Trifocal platform that performs on any optic

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All authors have no financial interests

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INTRODUCTION

- With the increase in patients' demand for spectacle independence after cataract surgery, a variety of advanced intraocular lenses (IOL) have been developed in recent years

- The technological advances of trifocal lenses are intended to answer **two specific questions:**
  1. **Do patients accept this new quality of vision?**
  2. **Is this quality of vision maintained over the time?**

MATERIAL AND METHODS

- **30 eyes** of 15 patients were evaluated in San Marino Hospital after implantation of **RayOne Trifocal IOL** (Group 1-20 eyes) and **Sulcoflex Trifocal IOL** (Group 2-10 eyes)
- Average Follow-up: 12 Months (Range 10-16 months)
- Average age: 71.81 (Range 53-84)

SULCOFLEX TRIFOCAL:

- 50% pseudophakic eyes
- 50% phaco + monofocal IOL in the bag + Sulcoflex Trifocal **(DUET PROCEDURE)**

EXCLUSION CRITERIA:

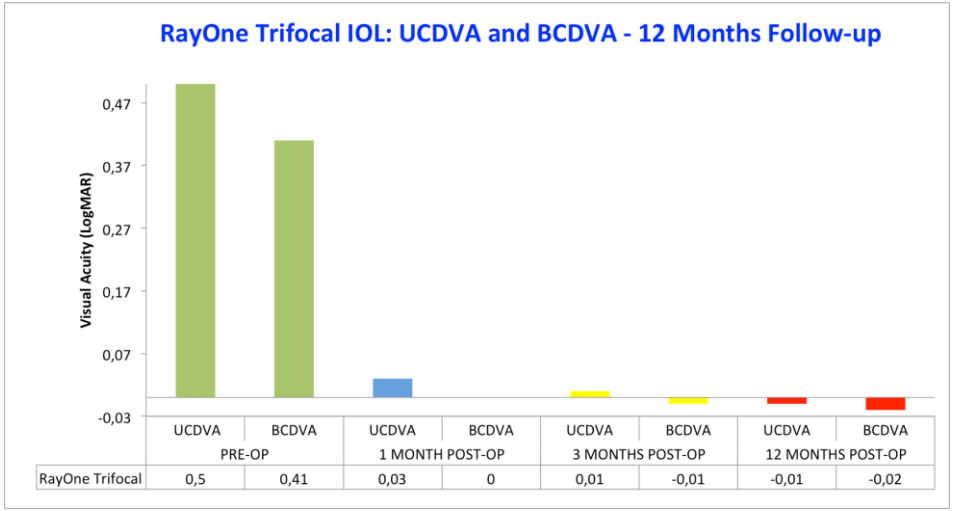
- Previous ocular surgery
- Regular corneal astigmatism > 0.75 D
- Irregular astigmatism and corneal opacities
- Glaucoma with impairment of GCL and RNFL
- Macular diseases

DATA EVALUATED:

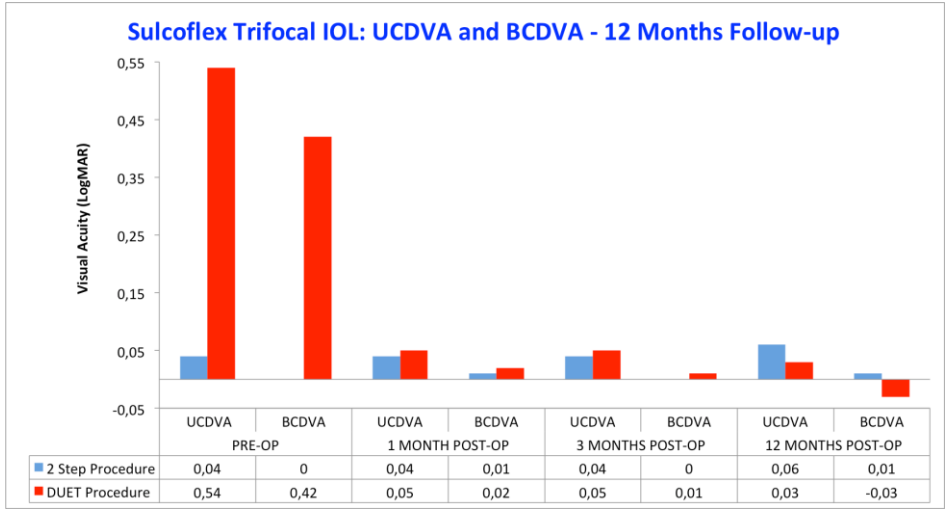
- Uncorrected Distance Visual Acuity **(UCDVA)** and Best Corrected Distance Visual Acuity **(BCDVA)** (LogMAR)
- Uncorrected and Best Corrected Near **(UCNVA, BCNVA)** and Intermediate Visual Acuity **(UCIVA, BCIVA)** (LogMAR) with MNread charts
- **Defocus curve** from -4.00 D to + 2.00 D
- **Contrast sensitivity** (mesopic 3 cd/m^2; photopic 85 cd/m^2) with MOS 22 (Dueffe Tecnovision)
- **Aberrometry** (OSIRIS – CSO)
- Patient satisfaction with a self-administered questionnaire (**NEI-RQL-42TM)**
- **PCO incidence** and IOL stability with digital photos of anterior segment

DISTANCE VISUAL ACUITY

- All patients in **RayOne Trifocal** Group achieved monocular **UCDVA of 0.1 LogMAR** or better
- 70% of patients in **Sulcoflex Trifocal** Group achieved monocular **UCDVA of 0.1 LogMAR** or better
- All patients of both Groups (RayOne and Sulcoflex Trifocal) achieved monocular **BCDVA of 0.1 LogMAR** or better



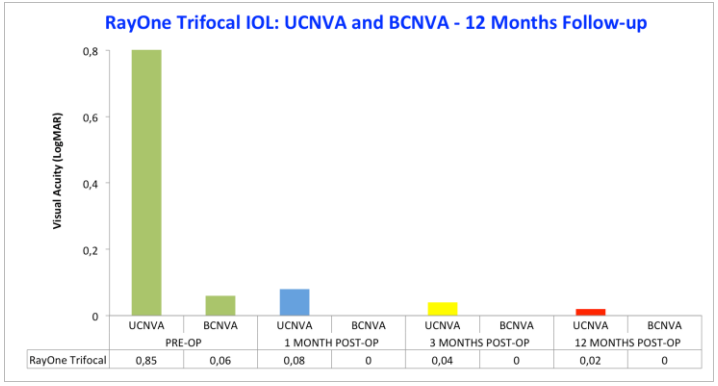
	UCDVA	BCDVA	UCDVA	BCDVA	UCDVA	BCDVA	UCDVA	BCDVA
	PRE-OP		1 MONTH POST-OP		3 MONTHS POST-OP		12 MONTHS POST-OP	
RayOne Trifocal	0,5	0,41	0,03	0	0,01	-0,01	-0,01	-0,02

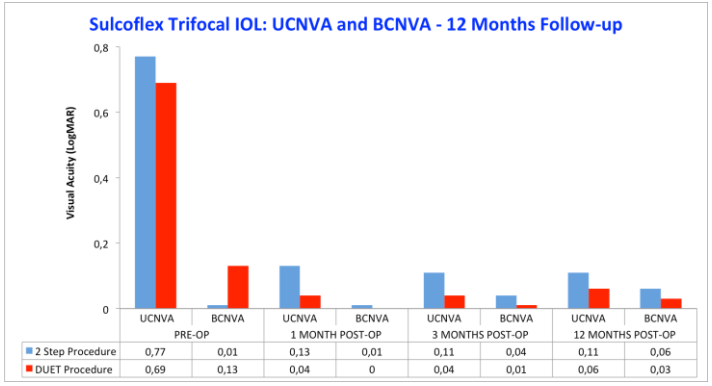


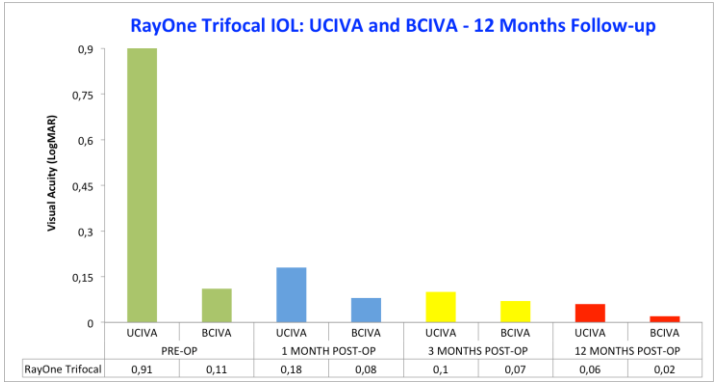
	UCDVA	BCDVA	UCDVA	BCDVA	UCDVA	BCDVA	UCDVA	BCDVA
	PRE-OP		1 MONTH POST-OP		3 MONTHS POST-OP		12 MONTHS POST-OP	
2 Step Procedure	0,04	0	0,04	0,01	0,04	0	0,06	0,01
DUET Procedure	0,54	0,42	0,05	0,02	0,05	0,01	0,03	-0,03

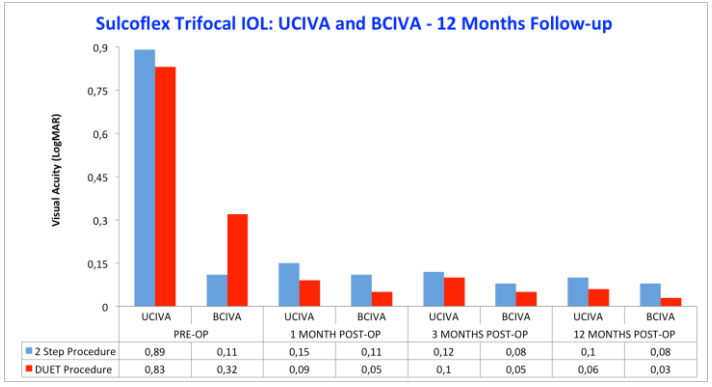
NEAR AND INTERMEDIATE VISUAL ACUITY

- All patients in **RayOne Trifocal** Group achieved monocular **UCNVA and UCIVA of 0.1 LogMAR** or better
- In **Sulcoflex Trifocal** Group, 70% and 100% of patients achieved respectively monocular **UCNVA and UCIVA of 0.1 LogMAR** or better
- **No statistically significant differences** were noted between 2 groups





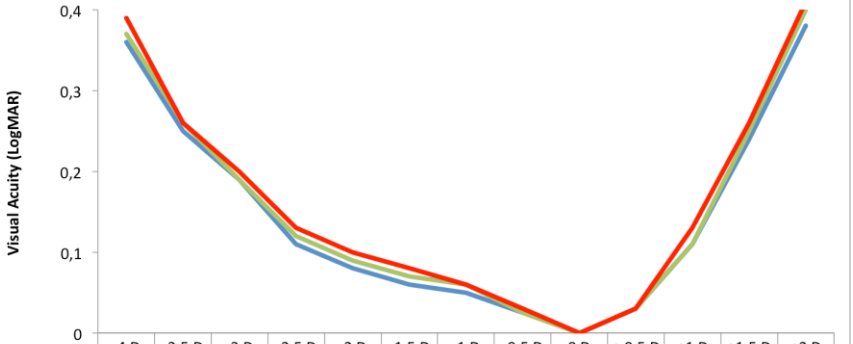




NEAR AND INTERMEDIATE VISION: DEFOCUS CURVE

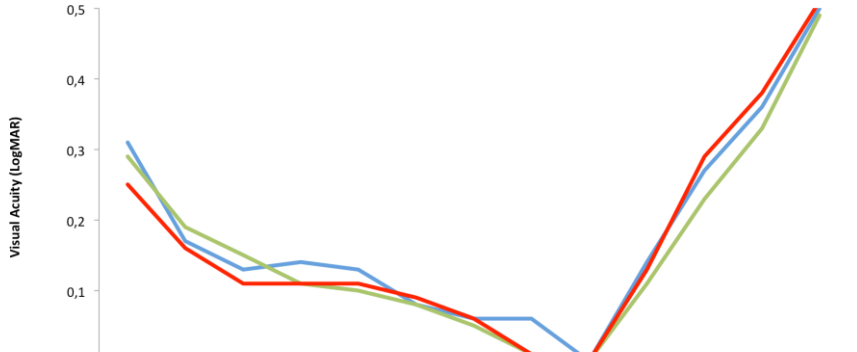
- At 12 months post-op, RayOne and Sulcoflex Trifocal Groups showed a **smooth transition phase** between the far and the near focus
- **From +0.50 D to -2.50 D**, visual acuity was on average **0.10 LogMAR** or better in all patients, demonstrating good intermediate vision
- **At -3.00 D** (near vision at 33 cm) **and -4.00 D** (near vision at 25 cm) visual acuity was on average **0.20 and 0.39 LogMAR for RayOne Trifocal** Group and **0.11 and 0.25 LogMAR for Sulcoflex Trifocal** Group
- There were **no statistically significant differences** between the two groups (p>0,01) and no statistically significant changes in defocus curve during the follow-up

RAYONE TRIFOCAL: DEFOCUS CURVE DURING FOLLOW-UP



	-4 D	-3,5 D	-3 D	-2,5 D	-2 D	-1,5 D	-1 D	-0,5 D	0 D	+ 0,5 D	+1 D	+1,5 D	+2 D
1 Month Post-op	0,36	0,25	0,19	0,11	0,08	0,06	0,05	0,025	0	0,03	0,11	0,24	0,38
3 Months Post-op	0,37	0,26	0,19	0,12	0,09	0,07	0,06	0,025	0	0,03	0,11	0,25	0,4
12 Months Post-op	0,39	0,26	0,2	0,13	0,1	0,08	0,06	0,03	0	0,03	0,13	0,26	0,41

SULCOFLEX TRIFOCAL: DEFOCUS CURVE DURING FOLLOW-UP

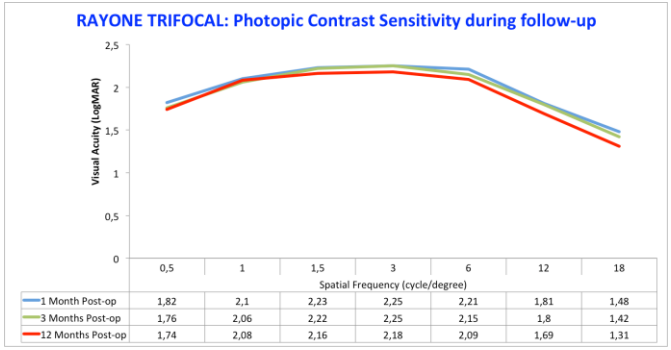


	-4 D	-3,5 D	-3 D	-2,5 D	-2 D	-1,5 D	-1 D	-0,5 D	0 D	+ 0,5 D	+1 D	+1,5 D	+2 D
1 Month Post-op	0,31	0,17	0,13	0,14	0,13	0,08	0,06	0,06	0	0,14	0,27	0,36	0,5
3 Months Post-op	0,29	0,19	0,15	0,11	0,1	0,08	0,05	0,01	0	0,11	0,23	0,33	0,49
12 Months Post-op	0,25	0,16	0,11	0,11	0,11	0,09	0,06	0,01	0	0,13	0,29	0,38	0,51

QUALITY OF VISION: CONTRAST SENSITIVITY

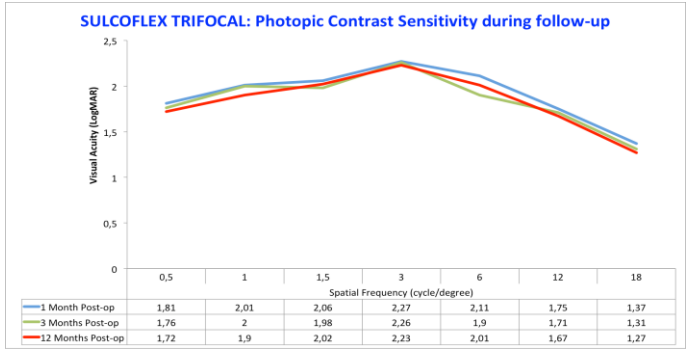
- Contrast sensitivity levels of both groups were within **normal limits under photopic** (85 cd/m^2) **and mesopic** (3 cd/m^2) **conditions** during the follow-up
- In photopic and mesopic condition **RayOne Trifocal** and **Sulcoflex Trifocal** Groups showed **similar results** throughout all spatial frequency
- During follow-up, there were **no statistically significant changes** in contrast sensitivity levels

RAYONE TRIFOCAL: Photopic Contrast Sensitivity during follow-up



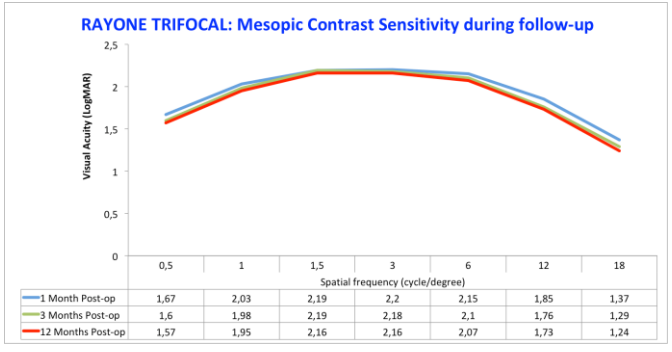
	0,5	1	1,5	3	6	12	18
	Spatial Frequency (cycle/degree)						
1 Month Post-op	1,82	2,1	2,23	2,25	2,21	1,81	1,48
3 Months Post-op	1,76	2,06	2,22	2,25	2,15	1,8	1,42
12 Months Post-op	1,74	2,08	2,16	2,18	2,09	1,69	1,31

SULCOFLEX TRIFOCAL: Photopic Contrast Sensitivity during follow-up



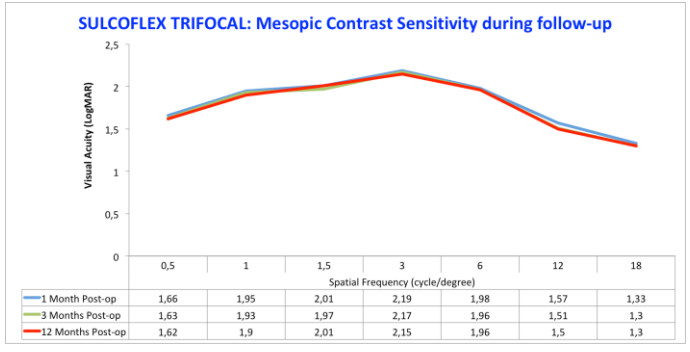
	0,5	1	1,5	3	6	12	18
	Spatial Frequency (cycle/degree)						
1 Month Post-op	1,81	2,01	2,06	2,27	2,11	1,75	1,37
3 Months Post-op	1,76	2	1,98	2,26	1,9	1,71	1,31
12 Months Post-op	1,72	1,9	2,02	2,23	2,01	1,67	1,27

RAYONE TRIFOCAL: Mesopic Contrast Sensitivity during follow-up



	0,5	1	1,5	3	6	12	18
	Spatial frequency (cycle/degree)						
1 Month Post-op	1,67	2,03	2,19	2,2	2,15	1,85	1,37
3 Months Post-op	1,6	1,98	2,19	2,18	2,1	1,76	1,29
12 Months Post-op	1,57	1,95	2,16	2,16	2,07	1,73	1,24

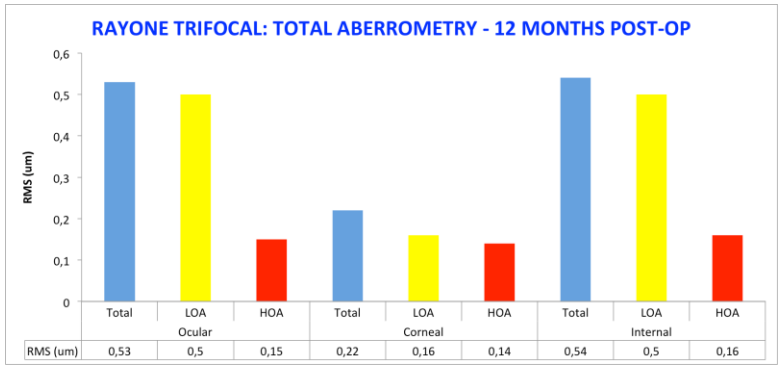
SULCOFLEX TRIFOCAL: Mesopic Contrast Sensitivity during follow-up

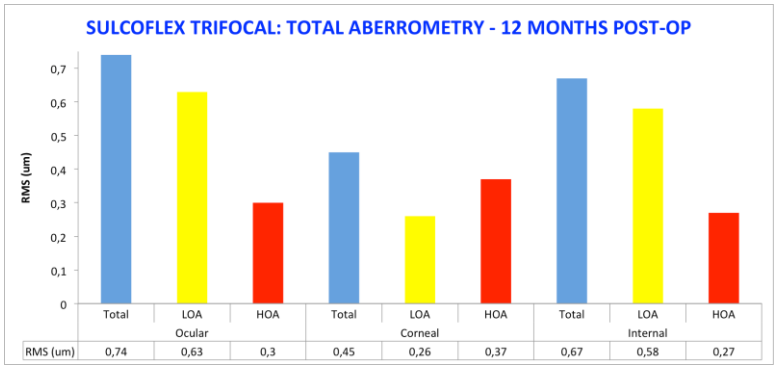


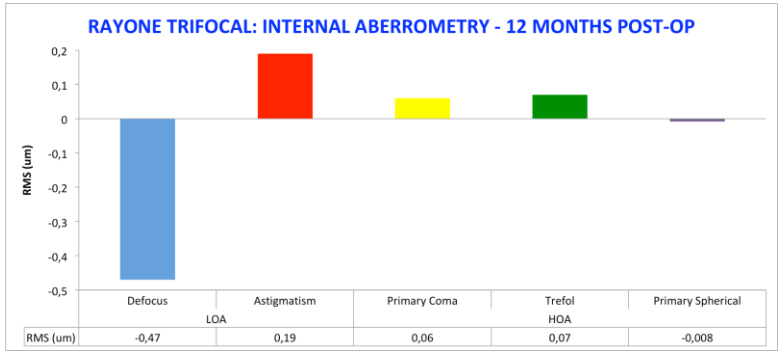
	0,5	1	1,5	3	6	12	18
	Spatial Frequency (cycle/degree)						
1 Month Post-op	1,66	1,95	2,01	2,19	1,98	1,57	1,33
3 Months Post-op	1,63	1,93	1,97	2,17	1,96	1,51	1,3
12 Months Post-op	1,62	1,9	2,01	2,15	1,96	1,5	1,3

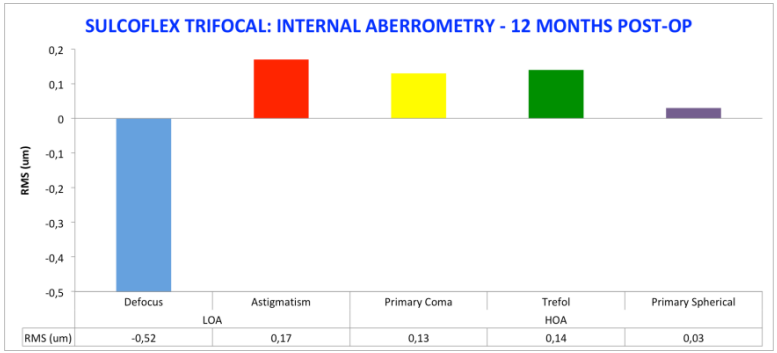
QUALITY OF VISION: ABERROMETRY

- **RayOne Trifocal** and **Sulcoflex Trifocal** Groups showed **low values of LOA and HOA** regarding ocular, corneal and internal aberrations in all patients
- **RayOne Trifocal** Group showed **lower internal LOA and HOA** aberrations than **Sulcoflex Trifocal** Group **(not statistically significant)**



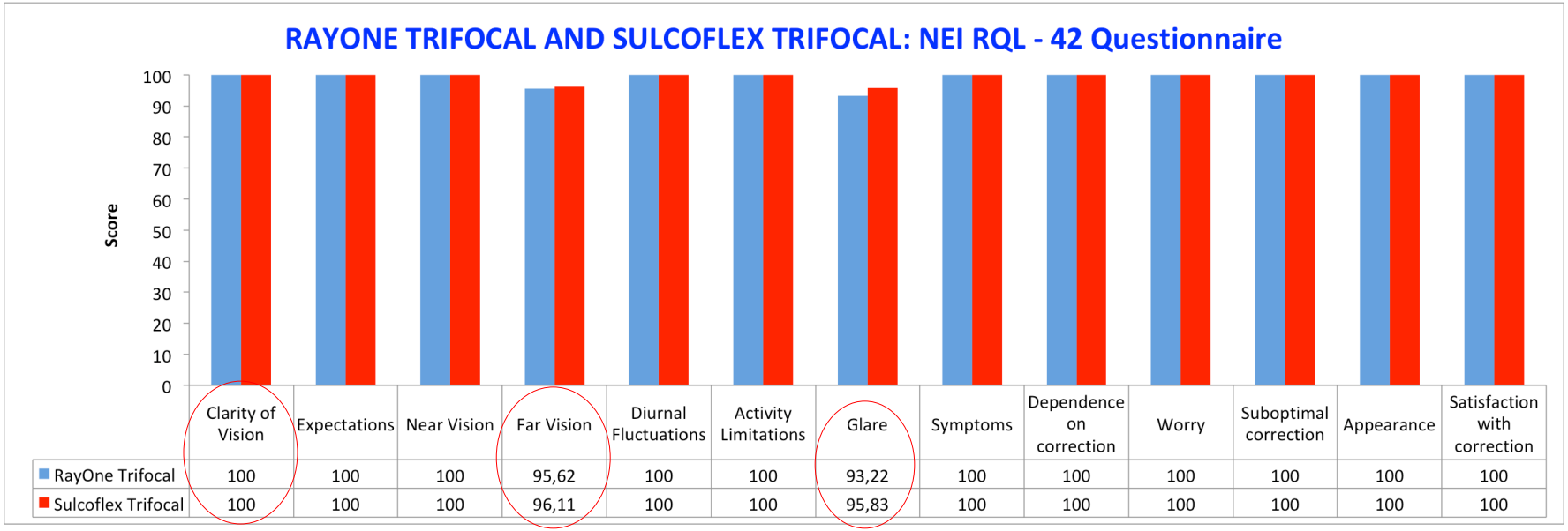






QUALITY OF VISION: PATIENT SATISFACTION

- 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** and **uSulcoflex Trifocal** IOL implantation
- Although **the "far vision" and "glare" category** have the lowest score compared to the others, overall they reached a **very high score (95/100)**



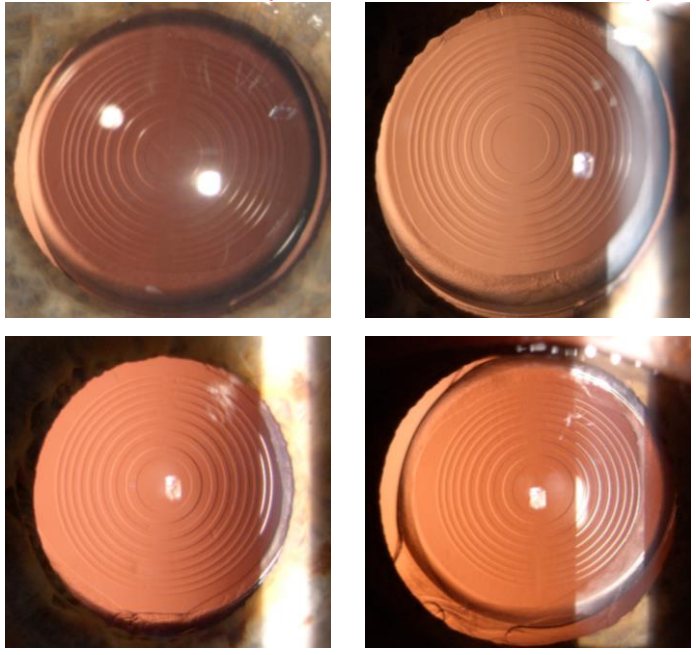
	Clarity of Vision	Expectations	Near Vision	Far Vision	Diurnal Fluctuations	Activity Limitations	Glare	Symptoms	Dependence on correction	Worry	Suboptimal correction	Appearance	Satisfaction with correction
RayOne Trifocal	100	100	100	95,62	100	100	93,22	100	100	100	100	100	100
Sulcoflex Trifocal	100	100	100	96,11	100	100	95,83	100	100	100	100	100	100

QUALITY OF VISION: PCO AND IOL STABILITY

- 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 Trifocal** and **Sulcoflex Trifocal** IOL
- IOL stability and centration was excellent during the follow-up: **no tilting or decentration** was reported in any case

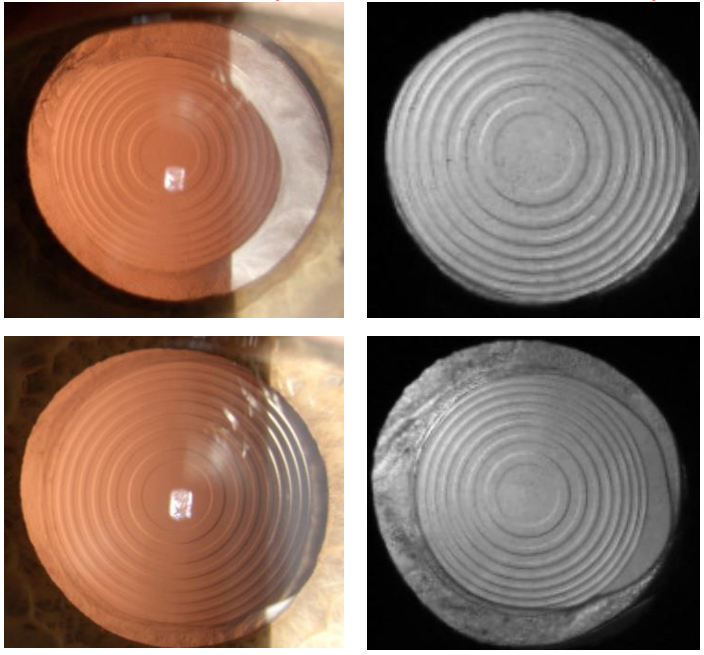
RayOne Trifocal

1 Month Post-op | 12 Months Post-op



Sulcoflex Trifocal

1 Month Post-op | 10 Months Post-op

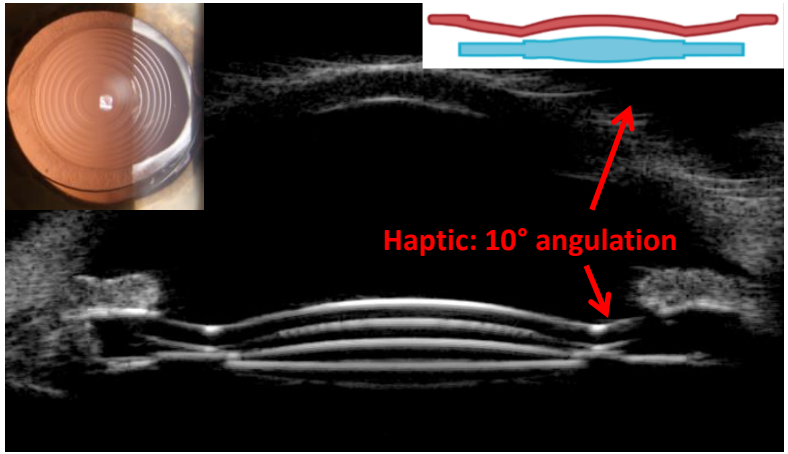


SULCOFLEX TRIFOCAL: CRITICAL QUESTIONS

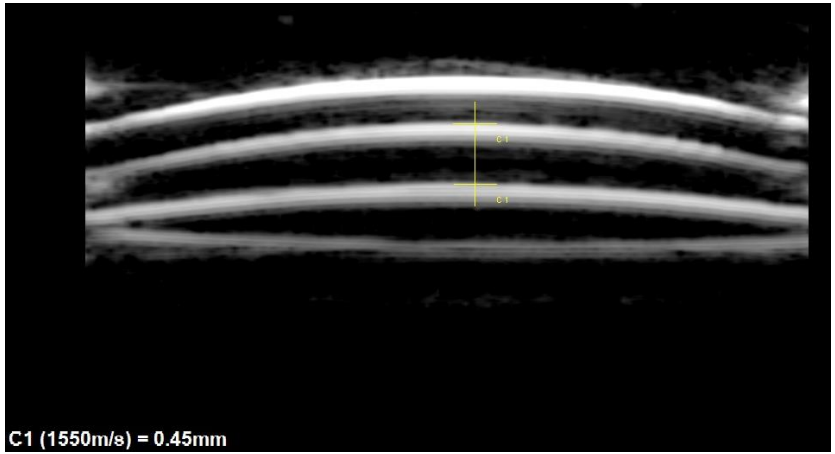
- **FIRST QUESTION:** Since it is implanted in the sulcus, **is there the possibility that it interacts with the IOL in the bag?**

UBM: CENTERING AND POSITIONING IN THE SULCUS

- We performed **UBM in all patients** at the 3 month post-op to observe the centering and positioning of the **Sulcoflex Trifocal** and its possible interaction with the surrounding ocular structures



Haptic angulation 10°: strong stability and centration



Posterior concave surface allows to obtain a good vaulting (400-450 microns): No interaction with primary IOL

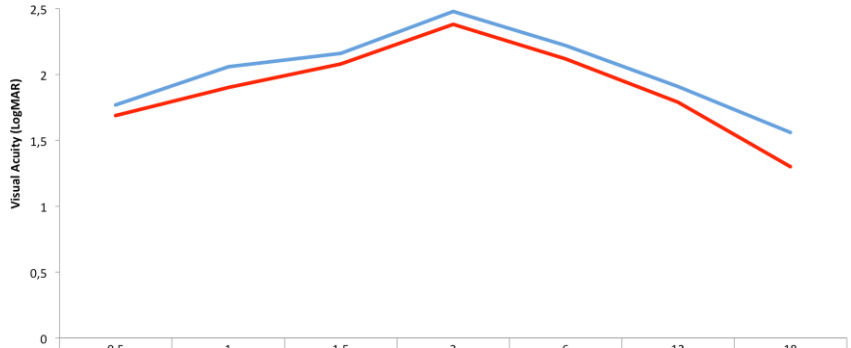
SULCOFLEX TRIFOCAL: CRITICAL QUESTIONS

- A pseudophakic patient has a very high visual quality
- **SECOND QUESTION:** By implanting a **Sulcoflex Trifocal** in the sulcus of a pseudophakic patient, **is there a risk of compromising visual quality?**

PHOTOPIC AND MESOPIC CONTRAST SENSITIVITY: PRE-SULCOFLEX VS POST-SULCOFLEX

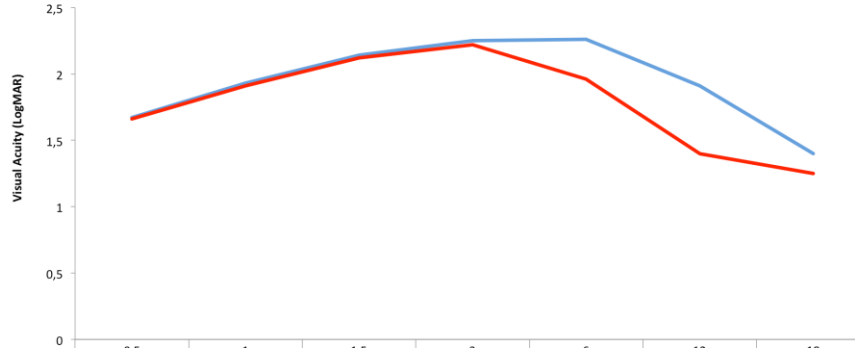
- **Post-op photopic contrast sensitivity** (85 cd/m^2) was **similar compared to pre-op** contrast sensitivity in pseudophakic eyes
- **In mesopic condition** (3 cd/m^2) after **Sulcoflex Trifocal** implantation there was a **reduction in contrast sensitivity** at higher spatial frequency > 12 cycle/degree **(not statistically significant)**
- During follow-up, there were **no statistically significant changes** in contrast sensitivity levels

2 STEP PROCEDURE: Photopic Contrast Sensitivity Pre-op vs 12 Months Post-op



	0,5	1	1,5	3	6	12	18
Pre-op	1,77	2,06	2,16	2,48	2,22	1,91	1,56
12 Months Post-op	1,69	1,9	2,08	2,38	2,12	1,79	1,3

2 STEP PROCEDURE: Mesopic Contrast Sensitivity Pre-op vs 12 Months Post-op



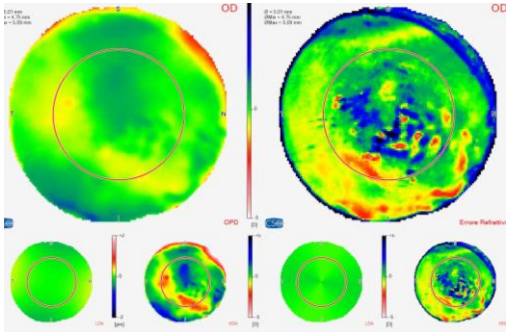
	0,5	1	1,5	3	6	12	18
Pre-op	1,67	1,93	2,14	2,25	2,26	1,91	1,4
12 Months Post-op	1,66	1,91	2,12	2,22	1,96	1,4	1,25

SULCOFLEX TRIFOCAL: CRITICAL ISSUES

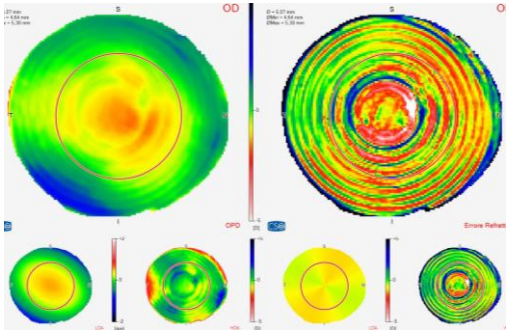
TOTAL AND INTERNAL ABERROMETRY

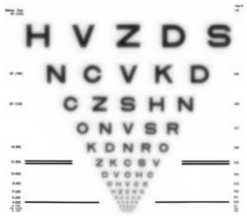
- **Sulcoflex Trifocal** IOL showed **low values of LOA and HOA regarding total and internal aberrations** in all patients
- **Internal aberrations are directly related to the IOL:** low values of RMS indicate a minimum dispersion of the light inside the eye and good quality of vision

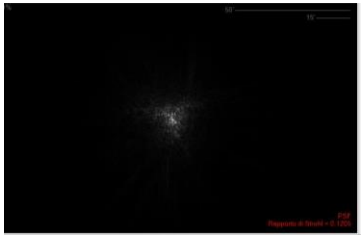
Pre-Sulcoflex



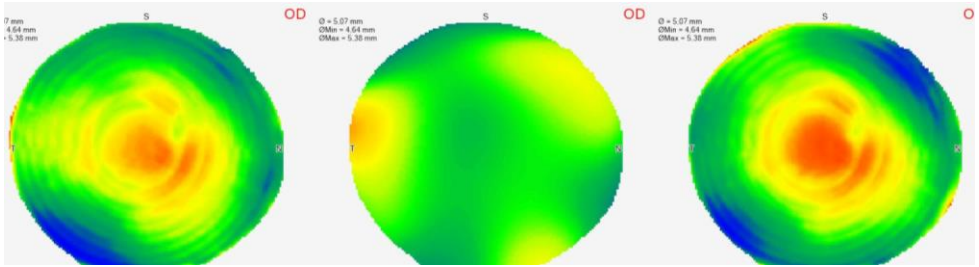
Post-Sulcoflex

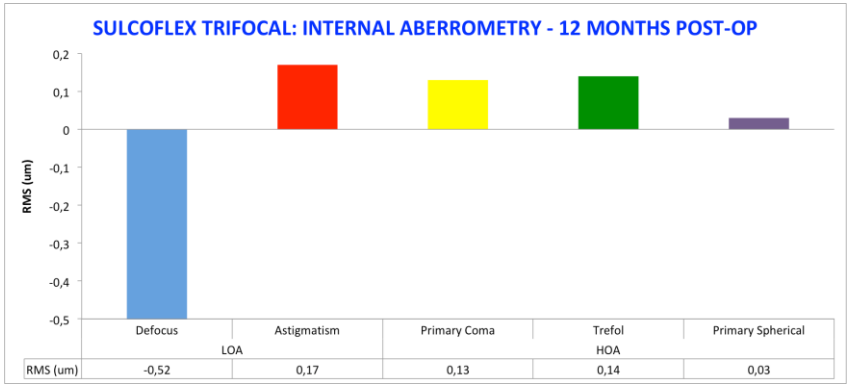






Ocular Corneal Internal





CONCLUSION: RAYONE TRIFOCAL & SULCOFLEX TRIFOCAL

- The RayOne Trifocal and Sulcoflex Trifocal provide a **very high level of spectacle independence**, with a high post-operative satisfaction
- RayOne Trifocal and Sulcoflex Trifocal IOL showed **similar results regarding visual outcomes, defocus curve, contrast sensitivity and internal aberrations**
- Both Trifocal IOLs demonstrated **long term stability, good centration and no PCO**
- **Sulcoflex Trifocal** showed **long term stability and centration** and **no interaction with primary IOL** during the follow-up in all patients
- This new trifocal IOLs offer a **valid alternative for spectacle independence** after cataract surgery in selected patients