New sulcus trifocal IOL Sulcoflex (Rayner): refractive performance and patient satisfaction

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SULCOFLEX® TRIFOCAL - RAYNER

SULCOFLEX ASPHERIC

+

RAYONE TRIFOCAL

SULCOFLEX® TRIFOCAL - RAYNER

SULCOFLEX ASPHERIC

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

Int Ophthalmol. 2018 Oct 29. doi: 10.1007/s10792-018-1027-7. [Epub ahead of print]

Outcomes of toric supplementary intraocular lenses for residual astigmatic refractive error in pseudophakic eyes.

McLintock CA[1,2], McKelvie J[3], Gatzioufas Z[3], Wilson JJ[4], Stephensen DC[4], Apel AJG[4,5].

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 K[1], 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 MI[1], 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 G[1], Amon M.

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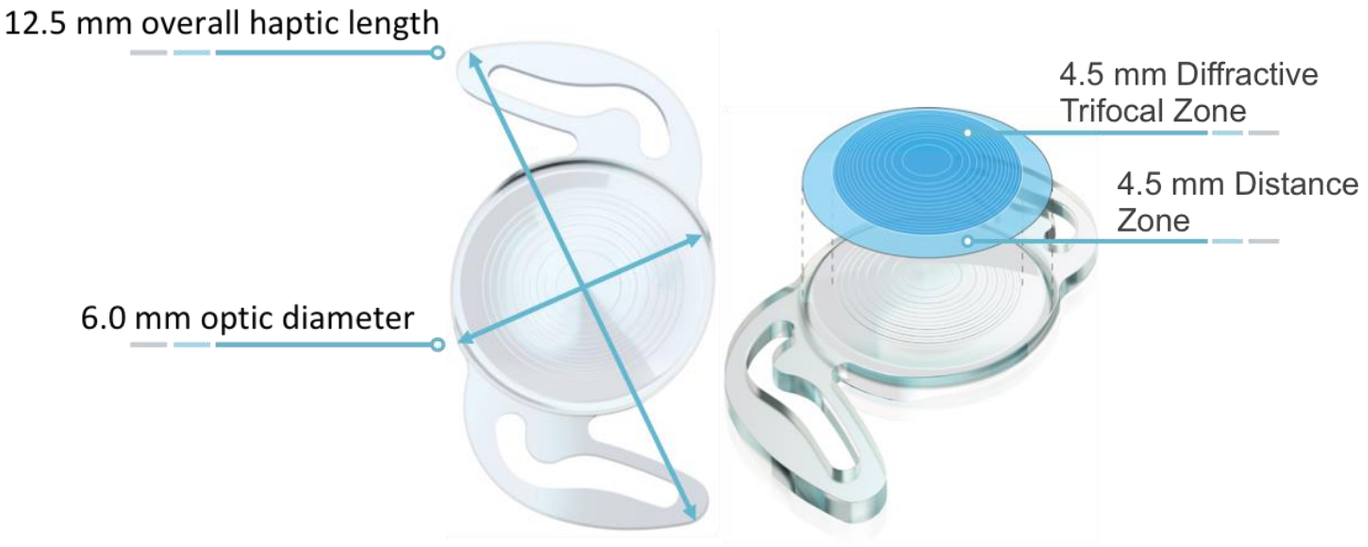
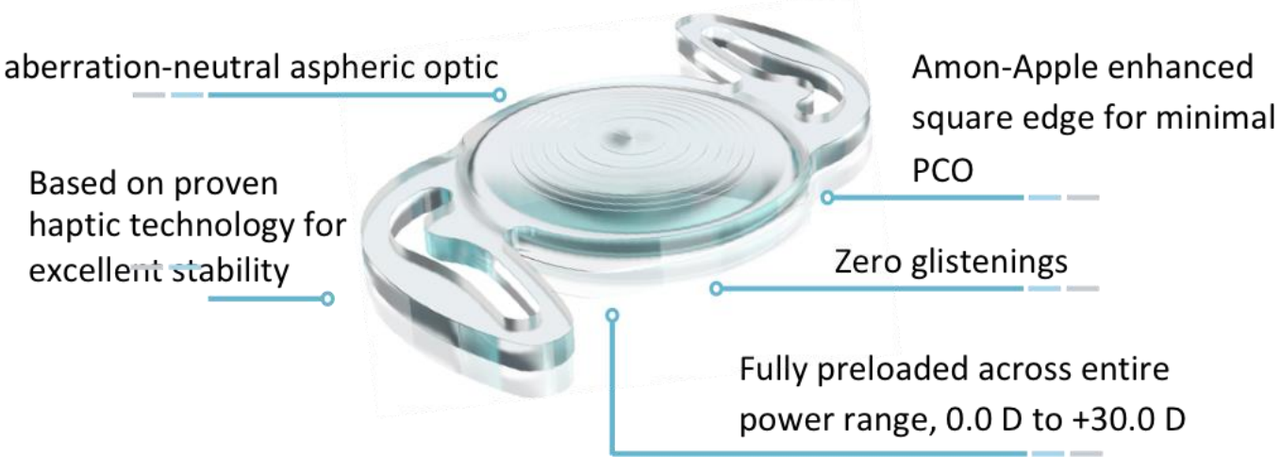
RAYONE TRIFOCAL





XXII CONGRESSO AICCER – MILANO 14-16 MARZO 2019

Ospedale di Stato della Repubblica di San Marino
Divisione di Oftalmologia
Direttore: Dott. Alessandro Mularoni

Performance visiva e stabilità della IOL trifocale RayOne (Rayner®)

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INTRODUCTION

With the increase in patients' demand for glasses independence after cataract surgery, a variety of advanced intraocular lenses (IOL) have been developed in recent years. Trifocal IOLs have three focal points, one for the distance, one for the intermediary and one for near vision. We report long term visual performance, patient satisfaction, stability and posterior capsular opacification (PCO) incidence in patients with bilaterally implantation of RayOne® Trifocal IOL (Rayner) compared to bilateral implantation of Acrysof IQ PanOptix® (Alcon).

RAYONE TRIFOCAL AND PANOPTIX IOL

Features:
- 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

RayOne PanOptix

MATERIALS AND METHODS

2 groups of 16 eyes each (8 patients for group) with bilateral cataract were evaluated in San Marino Hospital after implantation of RayOne Trifocal IOL (Group 1) and Acrysof IQ PanOptix IOL (Group 2)

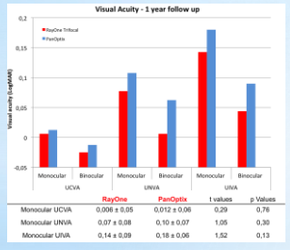
Minimum Follow-up: 12 months (range 12-18 months)
Data evaluated:
- Distance Uncorrected Visual Acuity (UCVA) (LogMAR)
- Near Uncorrected (UNVA) and Intermediate Uncorrected Visual Acuity (UIVA) (LogMAR) with MNread charts
- Contrast sensitivity with MOS 22 (Dueffe Tecnovision)
- Defocus curve from -4.00 D to + 2.00 D
- Aberrometry (OSIRIS – CSO)
- Patient satisfaction with a self-administered questionnaire (NEI-RQL-42™)
- PCO incidence and IOL stability with digital photos of anterior segment

Exclusion criteria:
- Previous ocular surgery (included refractive surgery)
- Regular corneal astigmatism greater than 0.75 D
- Irregular astigmatism and corneal opacities
- Glaucoma with impairment of GCL and RNFL
- Macular diseases

RESULTS

DISTANCE, NEAR AND INTERMEDIATE VISUAL ACUITY

- All patients in RayOne Group and PanOptix Group achieved monocular and binocular UCVA of 0.1 LogMAR or better.
- 11 eyes (68%) in RayOne Group and 10 eyes (62%) in PanOptix Group achieved monocular UNVA of 0.1 LogMAR or better; binocular UNVA was 0.1 LogMAR or better in all patients.
- 11 eyes (43%) in RayOne Group and 4 eyes (25%) in PanOptix Group achieved monocular UIVA of 0.1 LogMAR or better; binocular UIVA was 0.1 LogMAR or better in 15 eyes (93%) and 13 eyes (81%) of RayOne and PanOptix Group respectively.
- There were no statistically significant differences between the two groups in any case (p>0,01).



	RayOne	PanOptix	t values	p Values
Monocular UCVA	0,006 ± 0,05	0,012 ± 0,06	0,29	0,76
Monocular UNVA	0,07 ± 0,08	0,10 ± 0,07	1,05	0,30
Monocular UIVA	0,14 ± 0,09	0,18 ± 0,06	1,52	0,13

DEFOCUS CURVE

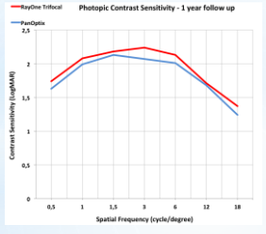
- At 12 months post-operatively, RayOne and PanOptix groups showed a smooth transition phase between the far and the near focus.
- From +0.50 D to -2.00 D, visual acuity was on average 0.10 LogMAR or better in RayOne and PanOptix patients, demonstrating good intermediate vision.
- At -2.50 D, corresponding to near vision at 40 cm, visual acuity in RayOne and PanOptix groups was on average 0.13 and 0.10 LogMAR respectively.
- At -3.00 D (near vision at 33 cm) and -4.00 D (near vision at 25 cm) visual acuity was on average 0.2 and 0.39 LogMAR LogMAR for RayOne group, and 0.15 and 0.34 LogMAR for PanOptix group.

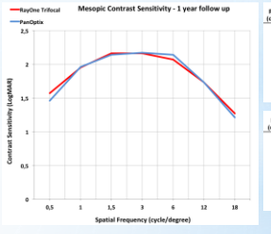
Defocus	RayOne	PanOptix	t values	p values
-4.00 D	0,39 ± 0,13	0,34 ± 0,10	1,10	0,27
-3.50 D	0,26 ± 0,10	0,24 ± 0,07	0,71	0,48
-3.00 D	0,20 ± 0,12	0,15 ± 0,08	1,17	0,24
-2.50 D	0,13 ± 0,11	0,1 ± 0,07	0,67	0,50
-2.00 D	0,09 ± 0,09	0,1 ± 0,08	0,08	0,93
-1.50 D	0,08 ± 0,07	0,1 ± 0,08	0,73	0,47
-1.00 D	0,06 ± 0,07	0,1 ± 0,08	1,21	0,23
-0.50 D	0,03 ± 0,04	0,01 ± 0,03	1,27	0,21
0 D	0	0		
+0.50	0,03 ± 0,06	0,01 ± 0,03	1,14	0,16
+1.00 D	0,13 ± 0,08	0,18 ± 0,08	1,85	0,07
+1.50 D	0,26 ± 0,10	0,38 ± 0,08	3,20	0,003
+2.00 D	0,4 ± 0,12	0,5 ± 0,09	2,48	0,018

- There were no statistically significant differences between the two groups (p>0,01), except at value of +1.50 D (p<0,01).
- Defocus curves are not fully representative of reading visual acuity as the effects of convergence and pupillary constriction are not taken in consideration.

CONTRAST SENSITIVITY

- Contrast sensitivity levels of the all groups were within normal limits under photopic (85 cd/m²) and mesopic (3 cd/m²) conditions throughout follow-up.
- In photopic condition PanOptix group showed lower contrast sensitivity than the RayOne group at all spatial frequency.
- In mesopic condition RayOne and PanOptix group showed similar results throughout all spatial frequency.





Photopic CS (cycle/degree)	RayOne	PanOptix	t values	p values
0,5	1,74 ± 0,17	1,63 ± 0,16	1,90	0,06
1	2,08 ± 0,22	1,98 ± 0,17	1,17	0,24
1,5	2,16 ± 0,11	2,13 ± 0,14	0,86	0,34
3	2,24 ± 0,22	2,07 ± 0,16	2,44	0,02
6	2,13 ± 0,19	2,01 ± 0,12	1,99	0,05
12	1,71 ± 0,19	1,68 ± 0,26	0,29	0,77
18	1,37 ± 0,36	1,24 ± 0,23	1,19	0,24

Mesopic CS (cycle/degree)	RayOne	PanOptix	t values	p values
0,5	1,57 ± 0,27	1,46 ± 0,23	1,19	0,24
1	1,95 ± 0,20	1,96 ± 0,21	0,05	0,95
1,5	2,16 ± 0,17	2,14 ± 0,15	0,25	0,8
3	2,16 ± 0,21	2,17 ± 0,13	0,06	0,94
6	2,07 ± 0,37	2,14 ± 0,19	0,65	0,51
12	1,73 ± 0,28	1,73 ± 0,23	0,09	0,92
18	1,27 ± 0,37	1,21 ± 0,35	0,41	0,68

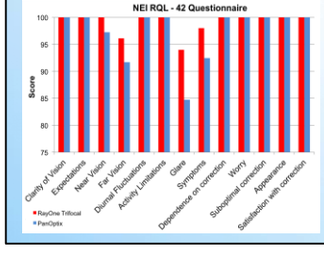
IOL STABILITY AND PCO INCIDENCE

- We evaluated IOL stability and Posterior Capsular Opacification (PCO) incidence with digital photo of anterior segment during the follow-up.
- No PCO was reported in any patients with RayOne and PanOptix IOLs.
- IOL stability and centration was excellent during the follow-up: no tilting or decentration was reported in any case.

14/11/17 11/01/19

PATIENT SATISFACTION

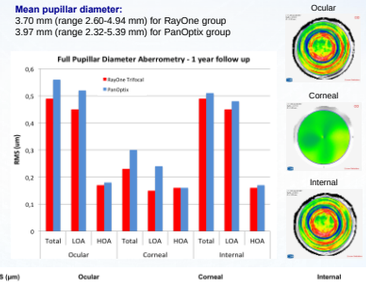
- Patient satisfaction was evaluated with a self-administered questionnaire (NEI RQL – 42).
- High patient satisfaction was found for both the RayOne and PanOptix group.
- Patient satisfaction for the glare and symptoms category was found greater in RayOne group than the PanOptix group.

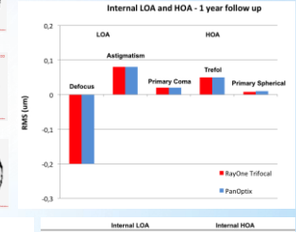


ABERROMETRY

- RMS values (µm) were better in RayOne group regarding ocular and internal aberrations.
- RayOne group showed lower LOA and HOA internal aberrations than PanOptix group (not statistically significant).
- Internal aberrations are directly related to the IOL: low values of RSM indicate a minimum dispersion of the light inside the eye.

Mean pupillar diameter:
3.70 mm (range 2.60-4.94 mm) for RayOne group
3.97 mm (range 2.32-5.39 mm) for PanOptix group





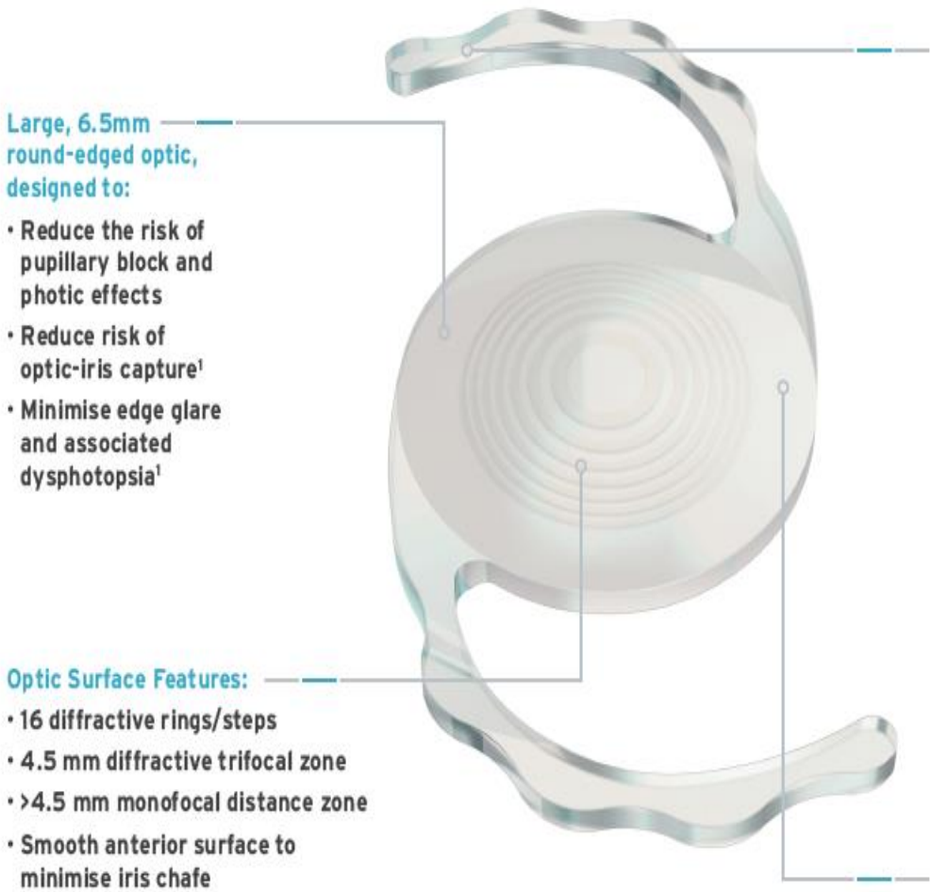
RMS (µm)	Ocular			Corneal			Internal		
	Total	LOA	HOA	Total	LOA	HOA	Total	LOA	HOA
RayOne	0,49 ± 0,23	0,45 ± 0,23	0,17 ± 0,07	0,23 ± 0,12	0,15 ± 0,10	0,16 ± 0,08	0,49 ± 0,22	0,45 ± 0,23	0,16 ± 0,05
PanOptix	0,56 ± 0,22	0,52 ± 0,22	0,18 ± 0,10	0,30 ± 0,09	0,24 ± 0,09	0,16 ± 0,07	0,51 ± 0,23	0,48 ± 0,22	0,17 ± 0,07
t values	0,80	0,83	0,39	1,62	2,26	0,04	0,27	0,39	0,21
p values	0,42	0,41	0,69	0,11	0,03	0,96	0,78	0,69	0,82

	Internal LOA			Internal HOA	
RMS (µm)	Defocus	Astigmatism	Primary Coma	Trefoil	Primary Spherical
RayOne	-0,20 ± 0,10	0,08 ± 0,02	0,02 ± 0,01	0,05 ± 0,02	0,008 ± 0,02
PanOptix	-0,20 ± 0,09	0,08 ± 0,05	0,02 ± 0,01	0,05 ± 0,02	0,01 ± 0,01
t values	0,16	0,07	0,62	0,11	0,15
p values	0,87	0,93	0,53	0,90	0,87

CONCLUSIONS

- The RayOne trifocal IOL provides a very good performance of the visual function after cataract surgery, with high levels of distance, intermediate and near visual acuity, strong reading performance, minimal internal aberrations induced, high patient satisfaction, no PCO incidence and high stability of IOL centration.
- RayOne Trifocal IOL showed similar results to PanOptix IOL regarding all evaluated data with no statistically significant differences.
- This new trifocal IOL offers a valid alternative for spectacle independence after cataract surgery in selected patients.

SULCOFLEX® TRIFOCAL - FEATURES



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

- Reduce the risk of pupillary block and photic effects
- Reduce risk of optic-iris capture[1]
- Minimise edge glare and associated dysphotopsia[1]

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

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 IOLs[5]
- Reduced risk of uveal contact and abrasion[1]
- Reduced Pigment Dispersion Syndrome[1]
- Smooth undulating haptics to minimise the risk of adverse tissue reaction in the sulcus

Rayacryl Material for:

- Good uveal Biocompatibility[7]
- Superb optical clarity - no vacuoles or glistenings[8]

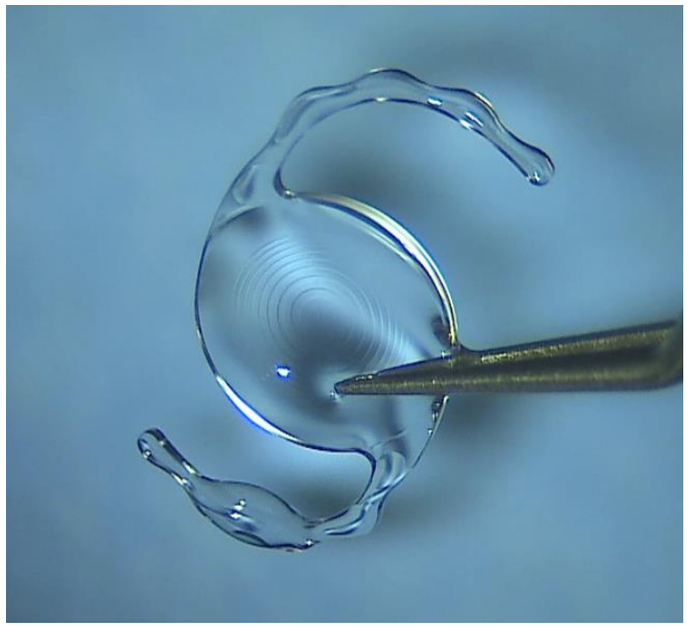
Sulcoflex Trifocal has been designed to offer the following patient benefits:

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

- Hydrophilic acrylic (Rayacrilyc)
- 6.50 mm x 14.00 mm
- 16 diffractive rings
- 4.5 mm diffractive trifocal zone
- > 4.5 mm monofocal distance zone
- Posterior concave surface
- Incision: 2.2 mm

- Range -3.0 / +3.0 (+/-0.50D)
- Range -1.0 / +1.0 (+/-0.25D)

Add +1.75 D Intermediate visual acuity (75 cm)
+3.50 D Near visual acuity (37.5 cm)



SULCOFLEX® TRIFOCAL

IMPLANTATION TECHNIQUE

TWO-STEP PROCEDURE:

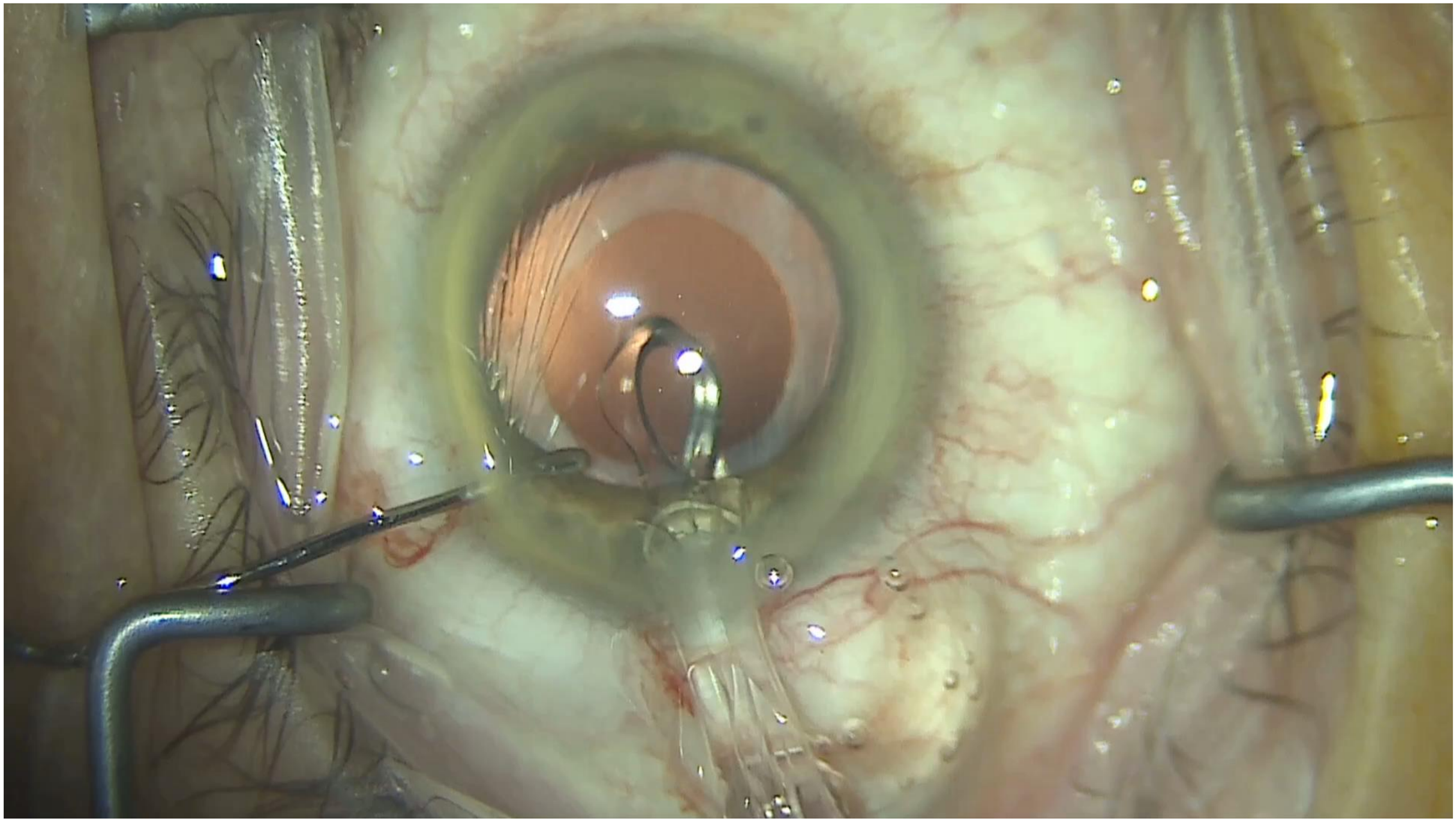
- First monfocal/monofocal toric IOL implant in the bag, then additional Sulcoflex implant: ideal technique for patients with uncertainty of refractive calculation
  - ✓ Previous refractive surgery
  - ✓ High myopia or hyperopia
  - ✓ Abnormal K

DUET PROCEDURE:

- Within the same surgical procedure with a single surgical session: ideal technique for

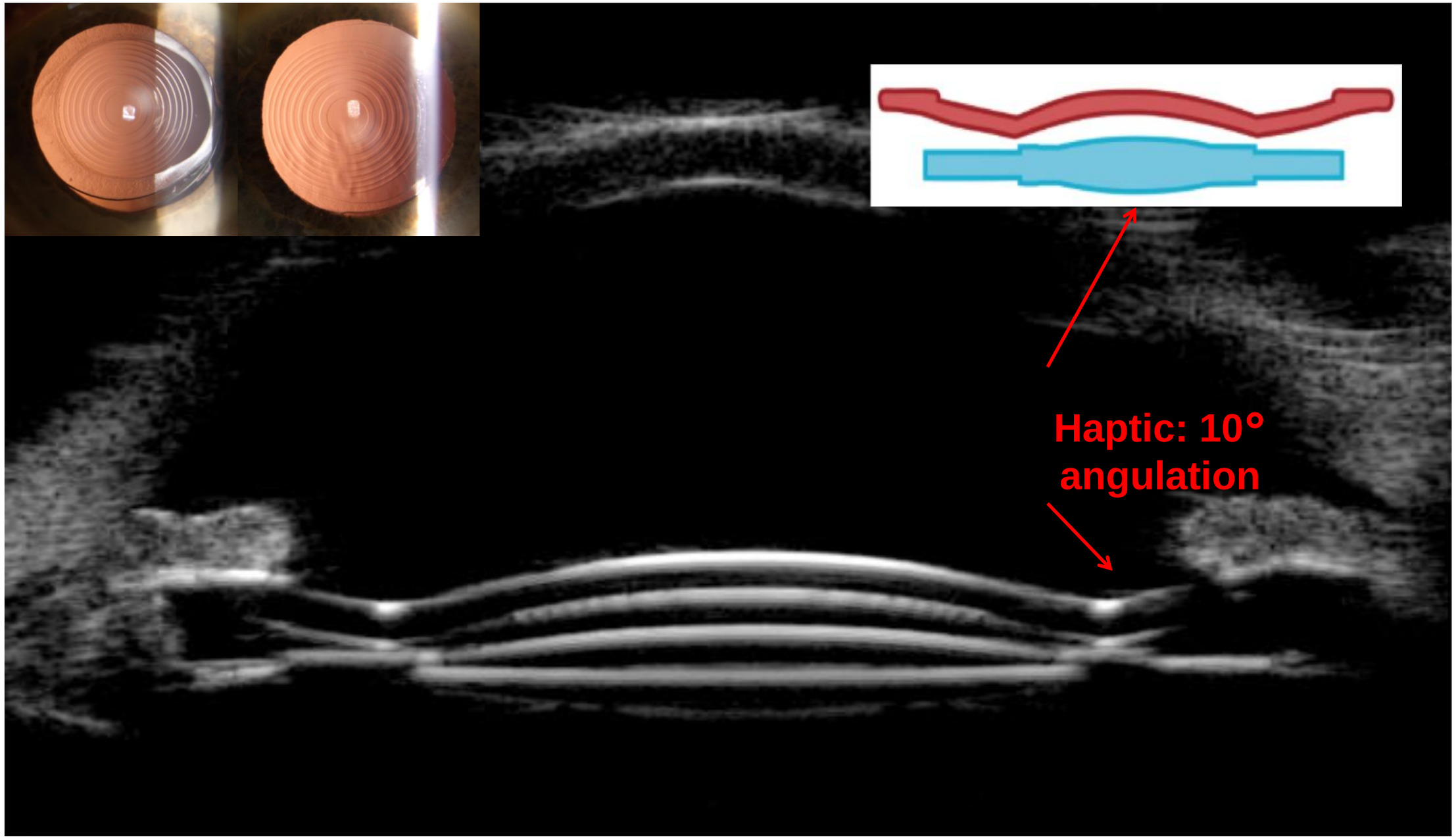
  - ✓ Patients with relative contraindications
  - ✓ Patients with psycho-attitudinal problems (neuroadaptation, tolerability)

SULCOFLEX® TRIFOCAL - RAYNER



SULCOFLEX® TRIFOCAL - RAYNER

UBM: IOL design and centration



- Posterior concave surface: minimal interaction with primary IOL
- Reduced refractive error (hyperopic defocus)

SULCOFLEX® TRIFOCAL - RAYNER

FIRST RESULTS AND VISUAL PERFORMANCE

6 eyes underwent Sulcoflex trifocal implantation

Evaluated data:

- Distance Uncorrected (UCVA) and Distance Best Corrected Visual Acuity (BCVA) (LogMAR)
- Near (UNVA) and Intermediate Visual Acuity (UIVA) (LogMAR) with MNread charts
- Contrast sensitivity with MOS 22 (Dueffe Tecnovision)
- Defocus curve from -4.00 D to +2.00 D
- Aberrometry (OSIRIS – CSO)
- Patient satisfaction with a self-administered questionnaire (NEI-RQL-42™)

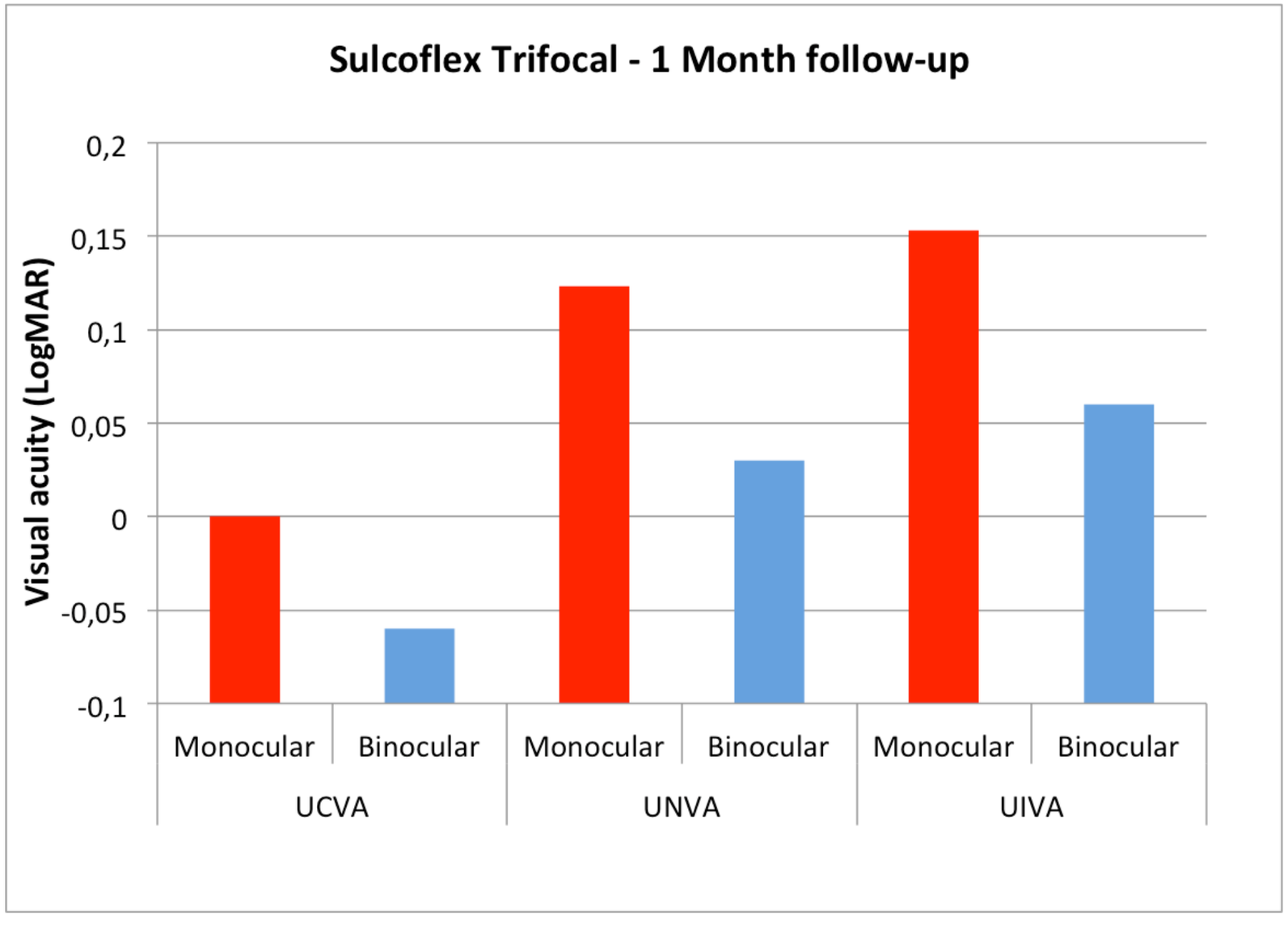
50% pseudophakic eyes, 50% phaco + monofocal IOL in the bag + Sulcoflex trifocal (DUET procedure)
Mean pupillar diameter: 4,28 ± 0,56 mm

EXCLUSION CRITERIA:

- Previous ocular surgery
- Regular corneal astigmatism greater than 0.75 D
- Irregular astigmatism and corneal opacities
- Glaucoma with impairment of GCL and RNFL
- Macular diseases

RESULTS – UCVA, UNVA, UIVA

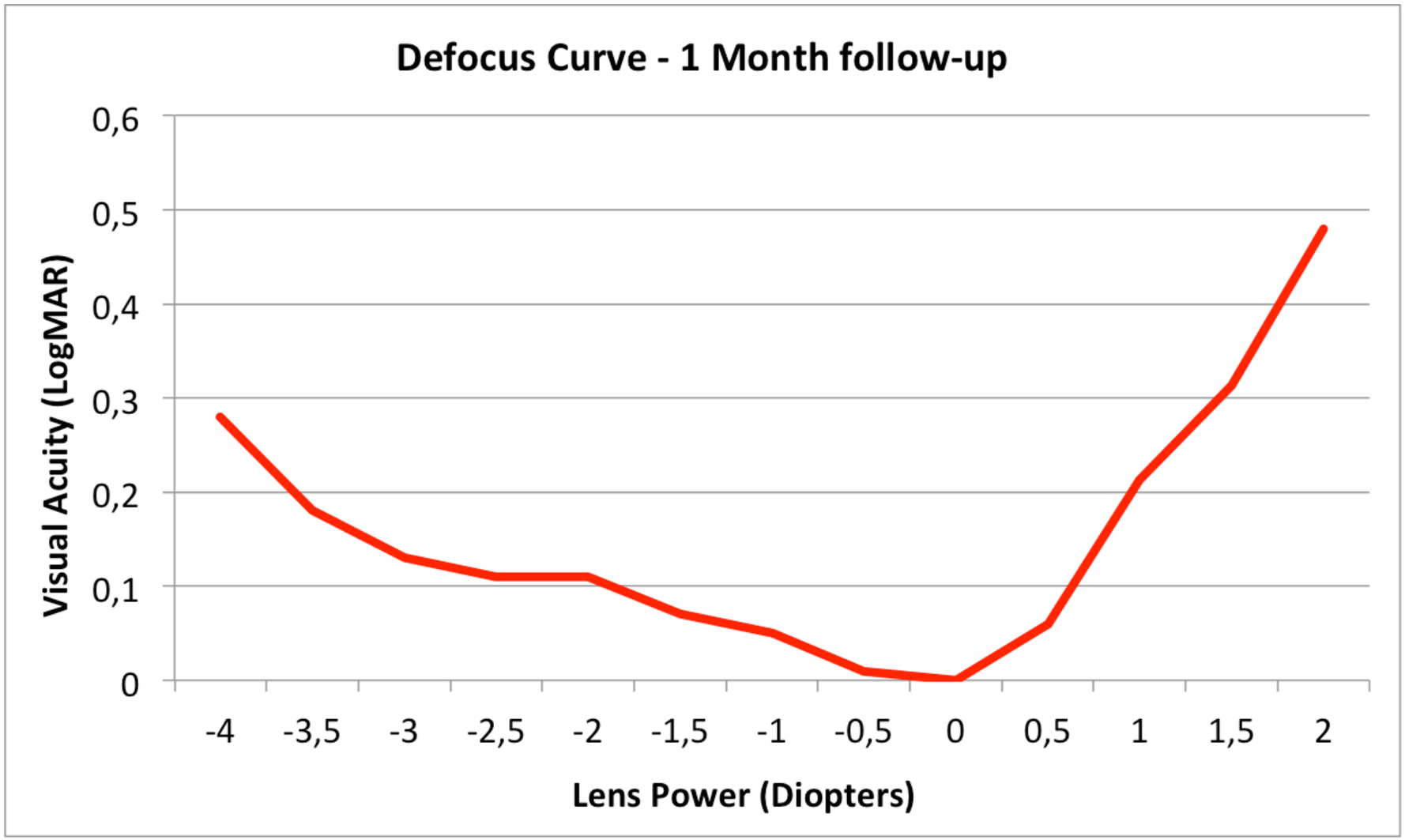
- All patients achieved Monocular and Binocular UCVA of 0.1 LogMAR or better, Monocular and Binocular UNVA (37.5 cm) and UIVA (70 cm) of 0.18 LogMar or better



Visual Acuity – 1 Month follow-up		
	Monocular	Binocular
UCVA	0 ± 0,06	-0,06 ± 0,05
UNVA	0,12 ± 0,04	0,03 ± 0,05
UIVA	0,15 ± 0,04	0,06 ± 0,05

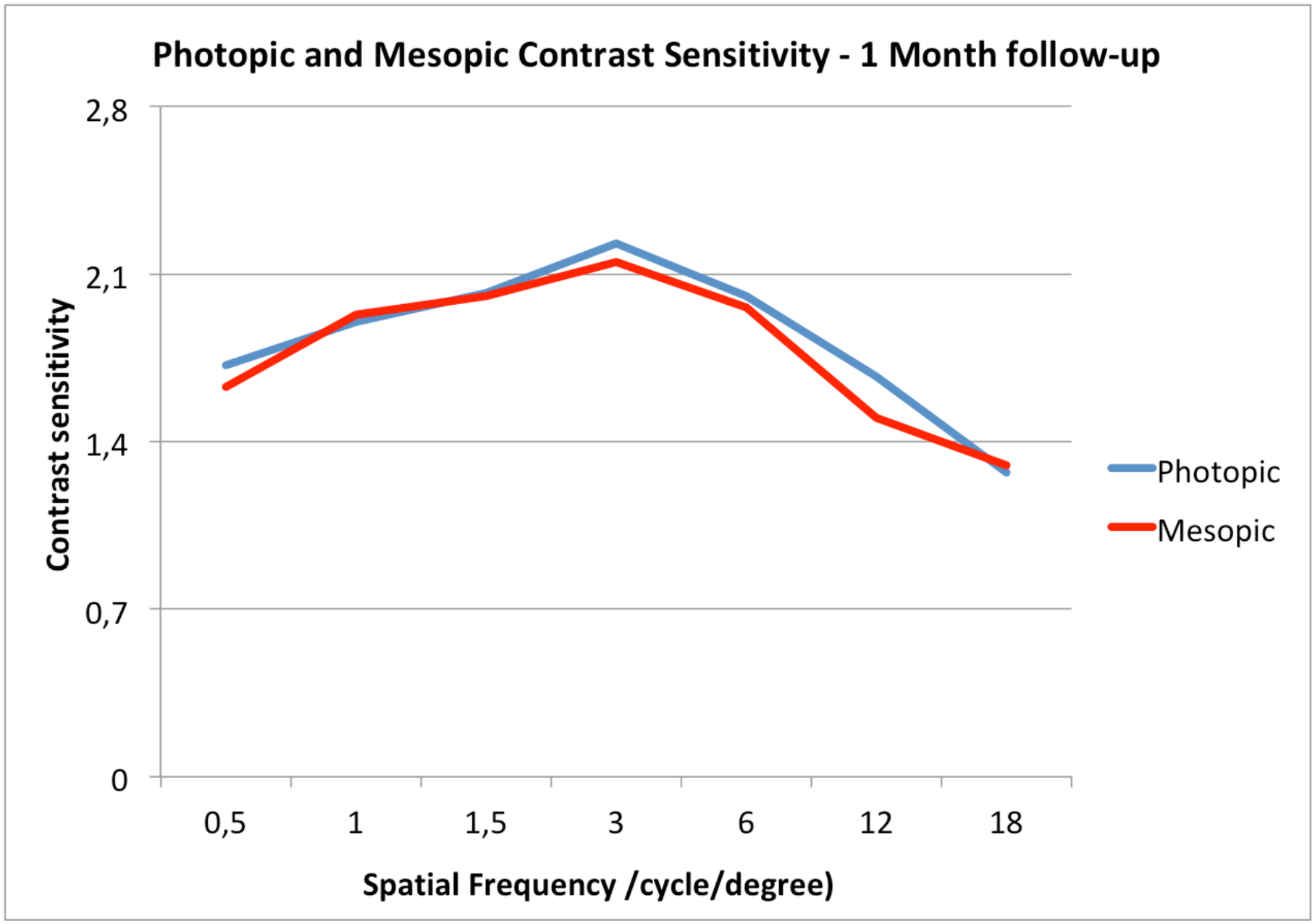
RESULTS – DEFOCUS CURVE

- At 1 month post-operatively, defocus curve showed a smooth transition phase between the far and the near focus
- At -1.50 D, corresponding to near vision at 70 cm, visual acuity was on average 0.07 LogMAR
- At -2.50 D, corresponding to near vision at 40 cm, visual acuity was on average 0.11 LogMAR
- Defocus curves are not fully representative of reading visual acuity as the effects of convergence and pupillary constriction are not taken in consideration



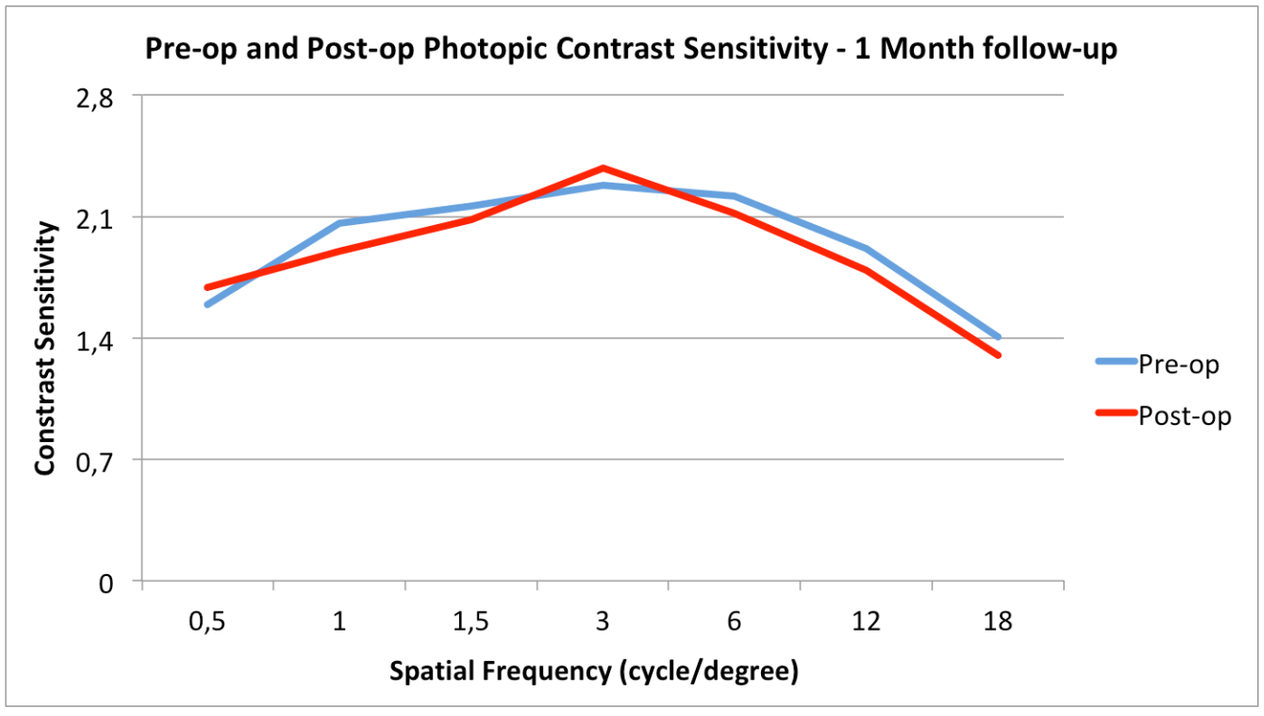
RESULTS – CONTRAST SENSITIVITY

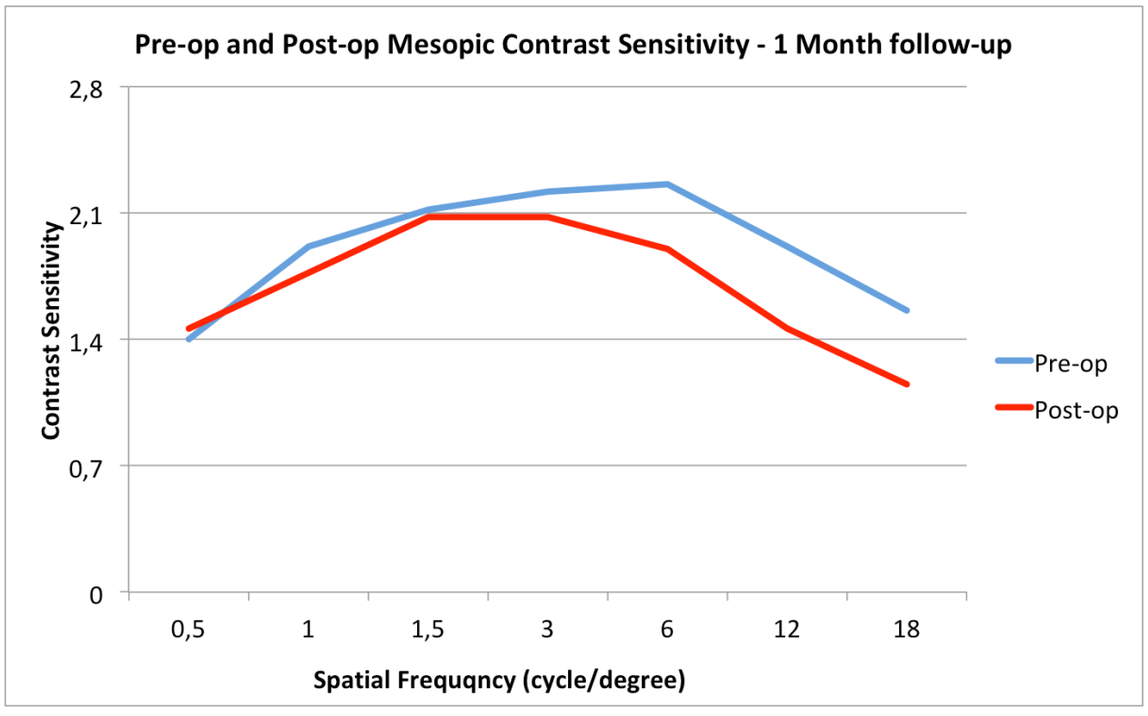
- At 1 month, contrast sensitivity levels was within normal limits under photopic (85 cd/m^2) and mesopic (3 cd/m^2) conditions
- At higher spatial frequency (> 6 cycle/degree) mesopic contrast sensitivity was lower than photopic



RESULTS – CONTRAST SENSITIVITY

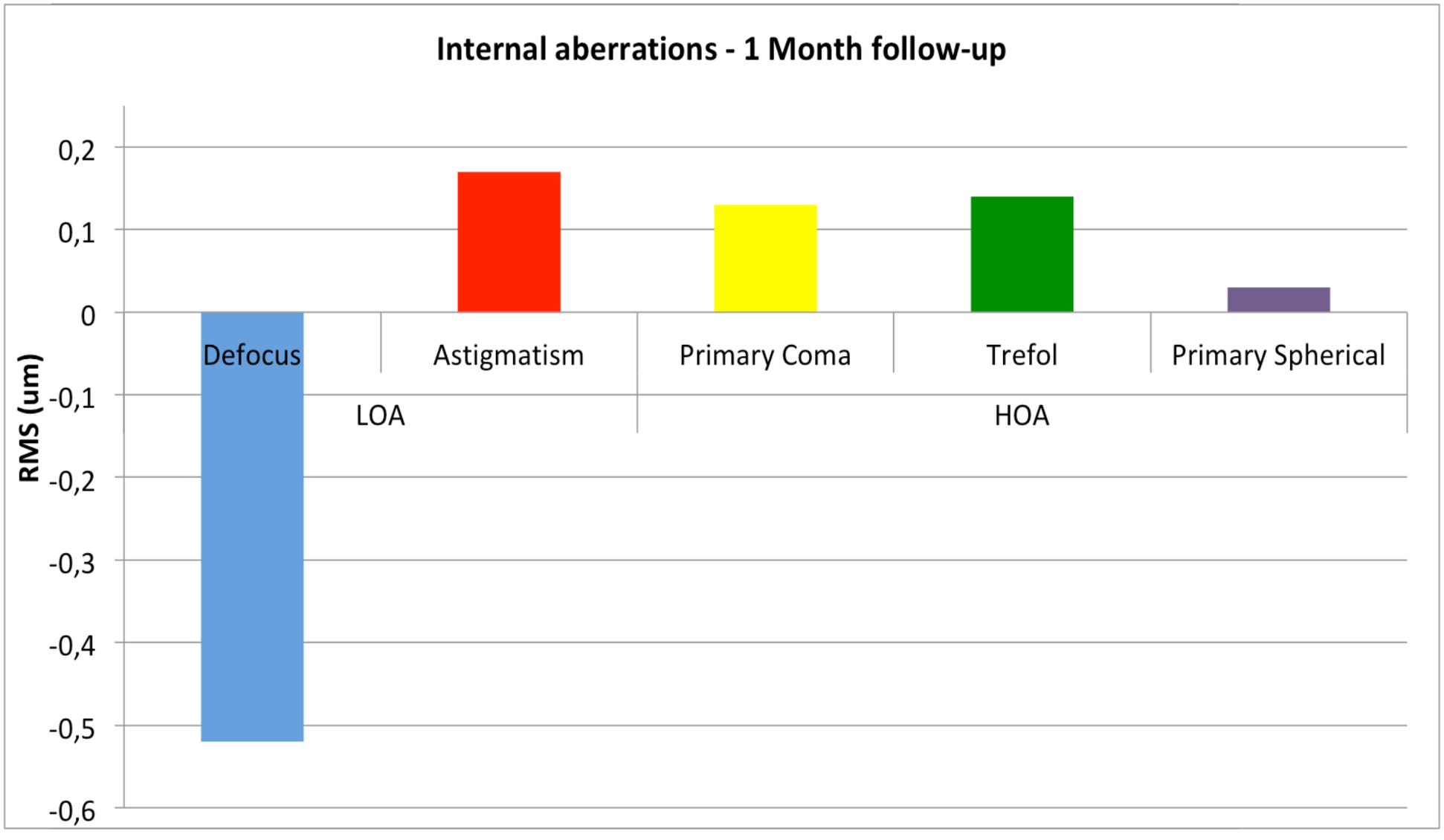
- Post-op photopic contrast sensitivity was similar compared to pre-op in pseudophakic eyes
- Post-op mesopic contrast sensitivity was lower compared to pre-op in pseudophakic eyes at higher spatial frequency (> 6 cycle/degree)

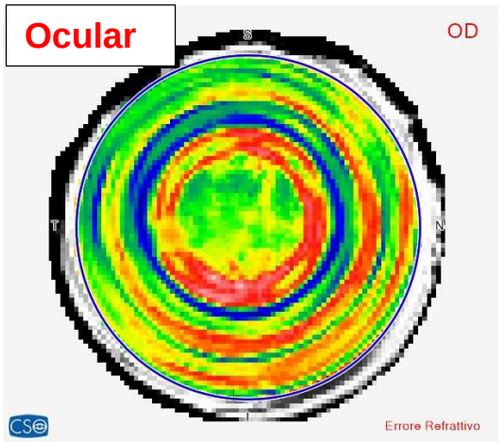


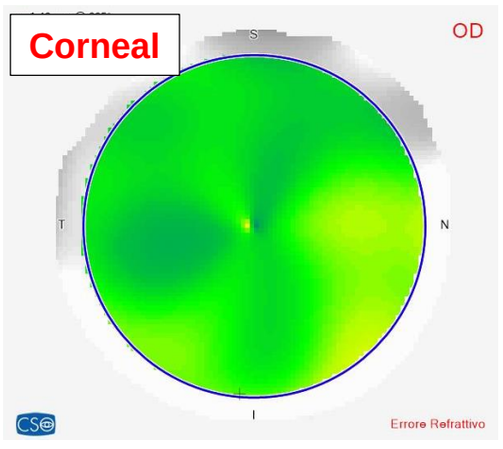


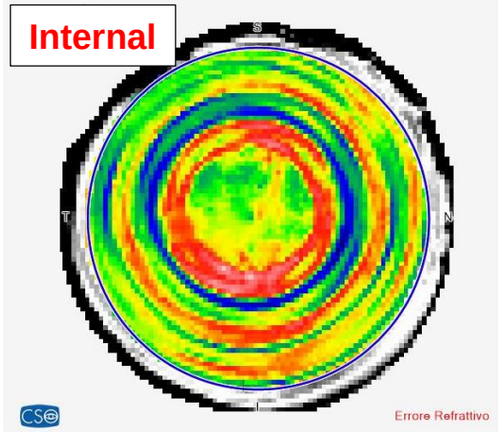
RESULTS – ABERROMETRY

- Sulcoflex Trifocal IOL showed 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



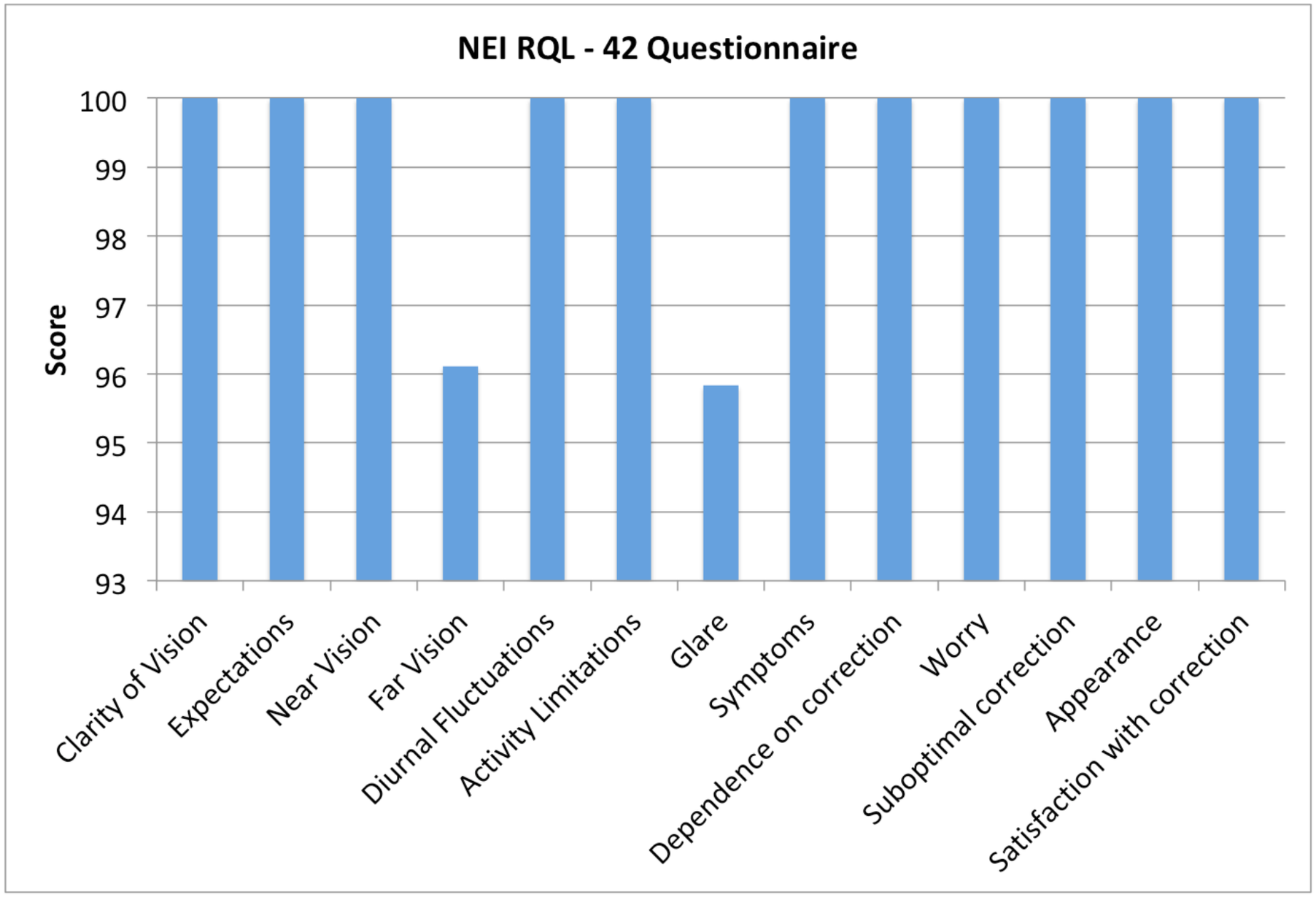






RESULTS – PATIENT SATISFACTION

- Patient satisfaction was evaluated with a self-administered questionnaire (NEI RQL – 42)
- High patient satisfaction was found in all patient underwent to a RayOne Trifocal IOL implantation
- Although the “far vision” and “glare” category have the lowest score compared to the others, overall it is a very high score (95/100)



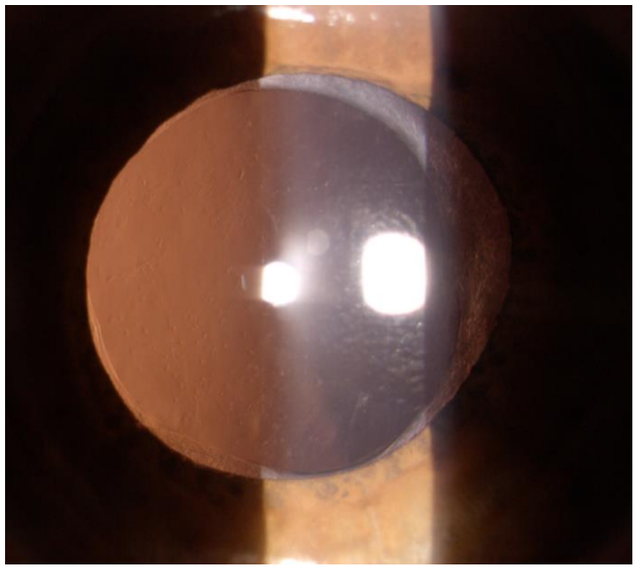
SULCOFLEX® TRIFOCAL – NEW INDICATIONS

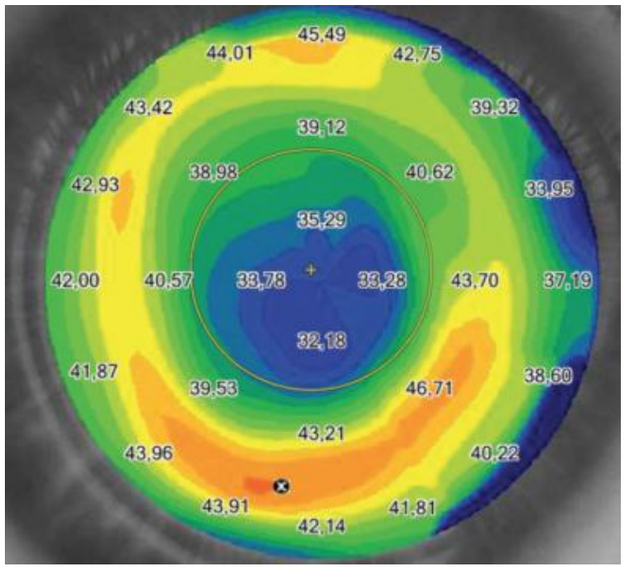
- Pseudophakic patients who want to be independent from glasses for near (with further possibility of correcting unplanned ametropias)

- Strongly motivated patients with relative contraindications to Trifocal IOLs (early maculopathy, early diabetic retinopathy, ocular hypertension): possibility to explant in the future (DUET procedure – reversibility)

- Unpredictability of calculation of IOL (refractive surgery, abnormal K, high myopia / hyperopia): first monofocal, then Trifocal in the sulcus (Two-step procedure)

- Patients with psycho-attitudinal problems (neuroadaptation, tolerability)





GRAZIE PER L'ATTENZIONE