

Adoption of advanced technology IOLs in cataract surgery



Sulcoflex Trifocal: Innovation in support of the best visual quality of patients

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HIGH TECH IOL: SAN MARINO EXPERIENCE

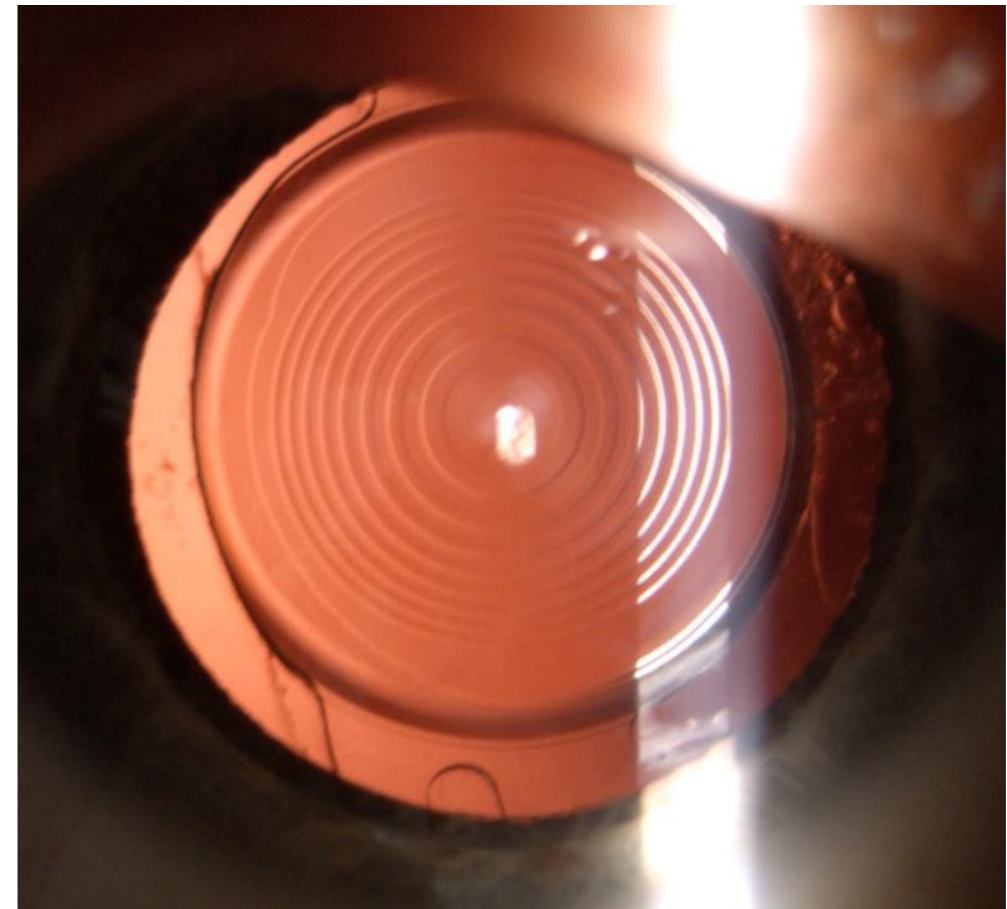
Co-payment system since June 2016 (“my” leadership started on June 2015) → which percentage?

- **2017 → 8.05%**

- ✓ Multifocal → 38.09%
- ✓ Toric → 44.44%
- ✓ Toric multifocal → 17.46%

- **2018: 10.03%**

- ✓ Multifocal → 46.30%
- ✓ Toric → 50%
- ✓ Toric multifocal → 3.70%



SULCOFLEX® TRIFOCAL - RAYNER

Sulcoflex Trifocal IOL is indicated for the correction of pseudophakic presbyopia, thereby reducing the need for spectacles.

Model Name:	Sulcoflex® Trifocal
Model Number:	IOL703F
Power Range:	<u>-3.0 D to +3.0 D (increments 0.5 D). -1.0 D to +1.0 D (increments 0.25 D)</u> Trifocal, diffractive, <u>+3.5 D near add and +1.75 D intermediate add at the IOL plane</u>

Aspheric Trifocal IOL	
Material:	<u>Single piece Rayacryl® hydrophilic acrylic</u>
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
Overall Diameter:	14.00 mm
Optic Diameter:	6.50 mm
Optic Shape:	Anterior convex, posterior concave
Asphericity:	<u>Aberration-neutral technology</u>
Haptic Angulation:	10° Posterior angulation
Haptic style:	Undulating and rounded C-loop haptics
Estimated constant for power calculation:	Expected lens position = 4.5 mm

SULCOFLEX® TRIFOCAL - RAYNER

Large, 6.5mm round-edged optic, designed to:

- Reduce the risk of pupillary block and photic effects
- Reduce risk of optic-iris capture¹
- Minimise edge glare and associated dysphotopsia¹

Optic Surface Features:

- 16 diffractive rings/steps
- 4.5 mm diffractive trifocal zone
- >4.5 mm monofocal distance zone
- Smooth anterior surface to minimise iris chafe

Sulcoflex Trifocal has been designed to offer the following patient benefits:

- Reduces visual disturbances
- Developed to be less dependent on pupil size or lighting conditions
- Improves distance vision in mesopic conditions



Large 14.0mm overall length with undulating haptics:

- Designed for stable fixation in the ciliary sulcus
- Unique undulating round edge haptic design with 10° angulation
- Excellent centration stability compared to capsular bag fixated multifocal IOLs⁵
- Reduced risk of uveal contact and abrasion¹
- Reduced Pigment Dispersion Syndrome¹
- Smooth undulating haptics to minimise the risk of adverse tissue reaction in the sulcus

Rayacryl Material for:

- Good uveal Biocompatibility⁷
- Superb optical clarity - no vacuoles or glistenings⁸

SULCOFLEX® TRIFOCAL - RAYNER

SULCOFLEX ASPHERIC



+

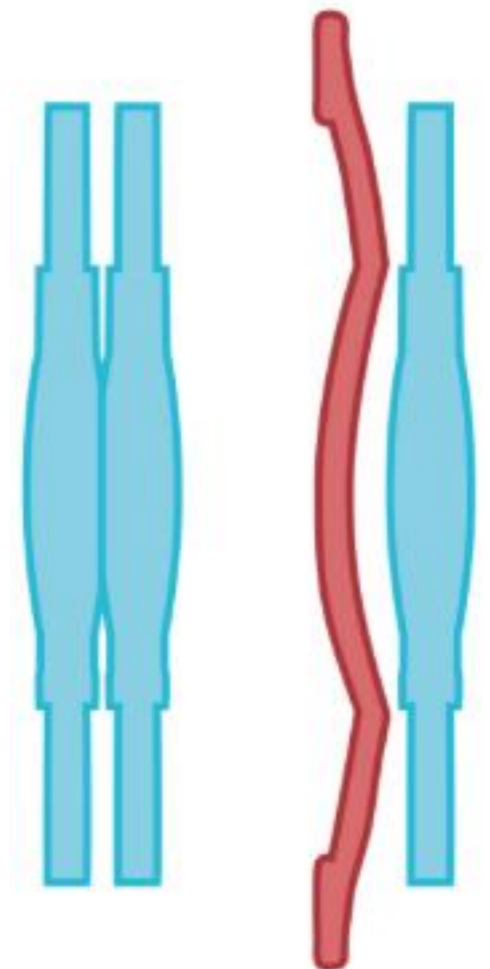
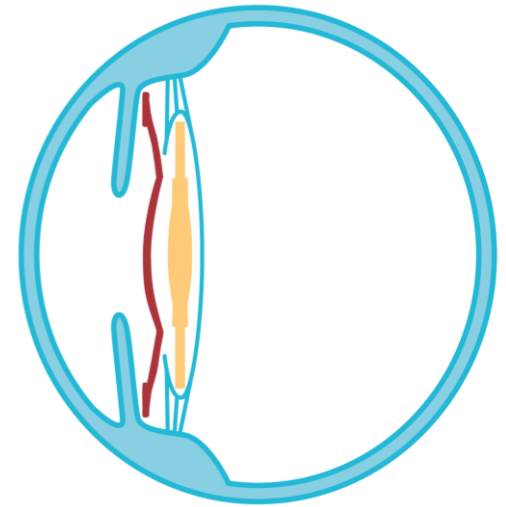
RAYONE TRIFOCAL



SULCOFLEX® TRIFOCAL - RAYNER

SULCOFLEX ASPHERIC

- Indicated for the correction of any residual pseudophakic ametropia
- Standard range from -5.0 D to +5.0 D
- Premium range extending from -10.0 D to +10.0 D
- Designed to be implanted in the ciliary sulcus following the primary implantation of a conventional IOL in the capsular bag
- Avoids the potential problems of conventional "piggy-back" IOLs:
 - ✓ Unique posterior concave surface, minimises the possibility of interaction with the primary IOL
 - ✓ Reduced likelihood of unwanted photopic effects
 - ✓ Reduced refractive error with hyperopic defocus



SULCOFLEX® TRIFOCAL - RAYNER

SULCOFLEX ASPHERIC

Model Name:	Sulcoflex Aspheric
Model Number:	653L
Power Range:	-10.0 to +10.0 D (0.5 D increments)
Optic Diameter:	6.50mm
Overall Length:	14.00mm

Delivery System	
Injector Type:	Sterile Single use loadable injector
Nozzle Size:	2.00 mm
Bevel Angle:	45°
Lens Delivery:	Single handed plunger

Aspheric Monofocal IOL	
Material:	<u>Single piece Rayacryl® hydrophilic acrylic</u>
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
Optic Shape:	<u>Posterior concave surface</u>
Asphericity:	<u>Anterior aspheric surface with aberration-neutral technology</u>
Optic Edge Design:	Round-edged optic
Haptic Angulation:	10°
Haptic style:	<u>Posterior haptic angulation</u>



SULCOFLEX® TRIFOCAL - RAYNER

SULCOFLEX ASPHERIC

- **Accuracy of results**
- **Sulcus stability**

J Refract Surg. 2012 Sep;28(9):614-9. doi: 10.3928/1081597X-20120809-01.

Correction of undesirable pseudophakic refractive error with the Sulcoflex intraocular lens.

Falzon K¹, Stewart OG.

J Refract Surg. 2011 Sep;27(9):693-6. doi: 10.3928/1081597X-20110512-01. Epub 2011 May 20.

Performance of the Sulcoflex piggyback intraocular lens in pseudophakic patients.

Khan MI¹, Muhtaseb M.

J Refract Surg. 2014 Apr;30(4):234-9. doi: 10.3928/1081597X-20140321-02.

Piggyback intraocular lens implantation to correct pseudophakic refractive error after segmental multifocal intraocular lens implantation.

Venter JA, Oberholster A, Schallhorn SC, Pelouskova M.

J Cataract Refract Surg. 2010 Jul;36(7):1090-4. doi: 10.1016/j.jcrs.2009.12.045.

New supplementary intraocular lens for refractive enhancement in pseudophakic patients.

Kahraman G¹, Amon M.

SULCOFLEX® TRIFOCAL - RAYNER

RAYONE TRIFOCAL

Features:

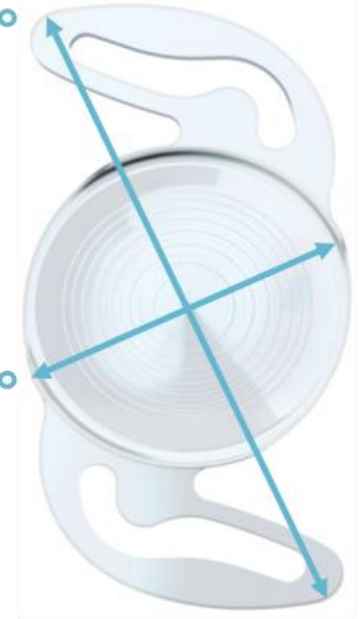
- 16 diffractive steps / rings
- 4.5 mm diffractive zone
- > 4.5 mm monofocal, distance

Benefits:

- Reduces visual disturbances
- Developed to be less dependent on pupil size or lighting conditions
- Improves distance vision in mesopic condition

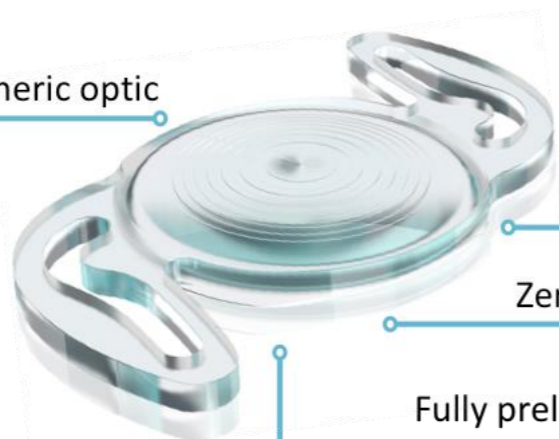
12.5 mm overall haptic length

6.0 mm optic diameter



aberration-neutral aspheric optic

Based on proven haptic technology for excellent stability



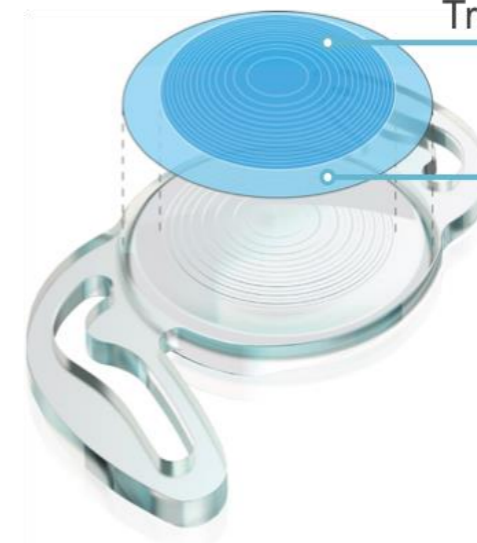
Amon-Apple enhanced square edge for minimal PCO

Zero glistenings

Fully preloaded across entire power range, 0.0 D to +30.0 D

4.5 mm Diffractive Trifocal Zone

4.5 mm Distance Zone



SULCOFLEX® TRIFOCAL - RAYNER

RAYONE TRIFOCAL

Model Name:	RayOne® Trifocal
Model Number:	RA0603F
Power Range:	0.0 D to +30.0 D (increments 0.5 D) <u>Trifocal, diffractive, +3.5 D near add and +1.75 D intermediate add at the IOL plane</u>

Delivery System	
Injector Type:	<u>Single use, fully preloaded IOL injection system</u>
Nozzle Size:	1.65 mm
Bevel Angle:	45°
Lens Delivery:	Single handed plunger

Aspheric Monofocal IOL	
Material:	<u>Single piece Rayacryl® hydrophilic acrylic</u>
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
Overall Length:	12.50 mm
Optic Diameter:	6.00 mm
Optic Shape:	Biconvex (positive powers)
Asphericity:	<u>Aberration-neutral technology</u>
Optic Edge Design:	Amon-Apple 360° enhanced square edge
Haptic Angulation:	0°, uniplanar
Haptic Style:	Closed loop with anti-vaulting haptic (AVH) technology



SULCOFLEX® TRIFOCAL - RAYNER

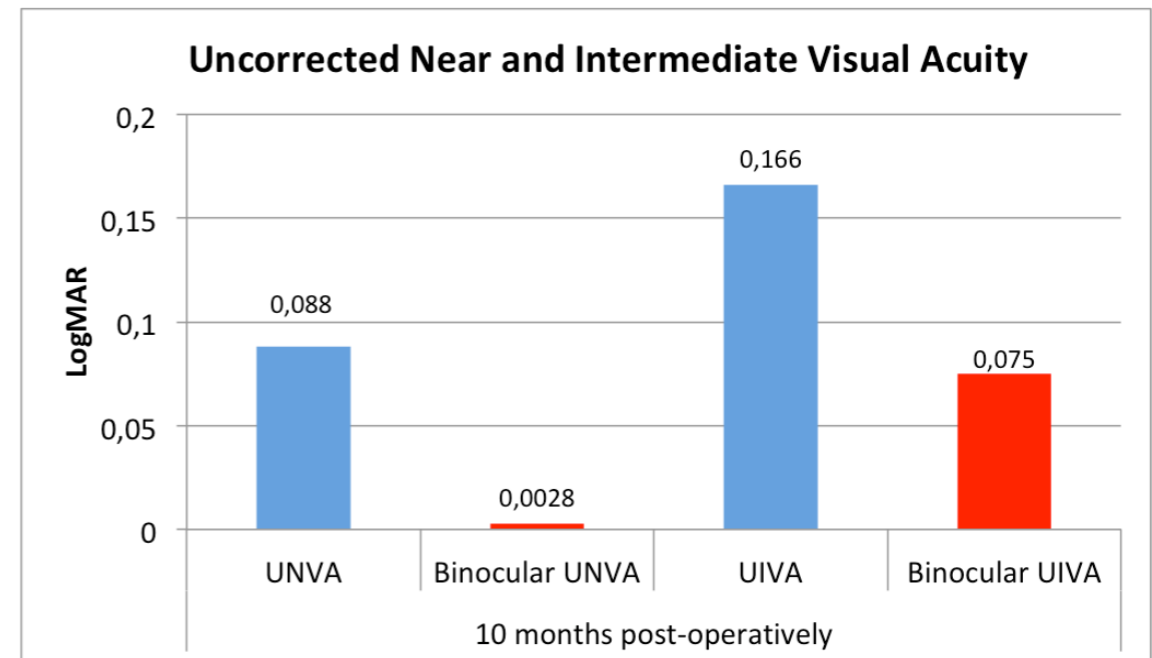
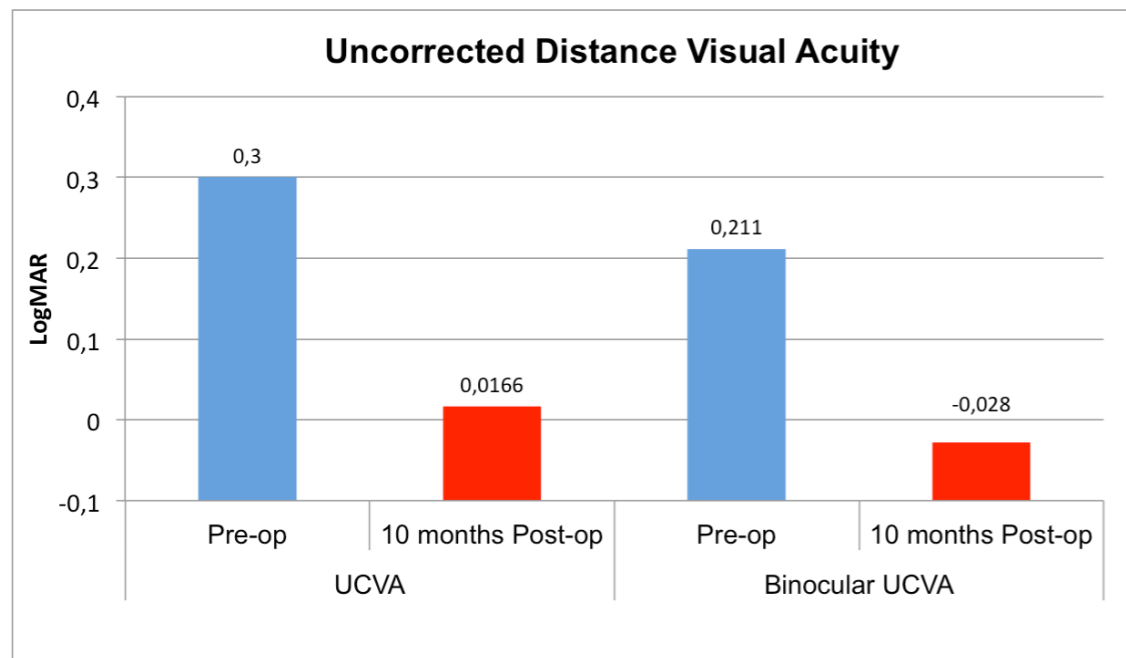
RAYONE TRIFOCAL – OUR RESULTS

- Evaluation of **visual performance**, **patient satisfaction**, **stability** and **posterior capsular opacification (PCO)** incidence in 6 patients underwent bilateral cataract surgery with implantation of new RayOne® (Rayner) trifocal intraocular lens
- Follow-up: 10 months
- Data evaluated:
 - ✓ **UCVA** and **BCVA** (LogMAR)
 - ✓ **Near** and **Intermediate** Visual Acuity (LogMAR) with MNread charts
 - ✓ **Contrast sensitivity** with MOS 22 (Dueffe Tecnovision)
 - ✓ **Defocus curve** from -4.00 D to + 4.00 D
 - ✓ **Aberrometry** (OSIRIS – CSO)
 - ✓ **Patient satisfaction** with a self-administered questionnaire (NEI-RQL-42TM)
 - ✓ **PCO incidence** and **IOL stability** with digital photos of anterior segment

SULCOFLEX® TRIFOCAL - RAYNER

RAYONE TRIFOCAL – OUR RESULTS

- All patients achieved UDVA of 0.1 LogMAR or better
- 8 patients (66%) achieved UNVA of 0.1 LogMAR or better
- 4 patients (33%) achieved UIVA of 0.1 LogMAR or better and 11 patients (91%) achieved UIVA of 0.2 LogMAR or better



SULCOFLEX® TRIFOCAL - RAYNER

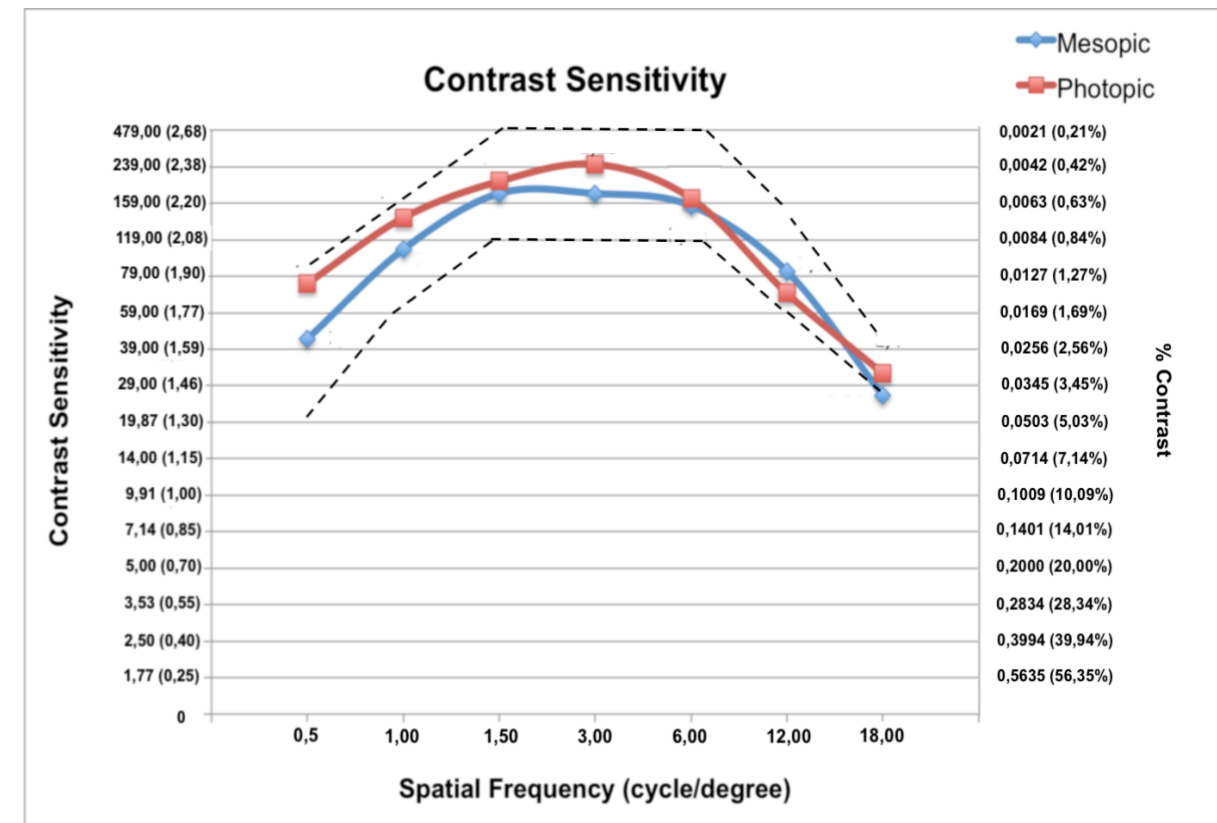
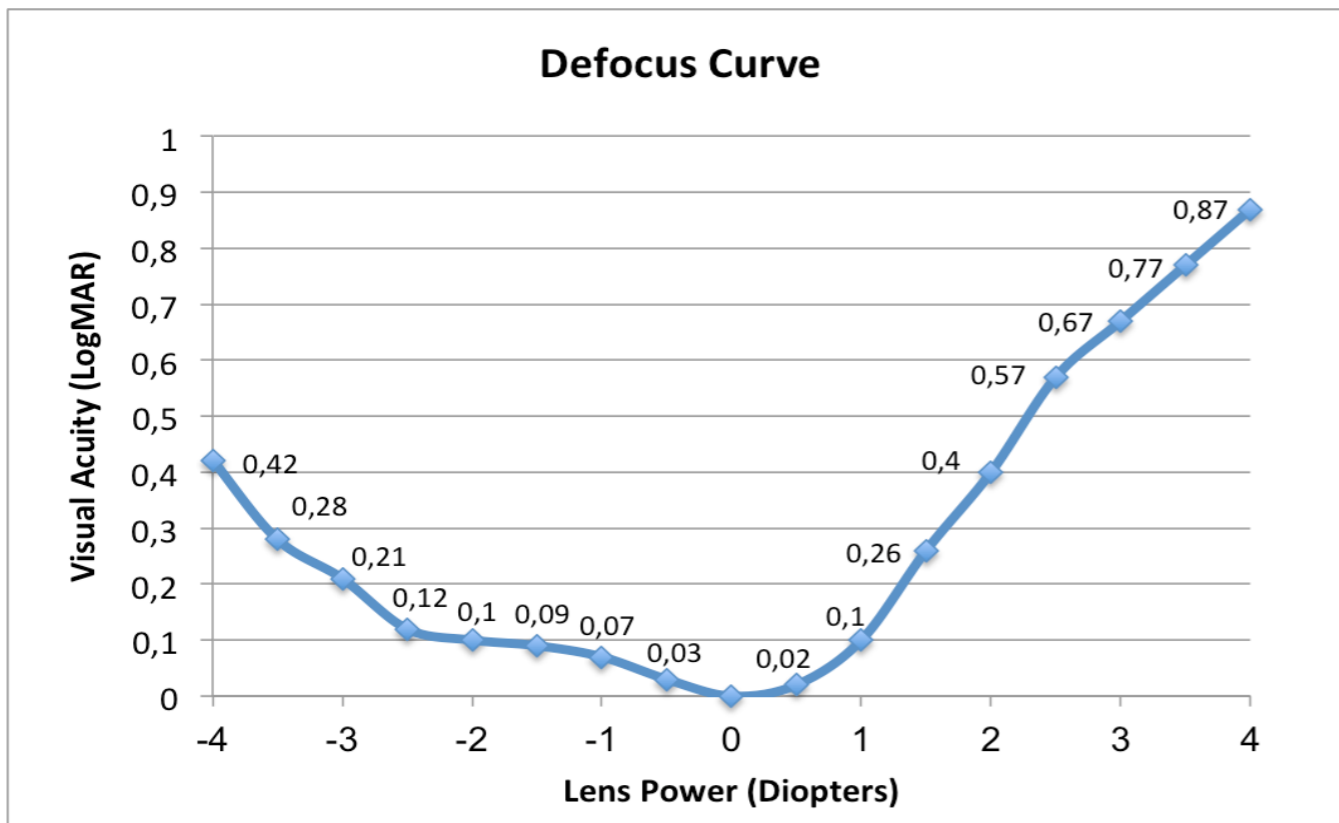
RAYONE TRIFOCAL – OUR RESULTS

Defocus curve:

- From +1.00 D to -2.00 D, visual acuity was >0.10 LogMAR in all patients, demonstrating good intermediate vision
- At -2.50 D, corresponding to near vision at 40 cm, visual acuity was 0.12 LogMAR or better

Contrast sensitivity:

- Contrast sensitivity levels were within normal limits both under photopic (85 cd/m²) and mesopic (3 cd/m²) conditions



SULCOFLEX® TRIFOCAL - RAYNER

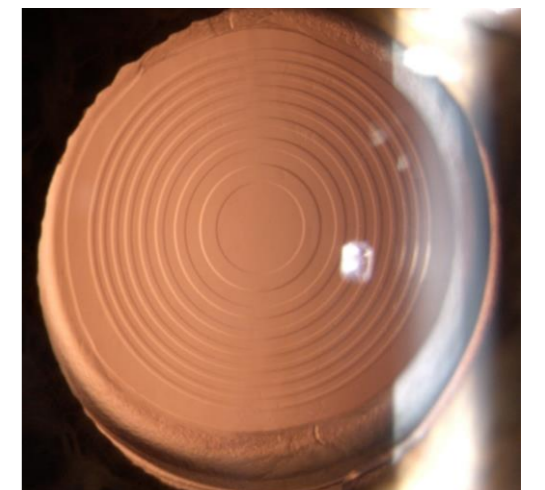
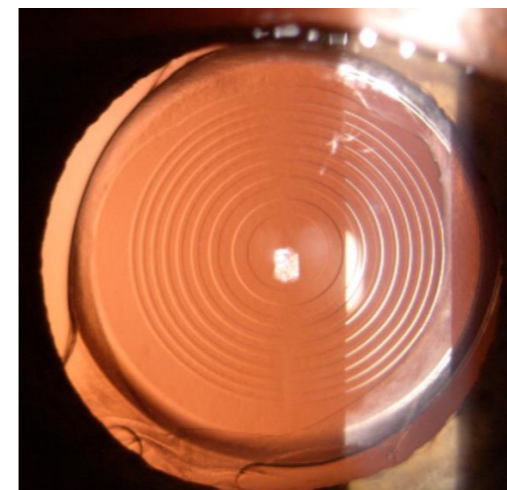
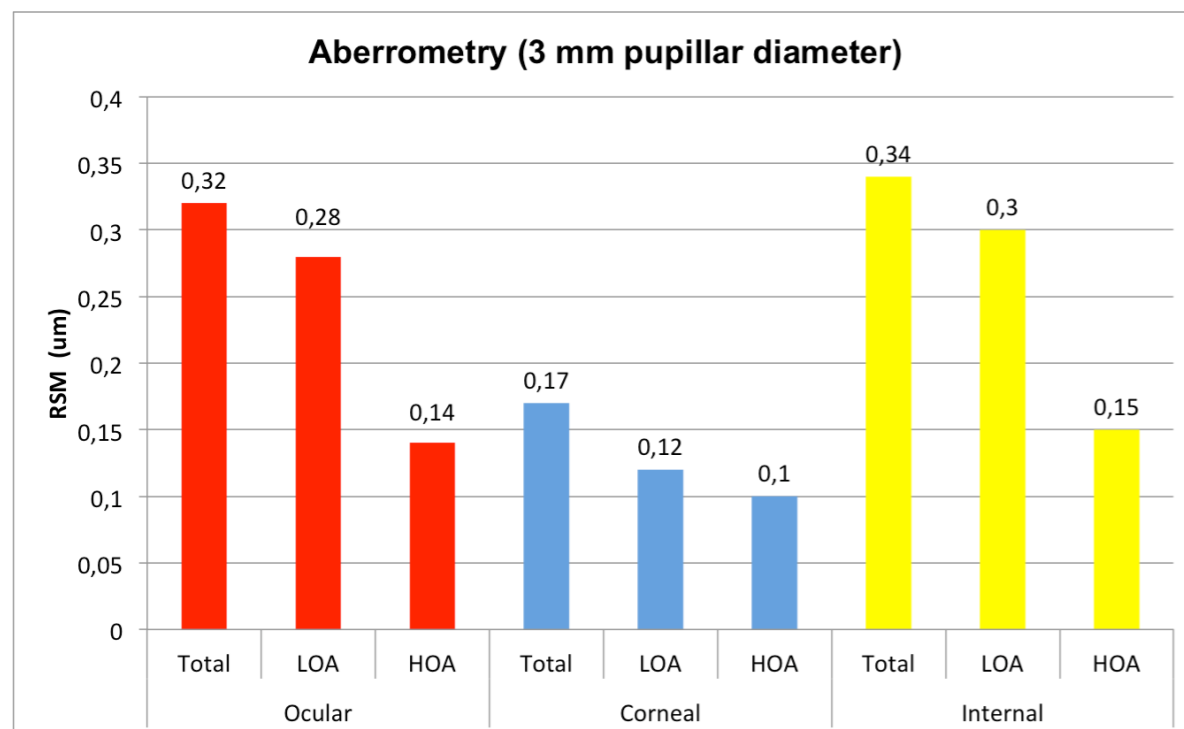
RAYONE TRIFOCAL – OUR RESULTS

Aberrometry:

- Low values of LOA and HOA regarding ocular, corneal and internal aberrations in all patients
- Internal aberrations are directly related to the IOL: low values of RSM indicate a minimum dispersion of the light inside the eye by the IOL

IOL stability and PCO incidence:

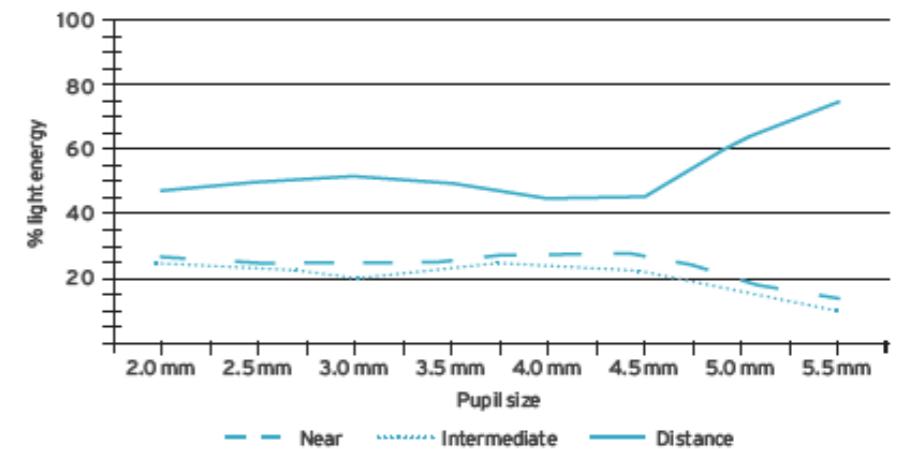
- PCO was no reported in all patients
- IOL stability and centration was excellent during the follow-up



SULCOFLEX® TRIFOCAL - RAYNER

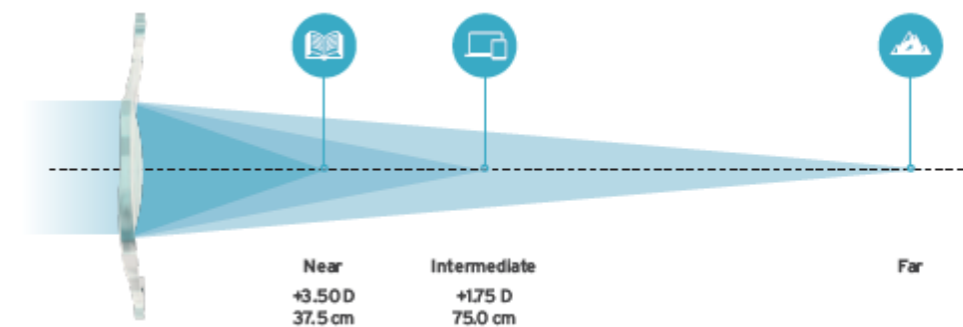
Diffraction step Trifocal technology reduces light loss to only 11%:

- 89% of light transmitted to the retina with a pupil of 3 mm
- Light Energy Split at 3.0 mm pupil:
 - ✓ 52% Distance
 - ✓ 22% Intermediate
 - ✓ 26% Near



Comfortable transition from near to distance activities :

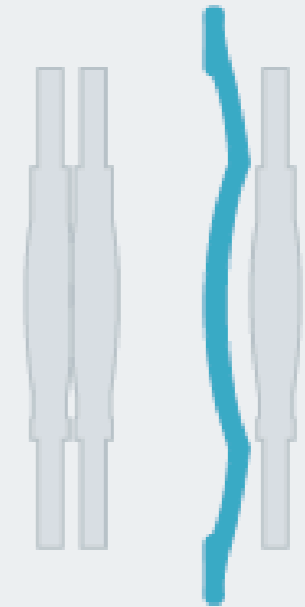
- Sulcoflex® Trifocal is designed with:
 - ✓ +3.50 D near add: 37.5 cm reading plane
 - ✓ +1.75 D intermediate add: 75.0 cm reading plane



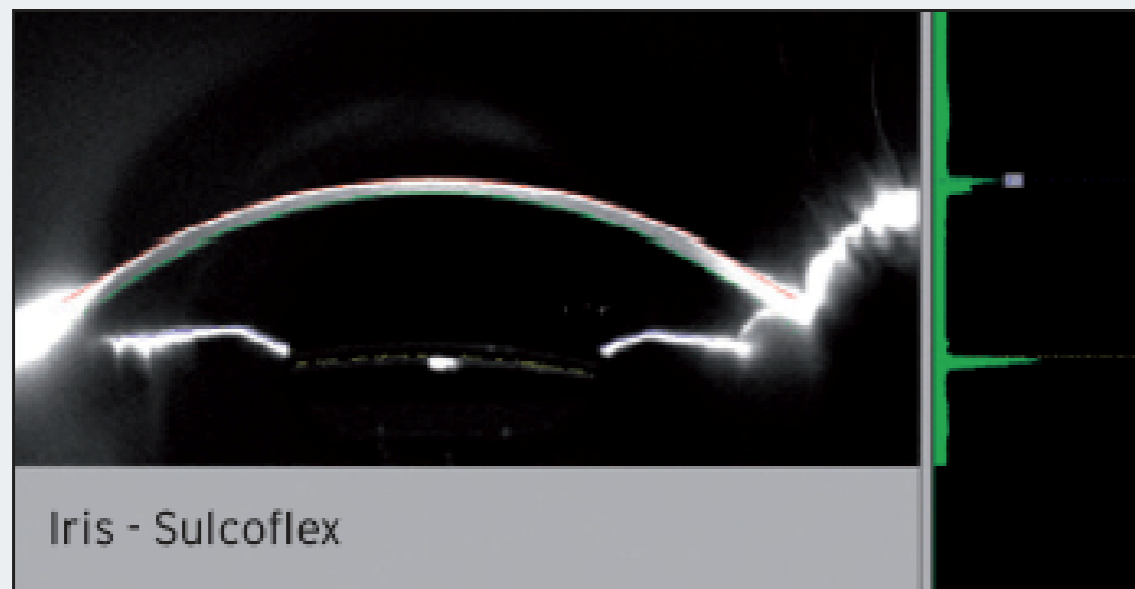
SULCOFLEX® TRIFOCAL - RAYNER

Designed to avoid the potential problems of conventional "piggy-back" IOLs^{1,6,9}

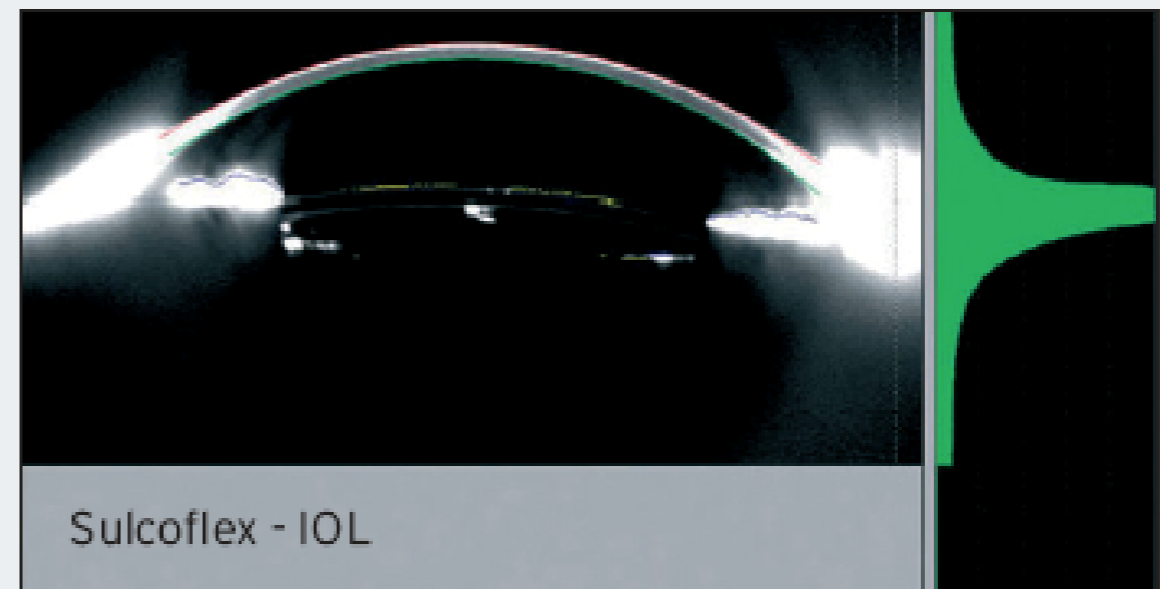
- Unique posterior concave surface minimises the possibility of interaction with the primary IOL
- Reduced likelihood of unwanted photopic effects
- Reduced refractive error with hyperopic defocus



Physical contact between the two IOLs minimised.



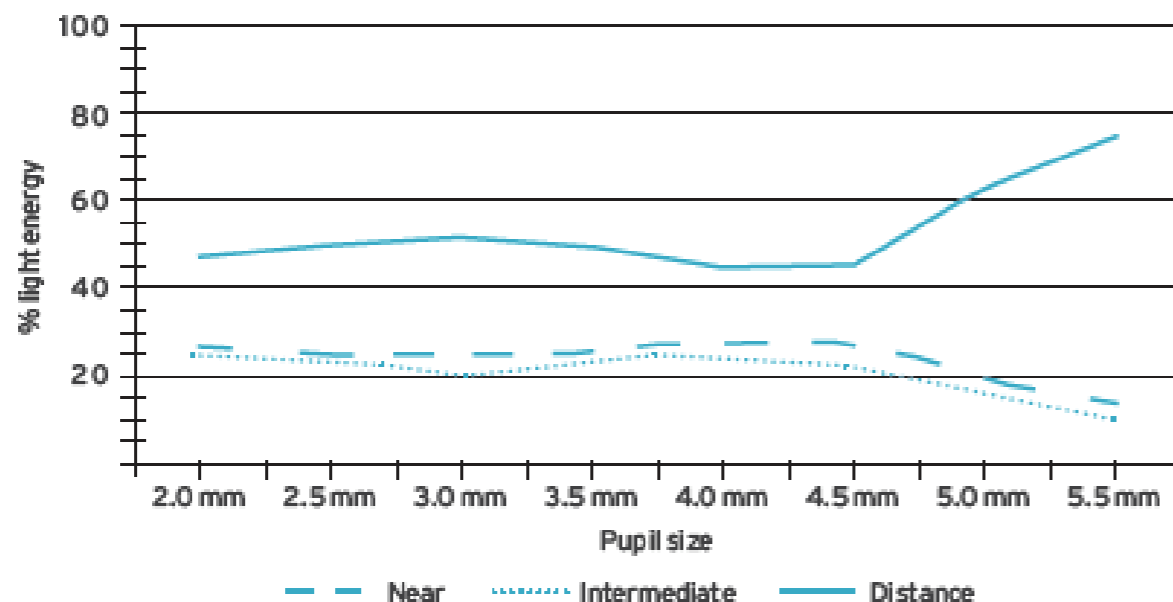
Iris - Sulcoflex



Sulcoflex - IOL

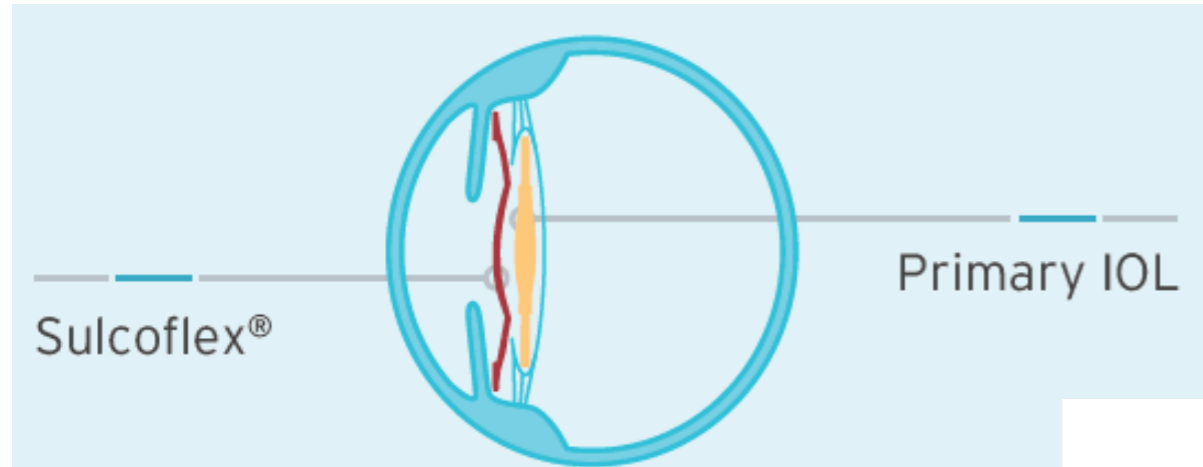
SULCOFLEX® TRIFOCAL - RAYNER

- Lens Design 6.50 mm Optic x 14.00 mm overall length with C-Loop 10 ° haptic angulation and continuous ripple for superior sulcus stability
- Optical thickness about 50% of a traditional IOL
- Front Convex optical profile bevel with neutral aberration with anti-glare edge
- Rear Optic profile concave trifocal with a diffractive diameter of 4.50 mm (16 double-profile rings diffractive and only 11% loss of brightness)



SULCOFLEX® TRIFOCAL - RAYNER

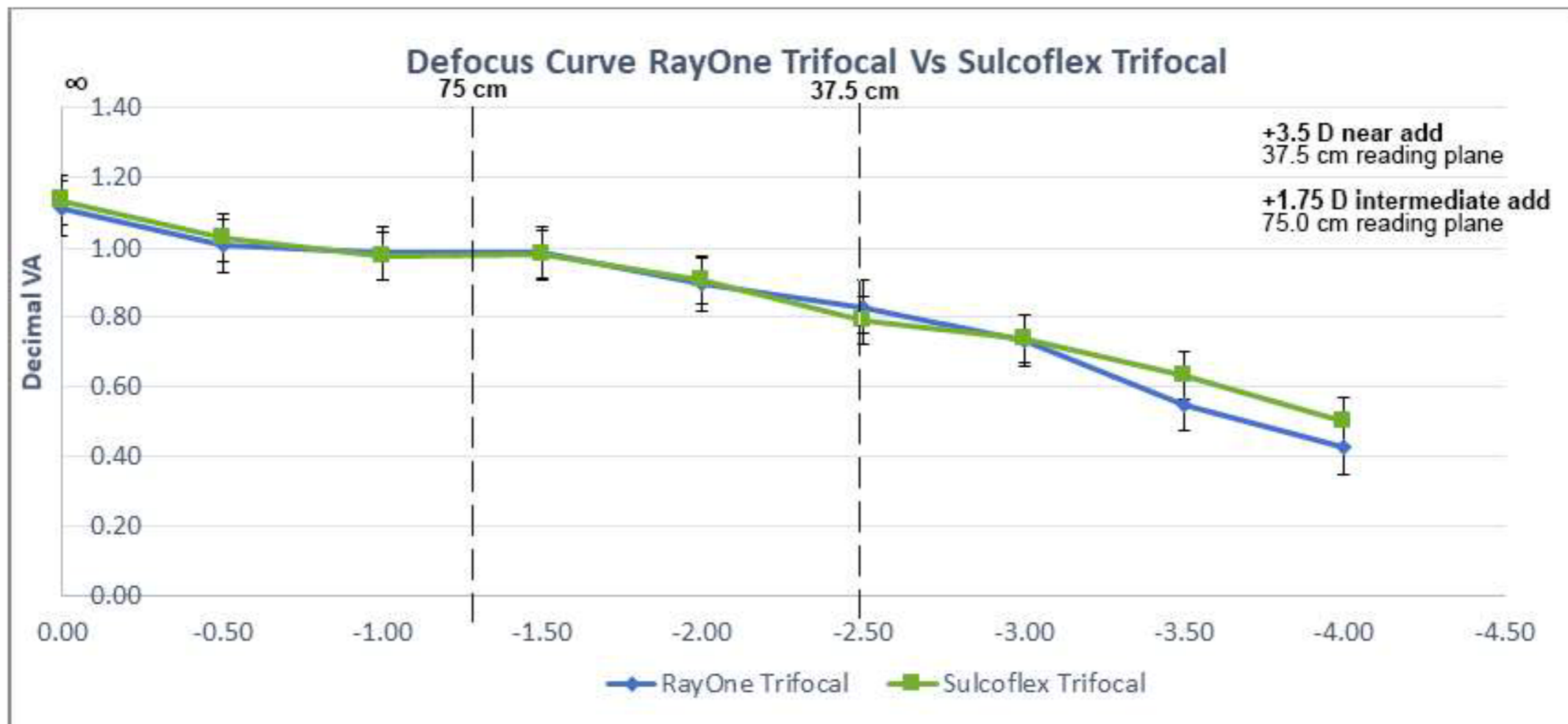
- Same diffractive profile in the Rayone trifocal lens
- Different positioning of the diffractive rings: anterior in the convex optics of Rayone trifocal, posterior in the concave optic of Sulcoflex trifocal
- The trifocal rear concave profile of Sulcoflex trifocal functions as a trait d'union between the two optics: IOL in the capsular bag and IOL in the sulcus



SULCOFLEX® TRIFOCAL - RAYNER

Defocus Curve

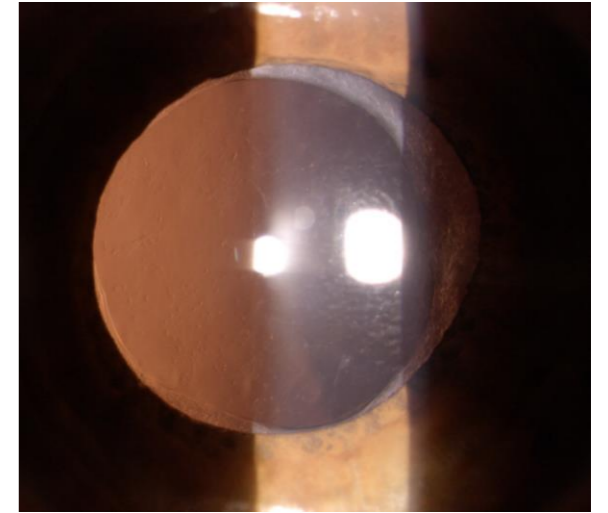
- Comparing the Defocus obtained from the 2 Rayner Trifocal lenses with the same design but different positioning (RayOne Trifocal vs Sulcoflex Trifocal) The perfect comparability is observed both in the distant and intermediate at 75 cm and in the near 37.5 Cm



*Dati: courtesy by Prof. Amon - one month study follow-up DUET procedure

CLINICAL CASE

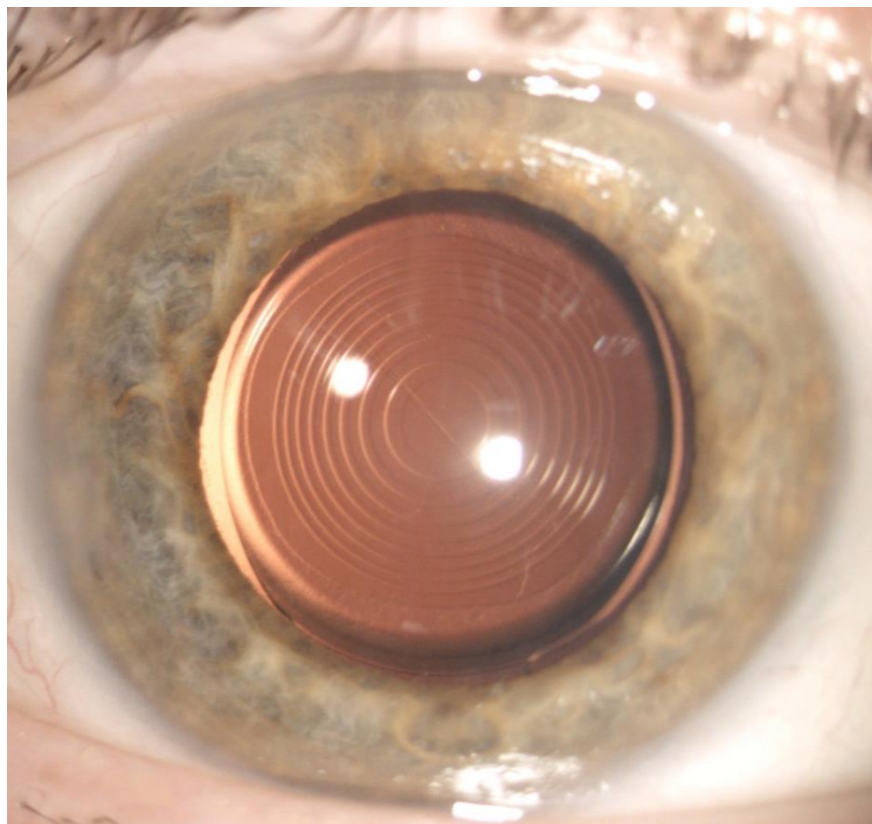
- Pz M 72 aa – Cataract OD
- In 2016: Phaco + IOL monofocal OS
- VOD 5/10 -3.00 sf; J 3 nat
- VOS 10/10 nat; J 3 +2.75 sf
- Wants to improve vision from afar, but keep independence from glasses (far and close)



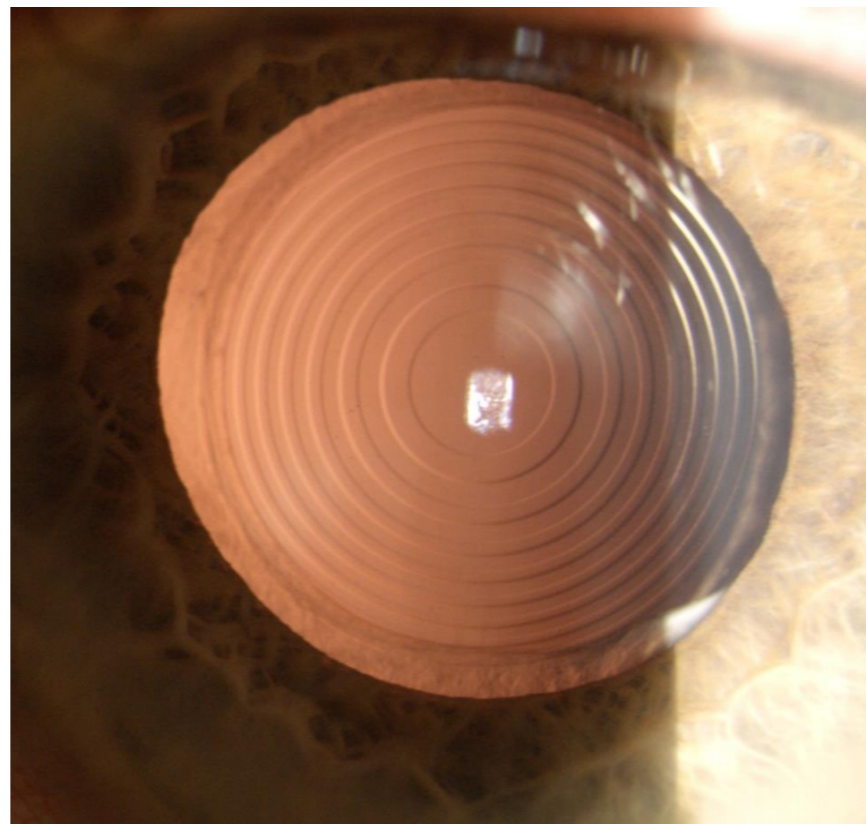
Surgical planning:

- OD RayOne Trifocal
- OS Sulcoflex Trifocal

OD



OS



SULCOFLEX® TRIFOCAL - RAYNER



SULCOFLEX® TRIFOCAL - RAYNER

SULCOFLEX: FIRST IMPLANTS

OD

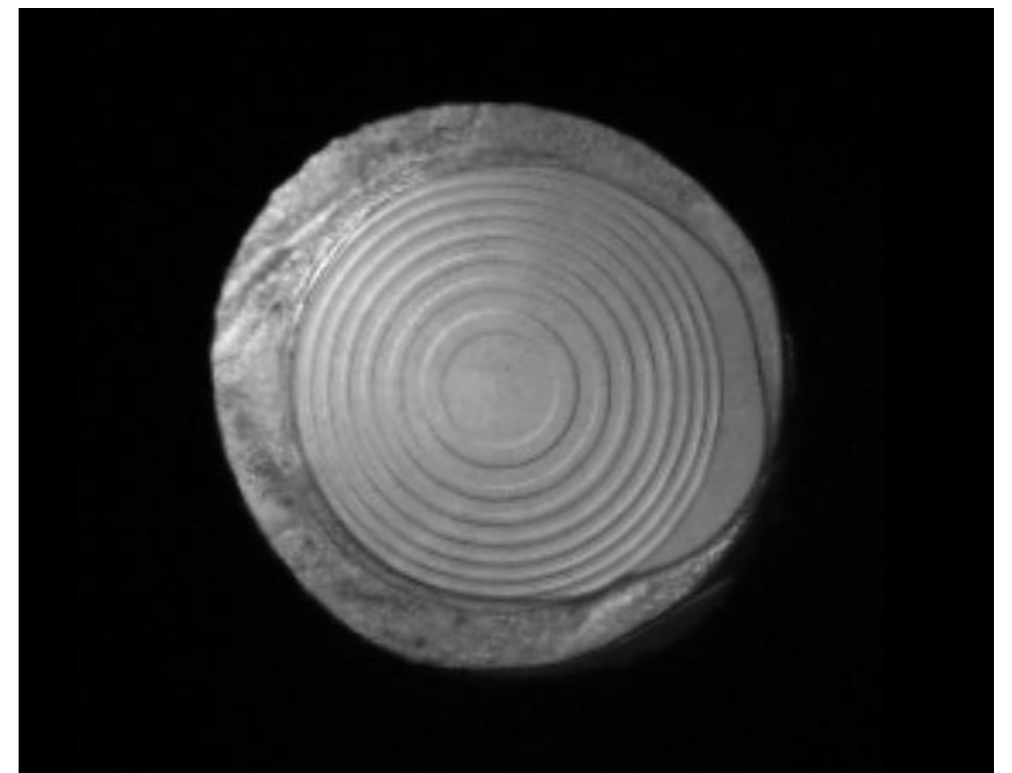
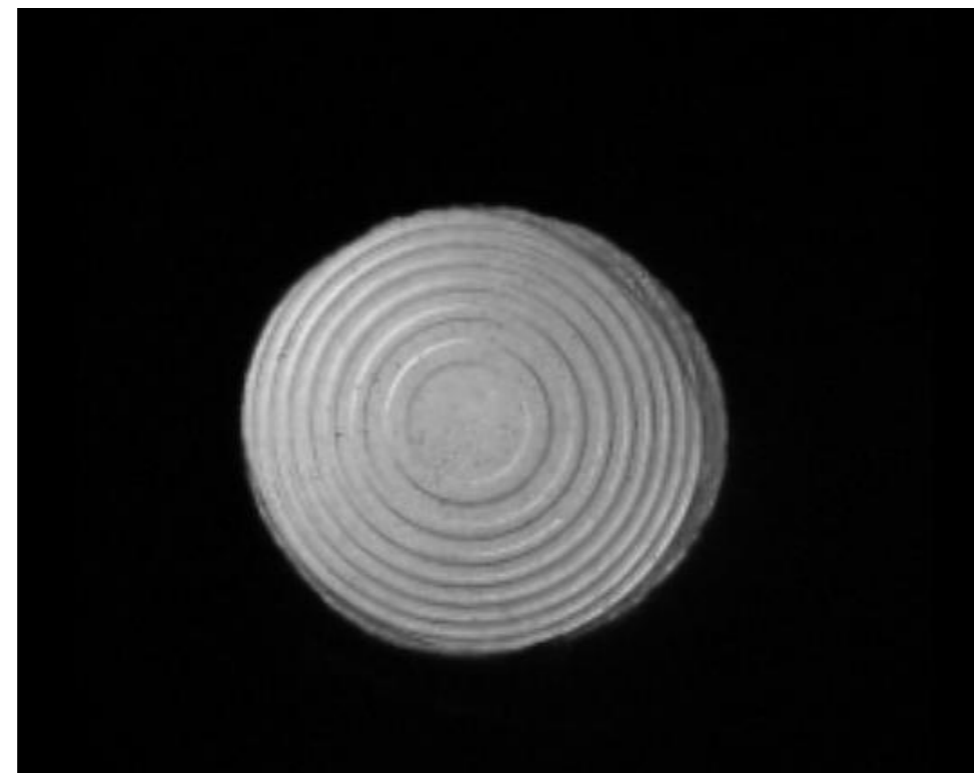
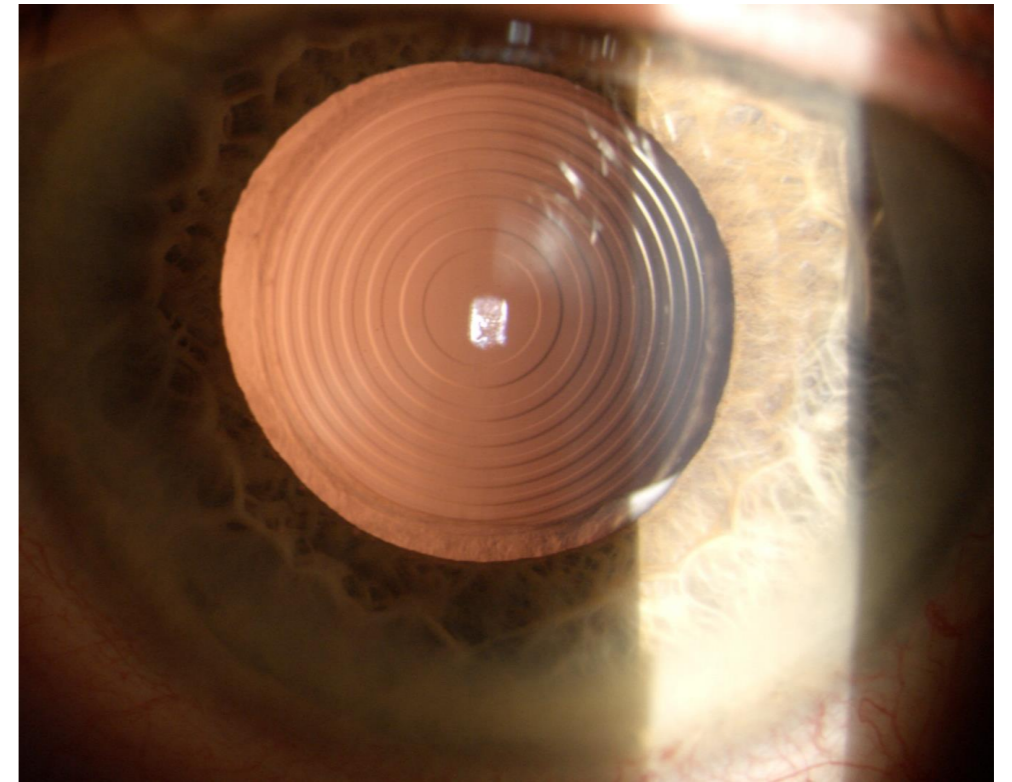
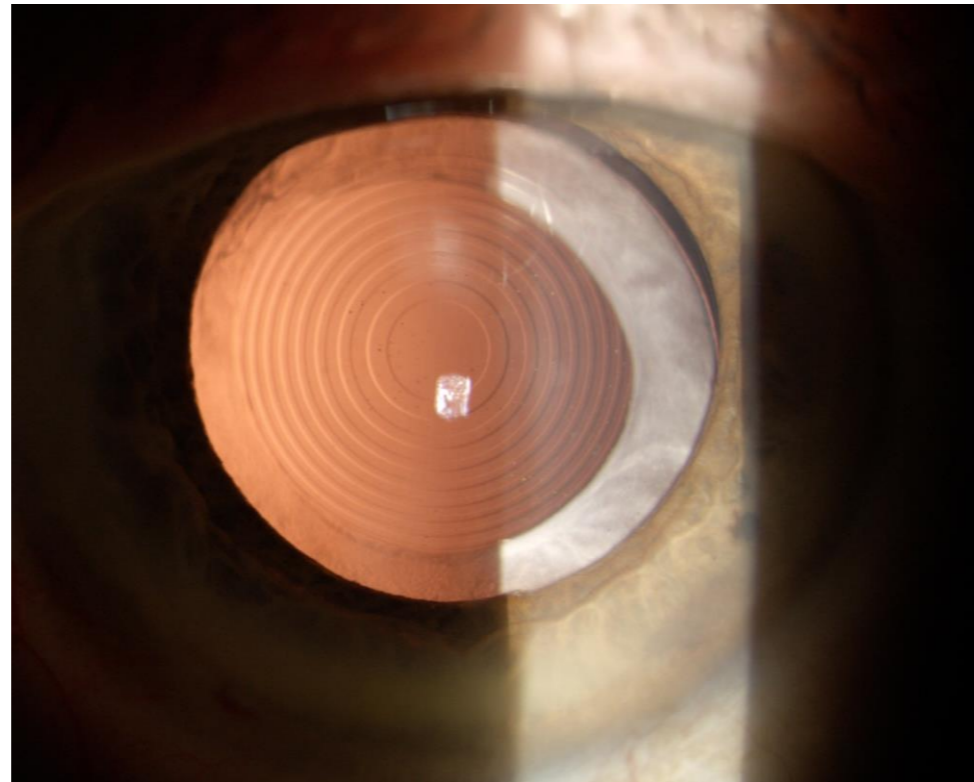
OS

**Post-op UCVA:
10/10 nat OO**

**Post-op UIVA:
J 3 nat OO**

**Post-op UNVA:
J 3 nat OO**

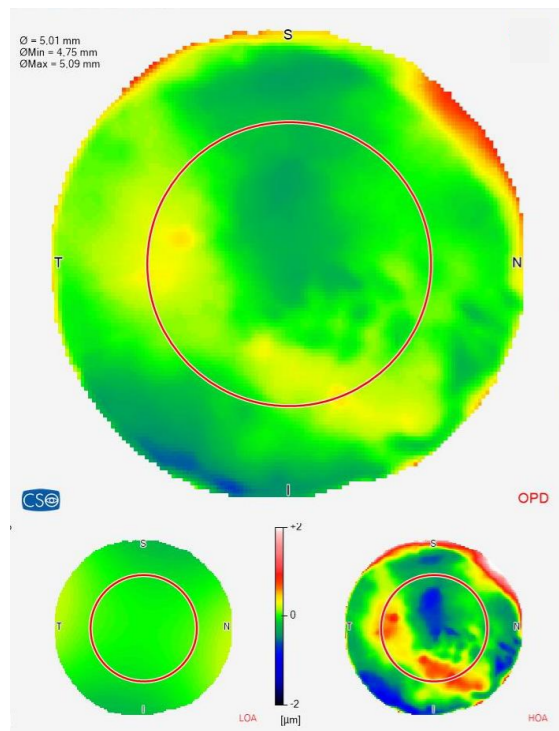
**High patient
satisfaction**



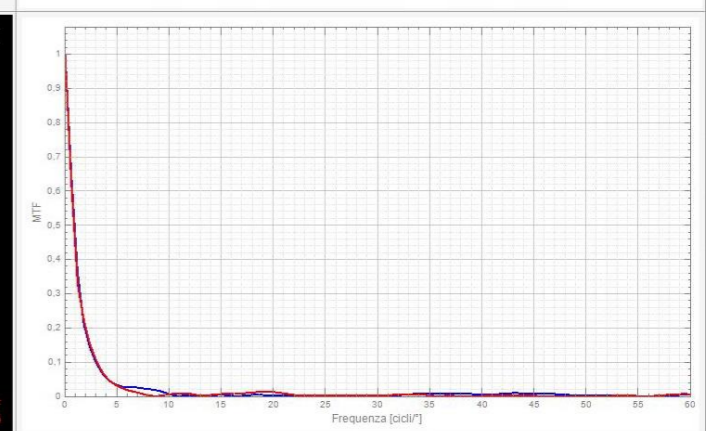
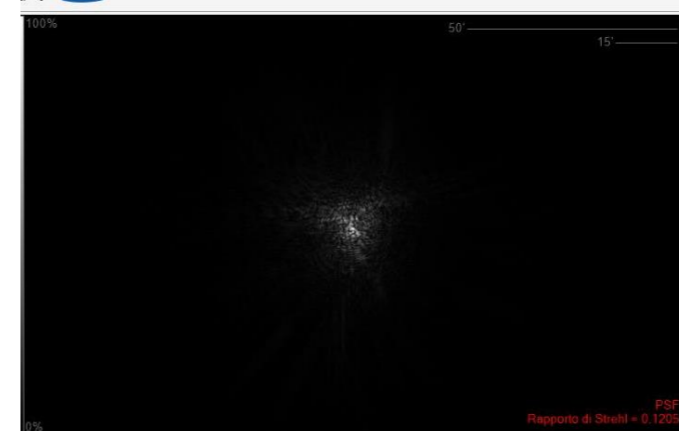
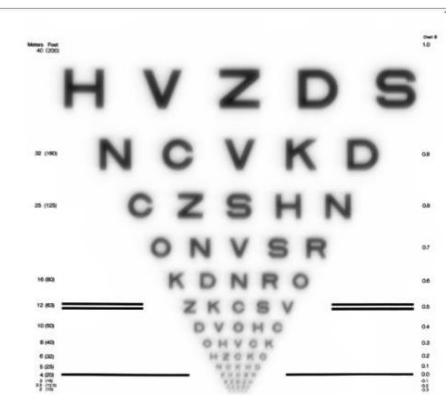
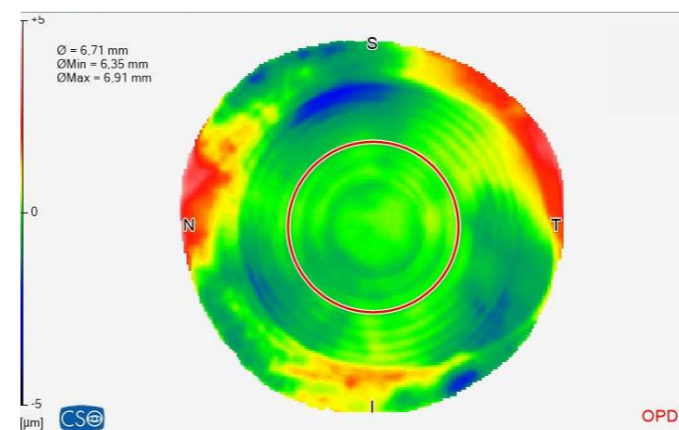
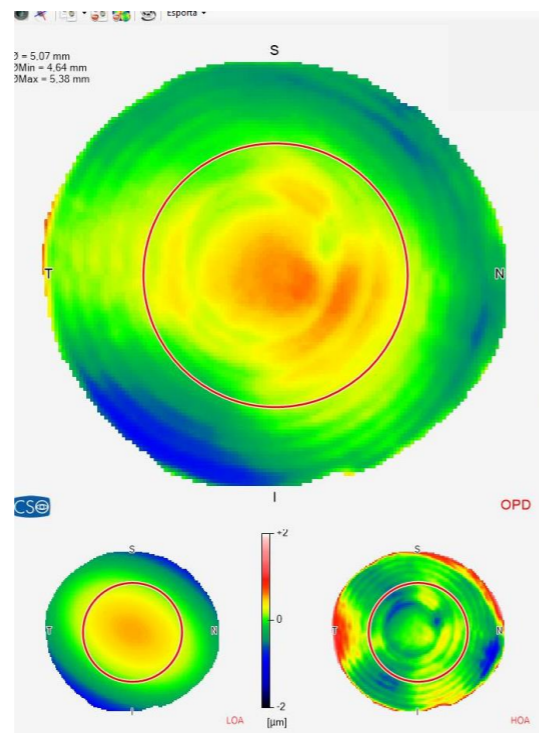
SULCOFLEX® TRIFOCAL - RAYNER

SULCOFLEX: FIRST IMPLANTS

Monofocal IOL



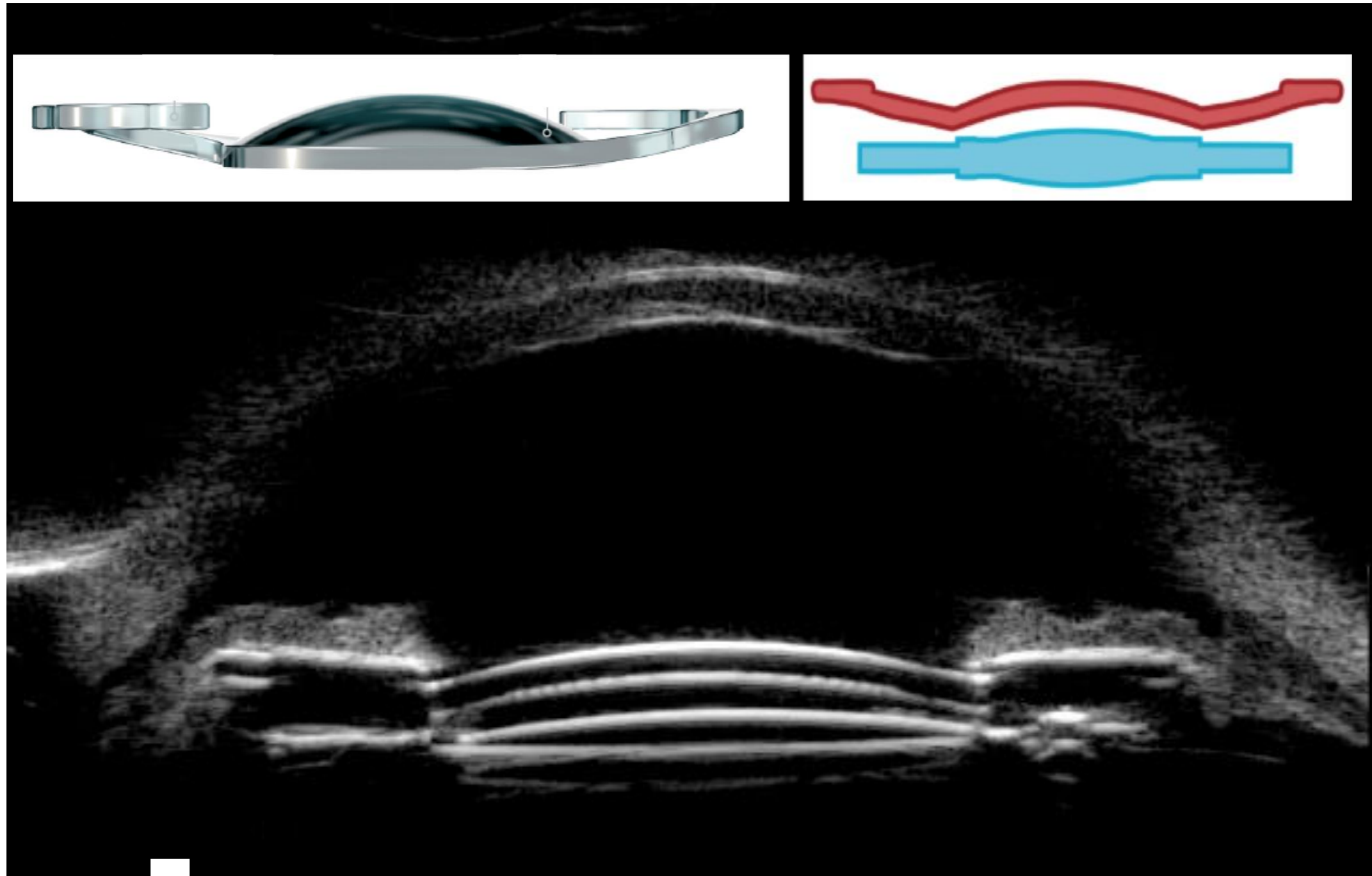
After Sulcoflex implant



SULCOFLEX® TRIFOCAL - RAYNER

SULCOFLEX: FIRST IMPLANTS

**UBM:
IOL design and centration**



NEXT MEETING...AICCER 2019

First results of Sulcoflex Trifocal implantation in a group of patients

XXII CONGRESSO AICCER

Associazione Italiana di Chirurgia della Cataratta e Refrattiva



AICCER

www.aiccer.it/congresso2019

14-16 marzo 2019 - Milano, MiCo
