Comparison of visual performance of 2 diffractive trifocal intraocular lenses: a randomised controlled trial

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• Aerie
• Alcon
• Bausch + Lomb
• Carl Zeiss Meditec AG
• Cristalens
• Croma Pharma
• Heidelberg Engineering
• Johnson & Johnson Vision Care
• Novartis
• Oculentis
• Rayner
• Roche

O. Findl - Scientific Advisor / Member of Scientific Advisory Board:
• Alcon
• Carl Zeiss Meditec AG
• Croma Pharma
• Johnson & Johnson Vision Care
• Merck

Personal financial interest in products:
• None
Trifocal IOLs

- Near vision
- Intermediate vision
- Far vision
Comparison of the two study lenses

RayOne Trifocal

- 4.5mm diffractive trifocal zone
- >4.5mm monofocal, distance

AT LISA tri 839 MP

- 4.34mm diffractive trifocal zone
- >4.34mm bifocal zone
Study design

• randomized, double-masked trial
• 88 eyes of 44 patients
  • one eye AT LISA tri 839 MP (Zeiss)
  • other eye RayOne Trifocal (Rayner)
    – randomized assignment of IOL
Inclusion criteria

- Senile cataract
- Scheduled cataract surgery for both eyes
- Motivated to be less spectacle dependent
- ≥ 21 years
- Corneal astigmatism ≤ 1.5 D (keratometry, IOL Master)

Exclusion criteria

- Pregnancy
- Retinitis pigmentosa, chronic uveitis, amblyopia
- Pupil misalignment > 1mm
- Previous LASIK / retinal surgery
Methods

• Main outcome
  • Change of uncorrected near visual acuity (UNVA)

• Secondary outcome
  • Uncorrected and best corrected distant visual acuity (UCDVA, BCDVA)
  • Uncorrected and distance corrected intermediate visual acuity (UCIVA, BIVA)
  • Distance corrected near visual acuity (DCNVA)
  • Defocus curve
  • Salzburg reading desk
  • Aston halometer
  • Contrast sensibility in miosis and mydriasis
  • Quality of vision questionnaire
Uncorrected VA

\[ p = 0.707 \quad p = 0.460 \quad p = 0.327 \]

\[ n = 40 \]

- Ray One Trifocal
- AT LISA tri
Distance corrected VA

n = 40

Ray One Trifocal
AT LISA tri

\( p = 0.527 \quad p = 0.519 \quad p = 0.193 \)
Defocus curve

-4 -3.5 -3 -2.5 -2 -1.5 -1 -0.5 0 0.5 1 1.5 2

logMAR

RayOne Trifocal
AT LISA tri

p=0.167
p=0.016
p=0.121
Salzburg Reading Desk

![Box Plots](image)

- **RayOne Trifocal**
  - Average time: 10.5 seconds
  - Average words per minute: 180

- **AT Lisa tri**
  - Average time: 12.3 seconds
  - Average words per minute: 150

- **Statistical Significance**
  - p-value for time: 0.633
  - p-value for words per minute: 0.258
Aston Halometer

p=0.434

RayOne Trifocal

AT LISA tri

TRI018 OD

RayOne Trifocal

AT LISA tri

TRI018 OS

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## OPTEC 6500 Vision Tester

<table>
<thead>
<tr>
<th></th>
<th>Photopic</th>
<th>Mesopic</th>
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<tr>
<td></td>
<td>RayOne Trifocal</td>
<td>AT LISA tri</td>
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<tr>
<td><strong>Miosis</strong></td>
<td>13.5 (± 5.9)</td>
<td>17.3 (± 7.4)</td>
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<td>p = 0.493</td>
<td>p = 0.082</td>
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<tr>
<td><strong>Miosis + Glare</strong></td>
<td>14.1 (± 6.7)</td>
<td>16.2 (± 7.0)</td>
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<tr>
<td></td>
<td>p = 0.808</td>
<td>p = 0.790</td>
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<tr>
<td><strong>Mydriasis</strong></td>
<td>9.0 (± 5.9)</td>
<td>12.3 (± 7.1)</td>
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<tr>
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<td>p = 0.293</td>
<td>p = 0.297</td>
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<tr>
<td><strong>Mydriasis + Glare</strong></td>
<td>6.3 (± 5.7)</td>
<td>9.0 (± 7.5)</td>
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<tr>
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<td>p = 0.691</td>
<td>p = 0.159</td>
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Decentration

![Graph showing decentration with RayOne Trifocal and AT Lisa tri data points.]

<table>
<thead>
<tr>
<th></th>
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<tbody>
<tr>
<td>Mean</td>
<td>0.92</td>
<td>0.94</td>
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<tr>
<td>SD</td>
<td>± 0.32</td>
<td>± 0.23</td>
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<tr>
<td>p</td>
<td>0.465</td>
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Tilt

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<tr>
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<tbody>
<tr>
<td><strong>Mean</strong></td>
<td>3.09</td>
<td>3.20</td>
</tr>
<tr>
<td><strong>SD</strong></td>
<td>± 0.91</td>
<td>± 0.94</td>
</tr>
<tr>
<td><strong>p</strong></td>
<td>0.779</td>
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</tbody>
</table>
Quality of vision

- Glare
- Haloes
- Starbursts
- Hazy vision
- Blurred vision
- Distortion
- Double vision
Quality of vision

- glare
- haloes
- starbursts
- hazy vision
- blurred vision
- distortion
- multiple images
- fluctuation of vision
- focusing difficulties
- depth perception

- never
- occasionally
- quite often
- very often

patients
Severity

- glare
- haloes
- starbursts
- hazy vision
- blurred vision

Severity levels:
- not at all
- mild
- moderate
- severe

Number of patients:
- glare: 10
- haloes: 15
- starbursts: 10
- hazy vision: 25
- blurred vision: 30

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Subjective Disturbance of Vision

Ray One Trifocal

AT LISA tri

n=23

Overall Disturbance  p=0.67

Subjective Starbursts.  p=0.34

Subjective Glare  p=0.63

Subjective Halo  p=0.43

Subjective Near Visual Acuity  p=0.37

Subjective Intermediate Visual Acuity  p=0.26

Subjective Distant Visual Acuity  p=0.20
Conclusions

RayOne Trifocal showed...

- trend for slightly better UCNVA and DCNVA
- significantly better VA in intermediate zone in defocus curve
- no significant difference concerning dysphotopsia
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