

# Effect of Face Mask on the Intraocular Lens Calculation in Patients Undergoing Cataract Surgery

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## Abstract

**Purpose:** To evaluate whether the use of face masks produces an alteration in the intraocular lens (IOL) calculation in patients undergoing cataract surgery.

**Methods:** A cross-sectional study including patients derived for cataract surgery was conducted over a period of three months during the coronavirus disease 2019 (COVID-19) pandemic. Biometric measurements were taken using IOLMaster 700 optical device (Carl Zeiss Meditec AG, Jena, Germany). Four measurements were taken in each patient: two initial measurements with the face mask and two additional measurements after 10 minutes without wearing the mask.

**Results:** A total of 58 eyes of 29 subjects were included in the study with a mean age of  $70.2 \pm 10.5$  years and 16 individuals being female (55%). Mask wear did not show statistically significant differences in biometric values and IOL power calculation compared to the measurements obtained without using the mask for all the parameters ( $p \geq 0.05$ ). Dahlberg's error was usually close to 0, coefficient of variation (CV) did not exceed 1% and intraclass correlation coefficient (ICC) was close to 1 in all cases.

**Conclusions:** There is a high degree of concordance between biometric measurements taken with and without the face mask, so no differences were observed in the estimated IOL power calculation. However, it is advisable to analyse each case individually and prescribe appropriate topical treatment if there are ocular surface symptoms related to mask use.

**Keywords:** Face mask; Dry eye; COVID-19; Biometry; Coronavirus Disease

**Abbreviations:** IOL: Intraocular lens; COVID-19: Coronavirus Disease 2019; CV: Coefficient Of Variation; ICC: Intraclass Correlation Coefficient; MADE: Mask-Associated Dry Eye; D: Diopters; AXL: Axial Length; DED: Dry Eye Disease; SD: Standard Deviation; CCT: central corneal thickness; WTW: White-To-White; IOLP: Intraocular Lens Power; K1: Keratometric Power in the Flattest Meridian; K2: Keratometric Power in the Steepest Meridian; ACD: Anterior Chamber Depth; OSD: Ocular Surface Disease.

## Introduction

During the COVID-19 pandemic, the concern for reducing disease transmission led to changes in human habits, such as the widespread use of face masks [1-3]. While essential for preventing coronavirus transmission, masks also caused ocular surface changes. The tear film is a crucial barrier against pathogen invasion, but it can be compromised by mask use. There have been several reports describing ocular irritation and dryness derived from its use, which have described this condition as mask-associated dry eye (MADE) [4-7]. The exhaled air escaping upward

from the edge of the mask stimulates tear film evaporation, which may lead to discomfort, inflammation and dry eye symptoms [5,8].

With the recent advances in modern optical instrument technologies and IOL design, cataract surgery is no longer a matter of replacing the natural lens with an IOL. Nowadays, patients have higher expectations for accurate refractive outcomes and excellent quality of vision after surgery. However, according to some studies, refractive errors of  $\pm 0.5$  diopters (D) or greater occur in 20% to 40% of cataract surgery cases [9-12]. Ocular biometry

for IOL power calculations has become increasingly important in clinical practice to achieve preoperatively intended outcomes. Keratometry and axial length (AXL) are the main parameters for IOL power calculations.

IOLMaster 700 is a non-contact biometric device based on scanning source optical coherence interferometry. Although this instrument is considered the gold standard in calculating IOL for cataract surgery [13-15], some studies have shown that an unstable tear film can produce optical aberrations, reducing the accuracy and repeatability of biometric measurements [16,17]. Inaccurate keratometric measurements lead to residual refractive errors, since the cornea is the largest refractive component of the eye, contributing 70% of its refractive power. Therefore, tear film stability is a fundamental factor in obtaining biometric measurements for calculating IOL power.

The repeatability of keratometric and anterior segment measurements has been studied and demonstrated with different devices in normal eyes and in patients with dry eye disease (DED) [16,18-20]. In individuals suffering from DED, the cornea has an irregular surface, measurements may not be as valid or reproducible, and there are no repeatability studies in association with mask wearing. During the biometric calculation in the COVID-19 period, patients did not remove their masks, and we do not know the impact this may have on IOL power calculation and the resulting refractive surprise.

## Materials and Methods

### Participant Selection and Recruitment

This cross-sectional study was conducted at Fundacion de Oftalmologia Medica de la Comunidad Valenciana (FOM, Valencia, Spain). Cataract patients that met inclusion/exclusion criteria were recruited over a three-month period during the COVID-19 pandemic. Written informed consent was obtained from all the patients, and they had the approval of the Clinical Research Ethics Committee at the previously mentioned hospital. The study was performed in accordance with the tenets of the Declaration of Helsinki. Inclusion criteria were individuals over 18 years old scheduled for cataract surgery for whom IOL Master 700 biometry could be performed.

Exclusion criteria were patients under 18 years old, contact lens use in the previous 7 days, prior eye surgeries, chronic dry eye treatment in the previous 14 days, ocular inflammation, allergic conjunctivitis, active eye infection, lens opacity preventing measurements with the IOL Master 700 biometer, chronic glaucoma treatment and extreme refractive errors (High myopia with AXL > 26 mm and/or > 6 D, hyperopia > 5 D, astigmatism > 3 D). The medical records of the patients were thoroughly revised to identify the selection criteria.

### Study Development

The patient's age, sex, ophthalmological history and topical

treatment were noted. Every patient underwent an ophthalmic examination including best-corrected visual acuity and slit-lamp biomicroscopy to confirm the inclusion and exclusion criteria. Biometry for IOL calculation was performed on all patients in the study using the same IOLMaster 700 optical biometer (Carl Zeiss Meditec AG, Jena, Germany). Each patient's measurements were taken at two different times: at first stage with the patient wearing a surgical face mask and in a second time without the mask. Two consecutive biometric measurements were taken on each eye included in the study with the mask properly positioned, and once patients confirmed to have been wearing the mask for at least 30 minutes before the examination.

After these measurements, patients went to an internal hall where they remained for 10 minutes without the face mask. Chairs were placed in this space for the patients, maintaining social distancing and ensuring that all safety measures were followed. Once the 10-minute rest period without the surgical face mask had elapsed, the patient was called back to consultation room to repeat the two consecutive biometric measurements without the face mask. Testing was conducted under the same temperature (20°C) and humidity (40-50%) conditions, which were verified with a thermometer and hygrometer.

### Sample Size Calculation

The sample size calculation was performed using GRANMO (7.2 software, Barcelona, Spain). Considering paired means (repeated within one group) and accepting an alpha risk of 0.05 and a beta risk of 0.2 in a two-tailed test, 23 subjects are required to detect a difference equal to or greater than 0.3 units. A standard deviation (SD) of 0.5 between measurements is assumed. A loss-to-follow-up rate of 5%, a 95% confidence level, and a precision of 5% were estimated.

### Statistical Analysis

Statistical analysis was performed using SPSS v23.0 (Armonk, NY, USA). First, the repeatability of measurements with and without the face mask was studied using Dahlberg's error, the CV, and the ICC, as well as a descriptive of the mean difference between the two measurements. Second, the concordance between the two methods (with and without the face mask) was evaluated. The statistical indices were calculated. Given the large sample size, a parametric approach was used.

A repeated measures t-test was applied to assess the existence of possible bias between the measurements. To complete the concordance analysis, the results obtained with each pair of methods were compared using regression models. This allowed visualization of the presence and linearity of bias, as well as the variability of the measurements. 95% confidence intervals were estimated for the coefficients, and their compatibility with the concordance hypothesis was examined. The significance level used in the analyses was 5% ( $\alpha=0.05$ ).

**Results**

A total of 58 eyes of 29 subjects were included in the study with a mean age of 70.2 ± 10.5 years and 16 individuals being female (55%). Each eye underwent 4 measurements (2 with surgical face

mask and 2 with no mask use). Overall, measurements taken with and without the face mask showed a high degree of concordance in our study, with no significant differences observed between them.

**Analysis of Measurement Repeatability with Face Mask**

**Table 1:** Measurement difference, 95% confidence interval, t-test for dependent samples (p-value) and estimators of intra-examiner error of the method for the measurements of the parameters with face mask: Dahlberg’s d, CV and ICC.

	Difference 1 <sup>st</sup> -2 <sup>nd</sup> measurement		95% confidence Interval for the difference		p-value	Dahlberg’s d	CV (%)	ICC
	Mean	SD	Low. lim.	Sup. Lim.				
K1	0,038	0,173	-0,007	0,083	0,100	0,124	0,287	0,991
K2	0,023	0,200	-0,030	0,075	0,393	0,141	0,321	0,990
AXL	-0,006	0,022	-0,011	0,000	0,049*	0,016	0,067	0,999
ACD	-0,001	0,014	-0,004	0,003	0,701	0,010	0,306	0,999
LT	0,000	0,014	-0,004	0,004	1,000	0,010	0,211	0,999
WTW	-0,021	0,144	-0,058	0,017	0,277	0,102	0,842	0,919
CCT	0,328	6,281	-1,324	1,979	0,693	4,409	0,806	0,990
IOLP	0,017	0,280	-0,056	0,091	0,641	0,197	0,897	0,992

K1 = keratometric power in the flattest meridian; K2 = keratometric power in the steepest meridian; AXL = axial length; ACD = anterior chamber depth; LT = lens thickness; WTW= white-to-white; CCT = central corneal thickness, IOLP = intraocular lens power; CV= coefficient of variation; ICC = intraclass correlation coefficient; SD = standard deviation. \*p<0,05; \*\*p<0,01; \*\*\*p<0,001.

Table 1 presents basic statistics for the difference between the two examiner measurements in the sample of 58 eyes, as well as those relating to the method error. Most of the means fall within the range of -0.05 to 0.05, so they are generally very close to 0. The difference for Central Corneal thickness (CCT) is the only one outside the range (0.328) and has the largest SD. This should be analyzed in perspective, as its scale is significantly larger than that of the other variables. All 95% confidence intervals include 0, which suggests that there are generally no differences between measurements.

When performing the student’s t-test for repeated measures, significance was reached by a narrow margin (p=0.049) for AXL. This suggests minimal bias, but despite this, the mean difference (-0.006) does not appear clinically relevant. The remaining statistics indicate that there are no overall problems for this variable. The table also shows Dahlberg’s d statistic, which typically takes values close to 0, except for CCT (4.41), where the scale appears to have a significant influence. This is an estimate of the absolute or technical measurement error. The values of Dahlberg’s d translate, in relative terms (when compared to the magnitude of what is being measured), into values for the method error (CV) that do not exceed 1%, indicating very high reproducibility.

Finally, the table provides the ICC, another indicator of the degree of concordance between the two assessments, which is highly sensitive to random (non-systematic) error. Values close to 1 were obtained, so reproducibility appears to be very good. The scatter plot for AXL, for which this minimal bias was detected, is shown below (Figure 1). A discordant data point is visible. Its simple exclusion ensures a non-significant mean difference. The next graph (Figure 2) shows that all 95% confidence intervals include 0. This indicates that there are no apparent differences between measurements. Due to the difference in magnitude between variables, CCT is not included, although its interval includes 0 (-1.324: 1.979).

**Analysis Of Measurement Repeatability Without the Face Mask**

Table 2 presents basic statistics for the difference between the two measurements without the face mask in the sample of 58 eyes, as well as those relating to the method error. The t-statistic revealed a slight statistical trend in CCT without the face mask (p = 0.064), but it does not appear to have clinical relevance. The Dahlberg’s error reaches 2.66 in CCT. When it is considered in relation to the magnitude of what is being measured, relative errors (CV) below 1% are obtained in all cases, which would be interpreted as very high reproducibility. The ICC values are

close to 1 in all cases, which is again interpreted as very high reproducibility. No systematic or random error pattern was detected in any case. Again, CCT was not included in the graph due

to differences in measurement scale, although it includes 0 in its 95% confidence interval (-0.054, 1.882) (Figures 3 and 4).

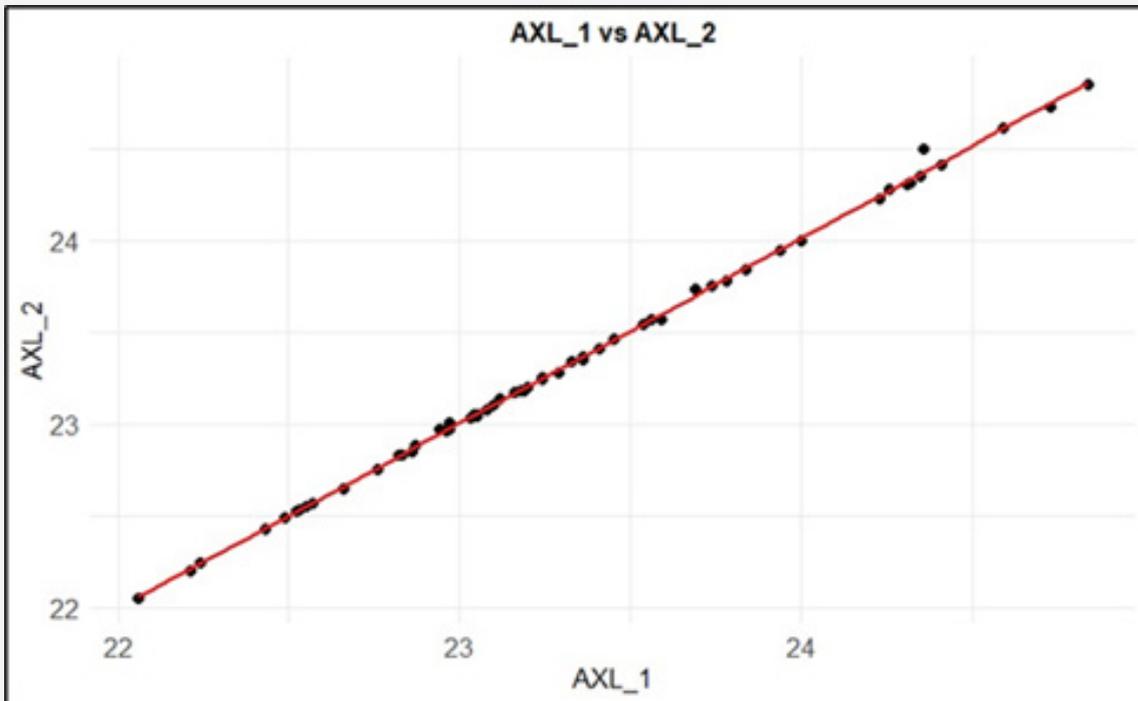


Figure 1: Scatter plot corresponding to axial length (AXL).

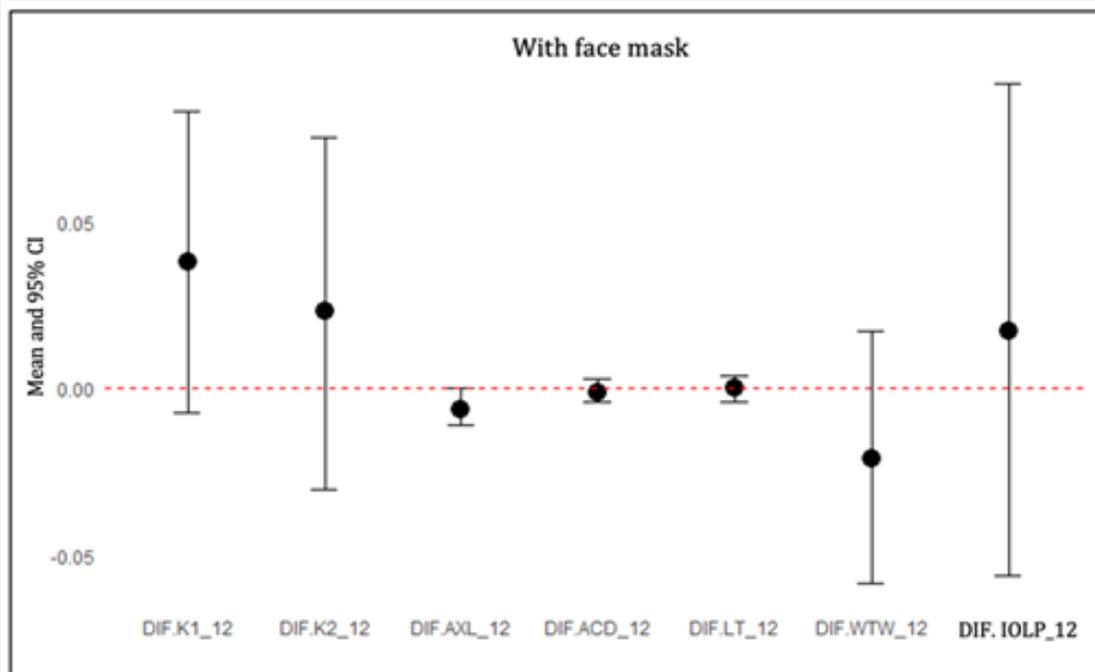
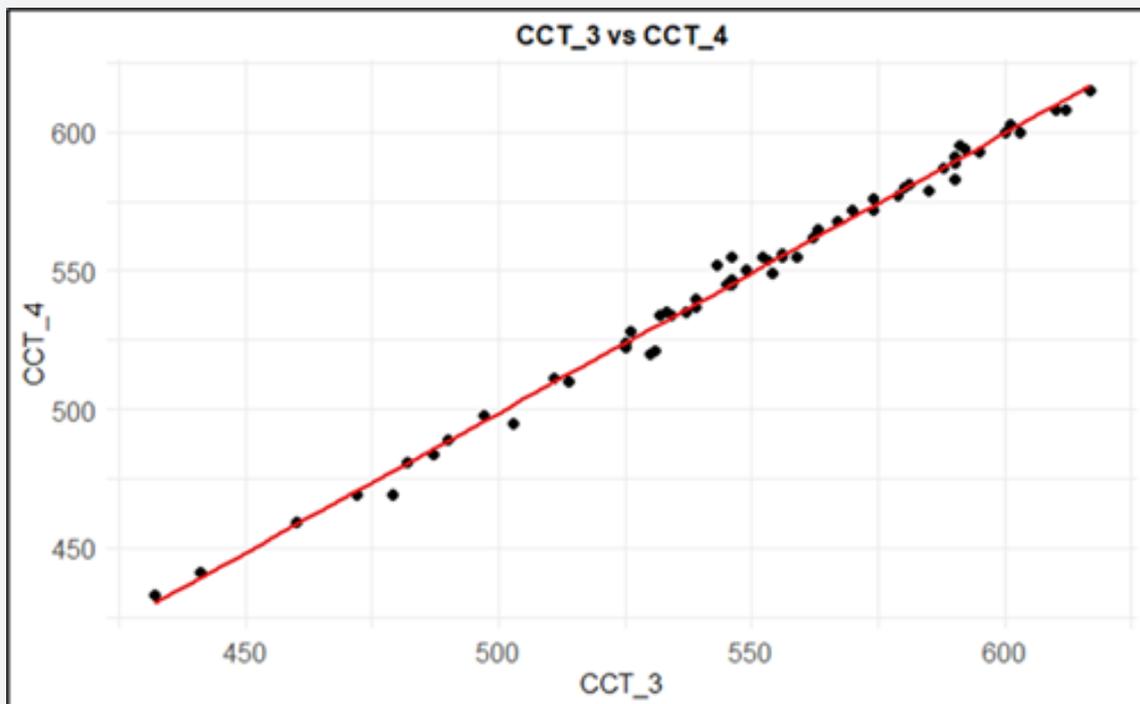


Figure 2: 95% confidence intervals (CI) of the different measurements with face mask.

**Table 2:** Measurement difference, 95% confidence interval, t-test for dependent samples (p-value) and estimators of intra-examiner error of the method for the measurements of the parameters without the face mask: Dahlberg's d, CV and ICC.

	Difference 1 <sup>st</sup> -2 <sup>nd</sup> measurement		95% confidence Interval for the difference		p-value	Dahlberg's d	CV (%)	ICC
	Mean	SD	Low. Lim.	Sup. Lim.				
K1	-0,051	0,260	-0,119	0,018	0,144	0,186	0,431	0,981
K2	0,003	0,152	-0,037	0,043	0,877	0,106	0,242	0,994
AXL	0,001	0,009	-0,001	0,004	0,311	0,006	0,027	1,000
ACD	0,002	0,016	-0,002	0,006	0,294	0,011	0,365	0,999
LT	0,000	0,010	-0,003	0,002	0,795	0,007	0,154	1,000
WTW	0,010	0,100	-0,016	0,037	0,436	0,071	0,586	0,961
CCT	0,914	3,682	-0,054	1,882	0,064	2,660	0,487	0,996
IOLP	0,017	0,280	-0,056	0,091	0,641	0,197	0,897	0,992

K1 = keratometric power in the flattest meridian; K2 = keratometric power in the steepest meridian; AXL = axial length; ACD = anterior chamber depth; LT = lens thickness; WTW= white-to-white; CCT = central corneal thickness, IOLP = intraocular lens power; CV = coefficient of variation; ICC = intraclass correlation coefficient; SD = standard deviation. \*p<0,05; \*\*p<0,01; \*\*\*p<0,001.



**Figure 3:** Scatter plot corresponding to central corneal thickness (CCT).

**Concordance Analysis Between with and without the Face Mask**

Table 3 presents basic statistics for the difference between with and without the face mask in the sample of 58 eyes, as well as those relating to the method error. The mean differences are very close to 0. Even in CCT, which is of high magnitude, this difference is less than 0.5. This first detail indicates that there appears to be no difference between the measurements with and without the

face mask. In fact, there are no significant results (by p-value of the t-test), only a slight trend in white-to-white distance (WTW) (p=0.095), although the other statistics show clear homogeneity between the measurements (a CV of 0.644% is very low, accompanied by an ICC of 0.952, very close to 1).

The following graph (Figure 5) represents each mean difference with its corresponding 95% confidence interval. It is clear how all parameters are unbiased and intersect the x-axis (line

y=0). Table 3 shows that the d-values are very small and generally close to 0 (except for CCT, again due to its high magnitude), which suggests a small absolute error between the methods. The CV is less than 1% for all parameters and the ICCs are very close to 1, which allows us to conclude that there is a small random error. Based on the overall interpretation, all indicators point to a high

level of concordance between biometric measurements with and without the face mask. Finally, it is shown the regression analysis for the comparative values between with and without face masks in the situation of intraocular lens power calculation (IOLP) (Figure 6, table 4).

**Table 3:** Difference in measurements with and without the face mask, 95% confidence interval, t-test for dependent samples (p-value) and error estimators for the determination of: Dahlberg's d, CV and ICC.

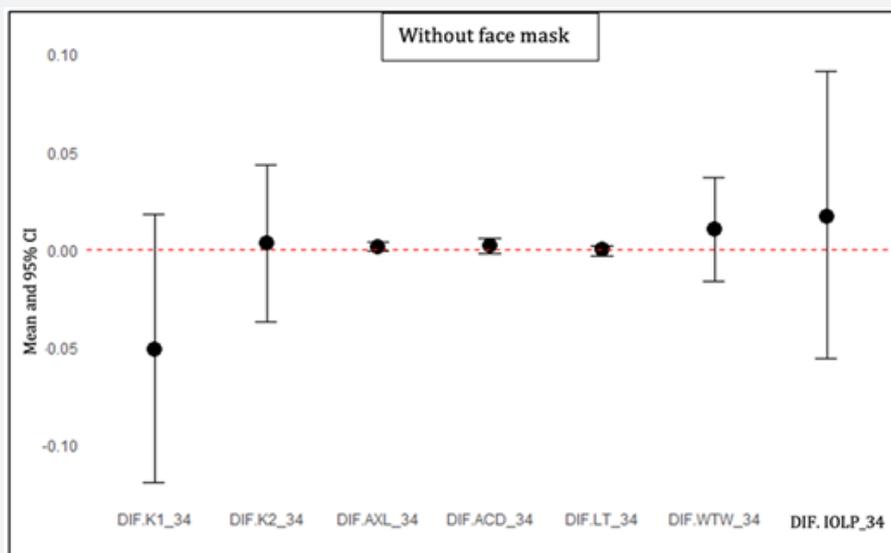
	Difference with/without mask		95% confidence Interval for the difference		p-value	Dahlberg's d	CV (%)	ICC
	Media	SD	Low. Lim.	Sup. Lim.				
K1	-0,003	0,159	-0,045	0,039	0,889	0,111	0,258	0,993
K2	-0,012	0,167	-0,056	0,031	0,571	0,117	0,268	0,993
AXL	-0,002	0,011	-0,005	0,001	0,104	0,008	0,034	1,000
ACD	0,000	0,018	-0,004	0,005	0,853	0,012	0,396	0,999
LT	0,000	0,009	-0,003	0,002	0,759	0,006	0,130	1,000
WTW	0,024	0,108	-0,004	0,053	0,095	0,078	0,644	0,952
CCT	0,414	3,788	-0,582	1,410	0,409	2,672	0,488	0,996
IOLP	-0,009	0,204	-0,062	0,045	0,749	0,143	0,652	0,996

K1 = keratometric power in the flattest meridian; K2 = keratometric power in the steepest meridian; AXL = axial length; ACD = anterior chamber depth; LT = lens thickness; WTW = white-to-white; CCT = central corneal thickness, IOLP = intraocular lens power; CV = coefficient of variation; ICC = intraclass correlation coefficient; SD = standard deviation. \*p<0,05; \*\*p<0,01; \*\*\*p<0,001.

**Table 4:** Results of simple regression model for mean IOLP without mask as a function of mean IOLP with mask. There is no bias (p=0.742) and concordance between techniques is accepted.

	Value	SD	t	CI 95 inf.	CI 95 sup.	p-value
Intercept	0,093	0,280	0,331	-0,469	0,654	0,742
Beta1	0,995	0,013	78,364	0,970	1,021	<0,001***

SD = standard deviation, CI = Confidence interval. \*p<0,05; \*\*p<0,01; \*\*\*p<0,001



**Figure 4:** 95% CI of the different measures without the face mask.

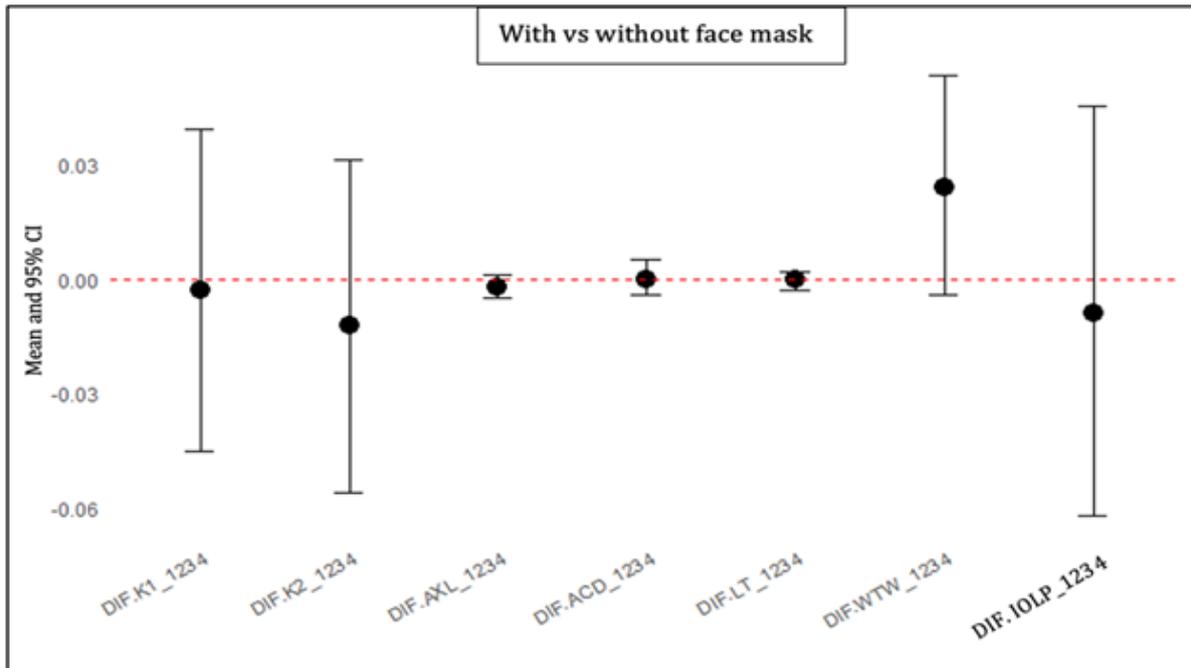


Figure 5: 95% CI of the mean differences between with and without the mask.

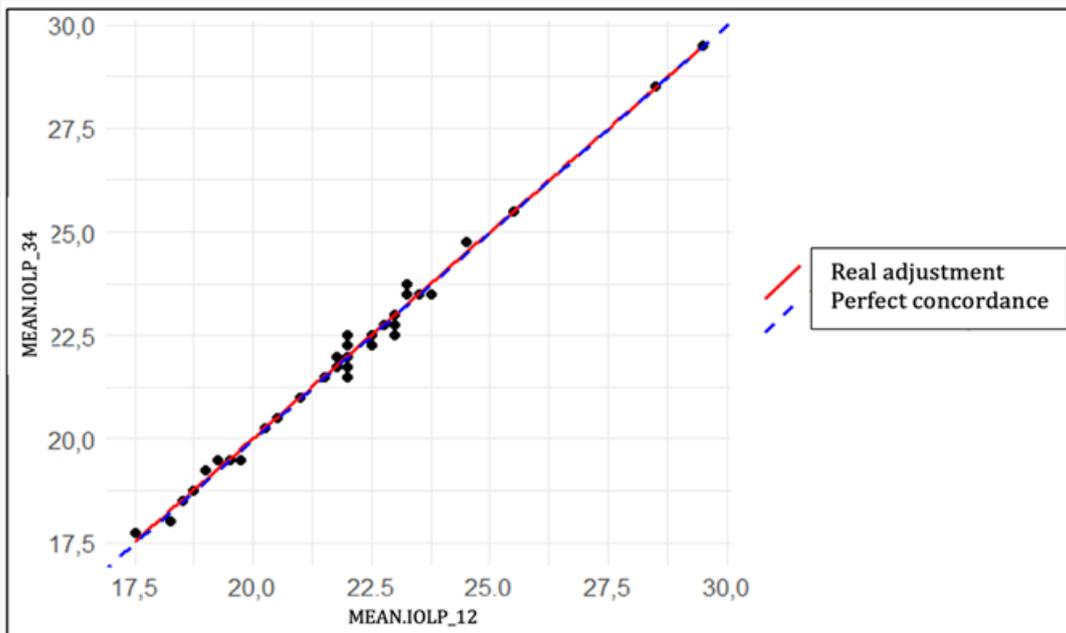


Figure 6: Regression line of IOLP values (solid line) and the theoretical line of perfect concordance (dashed line, with = without).

### Discussion

This study aimed to assess whether the use of face masks produces an alteration in the IOL calculation in patients

undergoing cataract surgery. Face masks were globally used during the COVID-19 pandemic, when both patients and healthcare professionals were required to wear them properly fitted [21] and there is certain evidence that during this period they contributed

to increasing the prevalence of ocular discomfort symptoms [5]. Since the tear film is unstable in some of the patients wearing face masks, light reflection using the IOLMaster 700 biometer may vary and lead to deterioration in measurement accuracy with their potential implications for the final refractive outcome after surgery.

It is difficult to evaluate the results in our study with those of literature because comparable studies are lacking. One of the most similar studies to ours in terms of association between ocular surface changes and IOL calculation found in the literature is that of Epitropoulos et al [16], although without correlation with the use of face masks. The purpose of their study was to evaluate the effects of tear osmolarity on the repeatability of keratometric measurements in patients undergoing cataract surgery. They observed greater variability in the mean keratometry measurement in the hyperosmolar group (i.e. DED) compared to the control group, with a difference greater than 1.0 D in corneal astigmatism. Furthermore, they described a higher percentage of eyes in the hyperosmolar group with a difference in the calculated IOLP greater than 0.5 D. All these alterations were statistically significant. However, when the subjects were grouped by perceived dry eye symptoms, no significant differences were found.

On the other hand, Hiraoka et al [18] found that the measurement repeatability of corneal curvature radius decreased in patients with DED compared to normal eyes. Moreover, shortened break-up time were correlated with a worsening in the measurement repeatability of corneal curvature radius and AXL. In this study measurements were assessed twice on the same day using IOL Master 500 and not the latest version of this device as in the present study.

Burgos-Blasco et al [22] studied whether the use of a face mask influenced the measurement of keratometric parameters, in this case without looking for an association with the final IOLP calculation in patients undergoing cataract surgery. Of 35 healthy eyes analyzed with the Pentacam Scheimpflug tomograph, no differences were found in mean keratometric power in the flattest meridian (K1), the steepest meridian (K2), medium and maximal keratometry with and without the face mask. The ICC was excellent for the four parameters analyzed, although it was low when measurements with the face mask were considered. Although alterations in the tear film with mask use have been described in the literature, no significant differences were found in the topographic variables, similar to our results in this aspect.

Other biometric variables apart from keratometry could be altered by using face masks, although this has not been studied in the literature. In our analysis, we correlated mask use with parameters such as anterior chamber depth (ACD), AXL, and CCT, finding no differences and a high degree of concordance between measurements taken with and without the face mask. In the study

conducted by Meyer et al [23], 97 patients with ocular surface disease (OSD) and 33 healthy individuals were studied. Corneal morphology was assessed using Scheimpflug photography, and corneal keratometry and density were analyzed in five anatomical corneal layers. Corneal density was significantly reduced in the epithelium, Bowman's membrane, and Descemet's membrane in patients with OSD compared to controls. Similar results regarding corneal density were obtained in the study by Wegener et al [24]. They also noted that corneal density was higher and very close to that of controls if the patient was treated with hydroxypropyl methylcellulose, which is found in tears and lubricating gels. These results show that OSD caused by face masks could affect different biometric variables, not just keratometry.

Regarding the type of face mask used, all patients in our study used surgical masks during the corresponding measurements. Therefore, a comparison with filtering facepiece or N95 respirators cannot be made in terms of the final calculation of IOLP or the alteration of keratometric parameters. However, the study conducted by Shalaby et al [25] compared the use of surgical masks and N95 respirators. In general, mask use for 60 minutes significantly worsened all tear film parameters in both groups, with greater deterioration after the use of surgical masks compared to N95 respirators. This latter finding could be due to the tighter fit provided by the N95 mask, which almost completely prevents airflow from the mask to the ocular region.

Although our research correlates face mask use with biometric measurements and compares patients who wear face masks with those who do not, it does not objectively quantify ocular surface involvement in each patient, despite many of them exhibited associated OSD symptoms during the examination. Other studies analyzed [7, 26-28] explain the results of questionnaires and tests related to associated OSD in the study group.

Finally, the American Society of Cataract and Refractive Surgery Clinical Committee reported a new consensus-based practical diagnostic OSD algorithm to aid surgeons in efficiently diagnosing and treating visually significant OSD before any refractive surgery is performed [29]. The report emphasized that the importance of addressing OSD cannot be underestimated because it potentially results in different adverse surgical outcomes. So, although no objective differences were found in this research in the calculation of IOLP between mask and no mask wearing, it is necessary to consider preoperative treatment of the ocular surface in patients with symptoms of DED, not only with the aim of increasing surgical refractive accuracy, but also to reduce OSD symptoms and infections in the postoperative period, which are often exacerbated by the procedure itself.

### Conclusion

Due to the recommendation and mandatory use of face masks during the COVID-19 pandemic, an increase in ocular symptoms was observed. Understanding the pathophysiological

mechanisms associated with the ocular surface alteration caused by masks helps us to focus on better treatment and design prevention strategies, especially when scheduling surgery where IOL calculation becomes necessary.

The increase in dry eye symptoms during the COVID-19 pandemic was multifactorial. Furthermore, face masks may have different effects on different individuals. Multiple variables can influence the magnitude of the effects of face masks on the ocular surface, such as the severity of dry eye, air humidity, the presence of concomitant pathology, the number of hours wearing a mask, and the type of face mask.

Despite the gradual reduction in mask use following the end of the pandemic, they are still widely used in healthcare facilities and public spaces. Their long-term effects on the eyes remain uncertain, as does their potential impact on visual, physical, and psychological well-being.

According to the results of our study, there is a high degree of concordance between biometric measurements taken with and without the face mask, so no differences were observed in the estimated IOLP. Even so, we believe it is advisable to analyze each case individually and to establish appropriate ocular surface treatment for those patients with symptoms associated with mask use.

Finally, although many symptoms associated with its use have been grouped under the term MADE, the mask is a protective factor that has proven to be effective in the transmission of COVID-19 and other respiratory viruses. In fact, it is a common recommendation in ophthalmological consultations due to the proximity to the patient's facial region during the clinical examination.

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