

**Cirugía de la catarata con implante
de la nueva lente intraocular
monofocal modificada RayOne
EMV para mini-monovisión:
nuestros primeros resultados.**



Fernando Llovet, MD, PhD

Unidad de Cirugía Refractiva, Cataratas y Presbicia
Profesor Asociado de Oftalmología, Universidad Cardenal Herrera-CEU, Valencia
Director de Publicaciones de la Sociedad Española de Cirugía Implanto-Refractiva (SECOIR)



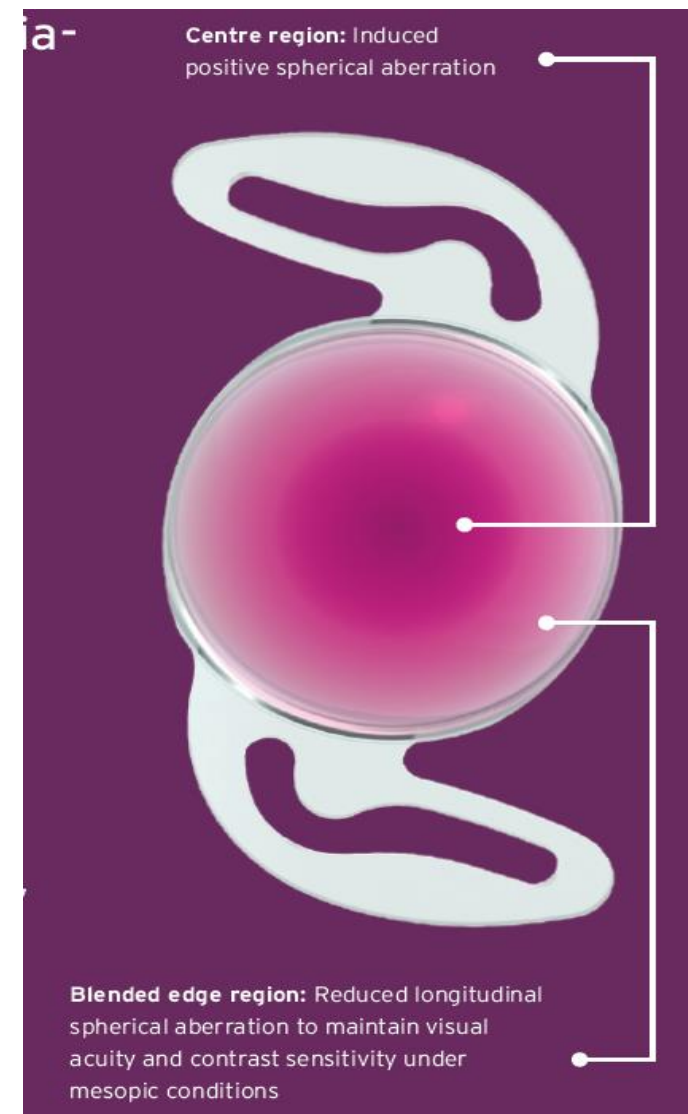
Cirugía de la catarata con implante
de la nueva lente intraocular
monofocal modificada RayOne EMV
para mini-monovisión:
nuestros primeros resultados.



Objetivos

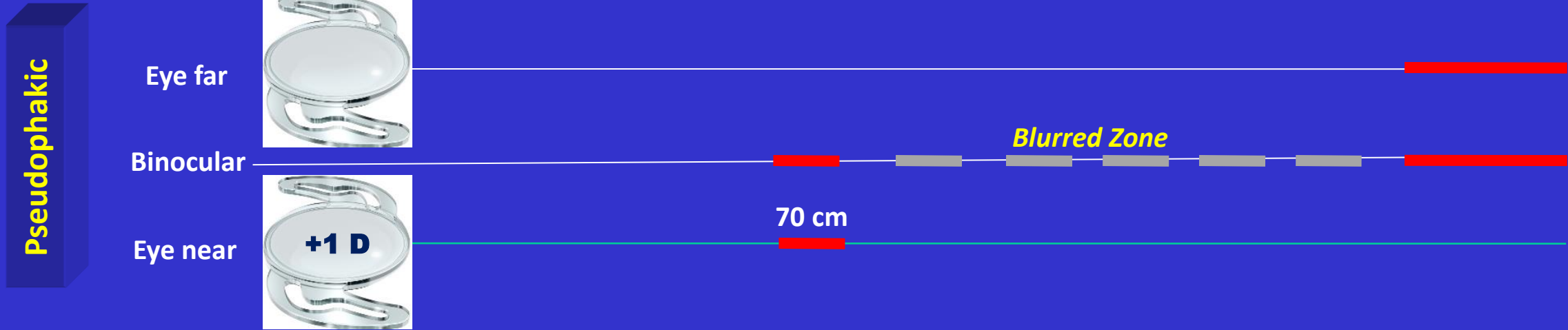
Objetivos

- ❑ Valorar los resultados visuales y la satisfacción del paciente tras la cirugía de catarata e implante bilateral de una **lente intraocular monofocal modificada (RayOne EMV) con monovisión**

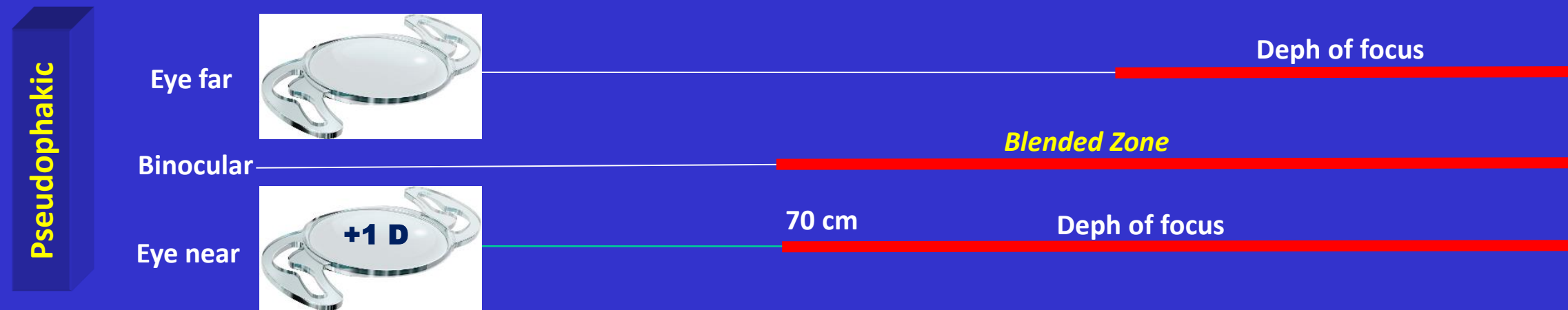


Los autores no tiene interés financiero

Mini-monovision with Monofocal standard IOL



Mini-monovision with Monofocal enhanced IOL



Cirugía de la catarata con implante
de la nueva lente intraocular
monofocal modificada RayOne EMV
para mini-monovisión:
nuestros primeros resultados.

FACO
EXTREMA

Método

Método

- Este estudio prospectivo observacional (C.I. 21/301-O_P) en una serie de pacientes (sometidos a cirugía de la catarata con facoemulsificación e implantación bilateral de una lente intraocular monofocal mejorada (monofocal-Plus) precargada **RayOne EMV®** (Rayner Intraocular Lenses Ltd. Worthing, Reino Unido).

Model Name	
Model Name	RayOne EMV
Model Number	RAO200E
Power Range	+10.0 to +30.0 D (0.5 D increments)
Delivery System Type	Fully preloaded IOL injection system
Incision Size	Sub 2.2 mm
Delivery System	
Injector Type	Single use, fully preloaded IOL injection system
Nozzle Size	1.65 mm
Bevel Angle	45°
Lens Delivery	Single handed plunger
Aspheric Monofocal IOL	
Material	Single piece Rayacryl hydrophilic acrylic
Water Content	26% in equilibrium
UV Protection	Benzophenone UV absorbing agent
UV Light Transmission	UV 10% cut-off is 380 nm
Refractive Index	1.46
ABBE	56
Overall Diameter	12.50 mm
Optic Diameter	6.00 mm
Optic Shape	Biconvex (positive powers)
Asphericity	Anterior aspheric surface, posterior surface aspheric or spheric depending on dioptric power
Optic Edge Design	Amon-Apple 360° enhanced square edge
Haptic Angulation	0°, uniplanar
Haptic style	Closed loop with anti-vaulting haptic (AVH) technology

Dra. Mar García Arenillas
Presidenta del CEIm Hospital Clínico San Carlos

CERTIFICA

- Que el CEIm Hospital Clínico San Carlos en su reunión de Comisión Permanente, acta 5.1/21, ha evaluado la respuesta a las aclaraciones solicitadas con anterioridad al proyecto:

Título: *ESTUDIO PARA LA EVALUACIÓN DE RESULTADOS VISUALES Y SATISFACCIÓN DEL PACIENTE TRAS IMPLANTE DELENTE INTRAOCULAR MONOFOCAL MODIFICADA PARA MONOVISIÓN*

Código Promotor: LIO_EMV21
Código Interno: 21/301-O_P

Tipo documento	Versión
Protocolo	Versión marzo 2021 - 30/04/2021
Hoja Información de Paciente	Versión 2 - 30/04/2021

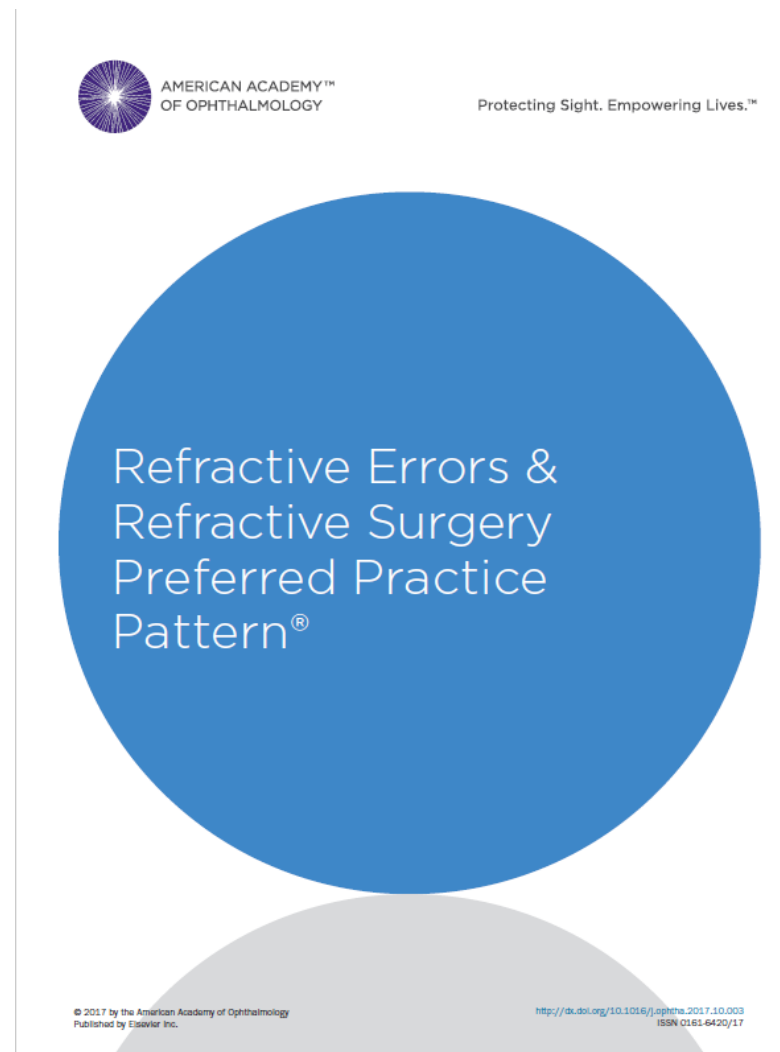
- Que en este proyecto:
 - Se cumplen los requisitos necesarios de idoneidad del protocolo en relación con los objetivos del estudio y están justificados los riesgos y molestias previsibles para el sujeto.
 - Son adecuados tanto el procedimiento para obtener el consentimiento informado como la compensación prevista para los sujetos por daños que pudieran derivarse de su participación en el proyecto.
 - La capacidad de los Investigadores y los medios disponibles son apropiados para llevar a cabo el proyecto, quedando detallado el listado de centros e investigadores previstos en el **anexo II**.
 - El alcance de las compensaciones económicas previstas no interfiere con el respeto a los postulados éticos.
 - El proyecto se plantea siguiendo los requisitos establecidos en la legislación vigente en cuanto a Investigación Clínica con Productos Sanitarios, y su realización es pertinente.
 - El procedimiento previsto para el manejo de datos personales es adecuado.

Método

☐ Se realizó un **examen oftalmológico completo** antes y después de la operación.

- Visual acuity (near, intermediate, distance)
- Refraction (near, intermediate, distance)
- IOP
- Biomicroscopy
- Ocular motility (Kappa angle, dominance)
- Pupillometry
- TBUT
- Pachimetry
- Corneal Topography
- Endothelial Count
- Fundus exploration (OCT)

☐ Los **criterios de inclusión** incluyeron ausencia de patología concomitante y astigmatismo ≤ 1 dioptría.



Método

Con una refracción objetivo de: **-1 D en el ojo no dominante y emetrópía para el dominante**

Goldberg et al. *BMC Ophthalmology* (2018) 18:293
https://doi.org/10.1186/s12886-018-0963-3

BMC Ophthalmology

RESEARCH ARTICLE

Open Access



Pseudophakic mini-monovision: high patient satisfaction, reduced spectacle dependence, and low cost

Debora Goetz Goldberg^{1*}, Michael H. Goldberg², Ridhi Shah¹, Jane N. Meagher² and Haresh Ailani²

Abstract

Background: Cataract surgery with pseudophakic mini-monovision has lower out-of-pocket patient expense than premium multifocal intraocular lenses (IOL). The purpose of this study was to evaluate patient-reported satisfaction and spectacle dependence for key activities of daily living after cataract surgery with pseudophakic mini-monovision. The study also examined statistical relationships between patient demographic variables, visual acuity and satisfaction.

Methods: Prospective cohort study of 56 patients (112 eyes) who underwent bilateral cataract surgery with pseudophakic mini-monovision. Mini-monovision corrects one eye for distance vision and the other eye is focused at near with -0.75 to -1.75 D of myopia. All patients with 1 diopter or greater of corneal astigmatism had a monofocal toric IOLs implanted or limbal relaxing incision. The main study outcomes were assessed at the last follow-up appointment and included refraction, visual acuity, patient reported spectacle use, and patient satisfaction. Descriptive statistics, correlation matrices and Pearson's chi-square tests were examined.

Results: Uncorrected visual acuity was significantly better post-operatively. Most patients reported the surgery met their expectations for decreased dependence on spectacles (93%). Most patients report little or no use of spectacles post-operatively for computer use (93%), distance viewing (93%) and general use throughout the day (87%). A small number of patients report spectacle use for reading (9%) and night driving (18%). There were no relationships detected between demographic variables and visual acuity or patient satisfaction.

Conclusions: Aging of the population presents one of the biggest challenges in the health sector, which includes a rising number of individuals with chronic vision impairment and increased demand for accessible treatment strategies. Cataract surgery with pseudophakic mini-monovision results in high patient satisfaction and considerable reduction in spectacle dependence. Pseudophakic mini-monovision technique is a low-cost, valuable option for patients who would like to reduce dependence on spectacles post-operatively and should be considered along with premium multifocal IOLs in options available for patients based on their needs, preferences and clinical indicators. Reducing spectacle dependence with the pseudophakic mini-monovision technique could improve the functionality, independence and quality of life for many patients who are unsuitable or are unable to pay additional fees associated with premium multifocal IOLs.

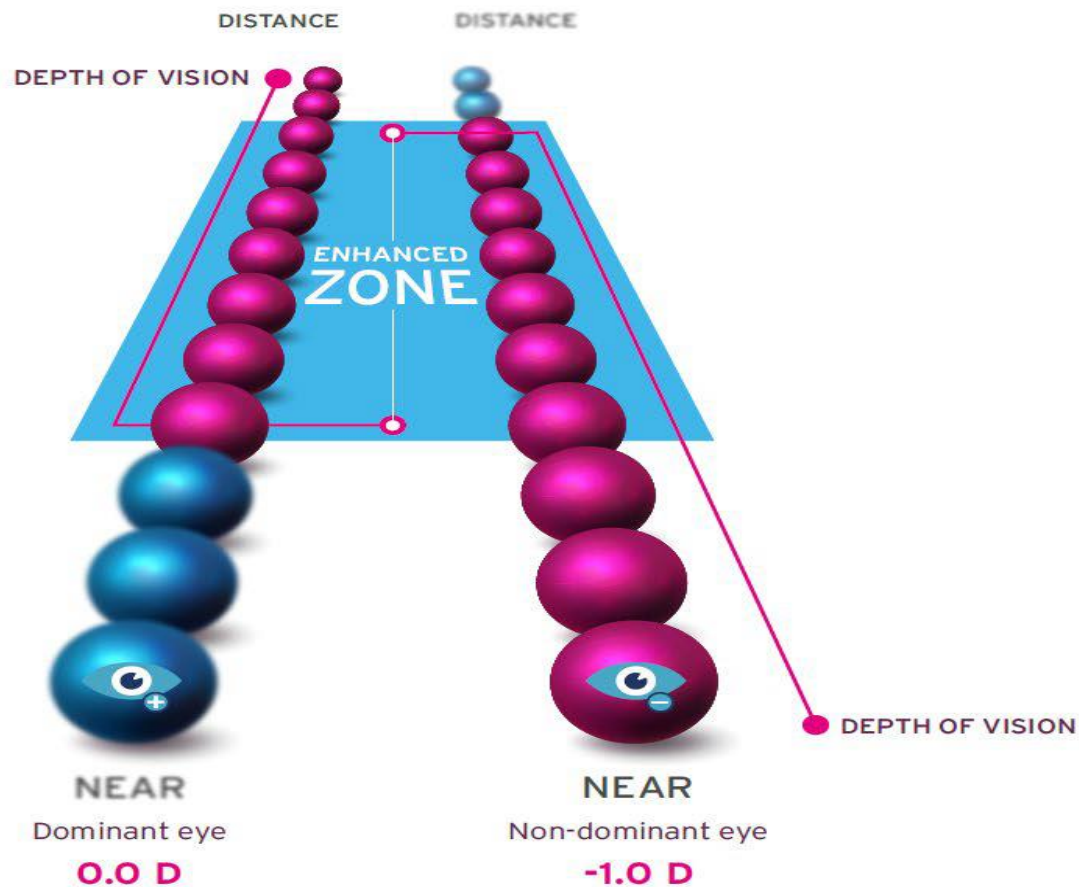
* Correspondence: dgoetz@gmu.edu

¹Department of Health Administration and Policy, George Mason University Peterson Family Health Sciences Hall, 4400 University Drive, MS: 1J3, Fairfax, Virginia 22030, USA

Full list of author information is available at the end of the article



© The Author(s). 2018 **Open Access** This article is distributed under the terms of the Creative Commons Attribution 4.0 International License (<http://creativecommons.org/licenses/by/4.0/>), which permits unrestricted use, distribution, and reproduction in any medium, provided you give appropriate credit to the original author(s) and the source, provide a link to the Creative Commons license, and indicate if changes were made. The Creative Commons Public Domain Dedication waiver (<http://creativecommons.org/publicdomain/zero/1.0/>) applies to the data made available in this article, unless otherwise stated.



Método

- Se valoró la **dominancia ocular motora y sensorial** para planificar la monovisión.

Hindawi Publishing Corporation
BioMed Research International
Volume 2013, Article ID 238943, 7 pages
<http://dx.doi.org/10.1155/2013/238943>



Research Article

Ocular Dominance and Visual Function Testing

D. Lopes-Ferreira, H. Neves, A. Queiros, M. Faria-Ribeiro, S. C. Peixoto-de-Matos, and J. M. González-Méijome

Clinical & Experimental Optometry Research Laboratory, Center of Physics, University of Minho, Gualtar, 4710-057 Braga, Portugal

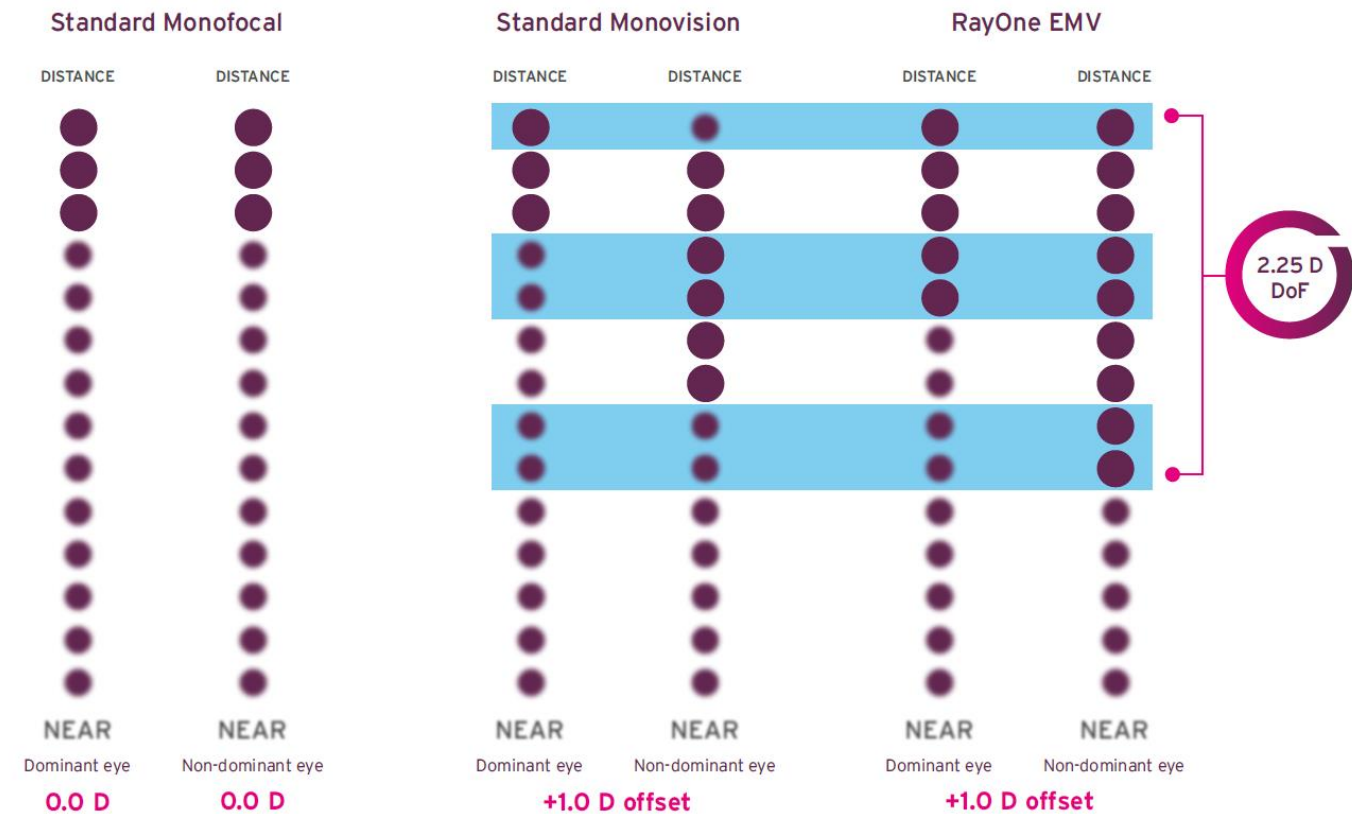
Correspondence should be addressed to J. M. González-Méijome; jgmeijome@fisica.uminho.pt

Received 18 July 2013; Accepted 1 September 2013

Academic Editor: Jacob J. Sosnoff

Copyright © 2013 D. Lopes-Ferreira et al. This is an open access article distributed under the Creative Commons Attribution License, which permits unrestricted use, distribution, and reproduction in any medium, provided the original work is properly cited.

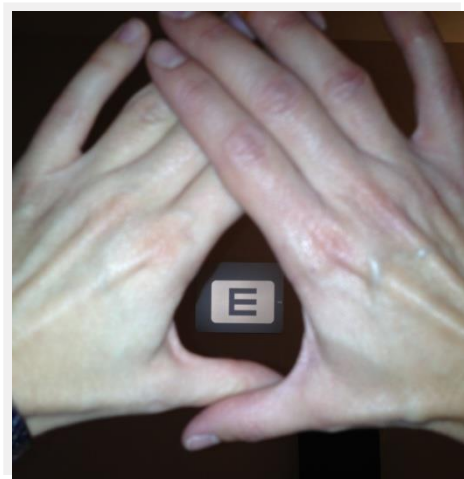
Purpose. To show the distribution of ocular dominance as measured with sensory and eye sighting methods and its potential relationship with high and low contrast LogMAR visual acuity in presbyopic subjects. *Method.* Forty-four presbyopes (48.5 ± 3.5 years) participated in this study. Ocular dominance was determined by eye sighting (hole-in-card) and sensorial (+1.50 D lens induced blur) methods. According to the dominance detected with each method (RE: right eye or LE: left eye), patients were classified in dominance type 1 (RE/RE), type 2 (RE/LE), type 3 (LE/RE) and type 4 (LE/LE). *Results.* Baseline refractive error (MSE) was RE: -0.36 ± 1.67 D and LE: -0.35 ± 1.85 D ($P = 0.930$). RE was the dominant eye in 61.4% and 70.5% of times as obtained from sensorial and sighting methods, respectively. Most frequent dominance was of type 1 (52.3%), in this case the RE showed statistically significant better distance low contrast LogMAR VA (0.04 LogMAR units) compared to the LE ($P < 0.05$). *Conclusions.* The dominance was more frequent in RE in this sample. The eye sighting and sensorial methods to define ocular dominance agreed in more than half of cases. Amount of MSE was not significantly different between dominant and non-dominant eye. But in case of right dominance, the RE presented better distance low contrast VA compared to the LE.



Método

Hole-in-hand test

❑ Se valoró la **dominancia ocular motora**



Método

Test del +1 plus

Se valoró la **dominancia ocular sensorial**

Journal of Vision (2015) 15(6):17, 1-12 <http://www.journalofvision.org/content/15/6/17> 1

The role of sensory ocular dominance on through-focus visual performance in monovision presbyopia corrections

The Institute of Optics, University of Rochester, Rochester, NY, USA
Center for Visual Science, University of Rochester, Rochester, NY, USA
Flaum Eye Institute, University of Rochester, Rochester, NY, USA

Len Zheleznyak 

Aixa Alarcon  Flaum Eye Institute, University of Rochester, Rochester, NY, USA

Center for Visual Science, University of Rochester, Rochester, NY, USA
Brain and Cognitive Sciences, University of Rochester, Rochester, NY, USA
Psychological Sciences and Vanderbilt Vision Research Center, Vanderbilt University, Nashville, TN, USA

Kevin C. Dieter 

The Institute of Optics, University of Rochester, Rochester, NY, USA
Center for Visual Science, University of Rochester, Rochester, NY, USA
Brain and Cognitive Sciences, University of Rochester, Rochester, NY, USA

Duje Tadin 

The Institute of Optics, University of Rochester, Rochester, NY, USA
Center for Visual Science, University of Rochester, Rochester, NY, USA
Flaum Eye Institute, University of Rochester, Rochester, NY, USA

Geunyoung Yoon 

Monovision presbyopia interventions exploit the binocular nature of the visual system by independently manipulating the optical properties of the two eyes. It is unclear, however, how individual variations in ocular dominance affect visual function in monovision corrections. Here, we examined the impact of sensory ocular dominance on visual performance in both traditional and modified monovision presbyopic corrections. We recently developed a binocular adaptive optics vision simulator to correct subjects' native aberrations and induce either modified monovision (1.5 D anisometropia, spherical aberration of -0.1 and -0.4 μm in distance and near eyes, respectively, over 4 mm pupils) or traditional monovision (1.5 D anisometropia). To quantify both the sign and the degree of ocular dominance, we utilized binocular rivalry to estimate stimulus contrast ratios that yield balanced dominance durations for the two eyes. Through-focus visual acuity and contrast sensitivity were measured under two conditions: (a) assigning dominant and nondominant eye to distance and near, respectively, and (b) vice versa. The results revealed that through-focus visual acuity was unaffected by ocular dominance. Contrast sensitivity, however, was significantly improved when the dominant eye coincided with superior optical quality. We hypothesize that a potential mechanism behind this observation is an interaction between ocular dominance and binocular contrast summation, and thus, assignment of the dominant eye to distance or near may be an important factor to optimize contrast threshold performance at different object distances in both modified and traditional monovision.

Introduction

As the population ages, an increasing portion is affected by presbyopia, the age-related loss of accommodation. While a wide variety of techniques are clinically available for regaining near vision by

Citation: Zheleznyak, L., Alarcon, A., Dieter, K. C., Tadin, D., & Yoon, G. (2015). The role of sensory ocular dominance on through-focus visual performance in monovision presbyopia corrections. *Journal of Vision*, 15(6):17 1-12. <http://www.journalofvision.org/content/15/6/17>, doi: 10.1167/15.6.17.

doi: 10.1167/15.6.17 Received November 3, 2014; published May 22, 2015 ISSN 1534-7362 © 2015 ARVO



Método

- ❑ **Cirugía bilateral secuencial diferida** (aprox. 7 días) con anestesia tópica y antibiótico intracameral.
- ❑ **Cálculo** de la potencia a implantar de LIO (IOL Master) con Haigis y Kane.
- ❑ Tratamiento **postop** estándar y controles según protocolo (24 h, 7 d, 1 mes, 3 meses)

Accuracy of 8 intraocular lens calculation formulas in relation to anterior chamber depth in patients with normal axial lengths



Sabite Emine Gökce, MD, Ildamaris Montes De Oca, MD, David L. Cooke, MD, Li Wang, MD, PhD, Douglas D. Koch, MD, Zaina Al-Mohtaseb, MD

Purpose: To determine the effect of anterior chamber depth (ACD) on the accuracy of 8 intraocular lens calculation formulas in patients with normal axial lengths (ALs).

Setting: Baylor College of Medicine, Alkek Eye center, Houston, Texas, USA.

Design: Retrospective case series.

Methods: Patients having cataract surgery with ALs between 22.0 mm and 25.0 mm were divided into 3 groups based on their preoperative ACD measurement. The mean prediction errors, mean absolute errors (MAEs), and median absolute errors for each group were calculated.

Results: For the ACD of 3.0 mm or less group and the ACD of 3.5 mm or more group, the Barrett Universal II, Holladay 2, Haigis,

and Olsen ray-tracing formulas had mean prediction error values that were not significantly different from zero. For the ACD of 3.01 to 3.49 mm group, all formulas had mean prediction error values that were not significantly different from zero. For the ACD of 3.0 mm or less group, the Barrett Universal II formula had a smaller median absolute error than the Haigis, Hoffer Q, and Olsen optical low-coherence reflectometry (OLCR) (Lenster) formulas and a smaller MAE than the Hoffer Q, Hill-RBF, and Olsen OLCR ($P < .05$). In the ACD of 3.5 mm or more group, the Barrett MAE was smaller than the Hoffer Q ($P < .05$); however, there were no significant differences between median absolute errors.

Conclusion: In eyes with normal ALs, taking preoperative ACD values into consideration might improve refractive outcomes.


J Cataract Refract Surg 2018; 44:362-368 © 2018 ASCRS and ESCRS

Método

- ❑ Después de la operación, los pacientes son evaluados para determinar el **resultado visual binocular**, sin corrección, en visión lejana, intermedia y de cerca, así como la **curva de desenfoque**, **sensibilidad al contraste** y los resultados informados por el paciente (PRO) utilizando la versión en español del **CAT- QUEST 9SF** y una encuesta de satisfacción propia.

ARTICLE

Validation of the Spanish Catquest-9SF in patients with a monofocal or trifocal intraocular lens



Mats Lundström, MD, PhD, Fernando Llovet, MD, PhD, Andrea Llovet, MD, Mercedes Martínez del Pozo, MD, Blas Mompean, MD, José-Vincente González, OD, Konrad Pesudovs, PhD

PURPOSE: To validate the Spanish Catquest-9SF and study patient-reported visual function after implantation of a trifocal versus a monofocal intraocular lens (IOL).

SETTING: Clínica Baviera, Valencia and Madrid, Spain.

DESIGN: Prospective case series.

METHODS: The Catquest-9SF was translated from English to Spanish according to a standard procedure. The Spanish version was validated through Rasch analysis. Patients completed the Catquest-9SF before cataract surgery and 3 months after the surgery. The change in patient-reported visual function caused by surgery, the level of achieved visual function, and satisfaction with vision after surgery were assessed for bilaterally implanted trifocal IOLs versus monofocal IOLs.

RESULTS: The Spanish Catquest-9SF showed very good psychometric properties. Patient-reported achieved visual function was significantly better for those with a trifocal IOL than for those with a monofocal IOL ($P < .001$). This was also true when the groups were matched for age and ocular comorbidity ($P = .006$). In multivariate analyses of all cases and matched cases (the same age and no comorbidity), the reported visual function was significantly better with trifocal IOLs than with monofocal IOLs ($P = .001$ and $P = .008$, respectively). There was greater improvement after trifocal IOL implantation in the matched cases, although not significant ($P = .103$).

CONCLUSIONS: Results show the Spanish version of Catquest-9SF is a valid patient questionnaire with good psychometric properties. Patients with a trifocal IOL implanted bilaterally reported better visual function than those with a monofocal IOL implanted bilaterally. The change in visual function after surgery was also greater in patients with a trifocal IOL.

Financial Disclosure: None of the authors has a financial or proprietary interest in any material or method mentioned.

J Cataract Refract Surg 2016; 42:1791–1796 © 2016 ASCRS and ESCRS

Cirugía de la catarata con implante
de la nueva lente intraocular
monofocal modificada RayOne EMV
para mini-monovisión:
nuestros primeros resultados.



Resultados

Resultados

- ❑ Número de pacientes: 45 (90 ojos)
- ❑ Género: 25 hombres y 20 mujeres
- ❑ Edad media: $72,4 \pm 7$ años (entre 47 y 85 años)



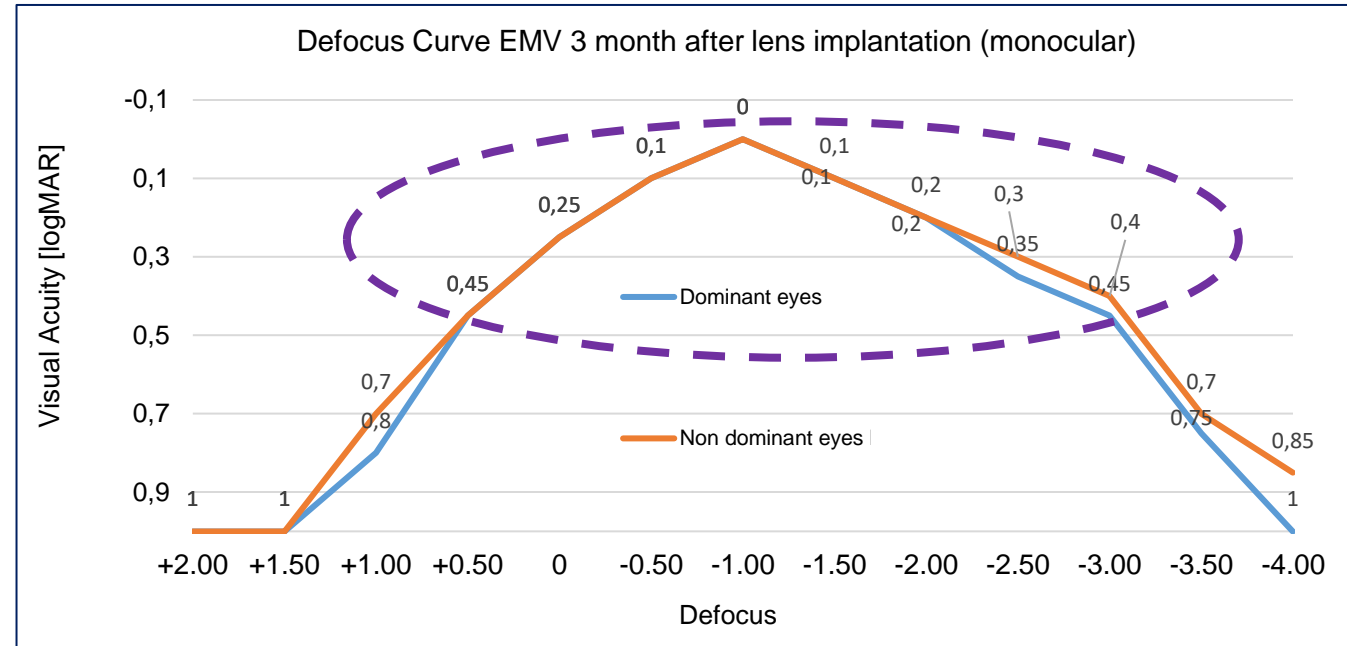
Resultados

	<u>Dominant eyes (N=45 eyes)</u> Targeted Emmetropia Achieved off set: -0.25D	<u>Non dominant eyes (N=45 eyes)</u> Targeted Offset -1.00D Achieved off set: -1 D	<u>Binocular (N= 90 eyes)</u>
Parameters	VA (LogMAR)	VA (LogMAR)	VA (LogMAR)
UDVA (mean ±SD)	0.0 ± 0.09	0.2 ±0.20	0.0 ±0.05 (20/20 Snellen) Improvement of 2 lines Compared to the VA of nondominant eyes
CDVA (mean ±SD)	0.0 ± 0.05	0.0 ±0.06	0.0 ±0.05 (20/20 Snellen)
UIVA @66cm (mean ±SD)	0.0 ± 0.05	0.3 ±0.17 (20/40 Snellen)	0.2 ±0.17 (20/32 Snellen) Improvement of 1 line Compared to the VA of nondominant eyes
UNVA @40cm (mean ±SD)	0.4 ± 0.12	0.4 ±0.13 (6 Jaeger)	0.3 ±0.14 (5 Jaeger) Improvement of 1 line Compared to the VA of nondominant eyes

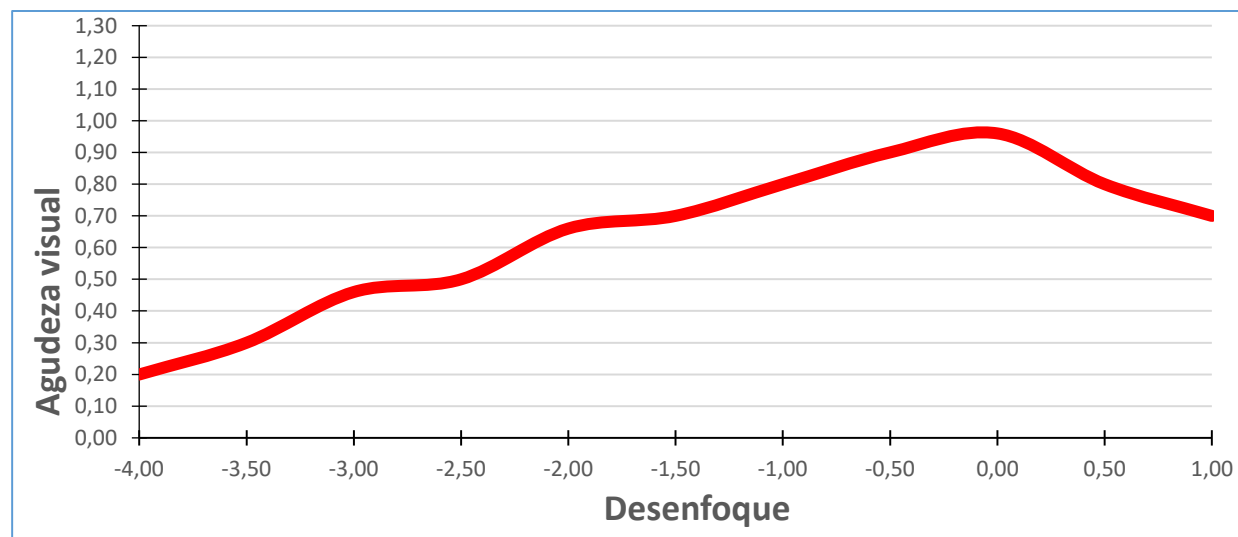
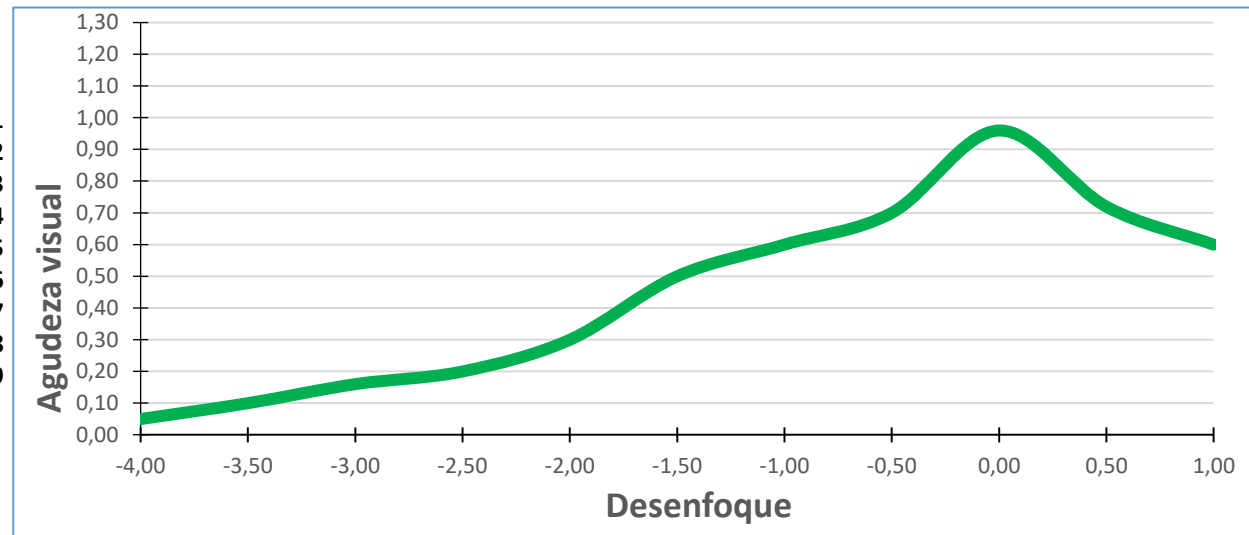
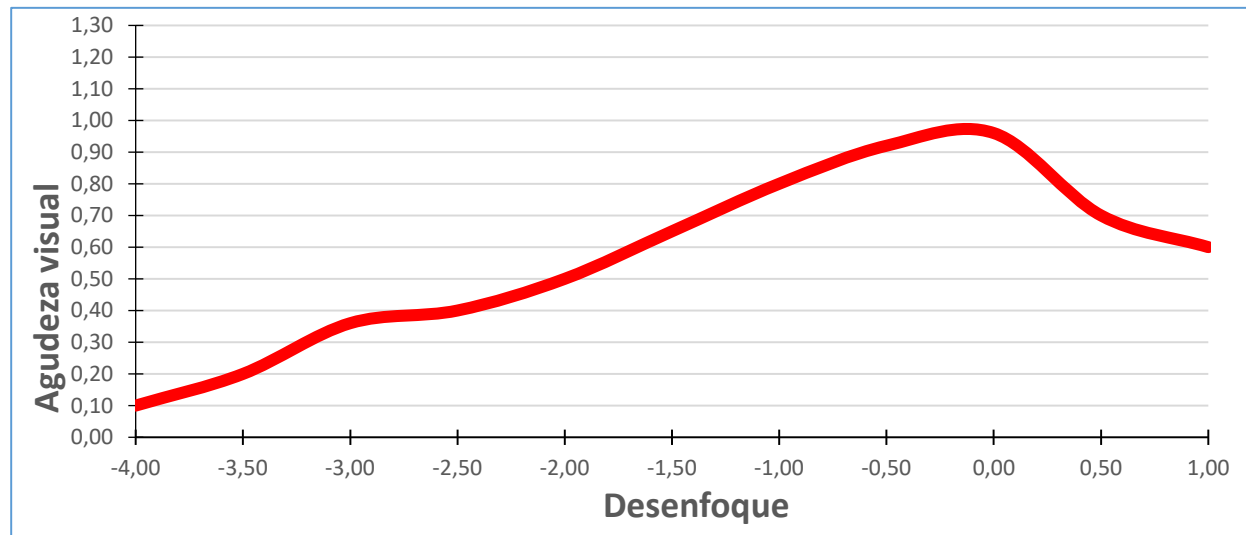
- Después de la intervención, el **EE medio** fue de:
 - 0,25 D (dominante)
 - 1 D (lector)
- Las **agudezas visuales** logMAR mostraron una media de
 - 0,0 ± 0,05 logMAR UDVA
 - 0,2 ± 0,17 logMAR UIVA
 - 0,3 ± 0,14 logMAR UNVA

Resultados

- La **curva de desenfoque monocular** evaluó la visión no corregida desde un rango de +2,0 D a -4,0 D en pasos de 0,50 D y mostró que ambos ojos habían alcanzado una agudeza visual media de 0,3 logMAR o mejor desde +0,50 D a -2,50 D a nivel de desenfoque, demostrando una amplia gama de visión funcional utilizable de cerca, intermedia y lejana.

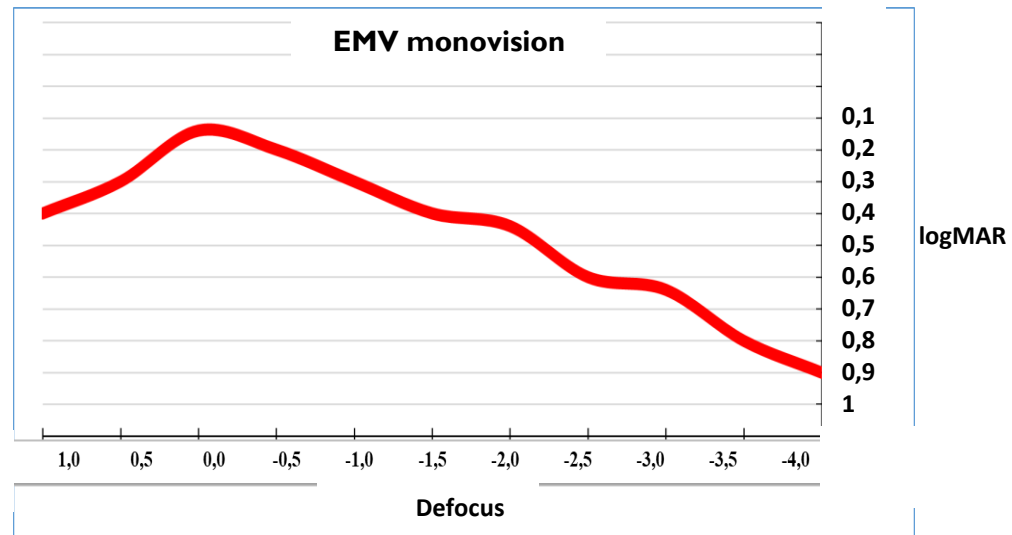
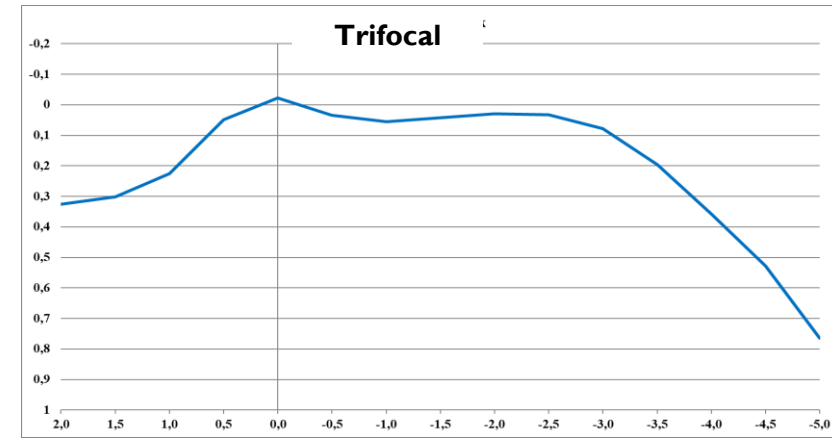
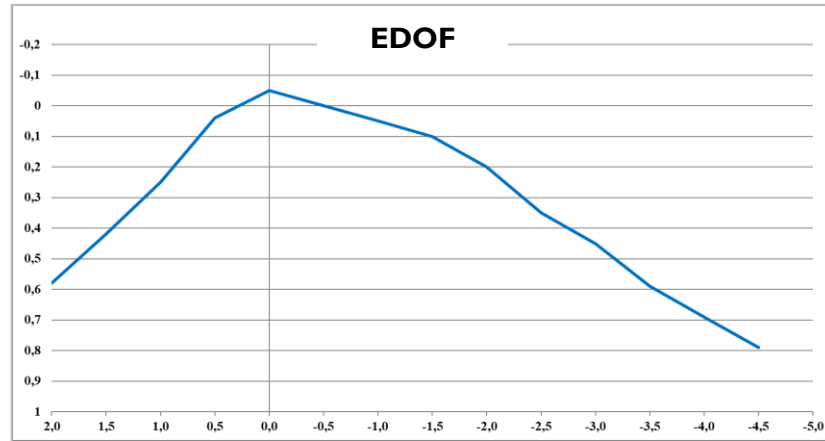
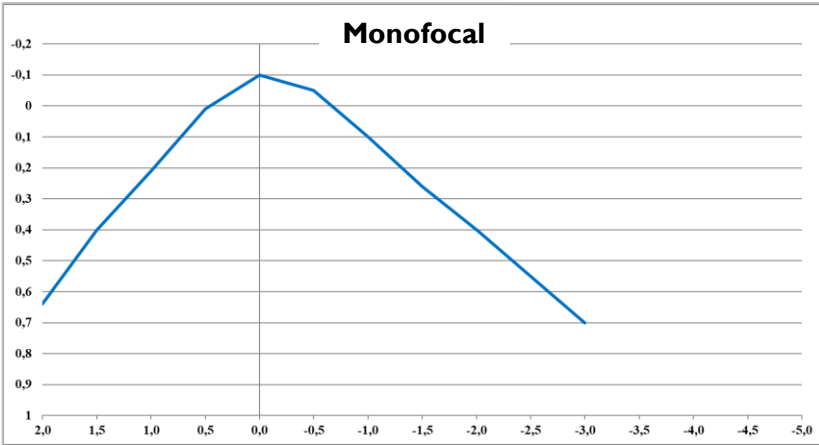


Resultados



Resultados

Curva de desenfoque

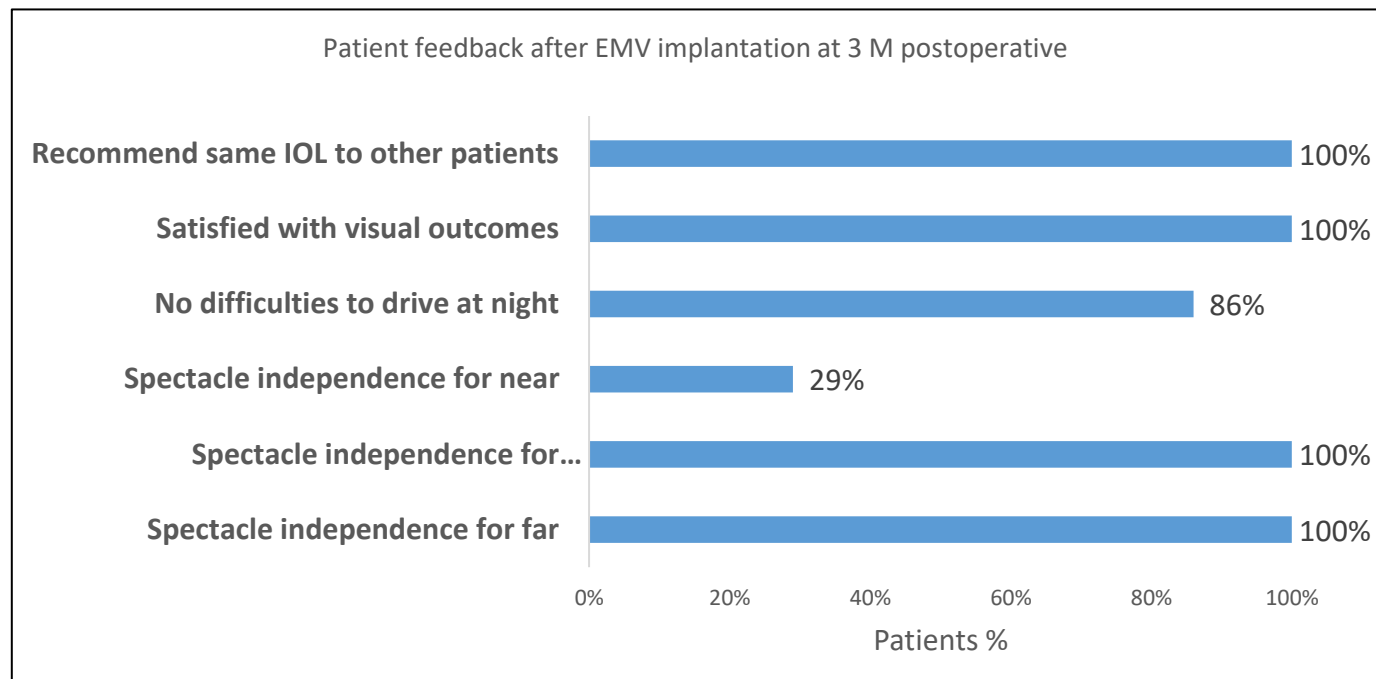


logMAR

Defocus

Resultados

- Los resultados de la **encuesta CAT-QUEST 9SF** encontraron que el 100 % de los pacientes tenían **independencia de gafas para la visión intermedia y lejana y más de una cuarta parte** de los pacientes no necesitaban gafas para tareas de **cerca**.
- Además, todos los pacientes informaron (PRO) que estaban satisfechos con su visión; el **86 % indicó que no tenía dificultad para conducir de noche**.





Conclusiones

Conclusiones

Los resultados de nuestro estudio provisional demuestran que **RayOne EMV monofocal** permite un **enfoque fiable para una monovisión mejorada**, con un **alto nivel de independencia de las gafas** para la visión de lejos, intermedia y de cerca funcional, respaldada por una curva de desenfoque muy amplia que subyace tras los **altos niveles de satisfacción** del paciente con su calidad de la visión y los resultados visuales.



Cirugía de la catarata con implante
de la nueva lente intraocular
monofocal modificada RayOne EMV
para mini-monovisión:
nuestros primeros resultados.

CLINICA BAVIERA
INSTITUTO OFTALMOLOGICO EUROPEO

Muchas gracias por su atención

flovet@clinicabaviera.com

FACO
EXTREMA