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FACULDADE DE MEDICINA
UNIVERSIDADE Ɖ
COIMBRA

MESTRADO INTEGRADO EM MEDICINA – TRABALHO FINAL

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Evaluating Biometric Outcomes in Cataract Surgery Using Subjective Refraction and Aberrometric Refraction

ARTIGO CIENTÍFICO ORIGINAL

ÁREA CIENTÍFICA DE OFTALMOLOGIA

Trabalho realizado sob a orientação de:

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FEVEREIRO/2021

EVALUATING BIOMETRIC OUTCOMES IN CATARACT SURGERY USING SUBJECTIVE REFRACTION AND ABERROMETRIC REFRACTION

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Este trabalho foi parcialmente apresentado no 38º Congresso da ESCRS em Outubro de 2020 (FP-456582 - Evaluating biometric outcomes in cataract surgery using subjective refraction and aberrometric refraction; Emmanuel Neves, Miguel Raimundo, Carlos Saraiva, Jorge Simão, Andreia Rosa, Conceição Lobo, Joaquim Murta)

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List of abbreviations

A – A constant

ACD – Anterior chamber depth

AR – Aberrometric refraction

Barrett UII – Barrett Universal II formula

D – Diopters

ETDRS - Early Treatment Diabetic Retinopathy Study

IOL – Intraocular lens

IQR – Interquartile range

K – Keratometry

LF – Lens factor

ME – Mean prediction error

MedAE – Median absolute prediction error

OPD – Optical path difference

SD – Standard deviation

SE – Spherical equivalent

SR – Subjective refraction

Abstract

Introduction: Subjective refraction is the natural refractive outcome evaluated in modern cataract surgery. However, it is, by definition, subjective and may be a source of noise that is difficult to remove and control for when evaluating biometric outcomes. Some ray tracing wavefront devices can derive spherocylindrical refraction from whole-eye aberrometry and may be able to estimate post-operative refractive error in a less patient- and operator-dependent way. In this work we compare both techniques for post-operative refractive evaluation following cataract surgery.

Methods: Prospective study including consecutive eyes submitted to uncomplicated cataract surgery with implantation of an Alcon AcrySof SN60AT intraocular lens. All patients underwent optical biometry (Allegro Biograph) and the post-operative spherical equivalent (SE) was estimated using the Barrett Universal II and Kane formulas. Post-operative subjective refraction (targeting red equal to green in duochrome test) was obtained from 6-12 weeks post-operatively. Same day aberrometric refraction (average of two measurements) was obtained in mesopic undilated conditions using the Tracey iTrace device. Prediction errors for both formulas were obtained by subtracting the pre-operative SE estimation from the post-operative SE using both techniques.

Results: Twenty-four eyes were included. While postoperative sphere was similar using both techniques (0.03 ± 0.38D vs 0.09 ± 0.26D, p=0.440), measured cylinder was significantly lower in subjective refraction (-0.57 ± 0.31D vs -0.86 ± 0.44D, p=0.014). Post-operative subjective SE was slightly but significantly smaller than aberrometric SE (-0.21 ± 0.27D vs -0.38 ± 0.30D, p=0.029), which can be explained by the higher measured aberrometric cylinder. Mean prediction errors for both formulas were higher using subjective refraction (Barrett: 0.410 ± 0.288D vs 0.230 ± 0.206D; Kane: 0.471 ± 0.314D vs 0.291 ± 0.285D; both p=0.029).

Discussion and Conclusion: In this exploratory study, we propose that aberrometric refraction could be used as an easy to obtain, operator and patient-independent supplementary outcome measure for evaluating biometric prediction errors and refractive outcomes following cataract surgery. Differences found between methods suggest that aberrometric refraction may better approximate preoperative predictions from modern formulas.

Keywords: Aberrometry; Cataract Extraction; Ocular Refraction

Resumo

Introdução: A refração subjetiva é o resultado refrativo natural avaliado na cirurgia de catarata moderna. Contudo, é, por definição, subjetiva e pode constituir uma fonte de ruído que é difícil de remover e controlar durante a avaliação dos resultados refrativos. Alguns dispositivos de análise de frente de onda por traçado de raios são capazes de derivar a refração esferocilíndrica a partir da aberrometria total ocular e podem ser capazes de estimar o erro refrativo pós-operatório de uma forma menos dependente do paciente e do operador. Neste trabalho comparamos ambas as técnicas para a avaliação refrativa pós-operatória após cirurgia de catarata.

Métodos: Estudo prospetivo incluindo olhos consecutivos submetidos a cirurgia de catarata não complicada com implantação de uma lente intraocular Alcon AcrySof SN60AT. Todos os pacientes foram submetidos a biometria ótica (*Allegro Biograph*) e o equivalente esférico pós-operatório (EE) foi estimado utilizando as fórmulas Barrett Universal II e Kane. A refração subjetiva pós-operatória (com o alvo de vermelho igual a verde no teste do duocromo) foi obtida 6-12 semanas pós-operatoriamente. No mesmo dia foi obtida refração aberrométrica (média de duas medições) em condições mesópicas sem dilatação utilizando o dispositivo Tracey iTrace. Erros de previsão para ambas as fórmulas foram obtidos subtraindo a estimativa pré-operatória do EE ao EE pós-operatório utilizando ambas as técnicas.

Resultados: Vinte e quatro olhos foram incluídos. A esfera pós-operatória foi semelhante utilizando ambas as técnicas (0.03 ± 0.38D vs 0.09 ± 0.26D, p=0.440). Contudo, o cilindro medido foi significativamente mais baixo na refração subjetiva (-0.57 ± 0.31D vs -0.86 ± 0.44D, p=0.014). O EE subjetivo pós-operatório foi ligeira mas significativamente menor do que o EE aberrométrico (-0.21 ± 0.27D vs -0.38 ± 0.30D, p=0.029), o que pode ser explicado pelo maior cilindro medido por aberrometria. Os erros de previsão médios para ambas as fórmulas foram mais elevados utilizando a refração subjetiva (Barrett: 0.410 ± 0.288D vs 0.230 ± 0.206D; Kane: 0.471 ± 0.314D vs 0.291 ± 0.285D; ambos p=0.029).

Discussão e Conclusão: Neste estudo exploratório, propomos que a refração aberrométrica possa ser usada enquanto uma forma fácil de obter medições de resultados suplementares e independentes de operador e paciente, para avaliação dos erros de previsão biométricos e resultados refrativos a seguir à cirurgia de catarata. As diferenças encontradas entre métodos sugerem que a refração aberrométrica pode aproximar-se mais das previsões pré-operatórias das fórmulas modernas.

Palavras-Chave: Aberrometria; Extração de Catarata; Refração Ocular

Introduction

Cataract surgery is one of the most commonly performed surgical procedures in the word and, due to the population ageing, the volume of cataract surgery is rising. (1) With the use of small and sutureless incisions,(2) modern optical biometry for the majority of patients,(3) modern intraocular lens (IOL) power prediction formulas (3) and constant optimization,(3) cataract surgery is no longer a procedure intended simply to restore sight, but a refractive procedure.(3)

Subjective refraction is the natural refractive outcome evaluated in modern cataract surgery. It is used for the optimization of the IOL constants,(3) as well as for the calculation of several parameters often used in IOL calculation studies, namely the refractive prediction error (difference between the measured and predicted postoperative refractive spherical equivalent),(4) mean absolute error (average of the absolute differences between actual and predicted refractive outcomes) (4) and median absolute error (central location of the absolute errors),(4) as well as the percentage of eyes within a certain range of prediction error.(4) However, subjective refraction is, by definition, subjective, and hence there is an intra- and interobserver inconsistency, along with variability in patient responses to slight changes in prescription, which limit the repeatability and precision of this procedure.(5) In fact, the standard deviation for subjective refraction is 0.39 diopters (D), which indicates a wide variability in the measurement of the refractive outcome.(3,6) The fact that the 95 % limits of interobserver agreement of the spherical equivalent for a subjective refraction are 0.62 to 0.75 D (which is twice the limits of agreement found for autorefraction or wavefront-guided refractions) also indicates a poor precision of this refraction method.(7) Interestingly, Norrby determined that the post-operative refraction is a significant contributor to the prediction error (26.98%), only surpassed by the inaccuracy of the IOL formulas' predictions of the post-operative IOL position (35.47%).(3,6)

Aberrometry uses wavefront sensing, which is a technique of measuring the complete refractive status of an optical system,(8) in which an infrared light source generates radiating waves of light. The deviation of the wavefront that originates from the measured optical system from a reference wavefront that comes from an ideal optic system is called the wavefront aberration.(8) The wavefront data that is captured by the sensor is generally decomposed by Zernike polynomials,(9) which encompass both lower-order aberrations (positive defocus (myopia), negative defocus (hyperopia) and regular astigmatism) and higher-order aberrations (for example spherical aberration, coma, trefoil, quadrafoil and secondary astigmatism).(10)

Ray tracing aberrometry is one of the techniques used for measuring ocular aberrations. It is based on the analysis of the retinal displacement of a set of sequentially projected beams (parallel to the visual axis), which allows the estimation of the wavefront aberration, based on the aforementioned Zernike coefficients.(11) From ray tracing aberrometry it is also possible to determine the spherocylindrical refraction that would be able to compensate for the aberration, and the pupil diameter.(11) Using subjective refraction as the standard, the Tracey device (a ray tracing aberrometer) demonstrated excellent accuracy and reproducibility in measuring refractive error both in normal eyes and eyes after corneal refractive surgery.(12)

In the context of pseudophakic eyes, the evidence regarding the comparison between manifest subjective refraction and the refraction obtained with the aberrometric technique is limited. Several investigators have studied the accuracy of aberrometric refraction in pseudophakic eyes, as well as its potential role in follow-up visits and spectacle prescriptions for cataract patients after surgery.(13) However, they used Nidek optical path difference (OPD)-Scan III, which is based on the dynamic skiascopy principle. Moreover, the cited study evaluated the repeatability and agreement of the time-based wavefront objective refraction using the aforementioned device but did not compare the refractive prediction error obtained with the aberrometer and with manifest refraction. Regarding the ray tracing technique, a study (14) reported that further work to refine the accuracy and range of the device was needed, as there was a mean spherical error of approximately 1.10 D. However, this study was published in 2002, and a first-generation prototype version (Tracey-1) was used. There is also a published abstract (15) which reports a good correlation between a modern ray tracing aberrometer (iTrace) and subjective refraction. Nonetheless, we are unaware of clinical studies that analyse, in pseudophakic eyes, objective ray tracing aberrometric refraction in comparison to manifest subjective refraction, in regard to the refractive prediction errors in cataract surgery. Hence, the purpose of this study is to investigate that, using modern IOL formulas (Kane and Barrett Universal II).

Methods

1. Study Design

This observational prospective consecutive case-series was conducted in the Department of Ophthalmology, Centro Hospitalar e Universitário de Coimbra. It was approved by the local Ethics Committee, and it followed the tenets of the Declaration of Helsinki. Informed consent was obtained from the subjects after explanation of the nature and possible consequences of the study.

2. Selection of Participants

A convenience sample consisting of twenty-four eyes of patients subjected to cataract surgery was recruited from the Ophthalmology Department of Centro Hospitalar e Universitário de Coimbra.

Inclusion criteria were patients 18 years and over having uncomplicated conventional cataract surgery performed by a single surgeon, with continuous curvilinear capsulorhexis and implantation of the monofocal IOL Alcon AcrySof SN60AT, through a clear cornea incision.

Exclusion criteria were factors that could impact the postoperative refraction, namely: preoperative ocular comorbidities that could impact refraction (corneal ectasias, previous refractive surgery, corneal scarring), intra-operative complications, post-operative complications and post-operative corrected distance visual acuity worse than 20/40. No eyes were excluded based on extreme biometric parameters.

3. Data Collection

Regarding the preoperative assessment, all patients underwent optical biometry. Using optical low-coherence reflectometry (ALLEGRO BioGraph (Wavelight, AG)), axial length, steep and flat keratometry, anterior chamber depth, lens thickness and central corneal thickness were determined. A keratometric index of refraction of 1.3320 was used for the keratometry measurements**.** The gender of the patient was also used by the Kane formula. The IOL power as well as the predicted postoperative SE were calculated using the Barrett Universal II and Kane formulas, using optimized IOL constants (Table 1).

Table 1 – Constants used for the different formulas.

Formula	IOL constant	Value
Barrett Universal II	Lens factor (LF)	1.64
Kane	A constant (A)	118.7

IOL – Intraocular lens

All patients underwent the same surgical procedure, by the same surgeon (M.R.): phacoemulsification with clear corneal incisions and a continuous curvilinear capsulorhexis. Foldable monofocal Alcon AcrySof SN60AT IOL were implanted in the bag.

Post-operative sphere, cylinder and SE (algebraic sum of the sphere with half of the cylinder) were obtained by subjective refraction (targeting red equal to green in duochrome test) from 6-12 weeks post-operatively, by a trained ophthalmologist, after autorefraction, using a standardized ETDRS letter chart in a 4-meter lane in subjectively mesopic conditions.

Same day aberrometric refraction (with determination of the sphere, cylinder and SE; average of two measurements) was obtained in mesopic undilated conditions, using the iTrace System (Tracey Technologies, Houston, Texas) in automatic acquisition mode.

4. Study Outcomes

The prediction error for each patient was calculated as the actual post-operative SE (obtained by subjective refraction or by aberrometric refraction) minus the predicted SE, using both Barrett Universal II and Kane formulas. The arithmetic mean of the prediction errors (mean prediction error, or ME) was then obtained, as well as the standard deviation of the prediction error, median prediction error and its interquartile range.

The percentage of eyes that had a prediction error within ± 0.25, 0.50, 1.00 and 2.00 D were calculated for each formula, using both subjective and aberrometric refraction.

5. Statistical Analysis

Data were expressed as means ± standard deviation of the mean.

The STATA 16 (StataCorp, Texas, USA) statistics software package was used for the analysis. The normality of the variables was determined by the Shapiro-Wilk test. Statistical hypothesis testing was conducted in order to compare the results obtained with aberrometric refraction and subjective refraction. The variables were sphere, cylinder magnitude, spherical equivalent, cylinder axis and mean prediction error for each formula. The paired student's *t*-test was used. A two-tailed statistical significance of 0.05 was established.

For the astigmatism analysis, as described by Thibos et al.,(16) conventional refraction values were converted to power vector M (identical to the SE) and Jackson cross-cylinder vectors J_0 and J_{45}. The paired *t*-test was also used.

$$M = Sphere + \frac{Cylinder}{2}$$

$$J_0 = -\left(\frac{Cylinder}{2}\right) * cos\ (2 * Axis)$$

$$J_{45} = -\left(\frac{Cylinder}{2}\right) * sin\ (2 * Axis)$$

Results

Our study population comprised 24 eyes of 20 patients. The characteristics of eyes included in the final analysis, including general biometric data, are displayed in Table 2.

Table 2 – Characteristics of eyes included in the final analysis.

Parameter	**Value: mean ± standard deviation (range)**
Axial length (mm)	23.27 ± 0.92 (21.84 – 25.23)
K value (D)	44.11 ± 1.68 (40.9 – 47.13)
ACD (mm)	2.67 ± 0.27 (2.18 – 3.18)
Gender distribution	8 male; 12 female

K – Keratometry, ACD – Anterior Chamber Depth

Regarding the postoperative refraction, the measured sphere was similar in subjective and aberrometric refractions, but the measured cylindrical error was significantly lower in subjective refraction. Interestingly, axis measurements between techniques were not significantly different (mean difference 6.17 ± 25.92 degrees, p=0.256, maximum observed difference in our sample of 55 degrees). Finally, using power vector analysis, which compounds both vectorial components (magnitude and axis) into a pair of cartesian coordinates (J0 and J45), no significant differences were observed. Post-operative subjective SE was slightly but significantly smaller than aberrometric SE, which can be explained by the higher measured aberrometric cylinder magnitude. These results are presented in Table 3, as means ± standard deviation of the mean, in diopters (D) or degrees.

Table 3 – Refractive parameters with both refraction systems.

	Subjective Refraction	Aberrometric Refraction	p-value*
SE (D)	-0.21 ± 0.27	-0.38 ± 0.30	0.029
Spherical error (D)	0.03 ± 0.38	0.09 ± 0.26	0.440
Cylinder magnitude (D)	-0.57 ± 0.31	-0.86 ± 0.44	0.014
Axis (degrees)	90.00 ± 39.12	96.17 ± 45.35	0.256
J0	-0.05 ± 0.19	0.04 ± 0.34	0.153
J45	-0.02 ± 0.26	0.08 ± 0.33	0.149

SE – Spherical equivalent

Data are expressed as mean ± standard deviation of the mean

* Paired t-test for mean differences

Mean Prediction Errors (ME) for both formulas were significantly higher using subjective refraction, as shown in Table 4. The Median Absolute Errors (MedAE) and Interquartile Ranges (IQR) were also higher with subjective refraction.

Table 4 – Prediction errors with both refraction systems, using Barrett and Kane formulas.

Formula	Subjective				Aberrometric				p-value*
	ME	**SD**	**MedAE**	**IQR**	**ME**	**SD**	**MedAE**	**IQR**	
Barrett UII	0.410	0.288	0.330	0.408	0.230	0.206	0.225	0.293	0.029
Kane	0.471	0.314	0.425	0.555	0.291	0.285	0.313	0.375	0.029

ME – mean prediction errors, SD – standard deviation, MedAE – median absolute error, IQR – interquartile range, Barrett UII – Barrett Universal II formula

* Paired t-test for mean differences between prediction errors obtained by subjective versus aberrometric postoperative refraction

The percentage of eyes that had a prediction error within ±0.25, 0.50, 1.00 D and 2.00 D for each formula, using both subjective and aberrometric refraction, is represented in Table 5 and Figure 1. Aberrometric refraction provided the highest proportion of eyes within ± 0.25 D (58.3 % with Barrett Universal II formula and 41.67 % with Kane formula) and ± 0.50 D (91.67 % with Barrett Universal II formula and 75 % with Kane formula).

Table 5 – Percentage of eyes within ±0.25, 0.50, 1.00 D and 2.00 D for each formula, with both refraction systems.

	± 0.25 D	**± 0.50 D**	**± 1.00 D**	**± 2.00 D**
Barrett UII (AR)	58.3 %	91.67 %	100 %	100 %
Kane (AR)	41.67 %	75 %	100 %	100 %
Barrett UII (SR)	25 %	66.67 %	100 %	100 %
Kane (SR)	25 %	58.33 %	100 %	100 %

AR – aberrometric refraction, SR – subjective refraction

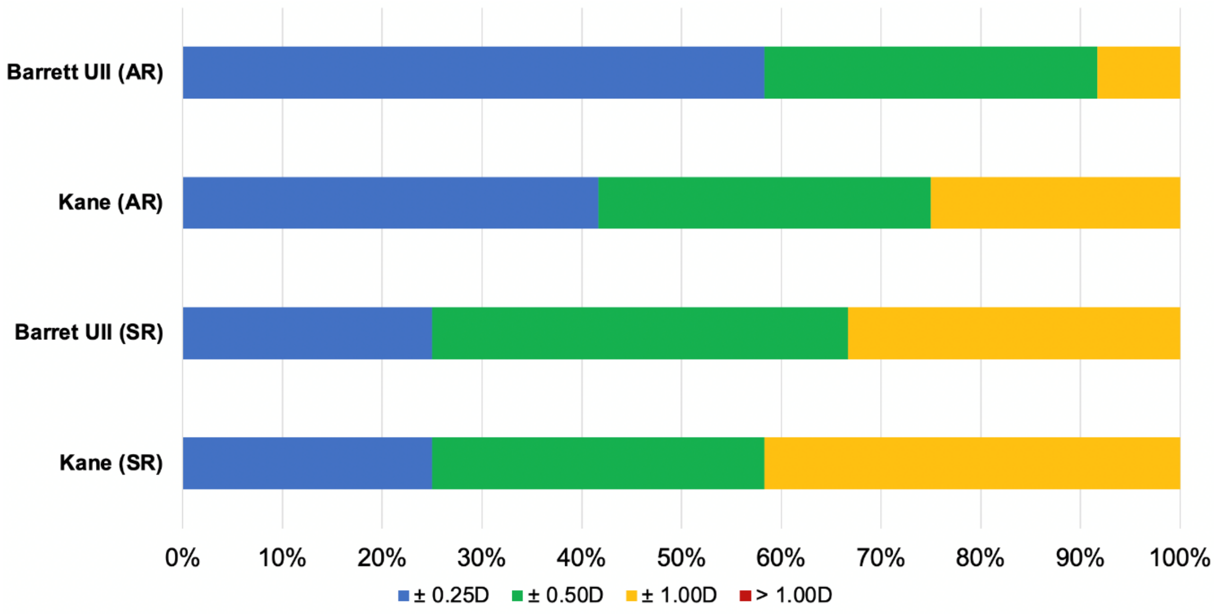

Figure 1 - Percentage of eyes within ±0.25, 0.50, 1.00 D and 2.00 D for each formula, with both refraction systems.

Discussion and Conclusion

In this study we have found that spherical power measured using subjective and aberrometric refraction was similar. While it is known that several aberrometers may cause instrument myopia of 0.3 or even 0.4 D,(17,18) since patients were pseudophakic, instrument myopia due to accommodation is unlikely or minor in effect. Moreover, our results suggest that spherical power was not significantly different between methods (p=0.440), which further supports this hypothesis.

On the other hand, the cylinder magnitude (and, therefore, the SE) was significantly (p=0.014) higher (more negative) in the aberrometric refraction. In fact, overestimation of astigmatism compared to manifest refraction is usual in autorefraction,(14,19,20) partly due to the fact that patients are accustomed and adjusted to visual perception without full correction of objectively measurable astigmatism,(21) and this overestimation of astigmatism has also been described in refractions obtained with aberrometers, including the Tracey wavefront aberrometer.(12, 22) Moreover, besides the aforementioned neural factors, refractive factors may also contribute to these differences. It is known that cylindrical and spherical lenses chosen by the patient during subjective refraction might compensate not only for the spherocylindrical lower-order aberrations, but also for part of the higher-order aberrations.(23) Higher-order aberrations can influence subjective refraction, and can be partially compensated for by using different cylindrical and spherical lenses during manifest refraction,(24,25,26) meanwhile wavefront measurements clearly split lower-order spherocylindrical components from higher-order aberrations.(23) Finally, varying pupil size during both refractions (with larger pupils associated with more low and high-order aberrations) could also contribute to differences between techniques. We purposefully performed examination in undilated mesopic conditions to better approximate real life conditions.

Interestingly, axis measurements were not significantly different between techniques. Also, using power vector analysis, which considers both magnitude and axis, no significant differences were observed. However, in IOL formula prediction error analysis, which is based on spherical equivalent comparisons, only the magnitude of the cylinder is considered, which was significantly smaller in subjective refraction.

The formulas used in this study were the Kane (theoretical optics and artificial intelligence based) and Barrett Universal II (theoretical optics only). The Kane formula is one of the most accurate formulas available, with the lowest mean absolute error, median absolute error, standard deviation and highest percentage of eyes within 0.50 D prediction errors in some studies.(27,28) The Barrett Universal II is also a very accurate formula.(27)

The aberrometric refraction wielded a significantly lower ME with both formulas, as well as higher percentage of eyes which had a prediction error within ±0.25 and 0.50 D, also with both formulas. Indeed, we believe this technique can alleviate some systematic bias found in subjective refraction, like the plano 20/20 bias, in which patients with 20/20 uncorrected visual acuity are attributed a plano refraction whereas a small refractive error (including small cylinders) could still be measured.(29) Furthermore, aberrometric refraction also helps to avoid the small myopic shift seen when refracting using 6 meter lanes.(29)

One limitation of this study is the small sample size (as a bigger sample would have allowed us to make subgroup analysis based on age, axial length and/or keratometry), as well as including both eyes of the same patient. Nonetheless, we find these limitations acceptable due to the exploratory nature of this study. A future study with a larger sample, pupillometry in both the subjective and aberrometric refraction arms and different IOL technologies (for instance multifocal IOLs with diffractive or new-generation refractive designs) is warranted.

We postulate that aberrometric refraction can be used as an easy way to obtain operator and patient-independent supplementary outcome measures for the evaluation of refractive outcomes following uncomplicated cataract surgery with implantation of monofocal intraocular lens. This study's results suggest that aberrometric refraction may better approximate preoperative predictions from modern biometric formulas. In the future, it could be interesting to explore the role of aberrometry in the postoperative evaluation of premium IOLs and/or complicated cataract surgery.

Acknowledgments

Agradeço ao Dr. Miguel Raimundo, por quem tenho profunda admiração, pela oportunidade de trabalhar com ele, pela incansável disponibilidade e, sobretudo, por ter suscitado o meu interesse pela Oftalmologia.

Agradeço à Professora Doutora Andreia Rosa a disponibilidade e supervisão assertiva, bem como o grande contributo na concepção do estudo e análise crítica dos resultados obtidos.

Ao Dr. Emmanuel Neves, pela ajuda fulcral na parte da colheita dos dados.

À minha família, em particular aos meus pais, à minha namorada e aos meus amigos, pelo apoio e carinho.

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