first operator (5.34 mm) and second operator (5.30 mm), $P = 0.25$. The precision limits (r, R) and CoVs were consistently lower for Hartmann-Shack aberrometer than Placido-disc topographer. The ICCs were slightly higher for Hartmann-Shack aberrometer than Placido-disc topographer in intra-session and inter-operator. Only one measurement in intra-session disagreed within ±0.5 mm and all measurements in inter-operator comparison were within ±0.5 mm for Hartmann-Shack wavefront aberrometer. In contrast, four measurements disagreed within ±0.5 mm in both intra-session and inter-operator comparisons for Placido-disc topographer (Table I, Table II).

Table I: Intra-session repeatability of mesopic pupillometry

Devices	Mean Difference (95% CI)	S_r	r	CoV	ICC	Disagree-ment ±0.5 mm
		mm		%		%
PD topo	-0.08 ± 0.28 (-0.18 to 0.01)	0.20	0.56	3.6	0.953	10.5
HS aber	0.01 ± 0.18 (-0.05 to 0.07)	0.13	0.35	2.4	0.963	2.6

PD topo: Placido-disc topographer; HS aber: Hartmann-Shack aberrometer;
CI: confident interval; S_r: repeatability precision; r: repeatability precision limit;
CoV: coefficient of variation; ICC: intraclass correlation coefficient.

Table II: Inter-operator reproducibility of mesopic pupillometry

Devices	Mean Difference (95% CI)	S_R	R	CoV	ICC	Disagree-ment ±0.5 mm
		mm		%		%
PD topo	0.06 ± 0.31 (-0.05 to 0.16)	0.22	0.61	4.0	0.950	10.5
HS aber	0.03 ± 0.18 (-0.03 to 0.10)	0.13	0.36	2.5	0.962	-

PD topo: Placido-disc topographer; HS aber: Hartmann-Shack aberrometer;
CI: confident interval; S_R: reproducibility precision; R: reproducibility precision limit;
CoV: coefficient of variation; ICC: intraclass correlation coefficient.

Inter-Device Agreement

The mean pupil size taken using Placido-disc topographer and Hartmann-Shack aberrometer were 5.61 ± 0.93 mm (95% CI: 5.31 to 5.91 mm) and 5.33 ± 0.65 mm (95% CI: 5.12 to 5.54 mm), respectively. The pupil size measured by Placido-disc topographer was larger than obtained by Hartmann-Shack aberrometer ($P = 0.02$). The range of the 95% LoA was approximately 3 mm with almost half (18 measurements) of Placido-disc topographer measurements were not within ±0.5 mm, and seven measurements were not within ±1 mm of Hartmann-Shack aberrometer measurements (Table III, Fig. 1).

Table III: Inter-device agreement of mesopic pupillometry

Compared Devices	Mean Difference (95% CI)	95% LoA	Disagreement ±0.5 mm	Disagreement ±1.0 mm
	mm		%	
PD topo vs HS aber	0.28 ± 0.71* (0.04 to 0.51)	-1.12 to +1.68	47.4	18.4

*Significant difference in mesopic pupillometry between two devices ($P = 0.02$).
PD topo: Placido-disc topographer; HS aber: Hartmann-Shack aberrometer;
CI: confident interval; LoA: limits of agreement.

DISCUSSION

Due to its dynamic behaviour and easily influenced by various internal and external factors, obtaining an accurate mesopic pupillometry posed a real challenge (5,6,12). An objective device (21) with a high level of precision is necessary to ensure the mesopic pupil size measurement is reliable for selecting OZ size in LASIK. In this present study, Placido-disc topographer provided

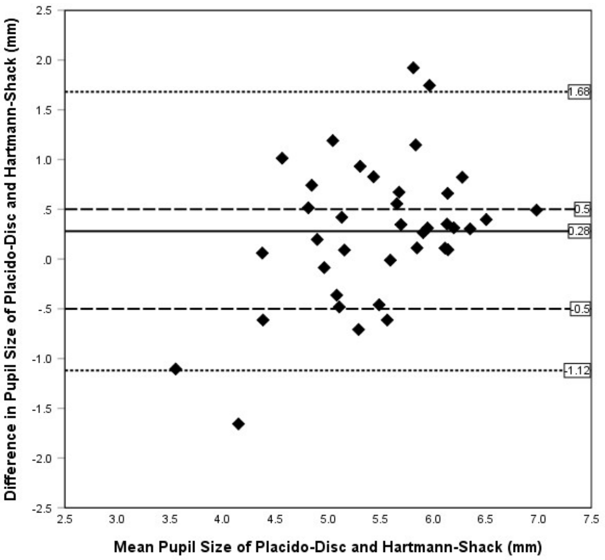

Figure 1: Bland-Altman analysis of inter-device agreement in mesopic pupillometry between Placido-disc topographer and Hartmann-Shack aberrometer. Solid line = mean difference; dashed lines = ±0.5 mm; dotted lines = lower/upper 95% limits of agreement

repeatable and reproducible mesopic pupillometry. Good repeatability was reported on other models of Placido-disc topographer (Technomed C-Scan; Humphrey Masterview; Alcon EyeMap) (27), but the methodology was not clearly described. Repeatability and reproducibility must be assessed in order to determine the precision of measurement (9). To the best of our knowledge, there was a study conducted on the repeatability of the topographers' pupillometry function (27), but the issue of reproducibility was not addressed. Reproducibility is crucial to ensure that the pupillometry device used in clinical practice provides a reliable result even after the measurements were repeated by different operators or at different sessions (22). This present study provides important additional information on the precision of a Placido-disc topographer (the Atlas 9000) in providing inter-operator reproducible result measuring mesopic pupil size.

Hartmann-Shack aberrometer in the present study revealed better repeatability and reproducibility in mesopic pupillometry. Previous studies conducted using the WaveScan aberrometer (11) and the WASCA aberrometer (28) also reported highly repeatable and reproducible results in measuring pupil size. Nevertheless, both of the studies were conducted in the scotopic condition (11,28). A study on pupillometry measurement in mesopic illumination (0.5 to 0.6 lux) reported low inter-operator reproducibility result using the Zywave Hartmann-Shack aberrometer (29). This discrepancy might be due to the Zywave's measurement algorithms in pupillometry function differs from the WASCA. Thus, even when both devices use the same technology, the reliability of the measurement produced is not congruent. Research on the measurement validity of each device is therefore warranted.

Both devices in this present study produced good repeatability and reproducibility results. However, Hartmann-Shack aberrometer provided higher repeatability and reproducibility than Placido-disc topographer in measuring mesopic pupil size with lower precision limits and CoV. Most of the repeated measurements using Hartmann-Shack aberrometer were within ±0.5 mm intra-session and inter-operator. Hartmann-Shack aberrometer is relatively easier to perform by aligning and focusing a reference box with the two measurement points, and the measurement completed in 13 ms. Placido-disc topographer needs adjustment of 22-concentric Placido-disc rings into optimum focus and the duration varies according to the experience of the operator. Hartmann-Shack aberrometer is by far a user-friendly device, faster and provides significantly better precision in terms of repeatability and reproducibility in mesopic pupillometry.

In terms of inter-device agreement, Placido-disc topographer and Hartmann-Shack aberrometer revealed a low agreement in measuring mesopic pupil size. Hartmann-Shack aberrometer underestimated mesopic pupillometry of Placido-disc topographer even when the internal illumination during measurement in Hartmann-Shack aberrometer was lower (4.8 lux versus 16.8 lux). Theoretically, dimmer illumination causes larger pupillary size in physiological condition (6,30). This underestimation is most probably influenced by higher induced accommodative-miotic due to shorter working distance (distance from the LED fixation target to the corneal plane of the subject's eye). The working distance for Hartmann-Shack aberrometer is approximately 5 cm, whereby for Placido-disc topographer is about 11 cm. Apart from the potential accommodation miosis reflex, the difference in the optical fogging system and the algorithm of both devices software in interpreting edge of the pupil may also contribute to this disagreement (11,21).

In this present study, comprehensive statistical analyses and strategies were employed in assessing the precision of pupillometry. These statistical analyses comprise the S_r, S_R, r, and R which are recommended to evaluate the precision of any diagnostic devices used in optometry and ophthalmology (22,24). Beyond that, the utilisation of the CoV and ICC which are commonly used in ocular biometric precision studies were also performed (15). We believe that this has strengthened our analysis of the clinical difference in pupil size measurement (4,12,20).

These are possible limitations of this study. This present study limited the pupillary measurement for LASIK refractive correction between -3.25 and -9.25 D. Yuen et al. (31) reported that the majority of LASIK patients had preoperative manifest spherical equivalent within this range. Thus, our findings may not be accurate for lower (≥ -3 D) or higher (≤ -9.5 D) myopes. Since our sample size calculation is based on the total number rather than specific age groups, no presbyopic age subject was recruited. Therefore, this present study could not provide any information on the repeatability and reproducibility of both devices on the effect of age in pupillary size.

CONCLUSION

Hartmann-Shack aberrometer has higher precision in mesopic pupillometry during LASIK preoperative assessment. The smaller pupillometry revealed in Hartmann-Shack aberrometer than in Placido-disc topographer may highlight that the device working distance, optical fogging system and software algorithm had a higher influence than internal illumination. Precise pupil size measurement in low ambient could help refractive surgeons to plan an appropriate ablation OZ, therefore minimising the spherical aberration and improving the contrast sensitivity.

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