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?
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/m²; photopic 85 cd/m²)* 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
• 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
• 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
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.
• Contrast sensitivity levels of both groups were within **normal limits under photopic** (85 cd/m²) and **mesopic** (3 cd/m²) **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
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)
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 decenteration was reported in any case.
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: 10° angulation

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/m²) was similar compared to pre-op contrast sensitivity in pseudophakic eyes
- In mesopic condition (3 cd/m²) 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
**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

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**SULCOFLEX TRIFOCAL: INTERNAL ABERRROMETRY - 12 MONTHS POST-OP**

<table>
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<th>RMS (µm)</th>
<th>Defocus</th>
<th>Astigmatism</th>
<th>Primary Coma</th>
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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.