

Accurate Intraocular Lens Position Determination in Pseudophakic Eyes

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RESUMO

Objectivos: O objectivo deste trabalho é validar aparelhos de medição de ACD_{post} baseados em técnicas de interferometria de coerência parcial, especificamente o Lenstar LS 900, (Haag-Streit AG, Köniz, Switzerland) e em tomografia óptica de coerência, o Visante OCT (Carl Zeiss Meditec Inc., Dublin, California, USA).

Material e Métodos: Um fantoma de um olho pseudofáquico foi construído para aferir a calibração dos aparelhos. Realizou-se um estudo clínico envolvendo 40 olhos pseudofáquicos no qual ACD_{post} foi medido 3 meses após a cirurgia com os dois aparelhos.

Resultados: As calibrações do Zeiss Visante revelarem um erro R.M.S menor que a resolução de $18\mu m$ do aparelho. As calibrações do Lenstar tinham um erro R.M.S da ordem da resolução do aparelho, $20\mu m$. No estudo clínico o Lenstar não mediu ACD_{post} 11% of the times. Adicionalmente o Lenstar mediu uma espessura média da IOL de $0.74\mu m$ com $\sigma = 0.08mm$ e uma taxa de falha de 16. Realizou-se análise BA para as medidas dos diferentes aparelhos e a diferença média encontrada foi de $74\mu m$, que se concluiu ser clinicamente insignificante, pelo que as medidas se podem considerar intercambiáveis.

Conclusões: Ambos os aparelhos realizaram medidas de ACD_{post} com exactidão. Os resultados do estudo clínico demonstram a intercambialidade das medidas in vivo. Estes resultados certamente contribuirão para a melhoria das metodologias de estimativa de ACD_{post} , e para a melhoria das metodologias de cálculo da potência da IOL.

Palavras Chave: Câmara anterior, Pseudofáquico, Fantoma, Lente intraocular, Medição

ABSTRACT

Objectives: This work seeks to validate postoperative Anterior Chamber Depth (ACD_{post}) measurement devices based in optical low-coherence reflectometry (Lenstar LS 900, (Haag-Streit AG, Köniz, Switzerland) and optical coherence tomography (Visante OCT, Carl Zeiss Meditec Inc., Dublin, California, USA).

Material and Methods: A pseudophakic eye phantom was built to check the calibration of both devices. A clinical study involving 40 pseudophakic eyes was conducted and 3 months after surgery ACD_{post} was measured with both devices and compared.

Results: Zeiss Visante calibrations had a R.M.S error smaller than the device's $18\ \mu\text{m}$ resolution in all the measurement sets. No span shift nor zero shift errors were found. Lenstar calibrations had a larger R.M.S error in the order of the device's $20\ \mu\text{m}$ resolution. In the clinical study, Lenstar failed to measure ACD_{post} 11% of the times. Additionally Lenstar measured an average IOL thickness of $0.74\ \mu\text{m}$ with $\sigma = 0.08\text{mm}$ and a 16% failure rate. Bland-Altman (BA) analysis was performed and a mean difference of $74\ \mu\text{m}$ between the measurements was found. The dioptric shift induced by the difference between measurements was calculated in a worst case scenario and a 0.18D difference was found. This is clinically insignificant and the measurements can be considered to be interchangeable.

Conclusions: Both devices performed accurate measurements of ACD_{post} . Results from the clinical trial proved the interchangeability of the measurements in vivo. This will certainly contribute to the improvement of ACD_{post} estimation methodologies and ultimately contribute to the improvement of IOL power calculation methodologies.

Keywords: Anterior Chamber, Pseudophakic, Eye Phantom, Intraocular Lens, Measurement

INTRODUCTION

In the context of cataract surgery the power of the implanted Intraocular Lens (IOL) is calculated with formulas derived by retrospective analysis of a large number of patients who had IOL implantation, and whose data was subjected to regression analysis, resulting in a power calculation formula, characterized by a set of constants which are calculated so that the postoperative refractive error averages zero. These formulas relate several biometric parameters measured preoperatively, such as the corneal power and the axial length of the eye, in order to calculate the power of the IOL. Another parameter taken into consideration when calculating the power is the Effective Lens Position, which acts as proxy to the physical

position of the IOL inside the eye, given by the Postoperative Anterior Chamber Depth (ACD_{post}). This estimate is of a major importance to the refractive outcome with errors in its estimation having a 42% relative contribution to the total refractive error, contrasting with a 36% relative contribution of axial length measurement errors and 22% relative contribution of corneal power measurement errors [1].

Due to the difficulty in effectively predicting ACD_{post} several authors have explored the possibility of using the symmetry of the eye in order to improve the refractive outcome [2–4]. By performing the surgery sequentially the refractive outcome of the first operated eye is assessed and its ACD_{post} measured. The power of the IOL to be implanted in the other eye is calculated considering these parameters

which results in an improved refractive outcome, compared with calculating the power of each IOL independently. This technique was shown to be more effective when the corneal power of the two eyes was similar (a corneal power difference smaller than 0.6D between the eyes) [5].

Currently there is a need to assess the accuracy of ACD_{post} measurement techniques, which is evidenced by the significant discrepancies among the results present in the literature. References [6–8] found the devices tested to not be interchangeable. Results from reference [9] were found to be interchangeable, which is contradictory to reference [6] results. This set of results urges the need for investigation regarding the accuracy of ACD_{post} measuring techniques since this parameter plays a fundamental role in the refractive outcome of cataract surgery. Accurately measuring ACD_{post} is therefore crucial in the following situations:

- Validation of IOL position prediction methods;
- Possible improvement of the refractive outcome of the second eye when using ACD_{post} measurements of the first eye to calculate the IOL power.

MATERIAL AND METHODS

A clinical study involving 25 patients scheduled for phacoemulsification cataract surgery was conducted at Hospital da Luz. Preoperative biometry was performed with the Lenstar LS 900. The mean preoperative values (\pm standard deviation) for axial length and corneal power were:

- 23.24 ± 0.55 (mm)
- 43.84 ± 1.37 (D)

All surgeries were performed by the same surgeon whom implanted the same IOL model in every patient: a biconvex 22D Alcon AcrySof single-piece SA60AT. 3 months after surgery subjective visual acuity evaluation was performed. 20/20 vision was achieved in all patients with the best optical correction. ACD_{post} was measured 3 months postoperatively with both the Lenstar LS 900 and Zeiss Visante OCT. Lenstar failed to measure ACD_{post} 13% of the times, which resulted in the exclusion of these cases from the following analysis, reducing the sample size from 40 to $n = 35$ eyes.

In order to assess the accuracy of ACD_{post} measurements made by the Zeiss Visante OCT and the Haag-Streit Lenstar LS 900 in a life-like and realistic scenario a pseudophakic

eye phantom was built. The phantom was built using laboratory grade optomechanical components, custom designed components and a 22D SA60AT Alcon AcrySof single-piece IOL, the same model implanted in all patients involved in the clinical trial.

Both devices measure the physical distance, d , through the optical path, $d = OP/n$, with n being the refractive index of the aqueous humor considering the dispersion caused by the light source's central wavelength:

- $\lambda_0 = 820\text{nm}$ for the Lenstar,
- $\lambda_0 = 1310\text{nm}$ for the Visante.

When air is inside the box this has to be accounted for as the results presented by the devices for ACD_{post} are divided by the refractive index of the aqueous. Data obtained by P. Schiebener et al., 1990, [15] regarding the refractive index of water for several combinations of wavelengths and temperatures was interpolated to find the refractive index for both devices at 37°C and 1MPa:

- $n(\lambda_0 = 820\text{nm}) = 1.32614$
- $n(\lambda_0 = 1310\text{nm}) = 1.32089$

These values were used to multiply the measurements presented by the device when the box was air filled. Measurements were made with water inside the phantom, emulating the aqueous humor. The relative displacements measured were fitted to the linear equation: $\Delta_{Device} = \Delta_{Phantom} \cdot a + b$, and the fit parameters a and b were calculated by least squares fitting. Ideally $a = 1$ and $b = 0$. Doing a calibration using relative displacements is not an effective way to check for the existence of a zero shift error since errors of this type affect all measurements equally and doing subtractions between absolute measurements may nullify its presence. It's therefore necessary to measure a physical reference of known length, in this case the IOL's thickness was used to check for the presence of a zero shift error. Span shift errors can still be effectively detected with this type of calibration.

Visante uses the refractive index of the aqueous humor, $n_{aq}(\lambda = 1310\text{nm}) \approx 1.323$, to convert optical path measurements into physical distances. Due to this the IOL thickness measured by the Visante, $t_{Visante}$, won't match the IOL's physical thickness, 0.668mm. As such it is necessary to calculate the value of the measurement using the correct refractive index. The optical path was calculated via:

$OP = t_{Visante} \cdot naq$, and the IOL's thickness was then calculated from:

$t_{IOL} = OP/n_{IOL}(\lambda = 1310nm)$. The IOL's refractive index was estimated to be $n(\lambda = 1310nm) \approx 1.535$. using data obtained by N. Sultanova et al., 2009, [18].

RESULTS

Bland-Altman (BA) analysis is a very useful method of assessing if the measurements are comparable to the extent that one can replace the other for the intended purpose of the measurement [14], being widely used when comparing biometric measurements. The BA plot in Figure 1 displays the differences between paired measurements against their paired mean. The dashed line in the middle of the plot represents the mean difference, $d=74 \mu m$, while the other two represent the limits of agreement $d \pm 1.96\sigma$, with $\sigma = 25 \mu m$.

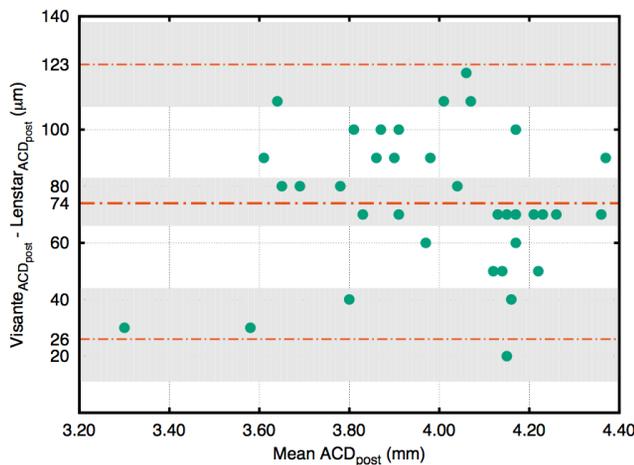


Figure 1: BA plot of ACD_{post} measurements.

Visante

Calibrations were obtained for $20 \mu m$ displacements of the IOL in air and water.

In Figure 2 relative displacement experimental data obtained with air inside the box is presented. Experimental data with water inside the box is presented in Figure 3 relative displacement. The R.M.S errors of the fits were found to be smaller than the device's $18 \mu m$ resolution in all the measurement sets. The fit parameters, $a=1.003 \pm 0.004$, $a=1.017 \pm 0.003$, and $b=5.45 \pm 1.96 \mu m$, $b=17.17 \pm 5.10 \mu m$ are also very close to the ideal value

indicating that measurements are being performed correctly, with no span shift error. This means that the device performs as expected across the measurement range.

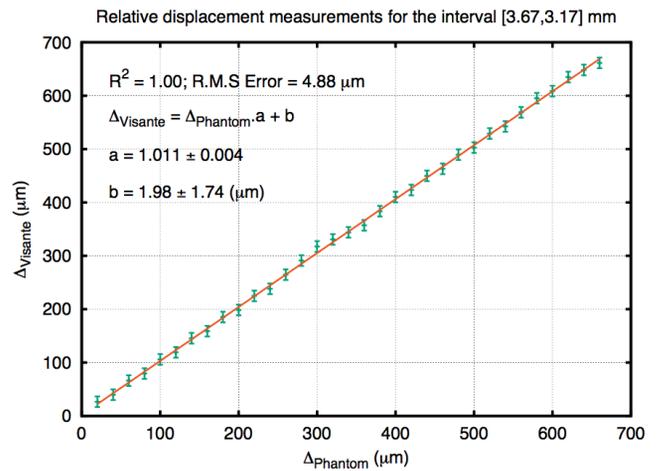


Figure 2: Visante measurements in air.

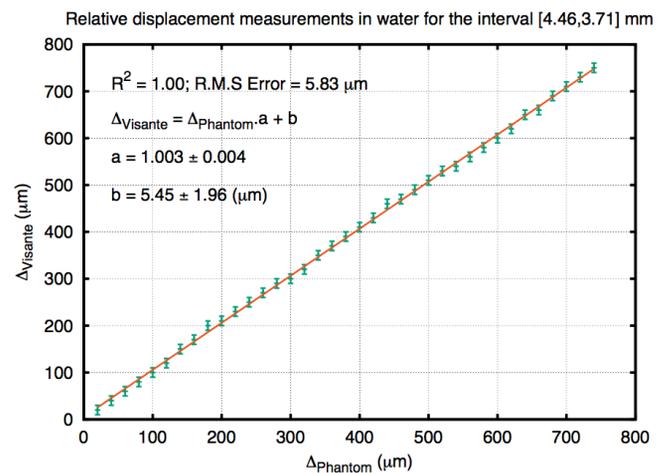


Figure 3: Visante measurements in water.

IOL Thickness Measurement

The central thickness corresponds to the thickest point of the lens and since it is difficult to exactly pinpoint several tomograms were acquired in different regions of the IOL. At the thickest point the value found was $0.61mm$, having a $56 \mu m$ deviation from the expected value, $0.668mm$.

Lenstar

This device allows measurements to be made along longer ranges and for this reason $50 \mu m$ IOL displacements were made, as seen in Figure 6. The fit parameters obtained

were $a = 1.017 \pm 0.003$ and $b = -17.17 \pm 5.10 \mu\text{m}$. The R.M.S error is $18.32 \mu\text{m}$.

It is important to check if the device accurately measures ACD_{post} when water is inside the box and for this reason acquisitions with $20 \mu\text{m}$ displacements were made, Figure 7. Fit parameters of $a = 1.054 \pm 0.022$ and $b = 4.25 \pm 4.74 \mu\text{m}$ were found, as well as a R.M.S error of $9.64 \mu\text{m}$, indicating that measurements are being performed correctly.

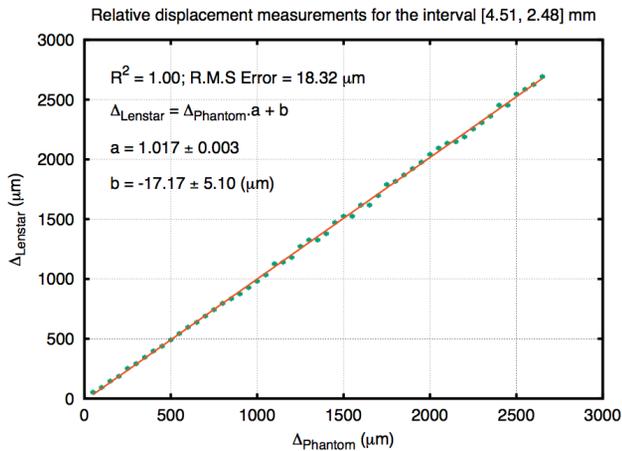


Figure 4: Lenstar measurements in air.

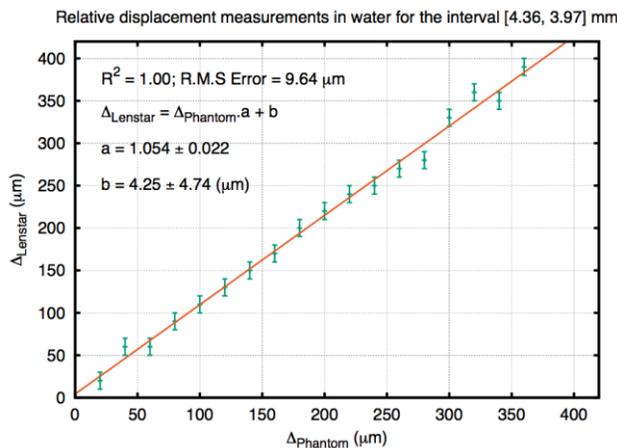


Figure 5: Lenstar measurements in water.

DISCUSSION

Thanks to BA analysis it is possible to conclude that a systematic difference between the measuring devices exists: the Visante consistently makes larger ACD_{post} measurements. This does not provide information regarding:

- Interchangeability of the measurements. We need to assess the clinical significance of the differences – that is, what is the consequence of using either measurement in an IOL power calculation formula, or what is the change in the final refraction of the patient considering an ACD_{post} shift of this magnitude;
- Accuracy of the measurements – only calibrations using physical references of known length can grant us a deeper insight on this matter. Since the devices share a common working principle it is plausible that both are committing the same systematic error and this has to be addressed.

In order to assess the clinical significance of the differences the refraction change induced in the spectacle plane by the discrepancy between the measurements was calculated using geometrical optics formulas and found to be 0.18D , which is clinically insignificant. These findings constitute a very strong indication that the results found are interchangeable. Although this is a good indicator that the measurements are being done correctly it is still necessary to assess their accuracy, which can be done via IOL thickness measurements. It's important to consider how IOL manufacturing tolerances affect this result. Current fabrication technologies allow IOLs to be fabricated with a $\pm 5 \mu\text{m}$ center thickness tolerance [16]. Assuming the tolerance of the IOL used to be five times this value the difference becomes $56 \pm 25 \mu\text{m}$. A measuring error of this magnitude is negligible, as previously found.

Results obtained through the clinical study show that results obtained with the Haag-Streit Lenstar are interchangeable with the ones of the Zeiss Visante, however inter-operator reproducibility of ACD_{post} measurements obtained with the Haag-Streit Lenstar has not been assessed in the literature. Moreover, this device had issues regarding accurate measurement of the IOL thickness in vivo, which is probably due to the difficulty in detecting the reflection from its posterior surface combined with an eventual mismatch of the refractive index of the IOL. It is important to beware that an accurate IOL thickness measurement will propagate its error to posterior eye structures which impacts the accuracy of axial length measurements. As such, performing biometry with this device in pseudophakic eyes will likely result in incorrect axial length measurements. When using the eye phantom the performance of this device was also found to be inferior to the one of the Visante.

CONCLUSIONS

The main purpose of this work was to assess the capability of accurately measuring ACD_{post} using devices commonly found in ophthalmological clinics.

The clinical study conducted gave us a clear indication that the devices under study, Lenstar LS 900 and Visante OCT, are interchangeable, and, thanks to the experimental work developed with the phantom, indeed accurate, with the Visante having a superior performance. The span shift error of this device is virtually non-existent and the IOL thickness was measured with a $56 \pm 25\mu m$ error, which, if considered to be the zero shift error is clinically insignificant. The Lenstar device would sometimes become uncooperative, not providing an ACD_{post} measurement, probably due to the fact the reflection from the frontal surface of the IOL is too dim, being regarded as noise by the software. On the other hand, the Visante OCT always provides tomographic images and even when the frontal surface of the IOL is not fully rendered the user can still measure its position accurately. So if the two devices are available, and the parameter of interest is ACD_{post} , the Visante OCT seems to be the best option. Only one IOL model was used during this work and it was possible to make accurate measurements with both devices. These results are valid for other IOLs as long as its reflective properties are similar to the one used in this work, however, due to the great number of IOLs available in the market this should be analyzed.

Knowing that interferometry based devices perform accurate measurements of ACD_{post} and ultimately contribute to the improvement of IOL power calculation methodologies.

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