Universidade do Minho
Escola de Ciências

Helena Isabel Ferreira Neves

Analysis of Light Visual Distortion and Quality of Vision with Different Multifocal Lens Designs for the Compensation of Presbyopia

November 2017

Analysis of Light Visual Distortion and Quality of Vision with Different Multifocal Lens Designs for the Compensation of Presbyopia
Helena Isabel Ferreira Neves
UMinho | 2017

FCT
Fundação para a Ciência e a Tecnologia
MINISTÉRIO DA EDUCAÇÃO E CIÊNCIA

COMPETE
PROGRAMA OPERACIONAL FACTORES DE COMPETITIVIDADE

QUADRO DE REFERÊNCIA ESTRATÉGICO NACIONAL
PORTUGAL 2007.2013

Governo da República Portuguesa

UNIÃO EUROPEIA
Fundo Social Europeu

Universidade do Minho
Escola de Ciências

Helena Isabel Ferreira Neves

Analysis of Light Visual Distortion and Quality of Vision with Different Multifocal Lens Designs for the Compensation of Presbyopia

PhD Thesis in Science
Specialty in Physics

PhD Thesis Under Supervision of:
Prof. Doutor José Manuel González-Méijome
Professor Catedrático da Escola de Ciências
Universidade do Minho

Prof. Doutor António Queirós Pereira
Professor Auxiliar do Departamento de Física
Escola de Ciências
Universidade do Minho

November 2017

STATEMENT OF INTEGRITY

I hereby declare having conducted my thesis with integrity. I confirm that I have not used plagiarism or any form of falsification of results in the process of the thesis elaboration. I further declare that I have fully acknowledged the Code of Ethical Conduct of the University of Minho.

University of Minho, 17th of November o f2017

Full name: Helena Isabel Ferreira Neves

Signature:

Helena Isabel Ferreira Neves

Para ti, avó.

ACKNOWLEDGEMENTS

Deixo todo o meu agradecimento aos meus pais, avós, e família pelos valores que me transmitiram ao longo da vida e por serem o pilar que está sempre presente para apoiar todas as decisões da minha vida. Agradeço o apoio e o entusiasmo, por me fazerem acreditar e me darem força para tentar ser cada vez mais e melhor.

A ti Rui, pelo amor, paciência e compreensão. Por me apoiares nesta "ausência presente", que nem sempre é fácil, e acima de tudo por aceitares percorrer todos os "Caminhos" comigo.

Aos meus orientadores Professor Doutor José Manuel González-Méijome e Professor Doutor António Queirós Pereira, aos quais serei eternamente grata pela disponibilidade que sempre demonstraram e pelo apoio e partilha de conhecimentos. Acima de tudo, agradeço por ter tido a oportunidade de fazer parte de um grupo de pessoas incríveis. Refiro-me a todos os colegas e professores, com os quais tive o gosto de partilhar experiências no Laboratório de Investigação em Optometria Clínica e Experimental (CEORLab). Para TODO o grupo: "If I have seen further it is by standing on the shoulders of Giants." – Isaac Newton.

A todos os meus amigos, com agradecimento especial à Rute que tanto me aturou e ajudou nesta jornada, Ana Amorim, Vânia, Marisa, Laura, Nery, Susana e Rui Ramoa, pela paciência constante, boa disposição mas, sobretudo, pela amizade. A todos que, directa ou indirectamente, contribuíram para o resultado final deste trabalho, aqui expresso o meu agradecimento.

Aos voluntários que participaram neste projeto, pela simpatia constante, submetendo-se aos procedimentos sempre com muita paciência e disponibilidade.

Ao Professor Doutor José Salgado-Borges, Professor Doutor Manuel Monteiro e restante equipa pela hospitalidade e todo o acompanhamento dado no âmbito das suas clínicas oftalmológicas. Ao Doutor Miguel Ángel Gil do Hospital de Sant Pau, Barcelona, sem o qual teria sido impossível ter desenvolvido este trabalho. À sua família, em particular à sua esposa Coni, pelo carinho com que me receberam e pela entrega pessoal para que tirássemos o maior partido da minha estadia.

À Universidade do Minho, por todas as condições que me foram proporcionadas através do Departamento de Física na realização deste trabalho e às empresas que forneceram os materiais necessários para a realização do trabalho.

À Fundação para a Ciência e Tecnologia (FCT - Ministério da Ciência e do Ensino Superior (MCES) pela bolsa de doutoramento (Helena Isabel Fereira Neves . SFRH/BD/78900/2011).

ABSTRACT

The present Thesis integrates the results of the studies conducted at the Clinical & Experimental Optometry Research Lab – Minho University (CEORLab) and in collaboration with hospital and clinics that were interested in knowing how we can quantify the sensations that the patients normally describe when using optical devices that change their quality of vision under certain conditions, as night time conditions.

In the second chapter of this thesis, we initially explain Night Vision Disturbances (NVD) in the form of haloes, glare, and starburst that affect many subjects when viewing under dim illumination conditions. First, we tried to define several terms relating to this topic due to a lack of standardization. Next, and due to lack of scientific validity of some tests, there were explained how some of them work and why they are sometimes hard to interpret by the physician and by the patient.

In chapter 3, we conducted measurements with the new prototype device Light distortion Analyzer (LDA) in a series of subjects to evaluate the repeatability of the prototype device under different conditions of brightness of the stimuli, pupil size, and different examination strategies previously configured in the software of the device. Simultaneously, the times of examination were recorded in order to determine if they are feasible in the clinical practice.

One of the goals of the present thesis, resulting in chapter 4, was to apply the measurement of disturbances in contact lens wearers. To test this, two different contact lens materials were fitted to subjects and the light disturbances were measured under different blinking intervals. This work concluded that the perception of light disturbance is affected by the frequency of blinking and this effect worsens with contact lenses. However, under frequent blinking it is not expected that the contact lens material do play a role in the measurement of light disturbance.

Chapter 5 reports the results of a study that investigated the impact of different multifocal contact lens (MFCLs) designs in the perception of light disturbance. The multifocal contact lenses produce multiple simultaneous foci that can compromise the quality of the images viewed by the subjects, especially under night vision conditions. The device used to measure

night vision disturbances NVD, the Light Distortion Analyzer (LDA), showed to be sensitive to differences in the patterns of disturbance generated by multifocal systems.

Besides quantifying NVD, subjective assessment of patient's complaints was measured by means of two questionnaires in chapter 6. We compared for three different multifocal soft contact lenses worn by presbyopic patients for a 15 days period, using the LDA to quantify the NVD and the questionnaires to know more about the subject's subjective perceptions.

NVD can be can be exacerbated by certain ocular conditions, such as cataract, and refractive surgery procedures. To understand the quality of vision of patients implanted with Multifocal IOL's, it is important to analyse not only visual acuity and contrast sensitivity, but also try to examine the disturbance caused by punctual sources of light under night vision conditions. The purpose of chapter 7 was to evaluate the light disturbance after refractive lens exchange (RLE) with diffractive bifocal and trifocal intraocular lenses (IOLs) in comparison to a monofocal procedure. Outcome measures showed the reliability of the Light Distortion Analyser (LDA) in finding increased light disturbance index (LDI) in the multifocal groups, as a result of the diffractive optics systems of the current lenses.

The perceptions of the patients involve much more factors than the optical ones measurable in the optical bench, as it was study in Chapter 8. However, this experiment confirms that the perception measured with LDA depends in part of the optical design of the lens and its physical performance, as might be anticipated.

RESUMO

A presente Tese integra os resultados dos estudos realizados no Clinical & Experimental Optometry Research Lab – Minho University (CEORLab) e em colaboração com hospitais e clínicas interessados em perceber como podemos quantificar as perceções que os pacientes normalmente descrevem ao utilizar dispositivos óticos que alteram sua qualidade de visão sob certas condições, como por exemplo, em condições noturnas.

No segundo capítulo, inicialmente descrevemos as Distorções da Visão Nocturna (NVD) sob a forma de halos, brilho e "starburst" que afetam muitos sujeitos ao visualizar objetos em condições de baixa iluminação. Primeiro, tentamos definir vários termos relacionados este tema devido à falta de padronização. Em seguida, e devido à falta de validade científica de alguns testes, foram explicados como alguns deles funcionam e por que às vezes são difíceis de interpretar pelo profissional da visão e de realizar pelo paciente.

No capítulo 3, realizamos medidas com o novo protótipo de quantificação das NVD, o Light Distortion Analyzer (LDA) numa série de condições para avaliar a repetibilidade do protótipo em diferentes condições de brilho dos estímulos, tamanho da pupila e diferentes estratégias de exame previamente configuradas em o software do dispositivo. Simultaneamente, os tempos de exame foram registrados para determinar a sua viabilidade para ser realizado em prática clínica.

Um dos objetivos da presente tese, que resultou no capítulo 4, consistiu em medir as NVD em usuários de lentes de contato. Para tal, dois materiais diferentes de lentes de contato foram adaptados em voluntários e as NVD medidas sob diferentes intervalos de pestanejo. Este trabalho concluiu que a percepção das NVD é afetada pelo material da lente de contacto e pela frequência de pestanej. O efeito de NVD piora com lentes de contato. No entanto, sob um pestanejo frequente, não se espera que o material da lente de contato desempenhe um papel muito importante na percepçãi das NVD.

O Capítulo 5 relata os resultados de um estudo que investigou o impacto de diferentes tipos de lente de contacto multifocais (MFCLs) na percepção de NVD. As lentes de contacto multifocais produzem múltiplos focos em simultâneo que podem comprometer a qualidade das imagens vistas pelos sujeitos, especialmente sob condições de visão noturna. O dispositivo usado para medir as distorções visuais noturnas, o Light Distortion Analyzer (LDA), mostrou-se sensível às diferenças nos padrões de distorção gerados pelos diferentes sistemas multifocais.

Além de quantificar as NVD, a avaliação subjetiva das queixas do paciente foi medida por meio de dois questionários no capítulo 6. Procedeu-se à comparação de três lentes de contato

multifocais diferentes usadas por pacientes présbitas por um período de 15 dias, utilizando o LDA para quantificar as NVD e os questionários para avaliar as percepções subjetivas dos sujeitos.

As NVD podem ser exacerbadas por certas condições oculares, como a catarata e procedimentos de cirurgia refractiva. Para entender a qualidade de visão dos pacientes implantados com lentes intra oculares (IOL) multifocais, é importante analisar não apenas a acuidade visual e a sensibilidade ao contraste, mas também tentar examinar as distorções visuais causadas por fontes pontuais de luz, principalmente em condições de visão noturna. O objetivo do capítulo 7 foi avaliar as NVD implantação de lentes intraoculares difractivas bifocais e trifocais em comparação com um procedimento controlo de implantação de uma lente intraocular monofocal. Os resultados mostraram que o Light Distortion Analyzer (LDA) em foi sensível para detetar o aumento do Índice de Distorção Luminosa (LDI) nos grupos multifocais, como resultado dos sistemas ópticos difractivos das lentes atuais.

As percepções dos pacientes envolvem muito mais fatores do que os ópticos mensuráveis no banco óptico, como foi estudado no Capítulo 8. No entanto, esta experiência confirma que a percepção medida com LDA depende, em parte, do design óptico da lente e sua desempenho físico, como poderia ser antecipado.

ÍNDICE

GLOSSARY OF TERMS & ABBREVIATIONS

AL	Axial Length
BFC	Best Fit Circle
BFC_{Irreg}	BFC Irregularity
$BFC_{IrregSD}$	Standard Deviation (SD) of the BFC Irregularity
BFC_{Orient}	Orientation of Best Fit Circle Center
BFC_{Rad}	Best Fit Circle Radius
BUT	Tear-film Break-up Time
CDVA	Corrected Distance Visual Acuity
CL	Contact lens
CNVA	Corrected Near Visual Acuity
CSF	Contrast Sensitivity Function
CT	Central Thickness
D	Diopter
DA	Disturbance Area
DK	Oxygem Permeability
EWC	Equilibrium Water Content
HOA	High-order Aberrations
IBI	Inter-blink Interval
IOL	Intra Ocular Lens
K	Keratometry
LD	Light Disturbances
LDA	Light Distrotion Analyser
LDI	Light Disturbance Index
LED	Light Emmiting Diodes
MFCL	Multifocal Contact Lenses
NIBUT	Non-invasive Tear Break-up Time
NVD	Night Vision Disturbances
OCT	Optical Coherence Tomography
OVD	Ophtalmic Viscosurgical Device

PCO	Posterior Capsule Opacification
Posop	Post Operation
Preop	Pre Operation
QoV	Quality of Vision
RLE	Refractive Lens Exchange
RMS	Root Mean Square
SA	Spherical Aberration
SCL	Soft Contact Lens
SD	Standard Deviation
T-test	T Student Test
UDVA	Uncorrected Distance Visual Acuity
UNVA	Uncorrected Near Visual Acuity
VA	Visual Acuity
X_{Coord}	Best Fit Circle Center xx´ Coordinates
Y_{Coord}	Best Fit Circle Center yy´ Coordinates

LIST OF FIGURES

LIST OF TABLES

PUBLICATIONS RELATED WITH THIS THESIS

Papers

Radiometric characterization of a novel LED Array System for Visual Assessment
Linhares JMM, Neves H, Lopes-Ferreira D, Faria-Ribeiro M, Peixoto-de-Matos SC, Gonzalez-Meijome JM
Journal of Modern Optics, 60:14, 1136-1144, DOI: 10.1080/09500340.2013.842614

Adaptation to Multifocal and Monovision Contact Lens Correction
Paulo RB Fernandes, Helena IF Neves, Daniela PL Ferreira, José MG Meijome.
Optom Vis Sci. 2013 Mar;90(3):228-35. DOI: 10.1097/OPX.0b013e318282951b.

Included in this Thesis:

Light-Distortion as a possible indicator of visual quality after refractive lens exchange with diffractive multifocal intraocular lenses
Brito P, Salgado-Borges J, Neves H, González-Méijome J, Monteiro M. J Cataract Refract Surg. 2015 Mar;41(3):613-22.

Validation Of A Method To Measure Light Distortion Surrounding A Source Of Glare
Ferreira-Neves H, Macedo-de-Araujo R, Rico-del-Viejo L, da-Silva A, Queirós A, Gonzalez-Meijome JM J. Biomed. Opt. 2015 Jul|;20(7):75002.

Oral presentations

9ª Jornada Científico-Técnica de Contactologia, Universidade do Minho, 3rd of March of 2014
"Curvas de Desfocado na Avaliação da Performance das LC Multifocais"
Neves H; González Méijome JM.

IX Conferências Abertas Optometria, Coimbra, 16 – 17th of November of 2013
"Performance Visual e Percepções Subjetivas de Usuários de Lentes de Contacto Multifocais"
Neves H; Lopes-Ferreira D; González Méijome JM.

8ª Jornada Científico-Técnica de Contactologia, Universidade do Minho, 19th of February of 2013
"O Mundo Real para os Pacientes Présbitas com LC Multifocais"
Neves H; Lopes-Ferreira D; González Méijome JM.

XXX Congress of the ESCRS, European Society Cataract and Refractive Surgery – Milan (Italy), 8 – 12th of September of 2012.
"Reduction of haloes by reducing the positive spherical aberration of the eye with a silicone hydrogel contact lens"
González-Méijome, JM; Neves, Helena; Peixoto-de-Matos, S; Queirós, A; Jorge, J.

9º International Conference of Optometry and Visual Sciences CIOCV'2012, University of Minho, Braga, 21 – 22nd of April of 2012

"Subjective Quality of Vision with the Quality of Vision Questionnaire (QoV) in Multifocal Contact Lenses Wearers"
Neves H.; Lopes-Ferreira D., Isla-Paradelo L.; Peixoto-de-Matos SC., Jorge J., González-Méijome JM.

"Contrast Sensitivity Function with Three Different Multifocal Contact Lenses Under Low Luminance and in the Presence of Glare"
Lopes-Ferreira D, Neves H, Isla-Paradelo L, Peixoto-de-Matos, SC., Madrid-Costa D, Jorge J, González-Meijóme JM.

"Contrast Sensitivity Function with Different Pupil Size after Wear of Three Multifocal Contact Lenses"
Isla-Paradelo L.,Neves H., Lopes-Ferreira D., Madrid-Costa D.,Queiros A., Fernandes P., González-Méijome JM.

22º Congresso Internacional de Optometría, Contactología y Óptica Oftálmica, Madrid (Espanha), 17 – 19th of February of 2012

"Evaluación de la distorsión luminosa con tres tipos de lentes de contacto multifocales hidrofílica"
Neves H., Lopes-Ferreira D., Isla-Paradelo L., Madrid-Costa D., Jorge J., Queirós A., González-Méijome J.M.

"Función de sensibilidad al contraste durante la adaptación de 3 tipos de lentes de contacto multifocales: estudio longitudinal"
Isla-Paradelo L, Neves H., Lopes-Ferreira D.., Madrid-Costa D., Jorge J., Queirós A., González-Méijome J.M.

"Alteraciones de la agudeza visual de alto y bajo contraste con tres tipos de lentes de contacto multifocales hidrofílicas"
Lopes-Ferreira D., Neves H., Isla-Paradelo L., Madrid-Costa D., Jorge J., Queirós A., González-Méijome J.M.

VII Conferências Abertas Optometria, Covilhã, 26 – 27th of November of 2011

"Avaliação da distorção luminosa com três tipos de lentes de contacto hidrófilas multifocais"
Neves H; Lopes-Ferreira D; González Méijome JM.

"Alterações na Acuidade Visual de Alto e Baixo Contraste com Lentes de Contacto Multifocais"
Lopes-Ferreira D, Neves H, González-Méijome, JM.

89th Annual Meeting of the American Academy of Optometry, Boston, EUA, 12-15th of October of 2011

"Contrast Sensitivity Function With Different Pupil Size, Illuminance And Glare In Asymmetric Multifocal Soft Lens Fitting In Presbyopic Patients"
Neves H, Isla-Paradelo L, Lopes-Ferreira D, Madrid-Costa D, Jorge J, González-Méijome JM

6ª Jornada Científico-Técnica de Contactologia – Braga, 22nd of February of 2011
"Impact of in vivo Soft Contact Lens Dehydration in Perception of Light Distortion" Neves H, Peixoto-de-Matos SC, Queiros A, Jorge J, Villa-Collar, González-Méijome JM.

Posters

11th International Conference of Optometry and Visual Sciences CIOCV'2014, University of Minho, Braga, 24 and 25th of May of 2014
"Quantitative and Qualitative Description of the Light Distortion as a Function of Spherical Aberration"
Araújo R, Rico-del-Viejo L, da Silva AC, Peixoto-de-Matos SC, Neves H, González-Méijome JM

Association for Research in Vision and Ophthalmology (ARVO) 2014, Orlando, Flórida, 4-8th of May of 2014
"Light Distortion Size with Multifocal Diffractive and Monofocal Aspheric Intra-ocular Lenses in Pseudophakic Patients"
González-Méijome, José M.; Ferreira-Neves, Helena; Brito, Pedro; Queirós, Antonio; Monteiro, Manuel; Salgado-Borges, José

37th Clinical Meeting of the British Contact Lens Association (BCLA) – Manchester, 6-9th of June of 2013
"Supplementary Reading Spectacles During Adaptation Period to Multifocal Contact Lenses in Presbyopes"
H Neves, D Lopes-Ferreira, L Isla-Paradelo, J Jorge, González-Méijome

10th International Conference of Optometry and Visual Sciences CIOCV'2013, University of Minho, Braga, 13 and 14 April 2013
"Evaluation of daily life tasks subjective performance with multifocal contact lenses in presbyopes"
H Neves, D Lopes-Ferreira, L Isla-Paradelo, J Jorge, González-Méijome

35th Clinical Meeting of the British Contact Lens Association (BCLA) – Manchester, 27-30th of May of 2011
"Impact of in vivo soft contact lens dehydration in perception of light distortion" Neves H, Peixoto-de-Matos SC, Queiros A, Jorge J, Villa-Collar, González-Méijome

Chapter 1

Thesis Overview

1. THESIS OVERVIEW

1.1 Introduction and Research Rationale

Light disturbances (LD) in the form of haloes, glare, and starburst affect many subjects when viewing under dim illumination conditions. These issues can be exacerbated by certain ocular conditions, some of them frequent such as cataract, and refractive surgery procedures.

Over the past decades, the measurement of these disturbances has been carried out in a non-formal manner like asking the patients to draw their perceptions. More recently, different devices and methods have been developed to quantitatively measure these disturbances.

The goal of the present thesis is to validate a new prototype device to quantify the light disturbances affecting the viewing of bright sources of light under night vision conditions and to evaluate its applicability in two main areas of current interest, the correction of presbyopia with multifocal contact lenses and with intra-ocular lenses. This includes an international collaboration in Chapter #8 carried out with Universidad Politécnica de Cataluña where I had the great opportunity to evaluate a great variety of intra-ocular devices implanted in patients undergoing cataract surgery.

The thesis document is structured in several cross-sectional studies to address several research questions:

- Is it possible to quantify in the clinical setting in a limited examination time the light disturbances using a novel prototype comprising physical LEDs controlled by a custom-made software?
- Can older patients perform the test easily and reliably?
- Is it possible to differentiate the disturbances induced by contact lenses comprising different optical designs?
- Is it possible to differentiate the disturbances induced by intra-ocular lenses comprising different optical designs and addition powers?

In order to answer these questions a set of independent but sequentially related works has been developed over the course of the Thesis Project as described below.

1.2 Structure of the Thesis Document

In order to make the work easy to follow, the flow chart in **Figure 1.1** represents the different studies conducted and presented in the thesis document in the form of Chapters. A brief summary of each chapter is presented below, and followed by a general overview of the main outcomes of the thesis. Each chapter and the final conclusions are explored in detail in their respective sections within the document. Each one of these chapters configures a research article already submitted for publication or intended to submit for publication.

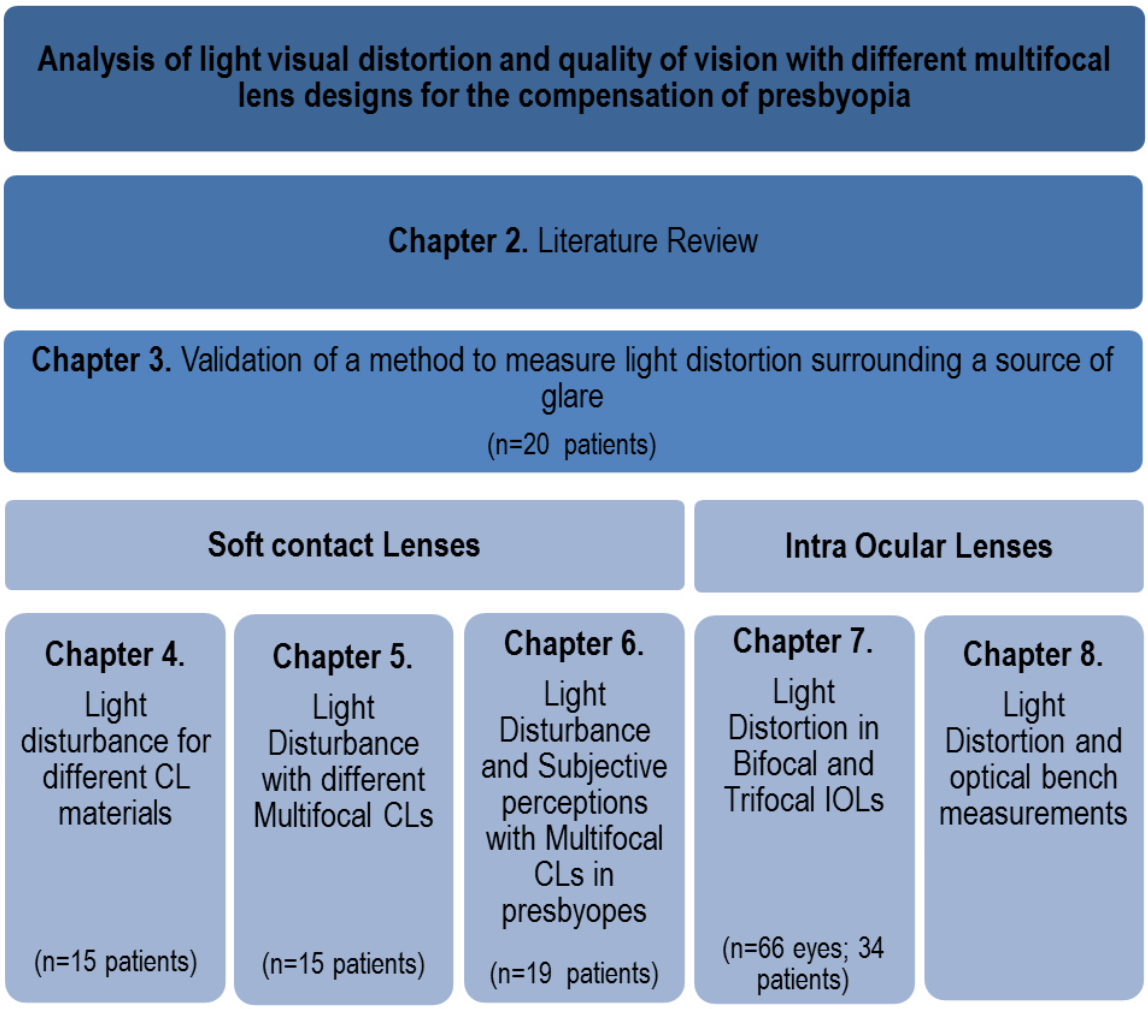


Figure 1.1 - Flow chart of the research rationale linking the studies and results chapters included in the thesis document.

1.2.1 Chapter 2. Literature review

This chapter includes a revision conducted at the beginning of the Thesis Project. It is focused on the different methods used to evaluate and quantify the light disturbances, with special emphasis on those with potential use in the evaluation of multifocal devices to correct presbyopia.

1.2.2 Chapter 3. Validation of a method to measure light disturbance surrounding a source of glare

In this chapter we conducted measurements with the new prototype device in a series of subjects to evaluate the repeatability of the prototype device under different conditions of brightness of the stimuli, pupil size, and different examination strategies previously configured in the software of the device. Simultaneously, the times of examination were recorded in order to determine if they are feasible in the clinical practice.

This work concludes that the device is repeatable intra-session and inter-session under different exam conditions and that the 30º in-out strategy of examination is the faster approach. This information is essential for the subsequent steps in the thesis development to apply the instrument in clinical settings.

1.2.3 Chapter 4. In-Vivo changes in light disturbance for two silicone hydrogel soft contact lenses

One of the goals of the present thesis was to apply the measurement of disturbances in contact lens wearers. The contact lens material acts as a source of instability of the tear film and this could affect the measurements due to larger scattering of light in case the surface of the lens dries out. To test this, two different contact lens materials were fitted to subjects and the light disturbances were measured under different blinking intervals.

This work concluded that the perception of light disturbance is affected by the frequency of blinking and this effect worsens with contact lenses. However, under frequent blinking it is not expected that the contact lens material do play a role in the measurement of light disturbance.

1.2.4 Chapter 5. Characterization of the impact of multifocal contact lens (MFCL) in light disturbance under night vision conditions

The multifocal contact lenses are highly dependent on the pupil size to achieve the desired performance. Under night vision conditions, and because of the multiple simultaneous foci created by the MFCL, the quality of the images may be compromised. This chapter reports the results of a study that investigated the impact of different multifocal contact lens (MFCLs) designs in the perception of light disturbance.

The device used to measure night vision disturbances NVD, the Light Distortion Analyzer (LDA), showed to be sensitive to differences in the patterns of disturbance generated by multifocal systems.

As a result of the comparison between the different multifocal designs, there was found an increase in NVD with the all MFCLs when comparing to the baseline condition. Different multifocal designs have different impacts in the perception of NVD, being the multizone refractive optics the one that exacerbated more the NVD, showing a less satisfactory performance.

1.2.5 Chapter 6. Light Disturbance and Subjective Perception of Presbyopes with Multifocal Contact Lenses

Subjective and psychophysical measures of NVD were compared for three different multifocal soft contact lenses in presbyopic patients for a 15 days period, using the LDA to quantify the NVD and the questionnaires to know more about the subject's subjective perceptions.

When comparing with the patient's spectacle correction, wearing a multifocal soft contact lens increases the perceptions of NVD. Although this effect is more present in the first 1-7 day of lens wear, after 15 days, and due to the binocular summation effect, the LDI is reduced for levels that are comparable to the baseline situation. Frequency and the severity of the symptoms evaluated in the QoV questionnaire increase after 15 days of lens wear when comparing to the baseline situation. From this trial, we can conclude that if the patient is fitted with lower addition multifocal soft contact lenses, it will not worsen their quality of vision over time in a significant

way comparing with their best correction in spectacles. If the fitting is with higher additions, the center near aspheric design and the asymmetric design are the ones that provide to the patients a smaller decrease in their QoV. The present work had the purpose to assess the subjective perceptions from the patient's point of view in what concerns to some daily-life tasks. Night vision was one of the tasks where the patients reported some degree of difficulty. Besides that, our results revealed high rates of satisfaction in certain areas, mainly related with esthetic perception and comparison against other types of vision correction, such has spectacle correction.

1.2.6 Chapter 7. Light disturbance with diffractive multifocal intraocular lenses (IOLs)

To understand the quality of vision of patients implanted with Multifocal IOL's, it is important to analyse not only visual acuity and contrast sensitivity, but also try to examine the disturbance caused by punctual sources of light under night vision conditions. The purpose of this chapter was to evaluate the light disturbance after refractive lens exchange (RLE) with diffractive bifocal and trifocal intraocular lenses (IOLs) in comparison to a monofocal procedure.

Outcome measures showed the reliability of the Light Distortion Analyser (LDA) in finding increased light disturbance index (LDI) in the multifocal groups, as a result of the diffractive optics systems of the current lenses.

1.2.7 Chapter 8. Relationship Between Clinical Light Disturbance Analysis In Pseudophakic Patients Implanted With 5 IOLs And Optical Bench Measures

This final study comprised the work developed during a residency at Hospital Sant Pau in Barcelona (Spain). It is a very comprehensive study involving several multifocal Intraocular Lenses implanted after cataract surgery in a sample of 119 subjects (including 12 controls with cataract). After analyzing the light disturbance with the LDA Device we observed that the size of the disturbance followed a parallel with the results obtained in the Optical Bench for the same IOLs when the halo around an extended object was analyzed. These preliminary results do not mean directly that we can infere directly the Subjective Light Disturbance experienced by the

patient from the optical bench measurements. In fact, the perceptions of the patient involve much more factors than the optical ones measurable in the optical bench. However, this experiment confirms that the perception measured with LDA depends in part of the optical design of the lens and its physical performance, as might be anticipated. This confirms in our opinion the utility of the device for assessment of pseudophakic patients implanted with IOLs.

Chapter 2

Literature Review

2. LITERATURE REVIEW

2.1 Introduction to night vision disturbances

There are many complaints about the methods and techniques used so far to measure night vision disturbances. There's a lack of standardization, lack of scientific validity of some tests and some of them are hard to interpret by the physician and by the patient. In the other hand, most of the tests have a high cost and can't correlate the results with the symptoms. Although there are different methods to quantify ocular scattering and other Night Vision Disturbances (NVD), there are few clinical reports to validate these systems for clinical practice.[1]

First, it is necessary to define several terms relating to this topic (since there is a great variety of definitions and words employed in several articles)

2.1.1 Concepts and definitions

Night vision disturbances: Glare, starburst, haloes, contrast sensitivity loss and image degradations among other disturbances are all included in the term of NVD. Some of the terms are described with more detail below.

- GLARE is a blurring or smearing of lights and can be differentiated at least into three types:
    - *Discomfort Glare* – produces subjective visual discomfort and fatigue without necessary interfering with visual performance.[2] This is only a physical term that refers to a light source and fully explains some night vision difficulties.[3]
    - *Disability Glare* – describes any subjective complaint of reduced visual performance and target visibility.[2,3] This type of glare occurs when a source of light is scattered by the ocular media leading to an image degradation, and this situation can happen when the luminance within the visual field is greater than the luminance to which the eyes are adapted to.[3] Other authors have defined disability glare as the temporary loss of visual function in the presence of a bright adjacent light source.[4]
    - Veiling Glare – glare caused by light scatter within the eye. The light is scattered onto the retinal image of interest and reduces the contrast of retinal image.[2]

- STARBURST is a common phenomenon that is also reported by patients who that were not submitted to any kind of surgery – can also happen to those who are undercorrected.[5]
- HALOS – are distinct rings around lights that can occur with or without associated starburst.[3] Halos can occur, for example, when the pupil diameter is greater than the optic zone after a refractive surgery[3], being also typically associated to multifocal contact or intraocular lenses.

In Figure 2.1 are represented the differences between a punctual source of light and the phenomenon of glare, halo and starburst. They all can occur simultaneously, being sometimes difficult for the patients to distinguish them. Although these terms are often used interchangeably, each represents a distinct effect with a particular cause.

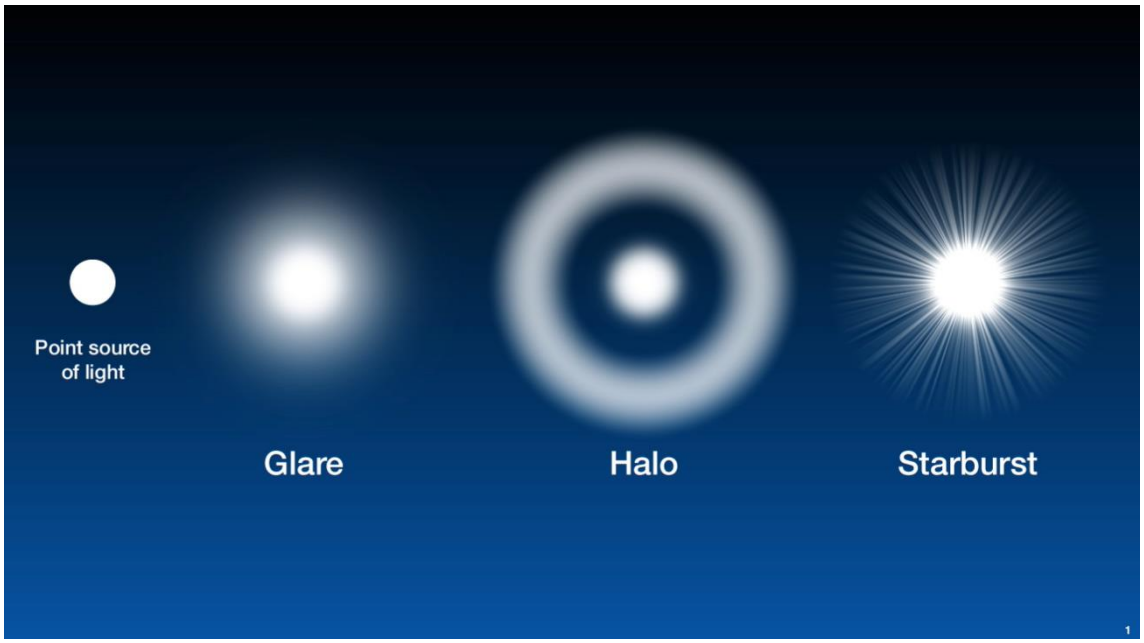


Figure 2.1 - Illustration of the differences between a punctual source of light and the night vision disturbances such as glare, halo and starburst. Available at: https://millennialeye.com/articles/2016-jul-aug/night-vision-and-presbyopia-correcting-iols/

OCULAR SCATTERING – defined as an "optical phenomenon that degrades the retinal image in the human eye, similar to the effects of ocular aberrations or diffraction. This is inherent to light propagation through media with optical inhomogeneity, characterized by special variations in the refractive index, small particles, foreign bodies, density fluctuations, surface roughness of the

different ocular optical elements. This non-uniformities can act as potential microscopic scatters and are able to reduce the retinal image quality, inducing a veil of straylight (that is the combined effect of light scattering and the diffuse reflectance from the various fundus layers[6]) over the retina.[1]

The scattering component that is the most important for optometrists and ophthalmologists is the forward-scattering which represents the scattered light that reaches the retina and presents a potential to induce a veiling luminance, reducing the retinal contrast. The other scattering component – backscattered light – is only suitable for quantify the quality of ocular tissues (used in slit lamp).[7] None of this components of scattering will be found in an ideal eye with perfect optical surfaces.[1]

The cornea and crystalline are also sources of back and forward-scattered light: especially when its transparency is affected.[1,8,9] The iris and sclera are also potential sources of forward scattering (because they are not totally transparent).[1] Other source of scattering might be the retina, once the light that reaches the retina is not all absorbed – part of it is reflected for others retinal areas, which contributes for intraocular scattering.[8,9] The vitreous humor is another scattering source – it can be changed in pathological conditions in which its transparency is affected. Summarizing, any ocular structure that presents changes in transparency will lead to an increase in ocular scattering.[1]

Measuring ocular scattering with optical approaches (Double-pass or Hartmann-shack) provide a more independent measurement of ocular scattering, because they are not based on patient's subjective responses.[1]

STRAYLIGHT - Ocular straylight is the combined effect of light scattering in the optical media and the diffuse reflectance from the various fundus layers.[6] Subjective assessment is usually done by questionnaires and psychometric questionnaires.

2.1.2 Methods and techniques for the evaluation of night vision disturbances

Psychophysical – Straylight/Scattering Methods

- DIRECT COMPENSATION METHOD[1]

Is a psychophysical method proposed by Van den Berg10 in the 80's.[10]

The objective of direct compensation method is measuring straylight induced by light scattering from a source of glare. To achieve this, this method has a bright ring-shaped light source, which flickers at a certain angular distance (Θ) from a dark test field. Due to scattering of light generated by intraocular layers, part of the light from the straylight source is projected on the retina and a little flicker on the test field is induced.

To determine the exact amount of straylight, a compensating light is presented on the test field, which flickers in counter-phase and adjustable frequency.

Thereby adjusting the amount of compensating light that is presented on the test field, the flicker perception may be extinguished - when the flicker is extinguished, the precise value of straylight is found. In other words, the subject is asked to adjust the luminance of the test-object in order to achieve annul flickering.[11]

- CONVENTIONAL STRAYLIGHT METER (CSLM) AND COMPUTER IMPLEMENTED STRAYLIGHT METER (NSLM)

The straylight meter is a small portable device based in direct compensation method, which was implemented in 1990[12] It is a glare disability and straylight test, where the intraocular forward light scatter can be determined by varying the luminance.[3]

The computer implemented straylight meter differs from the common straylight meter in that the luminance of the central detection field is constant and the knob doesn't have an end stop. It is possible to eliminate cues and avoid enhancing fraud. This instrument is used binocularly, once the patient looks at a computer screen and not in a test-tube.[13]

- COMPENSATION COMPARISON METHOD

The operation of this psychophysical method for measure retinal straylight (combined effect of scattering and diffuse reflectance from the various fundus layers)[6] is based on direct compensation method, with the difference that the centre of the test field is divided into two halves (Fig. 2.2). Besides the direct compensation method, this is the most standardized psychophysical method specifically designed for the quantification of intraocular light scattering.[11]

While at direct compensation the subject compares different stimuli sequentially, in this improved method, two stimuli of direct compensation method are presented and compared by the subject simultaneously.[14]

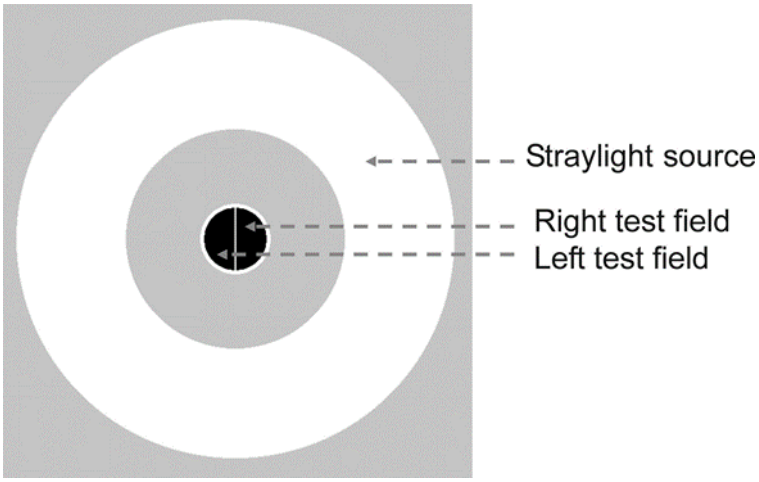


Figure 2.2 - Stimulus layout for the compensation comparison method for retinal straylight measurement.[14]

As seen in Figure 2.2, this method uses a stimulus consisting of a central and peripheral ring with light, where the central field of the test is divided in two halves – one with and one without counter phase compensation light. Thus, two flickers are perceived, in which one results from straylight only and the other results from a combination of straylight and compensation light (flickering in counter phase with this straylight). The task of the subject is to compare the two stimuli (which are presented simultaneously, as previously stated) and decide which half flickers strongly.[1,14] The answers are fitted to a psychometric curve, from which we can take the straylight parameter "s" ("scattering coefficient", expressed in log units) and quantify the scattering – the higher the log(s) value, the higher the intraocular magnitude of forward scattrering.[1]

This procedure has also the advantage of measuring the scattering at large eccentricities, where the scattering has a higher potential of degrading the retinal image.[1] However, the psychophysical methods have some limitations, such as the complexity of some tasks for the subject to perform. [11]

The device that is commercially available to measure the straylight based on the compensation comparison method is the C-Quant (manufactured by Oculus). C-Quant (Figure 2.3) is the abbreviation for Cataract-Quantifier and it's easy and quick to use, also being accurate.[15]

Figure 2.3 -Representation of the C-Quant instrument. Available at: http://www.oculus.de/en/sites/detail_ger.php?page=499

The basis for the commercial development of this device came from compensation comparison method – the most relevant psychophysical procedure described for measuring intraocular forward scattering (which operating mode has been previously discussed)[1] and which is an upgrade in terms of being comfortable and intuitive for the patients. It aims to quantify scattered light in clinical situations such as cataract, corneal haze, post-chirurgical and edema. However, correlations between straylight results and other vision tests with glare, and driving performance not yet been established.[15]

- THE REACTION TIME (SCATTERING METHOD)

Psychophysical method used for measuring ocular scattering (although it has not been clinically validated). This is a specific concept, which is defined as the time interval between the presentation of a stimulus and the subject's response. It is based on the idea that the reaction

time is significantly affected when a high magnitude of intraocular ocular scattering is presented.[26]

The patient has to say when he feels able to discriminate two different sinusoidal gratings in a controlled glare situation (GE – glare effect). After this, the intraocular scattering (also known as diffusion factor – DF) could be calculated by:[26]

DF = GE / Eg

Eg = illumination of the eye used to create the glare effect).

To calculate the GE:

$$GE = \frac{Y_g - Y_{wg}}{Y_{wg}} \times 100,$$

Yg – reaction time with glare

Ywg – without glare

For this procedure be clinically validated, this should be tested in large sample of patients, including post-chirurgical patients, patients with cataract or other pathologies – eyes with large amount of scattering.[1]

Objective – Scattering/Straylight methods

- DOUBLE-PASS SYSTEM. [1,16,17]

Double-pass systems are based on recording images from a point-source object after reflection on the retina and a double pass through the ocular media (with a camera conjugated with the retina).[11,18]

Thus, the light scattering can be measured by analysing the intensity of light in the peripheral part of double-pass Point Spread Function (PSF). This method is efficient for cases in which there is a large quantity of light scattered (as happens in cataracts and dry eyes). [19,20]

However, there are some obstacles in the measurements of scattering: around 1 degree of eccentricity, the light of the PSF is so dim that cannot be directly measured. Another limitation is based on the fact that diffuse light from deeper layers (such as the choroid) may be interpreted as scattered light during the analysis of the retinal image – which may lead to a overestimation of the optical PSF.[11] This effect can be softened by using shorter wavelenghts.[21]

The Optical Quality Analysis System – OQAS (Visiometrics, S.L., Spain) is the only instrument based on double-pass (DP) technique that is currently available for use in daily clinical practice[18] and provides data on the optical performance of the eye (diffraction, aberrations and scattering). It is designed on the basis of the asymmetric pattern of DP with different entrance and exit pupil sizes, and provides an objective estimation of intraocular scattering. The OQAS is based on the asymmetric scheme of DP technique – asymmetric aberrations such as coma cannot be measured by conventional DP symmetric system.[17]

This device uses an infrared laser diode (λ=780 nm) as point source that is projected onto the retina and suffers retinal reflections that double-pass the eye and are registered by a camera.[16] The OQAS (figure 2.4) can also evaluate the changes in the tear film over time and give results about its optical quality. A study provided by Martinez-Roda JA *et al* [17] demonstrated that OQAS has a good intra- and intersession repeatability.

Figure 2.4 - Representation of the OQAS instrument. Available at: (http://iqmedical.com.au/our_products/oqas_diagnostic_equipment)

- ANALYSIS OF THE DEGREE OF POLARIZATION OF LIGHT EMERGENT FROM THE EYE

This procedure was first described by Bueno *et al* [22] as a method of determining objectively the amount of scattered light in an optical system. This analysis is based on the degree of polarization of the light in images formed after double-pass the system. Measurements of polarization proprieties and aberrations are made by means of a dual apparatus composed of a modified DP imaging polarimeter and a wavefront sensor (considering that the light depolarization in an optical system related to scattering).[1]

Bueno *et al* [22] demonstrated that the degree of polarization is well correlated with the level of scattering in the system, showing that this polarimetric parameter provides accurate estimates of the amount of scattering in a system – and may determine that this technique can be used to quantify objectively the amount of light scattered by human eye. However, this method has never been used for clinical purposes.[1]

- PSF – Point spread function

Is defined as the light distribution on the retinal image that corresponds to a point object,[1] and can be measured by a double-pass device. It is well accepted that the external contour of the PSF corresponds to the scattering effect. [23] It is the consequence of the combined effect of light scatter caused by microscopic inhomegeinities and the wavefront aberrations.

- WIDE-ANGLE PSF

It is an objective optical experimental procedure (figure 2.5) that can overcome the limitations of optical systems so far existing, incorporating extended light sources and a method of analysis that allows reconstructing the PSF at higher eccentricities (can measure the PSF of the human eye in an angular range up to 8 degrees).[11] So it is possible to reconstruct part of the PSF spanning about six orders of magnitude in intensity.

The authors demonstrate that this instrument is able to measure the intensity of intraocular scattered light at large angles.[11]

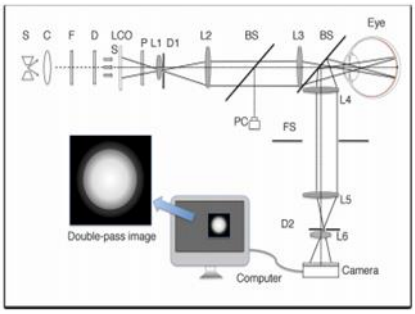


Figure 2.5 - Experimental setup of the wide-angle PSF.[11]

- WIDE-ANGLE PSF FOR DIFFERENT WAVELENGTHS

Recently, was published an article that mentions the use of an instrument based on double-pass principle for measure the straylight for different wavelengths.[6] As mentioned previously, a series of uniform discs are projected on the retina, allowing the uptake of wide angle PSF (in this case, until 7,3 degrees of visual angle). The difference on this system is that it allows doing the measures for different wavelengths, using a liquid-crystal wavelength tunable filter for selecting six different wavelengths between 500 and 650 nm. With this, the influence of wavelength on straylight at different visual angles can be studied (the wavelength dependence of straylight).

- ANALYSIS OF LIGHT SPOT IMAGES OBTAINED WITH A HARTMANN-SHACK SENSOR (FORWARD-SCATTERING)

This is an optical approach that was initially design for quantifying the lenticular forward scattering.[1] The Hartmann-Shack has a micro lens array conjugated to the anterior lens surface, so a localized lenticular source of scattering may affect a limited number of spots – the analysis of these spots who were affected by scattering give us information about the localization of and the level induced by a scatter source.[1]

There could be obtained five different forward scatter metrics that could be calculated from the brightness of pixels within an area containing each lenslet's PSF tail ("pixel neighborhood" – defined by the square perimeter surrounding the central location of each PSF of total pixels determined by average central locations spacing).[24]

However, this analysis as limitations for quantifying the forward scattering, so this is not a good procedure for analysing all ocular sources of scattering, only lenticular scattering sources.[1]

- PURKINJE IMAGES

There are also optical methods based on the analysis of Purkinje images that allows to objectively measure of the amount of scattered light associated with anterior segment of the eye, avoiding the contribution of the retina.[25]

The authors argue that this technique can be used in clinical environments to estimate the level of corneal haze in eyes that undergone to refractive surgery and the scattering due cataract development.[25]

However, these instruments analyse backscattered light, and what most concerns us is the forward-scatter.[11]

Subjective – Scattering/Straylight methods

- BAT (BRIGHTNESS ACUITY TEST)[3]

Is a hand-held instrument that the subject holds to their eye and projects a light onto a 60 mm diameter hemisphere through a 12mm central aperture.[27] The patient should be looking at Pelli-Robson, EDTRS or Regan acuity charts.

This instrument analyses the effect of light scattering trough the decrease in VA caused by a controlled glare source. In order to induce different contrasts, an uniform illumination is used with three different settings - High (white sand beach); Medium (clear day); Low (overhead lighting). If the vision decreases significantly, it may suggest that the patient has a cataract and thus it can help the surgeon in his decision for surgery.[27]

The test could be done with or without pupil dilatation, because dilatation can have an effect on glare testing with this device – some authors argue that perform BAT test in dilated eyes usually assigns incorrectly the loss in the VA to the effect of glare, so some results must be interpreted in the context of the effects of dilatation on VA.[27]

The BAT demonstrates that is a reliable predictor of outdoor visual acuity.[3]

- PELLI-ROBSON LETTER SENSIVITY CHART + BAT[3]

Although measuring contrast sensitivity (CS), this test can be used with the brightness acuity test (BAT) to measure glare disability (GD). These measurements are recommended to be done at a viewing distance of 1m and can be provided using letters of constant size and different contrasts (decreasing the contrast by a factor of 0.15 log units).[28]

- REGAN CHART + BAT [3]

Also evaluates contrast sensitivity and glare disability with BAT. Uses LogMAR acuity charts with letters of different contrasts. For evaluating the GD, it is recommended to be done at a 3m distance and in older or cataract patients to use 25% and 11% contrast charts.[2]

- NIGHT VISION TEST (NVT)

The Night Vision Test (NVT, figure 2.6) consists in a blackboard with a central light which contains red LEDs surrounding a central light – this allows measure the light scatter.[29] The luminance of the two sources can be changed through a remote control.

Kojima *et al* [29] did the NVT at 3m distance from the patient in a dark room (after 15 minutes adaptation to darkness), with the patient wearing mesopic glasses (Vector Vision, Greenvile, OH, USA). During the test, the patient was asked to look at the NTV board and trace the shape of the light using laser point device. Then, the examiner traced the shape on an exact replica of the NVT board.

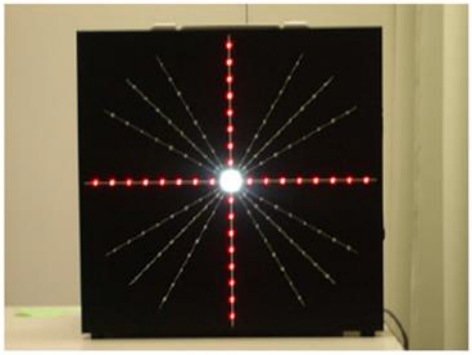


Figure 2.6 - The Night Vision Test. Central light – white LED; Reference lines – red LEDs.[27]

- VISTECH MCT 8000 (glare disability)

Measure the CS and glare disability with different contrast gratings. This instrument as the advantage of assessing contrast under different luminance conditions (low – 3dc/m2 and high – 125cd/m2), which is helpful to test the GD.[3]

- BERKELEY GLARE TEST[3] (glare disability)

Test used for measuring the GD using letters. More specifically, this test uses a low contrast Bailey-Lovie letter chart with a Plexiglas panel as background (Plexiglass is an acrylic sheet of material that is often clear or opaque. It is often used in the place of glass due to its lighter weight and safety factor as relates to breakage).

The chart is front illuminated (80cd/m2), and the glare source is provided by transillumination of the Plexiglas at illuminances of 300, 800 and 3000 cd/m2.

- MILLER-NADLER GLARE TESTER[3]

This test consists on a modified slide projector which uses constant-sized Landolt C rings surrounded by a broad glare source of constant luminance. The slides present a series of Landolt rings in different orientations and contrasts (2-92%), at a distance of 40cm. The endpoint of the test, that corresponds to the final glare disability score, is recorded as the last correctly identified ring orientation.

In the large multicentre PERK study[30], there were omissions of the glare measurement results performed by this test, because it was not sensitive enough to detect small but significant amounts of light scattering.[14]

A more recent variant of this test uses an Ipad, with the punctual central glare source, surrounded by the Landolt C rings for the subjects to identify.

- NIGHT VISION RECORDING CHART – NVCR (MODIFIED AMSLER)

This test operates under natural scotopic conditions and measures the size of the halos. The NVCR projects a small circle from a standard projector onto a screen in a dark room and the patients are asked to reproduce what they are seeing in a chart, as seen in Figure 2.7 (adapted from a Amsler grid).[3] However, this test was designed to map the size of halos only (and not starburst).[3]

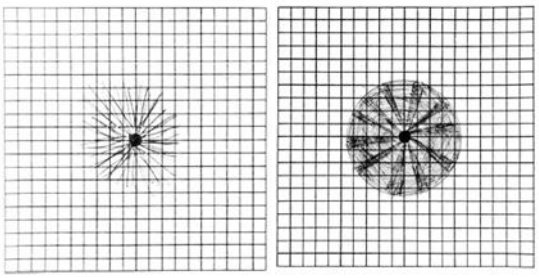


Figure 2.7 - Starburst (left) and halo (right) measured by NVCR.[3]

- TAKAGI CONTRAST GLARE TESTER CGT-1000

This device, represented in Figure 2.7, measures the CS with or without the presence of glare.[31] It measures CS at 6 target sizes (6.3°, 4.0°, 2.5°, 1.6°, 1.0°, and 0.7°) and 13 contrast levels (2.00 to 0.34 logCS, with an average step size of 0.15 logCS). A dark ring on a light background is used as stimulus and has duration of 0.2, 0.4 or 0.6 seconds (with an interval of 1, 2 or 3 seconds between presentations). When the subject sees the target they press a button and if the subjects had no response it means they didn't see the target.[31]

For testing glare, the device uses 12 white light emitting diodes in a ring around the screen at 11.8° from the center of the screen as glare source (the glare angle should be constant for the center for all sizes of target – but it varies by target size in outer edge of each target). It uses 3 glare settings (low, medium and high) and the intensity of the glare source and the illumination of the screen must be determined, for better control of environmental conditions.[31]

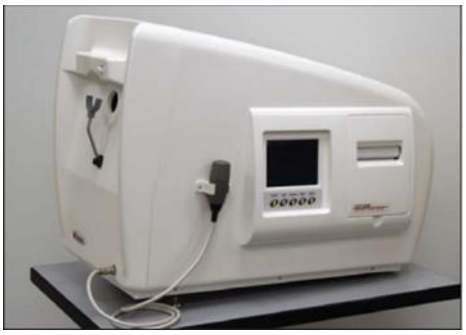


Figure 2.8 - The Takagi Contrast Glare Tester CGT-100.[29]

- STARLIGHTS SYSTEM (NOVOSALUD, VALENCIA, SPAIN)

This device contains a black screen whit a central light which acts as a fixation stimulus (subtending an angle of 0.34˚ - 1.2 cm) and light source. The central stimulus is surrounded by white LEDs distributed by 12 meridians with 30˚ of separation, each of which subtends an angle of 0.06˚ when the subject is 2.5m from the screen.[32]

The test must be done with the room in total darkness, where the luminance is about 0.17lux or 0.054cd/m2 (still in the range of what is considered night vision).[32] This device provides an index of light disturbance called the "disturbance index" and proved to be sufficiently sensitive to quantify the halo phenomena in subjects who had undergone LASIK surgery. [33]

- HALOMETER

This is another device to evaluate intraocular scattering, specifically the halo effect.[33] But the halo effect is not only due to scattering but also to wavefront aberrations.[1] So, this device is only helpful to obtain an idea of the ocular/vision quality.

This device consists in 2 boards inside a methacrylate box. In the front of the box, is a black cover also of methacrylate with several holes that allow the light exit from the LEDs (which are on the board).[33] The patient should sit in front of the device and see a black screen with several holes, where the central light source (which also serves as a fixation point) is surrounded by a series of light dots (organized in 12 radial lines). The device is connected to a computer that

stores all the data (Figure 2.9). The subject´s task is to discriminate the lateral luminous spots that surrounded the central spot.[33]

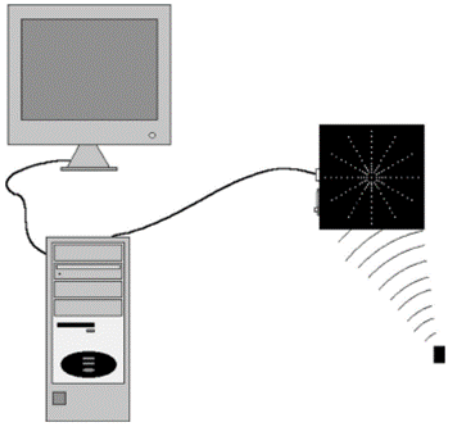


Figure 2.9 – Halometer scheme of experimental device[31]

According to Guitérrez *et al* [33], this device can accurately assess the influence of halos in vision, being this one of the major subjective complaints presented by patients undergoing refractive surgery or cataracts operations.

- NYKOTEST AND MESOTEST

These two devices can measure mesopic contrast sensitivity and glare sensitivity. The Nikotest has brighter illumination and has only one reading per level, while the value measured by the mesotest is the average of five measurements.[13]

2.2 Applications in ocular surgery

2.2.1 Application of quantifying methods in corneal and intraocular surgery

Night vision disturbances (NVD) can occur in patient with excellent visual acuity in photopic conditions. These disturbances can be originated by light dispersion phenomena which lead to the glare incapacity (retinal staylight) and scattering; can be due to light disturbance characterized by image distortion under low lighting conditions like starburst (star shaped) and

halo; finally, due to the decrease of contrast sensitivity under scotopic and mesopic both conditions.

Patients who had undergone refractive surgery frequently report NVD. According to Pop M. and Payette Y.[34] after LASIK surgery, halos are often manifested by patients. In a retrospective study, Jabbur *et al* [35] evaluated the main symptoms experienced by patients after LASIK, PRK, radial keratotomy and laser thermokeratoplasty surgeries. Their results concluded that, from all patients enrolled in the study, the 101 patients evaluated who had undergone LASIK surgery were those with the greater symptoms (83.2%).

In more detail, 43.5% of patients reported NVD, 26.1% glare and 16.7% reported difficulties in driving at night. Several studies[3,36,37] appointed that the result of this dissatisfaction may be due the refractive errors or irregular residual astigmatisms caused by radiofrequency ablation and myopic and deeper decentered optic zones/or astigmatic ablations.

In Table 2.1 it is presented a review of the studies about the incidence of complaints for various refractive surgeries NVD. Nighttime driving is one of the problems manifested by NVD patients. Schein *et al.*[38] in his study found that 29% of the subjects felt a worsening in night driving ability, after refractive surgery. Another study of Tahzib *et al.*[39], reports that 47.2% the subjects that undergone refractive surgery experiencing more glare from lights at night than before surgery (especially glare from oncoming headlights). The quantification of the symptoms experienced changes individually by the patient is normally done through questionnaires. Therefore, according to this limitation, it is important to evaluate the NVD in more objective terms.

To evaluate the optical quality of the eye after refractive surgery it is necessary to consider the available optical zone, pupil size and ablation depth, and for intraocular surgeries is crucial the selection of the optical design of the IOL and its centration[3].

Table 2.1 - Studies about the incidence of complaints for various refractive surgeries NVD

Author (year)	Number of patients	Type of surgery	NVD cases	NVD incidence (%)
Schein et al [38]	176		-	41,5
Bailey et al. [60]	604		-	27,2 (Glare) 30 (Halo) 27,2 (Starburst)
Pop y Payette [34] 1 month after-surgery 3 months after-surgery 6 months after-surgery 12 months after-surgery	 655 460 427 325		 172 58 31 16	 26,3 12,6 7,3 4,9
Hammond et al (2004)	8528		2	0,02
O'Doherty et al (2006)	49		12	24
Grimmett MR and Holland EJ. (1996)	31 eyes	Radial keratotomy	31	100 (disabling glare)
Bailey MD et al. (2003)	690	PRK	-	31.7 (34.3% for starburst 52,4% for halos and 61.5% for glare from oncoming headlight)

A way to measure light disturbance can be through the size of the image's degradation produced by a source of light that can be punctual or extensive. Many studies report that after LASIK surgery, the existence of disturbance phenomenon is very common. These are primarily due to:

i. *Changes of corneal transparency:* such as haze, especially in surgeries such as LASIK caused by the the flap and in specially in PRK, that leads to an increase of diffusion or scattering, making the haze visible to the observer[40]

ii. *High-order aberration Induction by treatment*: Seidel aberration, which include spherical aberration, primary coma, astigmatism, Petzval curvature and distortion[41]. After LASIK surgery, it is verified that there is a change of the natural aspheric (prolate-flatter in the periphery) shape of the cornea to oblate (steeper in the periphery) which leads to the increment of positive spherical aberration of the eye, which leads to an increment of some phenomenon such as glare, halos and starburst after surgery. The natural shape of the cornea is responsible for substantially reduce the eye's optical aberrations.[42]

   This alterations after surgery suggests that this is the main reason for the reduction in the vision's quality.[43,44,45,46,47]

iii. *Transition Phenomena between the ablationed area and non-ablationed zones in large pupils:* This last point is important especially in the case of small ablationed areas.

Sometimes, as a result of LASIK, smaller ablationed areas than intended are obtained, mainly due to decreased efficiency of lasers in the zone's peripheral parts.[48,49] However, one of the solutions to reduce these effects, resulted in an improvement in the laser algorithms.[36, 50] Another aspect to refer, relates to the pupil size. A study from Helgesen et al[51] comes to interesting results in this parameter. A significant correlation was found ($p<0.05$) among patients whose pupil in scotopic conditions exceeds 6 mm, and symptomatology in relation to vision in scotopic conditions (after surgery). Several studies[52,53,54] support the idea that large pupil sizes during scotopic conditions are predictive of greater problems with night vision after LASIK. As spoken in point ii), higher order's aberrations increase after a corneal refractive surgery. And the increase is greater the higher the size of the pupil, as reported in previous studies.[3,55,56] On the other hand, some studies report that after refractive surgery there is a lower incidence of visual disturbances.[57,58]

A study from Lackner B. *et al*[61] also intended to measure the glare and halos phenomenon in LASIK surgery operated patients. The size of the glare and halos were subjectively measured before LASIK surgery and after 1,3 and 6 months, under the same mesopic conditions. They concluded that 3 and 6 months after surgery the halos were 1.74 times larger than the preoperatively area (1.32 times larger in diameter than the pre-surgery). Despite the halos being bigger, there was a decrease in the 1 to 3 months and 3 to 6 months period.

A way to quantitatively evaluate the shape and size of light disturbance with a less subjective method is using Starlight Halometer (Figure 2.10). This instrument provides us this assessment of a value named Light Distortion index (HDI). The HDI is the percentage of the total area explored that is occupied by the NVD caused by a punctual source of light. A recent study from Gutiérrez et al.[31] concluded that the halometer is a sensitive tool to detect halos in 22 patients that undergone LASIK. The average Halo Disturbance Index (HDI) values before and after refractive surgery were $26.1 \pm 2.1\%$ and $52.8 \pm 3.3\%$ respectively ($p < 0.0001$).

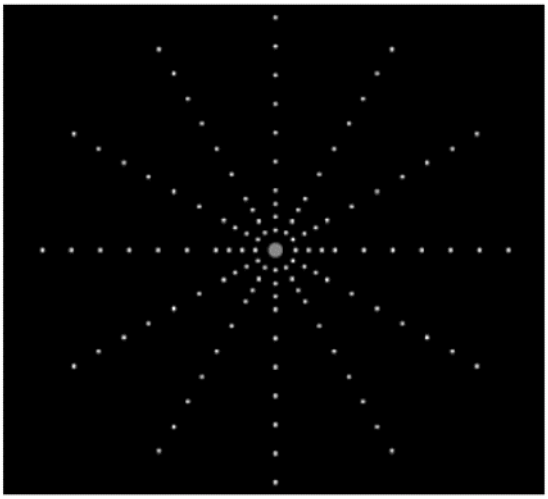


Figure 2.10 – Representation of the Starlight Halometer [30]

Villa et al[30] quantify the halo phenomena by objectively measuring the distortion in size and shape of the light source in night lighting conditions. Detection and quantification of image degradation were obtained using the Starlights Halometer (Novosalud, Valencia, Spain). For this study 55 patients were recruited (110 eyes) for undergoing LASIK surgery. The pre-surgery HDI results, were 0.32 (0.23) to a pupil of 6.27 (0.84) and after surgery of 0.69 (0.47) for a pupil of 6.16 (0.81) mm. According to the author of the study, these differences in pupil size should not cause changes in the HDI.

Starlight software can also be implemented for the evaluation of scotopic and mesopic vision's quality in cases of implantation of Intraocular Multifocal Lenses (IOL). A study of Pieh *et al* [62] intended to measure the halos diameter trough the Glare&Halo computer program (Fitzke FW and C Lohmann, Tomey AG) in patients with multifocal IOL . The results show that the halo extension depends on the pupil size, refractive power of the cornea, the lens itself and also on the additional power of focus to near vision. The size of the halo was greater in Multifocal lenses relatively to Monofocal lenses and the halos for the multifocal IOL had an irregular shape. Authors explain these results because of possible irregularities of the cornea, lens tilt, or a difficulty in recognizing the weak halo margins exactly. Another aspect to point out was that all patients feel the phenomenon of halos in scotopic vision while driving. A study of Featherstone KA *et al* [63] intended to compare the driving performance in patients implanted with multifocal IOL and monofocal IOL. They concluded that patients implanted with monofocal IOLs have a better driving performance than patients implanted with multifocal IOL. However, the differences found were not statistically significant.

Alongside these procedures, patients are often given questionnaires to evaluate in quantitative terms (on the scale) their satisfaction with the some parameters after surgery. A study of Brunette *et al* [64] evaluated 690 patients satisfaction after LASIK and PRK Refractive Surgery relatively to several important parameters about their work, especially the glare problems, night vision quality, as well as day and night driving impairments. A questionnaire on a scale of 1 to 5 was given to the patients (1 = very dissatisfied, 5 = very satisfied). The results show that 66.1% of the patients say that their night vision quality is not as good as in the daytime and 31.7% of the subjects said that night vision became worse, or much worse, after surgery. As for the night vision quality, we refer to all features that include light distortion. In detailed terms and percentages, 34.3% of patients reported that they have perception of stars around lights, 52.4% to have halos, fog, or haze around street lights, 11.6% double outline of images, 6.1% ghost images, and 23.1% details distortion. An important aspect to note in this questionnaire relates to glare. About 61.5% of the patients reported glare that increased the closest they were from cars headlights and 55.6% of these patients believes this situation worsened after the surgery. For night driving, 31.1% reported to have more difficulty driving at night or during the evening than before surgery and 89.1% of patients reported the daytime driving score of 5.

Optically, the glare disability can be measured when a light source (glare) is added to a contrast sensitivity test. When this light source is added, it will be scattered by the eye which leads to the NVD.

Cerviño *et al* [65] compared the disability glare in normal subjects (n = 30) and in LASIK patients (n = 36) and used the C-Quant. The results concluded that light scattering measures are greater in the operated subjects as compared to the control group; however, these differences are not statistically significant.

A study of Kamiya *et al* [66] intended to evaluate optical quality and intraocular scattering after posterior chamber phakic intraocular lens implantation. The optical quality was measured with the Optical Quality Analysis System (OQAS, Visiometrics, Terrassa, Spain) before and 3 months after the implementation of the ICL. The results concluded that there are no significant differences between certain optical quality parameters (cutoff frequency MTF, Strehl ratio, OSI, or OVs at contrasts of 100%, 20% and 9%) and the intraocular scattering between eyes that underwent to surgery and healthy eyes. It is necessary to quantitatively evaluate the scattering

after intraocular implantation of Phakic IOL since the same can be accentuated by tilt or decentration of the IOL.

Another important aspect to be taken into account is the presence of glistening in different IOLs materials. IOLs material degrades in the form of small aggregates (1.0 to 5.0 mm) of material formed within the bulk of the polymer. These changes adopt the form of micro bullae (glistening). A recent study[67] has showed that glistening can affect up to 86% of patients implanted with a new generation of yellow-tinted hydrophobic acrylic IOL.

The glistening can lead to a contrast sensitivity decrease and glare,[68] however, Christiansen *et al* [69] found no decreased visual acuity with best optical correction.[70] Besides that, according to Gunenc *et al* [71] only a high degree of glistening can be able to produce glare that leads to decreased contrast sensitivity.

Beheregaray *et al* [72] used the Optical Quality Analysis System (OQAS) to evaluate the scattering index (OSI) eye in patients with glistening. OSI represents the ratio of light intensity at an eccentric location of the image and the central part. Their results found a significant increase in the OSI parameter but failed to related effort it with high contrast visual acuity.

The IOLs are composed of different materials. The degree of chromatic aberration or glistening depends on the material's Abbe number. The higher the material's Abbe number, less chromatic aberration is manifested by the same. The natural crystalline lens has an Abbe number of 47. TECNIS Multifocal IOL (The Abbott Medical Optics Inc.; Santa Ana, CA) is made of an acrylic IOL material with a very high Abbe number (55), which means it has fewer chromatic aberrations and therefore provides a higher quality of vision.[73, 74]

The glistening is caused by differences between the refractive index of water (1.33) and LIO's material. The glistening presence is as bigger as greater the differences in these refractive indices are.

In cataract surgery or in refractive surgery, acrylic or silicone IOL can be implanted. In the USA about 63% of implanted IOL are acrylic.[70] The AcriSoft IOLs are an example of this type of implantation and its high refractive index, 1.55, causes the glistening to be highly reported by subjects (Figure 2.11).

Study*	Date	Number of Eyes	Frequency (%)
Dhaliwal[2]	1996	56	30.5
Mitooka†	1999	144	59.5
Miyata[7]	2000	49	57.0
Tognetto[8]	2002	41	67.5
Ahuja‡	2001	69	39.0
Gunenc[9]	2001	91	37.1
Christiansen[10]	2001	42	35.7
Davison[11]	2002	100	11.0
Present	2003	129	29.5

*First author only
†K. Mitooka, MD, and co-producers, "Glistening in Acrylic IOLs," film presented at the ASCRS Symposium on Cataract, IOL and Refractive Surgery, Seattle, Washington, USA, April 1999
‡N. Ahuja, MD, "Presence of Glistenings in Implanted IOLs," presented at the ASCRS Symposium on Cataract, IOL and Refractive Surgery, San Diego, California, USA, April 2001

Figure 2.11 – Reported frequency of glistenings in acrylic IOLs[70]

Other IOLs materials have lower refractive indices; 1.49 PMMA; 1.43 silicones; and 1.47 for the hydrophobic acrylic material (Sensar IOL, Abbott Medical Optics). Subjective complaints have been reported but objective analysis is required to establish the grading. In Figure 2.12 it is possible see examples of slit lamp grading of glistening. The intensity of glistening is made using a scale (in our case, 0-absent, 1, 2 or 3). However this value is very subjective and quantification may vary. There are studies that vary the maximum degree between 3 and 5.

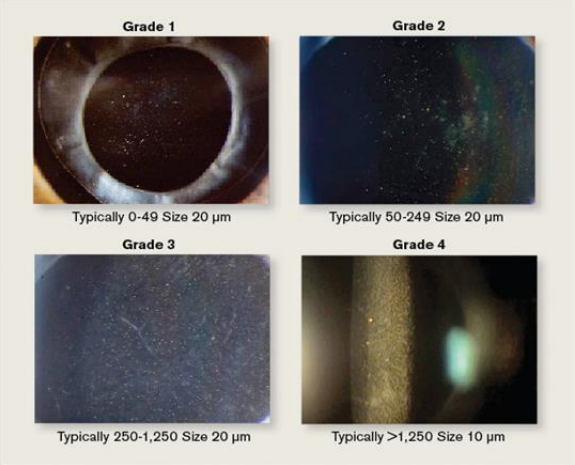


Figure 2.12 – Four examples of slit lamp grading of glistening. Available at: http://www.iolsafety.com/docman/doc_download/44-glistenings-in-alcon-acrysof-intraocular-lenses.html)

In table 2.2 it is possible to observe the correlation between glistening quantification with the area of scattering, and the typical size and number of microvacuolos.

Table 2.2 - Correlation between glistening quantification with the area of scattering, and the typical size and number of microvacuolos Available at: http://www.iolsafety.com/docman/doc_download/44-glistenings-in-alcon-acrysof-intraocular-lenses.html)

Grade	Scattering Area (% of 2 x 2 mm)	Numbers	Typical Sizes	Description
1	≤ 0.5%	0-50	20µ	Mild
2	≤ 2%	51-250	20µ	Moderate
3	≤ 10%	251-2500	20µ	High
4	> 10%	> 2500	10µ	Severe

On the other hand, there are authors who relate the formation of glistening with changes in temperature (the acrylic hydrophobic IOLs, since they are usually conditioned in their dry states before implantation). The differences between the average temperature and humidity before and after inserting, lead to the formation of glistening. They also relate the formation of glistening to mechanical forces, the presence of lipids or proteins in the aqueous humor or surface active ingredients in ophthalmic solutions.

Another phenomenon derived from the consequence of diffractive scattering light is the rainbow glare.[75] The lasers used in refractive surgery can lead to rainbow glare. This disturbance is derived from diffraction of light from the grating pattern created on the back surface of the LASIK flap after femtosecond laser exposure.[70] Several studies have documented the rainbow glare in the femtosecond LASIK surgeries[76,77] and a recent study of Ackermann *et al* [73] confirmed the presence of this disturbance on a femtosecond laser model eye treatment.

Within the femtosecond laser systems there are differences regarding energy and pulse rates: the IntraLase and Femtec the features high pulse energy and low pulse frequency. Already the Femto LDV is characterized by having low pulse energy and high pulse frequency.[78] Rainbow glare has recently been reported in 19% of the patients after IntraLASIK.[77] A study of a new laser model (whose improvements included an increased numerical aperture of the focusing optics, which will result in a smaller working distance under the cone) reached a reduction of 2,32% in the incidence, of the rainbow glare.[77]

Irregularities along the flap interface[79] and consequently the rainbow glare can be reduced as the use of higher pulse frequencies or with lower pulse energy.[76,77] A model characterized by these features is the InterLase 60 kHz model[76] in which there is an improvement in focusing optics of each pulse and reduces the separation between pulses.[76,77]

2.3 References

(1) Pinero DP, Ortiz D, Alio JL. Ocular scattering. *Optom Vis Sci* 2010;87:E682-E696.

(2) Regan D. The Charles F Prentice Award Lecture 1990: specific tests and specific blindeness: keys, locks, and parallel processing. Optometry & Vision Science 68, 489-512. 1991.

(3) Fan-Paul NI, Li J, Miller JS, Florakis GJ. Night vision disturbances after corneal refractive surgery. *Surv Ophthalmol* 2002;47:533-546.

(4) Drum B, Calogero D, Rorer E. Assessment of visual performance in the evaluation of new medical products. Drug discovery today: Technologies 4, 55-61. 2007.

(5) Jewelewicz DA, Evans R, Chen R, Trokel S, Florakis GJ. Evaluation of night vision disturbances in contact lens wearers . CLAO J 24, 107-110. 1998.

(6) Ginis HS, Perez GM, Bueno JM, Pennos A, Artal P. Wavelength dependence of the ocular straylight . *Invest Ophthalmol Vis Sci* 2013;54:3702-3708.

(7) Patel SV, Winter EJ, McLaren JW, Bourne WM. Objective measurement of backscattered light from the anterior and posterior cornea in vivo. *Invest Ophthalmol Vis Sci* 2007;48:166-172.

(8) van den Berg T.J.T.P. Analysis of intraocular straylight, especially in relation to age. Optometry and Vision Science 72[2], 52-59. 1995.

(9) van den Berg TJ, IJspeert JK, de Waard PW. Dependence of intraocular straylight on pigmentation and light transmission through the ocular wall . *Vision Res* 1991;31:1361-1367.

(10) van den Berg TJ. Importance of pathological intraocular light scatter for visual disability. *Doc Ophthalmol* 1986;61:327-333.

(11) Ginis H, Pérez GM, Bueno JM, Artal P. The wide-angle point spread function of the human eye reconstructed by a new optical method . *J Vis* 2012;12:1-10.

(12) van den Berg TJ, IJspeert JK. Clinical assessment of intraocular stray light. *Appl Opt* 1992;31:3694-3696.

(13) van Rijn LJ, Nischler C, Gamer D et al. Measurement of stray light and glare: comparison of Nyktotest, Mesotest, stray light meter, and computer implemented stray light meter. *Br J Ophthalmol* 2005;89:345-351.

(14) Franssen L, Coppens JE, van den Berg TJ. Compensation comparison method for assessment of retinal straylight. *Invest Ophthalmol Vis Sci* 2006;47:768-776.

(15) Jimenez JR, Ortiz C, Pérez-Oncón F, Castro J. Objective and subjective optical-quality measurements in subjects with keratitis and age-related macular degeneration . *Journal of Modern Optics* 2008;55:2371-2380.

(16) Vilaseca M, Peris E, Pujol J, Borras R, Arjona M. Intra- and intersession repeatability of a double-pass instrument. *Optom Vis Sci* 2010;87:675-681.

(17) Martinez-Roda JA, Vilaseca M, Ondategui JC et al. Optical quality and intraocular scattering in a healthy young population. *Clin Exp Optom* 2011;94:223-229.

(18) Artal P, Benito A, Perez GM et al. An objective scatter index based on double-pass retinal images of a point source to classify cataracts. *PLoS One* 2011;6:e16823.

(19) Benito A, Perez GM, Mirabet S et al. Objective optical assessment of tear-film quality dynamics in normal and mildly symptomatic dry eyes. *J Cataract Refract Surg* 2011;37:1481-1487.

(20) Nam J, Thibos LN, Bradley A, Himebaugh N, Liu H. Forward light scatter analysis of the eye in a spatially-resolved double-pass optical system. *Opt Express* 2011;19:7417-7438.

(21) Bueno JM, Berrio E, Ozolinsh M, Artal P. Degree of polarization as an objective method of estimating scattering. *J Opt Soc Am A Opt Image Sci Vis* 2004;21:1316-1321.

(22) Franssen L, Tabernero J, Coppens JE, van den Berg TJ. Pupil size and retinal straylight in the normal eye. *Invest Ophthalmol Vis Sci* 2007;48:2375-2382.

(23) Donnelly WJ, III, Pesudovs K, Marsack JD, Sarver EJ, Applegate RA. Quantifying scatter in Shack-Hartmann images to evaluate nuclear cataract . *J Refract Surg* 2004;20:5515-5522.

(24) Aguirre R, Colombo E, Issolio L, Luque S, Vilaseca M, Pujol J. Tiempo de reaccion y contraste umbral en la medida de la difusio ´n intraocular y el deslumbramiento . *Optica pura y aplicada* 2007;40:111-117.

(25) Wiggins MN, Irak-Dersu I, Turner SD, Thostenson JD. Glare testing in patients with cataract after dilation. *Ophthalmology* 2009;116:1332-1335.

(26) Elliott DB, Sanderson K, Conkey A. The reliability of the Pelli-Robson contrast sensitivity chart . *Ophthalmic Physiol Opt* 1990;10:21-24.

(27) Kojima T, Hasegawa A, Hara S et al. Quantitative evaluation of night vision and correlation of refractive and topographical parameters with glare after orthokeratology. *Graefes Arch Clin Exp Ophthalmol* 2011.

(28) Waring GO, III, Lynn MJ, Fielding B et al. Results of the Prospective Evaluation of Radial Keratotomy (PERK) Study 4 years after surgery for myopia. Perk Study Group. *JAMA* 1990;263:1083-1091.

(29) Pesudovs K. Takagi Glare Tester CGT-1000 for contrast sensitivity and glare testing in normal individuals and cataract patients. *J Refract Surg* 2007;23:492-498.

(30) Villa C, Gutierrez R, Jimenez JR, Gonzalez-Meijome JM. Night vision disturbances after successful LASIK surgery. *Br J Ophthalmol* 2007;91:1031-1037.

(31) Gutierrez R, Jimenez JR, Villa C, Valverde JA, Anera RG. Simple device for quantifying the influence of halos after lasik surgery. *J Biomed Opt* 2003;8:663-667.

(32) de Waard PW, IJspeert JK, van den Berg TJ, de Jong PT. Intraocular light scattering in age-related cataracts. *Invest Ophthalmol Vis Sci* 1992;33:618-625.

(33) Babizhayev MA, Minasyan H, Richer SP. Cataract halos: a driving hazard in aging populations. Implication of the Halometer DG test for assessment of intraocular light scatter. *Appl Ergon* 2009;40:545-553.

(34) Pop M, Payette Y. Photorefractive keratectomy versus laser in situ keratomileusis: a control-matched study. *Ophthalmology* 2000;107:251-257.

(35) Jabbur NS, Sakatani K, O'Brien TP. Survey of complications and recommendations for management in dissatisfied patients seeking a consultation after refractive surgery. *J Cataract Refract Surg* 2004;30:1867-1874.

(36) Hersh PS, Steinert RF, Brint SF. Photorefractive keratectomy versus laser in situ keratomileusis: comparison of optical side effects. Summit PRK-LASIK Study Group. *Ophthalmology* 2000;107:925-933.

(37) Johnson JD, Azar DT. Surgically induced topographical abnormalities after LASIK: management of central islands, corneal ectasia, decentration, and irregular astigmatism. *Curr Opin Ophthalmol* 2001;12:309-317.

(38) Schein OD, Vitale S, Cassard SD, Steinberg EP. Patient outcomes of refractive surgery. The refractive status and vision profile. *J Cataract Refract Surg* 2001;27:665-673.

(39) Tahzib NG, Bootsma SJ, Eggink FA, Nabar VA, Nuijts RM. Functional outcomes and patient satisfaction after laser in situ keratomileusis for correction of myopia. *J Cataract Refract Surg* 2005;31:1943-1951.

(40) Niessen U, Businger U, Hartmann P, Senn P, Schipper I. Glare sensitivity and visual acuity after excimer laser photorefractive keratectomy for myopia . *British Journal of Ophthalmology* 1997;81:140.

(41) Hansraj R, Oduntan AO, Rasengane TA. Visual acuity, contrast sensitivity and subjec¬tive perception of vision after lasik refractive surgery . *S Afr Optom* 2006;65:12-26.

(42) Kiely PM. The mean shape of the human cornea. *Optica Acta* 1982;29:1027-1040.

(43) Chisholm C. Refractive surgery in practice . *Optician* 2001;16-21.

(44) Steele C. Wavefront assisted LASIK for perfect visual outcomes? *Optom Today* 2001;41:42-46.

(45) Waring GO, III. Quality of vision and freedom from optical correction after refractive surgery. *J Refract Surg* 1997;13:213-215.

(46) Karpecki P. What's new in refractive surgery . *Rev Optom* 2001;71-74.

(47) Moreno-Barriuso E, Lloves JM, Marcos S, Navarro R, Llorente L, Barbero S. Ocular aberrations before and after myopic corneal refractive surgery: LASIK-induced changes measured with laser ray tracing. *Invest Ophthalmol Vis Sci* 2001;42:1396-1403.

(48) Charman WN. Mismatch between flap and stromal areas after laser in situ keratomileusis as source of flap striae. *J Cataract Refract Surg* 2002;28:2146-2152.

(49) Holladay JT, Janes JA. Topographic changes in corneal asphericity and effective optical zone after laser in situ keratomileusis. *J Cataract Refract Surg* 2002;28:942-947.

(50) Mrochen M, Kaemmerer M, Mierdel P, Seiler T. Increased higher-order optical aberrations after laser refractive surgery: a problem of subclinical decentration. *J Cataract Refract Surg* 2001;27:362-369.

(51) Helgesen A, Hjortdal J, Ehlers N. Pupil size and night vision disturbances after LASIK for myopia. *Acta Ophthalmol Scand* 2004;82:454-460.

(52) Roberts CW, Koester CJ. Optical zone diameters for photorefractive corneal surgery. *Invest Ophthalmol Vis Sci* 1993;34:2275-2281.

(53) Oliver KM, Hemenger RP, Corbett MC et al. Corneal optical aberrations induced by photorefractive keratectomy. *J Refract Surg* 1997;13:246-254.

(54) Rani A, Balasubramanya R, Sharma N et al. Outcomes after laser in situ keratomileusis retreatment in high myopes. *J Refract Surg* 2003;19:159-164.

(55) Miller JM, Anwaruddin R, Straub J, Schwiegerling J. Higher order aberrations in normal, dilated, intraocular lens, and laser in situ keratomileusis corneas. *J Refract Surg* 2002;18:S579-S583.

(56) Marcos S, Barbero S, Llorente L, Merayo-Lloves J. Optical response to LASIK surgery for myopia from total and corneal aberration measurements. *Invest Ophthalmol Vis Sci* 2001;42:3349-3356.

(57) Marmer RH. Radial keratotomy complications. *Ann Ophthalmol* 1987;19:409-411.

(58) Wang Y, Zhao K, Jin Y, Niu Y, Zuo T. Changes of higher order aberration with various pupil sizes in the myopic eye. *J Refract Surg* 2003;19:S270-S274.

(59) Carr J, Lichter H, Garcia Jeal. Spatially resolved refractometry: priciples and application of the Emory vision interwave aberrometer. In: Krueger R, Applegate R, MacRae SM, eds. *Wavefront customized visual correction: The quest for super vision II*. Thorofare: Slack Incorporated; 2004;155-160.

(60) Bailey MD, Mitchell GL, Dhaliwal DK, Boxer Wachler BS, Zadnik K. Patient satisfaction and visual symptoms after laser in situ keratomileusis. *Ophthalmology* 2003;110:1371-1378.

(61) Lackner B, Pieh S, Schmidinger G et al. Glare and halo phenomena after laser in situ keratomileusis. *J Cataract Refract Surg* 2003;29:444-450.

(62) Pieh S, Hanselmayer G, Lackner B et al. Tritan colour contrast sensitivity function in refractive multifocal intraocular lenses . *Br J Ophthalmol* 2001;85:811-815.

(63) Featherstone KA, Bloomfield JR, Lang AJ, Miller-Meeks JM, Woodworth G, Steinert RF. Driving simulation study: Bilateral Array multifocal versus bilateral AMO monofocal intraocular lenses. *Journal of Cataract & Refractive Surgery* 1991;25:1254-1262.

(64) Brunette I, Gresset J, Boivin JF et al. Functional outcome and satisfaction after photorefractive keratectomy. Part 2: survey of 690 patients. *Ophthalmology* 2000;107:1790-1796.

(65) Cervino A, Villa-Collar C, Gonzalez-Meijome JM, Ferrer-Blasco T, Garcia-Lazaro S. Retinal straylight and light distortion phenomena in normal and post-LASIK eyes. *Graefes Arch Clin Exp Ophthalmol* 2011;249:1561-1566.

(66) Kamiya K, Shimizu K, Igarashi A, Kobashi H, Ishii R, Sato N. Clinical evaluation of optical quality and intraocular scattering after posterior chamber phakic intraocular lens implantation. *Invest Ophthalmol Vis Sci* 2012;53:3161-3166.

(67) Colin J, Praud D, Touboul D, Schweitzer C. Incidence of glistenings with the latest generation of yellow-tinted hydrophobic acrylic intraocular lenses. *J Cataract Refract Surg* 2012;38:1140-1146.

(68) Dhaliwal DK, Mamalis N, Olson RJ et al. Visual significance of glistenings seen in the AcrySof intraocular lens. *J Cataract Refract Surg* 1996;22:452-457.

(69) Christiansen G, Durcan FJ, Olson RJ, Christiansen K. Glistenings in the AcrySof intraocular lens: pilot study. *J Cataract Refract Surg* 2001;27:728-733.

(70) Moreno-Montanes J, Alvarez A, Rodriguez-Conde R, Fernandez-Hortelano A. Clinical factors related to the frequency and intensity of glistenings in AcrySof intraocular lenses. *J Cataract Refract Surg* 2003;29:1980-1984.

(71) Gunenc U, Oner FH, Tongal S, Ferliel M. Effects on visual function of glistenings and folding marks in AcrySof intraocular lenses. *J Cataract Refract Surg* 2001;27:1611-1614.

(72) Beheregaray S, Yamamoto T, Hiraoka T, Oshika T. Influence of forward light scattering induced by sub-surface nano glistening of an intraocular lens on visual function . European Society of Cataract & Refractive Surgeons . 2012.

(73) Zhao B, Mainster MA. The effect of chromatic dispersion on pseudophakic optical performance . *Br J Ophthalmol* 2007;91:1225-1229.

(74) Negishi K, Ohnuma K, Hirayama N, Noda T. Effect of chromatic aberration on contrast sensitivity in pseudophakic eyes. *Arch Ophthalmol* 2001;119:1154-1158.

(75) van den Berg T.J.T.P., Coorpender SJ. The ciliary corona: physical model and simulation of the fine needles radiating from point light sources . *Invest Ophthalmol Vis Sci* 2005;46:2627-2632.

(76) Bamba S, Rocha KM, Ramos-Esteban JC, Krueger RR. Incidence of rainbow glare after laser in situ keratomileusis flap creation with a 60 kHz femtosecond laser. *J Cataract Refract Surg* 2009;35:1082-1086.

(77) Krueger RR, Thornton IL, Xu M, Bor Z, van den Berg TJ. Rainbow glare as an optical side effect of IntraLASIK. *Ophthalmology* 2008;115:1187-1195.

(78) Salomao MQ, Wilson SE. Femtosecond laser in laser in situ keratomileusis. *J Cataract Refract Surg* 2010;36:1024-1032.

(79) Sarayba MA, Ignacio TS, Tran DB, Binder PS. A 60 kHz IntraLase femtosecond laser creates a smoother LASIK stromal bed surface compared to a Zyoptix XP mechanical microkeratome in human donor eyes. *J Refract Surg* 2007;23:331-337.

Chapter 3

Validation of a method to measure light disturbance surrounding a source of glare

3. VALIDATION OF A METHOD TO MEASURE LIGHT DISTURBANCE SURROUNDING A SOURCE OF GLARE

3.1 Abstract

Purpose: To validate a new device dedicated to measure the light disturbances surrounding bright sources of light under different sources of potential variability.

Methods: Twenty subjects were involved in the study. Light disturbance has been measured using an experimental prototype (Light Distortion Analyzer, CEORLab, University of Minho, Portugal) comprising 24 LED arrays panel at 2 meters. Sources of variability included: intra-session and inter-session repeated measures, pupil size (3 vs 6 mm), defocus (+0.50) correction for the working distance, angular resolution (15° vs 30°), temporal stimuli presentation and pupil size.

Results: Size, shape, location and irregularity parameters have been obtained. At low speed of presentation of the stimuli, changes in angular resolution did not have an effect on the results of the parameters measured. Results did not change with pupil size. Intensity of the central glare source influenced significantly the outcomes. Examination time reduced by 30% when 30° angular resolution was explored instead of 15°.

Conclusions: Measurements were fast and repeatable under the same experimental conditions. Size and shape parameters showed the highest consistency, whereas location and irregularity parameters showed lower consistency. The system was sensitive to changes in the intensity of the central glare source but not to pupil changes in this sample of healthy subjects.

Key words: light disturbance; glare; haloes; pupil size; validation.

3.2 Introduction

Measurement of night vision disturbances (NVD) under dim light conditions has been a matter of interest for clinicians and researchers over the past decade. Although much earlier recognized, such phenomena have gained increased clinical relevance as a consequence of corneal refractive surgery[1-3] and implantation of intra-ocular lenses with complex optical designs.[4]

Under this generic concept of NVD, different entities are represented, including positive and negative dysphotopsia, halos, glare or starburst. Despite having different impact on the subjective optical quality of the eye, different manifestations are not easily distinguishable or measured independently. For that reason, Klyce has suggested to incorporate the term "light distortion" to include all of them.[5] Previous authors have suggested internal reflections in the intra-ocular prosthesis,[6] residual refractive error, higher order aberrations,[3] and ocular media opacities inducing light scattering[7] as potential etiological factors.

NVD are frequently self-reported by patients, but these are usually described as subjective complains, instead of objective and quantitative measures. With the increasing interest in intra-ocular surgery using different multifocal IOLs, there is a need to measure consistently the size and shape of such disturbances. Beyond the use of subjective questionnaires and psychometric questionnaires, measurement of glare, haloes and starburst or light disturbance as a comprehensive representation of those phenomena has been conducted with different methodologies[7]. Some of these methods are devoted to measure the intra-ocular scattering, while others intend to measure the light disturbance surrounding a bright spot of light against a dark background. This last approach can be done by using digital displays to project detection stimuli around sources of glare[8] or using methods to recognize letters or orientation of characters surrounding a bright glare source[9,10]. The characteristics of the glare and detection sources were frequently not fully disclosed and number of directions explored varied considerably between devices. Most of them reported only the size of the disturbance without specific reference to its position, shape or regularity.

Villa et al evaluated the light disturbance by presenting peripheral stimuli using a computer based facility to detect the size of the light disturbance surrounding a bright LED by presenting white stimuli in a computer video display unit.[3] Anera et al, used the same device to

evaluate the outcomes of a customized ablation compared with a standard algorithm for corneal refractive surgery.[11] Later on, a fully computerized version of this device has been used to evaluate the effect of optical opacities.[12] Sheppard et al used a custom software to present random letters radially towards a central source of glare until the patients could not recognize the letters. They evaluated size of the light disturbance surrounding a central source of glare in patients implanted with different multifocal IOLs.[10] More recently, Puell et al investigated the size of the halo in the general population using the commercial Vision Monitor device. This device measures the ability to recognize letters in three semi-meridians around a source of glare at 2.5 meters.[9] A recent development of these systems was the Rostock Glare Perimeter developed by Meikies et al that uses peripheral stimuli presented from a digital projector system to a wall or screen at 3.3 meters from the patient.[8]

We have developed a device to measure the light disturbance under more realistic and consistent conditions, using hardware with physical light emitting diodes (LEDs), instead of projected light spots,[12] for the generation of the light disturbance as well as for the detection of the peripheral stimuli. This allows us to overcome some of the limitations of previous methods. By using point sources instead of letters we aim to avoid that the outcomes of the test are limited simply because of reading (or acuity) limitations; using a detection, rather than resolution stimuli can also avoid the delay in response, increase the speed of the test, avoid loss of attention, being clinically applicable in elderly patients. Being a physical device instead of software running on a computer screen also ensures that the experimental conditions in different settings can be comparable. The luminance that can be achieved with this system ranges from 0 to 3000 cd/m2 for the central stimuli and 0 to 6 cd/m2 for the peripheral stimuli.[13] This system provides different metrics of size, shape, location and regularity offering more comprehensive information about the actual disturbance.

This feature might be useful in order to differentiate between the disturbances originated by different optical devices, even when their size might be the same; this might be a clear advantage in asymmetric and/or decentered optical designs. Other methods measure the light disturbance only in one direction and then consider that the same size is affected in all directions of the patient's field of view.[4,8,9]

With the present method we aim to evaluate the consistency of the LDA device under different sources of variability including spatial, temporal, and clinical routine issues (inter-session, intra-session, pupil size). It is also the aim of this work to estimate the duration of the examination under different conditions.

3.3 Material and Methods

3.3.1 Sample

Twenty healthy volunteers (12 females, 8 males) participated in the study. All subjects had normal ocular and general health, with ages ranging from 23 to 37 years (26.4±6.1 years). Inclusion criteria required that the subjects had no complaints of dry eye, do not wear contact lenses and present a tear-film break-up time (BUT) of at least 10 seconds measured prior to enrollment in the study.

All subjects were submitted to a full optometric examination including: objective and subjective refraction using an end-point criterion of maximum plus for the best visual acuity; pupil diameter measurement (NeurOptics® VIP™-200, CA, USA) and whole eye wavefront aberrometry using a Harmann–Shack aberrometer (IRX3, Imagine Eyes, Orsay, France).

Following the tenets of the Declaration of Helsinki all subjects signed an informed consent after the nature and possible consequences of the study had been explained

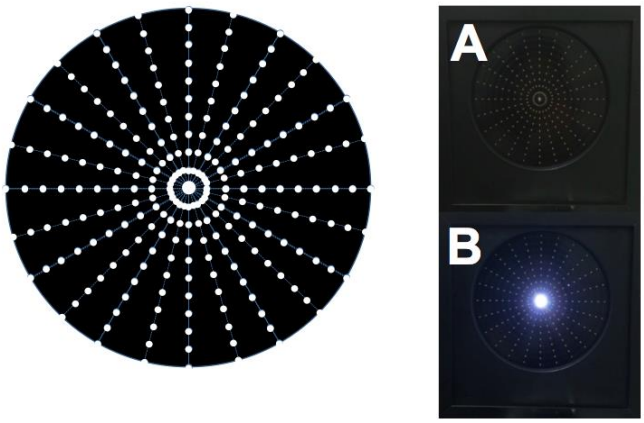


Figure 3.1 - Illustration of the distribution of 1 central source of light and 240 peripheral stimuli; central and peripheral stimulus at 15° semi meridians are turned-on. Device with the central LED light turned off (A) and turned on at minimum intensity (B).

3.3.2 Procedure

Light disturbance measurements were done using the Light Distortion Analyzer (LDA) developed at the CEORLab, University of Minho, Portugal. This is an experimental prototype device comprising an electronic black board with a central light source (LED) with a high intensity power output surrounded by 240 small LED sources with smaller intensity power outputs. The central LED is responsible for creating the glare condition while the surrounding LEDs are used as threshold discriminators at different positions and angular distances of the visual field.[13] The peripheral LED's are distributed in 24 semi-meridians with a minimum angular separation of 15º. Figure 3.1 represents the layout arrangement of the central white light emitting diodes (LED) and the surrounding smaller white LEDs. The central LED was a commercially available white LED from Agilent Technologies (ref. HLMP-CW47-RU000 from Agilent Technologies, Inc., Berkshire, United Kingdom); surrounding LEDs were commercially available white LED from Avago Technologies (ref. HSMW-CL25 from Avago Technologies, San Jose, California, United States). The calibration and radiometric description of the central and peripheral LEDs that constitute the device have been done and proved successful to use in visual assessments.[13] The physical display (electronic board) is connected to a control central control device (PC computer) and the subject being evaluated provides feedback to the system through a remote response device (PC mouse). Peripheral stimuli are presented around the central source of light using different sequences at random times from 250 to 750 milliseconds and the different semi-meridians are explored in random order. When the subject sees the peripheral stimulus, presses the mouse control button and the system presents the next semi meridian. Three evaluations are performed in each semi meridian before the instrument calculates the mean limit of the light disturbance. If the standard deviation (SD) of the three measurements in each semi meridian is above 20% of the mean value, the device automatically repeats the measurements in those semi meridians until it reaches values of SD below 20% of the mean.

Only the information of the right eye is presented in order to avoid duplication of the sample considering the related nature of the information obtained from both eyes of the same subjects.

Figure 3.2 shows the structure of the protocol of the study that was divided in two different phases.

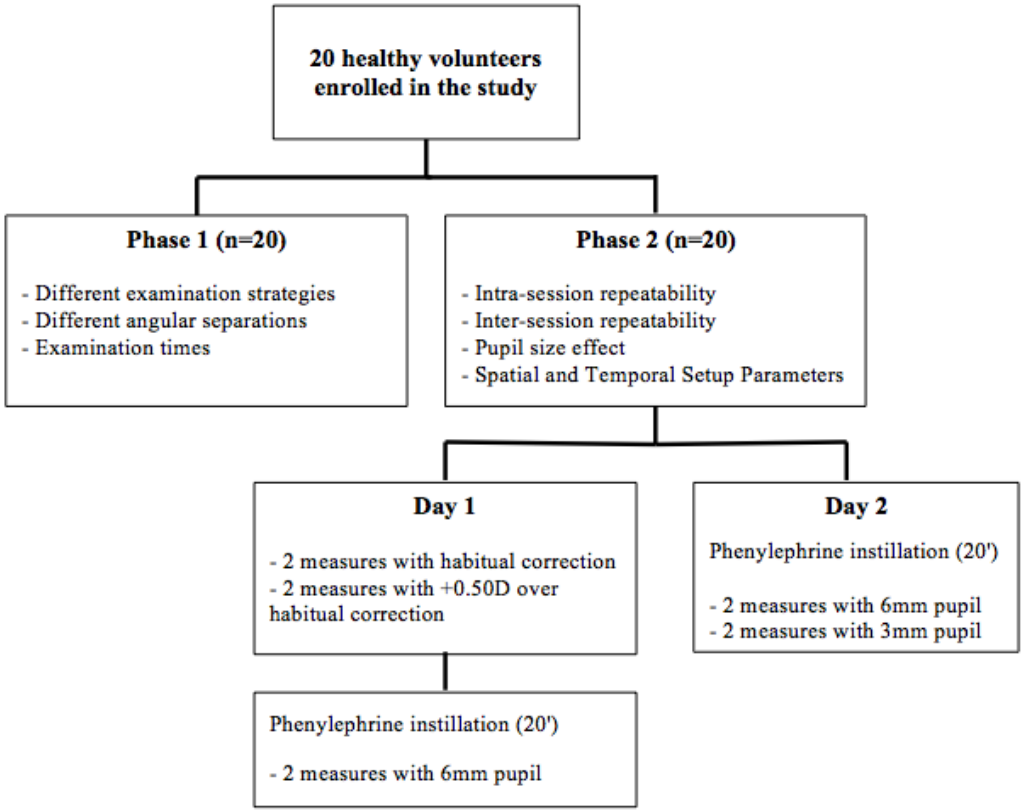


Figure 3.2 - Structure of the protocol of the study.

In the first phase of the study, the measurements were obtained using different examination strategies (In-out; Out-in; Subjective), different angular separations (15°/24 radial directions; 30°/12 radial directions), two different velocities of peripheral stimuli presentation times (ON-OFF intervals of 250 to 750 milliseconds) and the different semi-meridians were explored in random order. "In-out" refers to the strategy where the radial LEDs turn-on sequentially from the center to the periphery until detection; "out-in" refers to the strategy where LEDs turn-on from the periphery to the center until not detected; "subjective" refers to the exam where the subject moves the light along a radial direction until the edge of the disturbance is reached. The radial directions are randomly evaluated in all exam strategies. Examination time was recorded for later comparison between the different testing strategies. The speed of presentation of the stimuli (ON-OFF times) was random from 250 to 750 milliseconds in order to avoid false responses from the subject.

In the second phase of the study two different measurements were recorded in two different sessions using an "In-out" strategy with three different intensities for the central LED (minimum 1%-30 cd/m^2; medium 50%-1500 cd/m^2; maximum 100%-3000 cd/m^2). First, measurements

with natural pupil were done with and without a +0.50D lens to compensate the vergence induced by the fixation target placed at a 2 meters distance.

After the measurements with natural pupil, the patients were dilated with 1% phenylephrine (Davinefrina, DAVI II, Portugal) and, after 30 minutes, the measurements were repeated with artificial pupil of 6 mm in the first session and 3 and 6 mm in the second session.

All measurements were performed with the best distance correction from a distance of 2 meters from the display, with the room in total darkness while the patient was seated and stabilized using a chin rest, with the eyes at the level of the central source of light. All data obtained and processed for statistical analysis is the result of three repeated valid measures obtained by the instrument and averaged.

The system derives different metrics from each examination. They are summarized below:

- **Disturbance Area (DA):** is calculated as the sum of the areas of all triangles (or sectors) formed between each pair of semi-meridians under analysis, in mm^2.
- **Light Disturbance Index (LDI):** percentage of the total tested area that is not visible because of impairment by the light disturbance phenomena. It is calculated as the ratio of the area missed by the subject and the total area explored and is expressed as a percentage (%). Higher values of LDI are interpreted as the lower ability to discriminate surrounding small stimuli that are by the central source of light.
- **Best Fit Circle Radius (BFC_{Rad}):** as the disturbance area is formed by an irregular polygonal shape that results from the linking of the outer limits of the disturbance along each semi-meridian, a circle that best fits this shape is derived which radius is equal to the average length of the disturbance along each semi-meridian under evaluation (Length) expressed in mm.
- **Best Fit Circle Center Coordinates (X_{Coord} and Y_{Coord}):** defined as cartesian coordinates (x,y) in mm from the center of the display.
- **Orientation of Best Fit Circle Center (BFC_{Orient}):** angle of BFC center from the origin of coordinates (0,0), which is the center of the display. Expressed in degrees (°).
- **Best Fit Circle Irregularity (BFC_{Irreg}):** sum of the deviations between the actual disturbance area and the BFC outer perimeter along all the semi-meridians tested. It is a sum of

positive and negative values as the limit of the disturbance is in or out of the BFC perimeter and is expressed in mm.

- **Standard Deviation (SD) of the BFC Irregularity ($BFC_{IrregSD}$):** sum of the differences squared and divided by the number of semi-meridians tested (n). Higher values of $BFC_{IrregSD}$ mean a more irregular disturbance. Expressed in mm.

3.3.3 Statistical Analysis

Statistical analysis has been conducted using SPSS v21.0 (IBM Inc. IL). Normality was checked by the Shapiro–Wilk test and due to the nature of the data, non-parametric statistics were applied. For the multiple comparisons, a Friedman test with post-hoc correction has been applied and Wilcoxon signed ranks for pair-wise comparison. The level of statistical significance has been set at $p<0.05$. Spearman rank correlation coefficients (r) were calculated considering that a strong correlation classified as a coefficient greater than 0.8, moderately strong within the range of 0.5 to 0.8, fair within the range of 0.3 to 0.5, and poor at less than 0.3.[14]

3.4 Results

Average manifest spherical and cylindrical subjective refraction were +0.43±0.30D and -0.12±0.17D, respectively. Average maximum round pupil in mesopic conditions was 5.10±0.11mm under non-dilated conditions and 7.10±0.21mm after phenylephrine instillation. The average 4th order spherical aberration (SA) for a 6mm and 3mm pupil were 0.09±0.06μm and 0.01±0.02μm and total high order aberrations (HOAs) root mean square (RMS) were 0.38±0.15μm and 0.09±0.03μm, respectively. LDA parameters did not follow normal distribution according to the Shapiro-Wilk test. Therefore, non-parametric statistics were conducted. Table 3.1 shows the median and interquartile range for the data gathered in phase 1 of the study.

Table 3.1 - Statistical comparison (p) and correlation analysis (r) of the light disturbance parameters measured with patient's

LDA PARAMETERS			DA (mm^2)	LDI (%)	BFC_{Rad} (mm)	X_{Coord} (mm)	Y_{Coord} (mm)	BFC_{Orient} (degrees)	BFC_{Mag} (mm)	BFC_{MagSD} (mm)
Habitual Correction (Natural Pupil)										
Minimum intensity	Measure 1	Median	544	2.71	13.30	0.00	0.24	166.10	0.40	4.18
		IQR	728	3.63	8.00	0.33	0.46	120.00	0.75	1.13
	Measure 2	Median	704	3.50	15.30	-0.42	0.33	150.00	0.28	3.56
		IQR	576	2.87	6.30	0.91	1.05	97.50	0.24	0.94
Medium intensity	Measure 1	Median	768	3.82	16.00	0.00	-0.33	230.10	0.09	3.30
		IQR	312	1.56	2.65	1.15	0.46	105.00	0.22	0.84
	Measure 2	Median	768	3.82	16.00	0.00	0.00	180.00	0.23	2.15
		IQR	448	2.23	4.05	0.33	0.63	105.00	0.32	2.58
Maximum intensity	Measure 1	Median	992	4.93	18.00	-0.58	-0.33	210.00	0.40	3.11
		IQR	1024	5.09	7.40	0.90	0.76	38.80	0.28	1.59
	Measure 2	Median	1280	6.37	20.70	0.33	0.00	180.00	0.15	3.93
		IQR	1056	5.26	7.35	0.41	1.05	224.32	0.34	1.38
Habitual Correction +0.50D										
Minimum intensity	Measure 1	Median	768	3.82	16.00	-0.42	0.24	150.00	0.38	3.51
		IQR	600	2.99	6.05	0.70	0.79	64.40	0.23	1.55
	Measure 2	Median	768	3.82	16.00	0.00	0.09	150.00	0.23	3.08
		IQR	464	2.31	5.35	0.84	0.29	160.61	0.43	2.14
Medium intensity	Measure 1	Median	1184	5.89	20.00	0.00	0.00	180.00	0.10	4.15
		IQR	832	4.14	6.30	0.50	1.05	129.82	0.40	3.11
	Measure 2	Median	1024	5.09	18.70	-0.33	0.00	180.00	0.32	2.74
		IQR	792	4.04	6.70	0.79	1.13	99.15	0.19	1.35
Maximum intensity	Measure 1	Median	1712	8.51	24.00	0.00	0.24	165.00	0.27	4.91
		IQR	1816	9.03	11.35	0.96	1.74	124.95	0.63	0.59
	Measure 2	Median	1744	8.67	24.00	-0.33	-0.42	204.90	0.42	4.07
		IQR	1504	7.48	10.00	0.54	1.82	152.55	0.19	0.58
	Pupil 6mm Day1									
Minimum intensity	Measure 1	Median	384	1.91	11.30	0.00	-0.24	270.00	0.69	3.93
		IQR	1024	5.10	10.70	0.79	1.99	131.46	0.48	1.75
	Measure 2	Median	783	3.90	16.00	-0.09	-0.09	195.00	0.40	3.72
		IQR	680	3.38	6.65	0.67	1.20	111.32	0.41	1.07
Medium intensity	Measure 1	Median	976	4.85	18.00	0.09	-0.33	195.00	0.45	3.91
		IQR	1544	7.68	11.05	1.03	0.92	103.98	0.22	0.97
	Measure 2	Median	1120	5.57	19.30	0.24	-1.24	249.90	0.38	4.03
		IQR	1456	7.25	10.70	0.96	1.58	112.50	0.55	1.41
Maximum intensity	Measure 1	Median	1280	6.37	20.70	-0.24	-0.58	255.00	0.46	4.83
		IQR	1912	9.51	12.35	1.50	2.11	162.73	0.98	3.95
	Measure 2	Median	1536	7.64	22.70	-0.15	-1.15	263.79	0.21	4.31
		IQR	1896	9.43	11.65	0.49	1.46	95.19	0.20	1.52

LDA PARAMETERS (cont.)			DA (mm^2)	LDI (%)	BFC_{Rad} (mm)	X_{Coord} (mm)	Y_{Coord} (mm)	BFC_{Orient} (degrees)	BFC_{Irreg} (mm)	$BFC_{IrregSD}$ (mm)
Pupil 6mm Day2										
Minimum intensity	Measure 1	Median	704	3.50	15.30	0.09	-0.33	246.21	0.48	3.96
		IQR	1016	5.06	18.30	0.46	0.17	268.29	1.14	5.52
	Measure 2	Median	592	2.94	14.00	0.33	-1.49	241.94	1.09	3.53
		IQR	536	2.66	6.35	1.87	1.75	80.74	0.62	2.65
Medium intensity	Measure 1	Median	912	4.54	17.30	-0.91	-1.24	255.00	0.71	3.57
		IQR	1352	6.73	10.70	0.79	1.79	62.00	0.59	1.36
	Measure 2	Median	1152	5.73	19.30	-0.91	-0.58	240.00	0.50	4.15
		IQR	1296	6.45	9.65	1.70	1.75	137.04	0.93	5.26
Maximum intensity	Measure 1	Median	1696	8.44	24.00	-0.91	0.67	142.86	0.50	4.21
		IQR	1520	7.56	10.00	1.20	3.40	142.50	0.59	10.56
	Measure 2	Median	1376	6.84	21.30	0.00	0.00	180.00	0.48	3.38
		IQR	1664	8.28	11.65	0.38	2.65	129.56	0.50	3.78
Pupil 3mm Day2										
Minimum intensity	Measure 1	Median	704	3.50	16.00	0.07	-0.24	210.00	0.62	5.90
		IQR	1024	5.09	10.00	1.91	1.58	182.55	0.68	1.82
	Measure 2	Median	528	2.63	13.30	0.00	-0.49	265.89	0.44	5.10
		IQR	664	3.30	7.65	0.59	0.51	51.95	0.66	2.60
Medium intensity	Measure 1	Median	1248	6.21	20.70	-0.33	0.00	172.48	0.39	5.19
		IQR	1408	7.00	11.70	1.58	0.66	142.50	0.24	2.90
	Measure 2	Median	960	4.77	18.00	-0.67	0.33	150.00	0.50	3.19
		IQR	1096	5.45	10.30	0.79	1.65	84.39	0.70	7.60
Maximum intensity	Measure 1	Median	1840	9.15	24.70	0.91	0.24	79.49	0.68	4.51
		IQR	1696	8.43	12.65	1.78	2.91	186.34	0.83	7.54
	Measure 2	Median	1728	8.59	24.00	-0.42	0.58	120.00	0.21	3.84
		IQR	1584	7.88	12.65	0.37	2.00	130.30	0.45	4.51

Results are presented in the following sub-sections for the following factors: a) compensation of the vergence at the examination distance with 3 different intensities of the central source; b) intra-session agreement for the natural pupil size, 6 mm on session 1 and session 2 and 3 mm artificial pupils with 3 different intensities of the central source; c) inter-session agreement for the 6 mm pupil size on session 1 and session 2; d) pupil size for 6 and 3 mm artificial pupil size; e) intensity of the central source; f) spatial and temporal setup parameters.

3.4.1 Compensation of the Vergence induced by the Fixation Target

Table 3.2 shows the statistical comparison of the light disturbance parameters measured with the patient's habitual correction and by placing a +0.50D lens over the habitual correction

for compensating the vergence induced by the fixation target (2 meters). Results show that there were found no differences in terms of size (DA, LDI and BFC_{Rad}), location (X, Y and Axis) and irregularity (BFC_{Irreg} and $BFC_{IrregSD}$) of the light disturbance measured with different intensities of the central LED. The exception was the X coordinate of the BFC center with the maximum central LED intensity, in which the median value was significantly displaced towards negative values with the +0.50D lens (0.33mm vs -0.33mm, p=0.018). Correlations between the two measurements for all conditions were found to be strong (r=≥0.840) for all the size parameters with the Central LED light at minimum and medium intensities, being moderately strong with the maximum intensity (r=0.721).

Table 3.2 - Statistical comparison (p) and correlation analysis (r) of the light disturbance parameters measured with patient's habitual correction and using a +0.50D lens over the habitual correction for compensating the vergence induced by the target placed at 2 meters from the subject. Results are shown for an "In-out" strategy with three different intensities for the central LED (Minimum 1%-30 cd/m2; Medium 50%-1500 cd/m2; Maximum 100%-3000 cd/m2)

+0.50D OVER HABITUAL CORRECTION	Central LED at Minimum Intensity		Central LED at Medium Intensity		Central LED at Maximum Intensity	
	p	r	p	r	p	r
DA (mm^2)	0.528	**0.937+**	0.345	**0.847***	0.063	0.721
LDI (%)	0.528	**0.937+**	0.345	**0.847***	0.063	0.721
BFC_{Rad} (mm)	0.674	**0.927+**	0.207	**0.847***	0.063	0.721
X_{Coord} (mm)	0.344	0.127	0.116	0.579	**0.018**	0.615
Y_{Coord} (mm)	0.686	0.200	0.799	0.018	0.932	0.345
BFC_{Orient} (°)	0.080	0.664	0.553	-0.291	0.612	0.487
BFC_{Irreg} (mm)	0.735	**-0.090**	0.345	0.108	0.236	-0.286
$BFC_{IrregSD}$ (mm)	0.398	0.198	0.600	-0.327	0.612	-0.321

p:Wilcoxon Signed Ranks Test; r: Spearman's correlation; bold means statistical significant values; * correlation is significant at the 0.01 level; +correlation is significant at the 0.05 level

3.4.2 Intra-session

Table 3.3 shows the statistical comparison of two consecutive measures for different conditions to study the intra-session repeatability.

Results show that there were found no differences in terms of size (DA, LDI and BFC_{Rad}), location (X, Y and Axis) and irregularity (BFC_{Irreg} and $BFC_{IrregSD}$) of the light disturbance measured in all of central LED intensities between the two measures in the same session. This is true for all parameters, except for the $BFC_{IrregSD}$ with a 3mm pupil for minimum and maximum central LED intensities (both p=0.018). Correlations between the two measurements for all conditions were found to be strong for the size parameters (DA, LDI and $BFC_{Rad.}$). Moderately strong correlations

were found for the two pupil sizes in the $BFC_{IrregSD}$ parameter in all central LED light intensities except for 6mm pupil with the central LED light at minimum intensity (r=0.429).

Table 3.3 - Statistical comparison (p value) and correlation analysis (r) of the light disturbance parameters between two consecutive measurements in the same condition (for a pupil size of 3mm and 6mm). Results are shown for an "In-out" strategy with three different intensities for the central LED (Minimum 1%-30 cd/m2; Medium 50%-1500 cd/m2; Maximum 100%-3000 cd/m2)

INTRA-SESSION	Central LED at Minimum Intensity				Central LED at Medium Intensity				Central LED at Maximum Intensity			
	Pupil 6mm		Pupil 3mm		Pupil 6mm		Pupil 3mm		Pupil 6mm		Pupil 3mm	
	p	r	p	r	p	r	p	r	p	r	p	r
DA (mm^2)	0.866	**0.955+**	0.672	**0.964+**	0.735	**0.821***	0.833	**0.786***	0.735	**0.969+**	0.672	**0.999+**
LDI (%)	0.735	**0.955+**	0.735	**0.964+**	0.735	**0.821***	0.833	**0.786***	0.735	**0.821***	0.735	**1.000+**
BFC_{Rad} (mm)	0.734	**0.955+**	0.746	**0.964+**	0.866	**0.811***	0.833	**0.775***	0.734	**0.957+**	0.746	**0.995+**
X_{Coord} (mm)	0.735	0.414	0.176	-0.414	0.917	-0.429	0.237	-0.109	0.735	-0.487	0.176	-0.162
Y_{Coord} (mm)	0.310	-0.321	0.553	-0.679	0.398	0.180	0.249	0.250	0.310	0.679	0.553	0.536
BFC_{Orient} (°)	0.128	-0.450	0.237	0.107	0.799	0.180	0.866	0.571	0.128	0.464	0.237	-0.09
BFC_{Irreg} (mm)	0.204	0.393	**0.018**	0.036	0.866	-0.500	0.236	0.018	0.204	-0.273	**0.018**	0.250
$BFC_{IrregSD}$ (mm)	0.063	0.429	0.091	0.571	0.310	0.714	0.398	0.714	0.063	0.607	0.091	0.714

p:Wilcoxon Signed Ranks Test; r: Spearman's correlation; bold means statistical significant values;
*means correlation is significant at the 0.01 level; +means correlation is significant at the 0.05 level

3.4.3 Inter-session

Table 3.4 shows the statistical comparison of the light disturbance parameters measured in two different sessions (days) for a pupil size of 6mm. Results show that there were found no differences in terms of size (DA, LDI and BFC_{Rad}), location (X, Y and Axis) and irregularity (BFC_{Irreg} and $BFC_{IrregSD}$) of the NVD measured in all of central LED intensities, except for BFC_{Irreg} parameter with central LED at minimum intensity (medians: Day1=0.69mm, Day2: 0.48mm; p=0.028). Correlations between the two measurements were found to be moderately strong to strong (r>0.700) for all the size parameters, being fair to poor in the location and regularity parameters, except for BFC_{Irreg} with the central LED light at minimum intensity (r=0.821).

Table 3.4 - Statistical Statistical comparison (p value) and correlation analysis (r) of the light disturbance parameters measured in two different sessions (days) for a pupil size of 6mm. Results are shown for an "In-out" strategy with three different intensities for the central LED (Minimum 1%-30 cd/m²; Medium 50%-1500 cd/m²; Maximum 100%-3000 cd/m²)

INTER-SESSION (for 6mm pupil)	Central LED at Minimum Intensity		Central LED at Medium Intensity		Central LED at Maximum Intensity	
	p	r	p	r	p	r
DA (mm²)	0.866	**0.793***	0.499	**0.857***	0.735	**0.990+**
LDI (%)	0.866	**0.793***	0.499	**0.857***	0.735	0.714
BFC_{Rad} (mm)	0.733	**0.793***	0.400	**0.893+**	0.866	**0.773***
X_{Coord} (mm)	1.000	-0.667	0.398	-0.143	0.916	0.704
Y_{Coord} (mm)	0.310	-0.491	0.752	-0.054	1.000	0.216
BFC_{Orient} (°)	0.499	0.143	0.310	0.571	0.398	0.396
BFC_{Irreg} (mm)	**0.028**	**0.821***	0.310	-0.393	0.128	-0.054
$BFC_{IrregSD}$ (mm)	0.176	0.179	0.237	0.464	0.612	0.250

p:Wilcoxon Signed Ranks Test; r: Spearman's correlation; bold means statistical significant values;
*means correlation is significant at the 0.01 level; +means correlation is significant at the 0.05 level

3.4.4 Pupil-size

Table 3.5 shows the statistical comparison of the light disturbance parameters measured for a pupil size of 6mm and 3mm. Results show that there were found no differences in terms of size (DA, LDI and BFC_{Rad}), location (X, Y and Axis) and irregularity (BFC_{Irreg} and $BFC_{IrregSD}$) of the NVD measured in all of central LED intensities, except for BFC_{Irreg} parameter with central LED at minimum intensity that was found to be lower with a 3mm pupil (medians: 1.09mm vs 0.44mm, p=0.046).

Table 3.5 - Statistical comparison (p value) and correlation analysis (r) of light disturbance parameters measured for two different pupil sizes of 6 and 3mm. Results are shown for an "In-out" strategy with three different intensities for the central LED (Minimum 1%-30 cd/m²; Medium 50%-1500 cd/m²; Maximum 100%-3000 cd/m²)

PUPIL EFFECT (6mm vs 3mm)	Central LED at Minimum Intensity	Central LED at Medium Intensity	Central LED at Maximum Intensity
DA (mm²)	0.462	0.128	0.499
LDI (%)	0.462	0.128	0.499
BFC_{Rad} (mm)	0.528	0.176	0.553
X_{Coord} (mm)	0.528	0.498	0.352
Y_{Coord} (mm)	0.446	0.176	0.237
BFC_{Orient} (°)	0.128	0.128	0.499
BFCIrreg (mm)	**0.046**	0.612	0.612
$BFC_{IrregSD}$ (mm)	0.612	0.735	0.176

p:Wilcoxon Signed Ranks Test; bold means statistical significant values.

3.4.5 Central source intensity

Table 3.6 shows the effect of the different central LED light intensities on light disturbance for natural, 6mm and 3mm pupil sizes. It can be seen that there was found a significant increment of the size of the light disturbance along with an increment of the central LED light intensity (a<b<c). The location and shape parameters showed more independency of the central LED light intensity despite the differences found for the X coordinate with pupil (X_{medium}=0.00mm, $X_{maximum}$=0.33mm; p=0.043) and with a 3mm pupil ($X_{minimum}$=0.00mm, $X_{maximum}$=0.42mm; p=0.018).

Table 3.6 - Statistical comparison of the effect of different central LED light intensities in light disturbance measured with patient´s natural pupil size, for a pupil size of 6mm and 3mm. Results are shown for an "In-out" strategy with three different intensities for the central LED (a: Minimum 1%-30 cd/m²; b: Medium 50%-1500 cd/m²; c: Maximum 100%-3000 cd/m²)

Intensity Effect		Minimum (a)-Medium (b) Intensity	Minimum (a)-Maximum (c) Intensity	Medium (b)-Maximum (c) Intensity
Natural pupil	DA (mm²)	**0.027 (b>a)**	**0.028 (c>a)**	**0.028 (c>b)**
	LDI (%)	**0.027 (b>a)**	**0.028 (c>a)**	**0.028 (c>b)**
	BFC_{Rad} (mm)	**0.028 (b>a)**	**0.028 (c>a)**	**0.027 (c>b)**
	X_{Coord} (mm)	0.599	0.249	**0.043 (b>c)**
	Y_{Coord} (mm)	0.917	0.207	0.753
	BFC_{Orient} (°)	0.115	0.893	0.753
	BFC_{Irreg} (mm)	0.176	0.108	0.600
	$BFC_{IrregSD}$ (mm)	0.237	0.310	0.075
Pupil 6mm	DA (mm²)	**0.018 (b>a)**	**0.018 (c>a)**	**0.028 (c>b)**
	LDI (%)	**0.018 (b>a)**	**0.018 (c>a)**	**0.028 (c>b)**
	BFC_{Rad} (mm)	**0.018 (b>a)**	**0.018 (c>a)**	**0.041 (c>b)**
	X_{Coord} (mm)	0.310	0.933	0.445
	Y_{Coord} (mm)	1.000	0.735	0.933
	BFC_{Orient} (°)	0.753	0.612	0.176
	BFC_{Irreg} (mm)	0.866	0.612	0.398
	$BFC_{IrregSD}$ (mm)	0.176	1.000	0.063
Pupil 3mm	DA (mm²)	**0.046 (b>a)**	**0.028 (c>a)**	**0.028 (c>b)**
	LDI (%)	**0.046 (b>a)**	**0.028 (c>a)**	**0.028 (c>b)**
	BFC_{Rad} (mm)	**0.046 (b>a)**	**0.028 (c>a)**	**0.027 (c>b)**
	X_{Coord} (mm)	**0.018 (b<a)**	0.063	0.31
	Y_{Coord} (mm)	0.063	0.398	0.753
	BFC_{Orient} (°)	**0.018 (b<a)**	**0.028 (c<a)**	0.917
	BFC_{Irreg} (mm)	0.735	0.735	0.128
	$BFC_{IrregSD}$ (mm)	0.612	0.31	0.917

p:Wilcoxon Signed Ranks Test; bold means statistical significant values; a: median value with Central LED at minimum intensity; b: median value with Central LED at medium intensity; c: median value with Central LED at maximum intensity

3.4.6 Spatial and temporal setup parameters

Table 3.7 shows the comparison between the different spatial and temporal setups that can be used to measure light disturbance with the LDA. Changing the angular separation in the In-Out exam but maintaining low velocity of the peripheral stimulus (15) did not change the results of light disturbance in terms of size, location and regularity parameters. Notwithstanding, the same did not happen for higher velocity of the peripheral stimulus (25), in which there were found differences in the area of the disturbance ($DA_{15°}$=0.67±0.11 mm^2, $DA_{30°}$=0.61±0.08 mm^2, p=0.001) and radius of the BFC ($BFC_{Rad15°}$=16.22±1.20 mm^2, $BFC_{Rad30°}$=15.70±1.02 mm^2, p=0.010).

Table 3.7 - Statistical Comparison between the different spatial and temporal setups that can be used to measure light disturbance with the LDA

	Subjective 30°	In Out 15° 15	In Out 15° 25	In Out 30° 15	In Out 30° 25
DA (mm^2)					
Subjective 15°	**0.003**	0.952	0.054	0.501	0.751
Subjective 30°		0.240	**0.004**	0.378	0.070
In Out 15° 15			**0.001**	0.287	0.184
In Out 15° 25				**<0.001**	**0.001**
In Out 30° 15					**0.010**
LDI (%)					
Subjective 15°	**0.012**	0.940	0.057	0.852	0.526
Subjective 30°		0.433	**0.008**	0.349	0.067
In Out 15° 15			**0.001**	0.852	**0.019**
In Out 15° 25				**<0.001**	0.048
In Out 30° 15					**0.009**
BFC_{Rad} (mm)					
Subjective 15°	**0.010**	0.943	0.064	0.985	0.390
Subjective 30°		0.341	**0.007**	0.257	0.054
In Out 15° 15			**0.002**	0.985	**0.030**
In Out 15° 25				**<0.001**	**0.010**
In Out 30° 15					**0.008**
BFC_{Irreg} (mm)					
Subjective 15	0.940	**0.001**	**<0.001**	**<0.001**	**<0.001**
Subjective 30		**0.004**	**0.001**	**0.003**	**0.001**
In Out 15 15			0.418	0.503	**0.027**
In Out 15 25				0.699	0.409
In Out 30 15					0.119
$BFC_{IrregSD}$ (mm)					
Subjective 15°	0.191	**<0.001**	**<0.001**	**<0.001**	**<0.001**
Subjective 30°		0.065	**0.004**	**0.003**	**0.002**
In Out 15° 15			0.397	0.097	**0.007**
In Out 15° 25				0.434	0.113
In Out 30° 15					0.458

p:Wilcoxon Signed Ranks Test; bold means statistical significant values

On the contrary, when the angular separation was maintained and the velocity of the peripheral stimulus was changed, the light disturbance was slightly greater with higher velocity of the peripheral stimulus in terms of size (all $p<0.050$) but regularity parameters were maintained for both angular separations (all $p>0.050$). The subjective exam was found to be significantly altered when done with the two different angular separations in terms of the size of light disturbance, being slightly smaller with an angular separation of 30º ($BFC_{Rad30°}$=14.71±1.83 mm and $BFC_{Rad15°}$=15.39±1.64 mm, p=0.010). The two subjective exams, as it can be seen in figure 3.3, were the more time consuming, but reducing the angular separation from 30º to 15º allowed to significantly save almost half of the examination time (4:30 min when done in a 15º angular separation and 02:20 min when done in 30º). The same happened for the In-Out routine, in which increasing the angular separation (maintaining the velocity of the peripheral stimulus) allowed to significantly reduce the examination time (In-Out 15º15=01:35 min vs In-Out 30º15=00:51 min, $p<0.001$; In-Out 15º25=01:20 min vs In-Out 30º25=00:46 min, $p<0.001$).

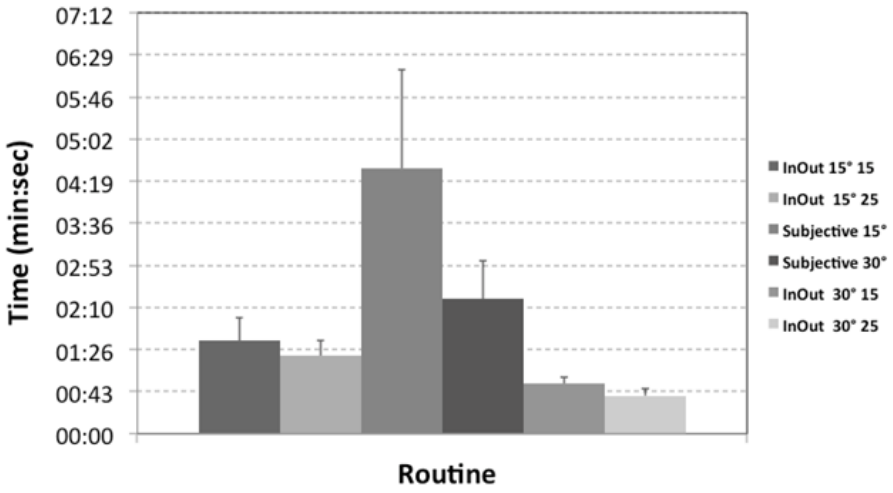


Figure 3.3 - Time spent doing the examination of light disturbance with the different routine settings. Each measurement is the results of the average of 3 repetitions along each radial direction with a standard deviation below 20% the value recorded.

3.5 Discussion

This is the third validation study conducted in apparatus intended to measure light disturbance analysis. The previous one was published by Gutiérrez et al, with the device Starlights published in the Journal of Biomedical Optics back in 2003,[15] and the other one

published by Meikies et al in 2014.[8] More recently, different studies have used other methodologies without known validation studies.[9,10,12] Differently from the previous devices, our system provides several metrics to characterize the size, shape, regularity and location of the light disturbance, while the previous devices concentrated only on the size of the photic phenomena.

With the present method we aim to overcome some of the limitations of previous methods.[3,4,8-10] Indeed, our results concerning the irregularity parameters show that the size of the disturbance cannot be assumed as being rotationally symmetric. Further, while some previous devices have been validated considering different experimental setups,[15] others have used single setups without mentioning the potential variability under different experimental conditions.[8,10]

The present study shows that the examination of the light disturbance size is consistent for different examination routines, among different days and is rapid. Factors such as the angular separation of the radial distances explored and speed of presentation of the stimuli have a minimal effect on the final outcomes. Increase in LDI and BFC_{Rad} with increasing central light intensity showed that the system is sensitive to changes in the source of glare by reflecting an increase in the size of the light disturbance. However, its location, shape and regularity represented by the parameters X_{Coord}, Y_{Coord}, BFC_{Orient}, BFC_{Irreg} and $BFC_{IrregSD}$ did not change.

The first validation experiment of this study ascertained the influence of measuring the size and shape of the NVD with patient's habitual correction and comparing it with the measurements when the vergence induce by the fixation target, that is a 2m distance from the subject, is compensated. It can be seen that in terms of size of the measurements, there is no need to compensate the vergence induced by the fixation target, once the size of the NVD between the two conditions is not statistically different and strongly correlated. This might be expected if we consider the simulations presented in figure 3.4 for an average eye with a +0.3 microns Zernike spherical aberration and a pupil size of 6 mm for a non-accommodating eye. While the positive defocus of -0.5 diopters (equivalent to defocus in the non-accommodating eye at 2 meters) would probably induce an increase in the size of the central light disturbance (panel 4A), full correction of such defocus (using the +0.50 diopters lens in our experiment) won't change much the apparent spread of light around the central spot of light (panel 4C). In the present study, patients had their pupil dilated but were able to accommodate considering that all

of them were young. Thus, we didn't anticipate a difference between both conditions. With the +0.50 lens, the patient would be able to see sharply the central target without accommodation. Without the compensation lens, the patient would require to accommodate approximately 0.50 D. This change could not change the subjective visualization of the central stimulus, or could even improve it by the reduction of the positive spherical aberration through accommodation.[16]

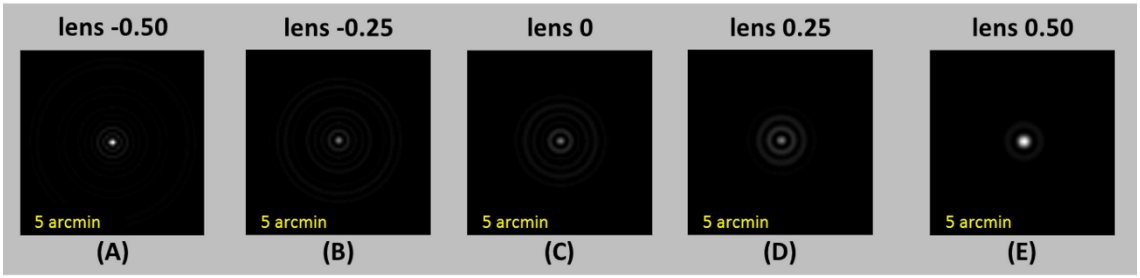


Figure 3.4 - Time Simulations of the point spread function for 0.25 defocus steps in a theoretical eye with +0.3 microns of Zernike spherical aberration under non-accommodation conditions. The situation where the vergence distance is not compensated is "lens -0.5" while the fully compensated situation for the 2 meters (0.5 vergence) correspond the "lens 0" condition.

In the present sample, changing pupil size from 3 to 6 mm did not have a significant impact on light disturbance. This is an expected results considering that all subjects enrolled had moderate positive or neutral spherical aberration for 6 mm pupil size. The role of the pupil in the optical quality is well known as the higher-order aberrations increase and as the pupil dilates. In fact, larger pupil sizes under photopic conditions are a contra-indicative for some treatments such as orthokeratology or refractive corneal surgery because of the high order aberrations induced.[17] Despite this, the role of the pupil size as a main contributor to light disturbances is not so evident. Villa-Collar et al have found a moderate but not significant positive correlation between the pupil size and the magnitude of the light disturbances.[3] This suggests that larger pupils are associated with stronger disturbances, but pupil size by itself is not responsible for such effects. However, this could be the case for highly aberrated eyes, after refractive surgery, or orthokeratology,[17] but not in normal eyes with average values of spherical aberration as is the case in the present sample. Santolaria et al, have recently measured the light disturbance in patients undergoing corneal reshaping with contact lenses using the same experimental device used in the present study. They computed the corneal aberrations for different apertures of 3,

4.5 and 6 mm. they did not find significant correlations with the light disturbance over a period of 1 month after treatment onset.[18] However, pupil might be relevant also when studying light disturbance induced by intra-ocular lenses with complex designs including diffractive apodized optics and multizone refractive optics.

The present device has shown to be sensitive to differences in light disturbance induced by IOL with different optical designs,[19] and multifocal contact lenses (*unpublished results*).

Another relevant result is the relationship between the intensity of the central source and the LDI. This trend could not be directly anticipated because the higher the brightness the more disturbances are usually reported by the patients but this could be partially compensated by the miosis induced. Apparently, in this study, the increase in disturbance by the distribution of more light over a large area of the retina is not counterbalanced by the miosis that would be expected under such condition. Pupil sizes measured for the central LED light at minimum, medium and maximum intensities were 6.58±0.08 mm, 5.11±0.11 mm and 4.44±0.14 mm, respectively. This effect might be even more significant in elderly patients with a smaller dynamic range between natural pupil miosis and mydriasis.

The present method also has some limitations. The system uses detection stimuli, rather than recognition stimuli such as letters or Landolt C's. This might allow the patient to provide a response even without recognizing the stimuli. This system prevents this effect by recording 3 different sets of measurement, with stimuli presented in random order. When the patient provides false positive responses, the standard deviation of the results in a given meridian will increase and the measure will be considered invalid. In the current setup, the system does not allow to identify islands of negative dysphotopsia isolated from the center source of light. However, the aim of this device is to evaluate the light disturbance surrounding a central source of light. Other methods, including automatic perimetry can be used to define negative dysphotopsia.[6] Most of the previous methodologies reported do not provide information about the time spent in each measurement and the number of measurements used to obtain a single measurement. Both are relevant facts, as this method would probably involve examinations to elderly patients where attention and fatigue are potential issues. Our method allows obtaining a single measurement in less than one minute per eye doing 3 repeated measures in this time.

As stated before, there are also several advantages of this instrument over the previous ones used for a similar purpose. First, being an entire physical device, without intervention of video display units, cathodic ray tubes, flat screens or multimedia data-show projector, has the potential to have more consistency among examinations conducted at different settings. Second, the flexibility of setting different exam configurations might allow expanding the role of the system to different applications. Third, the different outcome metrics allow reporting the shape, regularity and consistency of the results, and not only the average size of the light disturbance assumed as a rotationally symmetric anomaly. This might no longer be the case in astigmatic defocus, comatic aberrations or corrective optical devices or surgical procedures including decentered optics.

The present study is limited by the fact all the subjects are young and healthy. Considering that post-surgical or diseased patients could present significantly higher values of light disturbance, the results obtained in the present study cannot be directly extrapolated to those specific populations. For example, the examination time, might increase as the light disturbance increases. The difficulties found by older patients might be different from the ones found in the present sample. However, a recent study conducted in patients implanted with monofocal, bifocal and trifocal IOLs after cataract extraction demonstrated that the test is easily conducted in these clinical populations within acceptable time period.[19]

In summary, the present study shows that the LDA might be a useful device in evaluating the light disturbance, providing a comprehensive number of metrics to characterize the condition, and being robust to different sources of error in young healthy eyes. Specific clinical populations such as post-LASIK patients, post-corneal reshaping and post-cataract need to be addressed in future studies.

3.6 References

1. Fan-Paul NI, Li J, Miller JS, Florakis GJ. Night vision disturbances after corneal refractive surgery. Surv Ophthalmol 2002;47:533-46.

2. Lackner B, Pieh S, Schmidinger G *et al.* Glare and halo phenomena after laser in situ keratomileusis. J Cataract Refract Surg 2003;29:444-50.

3. Villa C, Gutierrez R, Jimenez JR, Gonzalez-Meijome JM. Night vision disturbances after successful LASIK surgery. Br J Ophthalmol 2007;91:1031-7.

4. Pieh S, Lackner B, Hanselmayer G *et al.* Halo size under distance and near conditions in refractive multifocal intraocular lenses. Br J Ophthalmol 2001;85:816-21.

5. Klyce SD. Night vision disturbances after refractive surgery: haloes are not just for angels. Br J Ophthalmol 2007;91:992-3.

6. Holladay JT, Zhao H, Reisin CR. Negative dysphotopsia: the enigmatic penumbra. J Cataract Refract Surg 2012;38:1251-65.

7. Pinero DP, Ortiz D, Alio JL. Ocular scattering. Optom Vis Sci 2010;87:E682-E696.

8. Meikies D, van der Mooren M, Terwee T, Guthoff RF, Stachs O. Rostock glare perimeter: a distinctive method for quantification of glare. Optom Vis Sci 2013;90:1143-8.

9. Puell MC, Perez-Carrasco MJ, Barrio A, Antona B, Palomo-Alvarez C. Normal values for the size of a halo produced by a glare source. J Refract Surg 2013;29:618-22.

10. Sheppard AL, Shah S, Bhatt U, Bhogal G, Wolffsohn JS. Visual outcomes and subjective experience after bilateral implantation of a new diffractive trifocal intraocular lens. J Cataract Refract Surg 2013;39:343-9.

11. Anera RG, Castro JJ, Jimenez JR, Villa C, Alarcon A. Optical quality and visual discrimination capacity after myopic LASIK with a standard and aspheric ablation profile. J Refract Surg 2011;27:597-601.

12. Castro JJ, Jimenez JR, Ortiz C, Alarcon A, Anera RG. New testing software for quantifying discrimination capacity in subjects with ocular pathologies. J Biomed Opt 2011;16:015001.

13. Linhares JMM, Neves H, Lopes-Ferreira D, Faria-Ribeiro M, Peixoto-de-Matos SC, Gonzalez-Meijome JM. Radiometric characterization of a novel LED array system for visual assessment. Journal of Modern Optics 2013;60:1136-44.

14. Chan YH. Biostatistics 104: correlational analysis. Singapore Med J 2003;44:614-9.

15. Gutierrez R, Jimenez JR, Villa C, Valverde JA, Anera RG. Simple device for quantifying the influence of halos after lasik surgery. J Biomed Opt 2003;8:663-7.

16. Lopez-Gil N, Peixoto-de-Matos SC, Thibos LN, Gonzalez-Meijome JM. Shedding light on night myopia. J Vis 2012;12:4.

17. Queiros A, Villa-Collar C, Gonzalez-Meijome JM, Jorge J, Gutierrez AR. Effect of pupil size on corneal aberrations before and after standard laser in situ keratomileusis, custom laser in situ keratomileusis, and corneal refractive therapy. Am J Ophthalmol 2010;150:97-109.

18. Santolaria-Sanz E, Cerviño A, Queiros A, Villa-Collar C, Lopes-Ferreira D, González-Méijome JM. Short-term changes in light distortion in orthokeratology subjects. Biomed Res Int 2015;2015:278425.

19. Brito P, Monteiro M, Neves H, González-Méijome JM, Salgado-Borges J. Light distortion analysis as a possible indicator of visual quality after refractive lens exchange with AT LISA diffractive multifocal intraocular lenses. J Cataract Refract Surg 2015;41:613-22.

Chapter 4

In-vivo changes in light disturbance with two silicone hydrogel soft contact lenses

4. IN-VIVO CHANGES IN LIGHT DISTURBANCE WITH TWO SILICONE HYDROGEL SOFT CONTACT LENSES

4.1 Abstract

Purpose: Dehydration of the surface of contact lens induces changes in the refraction and scattering of the light that are reported by the subjects as different forms of luminous distortion. The present work aims to evaluate if it is possible to detect differences in the size of light disturbance (LD) according to the material of the lens and of the inter-blink interval (IBI).

Methods: Fifteen healthy subjects (12 women and 3 men) with ages ranged from 20 to 23 years (20.7±0.98 years) participated in this study. LD was evaluated under conditions of low lightning with an experimental. The measures were obtained with and without silicone-hydrogel contact lenses of different materials (Acuvue Oasys - Senofilcon A and Acuvue Advance - Galyfilcon A) under two controlled IBI (12 blinks per minute and 4 blinks per minute).

Results: There were statistically significant differences in light disturbance index between both frequencies of blinking without lens and with both lenses ($p<0.050$). The lens of lower hydration showed a minor increase of LD particularly for the situation of the higher IBI ($p<0.001$).

Conclusions: The frequency of blinking affects the perception of LD from punctual light sources under low lighting conditions. This effect worsens significantly with soft contact lenses. The grade of hydration and the polymeric composition of the materials of silicone hydrogel contact lens potentially affect the perception of LD. This non-invasive methodology can be used to assess the visual performance of soft contact lenses and quantify the size and of the LD.

Key words: contact lens; silicone-hydrogel; dehydration; light disturbance; tear film.

4.2 Introduction

Over the last few years, there has been an increased interest in studying the optical quality of the eye. The tear film plays an important role to maintain its quality. The front surface of pre-corneal tear film is the most anterior optical surface of the eye and hence the most powerful once it is associated with the largest variation in refractive index. If tear thickness is maintained uniform, the combination cornea/tear will have almost exactly the same power as the cornea alone.[1]

This fact is only true if the tear film remains uniformly thick. However, some clinical studies have shown that the tear film is not stable and does not remain uniform on the surface of the eye during periods between blinks (inter-blink interval or IBI).[2–5] The local changes in tear film thickness cause an irregular air/tear interface and the tear film looks disrupted, a phenomenon that is clinically termed tear film break up (BUT), introducing aberrations into the eye's optical system.[1,6] The changes in tear film thickness associated with TBU disrupt the most important refractive surface of the eye, which may lead to reductions in its optical quality.[1,7–9]

For healthy subjects, the total aberrations start to decrease immediately after a blink, reaching a minimum at approximately 6 seconds. Then they become increasing, and even exceed the post blink level after approximately 10 seconds.[10] In subjects with dry eye, the tear film becomes more unstable. Stabilization of the tear film occurs 3 seconds after a blink.[11] Albarran *et al.*[1] observed a greater reduction in image quality in soft contact lens (SCL) wearers comparing to non-wearers. Blurry and unstable vision is a common symptom among contact lens (CL) wearers.[12] After a CL is placed on the eye, dehydration begins and continues further during the day depending potentially on the material properties, lens thickness, environmental conditions, tear composition, and blink function.[13,14] Liu *et al.*[15] found evidences that support the hypothesis that blurry vision symptoms reported by contact lens wearers are caused by poor quality of the retinal image due to tear TBU. Also, the TBU creates additional optical aberrations that contribute to the decline in the image quality, either objectively and psychophysically measured.[7] The ability of CLs to maintain its hydration during wear is considered as one of the most important parameters involved in CL tolerance. Despite different lens materials are available, there are no consistent indicators of the ability of the different CL's to maintain its hydration while they are on the eye which difficult the task when it comes to choose the right

material for the right subject. It is well known that at a same lens thickness hydrogel lens with higher water content dehydrate more during the same period than a CL of lower equilibrium water content (EWC).[16–18] Recently, several studies have evaluated the optical performance of different soft lens materials using aberrometry.[19,20] However, optical aberrations reflect a purely objective metric and not the subjective perception of the subject.

Contrary to wavefront aberrations, light disturbance can be measured using psychophysical methods and can be used to assess the effect of image quality degradation. This has the potential to provide a more realistic information of the subjective perception from the subject's point of view.[21]

This study aims to determine the impact of polymer bulk hydration of two different SCL materials and blink rate in light disturbance measured with a novel experimental device.

4.3 Material and Methods

4.3.1 Subjects

Fifteen subjects (12 women and 3 men) participated in this study. Their ages ranged from 20 to 23 (20.7±0.98 years). The study followed the tenets of the Declaration of Helsinki and was approved by the Institutional Review Board at University of Minho. All subjects signed an informed consent after the nature and possible consequences of the study had been explained. All subjects were emmetropes based on manifest subjective refraction (Sphere:+0.42±0.30D; Cylinder:-0.12±0.17D) and had normal ocular and general health. Inclusion criteria required that the subjects had no complains of dry eye, do not wear contact lenses and present a break-up time of at least 10 seconds measured prior to enrollment in the study.

4.3.2 Lenses and experimental conditions

Two different commercial silicone hydrogel CLs were used (Acuvue Oasys and Acuvue Advance from Johnson and Johnson, Jacksonville, FL). Their technical details are summarized in Table 4.1. As the subjects were emmetropes and placed at a 2m distance from the screen, a

+0.50D lens was used as it is the equivalent refraction in the ocular plan for that distance to avoid accommodation.

Table 4.1 - Technical details of Silicone Hydrogel Contact Lenses used in this study

	Acuvue Oasys	Acuvue Advance
Material	Senofilcon A	Galyfilcon A
Power (D)	+0.50	+0.50
Netting Agent	Hydraclear (NVP)	Hydraclear Plus (NVP)
ECW (%)	38	47
FDA	I	I
DK (barrer)	103	60
CT (mm)	0.08	0.08

ECW, equilibrium water content; DK, oxygen permeability; CT central thickness for a -3.00 lens.

Two inter-blink intervals (IBI) were tested: 12 blinks per minute and 4 blinks per minute. Lenses were worn contra-laterally by each subject. Lens assignment to right or left eye and the order of testing each blinking rate was randomly determined (http://www.randomization.com/). All measurements were done monocularly, and the first measures were always without CL ("PRE-" condition or "naked eye"). Examination was performed 5 minutes after lens insertion to allow for lens to settle on the eye with the subject in a dark room for dark adaptation 5 minutes before light disturbance examination.

4.3.3 Procedure

Light disturbance was analysed with an experimental prototype, the Light Distortion Analyzer[22] (CEORLab, University of Minho, Portugal), which consists of a central light source (LED) surrounded by 240 small LED sources distributed in 24 semi-meridians with an angular separation of 15°. In this experiment an angular separation of 30° was explored. Figure 4.1 represents the layout arrangement of the central white light emitting diodes (LED) and the surrounding smaller white LEDs. The central LED was a commercially available white LED from Agilent Technologies (ref. HLMP-CW47-RU000 from Agilent Technologies, Inc., Berkshire, United Kingdom); surrounding LEDs were commercially available white LED from Avago Technologies (ref - HSMW-CL25 from Avago Technologies, San Jose, California, United States). The calibration and radiometric description of the central and peripheral LEDs that constitute the device have been done and proved successful to use in visual assessments.[23] The subject was at a distance of 2.0m in a darkened room. The physical (electronic board) Display Device is connected to a control central control device (PC computer) via USB connection. The subject being evaluated

provides feedback to the system through a remote response device (PC mouse). Peripheral stimuli are presented around the central source of light from the inner to the outer part of the field at random times from 250 to 750 milliseconds. Semi-meridians are explored in random order. When the subject sees the stimulus, presses the mouse control and the system presents the next semi meridian.

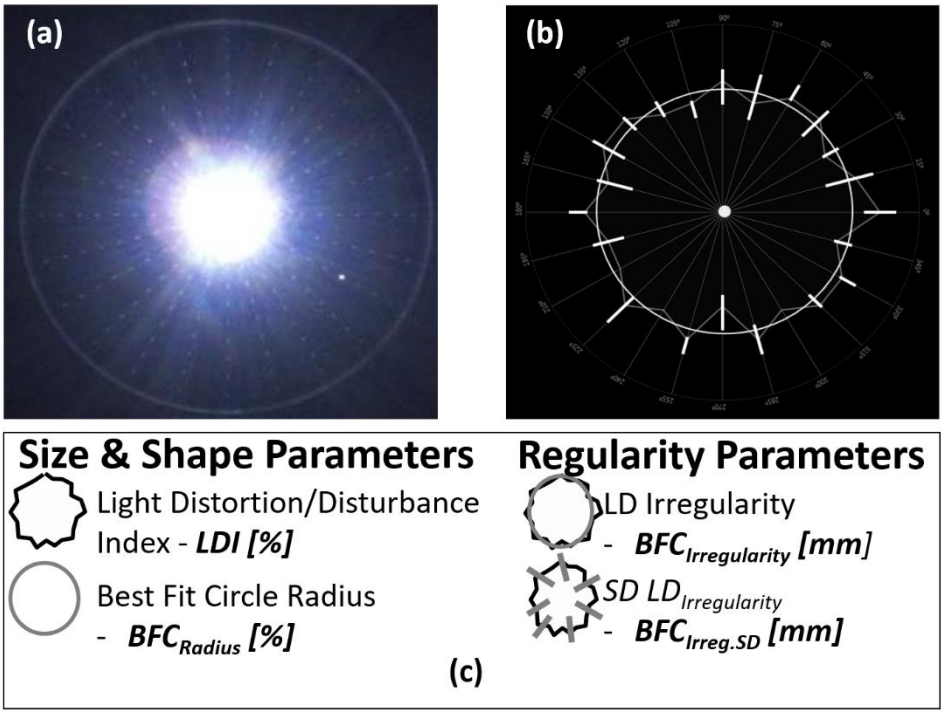


Figure 4.1 - Illustration of the distribution of main central source of light and peripheral stimuli in accordance with an exemplary embodiment of the present invention. On the above right: the experimental device LDA with the central LED light with one peripheral LED turned ON (a); on the above left an illustration of layout appearance of the size and shape of the light disturbance measured (b) and the size and shape and regular related parameters derived from the Light Distortion Analyzer (c)

After data collection and storage, a software tool then calculates three indices that determine the size and regularity of the disturbance surrounding the central source of light.

Light Disturbance Index (LDI) is calculated as the ratio of the area or points missed by the subject and the total area explored and is expressed as a percentage (%). The higher values of disturbance (LDI) are interpreted as the lower ability to discriminate surrounding small stimuli that are hidden by the spread of light from the central source.

Once the subject was in front of the screen with the head on a chin-rest, the test began. Every time the subject saw a stimulus, he had to press the button that gives feedback to the

central unit. The blink rate was controlled at 5 and 15 IBI by means of a periodic sound. A demonstration test was run before first measures for each subject.

4.3.4 Statistical Analysis

The SPSS Statistical Package v.21.0 (SPSS Inc., Chicago, IL, USA) was used to conduct the statistical analysis. Due to the reduced sample non-parametric analysis was used. The Wilcoxon signed-ranks Test was used to compare the LDI values between different experimental conditions. For statistical purposes, p value lower than 0.05 was considered statistically significant.

4.4 Results

There were found no differences in the LDI measured between both eyes for each IBI. Figure 4.2 shows the Light Disturbance Index (LDI) in the baseline situation where no contact lens was used. In the baseline condition, statistically significant lower LDI values were found for the shorter IBI, either for the eyes randomized to PRE-Oasys (5.45±2.81 vs 8.21±4.04, p=0.011) or PRE-Advance (5.05±3.08 vs 6.98±3.48, p=0.002).

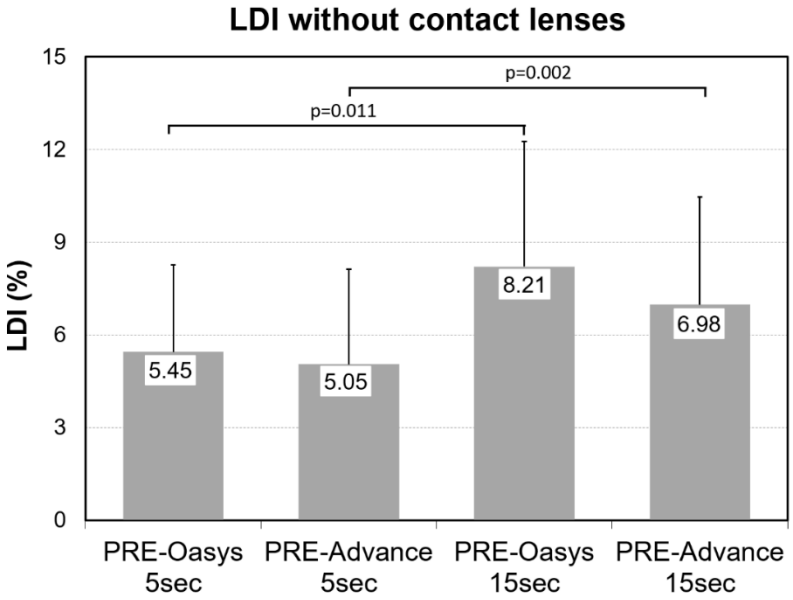


Figure 4.2 - Light Disturbance Index (LDI) measured for the "naked eye" (PRE-) for eyes assigned with Oasys and Advance, for a blinking rate of 12blinks/minute (PRE-Oasys 5sec and PRE-Advance 5sec) and 4blinks/minute (PRE-Oasys 15sec and PRE-Advance 15sec).

Figure 4.3 and 4.4 show the LDI values for the lens wearing condition compared with the baseline situation for Oasys and Advance contact lenses, respectively. Both lenses showed a lower LDI value with the shorter IBI of 5 sec. (11.23±4.63 for Oasys vs 15.94±12.39 for Advance) but the differences between lenses were not statistically significant.

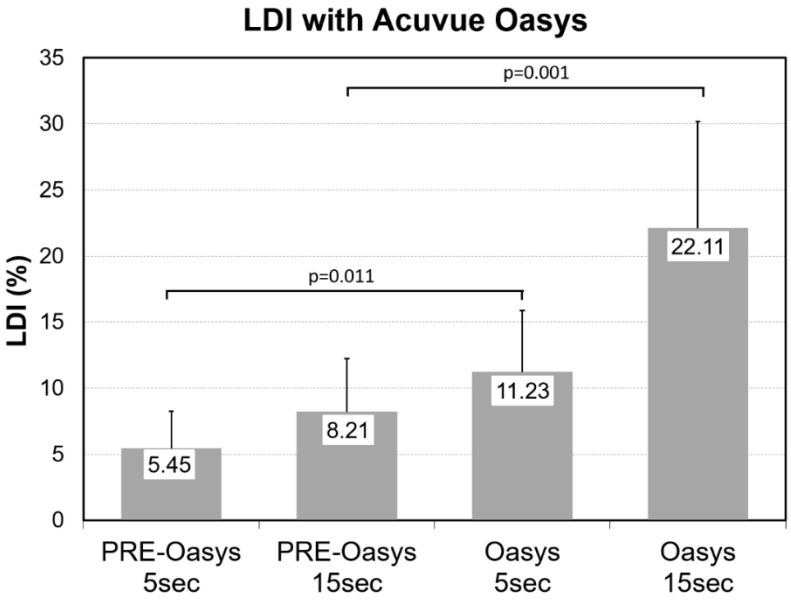


Figure 4.3 - Comparison of the Light Disturbance Index (LDI) measured for the naked eyes assigned with Acuvue Oasys lens (PRE-Oasys 5sec and PRE-Oasys 15sec) and the LDI with the lens inserted (Oasys 5sec and Oasys 15sec), for the two blinking conditions.

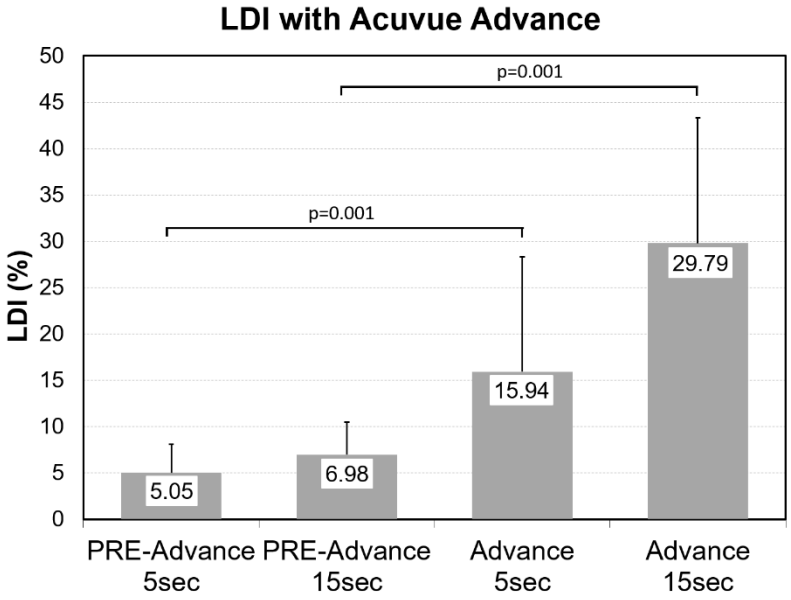


Figure 4.4 - Comparison of the Light Disturbance Index (LDI) measured for the naked eyes assigned with Acuvue Advance lens (PRE-Advance 5sec and PRE-Advance 15sec) and the LDI with the lens inserted (Advance 5sec and Advance 15sec), for the two blinking conditions.

Conversely, LDI values increased significantly for both lenses for the longer IBI of 15 sec. (22.11±8.07 for Oasys vs 29.79±13.52 for Advance) and the differences between lenses

became statistically significant (p=0.020) as it is shown in Figure 4.5 that graphically illustrates this direct comparison between the two materials.

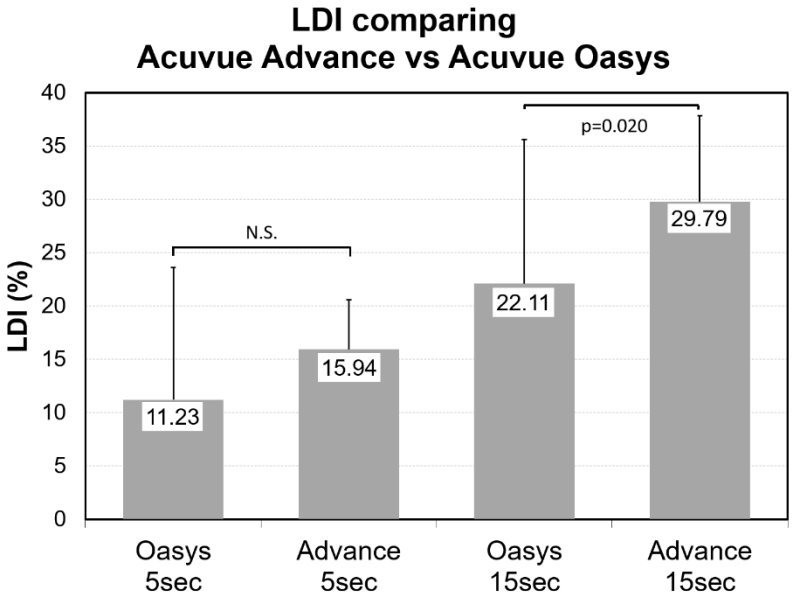


Figure 4.5 - Light Disturbance Index (LDI) measured for eyes assigned with Oasys and Advance, for a blinking rate of 12blinks/minute (Oasys 5sec and Advance 5sec) and 4blinks/minute (Oasys 15sec and Advance 15sec).

4.5 Discussion

The present work demonstrated that the differences in visual performance of two differences contact lens polymers can be assessed using psychophysical methods. This might be attributed to differences in the stability of the tear film at the anterior surface of the contact lens. Previous studies have demonstrated that contact lens wear and IBI interfere with optical aberrations, which suggests a role for the pre-lens tear film in increased aberrations with soft contact lens wear.[24] The optical design of the contact lenses can also affect the optical performance. An advantage of the present study is that both lenses have a very similar optical design but are made of different materials. Present results show that the perception of luminous disturbance under low lighting conditions is affected by the frequency of blinking. This phenomenon reflects the worsening of the optical quality of the lens that can be attributed to the increased optical aberrations due to the uneven optical surface[8,20,25,26] and increased scatter after tear break-up[1,27] as the lens dry out.

To date, the optical and visual performance has been evaluated using either objective methods (i.e. aberrometers and optical quality analyzers) or subjective methods (questionnaires). The use of psychophysical methods instead, has the ability of providing a quantitative metric from the subject's point of view, but is usually time consuming and impossible to use in a clinical setting. The non-invasive methodology used in the present work allows the measurement of light disturbance related with the superficial dehydration of different contact lenses materials in the clinical environment. It showed to be sensitive to quantify and discriminate the differences in the light disturbance caused by two different CL of different materials. Our results suggest that the lenses of higher hydration induce a greater effect of disturbance, mainly when there is a low frequency of blinking. This can be explained by the fact that silicone hydrogel lenses with higher EWC, in general, are associated with greater lens dehydration compared to lenses of lower EWC.[16,28] Those differences are not observed with shorter IBIs (higher frequency of blinking), presumably because the inter-blink time is inferior to the pre-lens tear break up time. In fact, a recent published review reporting different values of pre-lens tear film stability showed non-invasive tear break-up time (NIBUT) values superior to 5 seconds with silicone hydrogel lenses, which can explain the lack of differences between the two CLs materials when lower IBI is evaluated.[29] Consequently, under ideal conditions of IBI, the light disturbance should not be significantly different between the materials used in this study. However, under visual demanding conditions associated to increased IBI values such as night driving or prolonged visualization of video display units, increased light disturbance can adversely affect the visual performance and safety. The effect might be more severe for higher EWC contact lenses, which already have shown inferior NIBUT values[30] when compared with lenses of lower EWC[31] in previous studies. According to Toda *et al.*[32] prolonged eye opening induce a decreased quality of vision in eyes wearing soft contact lenses and under conditions in which blinking is restricted due to demanding visual task, such as visual display terminal work, reading, and driving.

In the present study we have not recorded information of the pre-lens tear break-up time or optical quality through objective methods. This might be considered a limitation in the interpretation of the present results as does not allow us to establish a causative relationship between decreased pre-lens tear break up time and increased light disturbance. However, the literature available in the field supports the assumption that the front ocular surface or the front

lens surface tear film might explain the increased scattering of light. As this was not a clinical study, the results are limited to the measure of light disturbance immediately after lenses fitting. The effects on the longer term need to be further investigated. Notwithstanding, Cheung *et al.*[30] showed that the NIBUT can slightly increase in silicone hydrogel lenses after 14 days of lenses wear, which also may lead to some improvements in light disturbance. Benito *et al.*[27] found a statistically significant correlation between clinical NIBUT and the NIBUT derived from an optical quality analyzer (OQAS, Visiometrics, Spain). Ferrer-Blasco *et al.*[33] also found a correlation between the NIBUT and the Strehl ratio in normal subjects. Furthermore, it is well recognized that contact lenses reduce the tear stability.[20,34] Thus, the same mechanism that relates decreased NIBUT and increased aberrations and scattering, might justify the findings of increased light disturbance of a punctual source of light observed with the light disturbance analyzer.

According to the present results, the light distortion analyzer (LDA) can be used as a tool for evaluating and quantify the light disturbance reported by patients when they are under dim light conditions and wearing contact lens. It is a relatively short test that can be used in the clinical setting to quantify the optical performance of contact lenses from the patient's point of view.

4.6 References

1. Albarrán C, Pons A, Montés R, Artigas J. Influence of the tear film on optical quality of the eye. *Contact Lens Anterior Eye*. 1997;20(4):129–135.

2. Korb DR, Baron DF, Herman JP, et al. Tear film lipid layer thickness as a function of blinking. *Cornea*. 1994;13(4):354–9.

3. Rengstorff RH. The precorneal tear film: breakup time and location in normal subjects. *Am J Optom Physiol Opt*. 1974;51(10):765–9.

4. Mengher LS, Bron AJ, Tonge SR, Gilbert DJ. A non-invasive instrument for clinical assessment of the pre-corneal tear film stability. *Curr Eye Res*. 1985;4(1):1–7.

5. Cho P, Brown B, Chan I, Conway R, Yaps M. Reliability of the tear break-up time technique of assessing tear stability and the locations of the tear break-up in Hong Kong Chinese. *Optom Vis Sci*. 1992;(69):879–885.

6. Himebaugh NL, Jayoung N, Bradley A, Liu H, Thibos LN, Begley CG. Scale and Spatial Distribution of Optical Aberrations Associated with Tear Break-up. *Optom Vis Sci*. 2012;89(11):1590–1600.

7. Tutt R, Bradley A, Begley C, Thibos LN. Optical and visual impact of tear break-up in human eyes. *Invest Ophthalmol Vis Sci*. 2000;41(13):4117–23.

8. Montés-Micó R. Role of the tear film in the optical quality of the human eye. *J Cataract Refract Surg*. 2007;33:1631–1635.

9. Hirohara Y, Mihashi T, Koh S, Ninomiya S, Maeda N, Fujikado T. Optical quality of the eye degraded by time-varying wavefront aberrations with tear film dynamics. *Jpn J Ophthalmol*. 2007;51(4):258–64.

10. Montés-Micó R, Alió JL, Muñoz G, Charman W. Temporal Changes in Optical Quality of Air–Tear Film Interface at Anterior Cornea after Blink. *Invest Ophthalmol Vis Sci*. 2004;45(6):1752–1757.

11. Montés-Micó R, Alió J, Charman W. Dynamic changes in the tear film in dry eyes. *Invest Ophthalmol Vis Sci*. 2005;46(5):1615–9.

12. Begley CG, Caffery B, Nichols KK, Chalmers R. Responses of contact lens wearers to a dry eye survey. *Optom Vis Sci*. 2000;77(1):40–6.

13. Brennan NA, Lowe R, Efron N, Harris MG. In vivo dehydration of disposable (Acuvue) contact lenses. *Optom Vis Sci*. 1990;67(3):201–3.

14. Refojo M. *Tear evaporation considerations and contact lens wear. Considerations in contact lens use under adverse conditions.* (Flatau PE E, ed.). Washington, DC: National Academy Press; 1991:38–43.

15. Liu H, Thibos L, Begley CG, Bradley A. Visual Psychophysics and Physiological Optics Measurement of the Time Course of Optical Quality and Visual Deterioration during Tear Break-Up. *Optom Vis Sci*. 2010;51:3318–3326.

16. Andrasko G. Hydrogel dehydration in various environments. *Int Contact Lens Clin*. 1983;10:22–28.

17. Maruyama K, Yokoi N, Takamata A, Kinoshita S. Effect of environmental conditions on tear dynamics in soft contact lens wearers. *Invest Ophthalmol Vis Sci*. 2004;45(8):2563–8.

18. González-Méijome J, López-Alemany A, Almeida J, Parafita M, Refojo M. Qualitative and Quantitative Characterization of the In Vitro Dehydration Process of Hydrogel Contact Lenses. *J Biomed Mater Res Part B Appl Biomater*. 2007;8(83B):512–526.

19. Montés-Micó R, Belda-Salmerón L, Ferrer-Blasco T, Albarrán-Diego C, García-Lázaro S. On-eye optical quality of daily disposable contact lenses for different wearing times. *Ophthal Physiol Opt*. 2013;33(5):581–91.

20. Koh S, Maeda N, Hamano T, et al. Effect of internal lubricating agents of disposable soft contact lenses on higher-order aberrations after blinking. *Eye Contact Lens*. 2008;34(2):100–5.

21. Villa-Collar C, Jiménez J, González-Méijome J. Objective Evaluation of Night Visual Distortion. *Eur Ophthalmic Rev*. 2007:2–5.

22. Ferreira-Neves H, Macedo-de-Araújo R, Rico-del-Viejo L, C. da-Silva A, Queirós A, González-Méijome JM. Validation of a method to measure light distortion surrounding a source of glare. Journal of Biomedical Optics 20(7), 075002 (July 2015).

23. Linhares JMM, Neves H, Lopes-Ferreira D, Faria-Ribeiro M, Peixoto-de-Matos SC, Gonzalez-Meijome JM. Radiometric characterization of a novel LED array system for visual assessment. *J Mod Opt*. 2013;60(14):1136–1144.

24. Jansen ME, Begley CG, Himebaugh NH, Port NL. Effect of contact lens wear and a near task on tear film break-up. *Optom Vis Sci*. 2010;87(5):350–7.

25. Himebaugh NL, Wright AR, Bradley A, Begley CG, Thibos LN. Use of retroillumination to visualize optical aberrations caused by tear film break-up. *Optom Vis Sci*. 2003;80(1):69–78.

26. Rae SM, Price HC. The effect of soft contact lens wear and time from blink on wavefront aberration measurement variation. *Clin Exp Optom*. 2009;92(3):274–82.

27. Benito A, Pérez GM, Mirabet S, et al. Objective optical assessment of tear-film quality dynamics in normal and mildly symptomatic dry eyes. *J Cataract Refract Surg*. 2011;37(8):1481–7.

28. Ramamoorthy P, Sinnott LT, Nichols JJ. Contact lens material characteristics associated with hydrogel lens dehydration. *Ophthal Physiol Optal Physiol Opt*. 2010;30(2):160–166.

29. Keir N, Jones L. Wettability and silicone hydrogel lenses: a review. *Eye Contact Lens*. 2013;39(1):100–8.

30. Cheung S-W, Cho P, Chan B, Choy C, Ng V. A comparative study of biweekly disposable contact lenses: silicone hydrogel versus hydrogel. *Clin Exp Optom*. 2007;90(2):124–31.

31. Pult H, Murphy PJ, Purslow C. A novel method to predict the dry eye symptoms in new contact lens wearers. *Optom Vis Sci*. 2009;86(9):E1042–50.

32. Toda I, Yoshida A, Sakai C, Hori-komai Y, Tsubota K. Visual Performance After Reduced Blinking in Eyes With Soft Contact Lenses or After LASIK. *J Refract Surg*. 2009;25(January):69–73.

33. Ferrer-Blasco T, García-Lázaro S, Montés-Micó R, Cerviño A, González-Méijome JM. Dynamic changes in the air-tear film interface modulation transfer function. *Graefes Arch Clin Exp Ophthalmol*. 2010;248(1):127–32.

34. González-Méijome JM, da Silva AC, Neves H, Lopes-Ferreira D, Queirós A, Jorge J. Clinical performance and "ex vivo" dehydration of silicone hydrogel contact lenses with two new multipurpose solutions. *Contact Lens Anterior Eye*. 2013;36(2):86–92.

Chapter 5

Characterization of the impact of multifocal contact lens in light disturbance under night vision conditions

5. CHARACTERIZATION OF THE IMPACT OF MULTIFOCAL CONTACT LENS IN LIGHT DISTURBANCE UNDER NIGHT VISION CONDITIONS

5.1 Abstract

Purpose: To examine the impact of four different multifocal contact lenses in light disturbance, under night vision conditions.

Methods: Fifteen emmetropic healthy subjects (10 women and 5 men) participated in this study. Visual disturbance caused by halo phenomena in mesopic conditions was measured with an experimental device. The measures were obtained with and without contact lens, monocularly. The four lens used were: Acuvue Oasys Multifocal (AC_Oas; Senofilcon A, 38% H_2O, -00/Add: +1.75), Proclear Multifocal N (PRC_N; Omafilcon A, 62% H_2O, -00/Add: +2.00), Purevision Multifocal Low Add (PRV_L; Balafilcon A, 38% H_2O) e Air Optix Multifocal (Air_Opt; Lotrafilcon B, 33% H_2O, Add: +2.00). All lenses were plano for distance vision.

Results: Comparing to the no contact lens wearing conditions, all lenses made a statistically significant increase of the light disturbance under night vision conditions. For the parameters DA, LDI and BFC_{Rad}, there was a statistically significant difference ($p<0.05$) between the Ac_Oas and the Air_Opt lenses, being Ac_Oas the lens that had a less satisfactory performance.

Conclusions: Wearing these multifocal lenses, the level of disturbance increased up to double the values of the non-wearing conditions. The lens with the major disturbance was the lens with multizone refractive optics, the one that is essential different from the remaining lenses. This device used to measure light disturbance is a useful instrument to measure the light disturbance with multifocal contact lens under night vision conditions. It showed to be sensitive to differences in the pattern of disturbance generated by multifocal systems.

Key words: multifocal contact lens, night vision disturbances, image degradation.

5.2 Introduction

Presbyopic correction is one of the most stimulating challenges for the ophthalmic industry. Companies in different areas as contact lenses industry are investing large amounts of financial resources to find out a perfect solution to correct presbyopia and allow patients to be more independent of wearing spectacle lenses. The results of the studies published in the end of the 80's and early 90's, reveal great limitations in the results obtained with multifocal and bifocal lenses, showing a decrease in visual acuity, contrast sensitivity and stereopsis. In the middle 90's appeared some new designs that, even with some limitations, increase the expectations of success when compared with their predecessors.[1] The contact lens wearing presbyopic population is underserved worldwide.[2] If provided with the opportunity to wear contact lenses, the presbyopic patient is often successful. However, despite the technological advances in the field of multifocal contact lenses, these efforts still represent a low impact in clinical practice.[3]

Multifocal Contact Lenses (MCL) provide correction for distance, intermediate and near vision because of the multiple simultaneous foci for different distances. This compromise the quality of the near and distance images, resulting in a decrease in contrast sensitivity and acuity for all viewing distances. Multifocal Lenses are highly dependent on pupil size to achieve the desired performance. By increasing pupil size the areas of the lens creating images on the retina might change thus creating challenging conditions for visualization of images under low-lighting conditions.[4]

Measurement of visual disturbances under night vision conditions is being proposed in the present work as a control guide to investigators and practitioners toward optimization of visual outcomes of untreated cataracts and multifocal contact lens use.

In this project we intend to quantify image degradations under night vision conditions and its effect on NVD, using an experimental device.

5.3 Material and Methods

5.3.1 Subjects

Fifteen subjects (10 women and 5 men) participated in this study. Their ages ranged from 19 to 27 (mean 21.8 years). The study followed the tenets of the Declaration of Helsinki and was approved by the Institutional Review Board at University of Minho. Informed consent was obtained from all patients after the nature and possible consequences of the study had been explained. All patients were emmetropes and had normal ocular and general health. Light disturbance was evaluated under conditions of low lightning with an experimental device. The measures were obtained without contact lens and with four different multifocal contact lenses and of different materials and under low lightning conditions.

5.3.2 Lenses

Four different commercial silicone hydrogel CL were used. Their technical details are summarized in table 5.1. All lenses were neutral for distance vision. With the exception for Ac_Oas, all the other lenses were aspheric with centre for near vision. The Ac_Oas had a multiconcentric design with alternating zones for distance and near vision.

Table 5.1 - Technical details of the MCL used in this study

Brand	Acuvue Oasys Multifocal	Proclear Multifocal N	Purevision Multifocal Low	Air Optix Multifocal
Acronym	AC_Oas	PRC_N	PRV_L	Air_Opt
USAN Generic Name	Senofilcon A	Omafilcon A	Balafilcon A	Lotrafilcon B
ECW (%)	38%	62%	38%	33%
BC (mm)	8.8	8.7	8.6	8.6
Ø(mm)	14	14.4	14.0	14.2
Add	Add: +1.75	Add: +2.00	Low Add	Add: +2.00

USAN, United States Adopted Names Council; EWC, equilibrium water content; BC, base curve; Ø, diameter.

5.3.3 Procedure

Measurements of LD were performed using an experimental device—LD Analyzer (LDA, CEORLab, Portugal).24 It consists of central 5mm white LED that acts as glare source

surrounded by arrays of 240 1mm white light source (LED) distributed in twenty-four semimeridians with a minimum angular separation of 15 deg and a linear separation of 10mm to cover an angular field of 10° at the distance of examination of 2 meters. Figure 1(a to c) represents the arrangement of the device. The technical specifications of the LEDs characteristics and examination procedures can be consulted in previously published work.22, 24 In brief in a darkened room the instrument presents the central source of glare at maximum intensity while the peripheral LEDs are presented and turn-on and turn-off sequentially around the central source of light using different sequences at random times from 250 to 750 ms and the different semimeridians are explored in random order. The patient is instructed to always fixate the central LED and provides feedback regarding the peripheral stimuli that can be seen by clicking a remote actuator and the system automatically evaluates the next semimeridian. All the semimeridians are examined three times at the same measurement. If the standard deviation (SD) of the three measurements in each semimeridian is above 20% of the mean value, the device automatically repeats the measurements in those semimeridians until it reaches values of SD below 20% of the mean. After data collection and storage, a software tool calculates indices that determine the size, shape, and regularity of the disturbance surrounding the central source of light. The disturbance area (DA) is calculated as the sum of the areas of all triangles (or sectors) formed between each pair of semi-meridians under analysis, in mm^2. The light disturbance index (LDI) is calculated as the ratio of the area of points missed by the subject and the total area explored and is expressed as a percentage (%). The higher values of disturbance are interpreted as the lower ability to discriminate surrounding small stimuli that are hidden by the disturbance induced from the central source of light. Best Fit Circle Radius (BFCRadius) is defined as the circle that best fits to the disturbance area resulting from the linear binding of all external points not seen by the subject along each meridian. This parameter is expressed in millimeters and is linearly related to LDI parameter. Irregularity of the disturbance area is derived as the deviation of the actual polygonal shape obtained from the BFC fit and is called the BFC Irregularity (BFCIrreg). The standard deviation of BFCIrreg, called BFCIrregSD, measures how asymmetric is the departure of the actual disturbance limits from the perfect circular shape of the BFC. Together, BFCIrreg and BFCIrregSD can be interpreted as the deviation of the actual disturbance from a perfectly rotational symmetric shape. The higher the value of this parameter, the larger the deviation from a circular shape, expressed in mm.

Once the patient was in front of the screen with the head on a chin-rest, and after an adaptation period of 3 minutes, the test began. The patient had to define the limit of the disturbance, in each semi-meridian.

5.3.4 Statistical Analysis

The SPSS Statistical Package v.17.0 (SPSS Inc., Chicago, IL, USA) was used to conduct the statistical analysis. For each lens, all parameters were analyzed with Kolmogorov-Smirnov test to evaluate normality in the distribution of the variables. All parameters showed significance levels sufficiently high ($p>0.05$) to assume normality. For comparison of the data we used the ANOVA (with Bonferroni correction) or equivalent non-parametric (Kruskal-Wallis) to compare the means of all clinical situations and Paired Sample T-test or nonparametric equivalent (Wilcoxon Signed Ranks) to comparison of means for each pair of lenses or between the situation without lens with each of the lens.

5.4 Results

Figures 5.1 to 5.3 show the size parameters of the disturbance measured with each of the four lenses when comparing to the baseline situation (without contact lenses).

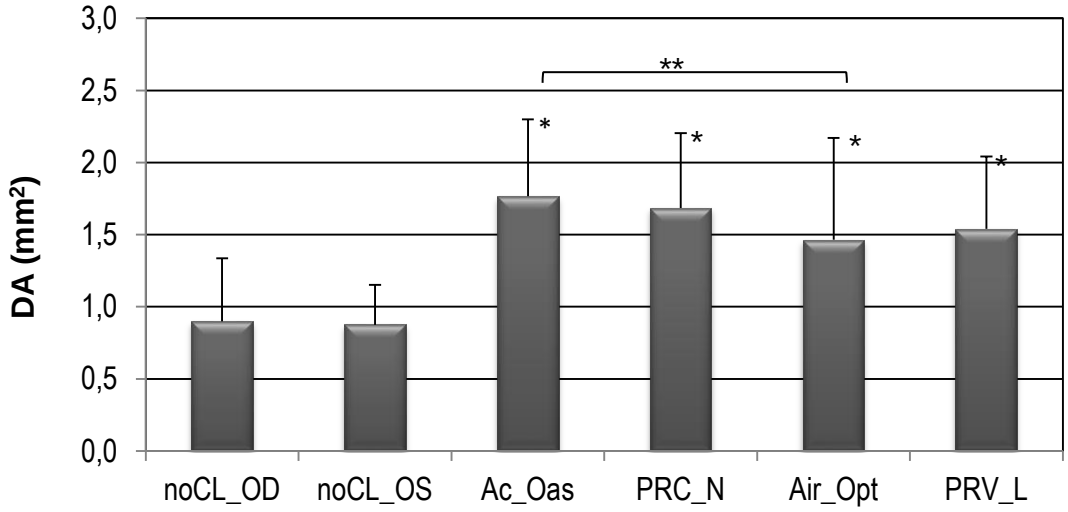


Figure 5.1 - Disturbance Area (DA) for the situations without contact lenses and with each of the four contact lenses. *means that the value is statistically significant when compared with the situation without contact lens. **means that there are statistically significant differences between the pair of lenses; noCL_OD and noCL_OS mean the situation without contact lens for the right or left eye, respectively.

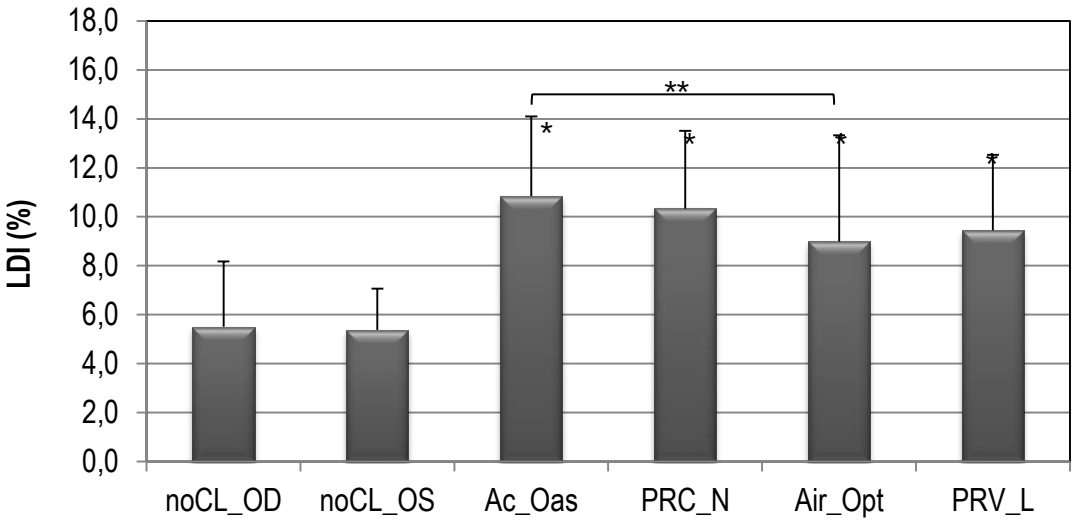


Figure 5.2 - Light Disturbance Index (LDI) for the situations without contact lenses and with each of the four contact lenses. * means that the value is statistically significant when compared with the situation without contact lens. ** means that there are statistically significant differences between the pair of lenses; noCL_OD and noCL_OS mean the situation without contact lens for the right or left eye, respectively.

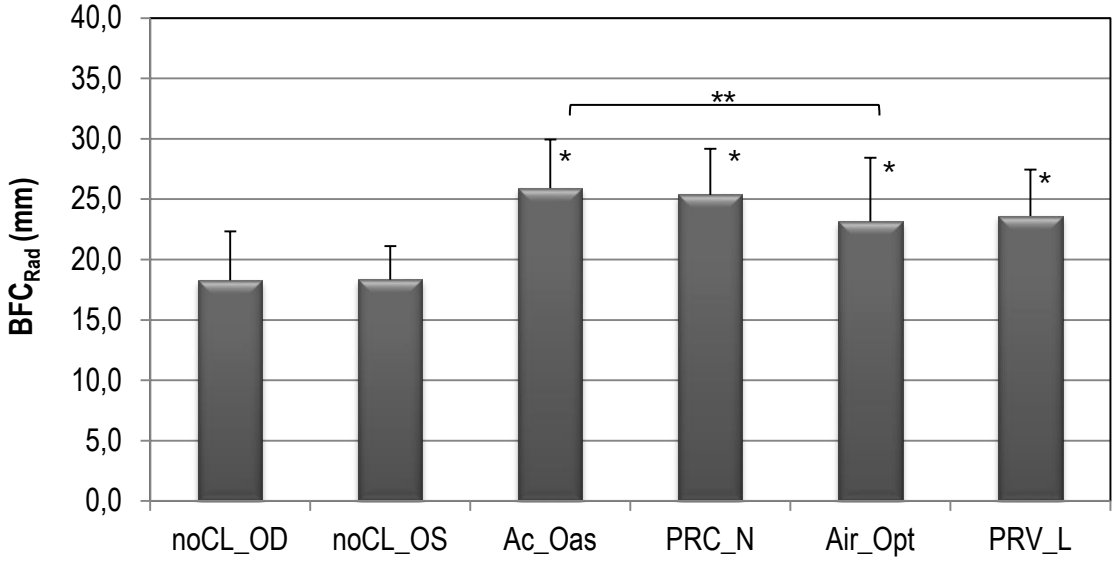


Figure 5.3 - . Best Fit Circle Radius (BFCRad) for the situations without contact lens and with each of the four contact lenses. * means that the value is statistically significant when compared with the situation without contact lens. ** means that there are statistically significant differences between the pair of lenses; noCL_OD and noCL_OS mean the situation without contact lens for the right or left eye, respectively.

All lenses cause a statistically significant increase in the size parameters (DA, LDI and BFCRad) of the disturbance measured ($p<0.05$) when comparing with no contact lens situation.

Besides that, there were found statistically significant differences between Ac_Oas and Air_Opt for the analyzed parameters, being the Air_Opt the lens that showed smaller Disturbance size.

Figures 5.4 and 5.5 show the parameters Best Fit Circle Irregularity (BFCIrreg) and Standard Deviation (SD) of the BFC Irregularity (BFCIrregSD), respectively, analyzed with and without CL. For these parameters, there were found no statistically significant differences ($p>0.05$) between the situations with and without contact lenses.

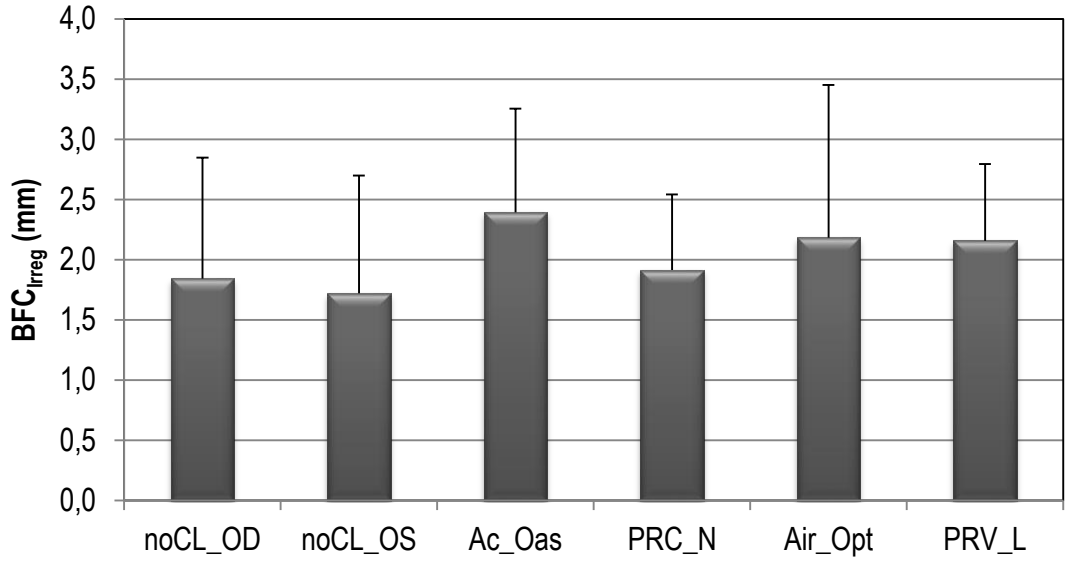


Figure 5.4 - Best Fit Circle Irregularity (BFCIrreg) for the situations without contact lens and with each of the four contact lenses. noCL_OD and noCL_OS mean the situation without contact lens for the right or left eye, respectively.

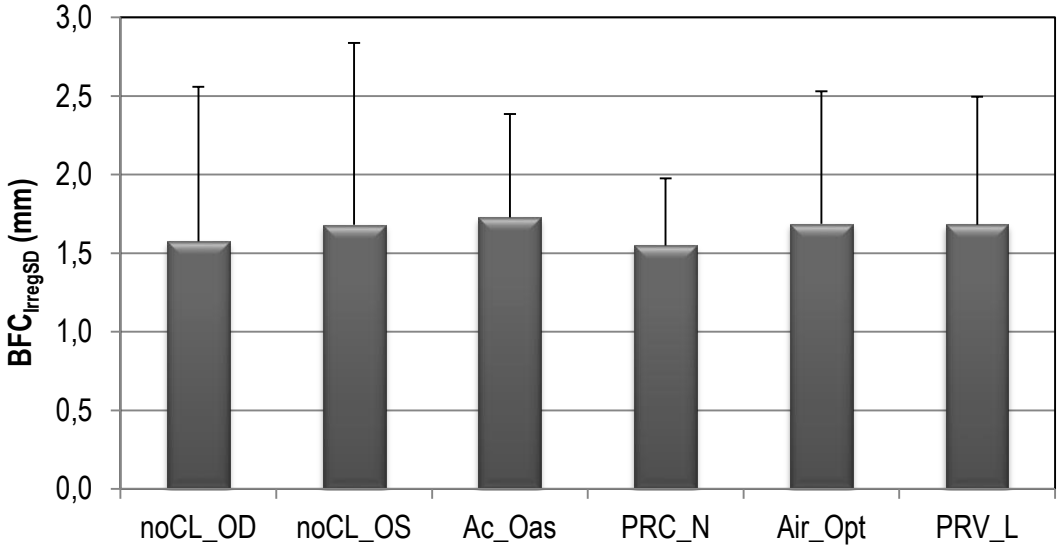


Figure 5.5 - Light Disturbance Index (LDI) measured for eyes assigned with Oasys and Advance, for a blinking rate of 12blinks/minute (Oasys 5sec and Advance 5sec) and 4blinks/minute (Oasys 15sec and Advance 15sec).

A comparison of all lenses for each parameter is presented on Table 5.2. The results showed that the Ac_Oas had the highest values in all parameters and the Air_Opt the lowest values, excepting on the irregularity parameters, had the lowest values. Despite the differences found in the comparison of the four lenses, they are not statistically significant (p>0.05).

Table 5.2 - Representation of the mean, standard deviation and value of statistical significance (p) for the difference between the lenses, to all analyzed parameters

	Ac_Oas	PRC_N	Air_Opt	PRV_L	p value
	Mean ± Standard Deviation				
Dist_Area (deg²)	0.92 ± 0.54	0.76 ± 0.41	0.57 ± 0.61	0.66 ± 0.54	0.309
Dist_Index (%)	5.67 ± 3.33	4.62 ± 2.51	3.49 ± 3.73	4.08 ± 3.29	0.311
BFC_Radius (mm)	8.05 ± 4.29	6.71 ± 3.26	4.73 ± 4.74	5.35 ± 4.71	0.162
Irreg_Mean (mm)	0.62 ± 1.14	0.00 ± 1.07	0.40 ± 1.20	0.39 ± 1.18	0.518
Irreg_SD (mm)	0.20 ± 1.15	-0.22 ± 1.21	0.07 ± 1.20	0.08 ± 1.36	0.818

P: value of statistical significance according to ANOVA (with Bonferroni correction).

Comparing the mean of the difference for each pair of lenses, shown on table 5.3, some differences were obtained. For the parameters DA, LDI and BFCRadius, there is a statistically significant difference (p<0.05) between the Ac_Oas and the Air_Opt lenses, being Ac_Oas the lens that had a less satisfactory performance.

Table 5.3 - Comparison of the mean difference for each pair of lenses for each parameter

		DA (mm²)	Dist_Index (%)	BFC_Radius (mm)	Irreg_Mean (mm)	Irreg_SD (mm)
Ac_Oas - PRC_N	Mean±SD	0.17±0.70	1.05±4.27	1.34±5.18	0.62±1.15	0.42±0.91
	p	0.366	0.356	0.333	0.055	0.097
Ac_Oas- Air_Opt	Mean±SD	0.36±0.63	2.18±3.85	3.32±4.92	0.22±1.11	0.13±1.82
	p	0.045*	0.046*	0.020*	0.460	0.780
Ac_Oas - PRV_L	Mean±SD	0.26±0.52	1.59±3.17	2.70±4.94	0.23±1.23	0.12±1.88
	p	0.073	0.073	0.053	0.483	0.809
PRV_L - Air_Opt	Mean±SD	0.19±0.69	1.13±4.21	1.98±4.96	-0.41±1.50	-0.28±1.84
	p	0.306	0.317	0.145	0.312	0.560
PRC_N - PRV_L	Mean±SD	0.09±0.63	0.54±3.85	-0.62±4.02	-0.39±1.53	-0.30±1.96
	p	0.586	0.599	0.559	0.335	0.564
Air_Opt- PRV_L	Mean±SD	-0.10±0.37	-0.59±2.30	1.36±4.30	0.01±1.08	-0.01±1.16
	p	0.331	0.335	0.242	0.968	0.962

* means the value of statistical significance according to Paired Sample T-test;

5.5 Discussion

Glare disability, image degradations (halos and starbursts) and loss of contrast sensitivity - grouped into the adapted term of night vision disturbances (NVD) - under low lightening conditions (scotopic and mesopic conditions) when the pupil is physiologically dilated are problems reported by patients who have otherwise excellent vision during the day.[4]

Optical systems with focal points lying behind each other always lead to an overlap of focused and out of focus image in the retina, causing this NVD, most often in conditions such as night driving. This is the case of every multifocal contact lens that creates different focal planes by incorporating different curvatures on the front or back surface. Not surprisingly, wearing these lenses, the level of disturbance increased up to double the values of the non-wearing conditions. This might be a quantitative expression of the symptoms reported in different studies regarding these devices. [5]

This symptoms are also reported by patients that undergone refractive surgery procedures and represent a major clinical problem for a patient who has had a successful refractive procedure. [4; 8; 9]

Not surprisingly, the lens with the major disturbance was the lens with multizone refractive optics, the one that is essential different from the remaining lenses. This approach had already revealed to be poorly successful when incorporated into intraocular lenses.[6; 7]

The Air_Opt lens, showed lower values of disturbance on almost all parameters. Contact lenses with lower hydration (ECW) do not dehydrate as quickly as the lens with higher ECW. Like Air_Opt is a lens with low ECW, we can put up the hypothesis that the tear film can keep the lens surface more regular, thus preventing this factor to contribute to an increase in light disturbance. However, the results of this study do not allow directly assess this possibility.

Over the last few years, there has been an increased interest in the study of the quality of the vision. But even today, after years of debate, the disagreement between patient's self-reported symptoms and the objective visual assessment as measured by the practitioner causes frustration for both patient and practitioner. Nowadays, with more precise methods to measure the quality of vision, it is possible to find correlations among all variables that interfere in the

process with a scientific basis, in order to develop effect methods to limit their impact on patient's quality of life.

To investigate the amount of aberrations induced with optical corrections and the related degree of NVD experienced by the patients is of major interest in order to develop strategies to minimize the complaints.[10]

The present work has demonstrated the analysis of the light disturbance experienced by patients wearing multifocal contact lenses in the laboratory is a sensitive measure of the potential NVD experienced in real life. Furthermore, the device has shown to be effective in discriminating the disturbance generated by different multifocal systems.

5.6 References

1. González-Méijome JM. Corrección de la presbicia, nuevos retos y oportunidades para la contactología del futuro. Ver y Oir. 2007;(Novembro):628-633.

2. Morgan PB, Woods CA, Jones D, Efron N, Tan K-ooi, Gonzalez MY, et al. International Contact Lens Prescribing in 2006. Contact Lens Spectrum. 2007 258 ;(January):34-38.

3. Morgan PB, Efron N. A decade of contact lens prescribing trends in the United Kingdom (1996–2005). Contact Lens & Anterior Eye. 2006

4. Fan-Paul N, Li J, Miller J, Florakis G. Night Vision Disturbances After Corneal Refractive Surgery. Survey of Ophthalmology. 2002 ;47(6):533-546.

5. Chu BS, Wood JM, Collins MJ. Effect of Presbyopic Vision Corrections on Perceptions of Driving Difficulty. Eye & Contact Lens. 2009 ;35(3):133-143.

6. Solomon R, Donnenfeld E. Refractive Intraocular lenses. Multifocal and Phakic IOLs. Int Ophthalmol Clin. 2006 ;46:23–146.

7. Kohnen T, Allen D, Boureau C. European multicenter study of the AcrySof ReSTOR apodized diffractive intraocular lens. Ophthalmology. 2006 ;113:578–584.

8. Collar CV, Gutirrez R, Jiménez JR, González-Méijome JM. Night vision disturbances after successful LASIK surgery. Br J Ophthalmol. 2007 ;1-8.

9. Villa Collar C. Objective Evaluation of Night Visual Distortion. European Ophtalmic Review. 2007 ;2-5.

10. López-Gil N, Montés-Micó R. New intraocular lens for achromatizing the human eye. J Cataract Refract Surg. 2007 ;33:1296-1302.

Chapter 6

Light Disturbance and Subjective Perception of Presbyopes with Multifocal Contact Lenses

6. MEASUREMENT OF LIGHT DISTURBANCE AND SUBJECTIVE PERCEPTION OF PRESBYOPES WITH THREE DIFFERENT MULTIFOCAL CONTACT LENSES

6.1 Abstract

Purpose: To measure the light disturbance and evaluate the subjective quality of vision and lens performance of presbyopic patients wearing three different multifocal soft contact lenses (MFCL) in a crossover randomized clinical trial.

Methods: Nineteen healthy subjects (6 women and 13 men) with mean age of 48.6 ± 3.7 years participated in this study. Each patient wore three different MFCL in random order: aspheric design (Air Optix Multifocal, Ciba Vision, Duluth, GA), multizone concentric (Acuvue Oasys for Presbyopia, Johnson & Johnson, Jacksonville, FL) and aspheric asymmetric design (Proclear Multifocal, Coopervision, Pleasanton, CA) for 15 days period, followed by a one week period of wash-out. Light disturbance was evaluated under conditions of low lightning with an experimental device (Light Distortion Analyzer –LDA- University of Minho, Portugal). They completed the QoV questionnaire before contact lens fitting (baseline) and at 7 and 15 days after using each lens. The outcome measures were QoV parameters for frequency, severity, and bothersome scored from 0 to 100 with higher scores indicating poorer quality of vision. Patients were then asked to fill a subjective questionnaire to assess their subjective perceptions with the use of these lenses after 7 and 15 of MFCL wear. A pair of +1.50 D supplementary reading spectacles (SRS) was given to be used at their discretion.

Results: Patients reported to worn their lenses for 6±2 days a week during 13±2 hours a day and this wearing pattern was not significantly different between lenses ($p>0.05$, ANOVA with Bonferroni correction). Only the Acuvue Oasys lens showed statistically significant higher QoV scores in frequency ($p<0.01$) and severity ($p=0.01$) of the symptoms after 7 and 15 days of lens use, against baseline. After 15 days of use, there were found differences between QoV scores with Acuvue Oasys and Proclear Multifocal in frequency ($p<0.05$) and severity ($p<0.05$), being the Proclear Multifocal the one that showed the lower scores. For the high add group, there were found differences in the frequency and severity of the symptoms for Acuvue Oasys ($p<0.01$; $p<0.01$) and Air Optix ($p<0.05$;$p<0.05$) when comparing the 7 and 15 days visit with baseline.

The subjective satisfaction for intermediate vision was better for Proclear compared to Oasys (Diff=2.0; p=0.010, ANOVA with Bonferroni correction). Otherwise the three lenses performed similarly. The highest rate was found for esthetic satisfaction (rated above 9 for all lenses), followed by satisfaction comparing MFCL with near vision or progressive add lenses in spectacles (rated above 7.5 for all lenses) and satisfaction with near (rated 7 with one lens and above 8 for the remaining two lenses). Using SRS over the MFCL was not significantly different between lenses ($p>0.05$, Chi^2 test) with 50% never using them, 30% using them rarely and 20% using them frequently after 15 days wearing each MFCL.

Conclusions: Comparing with the baseline situation, there were observed higher scores of the QoV outcome measures when the patients were using a multifocal contact lens. In all QoV measures along this study, we conclude that Acuvue Oasys is the lens that worsens most the quality of vision of the patients, while the Proclear Multifocal is the lens that the patients refer as the one which has lower effects on worsening their quality of vision. Unlike the low addition, fitting patients with high additions significantly decrease their quality of vision. Patients wearing MFCL report high rates of satisfaction in certain areas aspects of their subjective perception mainly related with esthetic perception and comparison against other types of vision correction. Patients reported that recognizing people at distance, reading distance placards and working on a computer were the daily-life tasks where they found more difficulties while using MFCL. SRS might be useful to perform challenging near tasks while adapting to MFCL. After 15 days of lens use, the patients become more independent of the SRS use.

Key words: multifocal contact lenses; presbyopia, reading spectacles; subjective performance

6.2 Introduction

There has been an increase in the proportion of the world population that becomes presbyopic due to a progressive aging of the population over the last decade. Consequently, the number of contact lens (CL) wearers requiring presbyopic correction has grown significantly.

Presbyopia correction with contact lenses (CL) is achieved with monovision and multifocal CL[1] with multifocal contact lenses (MFCL) representing the majority of fittings to patients over 45 years of age in most countries.[2] The extent of presbyopic patients to which multifocal and monovision lenses are prescribed varies considerably among countries[2,3] (ranging from 79 per cent of all soft lenses in Portugal to ALMOST zero in Singapore). MFCL incorporate aspheric, bifocal or multizone spherical or aspherical designs to create multiple foci and/or increasing in the depth of focus of the human eye at the expense of reducing the quality of vision due to increased higher order aberrations.[4]

Chu et al have recently concluded that monovision and multifocal contact lenses are among the presbyopic compensation methods that more significantly increase halos and glare sensation when compared with other methods as single vision and progressive add lenses for spectacles.[5]

According to Fernandes *et al.*[6] the simultaneous vision MFCL can potentially provide a better balance of real-world visual function because of minimal binocular disruption compared to MV lenses. As so, both aspheric and concentric simultaneous vision designs are among the most used in current practice and those are the ones we used on this clinical trial.

Recently, McAlinden *et al.* have developed a questionnaire that aims to assess the subjective Quality of Vision (QoV) by quantifying the frequency, severity and bothersome of glare, haloes, starbursts, hazy vision, blurred vision, distortion, double vision, fluctuation, focusing difficulties and depth perception.[7] However, this method has not been yet applied to MFCL fitting. Considering that most of the abovementioned symptoms are common to MFCL wearers at least during the initial adaptation process the QoV questionnaire might be a useful tool in identifying and quantifying the symptoms related with the degradation of the image quality that impairs the ability of some patients to adapt to MFCL in the short-term.

One of the current techniques to correct presbyopia with MFCL is based on simultaneous vision. Simultaneous vision contact lens designs provide coexisting clear vision at two or more distances due to the multiple powers positioned within the pupil at the same time.[4,8] Consequently, light rays from both distance and near targets are simultaneously projected on the retina. There are three designs available that use the simultaneous vision principle: aspheric; concentric/annular and diffractive.[1]

Multifocal Lenses are highly dependent on pupil size to achieve the desired performance. By increasing pupil size the areas of the lens creating images on the retina might change thus creating challenging conditions for visualization of images under low-lighting conditions.[9]

Subjective visual satisfaction and wearing success have been evaluated previously using different CL designs and wearing modalities.[10-14] Papas and co-workers[13] found significant reductions in subjective visual satisfaction because of ghosting, halos, lens comfort, visual quality, visual fluctuation, facial recognition, and overall satisfaction with four MFCL.

Considering that most of the abovementioned symptoms are common to MFCL wearers at least during the initial adaptation process, and some authors claim that those reductions were not justified by reductions in visual acuity (VA),[13] is it crucial not only to quantify the Night Vision Disturbances (NVD) reported by these subjects, but also evaluate subjective visual satisfaction to better understand the performance of MFCL wearers, beyond simply measuring VA.

As it regards to night vision conditions, some recent studies have addressed the effect of various presbyopic vision corrections on night-time driving performance.[5,15,16] One of these studies[16] concluded that MFCL are among the presbyopic compensation methods that more significantly increase halos and glare sensation when compared with other methods as single vision and progressive add lenses for spectacles.

Considering that different MFCL have different optical designs, they could interfere differently in the subjective quality of vision of patients. Thus, the aim of this study was to quantify the NVD reported by MFCL wearers and compare the subjective quality of vision related with daily life activities while using three different designs of MFCL for presbyopia correction fitted in random order to the same cohort of patients.

6.3 Material and Methods

This study was a prospective, double-masked, randomized clinical trial. Nineteen healthy subjects (6 women and 13 men) with mean age of 48.6±3.7 years participated in this study. The trial was conducted at the Clinical and Experimental Optometry Research lab (CEORLab, Minho University, Braga, Portugal). An internal review board reviewed the protocol of the study. Following guidelines of the Declaration of Helsinki, all patients signed a Consent Form once the objectives and procedures of the study were fully explained.

Inclusion criteria required that the patient had between 45 and 55 years of age, transparent ocular media and no active or recent ocular disease, nor were taking any ocular medication susceptible of inducing visual or refractive changes. Patients should present with a best spectacle corrected visual acuity of 0.00 logMAR units or better with a spherical refractive error between -5.00 and +2.00 D and with refractive cylinder below 1.00D. All patients had undergone a full ophthalmic examination including objective and subjective refraction using an end-point criterion of maximum plus for the best visual acuity. Visual acuity was measured at baseline and at each follow-up visit with a Logarithmic Visual Acuity Chart "ETDRS" (Precision Vision, IL) under high (100%) (CAT No. 2110) contrast (CAT No. 2153) conditions with a Cabinet Illuminator No. 2425 (Precision Vision, IL). The near VA was recorded at a distance of 40 centimeters using the 128 Logarithmic Visual Acuity Chart 2000 "New ETDRS" (Chart "1"- CAT No. 2106), as recommended, for high (100%) contrast.

6.3.1 Multifocal Contact Lenses

Multifocal lenses included in the study were AirOptix Multifocal (Ciba Vision, Duluth, GA), Acuvue Oasys for Presbyopia (Johnson & Johnson, Jacksonville, FL) and Proclear Multifocal (Coopervision, Pleasanton, CA). Acuvue Oasys for Presbyopia is a multiconcentric silicone hydrogel multifocal CL (Senofilcon A, 38% EWC, FDA group I) with 5 concentric annular areas of alternating distance (center-distance) and near power (add power); the lens include three different add powers (LO, MED, HI) prescribed in the dominant and non-dominant eye depending on the patient's near add. AirOptix Multifocal is an aspheric silicone hydrogel multifocal CL (Lotrafilcon B, 33% EWC, FDA group I) with three different add powers (LOW, MED, HI) located in the center of the lens (center-near design) prescribed in the dominant and non-dominant eye

depending on the patient's near add. Proclear Multifocal is an aspheric conventional hydrogel CL (Omafilcon A, 59% EWC, FDA group II) with asymmetric optical designs combining near and distance spherical areas linked through an aspheric intermediate area prescribed to the dominant eye (center-distance) and non-dominant eye (center-near) and add powers changing continuously from +1.00 to +4.00 in 0.50D steps; for the purpose of comparison with nomenclature followed for the other two lenses, we have considered LOW those add powers<=1.25, MID for add powers of +1.5, 1.75 and 2.0 and HIGH for add powers>2.0.

Figure 6.1 shows the optical design of each lens for a -2.00D distance correction with a medium add power (MED for Oasys and AirOptix and +1.50 for Proclear). Lenses were fitted following the manufacturer's protocol. In order to optimize patient's vision, some of them received different additions in dominant and non-dominant eye as recommended by each manufacturer.

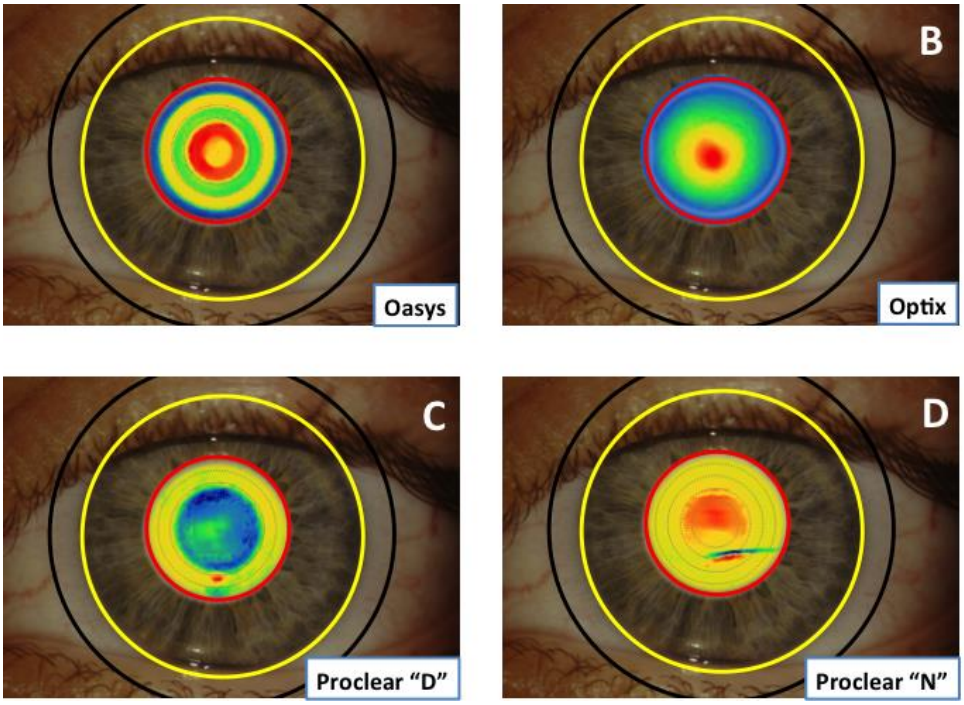


Figure 6.1 – Optical design of each lens for a -2.00D distance correction with a medium add power (MED for Oasys and Air Optix and +1.50 for Proclear).

6.3.2 Clinical Protocol

The clinical protocol followed is illustrated in figure 2. Each lens was used for a 15-day period, followed by a one-week wash-out period in which the patients wore their habitual spectacle correction.

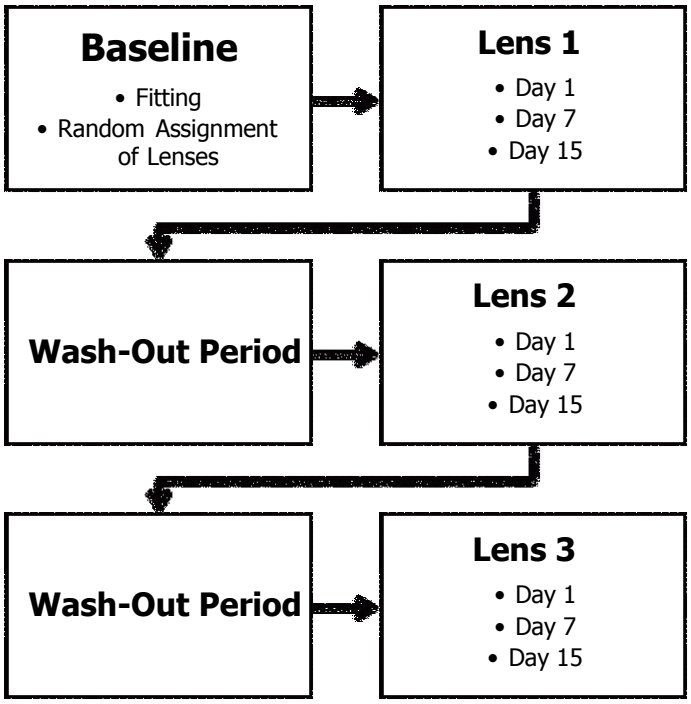


Figure 6.2 – Methodology followed in the study.

6.3.3 Ocular dominance

Eye dominance was identified using the "sensory dominance method"[17] in which the patient looked to a VA line of letters immediately below his/her best VA while a +1.50D lens was placed alternately in front of each eye for a few seconds; the dominant eye is the one in which the subject reported more blurred vision under binocular conditions. With all CL, the best distance and near VA and on-eye lens fit was ensured for each eye using standard optometric techniques. Patients were instructed on lens insertion, removal, and cleaning techniques.

6.3.4 Quality of Vision (QoV) Questionnaire

All patients filled the QoV questionnaire before contact lens fitting (baseline), 7 days and 15 days after lens dispensing. The outcome measures were QoV scores for symptom frequency, severity, and bothersome. The QoV scores range from 0 to 100 with higher scores indicating poorer quality of vision.

To evaluate the impact of lens addition power into the QoV scores, for each lens the sample was splitted in two groups (lower adds and higher adds). Once the QoV questionnaire refers to daily-life situations in which binocular vision is present relationship with the amount of add power in the lens must be considered from a binocular point of view in order to classify patients in high or low add the following criteria was established. We considered that patients with low addition in both eyes (LOW-LOW) or Low in one eye and med in the other eye (MED-LOW) were all part of the (lower add group). All the other possibilities of mixture of additions were in the HIGH group.

6.3.5 Subjective Questionnaire

The outcome measures were the subjective ratings of the patients in a visual analogue scale (0-10) for parameters related to lens handling, comfort and vision at different distances (Appendix I). Frequency of SRS use over their MFCL was rated as never, rarely frequently or very frequently. The patients also identified different daily-life tasks that they found more challenging to perform. This questionnaire was filled after 7 and 15 days of lens wear with each one of the 3 MFCL.

6.3.6 Light Distortion Analyzer (LDA)

Measurements of LD were performed using an experimental device—LD Analyzer (LDA, CEORLab, Portugal).24 It consists of central 5mm white LED that acts as glare source surrounded by arrays of 240 1mm white light source (LED) distributed in twenty-four semi meridians with a minimum angular separation of 15 degrees and a linear separation of 10mm to cover an angular field of 10º at the distance of examination of 2 meters. The technical specifications of the LEDs characteristics and examination procedures can be consulted in previously published work.[18] In brief in a darkened room the instrument presents the central

source of glare at maximum intensity while the peripheral LEDs are presented and turn-on and turn-off sequentially around the central source of light using different sequences at random times from 250 to 750 ms and the different semi meridians are explored in random order. The patient is instructed to always fixate the central LED and provides feedback regarding the peripheral stimuli that can be seen by clicking a remote actuator and the system automatically evaluates the next semi meridian. All the semi meridians are examined three times at the same measurement. If the standard deviation (SD) of the three measurements in each semi meridian is above 20% of the mean value, the device automatically repeats the measurements in those semi meridians until it reaches values of SD below 20% of the mean. After data collection and storage, a software tool calculates indices that determine the size, shape, and regularity of the disturbance surrounding the central source of light. The light disturbance index (LDI) is calculated as the ratio of the area of points missed by the subject and the total area explored and is expressed as a percentage (%). The higher values of disturbance are interpreted as the lower ability to discriminate surrounding small stimuli that are hidden by the disturbance induced from the central source of light.

Once the patient was in front of the screen with the head on a chin-rest, and after an adaptation period of 3 minutes, the test began. The patient had to define the limit of the disturbance, in each semi-meridian.

6.3.7 Statistical Analysis

The data were double entered into a Microsoft Excel spread sheet and analyzed using IBM SPSS Statistics software v.20 (SPSS Inc., Chicago, IL). Because this study examined variables measured on the same patient using different prescriptions, repeated-measures analysis of variance (ANOVA) was performed after verifying normality with Shapiro-Wilk test and homogeneity of variances with Levene test. Post hoc testing was performed using Bonferroni's method for multiple comparisons. The frequency of different symptoms among lenses was compared using the Chi2 test. The overall significance level was set at $p<0.05$.

6.4 Results

Average pupil size of patients was 4.46±0.80mm as measured under photopic conditions (85cd/m2) with the open-field Grand Seiko autorefractometer WAM-5500 (Grand Seiko Co. Ltd, Hiroshima, Japan) without cycloplegia.

The three lenses provided similar distance and near VA. Near and distance binocular VA with CL were, respectively, 0.00±0.12 and -0.15±0.05 for Acuvue Oasys, -0.04±0.10 and -0.12±0.08 for Air Optix and -0.03±0.12 and -0.14±0.05 for Proclear. Differences between lenses were not statistically significant. Patients reported to worn their lenses for 6±2 days a week during 13±2 hours a day and this wearing pattern was not significantly different between lenses ($p>0.05$, ANOVA with Bonferroni correction).

6.4.1 Quality of Vision Questionnaire (QoV)

There were found no differences between LOW and HIGH addition lenses for VA measured at 7 and 15 days visits. Also, there were found no differences between the three lenses (Table 6.1).

Table 6.1 - LogMAR distance visual acuity at 7 days and 15 days follow-up visits with each of the three lenses in the two groups

	7 days	15 days
Acuvue Oasys for Presbyopia	LOW:-0.17±0.06	LOW:-0.16±0.04
	HIGH:-0.02±0.13	HIGH:-0.14±0.05
AirOptix Multifocal	LOW:-0.15±0.07	LOW:-0.12±0.06
	HIGH:-0.14±0.06	HIGH:-0.12±0.09
Proclear Multifocal	LOW:-0.15±0.07	LOW:-0.16±0.05
	HIGH:-0.12±0.07	HIGH:-0.12±0.03

Figure 6.3 shows the average values of QoV scores for frequency, severity and bothersome at the 15 days visit. Statistically significant differences were found for frequency ($p=0.032$) and severity ($p=0.033$) of symptoms between Acuvue Oasys Multifocal and Proclear Multifocal, being the Acuvue the one that showed higher scores.

Differences against baseline were statistically significant for Acuvue Oasys Multifocal at 7 and 15 days visits for frequency ($p=0.005$, $p=0.003$) and severity ($p=0.016$, $p=0.01$).

When we analyze the variation of QoV scores from 7 to 15 days (Figure 6.4), we found that Air Optix and Proclear showed a decrease in the average of QoV scores, meanwhile the QoV scores for Acuvue Oasys increased. However, the differences found are not statistically significant.

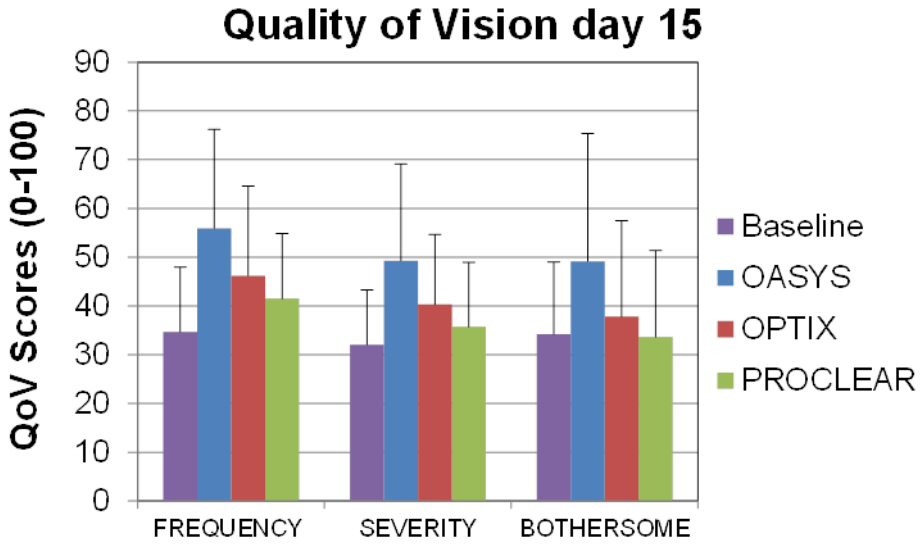


Figure 6.3 – Frequency, severity and bothersome QoV scores at baseline, after 15 days of lens wear for Oasys. AirOptix and Proclear multifocal contact lenses. Higher values represent a poorer quality of vision. Bars indicate standard deviation.

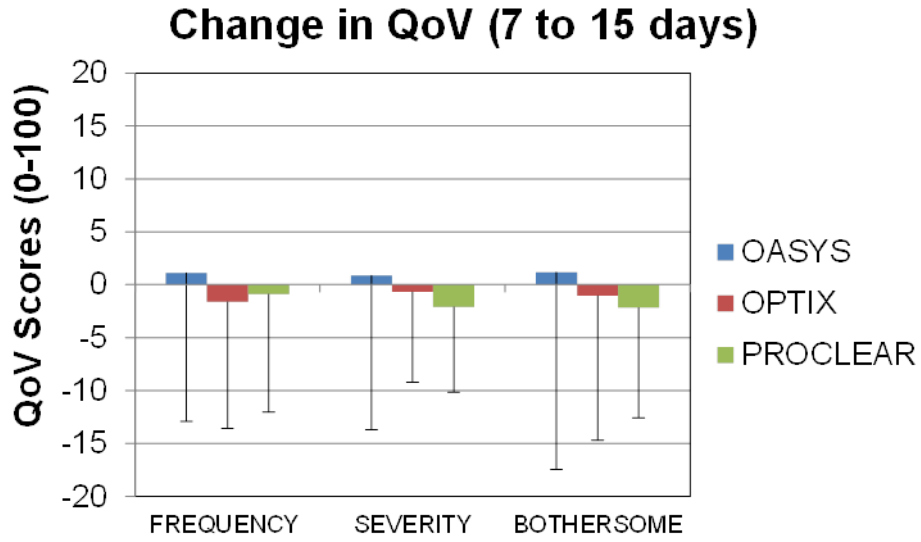


Figure 6.4 – Changes in frequency, severity and bothersome QoV scores from 7 to 15 days of lens wear for Oasys, AirOptix and Proclear multifocal contact lenses. Negative values represent an improvement in subjective quality of vision. Bars indicate standard deviation.

At the 7 days visit, differences between the two addition groups were found in Proclear Multifocal for frequency (p=0.017), severity (p=0.011) and bothersome (p=0.016) QoV scores. Those differences decreased at the 15 days visit, being the QoV severity score the only

statistically significant difference (p=0.036) between the two groups. At this visit, there were also found differences between the two groups in QoV severity scores (p=0.036) for Air Optix Multifocal.

Table 6.2 – Differences between the two addition groups in frequency, severity and bothersome QoV scores for each lens and each visit. P<0.05 means statistically significant differences between the two groups, being the higher scores always in the HIGH group.

		P value	
		7 days	15 days
Oasys	Frequency	0,803	0,914
	Severity	0,558	0,824
	Bothersome	0,688	0,937
Optix	Frequency	0,914	0,065
	Severity	0,824	**0,049**
	Bothersome	0,937	0,099
Proclear	Frequency	0,017	0,134
	Severity	0,011	0,036
	Bothersome	0,016	0,085

For each add group and for each of the three lenses, Table 6.2 shows the differences between visits and between lenses for frequency, severity and bothersome of the symptoms measured with the QoV questionnaire.

For the LOW add groups, there were found no statistically significant differences between visits for all lenses. Between lenses, there were only found differences between Acuvue Oasys and Proclear, in the severity (p=0.039) of the symptoms, being the Acuvue Oasys the lens that presented higher scores. For the HIGH addition group, there were found differences in the frequency of the symptoms between baseline and 7 and 15 days visits for Oasys (p=0.005; p=0.003) and Optix (p=0.042;p=0.038). The severity of the symptoms in this add group was only statistically different for Optix between baseline and 7 days visit.

6.4.2 Subjective Perceptions Questionnaire

The subjective satisfaction for intermediate vision was better for Proclear compared to Oasys (Diff=2.0; p=0.010, ANOVA with Bonferroni correction). Otherwise the three lenses

performed similarly. Esthetic satisfaction was rated with the highest satisfaction scores (rated above 9 for all lenses), followed by satisfaction comparing MFCL with near vision or progressive add lenses in spectacles (rated above 7.5 for all lenses) and satisfaction with near vision (rated 7 with one lens and above 8 for the remaining two lenses).

Figure 6.5 shows the frequency of use of SRS over MFCL after 15 days of lens wear. Need for SRS over the MFCL was not significantly different between lenses ($p>0.05$, Chi2 test) with 50% never using them, 30% using them rarely and 20% using them frequently after 15 days of adaptation. The distribution of reported need for SRS use was "never" (Oasys:31%; Proclear:44%; Optix:56%) or "rarely" (Oasis:44%; Proclear:28%; Optix:25%) using their at the 7 days visit, with some of them reporting a "very frequent" pattern of use (Oasys:13%; Proclear:6%; Optix:11%). Comparing 7 to 15 days visits, there was an increase in patients using SRS with Oasys (13% vs 18% report "very frequent" use and 13% vs 24% report "frequent" use), and a decrease in patients using SRS with Optix (13% vs 6% report "frequent" use). With Proclear, comparing 7 to 15 days visits there was an increase in patients reporting "never" using SRS (44% vs 50%).

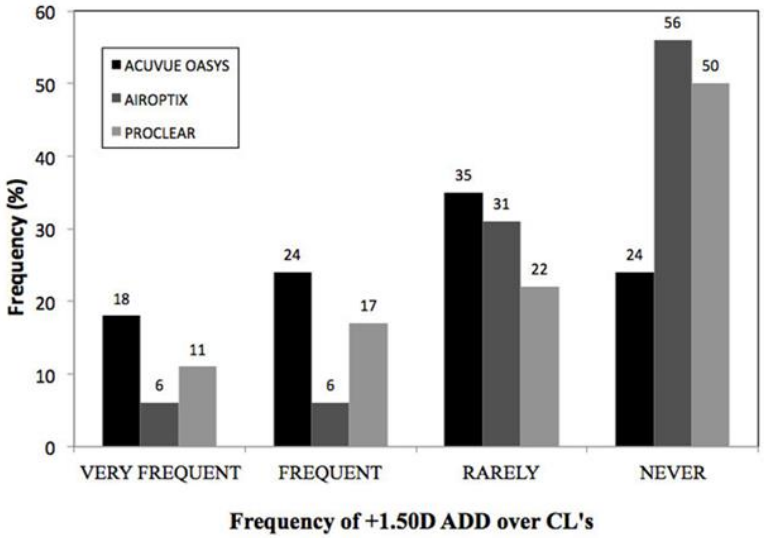


Figure 6.5 – Frequency of supplementary reading spectacles wear over all multifocal contact lenses after 15 days of lens wears.

Patients reported that recognizing people at distance, reading distance placards and working on PC were the daily-life tasks where they found more difficulties, being reported by 40

to 50% of patients with Acuvue Oasys, 30% with Air Optix and 25% with Proclear. However, these differences between lenses were not statistically significant.

6.4.3 Light Distorsion Analyzer (LDA)

Differences between the dominant and non-dominant eyes in terms of the LDI are represented below in Figure 6.6.

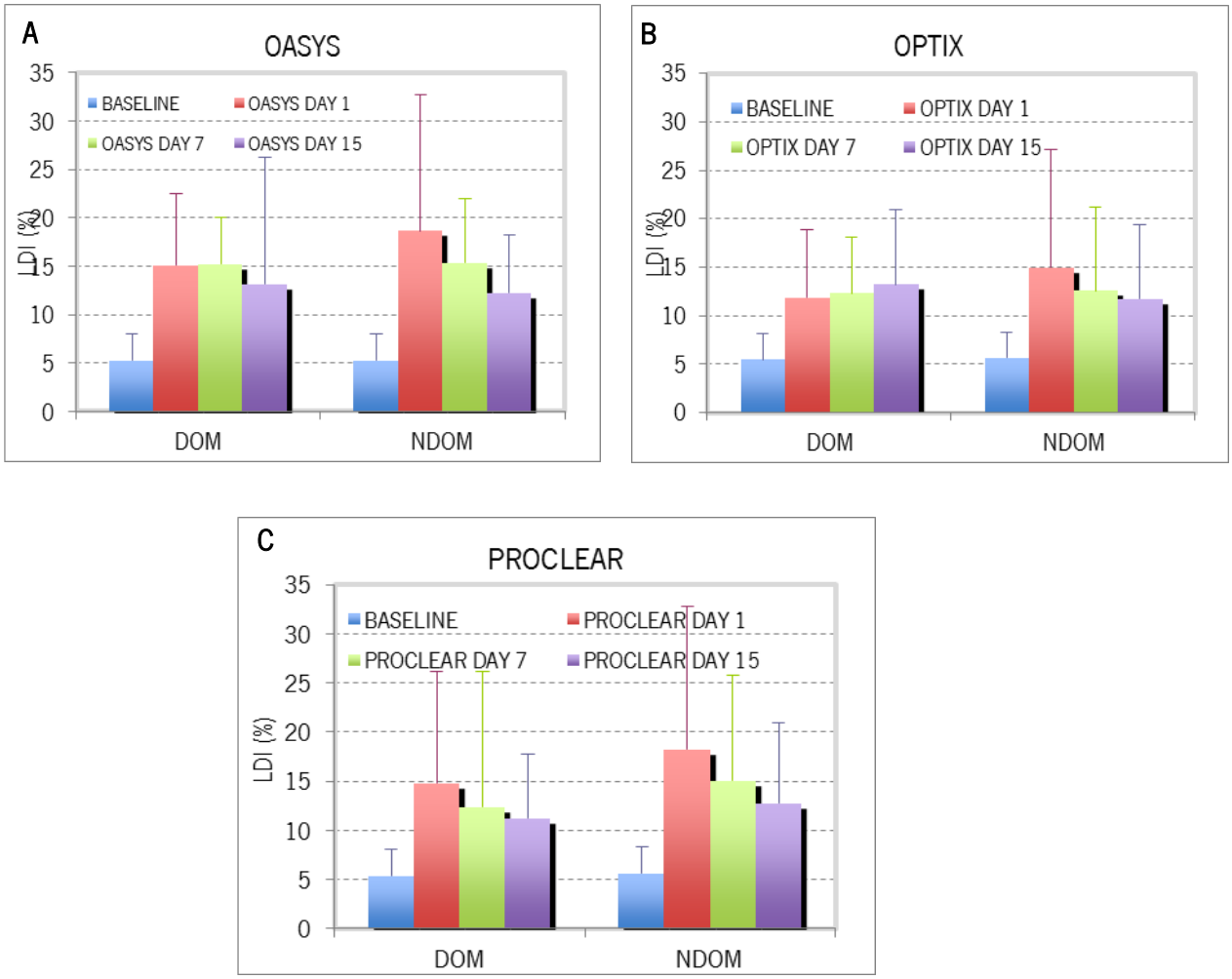


Figure 6.6 – Light Distortion Index (LDI) for the three studied lenses, at 1, 7 and 15 days visit for the dominant (DOM) and non-dominant eyes (NDOM).

The LDI increased, with all three lenses, in comparison with the baseline situation. This is true for the dominant and non-dominant eyes. Differences between dominant and non-dominant eyes are more notable in the first visit (Day1), for all lenses. As the time passes and the patient use the MFCL, the differences between both eyes tend be less evident in terms of LDI.

After 15 days of lens wear, LDI tend to values between 10-15%. This is true if the measures are done monocularly for all lenses. Besides that, and comparing to the baseline situation, it represents doubling or even tripling the LDI.

Binocularly, this effect is reduced due to the binocular summation. Figure 6.7 shows the comparison between the average values of the Dominant and Non-Dominant eyes and comparing with the values measured binocularly, after 15 days of lens wear. Binocularly, the LDI is reduced for all three evaluated lenses, and after 15 days of lens use. The binocular LDI decreases to 7.6±1.9, 7.5±2.1 and 7,1±2.6 for Acuvue Oasys, Air Optix and Proclear, respectively.

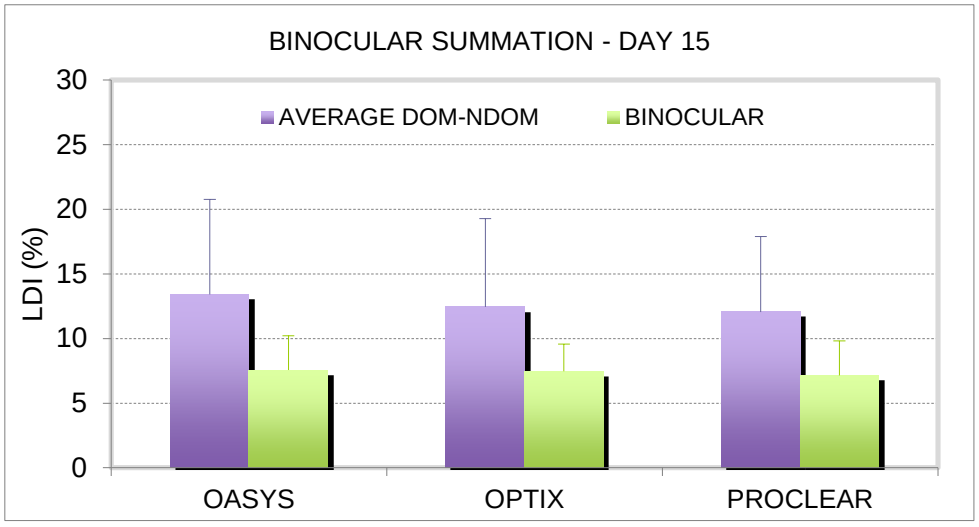


Figure 6.7 – Light Distortion Index (LDI) for the three studied lenses, at 1, 7 and 15 days visit for the dominant (DOM) and non-dominant eyes (NDOM).

6.5 Discussion

Subjective and psychophysical measures of NVD were compared for three different multifocal soft contact lenses in presbyopic patients for a 15 days period, using the LDA to quantify the NVD and the questionnaires to know more about the subject's subjective perceptions.

When comparing with the patient's spectacle correction, wearing a multifocal soft contact lens increases the perceptions of NVD. Although this effect is more present in the first 1-7 day of

lens wear, after 15 days, and due to the binocular summation effect, the LDI is reduced for levels that are comparable to the baseline situation.

Frequency and the severity of the symptoms evaluated in the QoV questionnaire increase when comparing to the baseline situation (patients corrected in spectacles). This happens for all lenses, but with Acuvue Oasys the patient's quality of vision decreases significantly. In contrast, the QoV worsens less with Proclear Multifocal.

When we analyze the changes in QoV of these patients over time we notice that, in average, Acuvue Oasys induce a decrease on the QoV from 7 to 15 days of lens use, meanwhile Air Optix and Proclear Multifocal induce a small increase.

In fact, this results that we obtained with this QoV questionnaire are consistent with the patient's complaints in terms of visual acuity and the perception of night visual disturbances measured with the LDA.

Ardaya et al have studied subject's subjective quality of vision with Acuvue Bifocal soft contact lens and found that, in higher addition powers, subjects have reported a reduction in the quality of distance vision with symptoms of fluctuating vision, ghosting/shadows and haloes around lights.[19]

In our trial, Acuvue Oasys showed to be independent of the addition, once there is no difference in the QoV scores between the two addition groups, in both 7 and 15 days visit. It is, Acuvue Oasys decrease the QoV in a similar way, whether the patient is using a low addition or a high addition. This differences obtained in our study from the previous mentioned one, may be due to the new design of the Acuvue Oasys lens that has an aspheric transition between the far and near zones of the lenses, fact that doesn't exist in the Acuvue Bifocal lens where the transitions between the two zones are more drastic. However, our findings suggest that with higher additions, the QoV of the patients decrease in a significant way from the baseline visit to 7 and 15 days visit, which doesn't happen with the lower additions.

As it concerns to Air Optix, our data suggest that at the time of the 15 days visit there is a significant increase in the severity of the symptoms if the patient is fitted with higher additions, although those differences are not significant over time. During this adaptation process, at the 7

days visit the frequency of the symptoms increase but that is not true at the subsequent visit. That suggests that is a process of adaptation to the lens design that allows the patient to ignore and despise the causes of the symptoms, and at the end of the adaptation process, the symptoms are very similar to those reported with their best correction in spectacles.

Analyzing the results from the fittings with Proclear lens, at the 7 days visit, there were found higher scores in the frequency, severity and bothersome of the symptoms with higher addition fittings, being the severity the only parameter which remains statistically different at the 15 days visit. Despite that, and as it also happened with the Air Optix lens, there were not observed differences at the end of the fitting time in the QoV questionnaire scores and they showed to be similar with the ones obtained with their spectacles.

From this trial, we can conclude that if the patient is fitted with lower addition multifocal soft contact lenses, it will not worsen their quality of vision over time in a significant way comparing with their best correction in spectacles. But this if the fitting is with higher additions, the center near aspheric design and the asymmetric design are the ones that provide to the patients a smaller decrease in their QoV. This can be overcome if the patients are fitted earlier, where any lens of the ones studied will show good results.

According to our results, one of the reasons to use contact lenses in general is the esthetic motivation considering the "virtual" absent of the corrective device when compared to spectacle lenses. This has been well portrayed in the present sample where the patients rated this aspect over 9 in 10 with all lenses. The convenience of having a permanent near, intermediate and distance vision correction might have also contributed to the fact that patients rated over 8 in 10 all MFCL used in this study compared to their habitual spectacle lenses.

Clinical trials use to report VA values and other clinical parameters related to visual function.[20-24] However, subjective perceptions from the patient's point of view are also very important to ensure the motivation and willingness to continue using this mode of vision correction.

The present work had the purpose to assess the subjective perceptions from the patient's point of view in what concerns to some daily-life tasks. As reported by several clinical trials,[6,11] current performance of MFCL has improved significantly, being superior to MV. We found

that patients wearing MFCL report a high rate of satisfaction in certain areas, mainly related with esthetic perception and comparison against other types of vision correction. Subjective near performance was also rated high, while intermediate and distance vision was rated slightly lower. This good near performance might be explained partially by the existence of residual amplitude of accommodation due to our patient's age or for more challenging near vision tasks. However, this might be radically different for older patients with more advanced presbyopia.

Gispets and co-workers[25] evaluated task-oriented visual satisfaction and wearing success with simultaneous vision multifocal two types of soft contact lenses (Acuvue Bifocal and Proclear multifocal lenses). They observed that visual satisfaction decreased for tasks involving higher visual demands for near and distance vision rather than for intermediate vision or a combination of near and distance vision.

The present results are also very encouraging when we observe the frequency of SRS. To our knowledge this strategy had not been tested before with the more recent soft MFCL optical designs. We provided each patient with SRS to use at their discretion. After 15 days, most of the patients 50% reported not using them at all and 30% reported to use them rarely. This should not be surprising considering that the patients reported satisfactory visual performance at near, either subjectively reported or as measured with the ETDRS near charts, which demonstrates that they can perform most of their daily visual tasks without any additional aid.

Conversely, despite the good performance of patients regarding LogMAR VA at distance, they subjectively reported some degree of difficulty performing some distance vision tasks. As it concerns to the daily-life tasks evaluated, patients reported that recognizing people at distance, reading distance placards and working on PC were the daily-life tasks where they found more difficulties while using MFCL. This fact is in agreement with a recent study from Chu et al[16] that found that patients with MFCL showed a longer duration of recognition of distance targets and a smaller distance for recognition of traffic signs compared to MV and both groups performing worse than those with single vision or progressive add spectacles. This lack of subjective quality of vision might be related with the increased aberrations induced by the multifocal surface of the lenses.[4,26]

Altogether, this information might suggest a slightly different approach when fitting MFCL in presbyopic patients. One possible alternative to increase add power to improve near visual

acuity, add power could be kept lower to preserve better distance visual acuity at the expense of using SRS to improve near vision for the most challenging near vision tasks. Additionally, MFCL wear requires high levels of commitment to adaptation by the patient than monofocal designs, and a successful fitting may be associated with patients with a higher motivation.[1,27] Showing the patients that they can do their daily-life tasks with their lenses can help them to adapt and be motivated during the initial adaptation period. As the patient adapts to the new device and to the challenges imposed by the simultaneous vision with MFCL, the lenses addition could be increased to allow the patient being more independent of the SRS use. The traditional fitting approach, requiring a compromise between distance and near vision with the MFCL might disappoint the patient under certain circumstances during the initial fitting period.

Night vision was also one of the tasks where the patients reported some degree of difficulty. Particularly challenging visual tasks such as night driving were found to be the most affected for this modality of contact lens wear, in agreement with the study by Chu et al.[16] The same study reported that patients with MFCL showed a longer duration of recognition of distance targets and a smaller distance for recognition of traffic signs, performing worse than those with single vision or progressive add spectacles.

In conclusion, the results from the present study may contribute to increase our understanding of MFCL fitting and provide alternative ways to evaluate and satisfy the patient. Our results revealed high rates of satisfaction in certain areas, mainly related with esthetic perception and comparison against other types of vision correction, such has spectacle correction. The use of SRS over the MFCL on the first days of the adaptation can be a strategy to consider when the patient needs sharper near vision, once it will not obligate to prescribe higher addition and consequently not taking the risk of worsening distance vision. Trying to show the patients that with MFCL they can do their normal daily-life tasks may help them to continue using this type of vision correction.

6.6 References

1. Bennet ES. Contact lens correction of presbyopia. Clin Exp Optom. 2008;91(3):265–78.

2. Morgan PB, Efron N, Woods CA, Consortium TICLPS. An international survey of contact lens prescribing for presbyopia. Clin Exp Optom. 2011 Jan;94(1):87–92.

3. Morgan PB, Efron N. Contact lens correction of presbyopia. Contact Lens & Anterior Eye. 2009 Aug;32(4):191–2.

4. Peyre C, Fumery L, Gatinel D. Comparaison des aberrations optiques oculaires d ' ordre élevé induites par différentes géométries de lentilles multifocales. J. Fr. Ophtalmol. 2005;28(6):599–604.

5. Chu BS, Wood JM, Collins MJ. The effect of presbyopic vision corrections on night-time driving performance. IOVS. 2010;51(0):4861–6.

6. Fernandes P, Neves H, Lopes-Ferreira D, Jorge J, González-Méijome JM. Adaptation to Multifocal and Monovision Contact Lens Correction. *Optom Vis Sci*. 2013

7. Mcalinden C, Pesudovs K, Moore JE. The Development of an Instrument to Measure Quality of Vision : The Quality of Vision (QoV) Questionnaire. Invest Ophthalmol. 2010;51(11):5537–45.

8. Fisher K, Bauman E, Schwallie J. Evaluation of two new soft contact lenses for correction of presbyopia: the Focus Progressives multifocal and the Acuvue Bifocal. ICLC. 1999 Jul 1;26(4):92–103.

9. Fan-Paul N, Li J, Miller J, Florakis G. Night Vision Disturbances After Corneal Refractive Surgery. Survey of Ophthalmology. 2002 ;47(6):533-546.

10. Gupta N, Naroo SA, Wolffsohn JS. Visual Comparison of Multifocal Contact Lens to Monovision. Optom Vis Sci. 2009;86(2):98–105.

11. Richdale K, Mitchell L, Zadnik K. Comparison of Multifocal and Monovision Soft Contact Lens Corrections in Patients With Low-Astigmatic Presbyopia. Optom Vis Sci. 2006;83(5):266–273.

12. Situ P, Du Toit R, Fonn D, Simpson T. Successful monovision contact lens wearers refitted with bifocal contact lenses. Eye & Contact lens. 2003;29(3):181–4. doi:10.1097/01.ICL.0000072827.42925.49.

13. Papas EB, Decenzo-Verbeten T, Fonn D, et al. Utility of short-term evaluation of presbyopic contact lens performance. Eye & Contact lens. 2009;35(3):144–8. doi:10.1097/ICL.0b013e3181a20361.

14. Gispets J, Pujol J, Vilaseca M. Task oriented visual satisfaction and wearing success with two different simultaneous vision multifocal soft contact lenses. J Optom. 2011;4(3):76–84.

15. Chu BS, Wood JM, Collins MJ. Influence of presbyopic corrections on driving-related eye and head movements. *Optom Vis Sci*. 2009;86(11):E1267–75.

16. Chu BS, Wood JM, Collins MJ. Effect of presbyopic vision corrections on perceptions of driving difficulty. *Eye & Contact lens*. 2009;35(3):133–43.

17. Rubin ML. Success of Monovision in Presbyopes : Review of the Literature and Potential Applications to Refractive Surgery. *Surv Ophthalmol*. 1996;40(6):491–499.

18. Linhares JMM, Neves H, Lopes-Ferreira D, Faria-Ribeiro M, Peixoto-de-Matos SC, Gonzalez-Meijome JM. Radiometric characterization of a novel LED array system for visual assessment. Journal of Modern Optics 2013;60:1136-44.

19. Ardaya D, DeVuono G, Lin I, et al. The effect of add power on distance vision with the Acuvue Bifocal contact lens. Optometry. 2005;75(5):169–174.

20. Gupta N, Naroo SA, Wolffsohn JS. Visual Comparison of Multifocal Contact Lens to Monovision. Optom Vis Sci. 2009;86(2):98–105.

21 García-Lázaro S, Ferrer-Blasco T, Radhakrishnan H, Albarrán-Diego C, Montés-Micó R. Visual comparison of an artificial pupil contact lens to monovision. *Optom Vis Sci*. 2012;89(7):E1022–9. doi:10.1097/OPX.0b013e31825da324.

22. Rajagopalan AS, Bennet ES, Lakshminarayanan V. Visual Performance of Subjects Wearing Presbyopic Contact Lenses. *Optom Vis Sci*. 2006;83(8):611–615.

23. Ferrer-Blasco T, Madrid-Costa D. Stereoacuity with Simultaneous Vision Multifocal Contact Lenses. *Optom Vis Sci*. 2010;87(9):663–668.

24. Applegate R, Marsack JD, Ramos R, Sarver EJ. Interaction between aberrations to improve or reduce visual performance. *J Cataract Refract Surg*. 2003;29(8):1487–1495. doi:10.1016/S0886-3350(03)00334-1.

25. Gispets J, Pujol J, Vilaseca M. Task oriented visual satisfaction and wearing success with two different simultaneous vision multifocal soft contact lenses. *J Optom*. 2011;4(3):76–84.

26. Legras R, Benard Y, Rouger H. Through-focus visual performance measurements and predictions with multifocal contact lenses. *Vision Res*. 2010;50(12):1185–93. doi:10.1016/j.visres.2010.04.001.

27. Woods RL, Colvin CR, Vera-diaz FA, Peli E. Visual Psychophysics and Physiological Optics A Relationship between Tolerance of Blur and Personality. *Invest Ophthalmol Vis Sci*. 2010;51(11):6077–6082. doi:10.1167/iovs.09-5013.

Chapter 7

Light disturbance with diffractive multifocal IOL

7. LIGHT DISTURBANCE WITH DIFFRACTIVE MULTIFOCAL IOL

7.1 Abstract

Purpose: To study the perception of light distortion after refractive lens exchange (RLE) with diffractive multifocal intraocular lenses (IOLs).

Setting: Clínica Oftalmológica das Antas, Porto, Portugal.

Design: Retrospective comparative study.

Methods: Refractive lens exchange was performed with implantation of an AT Lisa 839M (trifocal) or 909MP (bifocal toric) IOL, the latter if corneal astigmatism was more than 0.75 diopter (D). The postoperative visual and refractive outcomes were evaluated. A prototype light-distortion analyzer (LDA) was used to quantify the postoperative light-distortion indices. A control group of eyes in which a Tecnis ZCB00 1-piece monofocal IOL was implanted had the same examinations.

Results: A trifocal or bifocal toric IOL was implanted in 66 eyes. The control IOL was implanted in 18 eyes. All 3 groups obtained a significant improvement in uncorrected distance visual acuity (UDVA) ($P < .001$) and corrected distance visual acuity (CDVA) ($P = .001$). The mean uncorrected near visual acuity (UNVA) was 0.123 logMAR with the trifocal IOL and 0.130 logMAR with the bifocal toric IOL. The residual refractive cylinder was less than 1.00 D in 86.7% of cases with the toric IOL. The mean light-distortion index (LDI) was significantly higher in the multifocal IOL groups than in the monofocal group ($P < .001$), although no correlation was found between the LDI and CDVA.

Conclusions: The multifocal IOLs provided excellent UDVA and functional UNVA despite increased light-distortion indices. The LDA reliably quantified a subjective component of vision distinct from visual acuity; it may become a useful adjunct in the evaluation of visual quality obtained with multifocal IOLs.

Key words: Multifocal contact lens; light disturbance.

7.2 Introduction

In the past few years, various multifocal intraocular lenses (IOL) have been developed in an attempt to provide patients with functional visual acuity for all distances. However, to achieve spectacle independence, it is also important to correct significant corneal astigmatism, which is estimated to be present in approximately 30% of eyes having cataract surgery.[1,2] To address such problems, recent multifocal IOL models incorporate a toric component, allowing cataract and refractive surgeons to correct almost any refractive error. Nevertheless, despite good visual acuity results,[3–6] most refractive surgeons will at some point encounter patients who are unhappy with the inadequate quality of their vision.[7,8] There are many reports of insufficient intermediate vision,[9,10] decreased contrast sensitivity,[11–13] and increased photic phenomena,[14,15] all which can be sufficiently severe to require IOL explantation.[7,8,16]

To understand the visual quality obtained with such multifocal IOLs, it is important to analyze more than just visual acuity and contrast chart results. Photic phenomena might be related to abnormalities in light transmission through ocular media.[17] Accordingly, recent studies used a double-pass imaging device to analyze intraocular light scattering. Results showed a significant correlation between the objective scatter index and cataract density.[18–20] This technology also has been successfully applied to patients with phakic IOLs,[21] eyes with multifocal IOLs,[22] and even eyes that have had laser corneal ablation procedures.[23] Although such a device is an effective means for optical quality analysis, the results are provided as quantitative numeric values and therefore do not readily translate the subjective visual experience reported by pseudophakic individuals; namely, as it pertains to assessing the impairment caused by photic phenomena.

Attempts to understand the impact of vision quality in daily activities have resulted in the development of visual function questionnaires,[24,25] however, the application of such questionnaires in everyday clinical practice is not always feasible. Thus, it would be interesting to have a reliable, quick examination to evaluate the overall postoperative visual performance. The light distortion analyzer (LDA) is a prototype device developed at the Physics Department, University of Minho, Braga, Portugal, to characterize the size and shape of the light distortion surrounding a central bright light source, such as that visualized by the tested subjects. The results obtained with such a device could theoretically serve as an indicator of visual quality. It would then be interesting to

evaluate the LDA results in patients having refractive surgery; namely, those who recently had multifocal IOL implantation.

One of the most recent lines of multifocal IOLs is the AT Lisa brand (Carl Zeiss Meditec AG), which includes the trifocal 839M and the bifocal toric 909MP. Such IOLs have a diffractive structure with smooth steps (phase zones) between the principal diffractive zones, which, according to the manufacturer, results in decreased light scattering and improved image quality.

Adopting the perception of light distortion as an indicator of visual quality, we used the LDA device in patients with the AT Lisa multifocal IOLs to determine possible correlations between visual acuity, residual refractive errors, and light-distortion indices. By comparing the results with those of monofocal IOL cases, we intended to elaborate on the visual quality obtained with these multifocal IOLs.

7.3 Material and Methods

This observational study comprised 2 groups of patients in whom refractive lens exchange (RLE) and implantation of an AT Lisa trifocal 839M (trifocal group) or the bifocal toric 909MP (bifocal toric group) diffractive multifocal IOL were performed. The bifocal toric model was chosen if significant corneal astigmatism (≥1.00 diopter [D]) was present. A control group (monofocal group) comprised healthy patients with visually significant cataract who had phacoemulsification and implantation of a 1-piece monofocal IOL (Tecnis ZCB00, Abbott Medical Optics).

All RLE patients met the following inclusion criteria: 48 years or older with significant refractive errors (sphere ≥1.50 D, cylinder ≥1.00 D) and a manifest desire to obtain spectacle independence. Exclusion criteria included evidence of corneal opacities or irregular astigmatism, history of macular disease, optic neuropathies, and previous corneal or vitreoretinal surgery. Eyes with intraoperative complications, such as posterior capsule rupture or radial capsule tears, did not have multifocal IOL implantation and therefore were not included in this study.

Preoperatively, all patients had a complete ophthalmologic examination including corneal tomography (TMS-5, Tomey Corp.) to rule out ectasia and spectral-domain optical coherence

tomography (OCT) (Cirrus HD-OCT, Carl *Zeiss* Meditec AG) to characterize the macular status. Intraocular lens power was determined using optical biometry (IOLMaster, Carl Zeiss Meditec AG) with the manufacturer-labeled A-constants (118.3 for the multifocal IOLs; 119.3 for the monofocal IOL). The SRK/T formula[26] was used for axial lengths (AL) of at least 22.0 mm and the Haigis formula for AL lower than 22.0 mm. Biometric values obtained for the multifocal IOL cases were inserted into the Z-Calc application[A] to obtain a precise IOL power with a target of emmetropia.

7.3.1 Intraocular lenses

The multifocal IOLs were the AT Lisa 839M and the AT Lisa 909MP. The 909MP is a diffractive bifocal toric IOL with a 6.0 mm optic and an overall length of 11.0 mm, providing aspheric aberration correction and a near addition (add) of +3.75 D at the IOL plane. It is of a foldable hydrophilic acrylic material with hydrophobic surface properties, and its single-piece 4-haptic design allows implantation in the capsular bag through incisions as small as 1.8 mm. Two opposing lines visible in the outer part of the IOL optic provide guidance for correct alignment of the IOL with the steeper meridian of the cornea. The asymmetric light distribution profile allocates 65% of light to the distant focus and 35% to the near focus, regardless of pupil size.

The multifocal 839M is a nontoric diffractive multifocal IOL very similar to the bifocal toric model but has trifocal properties, providing a near add of +3.33 D and an intermediate add of +1.66 D at the IOL plane. The trifocal zone is in the central 4.34 mm of the IOL optic, and the remaining peripheral area is bifocal to optimize night vision. It also has asymmetric light distribution properties, allocating 50%, 20%, and 30% of light to the far, intermediate, and near foci, respectively.

The control group (Group 3) had implantation of a 1-piece Tecnis ZCB00 IOL. This monofocal IOL is of hydrophobic acrylic material with a 6.0 mm diameter optic, biconvex shape, and with anterior aspheric surface. It has an overall diameter of 13.0 mm and offset loop haptics that allow stable 3-point capsular bag fixation.

7.3.2 Surgical technique

One of 2 surgeons (M.M., J.S.B.) performed RLE and cataract surgery procedures using a standard phacoemulsification technique (Infiniti Vision System, Alcon Laboratories, Inc.) through a 2.2 mm clear corneal incision placed on the 120-degree corneal meridian. A continuous curvilinear capsulorhexis with a target diameter of 5.5 mm diameter was created. The IOL was placed in the capsular bag, and extra care was taken when aspirating the ophthalmic viscosurgical device (OVD) to ensure correct and sustainable IOL centration. In eyes having toric IOLs implantation, the 180-degree meridian was marked with the patient seated at the slit-lamp using a Geuder horizontal marker (G-33763) and the steep corneal meridian was marked intraoperatively using the Geuder measuring ring (G-33762). Correct IOL orientation was assessed when the IOL was being implanted in the bag and after OVD aspiration (Figure 7.1). Postoperatively, patients were prescribed dexamethasone 0.1%, ofloxacin 0.3%, and flurbiprofen 0.3% eyedrops 4 times a day for 3 weeks.

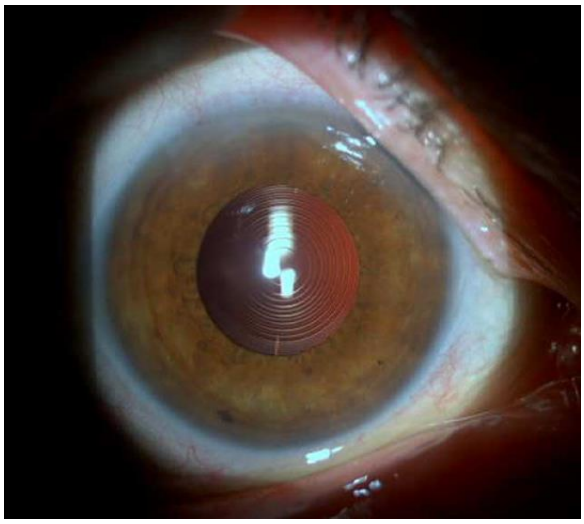


Figure 7.1 – Slit-lamp photograph of the bifocal toric IOL aligned with the corneal meridian at 80 degrees in a patient with a preoperative refraction of −5.00 −1.25 × 180 and 2.03 D of corneal astigmatism at 168 degrees. With 8 months of follow-up, a −0.75 D postoperative refraction was verified, indicating stable toric correction

7.3.3 Light distortion analysis protocol

The clinical records of all patients having surgery between November 2012 and September 2013 were retrospectively reviewed. The following clinical variables were retrieved: age, sex, preoperative uncorrected distance visual acuity (UDVA), corrected distance visual acuity

(CDVA), preoperative manifest refraction, keratometry (K) readings, AL, IOL dioptric power, and follow-up time. All cases were then sequentially scheduled for a complete postoperative ophthalmologic examination including UDVA and CDVA determination using a Snellen chart at 6 m, uncorrected near visual acuity (UNVA) and corrected near visual acuity (CNVA) measured with a Jaeger chart at 33 cm, slit-lamp biomicroscopy, Goldmann applanation tonometry, fundoscopy, and tear-film evaluation by the Schirmer test.

Exclusion criteria for examination with the LDA device were the following: any sign of corneal disease as well as a Schirmer test of less than 10.0 mm, any degree of posterior capsule opacification (PCO), and visible IOL decentration or tilt. In this study, cases with Sjögren syndrome, rheumatic diseases, diabetes mellitus, or a history of radiotherapy were also excluded to minimize the effect of significant dry-eye disease.

After slit-lamp examination, all included cases had light-distortion evaluation with the LDA and wavefront aberrometry (Wavescan Wavefront System, Abbott Medical Optics, Inc.).

The light-distortion analyzer (HLMP-CW47-RU000, Agilent Technologies) is an experimental device consisting of a central white light–emitting diode (LED) surrounded by 240 small, white LEDs (HSMW-CL25, Avago Technologies) distributed in 24 semimeridians with an angular separation of 15 degrees and covering an area of 10 degrees at a 2 m examination distance (Figure 7.2). The physical display device is connected to a computer with dedicated software. The subject being evaluated provides feedback to the system through a remote response device. Peripheral stimuli (the smaller LEDs) are presented around the central source of light from the inner to the outer part of the test field at random time intervals from 250 to 750 milliseconds. Semimeridians are explored in random order. The subject was seated 2.0 m from the display device in a darkened room and was instructed to press the response device as soon as the small LED was visualized as distinct from the central white LED. With each response, the system proceeds to the next semimeridian, and the process repeats until all meridians are tested. The test was performed first on the right eye, then on the left eye, and finally binocularly.

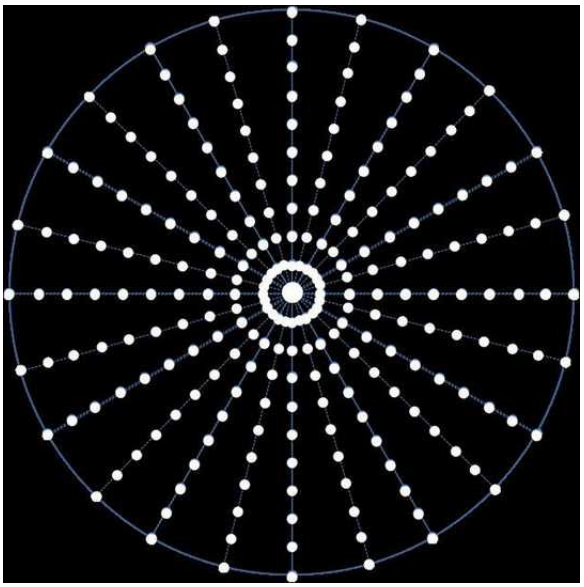


Figure 7.2 – Distribution of the main central light source and smaller peripheral light stimuli in accordance with the display used in the prototype light-distortion analyzer.

Once the testing procedure is complete, the software calculates several indices that determine the size and regularity of the distortion surrounding the central source of light. The light distortion index (LDI) is calculated as the ratio of the area of points missed by the subject and the total area explored and is expressed as a percentage. The best-fit circle radius (BFCRad) is defined as the circle that best fits the distortion area resulting from the linear binding of all points in each meridian of the device. This parameter is expressed in millimeters and is linearly related to the LDI parameter. The higher the values of the best-BFCRad and LDI, the lower the ability to discriminate small light stimuli surrounding a central source of light. The deviation of the obtained polygonal shape from the best-fit circle fit is called the best-fit circle irregularity. The standard deviation of best-fit circle irregularity (BFCIrregSD) measures the asymmetry of the actual limits of the distortion from the perfect circular shape of the best-fit circle and indicates the light-distortion irregularity.

For each case, the light-distortion testing procedure was performed 3 times with the subject wearing spectacle correction. The values obtained on the third examination were chosen for statistical analysis.

7.3.4 Statistical Analysis

All results were analyzed using SPSS for Windows software (version 19.0, International Business Machines Corp.). Evaluation of data normality was performed using the Kolmogorov-

Smirnov test. Parametric variables were compared using 1-way analysis of variance with Tukey post hoc analysis. When comparing data between 2 groups, the Student t test for independent samples was used. For comparison of preoperative data and postoperative data, the paired samples t test was used. For nonparametric variables, the Kruskal-Wallis was used to assess the significance of differences between the 3 groups or the Mann-Whitney U test to compare values between 2 independent groups. The Wilcoxon signed-rank test was used to compare paired nonparametric data. Significant correlations were assessed using Pearson or Spearman correlation coefficients according to the normality of data. A P value less than 0.05 was considered significant for all tests.

7.4 Results

The study enrolled 66 eyes of 34 patients divided into 3 study groups. The trifocal group comprised 33 eyes; the bifocal toric group, 15 eyes; and the monofocal group, 18 eyes.

Table 7.1 shows the demographic and preoperative data by IOL group. Patients in the multifocal IOL groups were younger than those in the monofocal IOL group, although the difference was not statistically significant (p=0.052). There was also no difference in the ratio of men to women. The mean follow-up time was significantly lower in the bifocal toric group (p=0.012), although no difference was found between the trifocal group and the control group. The mean flat K value was lower in the bifocal toric group (42.35 D) than in the trifocal group (43.69 D) or the control group (43.34 D) (p=0.023), corresponding to statistically significantly higher corneal astigmatism values in the bifocal toric group and therefore a significantly higher preoperative cylinder power (both p<0.001). The mean pupil diameter overall was 5.78 mm ± 1.04 (SD), with no significant difference between thee 3 IOL groups. There was also no significant between-group difference in the mean preoperative manifest sphere (overall 0.25±2.45 D; range −7.50 to +7.00 D), AL (overall 23.34±0.97 mm; range 21.11 to 26.37 mm), or IOL spherical power (overall 20.70±3.26 D; range 8.00 to 28.00 D).

Table 7.1 - Preoperative demographic, refractive and biometric data

Parameter	Trifocal Group	Toric Bifocal Group	Monofocal Group	*p* Value
Sex (n)				0.522
Male	8	5	4	
Female	8	3	5	
Mean age (y) ± SD	57.93 ± 6.60	57.14 ± 11.34	63.17 ± 2.81	0.052
Sphere (D)				
Mean ± SD	+0.86 ± 1.62	–0.36 ± 3.87	–0.31 ± 1.98	0.233
Range	–2.50, +4.25	–7.50, +7.00	–3.00, +2.25	
Cylinder (D)				
Mean ± SD	–0.69 ± 0.46	–1.93 ± 1.21	–0.86 ± 0.51	<0.001
Range	–1.50, 0.00	–4.50, –1.00	–1.75, 0.00	
Corneal astigmatism (D)				
Mean ± SD	0.59 ± 0.36	1.87 ± 0.91	0.62 ± 0.46	<0.001
Range	0.17, 1.06	1.08, 4.50	0.09, 1.41	
Axial length (mm)				
Mean ± SD	23.24 ± 0.79	23.72 ± 1.46	23.12 ± 0.71	0.490
Range	22.04, 24.72	21.11, 26.37	22.31, 24.30	
IOL sphere (D)				
Mean ± SD	21.22 ± 1.95	19.56 ± 4.99	21.24 ± 1.28	0.278
Range	17.00, 26.00	8.00, 28.00	16.50, 24.00	
Mean IOL cylinder (D) ± SD	—	1.86 ± 0.85	—	—
Mean follow-up (mo) ± SD	10.27 ± 4.16	7.13 ± 3.48	8.55 ± 2.17	0.012

7.4.1 Visual acuity and refraction

Between Groups

Table 7.2 shows the overall postoperative visual and refractive outcomes. All 3 groups had a statistically significant improvement in UDVA and CDVA (both p=0.001). The postoperative refractive sphere was less than 1.00 D in 63 cases (95.4%), with 38 (57.8%) attaining a residual sphere of less than 0.50 D. There was no statistically significant difference in UDVA, CDVA, or UNVA between the 2 multifocal groups; however, the mean UNVA was statistically significantly inferior than the mean CNVA in the monofocal IOL group (p<0.001). The mean CNVA was similar in the 2 multifocal groups and inferior to that in the monofocal group, although the differences were not statistically significant (p=0.303).

There were no statistically significant differences in postoperative refractive sphere between the 3 groups. However, the postoperative refractive cylinder was statistically significantly higher in the monofocal group than in the 2 multifocal groups (p=0.014).

No significant between-group differences were found in wavefront root-mean-square (RMS) total aberrations, RMS higher-order aberrations, mean coma, or mean spherical aberration.

Table 7.2 – Visual and refractive outcomes by IOL group

Parameter	Trifocal Group	Toric Bifocal Group	Monofocal Group	*p* Value
Preop UDVA				
Mean ± SD	0.136 ± 0.097	0.356 ± 0.356	0.305 ± 0.105	< 0.001
Range	0.05, 0.50	0.05, 1.00	0.20, 0.50	
Postop UDVA				
Mean ± SD	0.022 ± 0.037	.042 ± 0.045	0.051 ± 0.037	0.010
Range	0.00, 0.15	00.00, 0.10	0.00, 0.10	
Preop CDVA				
Mean ± SD	0.010 ± 0.024	0.043 ± 0.041	0.273 ± 0.108	<0.001
Range	0.00, 0.10	0.00, 0.10	0.10, 0.50	
Postop CDVA				
Mean ± SD	0.001 ± 0.008	0.010 ± 0.020	0.008 ± 0.018	0.133
Range	0.00, 0.05	0.00, 0.05	0.00, 0.05	
Preop CNVA				
Mean ± SD	0.021 ± 0.025	0.048 ± 0.049	0.171 ± 0.060	<0.001
Range	0.00, 0.05	0.00, 0.18	0.00, 0.30	
Postop UNVA				
Mean ± SD	0.123 ± 0.054	0.130 ± 0.068	—	0.540
Range	0.00, 0.20	0.00, 0.20	—	
Postop CNVA				
Mean ± SD	0.017 ± 0.029	0.026 ± 0.041	0.006 ± 0.015	0.303
Range	0.00, 0.10	0.00, 0.10	0.00, 0.04	
Postop sphere				
Mean ± SD	–0.03 ± 0.44	0.28 ± 0.62	–0.092 ± 0.304	0.175
Range	–0.75, +1.00	–0.75, +1.50	–0.75, +0.50	
Postop cylinder				
Mean ± SD	–0.43 ± 0.36	–0.41 ± 0.41	–0.776 ± 0.310	0.014
Range	–1.00, –0.25	–1.25, 0.00	–1.25, –0.25	

CDVA = corrected distance visual acuity; CNVA = corrected near visual acuity; UDVA = uncorrected distance visual acuity; UNVA = uncorrected near visual acuity

Trifocal Group

Analysis of the change in refraction and visual acuity by IOL group showed that the trifocal group had a statistically significant improvement in UDVA (p<0.001), with 30 cases (90.9%) obtaining a UDVA of less than 0.1 logMAR and all obtaining a CDVA of less than 0.1 logMAR (p=0.020). There were significant reductions in spherical power (p=0.007) and cylindrical power (p=0.007). The subjective spherical power was less than 0.50 D by 17 cases (51.5%). The UNVA was 0.1

logMAR or less in 20 cases (60.6%). Significant correlations were found between postoperative UDVA and IOL power (p=0.007) and between postoperative UDVA and postoperative refractive cylinder (p=0.049). Significant correlations were also found between UNVA and corneal astigmatism (p=0.044) and between UNVA and postoperative cylinder (p=0.003). The latter variable was also significantly correlated with higher RMS total aberrations (p<0.001).

Bifocal Toric Group

The bifocal toric group had significant improvements in UDVA (p=0.004), with 9 cases (60.0%) obtaining a UDVA less than 0.1 logMAR and all obtaining a CDVA of less than 0.1 logMAR (p=0.015). The postoperative refractive sphere (p=0.008) and cylinder (P = .004) were also significantly improved. The subjective spherical power was less than 0.50 D in 9 cases (60.0%), and the subjective cylinder was less than 1.00 D in 13 cases (86.7%). The mean cylinder reduction was 1.53±1.33 D, corresponding to 71.46% of mean cylinder magnitude. This favorable outcome was seen equally in cases with corneal astigmatism of 2.00 D or less and in cases with more than 2.00 D of corneal astigmatism (p=0.571, Fisher exact test). There were significant correlations between postoperative UDVA and postoperative subjective sphere (p=0.012) and between postoperative UDVA and cylinder (p<0.001). There were also significant correlations between UNVA and postoperative subjective sphere (p<0.001) and between UNVA and cylinder (p=0.028).

Monofocal Group

The monofocal group had a statistically significant improvement in UDVA (p<0.001), with 12 cases (66.7%) obtaining a UDVA of less than 0.1 logMAR and all obtaining a CDVA of less than 0.1 logMAR (p<0.001). A significant reduction in spherical power (p<0.001) was found, with all cases achieving a residual sphere of less than 1.00 D and 6 cases (33.3%) a spherical refraction of less than 0.50 D. No significant change was found in the postoperative refractive cylindrical power (p=0.487). A significant correlation was found between the postoperative UDVA and the postoperative cylindrical power (p=0.001).

7.4.2 Light distortion

Between Groups

The mean LDI and BFC_{Rad} were significantly lower in the monofocal group than in the multifocal groups (p<0.001) (Figure 6.3). The $BFC_{IrregSD}$ index was significantly higher in the bifocal toric group than in monofocal or trifocal group (Table 6.3).

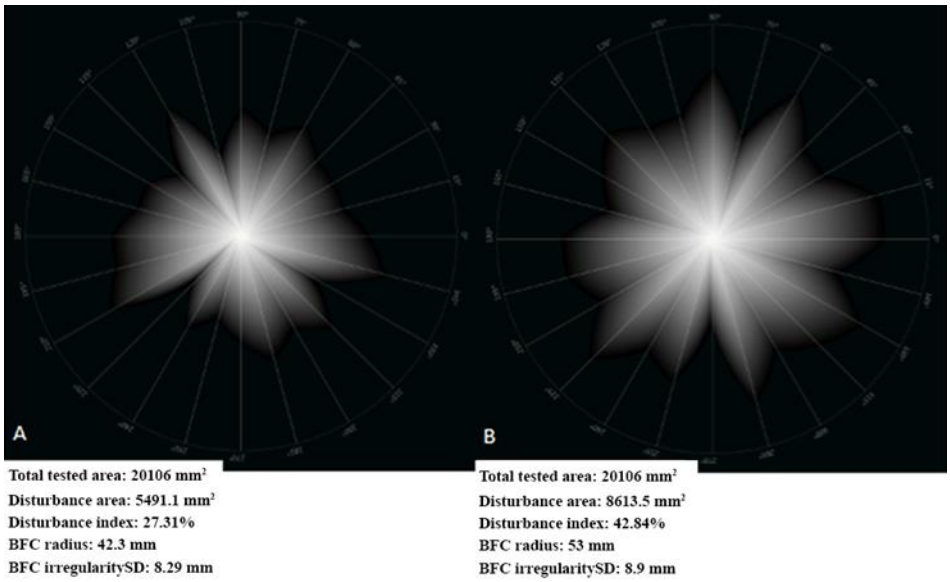


Figure 7.3 –A: Light distortion analyzer results in a 67-year-old patient with a monofocal IOL, indicating a distortion index of 27% with a postoperative refraction of +1.00 −0.75 × 180. B: Light-distortion analyzer results in a 63-year-old patient with a trifocal IOL, indicating a distortion index of 43% with a postoperative refraction of +0.50 −0.50 × 155 (BFC = best-fit circle).

There was no significant difference in the LDI or BFC_{Rad} between the 2 multifocal groups, despite a tendency toward higher values in the bifocal toric group. In contrasts, the $BFC_{IrregSD}$ was statistically significantly higher in the bifocal toric group (p=0.015).

Table 7.3 –Mean (± SD) results for light distortion analyzer (LDA) by study group

Parameter	Trifocal Group	Toric Bifocal Group	Monofocal Group	*p* Value
LDI (%)				
Monocular	46.97 ± 17.27	53.57 ± 18.55	23.94 ± 14.89	<0.001
Binocular	29,29 ± 9.19	40.49 ± 12.00	15.28 ± 6.87	
BFC_{Rad} (mm)				
Monocular	55.28 ± 10.03	58.89 ± 10.86	38.14 ± 12.09	<0.001
Binocular	43.84 ± 6.83	47.84 ± 11.04	28.24 ± 8.01	
$BFC_{IrregSD}$				
Monocular	5.71 ± 3.15	7.25 ± 3.58	4.36 ± 3.63	0.007
Binocular	4.75 ± 1.01	6.20 ± 1.73	3.81 ± 1.18	

No significant correlations were found between LDI or BFC_{Rad} and the following clinical variables: age, sex, preoperative sphere, preoperative cylinder, AL, IOL sphere power, IOL cylinder power, corneal K values, pupil size, postoperative UDVA, CDVA, or CNVA. A nearly significant correlation with postoperative follow-up time was seen for LDI (p=0.058) and BFC_{Rad} (p=0.051).

Trifocal Group

In the trifocal group, a significant correlation was found between the LDI and follow-up time (p=0.007). Also, the $BFC_{IrregSD}$ correlated significantly with the postoperative sphere (p=0.010) and corneal astigmatism (p=0.015).

Bifocal Toric Group

In the bifocal toric group, a significant direct correlation was found between the LDI and the postoperative subjective sphere (p=0.001). Also, a significant inverse correlation was found with the postoperative cylinder refraction (p=0.012). The $BFC_{IrregSD}$ was also correlated with postoperative subjective sphere power (p=0.003).

Monofocal Group

In the monofocal group, that there was a significant inverse correlation between the LDI and the postoperative cylinder (p=0.001). No significant correlations for $BFC_{IrregSD}$ were found.

Binocular Conditions

Light-distortion indices were significantly lower when measured under binocular conditions in all IOL groups (p<0.001, LDI, BFC_{Rad}; p=0.040, $BFC_{IrregSD}$). The LDA outcomes in 9 cases with bilateral monofocal IOLs were better than in the 15 cases with bilateral trifocal IOLs (p<0.001, LDI p=0.041, $BFC_{IrregSD}$) and then in the 6 cases with bilateral bifocal toric IOLs (p<0.001, LDI; p=0.017, $BFC_{IrregSD}$). Comparison of the 2 multifocal groups showed a statistically significantly lower LDI in the trifocal group (p=0.035).

7.5 Discussion

The development of presbyopia-correcting IOLs and the availability of precise optical biometry measurements has been a major clinical breakthrough in ophthalmology in the past few years. It is rewarding to verify that with modern IOL calculation technology, reliable refractive correction is an expectable outcome. Such accuracy is particularly important in the case of multifocal IOLs because it has been reported that a residual cylinder of 1.50 D has a significant impact on the optical performance of diffractive multifocal IOLs.[27] Accordingly, the majority (57.8%) of our cases obtained a residual sphere of less than 0.50 D and 86.7% of cases implanted with the AT Lisa 909MP bifocal toric IOL achieved a stable residual cylinder of less than 1.00 D. Such results are similar to the percentages reported by Visser et al.[28] and Bellucci et al.,[29] indicating the effectiveness of the IOL in correcting corneal astigmatism. That the residual cylinder refraction was significantly correlated not only with uncorrected distance and near visual acuities but also with the light-distortion index in the trifocal group (AT Lisa 839M IOL) and monofocal group (Tecnis ZCB00 IOL) (the latter 2 groups including cases with significant corneal astigmatism) underlines the importance of correcting preoperative corneal astigmatism to obtain the best visual outcomes.

In this study, patients in both multifocal IOL groups achieved satisfactory UNVA. The mean UNVA was 0.123±0.054 logMAR in the trifocal group and 0.130±0.068 logMAR in the bifocal toric group, results that are better than those in previous studies.[5,6,28,29] Although different study methodologies, namely in near visual acuity assessment, explain some differences in the UNVA results, we believe the good outcomes in our series can at least in part be explained by a series of clinical aspects. That is, all our cases were purely RLE procedures because no eye had visually significant lens opacity. Thus, the mean age was somewhat lower than in previous studies[28,29] and patients had a strong motivation for spectacle-free vision. In addition, attention was given to tear-film function by excluding cases with systemic conditions potentiating dry-eye disease and by carefully evaluating tear-film status during slit-lamp ophthalmologic examination. Dry-eye disease should not be taken lightly when considering multifocal IOL implantation. In a recent study, there was significantly increased ocular light scattering in cases with mild to moderate dry eye.[30] Considering that diffractive multifocal IOL optics imply simultaneous light distribution to different focal points, the impact of dry eye–induced light scattering will add to an overall diminished visual quality. Also, even though the bifocal toric IOL has a near add of 3.75 D

versus the 3.33 D add of the trifocal IOL as well as a higher percentage of light assigned to the near focus, patients with the trifocal IOL had slightly better UNVA outcomes than those with the bifocal toric IOL. This could be partially explained by the lower mean follow-up time in the bifocal toric group; it is well known that by the process of neuroadaptation, visual acuity with multifocal IOLs tends to improve over time. More important, in both multifocal IOL groups, there were significant correlations between residual refractive error and UNVA. More specifically, the bifocal toric group had a higher residual hyperopic error that may have nullified its superior near add. This is an important observation because the bifocal toric group in this study represents our first cases of implantation of that type of IOL; thus, there was an inherent learning curve before optimum visual and refractive results could be obtained. Nevertheless, both multifocal IOLs provided satisfying UNVA; more important, all RLE patients were satisfied with the overall visual outcomes and with the level of spectacle independence postoperatively.

Considering LDA results, despite the similar CDVA and patient age between the 3 groups, the multifocal IOL groups had a significantly higher LDI. This means that the LDA reliably identified a subjective component of vision, distinct from Snellen chart visual acuity. To our knowledge, this is the first study to use an experimental device to quantify the subjective perception of light distortion after lens surgery. Previous studies evaluated intraocular straylight after multifocal IOL implantation,[22,31] reporting significant levels of straylight in multifocal IOLs compared with levels in monofocal IOLs.[31,32] Similar to such reports, our patients had no signs of PCO or ocular surface disease, and the LDA examination was performed under best refractive correction to nullify refractive defocus, leading us to believe that the increased LDI in the multifocal IOL groups is related to the diffractive optics system of current multifocal IOLs. Nevertheless, we verified that the addition of a focal point for intermediate distance vision (present in the AT Lisa 839M IOL) did not cause a significant increase in light-distortion indices compared with the bifocal toric AT Lisa 909MP IOL. Finally, we found that the light-distortion indices significantly improved under binocular viewing conditions, corroborating the current knowledge that multifocal IOLs perform better when implanted bilaterally.[33]

The main advantage of the LDA over other devices, such as the Optical Quality Analysis System (Visiometrics) or the C-Quant (Oculus), is that the results are displayed as an approximate graphic representation of the light distortion as visualized by the patient, giving a qualitative characteristic to the results. Although still in its early stages, we believe the use of

ocular light-transmission analyzers will become indispensable in the postoperative evaluation of the quality of vision conferred by multifocal IOLs. In that sense, the LDA may be helpful when studying cases of bothersome positive dysphotopsia and therefore allow the surgeon to whether if IOL explantation is warranted.

Considering that multifocal IOLs are gaining favor as the lens surgery of choice to correct presbyopia,[34] it will be interesting to apply this technology to different multifocal IOL models to characterize overall visual quality.

Overall our results are in accordance with current consensus[35,36] that spectacle-free functional visual acuity is a real possibility for lens surgery candidates. Nevertheless, it is clear that the surgeon still faces a tradeoff between offering the best possible visual quality with a monofocal IOL and progressive spectacles or providing spectacle independence with a multifocal IOL, but with reduced optical performance resulting from the simultaneous focal points. It seems that despite all technological progress, the role of the surgeon is still the key to patient satisfaction, which continues to rely on judicious clinical assessment. A recent review paper for the American Society of Cataract and Refractive Surgery Cataract Clinical Committee[37] detailed several clinical characteristics that help surgeons identify ideal candidates for multifocal IOLs. In our opinion, the most important factor is good clinical assessment of patient motivation for spectacle-free vision complemented by a thorough ophthalmologic examination with particular attention to the status of the ocular surface.

In conclusion, in this study the 2 AT Lisa diffractive multifocal IOL models provided excellent visual and refractive outcomes. In addition, we described an experimental methodology to characterize the perception of light distortion. In the future, the application of devices, such as the LDA, to evaluate the visual outcomes with several presbyopic IOLs will provide clues to the expected overall optical performance.

7.6 References

1. Hoffer KJ. Biometry of 7,500 cataractous eyes. Am J Ophthalmol 1980; 90:360–368

2. Hoffmann PC, Hütz WW. Analysis of biometry and prevalence data for corneal astigmatism in 23,239 eyes. J Cataract Refract Surg 2010; 36:1479–1485

3. Packer M, Chu YR, Waltz KL, Donnenfeld ED, Wallace RB III, Featherstone K, Smith P, Bentow SS, Tarantino N. Evaluation of the aspheric Tecnis multifocal intraocular lens: one-year results from the first cohort of the Food and Drug Administration clinical trial. Am J Ophthalmol 2010; 149:577–584. Available at: http://www.ajo.com/article/S0002-9394(09)00810-1/pdf. Accessed November 19, 2014

4. Gierek-Ciaciura S, Cwalina L, Bednarski L, Mrukwa-Kominek E. A comparative clinical study of the visual results between three types of multifocal lenses. Graefes Arch Clin Exp Ophthalmol 2010; 248:133–140

5. Mojzis P, Peña-García P, Liehneova I, Ziak P, Alió JL. Outcomes of a new diffractive trifocal intraocular lens. J Cataract Refract Surg 2014; 40:60–69

6. Alió JL, Piñero DP, Tomás J, Plaza AB. Vector analysis of astigmatic changes after cataract surgery with implantation of a new toric multifocal intraocular lens. J Cataract Refract Surg 2011; 37:1217–1229

7. de Vries NE, Webers CAB, Touwslager WRH, Bauer NJC, de Brabander J, Berendschot TT, Nuijts RMMA. Dissatisfaction after implantation of multifocal intraocular lenses. J Cataract Refract Surg 2011; 37:859–865

8. Woodward MA, Randleman JB, Stulting RD. Dissatisfaction after multifocal intraocular lens implantation. J Cataract Refract Surg 2009; 35:992–997

9. Hütz WW, Eckhardt HB, Röhrig B, Grolmus R. Intermediate vision and reading speed with array, Tecnis, and ReSTOR intraocular lenses. J Refract Surg 2008; 24:251–256

10. Blaylock JF, Si Z, Vickers C. Visual and refractive status at different focal distances after implantation of the ReSTOR multifocal intraocular lens. J Cataract Refract Surg 2006; 32:1464–1473

11. Fernández-Vega L, Alfonso JF, Baamonde B, Madrid-Costa D, Montés-Micó R, Lozano J. Visual and refractive outcomes in hyperopic pseudophakic patients implanted with the Acri.LISA 366D multifocal intraocular lens. Am J Ophthalmol 2009; 148:214–220

12. Zhao G, Zhang J, Zhou Y, Hu L, Che C, Jiang N. Visual function after monocular implantation of apodized diffractive multifocal or single-piece monofocal intraocular lens; randomized prospective comparison. J Cataract Refract Surg 2010; 36:282–285

13. Alió JL, Plaza-Puche AB, Piñero DP, Amparo F, Rodríguez-Prats JL, Ayala MJ. Quality of life evaluation after implantation of 2 multifocal intraocular lens models and a monofocal model. J Cataract Refract Surg 2011; 37:638–648

14. Souza CE, Muccioli C, Soriano ES, Chalita MR, Oliveira F, Freitas LL, Meire LP, Tamaki C, Belfort R Jr. Visual performance of AcrySof ReSTOR apodized diffractive IOL: a prospective comparative trial. Am J Ophthalmol 2006; 141:827–832

15. Sen HN, Sarikkola A-U, Uusitalo RJ, Laatikainen L. Quality of vision after AMO Array multifocal intraocular lens implantation. J Cataract Refract Surg 2004; 30:2483–2493

16. Galor A, Gonzalez M, Goldman D, O'Brien TP. Intraocular lens exchange surgery in dissatisfied patients with refractive intraocular lenses. J Cataract Refract Surg 2009; 35:1706–1710

17. van den Berg TJTP. Importance of pathological intraocular light scatter for visual disability. Doc Ophthalmol 1986; 61:327–333

18. Artal P, Benito A, Pérez GM, Alcón A, De Casas Á, Pujol J, Marín J. An objective scatter index based on double-pass retinal images of a point source to classify cataracts. PLoS One 2010; 6(2):e16823. Available at: http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3033912/pdf/pone.0016823.pdf. Accessed November 19, 2104

19. Cabot F, Saad A, McAlinden C, Haddad NM, Grise-Dulac A, Gatinel D. Objective assessment of crystalline lens opacity level by measuring ocular light scattering with a double-pass system. Am J Ophthalmol 2013; 155:629–635

20. Vilaseca M, Romero MJ, Arjona M, Luque SO, Ondategui JC, Salvador A, Güell JL, Artal P, Pujol J. Grading nuclear, cortical and posterior subcapsular cataracts using an objective scatter index measured with a double-pass system. Br J Ophthalmol 2012; 96:1204–1210

21. Kamiya K, Shimizu K, Saito A, Igarashi A, Kobashi H. Comparison of optical quality and intraocular scattering after posterior chamber phakic intraocular lens with and without a central hole (Hole ICL and Conventional ICL) implantation using the double-pass instrument. PLoS One 2013; 8(6):e66846. Available at: http://www.plosone.org/article/fetchObject.action?uri=info%3Adoi%2F10.1371%2Fjournal.pone.0066846&representation=PDF. Accessed November 19, 2014

22. Castillo-Gómez A, Carmona-González D, Martínez-de-la-Casa JM, Palomino-Bautista C, García-Feijoo J. Evaluation of image quality after implantation of 2 diffractive multifocal intraocular lens models. J Cataract Refract Surg 2009; 35:1244–1450

23. Ondategui JC, Vilaseca M, Arjona M, Montasell A, Cardona G, Güell JL, Pujol J. Optical quality after myopic photorefractive keratectomy and laser in situ keratomileusis: comparison using a double-pass system. J Cataract Refract Surg 2012; 38:16–27

24. Mangione CM, Lee PP, Gutierrez PR, Spritzer K, Berry S, Hays RD; for the National Eye Institute Visual Function Questionnaire Field Test Investigators. Development of the 25-item National Eye Institute Visual Function Questionnaire. Arch Ophthalmol 2001; 119:1050–1058. Available at: http://archopht.jamanetwork.com/data/Journals/OPHTH/6709/EEB90033.pdf. Accessed November 19, 2014

25. McAlinden C, Pesudovs K, Moore JE. The development of an instrument to measure quality of vision: the Quality of Vision (QoV) questionnaire. Invest Ophthalmol Vis Sci 2010; 51:5537–5545. Available at: http://www.iovs.org/content/51/11/5537.full.pdf. Accessed November 19, 2014

26. Retzlaff JA, Sanders DR, Kraff MC. Development of the SRK/T intraocular lens implant power calculation formula. J Cataract Refract Surg 1990; 16:333–340; erratum, 528

27. Hayashi K, Manabe S-i, Yoshida M, Hayashi H. Effect of astigmatism on visual acuity in eyes with a diffractive multifocal intraocular lens. J Cataract Refract Surg 2010; 36:1323–1329

28. Visser N, Nuijts RMMA, de Vries NE, Bauer NJC. Visual outcomes and patient satisfaction after cataract surgery with toric multifocal intraocular lens implantation. J Cataract Refract Surg 2011; 37:2034–2042

29. Bellucci R, Bauer NJC, Daya SM, Visser N, Santin G, Cargnoni M, Nuijts RMMA, for the Lisa Toric Study Group. Visual acuity and refraction with a diffractive multifocal toric intraocular lens. J Cataract Refract Surg 2013; 39:1507–1518

30. Diaz-Valle D, Arriola-Villalobos P, García-Vidal SE, Sánchez-Pulgarín M, Borrego Sanz L, Gegúndez-Fernández JA, Benitez-del-Castillo JM. Effect of lubricating eyedrops on ocular light scattering as a measure of vision quality in patients with dry eye. J Cataract Refract Surg 2012; 38:1192–1197

31. de Vries NE, Franssen L, Webers CAB, Tahzib NG, Cheng YYY, Hendrikse F, Tjia KF, van den Berg TJTP, Nuijts RMMA. Intraocular straylight after implantation of the multifocal AcrySof ReSTOR SA60D3 diffractive intraocular lens. J Cataract Refract Surg 2008; 34:957–962

32. Ferrer-Blasco T, Montés-Micó R, Cerviño A, Alfonso JF. Light scatter and disability glare after intraocular lens implantation [letter]. Arch Ophthalmol 2009; 127:576–577. Available at: http://archopht.jamanetwork.com/data/Journals/OPHTH/10060/elt0409_576_577.pdf. Accessed November 19, 2014

33. Alfonso JF, Fernández-Vega L, Señaris A, Montés-Micó R. Prospective study of the Acri.LISA intraocular lens. J Cataract Refract Surg 2007; 33:1930–1935

34. Mesci C, Erbil HH, Olgun A, Yaylali SA. Visual performances with monofocal, accommodating, and multifocal intraocular lenses in patients with unilateral cataract. Am J Ophthalmol 2010; 150:609–618

35. Bellucci R. Multifocal intraocular lenses. Curr Opin Ophthalmol 2005; 16:33–37

36. de Vries NE, Nuijts RMMA. Multifocal intraocular lenses in cataract surgery: literature review of benefits and side effects. J Cataract Refract Surg 2013; 39:268–278

37. Braga-Mele R, Chang D, Dewey S, Foster G, Henderson BA, Hill W, Hoffman R, Little B, Mamalis N, Oetting T, Serafano D, Talley-Rostov A, Vasavada A, Yoo S, for the ASCRS Cataract Clinical Committee. Multifocal intraocular lenses: relative indications and contraindications for implantation. J Cataract Refract Surg 2014; 40:313–322

Chapter 8

Light Disturbance in patients implanted with IOLs and Optical Bench measures

8. RELATIONSHIP BETWEEN CLINICAL LIGHT DISTURBANCE ANALYSIS IN PSEUDOPHAKIC PATIENTS IMPLANTED WITH 5 IOLS AND OPTICAL BENCH MEASURES

8.1 Abstract

Purpose: Optical bench measurements of dysphotopsia do not correlate much with the clinical performance of pseudophakic multifocal intra-ocular lenses (IOLs). The purpose of this study was to investigate how correlated are optical bench measurements based on MTF computation with clinical measurements using a new prototype to measure light disturbances under dim illumination conditions.

Setting: Department of Ophthalmology, Hospital de S. Pau, Barcelona, Spain

Methods: Patients were bilaterally implanted with 5 different multifocal IOL (20 in each group) including bifocal (SF25T0 +2.50D, n=18; ZKB00 +2.75D, n=16; ZLB00 +3.25D, n=18; and LISA809, n=19) and trifocal (LISA839, n=15). Two age-matched groups acted as controls, one implanted with monofocal IOL (n=15) and another one of phakic patients with cataracts (n=13). Clinical measures of light disturbance were obtained with a prototype device (LDA, University of Minho, Portugal).

Results: Disturbance index (% area covered by halo induced by central source of light) varied from 28.23±15.58% for SV25T0 to 38.88±15.58% for LISA809. Halo sizes between IOLs were not significantly different in size ($p>0.05$, ANOVA) but halo was significantly larger than the one induced by monofocal IOL (20.58±13.53%; $p<0.05$ for all comparisons) but significantly lower than patients with cataracts (68.35±32.59%, $p<0.05$ for all comparison).

Conclusions: We have observed a significant increase in halo size induced by bifocal and trifocal diffractive IOLs compared to monofocal IOL in pseudophakic patients after cataract extraction. However, on average pseudophakic patients implanted with those IOLs reduced their night vision disturbances compared to phakic cataract patients.

Key words: pseudophakia; multifocal IOL; dysphotopsias; optical bench; optical quality

8.2 Introduction

Development of new optical devices to replace the crystalline lens of the eye and provide functional vision at different distances in the non-accomodating eye has evolved in the last decade. Visual optics applied to this field has resulted in multitude of new intraocular lens (IOL) designs, some of them with better clinical results than others. Once the devices have proved to provide sharp distance vision and extension of the range of vision to closer distances, the main challenge has been to keep symptoms of dysphotopsia or photic phenomena under control. Dysphotopsia in the form of halos, glare and/or starburst are inherently linked to the optical designs of the IOLs that form several foci along or slightly eccentric to the visual axis, that overlap in the retinal plane (ref). Optical design has been able to develop designs that are more effective than others at reducing these symptoms. However, objective measurements of such effects have been limited to optical bench measurements that usually do not correlate with the clinical reporting of patients once the IOLs are implanted.

With the lack of correlation between optical bench and clinical measures of dysphotopsoia the main goal of the present study was to correlate both using new experimental and clinical approaches in a set of 4 different multifocal IOLs involving different optical principles to generate multifocality. To our knowledge this is the first study correlating in-vitro measurements of halo with clinical measures of light disturbance in pseudophakic patients.

8.3 Material and Methods

This study was conducted at Department of Ophthalmology, Hospital da S. Pau, (Barcelona, Spain). The protocol was approved by the Ethics Committee of the Hospital and the research was settled in collaboration with the Clinical and Experimental Research Laboratory

(CEORLab) at University of Minho in Braga, Portugal. The principles of Good Clinical Practice were adhered to throughout in accordance with the Declaration of Helsinki.

A prospective longitudinal not masked study was conducted in consecutive candidates to sequential bilateral cataract surgery or refractive lens exchange from April 2015 to February 2016 ending the follow up in September 2016. Postoperative outcomes were assessed 1, 3 and 6 months after second eye surgery. Before data collection patients were instructed on the purpose of the study and procedures used, and signed a consent form before formal enrollment.

A total of 119 eligible patients including 12 control subjects with cataract (48 females and 9 males) aged 42 to 79 years (mean 61.53±8.92 years) were identified by participating surgeon at their preoperative assessment, given an explanation of the study and its aims and detailed information to be comprehensible to a non-expert person.

The principle inclusion criteria were (i) motivation, (ii) ability to return for follow-up up to 6 months post-surgery and (iii) ability to provide the mentioned informed consent. Exclusion criteria included amblyopia, glaucoma history, corneal disease, previous corneal or intraocular surgery, severe dry eye, abnormalities of iris or pupil disability, retinal pathology or history of ocular inflammation, post-op refractive error higher than ±0.50 and unaided post-op visual acuity bellow 0.10 logMAR or worst. Also was imposed that at any patient was performed additional secondary refractive procedure after surgery.

Our study was powered to have an 80% chance of detecting a 10 unit reduction in quality of vision symptoms after bilateral multifocal IOL implantation using significance threshold set at $P<0.017$ considering the multiple comparisons over the 3 follow-up visits. The null hypothesis was that symptoms would not change over the follow-up period. By allowing for 10% patient dropout, a recruitment target of 20 patients in total was set. This power analysis was based on background data from a previous studies measuring light disturbance in pseudophakic patients implanted with multifocal IOLs considering a mean score in light disturbance of of 45±15 to detect a variation of 15 units in score.

Prior to surgery, a comprehensive ophthalmologic examination was performed, including manifest and cycloplegic refraction, keratometry, corneal topography to assess preoperative astigmatism, slit–lamp biomicroscopy, Goldmann applanation tonometry, and dilated fundal

examination. Surgical procedures were conducted by the same experienced surgeon (M.A. G-A) under local anesthesia through a micro incision of 2.2mm. Ophthalmological examination also included optical biometry and anterior surface optical tomography for the calculation of the power of the IOL. Optical biometry was performed with the Lenstar LS 900 (Haag-Streit AG, Koeniz, Switzerland) and anterior surface optical tomography with the Orbscan Topography System II (Orbscan, Inc., Salt Lake City, UT, USA). The targeted refraction was emmetropia in both eyes. All biometry was carried out by a single, experienced ophthalmic technician. Surgical procedures with IOL implantation were conducted with a difference of 7 days between eyes. Phacoemulsification was followed by irrigation and aspiration of the cortex and IOL implantation in the capsular bag. All the procedures were uneventful, and none of the patients had any significant intraoperative complications.

8.3.1 Intraocular lenses

Multifocal IOLs implanted were those presented in Table 8.1.

Table 8.1 – Baseline Characteristics

Lens (Number of Patients)	AcrySof ReSTOR SV25T0 (20)	Tecnis ZKB00 (18)	AT LISA TRI 839MP (15)	Tecnis ZLB00 (20)	AT LISA 809M (20)	Tecnis ZCB00 (14)	Cataract (12)
Geometry	Híbrid-central diffractive periphery refractive	Difractive	Difractive trifocal	Difractive	Difractive bifocal	Mono-focal	-
Spherical/ Aspheric (SA Induced)	Aspheric (-0.20)	Aspheric (-0.27)	Aspheric (-0.18)	Aspheric (-0.27)	Aspheric (-0.18)	Aspheric (-0.27)	-
Adition in the lens (spectacle plane)	+2.5 (≈+1.75)	+2.75 (≈+2.00)	Near +3.33 intermediate +1.66 (≈+2.75 / +1.25)	+3.25 (≈+2.75)	+3.7 (≈+3.00)	-	-
Material	Acrylic hydrophobic	Acrylic hydrophobic	Acrylic hydrophobic / hydrophilic surface	Acrylic hydrophobic	Acrylic hydrophobic / hydrophilic surface	Acrylic hydrophobic	-
Optic Diameter	6 mm	6 mm	6 mm	6 mm	6 mm	6 mm	-
Support	Haptics	Haptics	Plato	Haptics	Plato	Haptics	-

8.3.2 Main Outcome Measures

Main outcome measures will be the monocular visual acuity (VA) and light distortion (LD) analysis for size, shape and regularity of the halo surrounding a source of glare (Ferreira-Neves et al, 2015; Brito et al, 2015). Subjective quality of vision was measured with the QoV questionnaire (McAlinden, 2010) and glare was also measured with the C-Quant (Oculus, Germany). All measures were done between 4 and 6 months after second eye surgery. The examiner was not masked to the lens type and binocular defocus curves were measured with no correction. Light distortion was analysed with an experimental prototype, the Light Distortion Analyzer[22] (CEORLab, University of Minho, Portugal), which consists of a central light source (LED) surrounded by 240 small LED sources distributed in 24 semi-meridians with an angular separation of 15º. In this experiment an angular separation of 30º was explored. Figure 8.1 represents the layout arrangement of the central white light emitting diodes (LED) and the surrounding smaller white LEDs. The central LED was a commercially available white LED from Agilent Technologies (ref. HLMP-CW47-RU000 from Agilent Technologies, Inc., Berkshire, United Kingdom); surrounding LEDs were commercially available white LED from Avago Technologies (ref - HSMW-CL25 from Avago Technologies, San Jose, California, United States). The calibration and radiometric description of the central and peripheral LEDs that constitute the device have been done and proved successful to use in visual assessments.[23] The subject was at a distance of 2.0m in a darkened room. The physical (electronic board) Display Device is connected to a control central control device (PC computer) via USB connection. The subject being evaluated provides feedback to the system through a remote response device (PC mouse). Peripheral stimuli are presented around the central source of light from the inner to the outer part of the field at random times from 250 to 750 milliseconds. Semi-meridians are explored in random order. When the subject sees the stimulus, presses the mouse control and the system presents the next semi meridian.

Once the testing procedure is complete, the software calculates several indices that determine the size and regularity of the distortion surrounding the central source of light (Figure 8.2). The light distortion index (LDI) is calculated as the ratio of the area of points missed by the subject and the total area explored and is expressed as a percentage. The best-fit circle radius (BFCRad) is defined as the circle that best fits the distortion area resulting from the linear binding of all points in each meridian of the device. This parameter is expressed in millimeters and is linearly related to the LDI parameter. The higher the values of the best-BFCRad and LDI, the

lower the ability to discriminate small light stimuli surrounding a central source of light. The deviation of the obtained polygonal shape from the best-fit circle fit is called the best-fit circle irregularity. The standard deviation of best-fit circle irregularity (BFCIrregSD) measures the asymmetry of the actual limits of the distortion from the perfect circular shape of the best-fit circle and indicates the light-distortion irregularity.

For each case, the light-distortion testing procedure was performed 3 times with the subject wearing spectacle correction. The values obtained on the third examination were chosen for statistical analysis.

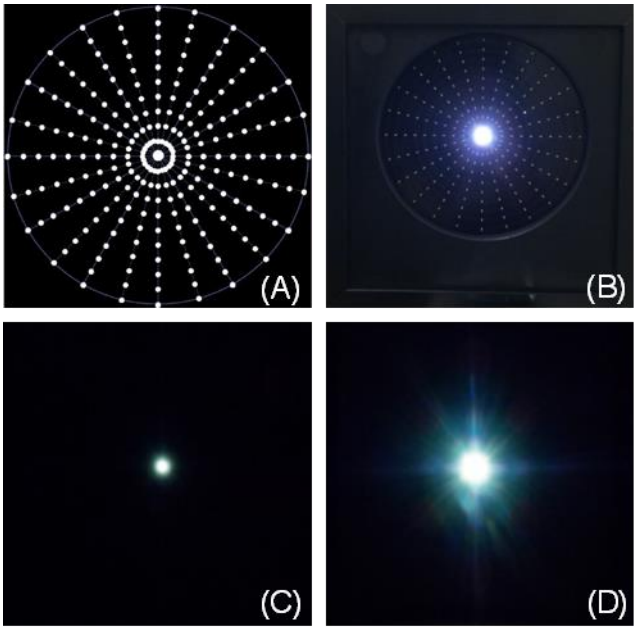


Figure 8.1 - Distribution of the main central light source and smaller peripheral light stimuli in accordance with the display used in the prototype light-distortion analyzer; (B) actual appearance of the LED hardware with the central glare source and one peripheral stimuli (5th circle at 30°) turned-on; (C) central glare source presented in total darkness displaying very small distortion; (D) central glare source presented in total darkness displaying large distortion.

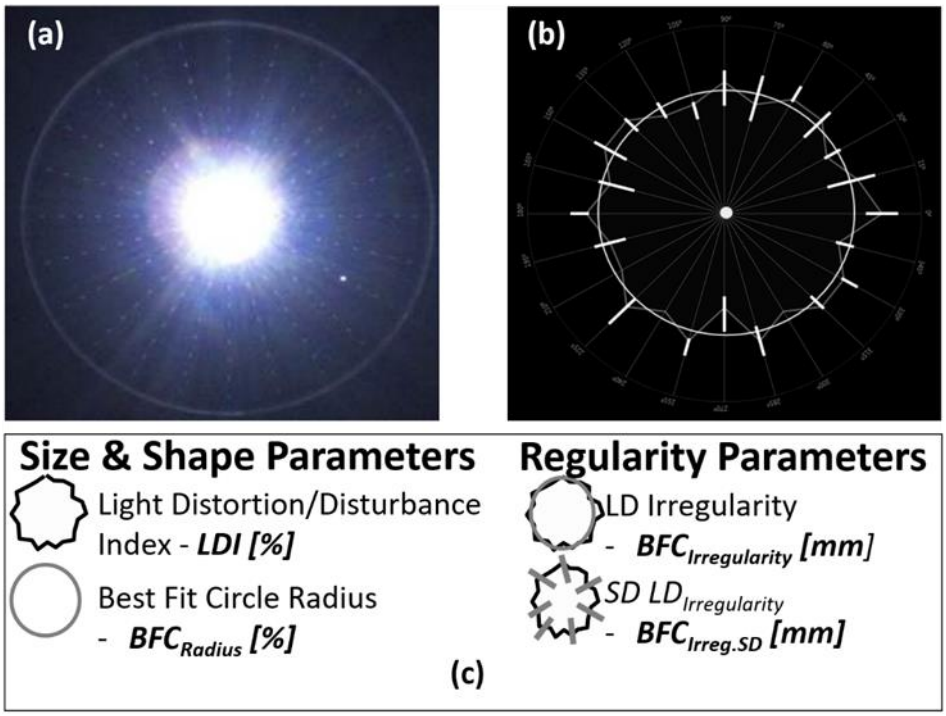


Figure 8.2 - Illustration of the distribution of main central source of light and peripheral stimuli in accordance with an exemplary embodiment of the present invention. On the above right: the experimental device LDA with the central LED light with one peripheral LED turned ON (a); on the above left an illustration of layout appearance of the size and shape of the light disturbance measured (b) and the size and shape and regular related parameters derived from the Light Distortion Analyzer (c).

8.3.3 Statistical Analysis

Statistical analysis was conducted using SPSS for Windows software (version 22, SPSS, Inc.). Analyses include descriptive data for patient demographics and visual and refractive outcomes. The results on VA and contrast sensitivity are reported as binocular outcomes. Normality of data distribution was assessed using the Shapiro-Wilk test. One-way analysis of variance (ANOVA) were used for parametric data with a post hoc Bonferroni test or Kruskal-Wallis with multiple post-hoc comparisons was used to compare the results between assessed moments. Correlations were assessed using Pearson Correlation or non-parametric Spearman correlation. For all statistical analyses the level of significance was a P value was lower than 0.05. Multiple post-hoc comparisons were considered significant when P value was under 0.05/5 = 0.01

8.4 Results

Figure 8.3 and 8.4 presents the values of the light disturbance measured with the LDA in each subgroup, under monocular (right and left eye) and binocular conditions, respectively. The higher values of disturbance are for the cataract group. In general bifocal IOLs with lower values of addition power, and trifocals are those presenting lower values of disturbance. Bifocal IOls with higher adds present the largest values.

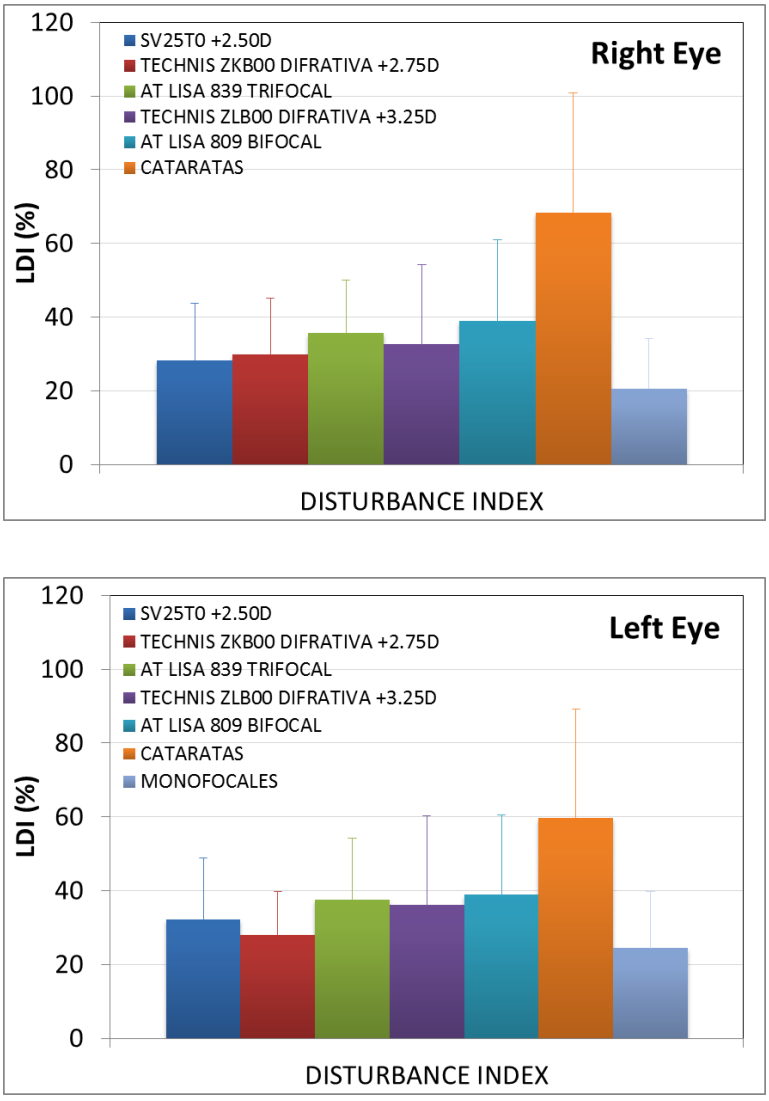


Figure 8.3 - Monocular (right and left eye) value of light disturbance index (LDI, %) for the 5 multifocal IOL evaluated, the monofocal IOL and the cataract group.

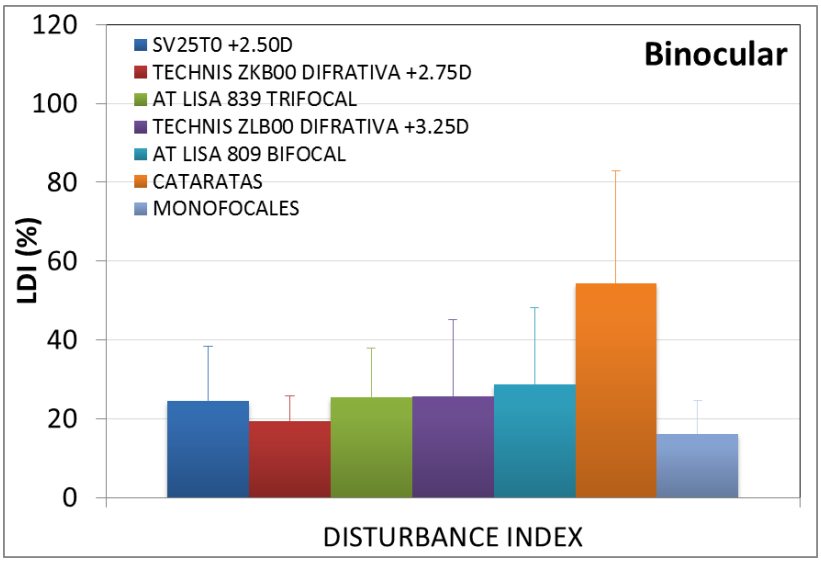
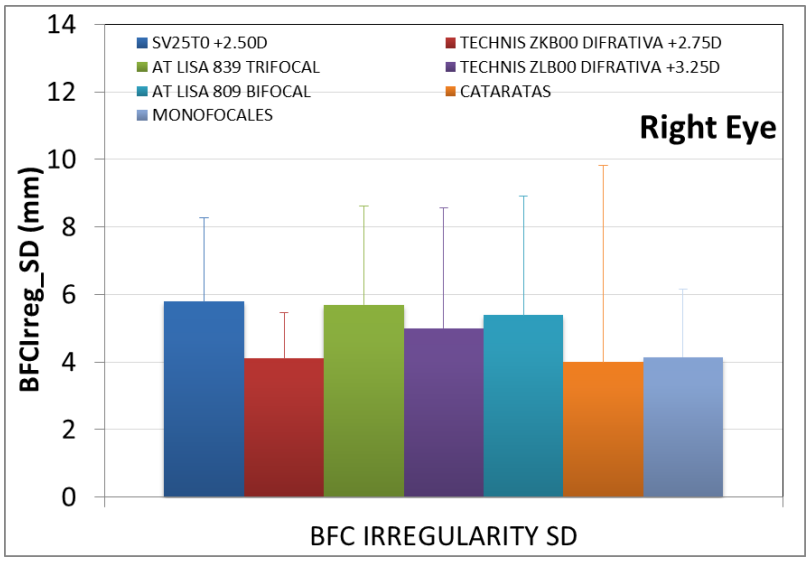


Figure 8.4 - Binocular value of light disturbance index (LDI, %) for the 5 multifocal IOL evaluated, the monofocal IOL and the cataract group.

In figures 8.5 and 8.6 are presented the irregularity of the light disturbance expressed by the SD of the best fit circle to the light disturbance as described in Methods. The irregularity of the distortions measured showed to be somewhat increased when compared with monofocal IOLs. The irregularity of the distortion area is derived as the deviation of the actual polygonal shape obtained from the BFC fit and is called the BFC Irregularity (BFCIrreg). The standard deviation of BFCIrreg, called BFCIrregSD measures how asymmetric is the departure of the actual limits of the distortion from the perfect circular shape of the BFC. The BFCIrregSD can be interpreted as the deviation of the actual distortion from a perfectly rotational symmetric shape. The higher value of this parameter, the larger the deviation from a circular shape and it is expressed in mm.



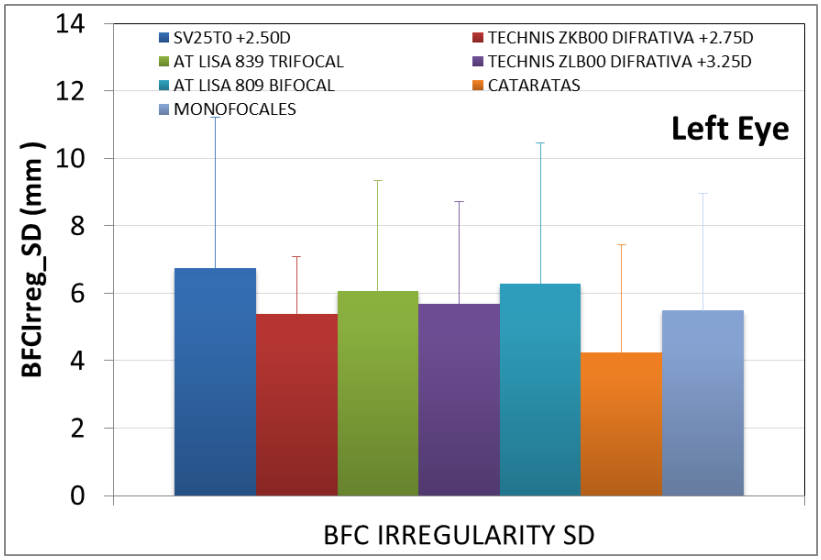


Figure 8.5 - Monocular (right and left eye) value of standard deviation of the best fit circle (BFCIrreg_SD) for the 5 multifocal IOL evaluated, the monofocal IOL and the cataract group.

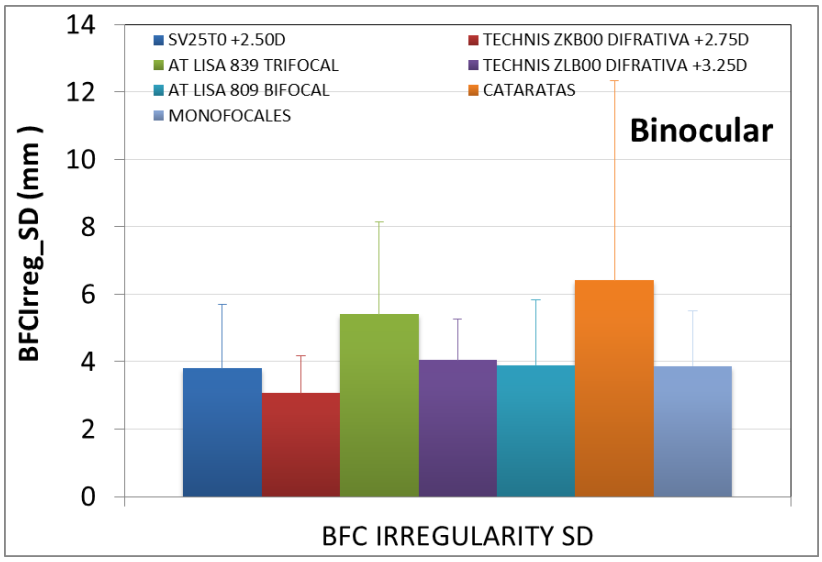


Figure 8.6 - Binocular value of standard deviation of the best fit circle (BFCIrreg_SD) for the 5 multifocal IOL evaluated, the monofocal IOL and the cataract group.

Figure 8.7 shows the results in the optical bench for 4 of the 5 IOLs used in this study. Again the lenses with higher adds present larger values of disturbance. This study also shows that the size is pupil dependent with larger pupils being subjected to larger disturbances.

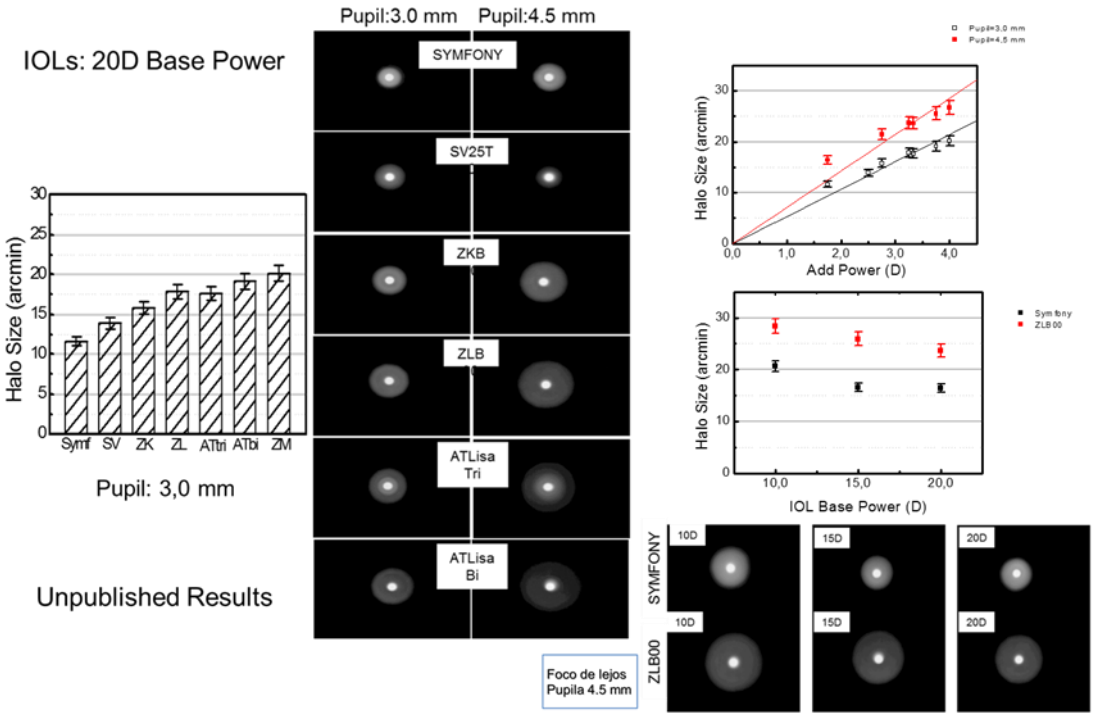


Figure 8.7 - Halo size analyzed in the optical bench.

Table 8.2 and figure 8.8 show the values of glare measured with the C-Quant.

Table 8.2 – Values of glare measured with C-Quant.

	LOG (s)		
	Mean	Median	Standard deviation
ReSTOR SV25T0	1.18	1.11	0.27
Tecnis ZKB00	1.17	1.13	0.29
AT LISA TRI 839MP	1.05	1.06	0.14
Tecnis ZLB00	1.15	1.11	0.27
AT LISA 809M	1.12	1.08	0.26
Monofocal	1.14	1.07	0.21
Cataracts	1.69	1.71	0.32

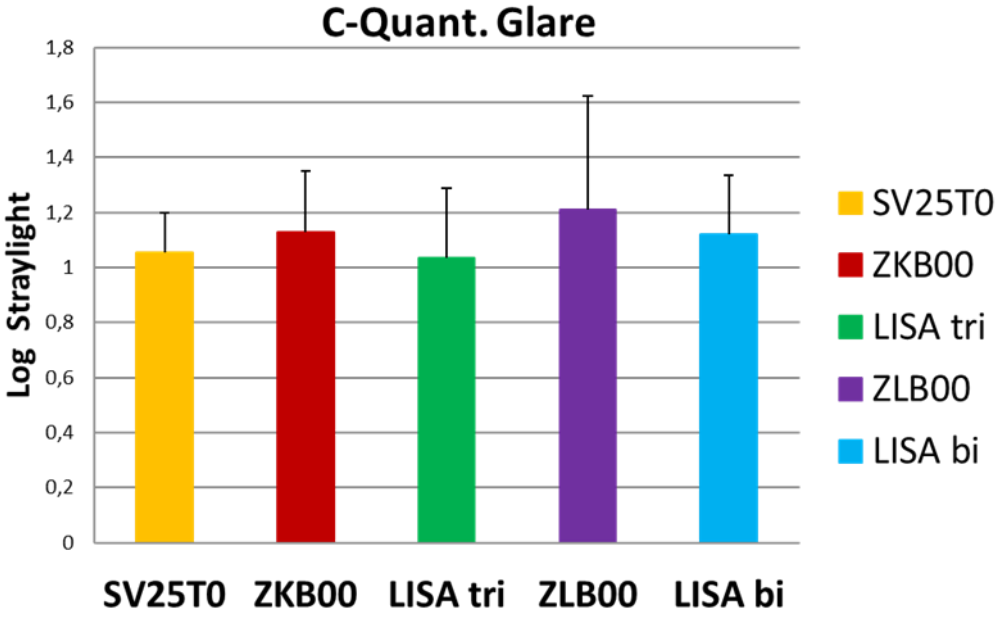


Figure 8.8 - Values of glare measured with C-Quant

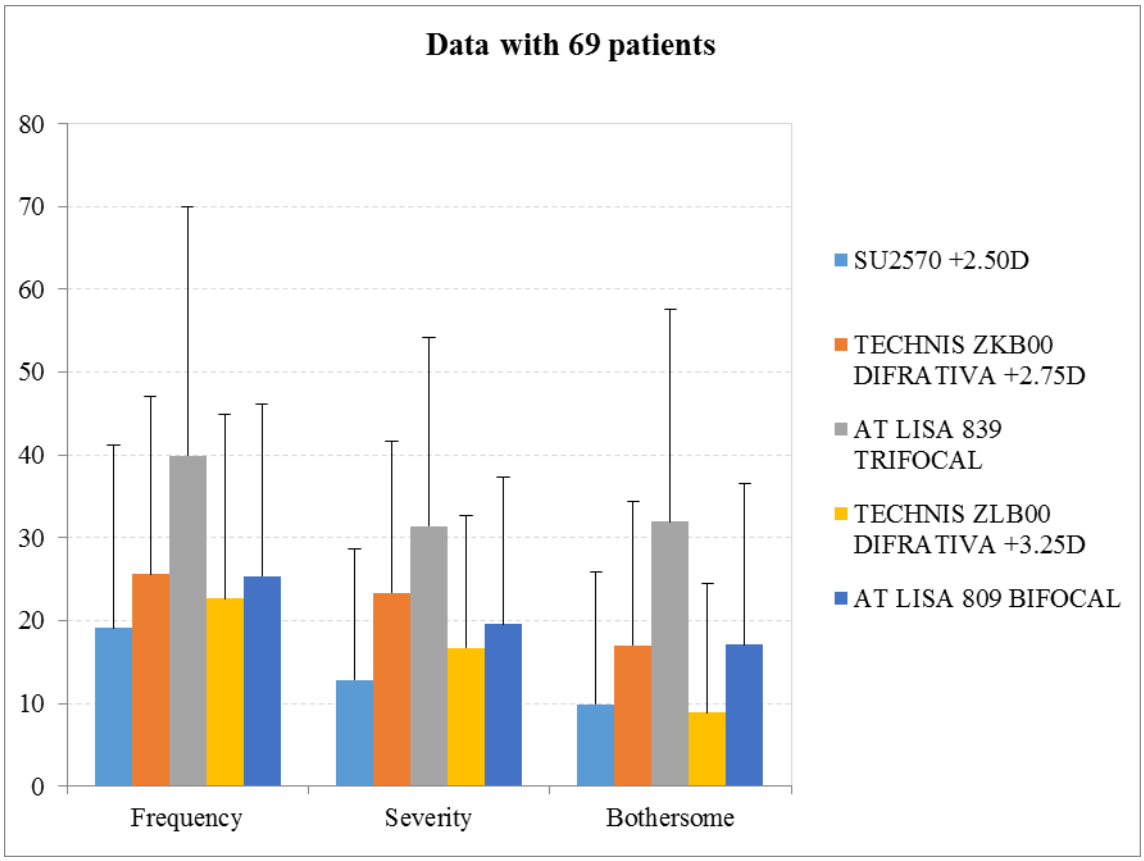


Figure 8.9 – Quality of Vision Questionnaire

8.5 Discussion

This study investigated a large number of IOLs implanted in patients undergoing cataract surgery. We have observed that IOLs with higher adds and bifocal design induce the larger halo size. This might be particularly relevant for larger pupil diameters as shown in the optical bench analysis what might be also relevant in driving performance. In fact, most patients have stronger symptoms when they drive at night after being implanted with these IOls.

The conclusions of this preliminary work can be summarized as follow:

However, in binocular conditions all IOLs showed irregularity values similar to a monofocal IOL, except the trifocal that maintained higher values of irregularity.

There is an effect of binocular summation, that can reduce the irregularity of the distortion comparing to the monocular measurements.

The size of the distortions measured with all IOLs showed to be increased when compared with monofocal IOLs.

The increase was less noticed for the low addition lenses. With higher addition lenses, the LDI values reached up to a double of the values measured with monofocal IOLs.

Cataracts can cause a severe impairment in patient's vision under night vision conditions, with LDI values reaching up to 50-70%.

There is an effect of binocular summation that can reduce the LDI up to 10% comparing to the monocular measurements.

After analyzing the light disturbance with the LDA Device we observed that the size of the disturbance followed a parallel with the results obtained in the Optical Bench for the same IOLs when the halo around an extended object was analyzed. These preliminary results do not mean directly that we can infere directly the Subjective Light Disturbance experienced by the patient from the optical bench measurements.

In fact, the perceptions of the patient involve much more factors than the optical ones measurable in the optical bench. However, this experiment confirms that the perception measured with LDA depends in part of the optical design of the lens and its physical performance, as might be anticipated. This confirms, in our opinion, the utility of the device for assessment of pseudophakic patients implanted with IOLs.

8.6 References

Alfonso JF, Fernández-Vega L, Valcárcel B, Ferrer-Blasco T, Montés-Micó R. Outcomes and patient satisfaction after presbyopic bilateral lens exchange with the ResTOR IOL in emmetropic patients. J Refract Surg. 2010 Dec;26(12):927-33.

Alio JL, Grzybowski A, El Aswad A, Romaniuk D. Refractive lens exchange. Surv Ophthalmol. 2014 Nov-Dec;59(6):579-98.

Alió JL, Grzybowski A, Romaniuk D. Refractive lens exchange in modern ractice: when and when not to do it? Eye Vis (Lond). 2014 Dec 10;1:10

Alió JL, Vega-Estrada A, Plaza-Puche AB. Clinical outcomes with a new microincisional diffractive multifocal IOL. Eye Vis (Lond). 2015 Jan 31;2:2.

Altaie R, Ring CP, Morarji J, Patel DV, McGhee CN. Prospective analysis of visual outcomes using apodized, diffractive multifocal intraocular lenses following phacoemulsification for cataract or clear lens extraction. Clin Exp Ophthalmol. 2012 Mar;40(2):148-54.

Anderle R, Ventruba J. The current state of refractive surgery. Coll Antropol. 2013 Apr;37 Suppl 1:237-41.

Blaylock JF, Si Z, Aitchison S, Prescott C. Visual function and change in quality of life after bilateral refractive lens exchange with the ReSTOR multifocal intraocular lens. J Refract Surg. 2008 Mar;24(3):265-73.

Brito P, Salgado-Borges J, Neves H, Gonzalez-Meijome J, Monteiro M. Light-distortion analysis as a possible indicator of visual quality after refractive lens exchange with diffractive multifocal intraocular lenses. J Cataract Refract Surg. 2015;41:613-22.

Chang JS, Ng JC, Chan VK, Law AK. Visual outcomes and patient satisfaction after refractive lens exchange with a single-piece diffractive multifocal intraocular lens. J Ophthalmol. 2014;2014:458296.

Chang JS, Ng JC, Lau SY. Visual outcomes and patient satisfaction after presbyopic lens exchange with a diffractive multifocal intraocular lens. J Refract Surg. 2012 Jul;28(7):468-74.

Dick HB, Gross S, Tehrani M, Eisenmann D, and Pfeiffer N. Refractive lens exchange with an array multifocal intraocular lens. J Refract Surg. 2002, vol. 18, no. 5, pp. 509–518.

Ferreira-Neves H, Macedo-de-Araújo R, Rico-del-Viejo L, Silva AC, Queirós A, González-Méijome JM. Validation of a method to measure light distortion surrounding a source of glare. J Biomed Optics; 20(7):75002.

Hall NF, Lempert P, Shier RP, et al. Grading nuclear cataract: reproducibility and validity of a new method. Br J Ophthalmol 1999;83:1159-1163.

Hoffman RS, Fine IH, Packer M. Refractive lens exchange as a refractive surgery modality. Curr Opin Ophthalmol. 2004 Feb;15(1):22-8.

Holzer MP, Rabsilber TM, Auffarth GU. Presbyopia correction using intraocular lenses] Ophthalmologe. 2006 Aug;103(8):661-6.

Kook D, Kampik A, Kohnen T. [Complications after refractive lens exchange]. Ophthalmologe. 2008 Nov;105(11):1005-12.

Leccisotti A. Secondary procedures after presbyopic lens exchange. J Cataract Refract Surg. 2004 Jul;30(7):1461-5.

Linhares JMM, Neves H, Lopes-Ferreira D, Faria-Ribeiro M, Peixoto-de-Matos SC, González-Méijome JM. Radiometric characterization of a novel led array system for visual assessment. Journal of Modern Optics. 2013;60:1136-44.

Rosen E, Alió JL, Dick HB, Dell S, Slade S. Efficacy and safety of multifocal intraocular lenses following cataract and refractive lens exchange: Metaanalysis of peer-reviewed publications. J Cataract Refract Surg. 2016 Feb;42(2):310-28.

McAlinden C, Pesudovs K, Moore JE. The development of an instrument to measure quality of vision: the Quality of Vision (QoV) questionnaire. Invest Ophthalmol Vis Sci. 2010;51:5537-45.

Mojzis P, Peña-García P, Liehneova I, Ziak P, Alió JL. Outcomes of a new diffractive trifocal intraocular lens. J Cataract Refract Surg. 2014 Jan;40(1):60-9. doi: 10.1016/j.jcrs.2013.06.025.

Moyal L, Abrieu-Lacaille M, Bonnel S, Sendon D, de Rivoyre B, Berguiga M, Rambaud C, Froussart-Maille F, Rigal-Sastourné JC. [Comparison of two different surgical treatments of presbyopia for hyperopic patients over 55 years old: Presbylasik (Supracor) and Prelex (presbyopic lens exchange)]. J Fr Ophtalmol. 2015 Apr;38(4):306-15.

Packer M, Fine IH, Hoffman RS. Refractive lens exchange with the array multifocal intraocular lens. J Cataract Refract Surg. 2002 Mar;28(3):421-4.

Ribeiro FJ, Castanheira-Dinis A, Dias JM. Personalized pseudophakic model for refractive assessment. PLoS ONE 2012;7(10):e46780.

Saragoussi JJ. [Presbyopia surgery: principles and current indications]. J Fr Ophtalmol. 2007 May;30(5):552-8.

Venter JA, Pelouskova M, Bull CE, Schallhorn SC, Hannan SJ. Visual outcomes and patient satisfaction with a rotational asymmetric refractive intraocular lens for emmetropic presbyopia. J Cataract Refract Surg. 2015 Mar;41(3):585-93.

Chapter 9

General overview of results, conclusions and future work

9. GENERAL OVERVIEW OF RESULTS, CONCLUSIONS AND FUTURE WORK

9.1 General overview of results

The present work had as main goals the development and validation of a new experimental device, capable of quantifying night vision disturbances. That was accomplished due to a series of systematic evaluations that turned it possible to use in the clinical practice, providing a comprehensive number of metrics to characterize the condition and within acceptable examination time. It was then tested in young healthy subjects wearing contact lenses (monofocal and multifocal) and in prebyopic patients wearng MFCs or after Multifocal IOL implantation.

9.2 Conclusions

Taking into account the findings of this work carried throughout the development of this project, we can arrive to the following conclusions:

1. The Light Distortion Analyzer (LDA) developed to quantify Night Vision Disturbances (NVD) showed to be sensitive to different intensities of the central glare source.
2. Measurements of NVD done with the LDA are fast and repeatable under the same experimental conditions and are consistent in terms of size and shape of the distortions.
3. To date, the optical and visual performance has been evaluated using either objective methods (i.e. aberrometers and optical quality analyzers) or subjective methods (questionnaires). The LDA inclusively allowed quantifying the increased distortions caused by the disruption of the tear film in normal young subjects, after a long period without blinking (15 seconds blinking interval vs 5 seconds blinking interval). The same mechanism that relates decreased NIBUT and increased aberrations and scattering, might justify these findings, and the device was sensible to detect them.
4. The use of contact lenses may worsen the perception of NVD. The higher the water content and the longer the inter blink interval (IBI), the worse the NVD.
5. Even when patients reach good VA, the analysis of NVD is recommended when there are complaints of visual problems, especially under certain lighting conditions and being a CL wearer. Poor quality of vision under low lighting conditions may be the cause of the complaints.

6. Contact lenses of higher hydration induce a greater effect of disturbance, mainly when there is a low frequency of blinking. However, under visual demanding conditions associated to increased IBI values such as night driving or prolonged visualization of video display units, increased light disturbance can adversely affect the visual performance and safety.
7. Wearing multifocal contact lenses can increase de percentage of NVD up to double the values of the non-wearing conditions.
8. Multizone refractive optics presented the major percentage of NVD.
9. LDA showed to be sensitive to differences in the pattern of disturbance generated by different multifocal systems and to be a useful instrument to measure the light disturbance with multifocal contact lens under night vision conditions.
10. The multifocal contact lens that showed lower values of disturbance on almost all parameters in young healthy subjects was the lens with lower Equilibrium water content (EWC). Contact lenses with lower hydration (ECW) do not dehydrate as quickly as the lens with higher ECW.
11. Quality of vision in presbyope patients with MFCLs decreases comparing to the baseline situation (patients best correction in spectacles) and they report higher frequency and severity of the symptoms associated with NVD. This happens for all lenses, but with multizone refractive optics, the patient's quality of vision decreases significantly.
12. From this trial, we can conclude that if the patient is fitted with lower addition multifocal soft contact lenses, it will not worsen their quality of vision over time in a significant way comparing with their best correction in spectacles. But this if the fitting is with higher additions, the center near aspheric design and the asymmetric design are the ones that provide to the patients a smaller decrease in their QoV. This can be overcome if the patients are fitted earlier, where any lens of the ones studied will show good results.
13. One of the reasons to use MFCLs is the esthetic motivation considering the "virtual" absent of the corrective device when compared to spectacle lenses(patients rated this aspect over 9 in 10) with all lenses.
14. The convenience of having a permanent near, intermediate and distance vision correction might have also contributed to the fact that patients rated over 8 in 10 all MFCL used in this study compared to their habitual spectacle lenses.

15. Fitting patients with lower addition multifocal soft contact lenses will not worsen their quality of vision over time in a significant way comparing with their best correction in spectacles.
16. One possible alternative to increase add power to improve near visual acuity, add power could be kept lower to preserve better distance visual acuity at the expense of using supplementary reading spectacles (SRS) to improve near vision for the most challenging near vision tasks.
17. The two diffractive multifocal IOL models provided excellent visual and refractive outcomes. As so, excellent UDVA and functional UNVA despite increased light disturbance indices.
18. Despite the similar CDVA and patient age between the 3 groups, the multifocal IOL groups had a significantly higher LDI. This means that the LDA reliably identified a subjective component of vision, distinct from Snellen chart visual acuity.
19. Cataracts can cause a severe impairment in patient's vision under night vision conditions.
20. There is an effect of binocular summation that can reduce the LDI up to 10% comparing to the monocular measurements in patients implanted with multifocal IOLs.
21. The size of the disturbance followed a parallel with the results obtained in the Optical Bench for the same IOLs , however, these preliminary results do not mean directly that we can infere the Subjective Light Disturbance experienced by the patient from the optical bench measurements.
22. The perceptions of the patient involve much more factors than the optical ones measurable in the optical bench.
23. The measures obtained of NVD with the LDA depend in part of the optical design of the lens and its physical performance. This confirms the utility of the device for assessment of pseudophakic patients implanted with IOLs.

9.3 Future work

The validation study of the LDA is limited by the fact all the subjects were young and healthy. Considering that post-surgical or diseased patients could present significantly higher values of light disturbance, we cannot directly extrapolate to those specific populations. For example, the examination time, might increase as the light disturbance increases. The difficulties found by older patients might be different from the ones found in the present sample.

Besides that, a recent study conducted in patients implanted with monofocal, bifocal and trifocal IOLs after cataract extraction demonstrated that the LDA test is easily conducted in these clinical populations within acceptable time period.[1]

One other aspect that could be done in the future is to have a more numerous sample to be able to divide them in groups, which would give more cohesion to the results obtained.

In future works, it would be important to associate exams of contrast sensitivity and the measurement of high order aberrations in order to correlate those values with the LDI measured with the LDA.

In addition, attention was given to tear-film function by excluding cases of dry eye for the research with IOL implantation, with systemic conditions potentiating dry-eye disease and by carefully evaluating tear-film status during slit lamp ophthalmologic examination. Specific clinical populations such as post-LASIK patients, post-corneal reshaping, cataracts, dry eye patients, keratoconus and other ocular diseases need to be addressed in future studies.

Although still in its early stages, we believe the use of ocular light-transmission analyzers will become indispensable in the postoperative evaluation of the quality of vision conferred by multifocal IOLs. In that sense, the LDA may be helpful when studying cases of bothersome positive dysphotopsia and therefore allow the surgeon to whether if IOL explantation is warranted.

Considering that multifocal IOLs are gaining favor as the lens surgery of choice to correct presbyopia2 it will be interesting to apply this technology to different multifocal IOL models to characterize overall visual quality.

9.4 References

1. Cabot F, Saad A, McAlinden C, Haddad NM, Grise-Dulac A, Gatinel D. Objective assessment of crystalline lens opacity level by measuring ocular light scattering with a double-pass system. Am J Ophthalmol 2013; 155:629–635

2. Mesci C, Erbil HH, Olgun A, Yaylali SA. Visual performances with monofocal, accommodating, and multifocal intraocular lenses in patients with unilateral cataract. Am J Ophthalmol 2010; 150:609–618