

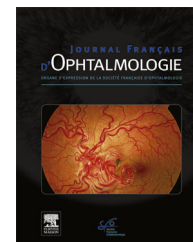


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ORIGINAL ARTICLE

# Effect of pharmacological pupil dilation on measurements and iol power calculation made using the new swept-source optical coherence tomography-based optical biometer

*Effet de la dilatation pharmacologique de la pupille sur les mesures biométriques et la prédiction de l'implant intraoculaire avec le nouveau biomètre optique basé sur la tomographie par cohérence optique swept-source*

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## KEYWORDS

Swept source optical coherence tomography;

## Summary

**Purpose.** – To determine whether pupil dilation affects biometric measurements and intraocular lens (IOL) power calculation made using the new swept-source optical coherence tomography-based optical biometer (IOLMaster 700®; Carl Zeiss Meditec, Jena, Germany).

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Pupil dilation;  
Biometry;  
Cataract;  
IOLMaster 700®

**Procedures.** — Eighty-one eyes of 81 patients evaluated for cataract surgery were prospectively examined using the IOLMaster 700® before and after pupil dilation with tropicamide 1%. The measurements made were: axial length (AL), central corneal thickness (CCT), aqueous chamber depth (ACD), lens thickness (LT), mean keratometry (MK), white-to-white distance (WTW) and pupil diameter (PD). Holladay II and SRK/T formulas were used to calculate IOL power. Agreement between measurement modes (with and without dilation) was assessed through intraclass correlation coefficients (ICC) and Bland-Altman plots.

**Results.** — Mean patient age was  $75.17 \pm 7.54$  years (range: 57–92). Of the variables determined, CCT, ACD, LT and WTW varied significantly according to pupil dilation. Excellent intraobserver correlation was observed between measurements made before and after pupil dilation. Mean IOL power calculation using the Holladay 2 and SRK/T formulas were unmodified by pupil dilation.

**Conclusions.** — The use of pupil dilation produces statistical yet not clinically significant differences in some IOLMaster 700® measurements. However, it does not affect mean IOL power calculation.

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## MOTS CLÉS

Cohérence optique  
*swept-source* ;  
Dilatation pupillaire ;  
Biométrie ;  
Cataracte ;  
IOLMaster 700®

## Résumé

**Propos.** — Déterminer si la dilatation pupillaire modifie les mesures biométriques et le calcul de la puissance de l'implant intraoculaire obtenus avec un nouveau biomètre optique basé sur la tomographie par cohérence optique *swept-source* (IOLMaster 700® ; Carl Zeiss Meditec, Jena, Allemagne)

**Méthodes.** — Nous avons évalué prospectivement 81 yeux de 81 patients prévus pour la chirurgie de la cataracte au moyen du biomètre IOLMaster 700®, avant et après dilatation pupillaire avec tropicamide 1 %. Les mesures réalisées ont été : longueur axiale (AL), épaisseur cornéenne centrale (CCT), profondeur de la chambre antérieure (épaisseur cornéenne exclue) (ACD), épaisseur cristallinienne (LT), kératométrie moyenne (MK), distance blanc à blanc (WTW) et diamètre pupillaire (PD). Les formules Holladay II et SRK/T ont été employées pour calculer la puissance de l'implant intraoculaire. Nous avons évalué la concordance entre les deux méthodes de mesure (sous dilatation pupillaire et sans) au moyen des coefficients de corrélation intraclass (ICC) et des graphiques de Bland-Altman.

**Résultats.** — La moyenne d'âge des patients était de  $75,17 \pm 7,54$  ans (intervalle : 57–92). Parmi les variables mesurées, la CCT, l'ACD, la LT et la WTW montraient des variations significatives en fonction de la dilatation pupillaire. On a observé une excellente corrélation intra-observateur entre les mesures réalisées avant et après la dilatation pupillaire. Celle-ci ne modifiait pas la prédiction de la puissance moyenne de l'implant avec Holladay 2 et SRK/T.

**Conclusions.** — L'emploi de tropicamide 1 % produit des différences significatives du point de vue statistique mais pas clinique sur certaines mesures réalisées avec IOLMaster 700®. Cependant, la mesure de la puissance moyenne de l'implant intraoculaire n'est pas affectée.

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## Introduction

The success of cataract surgery depends on many factors, one of the most important being accurate calculation of intraocular lens (IOL) power [1]. Three main measurements are used for IOL calculation: axial length (AL), anterior chamber depth (ACD) and corneal power. In addition, some fourth generation formulas such as Holladay 2, also requires lens thickness (LT) and white-to-white distance (WTW). AL and ACD are normally determined through ultrasound or optical biometry. Currently used optical methods include the IOLMaster 500® (Carl Zeiss Meditec AG, Jena, Germany)

based on partial coherence interferometry, the LENSTAR 900® (Haag-Streit AG, Koeniz, Switzerland), which uses optical low-coherence reflectometry (OLCR) powered by a superluminescent diode (SLD) and the newly developed IOLMaster 700® (Carl Zeiss Meditec AG, Jena, Germany) based on Swept Source optical coherence tomography (SS-OCT) technology. For more than 15 years, the IOLMaster 500® has been the benchmark for optical biometry measurements, offering high precision and good resolution for axial length (AL), anterior chamber depth (ACD) and corneal curvature [2]. Moreover, the LENSTAR®, which also measures lens thickness (LT) and central corneal thickness (CCT), has

shown good reproducibility [3] and good correlation with the IOLMaster 500<sup>®</sup> [4]. The new IOLMaster 700<sup>®</sup>, the first SS-OCT-based biometer, has so far shown excellent repeatability and reproducibility, along with very high agreement with the IOLMaster 500<sup>®</sup> [5].

The effects of pupil dilation on optical biometry measurements have been fairly well established. Thus according to several reports, pharmacological mydriasis does not seem to significantly affect IOLmaster 500<sup>®</sup> measurements and IOL predictions [6–8] and similar results have been reported for LENSTAR<sup>®</sup> [9,10].

To the best of our knowledge, no studies have hitherto studied the effect of pupil dilation on the accuracy of IOLMaster 700<sup>®</sup> measurements.

The purpose of the current study was to determine the influence of pharmacological pupil dilation on measurements using the new IOLMaster 700<sup>®</sup>. To determine the clinical significance of possible differences in measurements, we also calculated IOL powers.

## Patients and methods

The subjects for this randomized diagnostic technology evaluation study were consecutively recruited among patients scheduled for cataract surgery at our department. The inclusion criterion was age-related cataract (including mild cataract). Exclusion criteria were prior eye surgery, an active ocular pathology such as uveitis or retinal degeneration and inability to fixate because of an eye disease and prior contact lens use. When both eyes met these criteria, only the right eye was included into the study, because measurements will be more similar between fellow eyes than individuals [11]. The study protocol adhered to the tenets of the Declaration of Helsinki and Spanish legislation and was approved by our Institutional Clinical Research Ethics Committee. Before recruitment, written legally-binding informed consent was obtained from each patient.

After a brief biomicroscopy examination without instillation of drops to confirm the diagnosis of cataract, non-contact biometric measurements were obtained in all participants using the IOLMaster 700<sup>®</sup>. Subjects were tested between 8 am and 3 pm in a small, diffusely lit office which was centrally heated to a temperature of 21 °C to 25 °C. There were no ventilation ducts over the equipment. Subjects were asked to blink just before measurements so that the tear film over the cornea would be optically smooth. IOLMaster 700<sup>®</sup> measurements were only accepted when validated by the device's inbuilt quality test. The data recorded were AL, CCT, ACD (aqueous chamber depth, measured as endothelium to lens distance), LT, mean keratometry (MK), WTW and pupil diameter (PD). Next, all patients underwent a full ophthalmic examination including Snellen visual acuity, complete slit-lamp biomicroscopy and Goldmann applanation tonometry. The pupil was then dilated using tropicamide 1% (Tropicamida, Alcon Cusi, Barcelona, Spain) and a fundus examination performed. After fundoscopy, the patients were once again subjected to the same IOLMaster 700<sup>®</sup> procedure as before dilation and the same data were recorded. Both examinations were performed for each participant by the same examiner.

The IOL power required for emmetropia using an A-constant of 118.0 with the Holladay 2 and SRK/T IOL formulas was calculated after the examination.

For a descriptive statistical analysis, we used Excel 2011 (Microsoft Corp. Redmond, WA, USA) with SPSS software (version 18.0, SPSS Inc.). Results are shown as mean  $\pm$  standard deviation (SD). Significance was set at  $P \leq 0.05$ . Data were compared using a paired-sample *t* test. Consistency between pre- and post dilation measurements was assessed through intraclass correlation coefficients (ICC) at the 95% confidence level. Bland-Altman plots were also constructed to compare the two sets of measurements [12]. We also calculated proportions of main measurement differences falling within the clinically acceptable ranges defined by Jasvinder et al. [13]: IOL power within 1 diopter (D), 1D to 2D or more than 2D; AL within 0.33 mm or 0.10 mm; and MK within 1D or 0.5D. Ninety-five percent limits of agreement for each measurement were computed as the mean  $\pm$  2 SD of the difference between pre- and post dilation values.

## Results

The study sample was comprised of 81 eyes of 81 patients (52 women) of mean age  $75.17 \pm 7.54$  years (range: 57–92). In 71 (86.6%) participants, the eye examined was the right eye.

Of the data determined (Table 1), CCT, ACD, LT and WTW differed significantly before and after pupil dilation (Table 2). Good correlation was indicated by the ICC (Table 2) for all the variables. The IOL power prediction data are provided in Table 3. No statistical differences were detected in IOL power predictions based on pre- and post dilation measurements (Table 4). Agreement between both IOL formulas was excellent.

The Bland-Altman plots illustrate post dilation measurement differences and the differences in IOL power calculated using both formulas (Fig. 1), along with the 95% LoA.

Measurement differences were all clinically acceptable: AL was within 0.33 mm in all eyes and within 0.10 mm in 77 eyes (95.06%); and MK was within 0.5D in 77 eyes (95.06%) and within 1D in 80 eyes (98.76%). Finally, IOL powers

**Table 1** IOLMaster 700<sup>®</sup> measurements (means  $\pm$  SD) made before and after pupil dilation.

Variable	No dilation	Dilation
AL/mm	23.526 $\pm$ 1.66	23.523 $\pm$ 1.66
CCT/ $\mu$ m	544.06 $\pm$ 35.92	546.47 $\pm$ 35.94
ACD/mm	2.531 $\pm$ 0.38	2.58 $\pm$ 0.39
LT/mm	4.717 $\pm$ 0.42	4.706 $\pm$ 0.42
[K]/D	44.351 $\pm$ 1.52	44.344 $\pm$ 1.51
WTW/mm	11.847 $\pm$ 0.39	11.879 $\pm$ 0.4
PD/mm	3.765 $\pm$ 0.91	6.458 $\pm$ 0.73

AL: axial length; CCT: central corneal thickness; ACD: anterior chamber depth; LT: lens thickness; [K]: mean keratometry; D: diopters; WTW: white-to-white distance; PD: pupil diameter.

**Table 2** Agreement between measurements made before and after pupil dilation.

Variable	Mean difference	P	ICC	CI (95%)	95% LoA	
					Lower	Upper
AL/mm	0.0032 ± 0.034	0.398	1	1–1	–0.0648	0.0712
CCT/μm	–2.407 ± 8.84	0.016	0.968	0.951–0.979	–20.087	15.273
ACD/mm	–0.048 ± 0.031	<0.001	0.989	0.983–0.993	–0.11	0.014
LT/mm	0.0109 ± 0.018	<0.001	0.999	0.998–0.999	–0.0251	0.0469
MK/D	0.0075 ± 0.223	0.762	0.989	0.983–0.993	–0.4385	0.4535
WTW/mm	–0.032 ± 0.115	0.014	0.956	0.932–0.971	–0.262	0.1471

ICC: intraclass correlation coefficient; CI: confidence interval; LoA: limits of agreement; AL: axial length; CCT: central corneal thickness; ACD: endothelium to lens distance; LT: lens thickness; MK: mean keratometry; WTW: white-to-white distance.

**Table 3** Mean of IOL power predictions (in diopters) before and after pupil dilation.

Formula	No dilation	Dilation
Holladay 2	19.07 ± 4.49	19.05 ± 4.45
SRK/T	19.27 ± 4.51	19.29 ± 4.49

calculated with the SRK/T formula were all within 1D, while only in four eyes (4.94%) predicted lens power using the Holladay 2 formula differed by 1D to 2D.

## Discussion

The results of our study indicate that pupil dilation affect some IOLMaster 700<sup>®</sup> measurements. Given the established excellent intraobserver repeatability of the IOLMaster 700<sup>®</sup> [5], we can assume that the differences observed were attributable to pupil dilation. Notwithstanding, these statistical differences were clinically insignificant since IOL power predictions were unaffected. Only in four IOL power predictions (with the Holladay 2 formula) did the difference exceed 1D. In addition, there was excellent agreement in all measurements before and after pupil dilation and ICCs were higher than 0.95 for all variables.

In three studies examining the effect of pupil dilation in IOLMaster 500<sup>®</sup> measurements [6–8], no effects were observed on AL and only one study reported a significant difference in pre- and post dilation MK data [6]. In addition, in the only one study in which the ACD was measured, this variable was found to increase after pupil dilation. Two further studies have also addressed the influence of pupil dilation

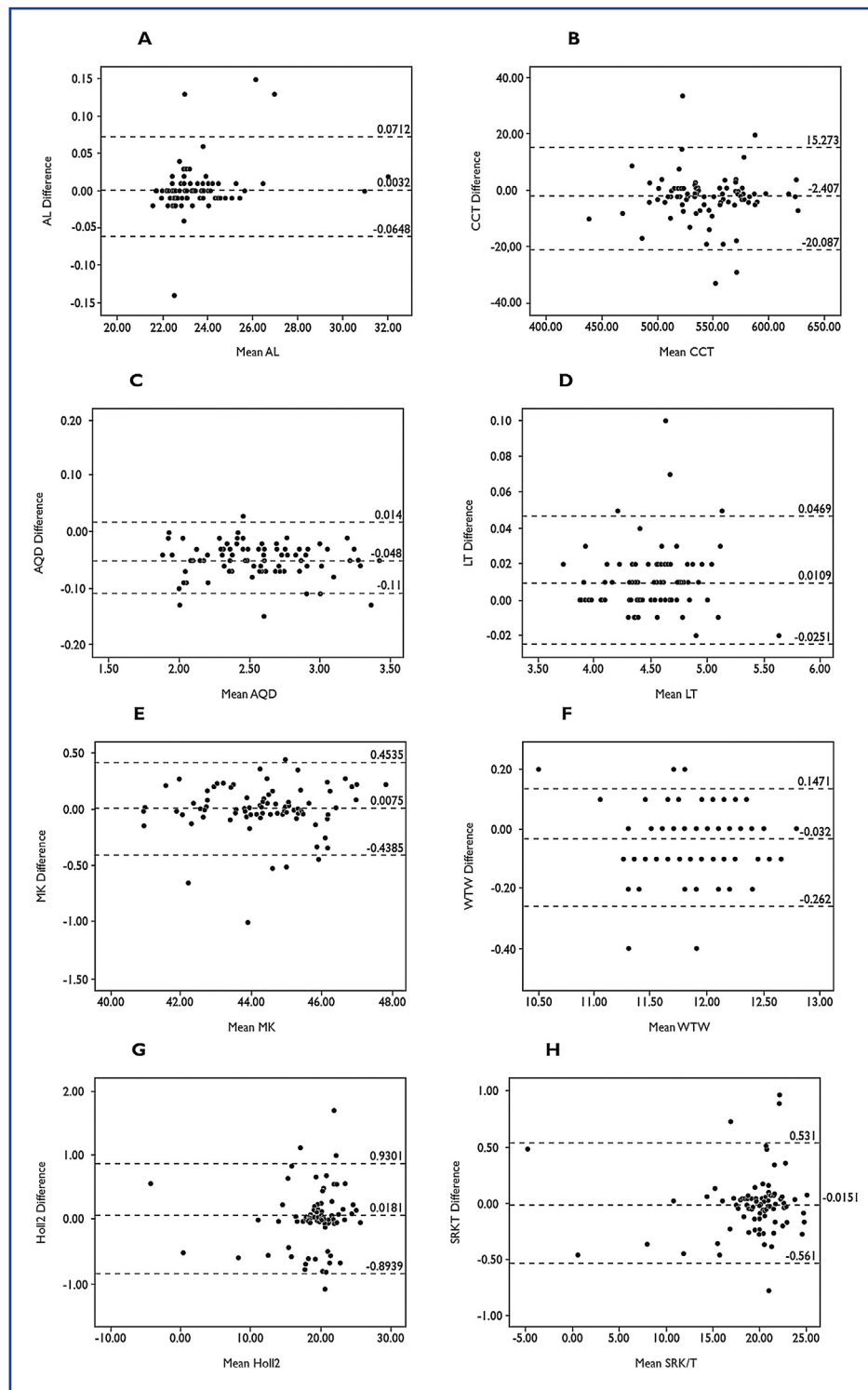
on the accuracy of LENSTAR<sup>®</sup> measurements [9,10]. These investigations detected no significant differences in AL or MK data, whereas both studies found that ACD was significantly greater in response to pupil dilation. Other variables, such as LT, CCT or WTW, were not significantly modified after pupil dilation [10].

The findings of the present study are fairly consistent with data on the effects of pupil dilation reported for other optical biometry devices. Thus, no significant change in AL is produced in response to pupil dilation using both the IOLMaster 500<sup>®</sup> and LENSTAR<sup>®</sup> [6–10]. The slight, though significant, increase in CCT observed in our study is consistent with the findings of other authors, who noted significant increases in CCT after pupil dilation with tropicamide eye drops [14,15]. No clear cause was identified for this effect. A deeper anterior chamber after pupil dilation has been described for the IOLMaster 500<sup>®</sup> [8] and LENSTAR<sup>®</sup> [9,10]. This deepening of the anterior chamber seems to be secondary to a widening of the anterior chamber angle, as reported previously in one study which evaluated the effect of tropicamide 1% on anterior segment geometry with ultrasound biomicroscopy [16]. Significant LT changes have been attributed to accommodation [17], but not to the use of tropicamide 1% [16]. The cause of the thinner LT after pupil dilation found in the present study is unknown, but maybe secondary to the rearward movement of the iris plane due to the anterior chamber angle widening. Although, the significant decrease in LT of 11 microns observed in our study is clinically insignificant. In the only study in which a change in MK measured by optical biometry was detected after pupil dilation, the authors attributed this to chance [6]. Effectively, other optical biometry studies have revealed no change in corneal curvature after pupil dilation [7–10] and

**Table 4** Agreement between predicted IOL power (in diopters) based on measurements made before and after pupil dilation.

Formula	Mean difference	P	ICC	CI (95%)	95% LoA	
					Lower	Upper
Holladay 2	0.0181 ± 0.456	0.721	0.995	0.992–0.997	–0.8939	0.9301
SRK/T	–0.0151 ± 0.273	0.618	0.998	0.997–0.999	–0.561	0.531

ICC: intraclass correlation coefficient; CI: confidence interval; LoA: limits of agreement.



**Figure 1.** Bland-Altman plots showing agreement between measurements taken with the IOLmaster 700<sup>®</sup> before and after pharmacological pupil dilation. The middle line shows the mean difference and the bottom and top lines indicate the lower and upper 95% limits of agreement, respectively. A: AL measurements; B: CCT measurements; C: ACD measurements; D: LT measurements; E: MK measurements; F: WTW measurements; G: IOL power calculated with the Holladay 2 formula, and H: IOL power calculated with the SRK/T formula. (AL: axial length; CCT: central corneal thickness; ACD: endothelium to lens distance; LT: lens thickness; MK: mean keratometry; D: diopters; WTW: white-to-white distance; PD: pupil diameter; IOL: intraocular lens).



this lack of effect was also reported for two different corneal topography systems [15,18]. In our study, a slight but significant increase after pupil dilation was also produced in the WTW distance. We attribute this to the variability of the measurement process itself.

Excellent agreement was detected here between pre- and post dilation measurements, with similar results to those observed in interoperator repeatability measurements [5].

The accurate determination of AL and MK is crucial for IOL power calculation [19]. For this purpose, most ophthalmologists use third-generation IOL formulas, and the SRK/T [20] is probably the most widely used today for IOL prediction. This formula uses AL and corneal curvature to estimate the effective lens position (ELP). Thus, errors in AL or MK may easily give rise to unexpected refractive errors. Our results indicate that pupil dilation does not significantly affect SRK/T IOL calculation using the IOLMaster 700°. This was expected because of the high agreement between pre- and post dilation AL and MK measurements observed. In addition, predicted IOL power calculated with the SRK/T formula was within 1D in all eyes and within 0.5D to 1D in only five eyes (6.17%) (Fig. 1). Worst agreement was reported for the IOLMaster 500° [6] in that predicted IOL power varied by 0.5D to 1D in 12% of eyes and was within 1D and 2D in 4% after pupil dilation. Similarly, 9.1% of the eyes in one of the LENSTAR° studies [9] showed differences in IOL power calculated with the SRK/T formula from 0.5D to 1D. However, in the other report [10], results were similar to those of the present study, in which no eyes showed a calculated IOL power difference above 1D and only 6.94% of the eyes returned a power calculation within 0.5D to 1D using the SRK/T IOL formula.

The newer fourth-generation IOL formulas such as Holladay 2 [21] or Olsen et al. [22], besides AL and MK, consider other variables provided by the IOLMaster 700°, like ACD (epithelium to lens distance), LT and WTW, for ELP estimation. We observed significant differences in these three variables after pupil dilation. Despite this, mean IOL power calculated with the Holladay 2 formula was significantly unaffected by pupil dilation, with the exception of four eyes (4.94%), which showed a difference of 1D to 2D, and 22 eyes (27.16%) with a value within 0.5D to 1D. These results are quite different to those obtained with the SRK/T formula based only in two ocular measurements, which did not change significantly with pupil dilation. In contrast, significant effects of dilation were produced on some of the other ocular variables included in the Holladay 2 IOL formula. Although the difference in mean theoretical IOL power was smaller than 0.02D, this could have affected the IOL chosen for implantation in almost one third of patients. The real impact on final refractive error after cataract surgery would, nevertheless, be small. The effects of pupil dilatation on IOL power predictions using the Holladay 2 formula for the IOLMaster 500° have not been examined. In one such study for LENSTAR° [10], 8.33% of the eyes showed predicted lens power with differences higher than 0.5D after pupil dilation.

There are some limitations to our study. First of all, our sample did not include short eyes (<21.5 mm) for which different results might be expected. In addition, patients with active ocular diseases as well as macular diseases were excluded, so results are not representative of all cataract

patients. Finally, the lack of repeatability tests and a control group could be a drawback, though the repeatability of IOLMaster 700° measurements has been shown to be excellent [5].

The participants of this study were recruited from a continuous cohort. As inclusion criteria were not strict, they represent, as far as possible, patients examined in routine clinical practice. Thus, we did not restrict comparisons to patients with the same degree of cataract severity or adjust for potential effects of age or gender.

In conclusion, given the need for pharmacological pupil dilation in any preoperative ophthalmic examination, the effects of this factor on measurements made using an optical biometry device need to be well established. Our finding indicate we can expect no significant impact of pupil dilation on IOL power predictions based on IOLMaster 700° measurements.

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## Disclosure of interest

The authors declare that they have no competing interest.

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