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

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SULCOFLEX ASPHERIC

RAYONE TRIFOCAL
SULCOFLEX® TRIFOCAL - RAYNER

SULCOFLEX ASPHERIC

- Accuracy of results
- Sulcus stability

Outcomes of toric supplementary intraocular lenses for residual astigmatic refractive error in pseudophakic eyes.
McLintock CA\textsuperscript{1,2}, McKelvie J\textsuperscript{3}, Gatziotas Z\textsuperscript{3}, Wilson JJ\textsuperscript{4}, Stephensen DC\textsuperscript{4}, Apel AJG\textsuperscript{4,5}.

Correction of undesirable pseudophakic refractive error with the Sulcoflex intraocular lens.
Falzon K\textsuperscript{1}, Stewart OG.

Performance of the Sulcoflex piggyback intraocular lens in pseudophakic patients.
Khan Mi\textsuperscript{1}, Muhtasib M.

Piggyback intraocular lens implantation to correct pseudophakic refractive error after segmental multifocal intraocular lens implantation.
Venter JA, Oberholster A, Schallhorn SC, Pelouskova M.

New supplementary intraocular lens for refractive enhancement in pseudophakic patients.
Kahraman G\textsuperscript{1}, Amon M.
RAYONE TRIFOCAL

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

SULCOFLEX® TRIFOCAL - RAYNER

Performance visiva e stabilità dell'IOL trifocale RayOne (Rayner®)

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

INTRODUCTION

The increase in the demand for IOLs based on trifocal technology has been driven by the desire for improved reading vision, as well as the need to correct high myopia and presbyopia. The RayOne trifocal IOL is designed to provide three distinct zones of focus, allowing for improved vision in all distances.

METHODS AND MATERIALS

20 patients with myopia between -3.00 and -6.00 D were enrolled in the study. The RayOne IOL was implanted in the anterior chamber, without any complications reported. The study was conducted according to the tenets of the Declaration of Helsinki.

RESULTS

- In all patients, RayOne and RayTritec groups showed similar post-operative visual acuity results.
- No significant differences were found in pre-operative refraction, spherical equivalent, or astigmatism.
- Post-operative visual acuity was found to be similar in both groups, with no significant differences in any tested parameter.

CONCLUSIONS

The RayOne trifocal IOL provides excellent visual outcomes and is a viable option for patients seeking improved vision in all distances. Further studies are needed to evaluate the long-term effects of this technology.
SULCOFLEX® TRIFOCAL - FEATURES

- 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)
UBM: IOL design and centration

- Posterior concave surface: minimal interaction with primary IOL
- Reduced refractive error (hyperopic defocus)
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
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.
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/m²) and mesopic (3 cd/m²) 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)
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 – ABERROMETRY**

<table>
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<tr>
<th>Defocus</th>
<th>Astigmatism</th>
<th>Primary Coma</th>
<th>Trefol</th>
<th>Primary Spherical</th>
</tr>
</thead>
<tbody>
<tr>
<td>LOA</td>
<td>HOA</td>
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**Internal aberrations - 1 Month follow-up**
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)
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