

ETHICS IN REFRACTIVE LENSECTOMY

Dr. Jorge L. Alió del Barrio MD, PhD, FEBOS-CR, FWCRS

Medical Director, Vissum (Miranza Group), Alicante (Spain)

Professor of Ophthalmology, Universidad Miguel Hernández, Alicante (Spain)

Refractive Lensectomy in Europe

¿Are we being responsible?



Questionable Indications

- Young Hyperope without presbyopia
- High Myope without cataract
- Cornea guttata
- Maculopathy
- Moderate Amblyopia
- Estrabismus

All these is arriving to my clinic

operated with Trifocal IOL!

Perfect Example: Hyperopia

- **Modern LASIK outcomes** with excimer platforms with cyclotorsion control, fast repetition rate, and optimized aspheric profiles have proven to be **safe and effective** for the management of **hyperopia up to +6.00/+6.50 D**
- So.....why Hyperopic LASIK is so unpopular among a number of surgeons?
 - Actually, **it is commonly thought that LASIK is recommended for myopia**
 - Where is this false rule coming from?
- **Potential reasons:**
 - Not all lasers treat hyperopia
 - Hyperopic LASIK is technically more demanding (large flap)
 - Management of latent hyperopia and postop spasmus

EXCUSES



Result of this Untruth

This mysterious “rule” together with the success of Trifocal IOLs is pushing many surgeons to recommend RLE in young hyperopes even without presbyopia.

Statement: “for hyperopia of greater than +4.00 D refractive lens exchange remains the only surgical option.”



ORIGINAL ARTICLE

Bilateral Refractive Lens Exchange With Trifocal Intraocular Lens for Hyperopia in Patients Younger Than 40 Years: A Case–Control Study

ABSTRACT

PURPOSE: To evaluate visual outcomes, satisfaction, and spectacle independence in non-presbyopic hyperopic patients who underwent bilateral refractive lens exchange with a trifocal intraocular lens (IOL) and to compare them with presbyopic hyperopic patients.

METHODS: In this retrospective study, patients younger than 40 years underwent bilateral refractive lens exchange with a diffractive trifocal IOL (FineVision Micro F; PhosOL SA) for hyperopia with at least 3 months of follow-up. A control group of patients older than 50 years was matched by axial length, sex, and follow-up. Safety, efficacy, predictability, patient satisfaction, and spectacle independence were evaluated.

RESULTS: One hundred thirty-three patients (average age = 36.94 ± 2.91 years; range = 21.50 to 40 years) were included in this study. After a mean follow-up of 8.83 ± 5.69 months

(range = 2.75 to 77.63 months), the safety and efficacy indexes and predictability within ± 1.00 diopters (DI) were 1.00%, 0.98%, and 99.62%, respectively, which was not different from the control group ($P > .05$). No intraoperative complications were recorded. The only postoperative complication was posterior capsule opacification in 21 eyes (7.89%), which was similar to the control group ($P = .05$). Ninety-seven percent of patients in each group expressed that they were satisfied and all of them in each group reported that they did not use spectacles for distance, intermediate, or near vision.

CONCLUSIONS: Refractive lens exchange and trifocal IOL implantation for hyperopia in patients without presbyopia provided the same good visual outcomes as in presbyopic patients with a high rate of patient satisfaction and spectacle independence.

[J Refract Surg. 2021;37(8):624–631.]

Surgical correction of hyperopia is challenging in young patients. Laser corneal refractive surgery is usually limited to +4.00 diopters (D).¹ However, higher order corneal aberrations and regression remain important challenges after laser in situ keratomileusis (LASIK) ablation for high hyperopia.² The phakic intraocular lens (IOL) is a viable option in higher ranges of hyperopia, although affected eyes usually have a shallow anterior chamber.³ In such cases, refractive lens exchange remains the only surgical option and could benefit the eye in terms of a re-

duced risk of angle-closure glaucoma.⁴ However, there are some concerns with refractive lens exchange in younger patients that include loss of accommodation, complications, and loss of lines of vision because the magnifying effect of the positive lens has been omitted. The United States Food and Drug Administration has not approved the use of pseudophakic IOLs for the sole purpose of correcting refractive error in the absence of visually significant cataract, and some ophthalmological institutions do not recommend refractive lens exchange for hyperopia in patients younger

- **Technology:** *Amaris Schwind*
- **Hyperopia range:** ≥ 3.50 and $\leq 6.50D$
- **Inclusion criteria:**
 - Latent hyperopia $\leq 1.25D$
 - Maximal cycloplegic hyperopia of $+7.00D$
 - Expected postop K2 $< 50D$.

Study sample: 92 eyes (64 patients)

Mean age: 34.6 ± 10.4 years

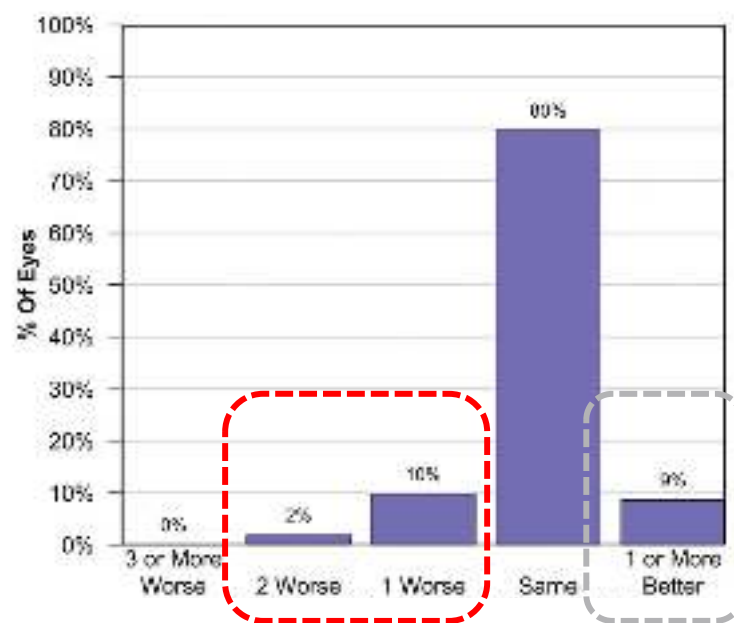
Mean OZ: $6.76 \pm 0.22mm$



Alió Del Barrio JL, Milán-Castillo R, Canto-Cerdan M, Molina-Lespron A, Alió JL. **FS-LASIK for the treatment of moderate-to-high hyperopia.** J Cataract Refract Surg. 2023 Jun 1;49(6):558-564.

Efficacy & Safety:

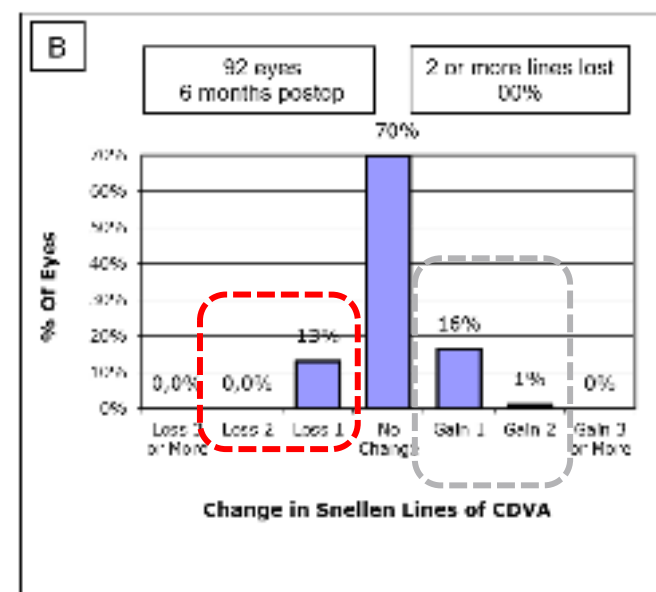
RLE
(young hyperopes)



Efficacy Index: 0.98

Safety Index: 1.02

LASIK ≥ 3.5 & $\leq 6D$



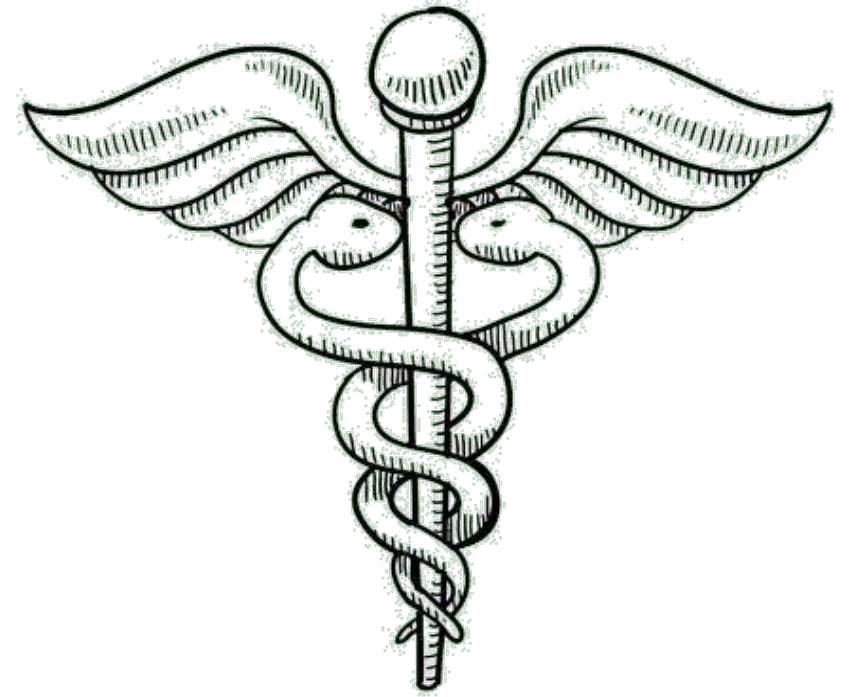
Change in Corrected Distance Visual Acuity

- Efficacy Index: 0.91
- Safety Index: 1

Limit Age for RLE?

1. Is it ethical to perform RLE just for refractive purposes in such young patients with **degrees of hyperopia** in many cases **well managed with modern laser refractive surgery**?
2. **How all these different trifocal IOLs** from different companies and different materials **are going to optically perform in 40, 50 or even 60 years?**

First



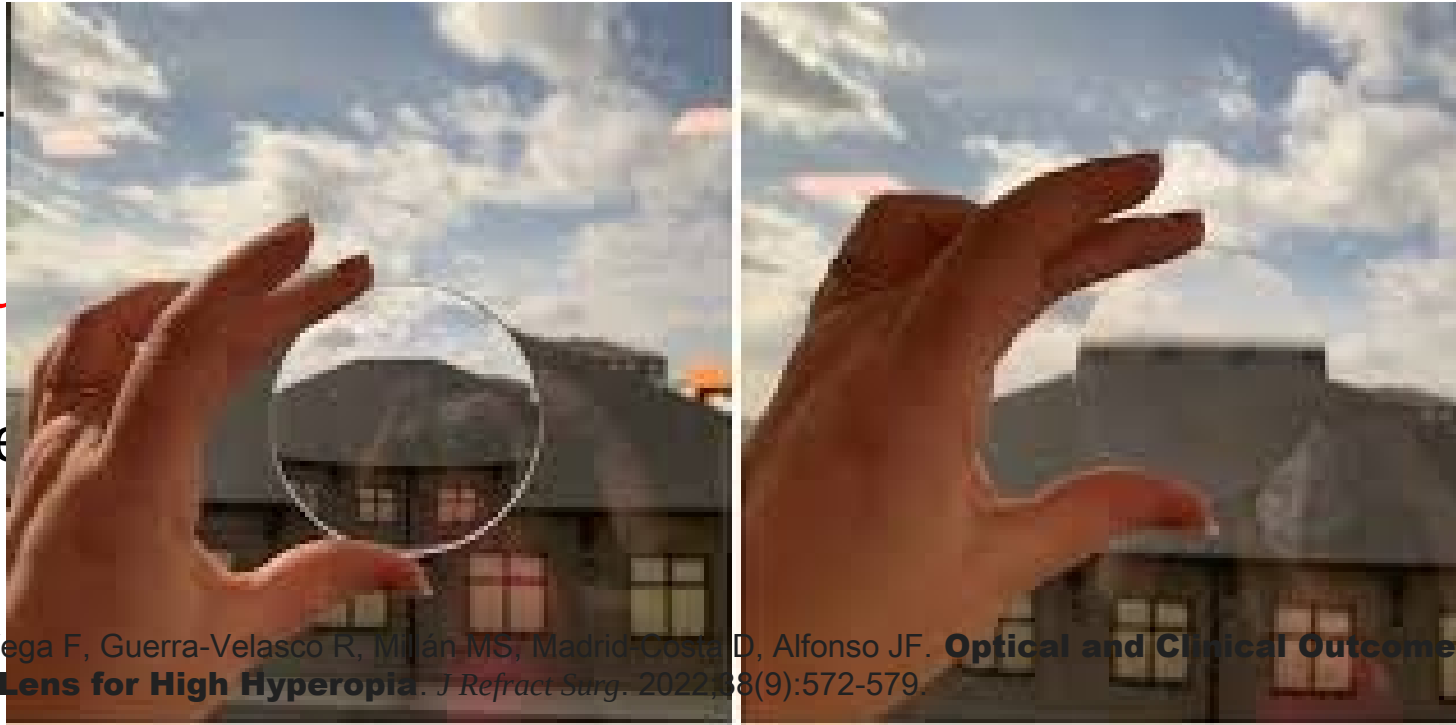
Do No Harm

¿MF IOLs in High Hypeopia?

NO

Limitations of MF IOLs in High Hyperopia

- Image minimization effect
 - **Controversial to implant Trifocals above +30D** (image minification effect + CS loss)
- Many MF IOLs (e.g., +30D)
- **Monofocal plus** (e.g., +30D) and near outcomes due to stronger



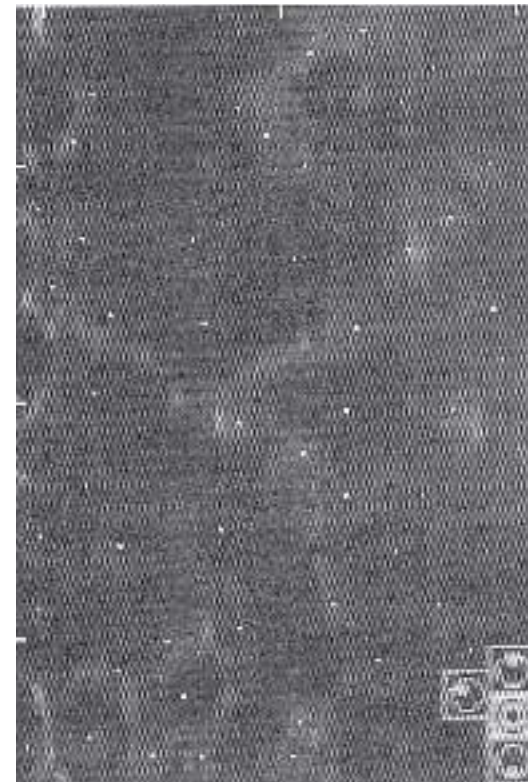
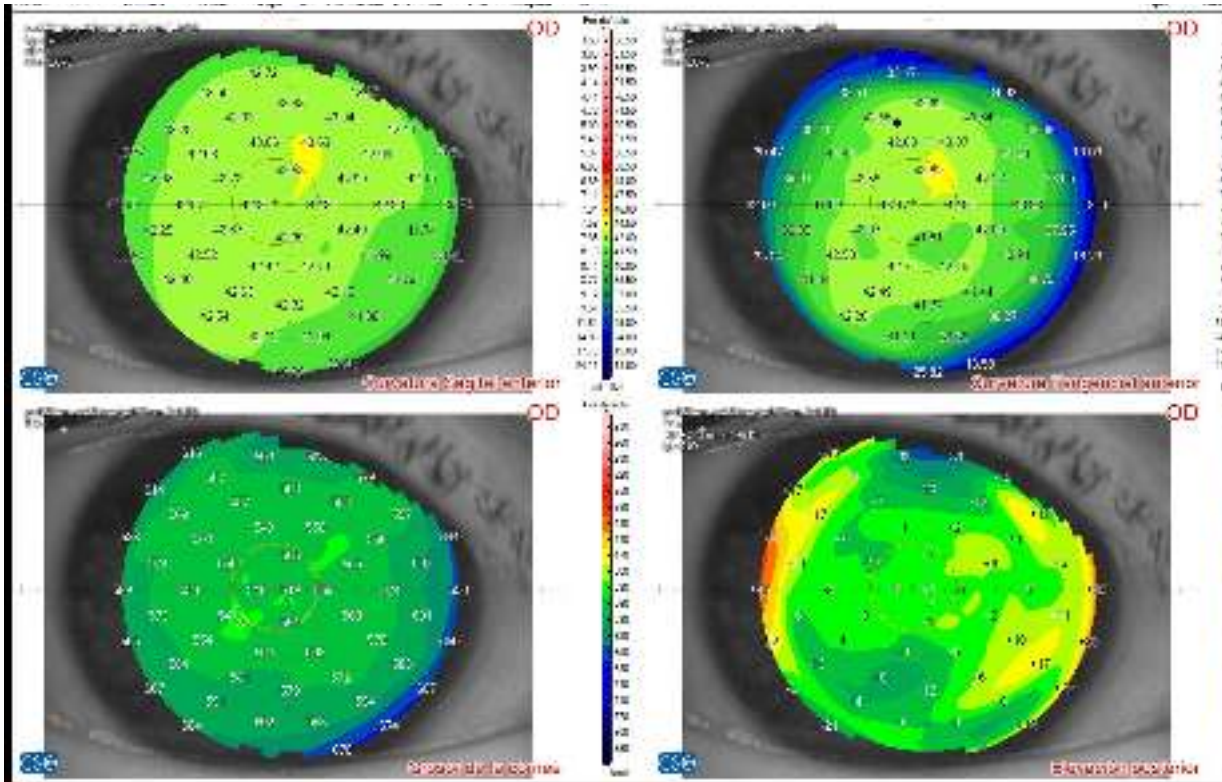
Fernández-Vega-Cueto L, Vega F, Guerra-Velasco R, Millán MS, Madrid-Costa D, Alfonso JF. **Optical and Clinical Outcomes of an Enhanced Monofocal Intraocular Lens for High Hyperopia.** *J Refract Surg.* 2022;38(9):572-579.

¿MF IOLs in Cornea Guttata?

NO

Case Report

- *FED patient.*
- *Trifocal BE elsewhere*



Post Trifocal VA

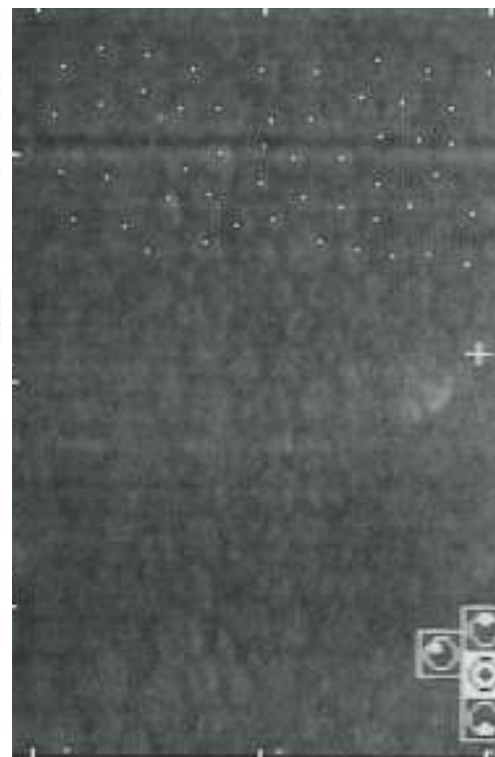
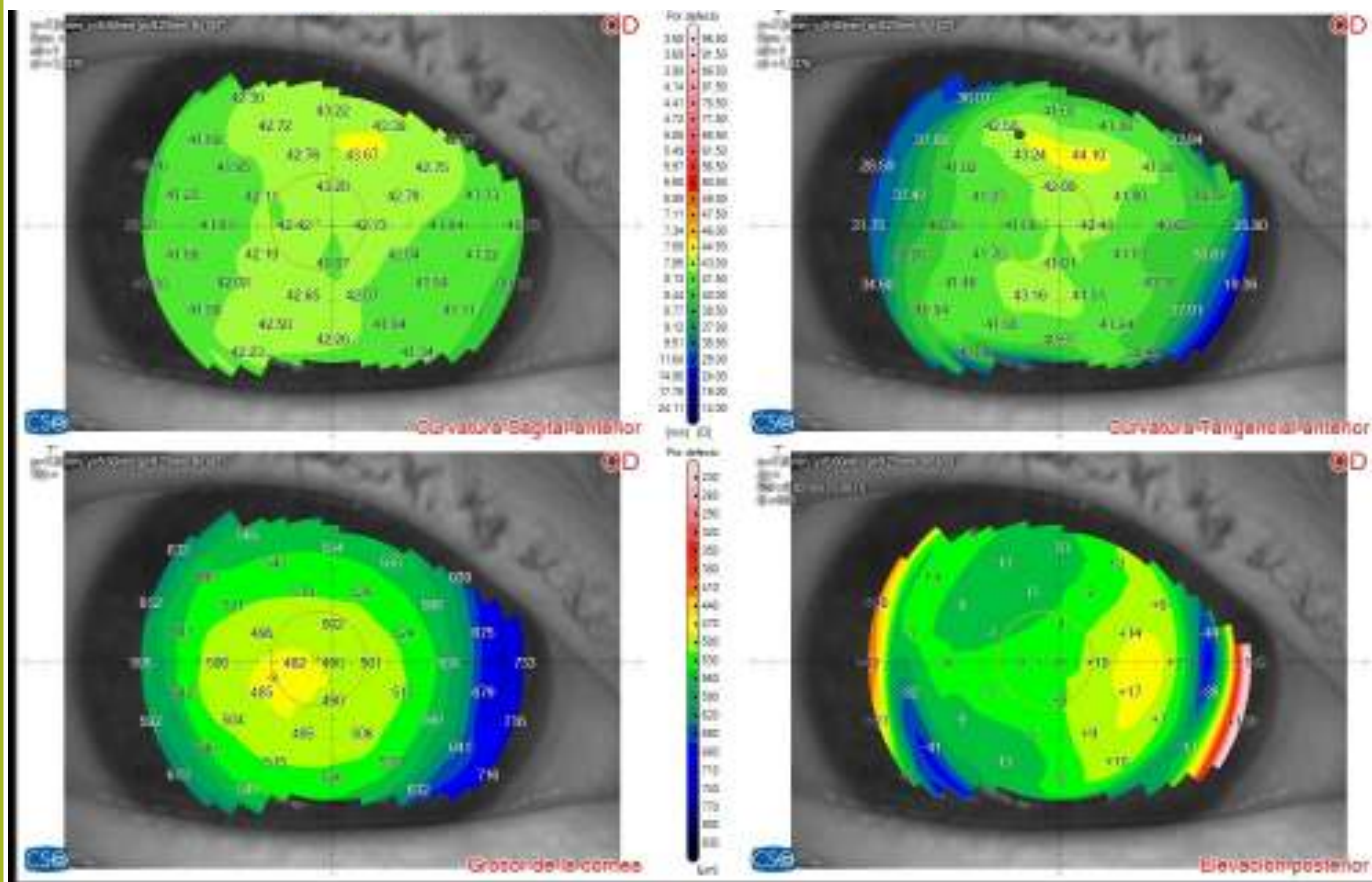
BE

UDVA: 0.4

CDVA: 0.4

Case Report

- DMEK BE



Post DMEK VA

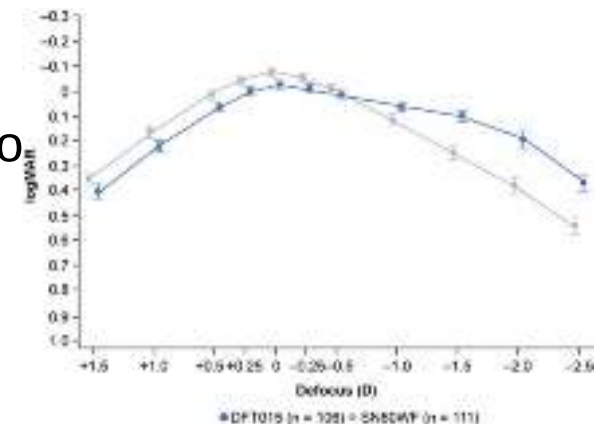
BE

UDVA: 1

UNVA: 1

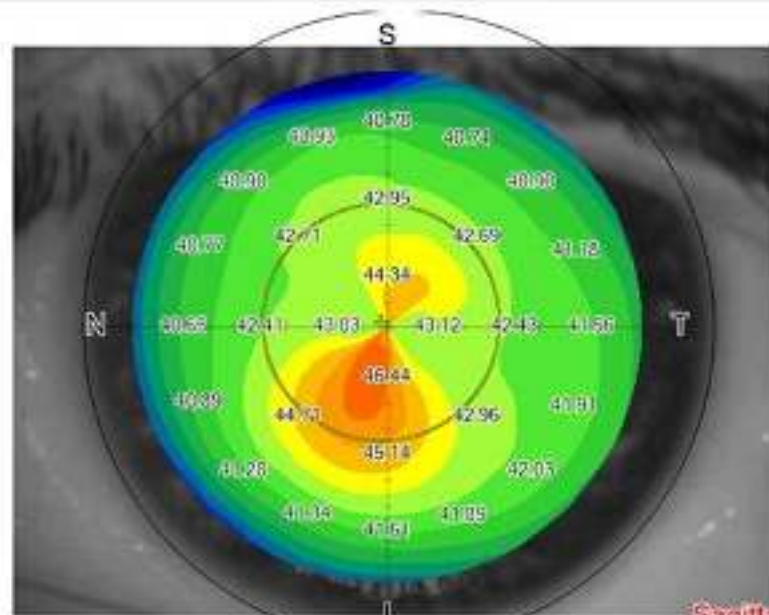
Multifocal IOLs & Guttata

- Mild isolated guttas (*No FED*): no restrictions
- Central moderate guttata (*No FED*):
 - Skip Multifocals.
 - Never hydrophilic IOLs
 - ¿Real EDOF? Controversial, variable outcomes
- Severe guttata (*FED*):
 - Skip all types of premium IOLs (including monofocal plus). Only regular mo
 - Never hydrophilic IOLs
 - Phaco-DMEK: EDOF IOL? Possible



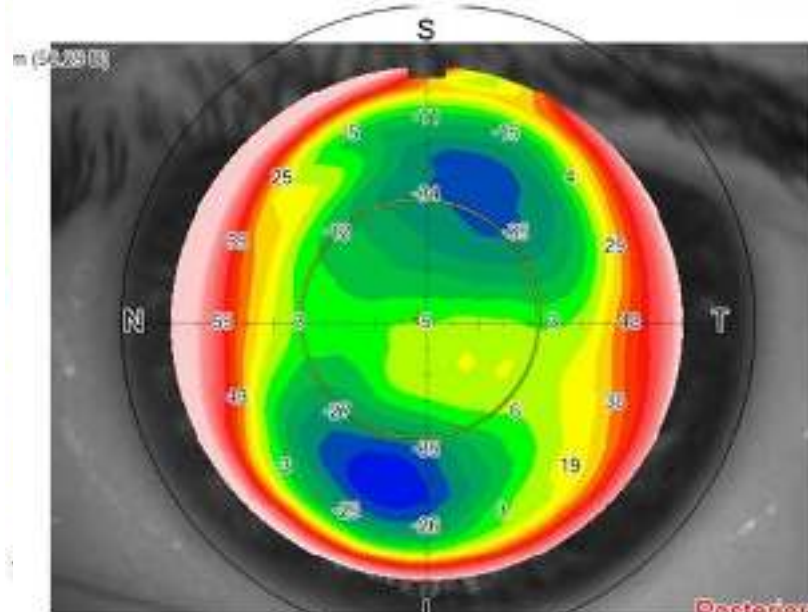
¿MF IOLs in KC?

NO



OS

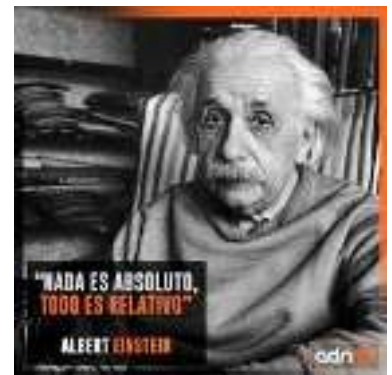
Sagittal anterior



OS

Posterior elevation

2 ¹² Astigmatism	2.42 μ m @ 153°	
2 ¹¹ Trifol	0.45 μ m @ 29°	
2 ¹⁰ Coma	0.55 μ m @ 103°	
2 ⁹ Quadriol	0.12 μ m @ 71°	
2 ⁸ Astigmatism II	0.56 μ m @ 73°	
2 ⁷ Spherical ab.	-0.50 μ m	
2 ⁶ Pentafol	0.07 μ m @ 36°	
2 ⁵ Trifol II	0.21 μ m @ 21°	
2 ⁴ Coma II	0.16 μ m @ 253°	
2 ³ Exafol	0.03 μ m @ 9°	
2 ² Quadriol II	0.09 μ m @ 27°	
2 ¹ Astigmatism III	0.22 μ m @ 163°	
2 ⁰ Spherical ab. II	0.26 μ m	
2 ¹⁷ Eptafol	0.02 μ m @ 15°	
2 ¹⁶ Pentafol II	0.04 μ m @ 38°	
2 ¹⁵ Trifol III	0.11 μ m @ 49°	
2 ¹⁴ Coma III	0.04 μ m @ 63°	

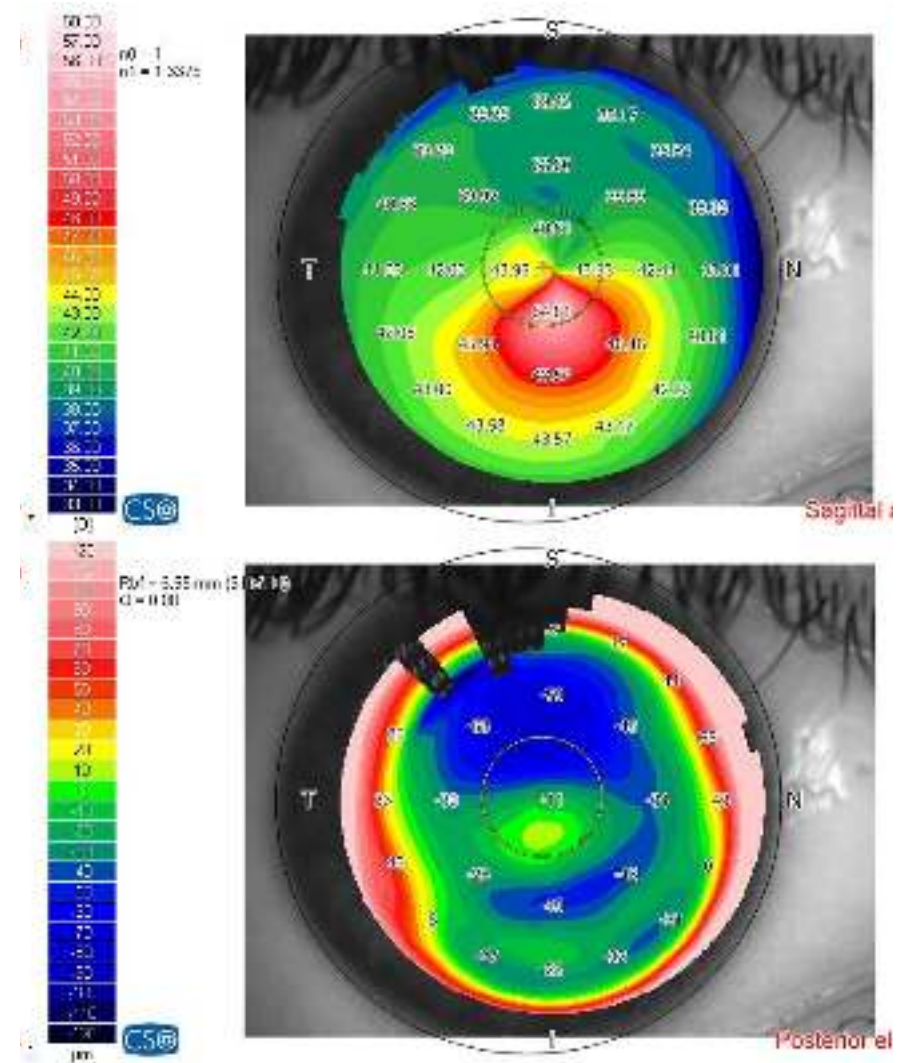


1. Preoperative Selection

KC is a progressive disease characterized by thinning and protrusion of the cornea. This results in high irregular astigmatism and myopia and a reduced visual acuity

Key elements:

- Amount of irregular astigmatism
- CDVA before cataract development



Multifocal IOLs in established KC?

- Almost no scientific evidence, so **evidence based recommendation: reject or caution**
 - 9 patients with “frank” keratoconus implanted with trifocal IOL
 - MRSE ± 0.50 D achieved 94%
 - **17% lost 1 line of CDVA**
 - 78% independent of glasses for all distances.
 - One patient required an IOL exchange due to photic phenomena

Multifocal IOLs & KC

Key elements:

- Amount of irregular astigmatism
- CDVA before cataract development

- Stable Fruste or Subclinical disease (*low aberrations*): no restrictions
- Mild disease (*low to moderate aberrations*):
 - Monofocals with monovision versus Low Power Refractive IOLs (Lentis Comfort)
 - ¿Real EDOF? Controversial, summation effect of corneal and IOL aberrations
- Moderate disease (*high aberrations*): no premium IOLs

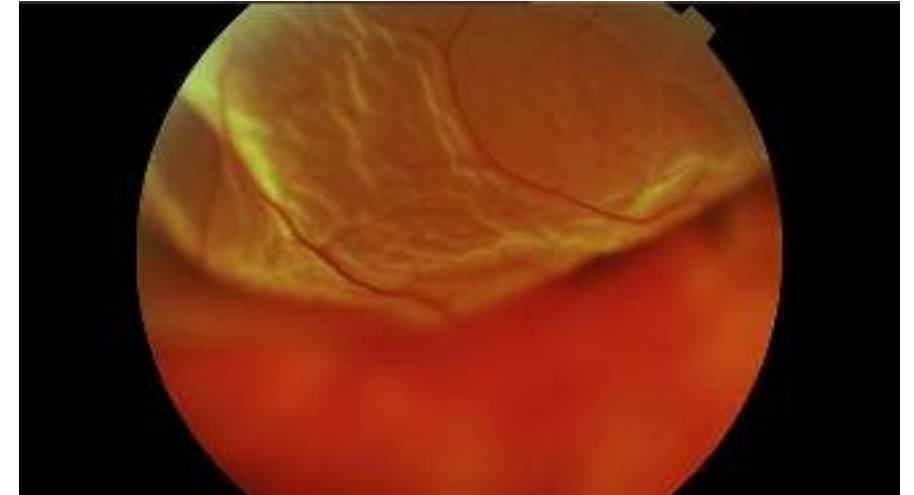
¿MF IOLs in Very High Myopia?

NO

Ideal Age for Refractive Lens Exchange?

Hyperopes >45 years

Myopes >55 years



Why? Post-Phaco Ret Detachment

Risk:

- Normal eye: <0.5%
- High Myopia (AL>26mm): 2,7%.

Higher as larger is the AL and lower the age (<50 años)

Risk factors:

Lower age (linked to PVD)

Longer AL

Previous ret detachment on the contralateral eye

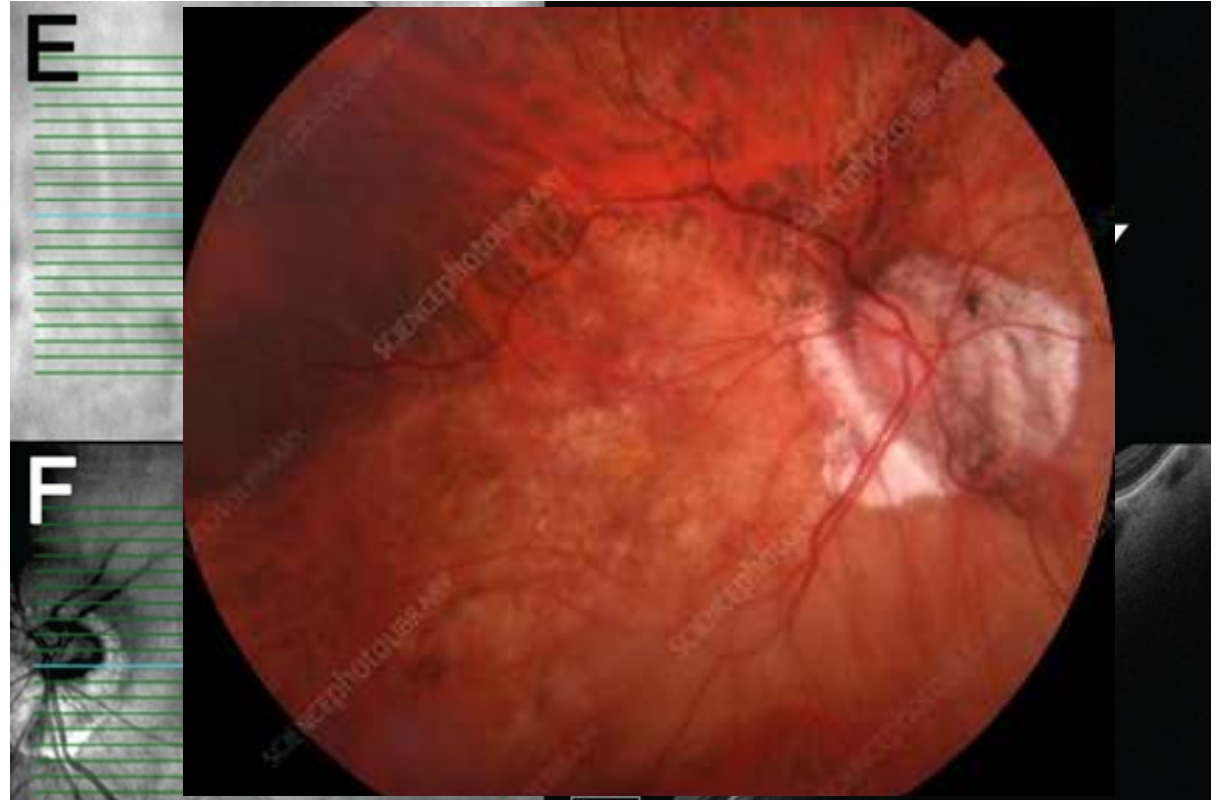
PC rupture

Aphakia

Symptomatic peripheral retina lesions

Limitations of MF IOLs in High Myopia

- Macular Tilt
- Myopic atrophic maculopathy
- Many MF IOL models not available below +10D (some up to +6D)



¿MF IOLs in Amblyopia?

NO

Multifocal IOLs & Amblyopia

- Mild disease ($CDVA \geq 0.9$): no restrictions
- Moderate disease ($CDVA \geq 0.6-0.7$): EDOF versus Monofocal Plus
- Severe disease ($CDVA < 0.6$): Monofocals



Jorge.aliodelbarrio@vissum.com

VISSUM

GRUPO MIRANZA

