Criteria of Selection and Indication, Results and Satisfaction, In Presbyopia Surgery with RayOne Trifocal premium lens

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Clinica Baviera, Spain
NO FINANCIAL INTEREST
0. Two Questions, Two Ideas
Which patients are suitable for a MIOL?

“The main indication is the presbyopic patient”

Also in:

- Cataract surgery
- RLE for:
  - Dysfunctional Lens Syndrome
  - High ametropia (especially hyperopia)
When to implant a MIOL?

“When it is possible to obtain the emmetropia”

You need a perfect surgery but also:
- Select the good candidate
- Have equipment for after-surgery enhancements
- Be prepared to manage the unsatisfied patient

“If you can deliver a perfectly emmetropic eye at the end of surgery, you have no problem implanting a MIOL”

(Robert M. Kershner, MD)
1. Patient selection

**Before the operation:** patient selection
1.1. Anamnesis

“The first contact establishes doctor-patient relationship...and obtain important data “

- **Occupation** and particular needs such as:
  - Professional driving
  - Intensive near vision using
  - Hunting, Olympic shooting...

- **Personality** and mental disorders:
  - High demand and expectations
  - Problems to be adapted, obsession
  - Medication (dilates pupil)

- **General health** problems:
  - Diabetes
  - Age: advanced senility?
  - Cataract old patients usually very pleased
1.2. Diagnosis and prognosis

*Explain: “What happens, why it happens and what can we obtain”*

- **Diagnosis:**
  - Presbyopia
  - Ametropia
  - Level

- **Specific features:**
  - Dry eye
  - Ambliopia

- **Prognosis:**
  - Near/Intermediate/Distance visions
  - Glasses independence
  - Dissatisfaction causes
1.3. Information and Informed Consent

“Exhaustive oral and written information”

- Information:
  - Custom explanation
  - Medical report

- Informed Consent:
  - Endorsed by Scientific Society
  - Personalized

- Attached Information:
  - “Multifocal vision”
1.4. Follow-up

“Establish a protocol and report on the post-op evolution”

- **Immediate Post-op:**
  - Inflammation, IOP, Lens position...

- **Visual and refractive evolution:**
  - Protocol: next day, 1 week, 1 month, 3 month

- **End of surgical process:**
  - Outcomes
  - Satisfaction
  - dissatisfaction causes
  - Medical report
2. Pre-operative evaluation

Before the operation: standard patient evaluation and...
2.1. Standard exploration

“Lens surgery is also refractive surgery and it is necessary to perform the standard exploration”

- Visual acuity (near, intermediate, distance)
- Refraction (near, intermediate, distance)
- IOP
- Biomicroscopy
- Ocular motility (Kappa angle, dominance)
- Pupillometry
- TBUT
- Pachimetry
- Corneal Topography
- Endothelial Count
- Fundus exploration (OCT)
2.2. Surface disease

“It is essential to study of the ocular surface”

Rule-out:

- Corneal Fuchs dystrophy
- Severe dry eye
- Corneal scars, infiltrates
- Corneas non-suitable for laser correction (KC)

Corneal Topography and Endothelial Count are mandatory!
2.3. Pupil size

“Really is important the size and the pupillary function”

- You need a pupil that is small enough when accommodating and not very large by night to avoid halos and permit reading.

- Evaluate pupil function, don’t see the patient after dilation.
2.4. Kappa angle

- Diffractive lenses tolerate better the kappa angle than refractive lenses.
- In patients with a larger angle k, the choice to implant a trifocal IOL **should be carefully evaluated**.
2.5. Fundus evaluation

“Mandatory in intraocular surgery”

Perform routine macular OCT
(next to a good fundus examination)

- Epiretinal membranes: easy to overlook and can progress faster after surgery
- Patient with moderate stable macular disease: expect less distance and near VA and inform the patient accordingly
2.6. Accurate biometry

“Special attention to the IOL calculation”

- Use **optical interferometry** (if necessary: immersion biometry)

- **Personalize lens constants** by studying deeply your first cases with every new lens

- **Recalculate** lens power for the **second eye** if inaccurate first eye result (account for half the error)

- Use **new generation** formulae such as Haigis, Olsen and Barret. SRK-T preferred in myopic, Hoffer-Q in hyperopic
2.7. Astigmatism correction

“Always plan in advance the management of astigmatism”

- What to do with the previous or induced astigmatism (SIA & TIA)

  - Skill one or more **techniques** and have them available: AK and LRI, (manual or femtosecond), Lasik, PRK, toric lenses

  - **Consider corneal** astigmatism (anterior and posterior)

  - **Consider toric implant**: >? D astigmatism
2.8. Refractive error

“Also want to remove glasses for far”

- Better: **hyperopic** that only wear glasses for reading
- Worse: **myopic** that take glasses off for reading

- **Attention to very myopic eyes**
- **Be careful in amblyopic or anisometropic eyes**
3. Implanting multifocal lenses

During the operation
3.1. Incision

“Be careful: do NOT induce astigmatism”

- Place it in the correct axis (ink-marks if needed at the slit lamp)
- Take WTW measurements into account
- If no astigmatism, make anastigmatic incisions (limbal-short-temporal)
- Consider simultaneous LRI or AK, or paired incisions
3.2. Capsulorhexis (CCC)

“Should cover the edge of the optics”

- Must be:
  - Perfectly **centred**
  - Perfectly **round**
  - Perfectly **sized**
3.3. Iris

“*Take care of the iris*”

**ATTENTION to the IFIS**

- Don’t overstretch the pupil, consider using iris hooks if IFIS or small pupils
- Respect the iris with the phaco tip
- Avoid iris herniation
- Avoid postoperative high intraocular pressure
3.4. IOL implant

“Implanting in-the-bag”

→ Caution
  - Broken/very weak zonulae
  - Broken/very asymmetric capsulorhexis
  - Broken lens haptic
  - Capsular rupture with vitreous loss
4. Post-operative management
Problems:
1. Lens decentration
2. Refractive residual error
3. Dysphotopsias
4. Blurred vision
5. Dry eye
6. Posterior capsule opacity

No complications, good result

Neuroadaptation!

Happy patient

Unhappy patient

Dissatisfaction after multifocal intraocular lens implantation

Maria A. Woodward, MD, J. Bradley Rinderman, MD, R. Doyle Wolting, MD, PhD

PURPOSE: To analyze the reasons for patient dissatisfaction after phakemultifocal with multifocal intraocular lens (IOL) implantation and the outcomes after reinsertion.

METHODS: This retrospective review comprised cases of patients dissatisfied with visual outcomes after multifocal IOL implantation. Outcomes analysis included the visual condition and treatment modality for each case, and the degree of clinical improvement after reinsertion.

RESULTS: Thirty-two patients (54 eyes) reported various visual complaints after multifocal IOL implantation. Of these, 28 eyes (53%) were satisfied with the visual outcomes, with 15 (28%) reporting best corrected vision (BCVA), 13 (24%) reporting photopic vision, and 13 (24%) reporting dark adaptation. Causes of visual complaints included astigmatism (17 eyes, 29%), dry eye syndrome (12 eyes, 21%), posterior capsule opacification (9 eyes, 16%), and uncontrolled refraction (7 eyes, 13%). Causes of visual disturbances included 30 eyes (54%), 15 eyes (28%), and 10 eyes (18%), respectively. The outcomes of each patient were analyzed, and the degree of clinical improvement after reinsertion was determined.

CONCLUSIONS: Complaints of visual disturbances and photonic phenomena after multifocal IOL implantation were effectively managed with appropriate treatment. Two eyes (7%) required additional IOL, and additional IOL exchanges were performed in 11 eyes (18%) to achieve the best visual outcome.
5. Our study (methods)
5.1. Inclusion criteria

☐ Prospective study
  ▪ Multicenter, Clinica Baviera, Spain
  ▪ Multi surgeon
  ▪ Performed in accordance with the principles of the Declaration of Helsinki
  ▪ Approval from the Clinica Baviera Medico-Legal Committee
  ▪ Information and Informed Consent

☐ Age < 70
☐ Refraction pre-op: sph. −6,00 to +6,00 D, corneal astigmatism < 2,50 D
☐ Bilateral implant
☐ RLE or cataract with phacoemulsification
☐ Target emmetropia in both eyes
☐ Follow-up ≥ 1 month

☐ Exclusion criteria: amblyopia, previous corneal surgery, clinically significant corneal endothelial dystrophy, history of corneal disease, history of retinal detachment, neuro-ophthalmic disease, pregnancy, and intraoperative or postoperative complications
5.2. Pre-op evaluation (exhaustive)

- **Refractive status**
- Uncorrected distance visual acuity (UDVA) (Snellen test)
- Corrected distance visual acuity (CDVA)
- Uncorrected intermediate visual acuity (UIVA) at 80 cm (Jaeger test)
- Uncorrected near visual acuity (UNVA) at 40 cm (visual acuities were tested under photopic conditions, at approximately 85 cd/m2) (Jaeger test)

- Corneal topography
- Pupillometry
- Ocular surface (TBUT and Schirmer test)
- Slit-lamp and eye fundus evaluation
- Endothelial cell count analysis
- Optical biometry by partial coherence interferometry (PCI)
  - OCT macular
5.3. Post-op evaluation

“Follow-up according to protocol”

- Follow-up assessment within 24 hours of the surgery, and then 5–7 days, 1 month, and 3 months postoperatively

- Ocular status and IOL position

- Visual acuity and refractive outcomes
  - UDVA mono & binocular
  - CDVA mono & binocular
  - UIVA mono & binocular
  - UNVA mono & binocular
  - CDIVA mono & binocular
  - CDNVA mono & binocular

- Contrast Sensitivity
- Defocus curve
- Aberrometry
5.4. Satisfaction evaluation

- Patient satisfaction data derived from the Clínica Baviera Satisfaction Questionnaire
6. Our study (preliminary results)
6.1. Record and analysis

- The data is obtained from the central computerized medical file system. Clínica Baviera

- Routine pre-op and post-op outcomes and complications were collected and analyzed

- Results are expressed as the mean ± standard deviation. A P value of less than .05 was considered statistically significant

- Statistical calculations were performed using R software version 3.2.1. Preoperative outcomes were compared with postoperative results using a paired test
6.2. Pre-operative Data
### 6.2.1. Pre-operative Data *(average age)*

<table>
<thead>
<tr>
<th>Variable</th>
<th>N</th>
<th>Min</th>
<th>Max</th>
<th>Mean</th>
<th>SD</th>
<th>Median</th>
<th>Q25</th>
<th>Q75</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>74</td>
<td>36</td>
<td>70</td>
<td><strong>56.84</strong></td>
<td>7.48</td>
<td>56</td>
<td>52</td>
<td>62</td>
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</table>
6.2.2. Pre-operative Data (*refraction*)

<table>
<thead>
<tr>
<th>Variable</th>
<th>N</th>
<th>Min</th>
<th>Max</th>
<th>Mean</th>
<th>SD</th>
<th>Median</th>
<th>Q25</th>
<th>Q75</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sphere (D)</td>
<td>148</td>
<td>-6.25</td>
<td>7</td>
<td>1.51</td>
<td>2.5</td>
<td>1.75</td>
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<td>3</td>
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<tr>
<td>Cylinder (D)</td>
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<td>0</td>
<td>-0.6</td>
<td>0.49</td>
<td>-0.5</td>
<td>-0.75</td>
<td>-0.25</td>
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<tr>
<td>Spherical Equivalent (D)</td>
<td>148</td>
<td>-6.5</td>
<td>6.62</td>
<td>1.22</td>
<td>2.52</td>
<td>1.44</td>
<td>0.31</td>
<td>2.72</td>
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</table>
6.2.3. Pre-operative Data \((\text{AL, IOL power})\)

<table>
<thead>
<tr>
<th>Variable</th>
<th>N</th>
<th>Min</th>
<th>Max</th>
<th>Mean</th>
<th>SD</th>
<th>Median</th>
<th>Q25</th>
<th>Q75</th>
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</thead>
<tbody>
<tr>
<td>AL (mm)</td>
<td>148</td>
<td>20.29</td>
<td>26.43</td>
<td>22.97</td>
<td>1.16</td>
<td>22.81</td>
<td>22.19</td>
<td>23.68</td>
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<tr>
<td>IOL power (D)</td>
<td>148</td>
<td>12.5</td>
<td>29.5</td>
<td>22.92</td>
<td>3.44</td>
<td>23</td>
<td>20.88</td>
<td>25</td>
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</tbody>
</table>
### 6.2.4. Pre-operative Data *(vision)*

<table>
<thead>
<tr>
<th>Variable (logMAR)</th>
<th>N</th>
<th>Min</th>
<th>Max</th>
<th>Mean</th>
<th>SD</th>
<th>Median</th>
<th>Q25</th>
<th>Q75</th>
</tr>
</thead>
<tbody>
<tr>
<td>UNVA (monocular)</td>
<td>148</td>
<td>0</td>
<td>0,7</td>
<td>0,33</td>
<td>0,25</td>
<td>0,15</td>
<td>0,15</td>
<td>0,52</td>
</tr>
<tr>
<td>UIVA (monocular)</td>
<td>148</td>
<td>0,7</td>
<td>0,7</td>
<td>0,7</td>
<td></td>
<td>0,7</td>
<td>0,7</td>
<td>0,7</td>
</tr>
<tr>
<td>UDVA (monocular)</td>
<td>148</td>
<td>0</td>
<td>1,7</td>
<td>0,63</td>
<td>0,47</td>
<td>0,52</td>
<td>0,3</td>
<td>0,8</td>
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<tr>
<td>CDVA (monocular)</td>
<td>148</td>
<td>-0,03</td>
<td>1,3</td>
<td>0,06</td>
<td>0,15</td>
<td>0,01</td>
<td>0</td>
<td>0,05</td>
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</tbody>
</table>
### 6.2.5. Pre-operative Data (vision)

<table>
<thead>
<tr>
<th>Variable (logMAR)</th>
<th>N</th>
<th>Min</th>
<th>Max</th>
<th>Mean</th>
<th>SD</th>
<th>Median</th>
<th>Q25</th>
<th>Q75</th>
</tr>
</thead>
<tbody>
<tr>
<td>UNVA Binocular</td>
<td>74</td>
<td>0</td>
<td>0,7</td>
<td>0,24</td>
<td>0,23</td>
<td>0,15</td>
<td>0,15</td>
<td>0,3</td>
</tr>
<tr>
<td>UIVA Binocular</td>
<td>74</td>
<td>0,3</td>
<td>0,7</td>
<td>0,5</td>
<td>0,28</td>
<td>0,5</td>
<td>0,4</td>
<td>0,6</td>
</tr>
<tr>
<td>UDVA Binocular</td>
<td>74</td>
<td>0</td>
<td>1,7</td>
<td>0,46</td>
<td>0,41</td>
<td>0,4</td>
<td>0,21</td>
<td>0,7</td>
</tr>
<tr>
<td>CDVA Binocular</td>
<td>74</td>
<td>-0,08</td>
<td>0,52</td>
<td>0,03</td>
<td>0,09</td>
<td>0</td>
<td>0</td>
<td>0,01</td>
</tr>
</tbody>
</table>
6.3. Post-operative Data

Visual and refractive results after surgery
### 6.3.1. Post-operative Data (*refractive*)

<table>
<thead>
<tr>
<th>Variable</th>
<th>N</th>
<th>Min</th>
<th>Max</th>
<th>Mean</th>
<th>SD</th>
<th>Median</th>
<th>Q25</th>
<th>Q75</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Sphere (D)</strong></td>
<td>96</td>
<td>-2.5</td>
<td>1</td>
<td>-0.06</td>
<td>0.51</td>
<td>0</td>
<td>-0.25</td>
<td>0.25</td>
</tr>
<tr>
<td><strong>Cylinder (D)</strong></td>
<td>96</td>
<td>-1.75</td>
<td>0</td>
<td>-0.38</td>
<td>0.38</td>
<td>-0.25</td>
<td>-0.75</td>
<td>0</td>
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<tr>
<td><strong>Spherical Equivalent (D)</strong></td>
<td>96</td>
<td>-2.88</td>
<td>0.75</td>
<td>-0.25</td>
<td>0.52</td>
<td>-0.12</td>
<td>-0.5</td>
<td>0</td>
</tr>
</tbody>
</table>

Final spherical equivalent next to zero
6.3.2. Post-operative Data (Spherical Equivalent)

96 % the SE in plus minus one diopter

\[ y = 0.25 + 1x, \quad r^2 = 0.96, \quad \text{RMSE} = 0.52 \]

\[ N = 96, \quad \text{Pearson} = 0.979, \quad p = 0.000 \]

\[ \pm 0.25 \quad 71\% \]
\[ \pm 0.50 \quad 85\% \]
\[ \pm 1.00 \quad 96\% \]
### 6.3.3. Post-operative Data *(visual acuity monocular)*

<table>
<thead>
<tr>
<th>Monocular (n 96)</th>
<th>Min</th>
<th>Max</th>
<th>Mean</th>
<th>SD</th>
<th>Median</th>
<th>Q25</th>
<th>Q75</th>
</tr>
</thead>
<tbody>
<tr>
<td>UNVA (LogMAR)</td>
<td>0</td>
<td>0,52</td>
<td><strong>0,12</strong></td>
<td>0,09</td>
<td>0,1</td>
<td>0,1</td>
<td>0,15</td>
</tr>
<tr>
<td>UIVA (LogMAR)</td>
<td>0</td>
<td>0,52</td>
<td><strong>0,23</strong></td>
<td>0,14</td>
<td>0,15</td>
<td>0,15</td>
<td>0,3</td>
</tr>
<tr>
<td>UDVA (LogMAR)</td>
<td>0</td>
<td>0,7</td>
<td><strong>0,06</strong></td>
<td>0,1</td>
<td>0,04</td>
<td>0</td>
<td>0,08</td>
</tr>
<tr>
<td>CDVA (LogMAR)</td>
<td>0</td>
<td>0,1</td>
<td><strong>0,02</strong></td>
<td>0,03</td>
<td>0</td>
<td>0</td>
<td>0,02</td>
</tr>
</tbody>
</table>

Excelent results in monocular visual acuity in the tree distances
# 6.3.4. Postoperative Data *(visual acuity binocular)*

<table>
<thead>
<tr>
<th>Binocular</th>
<th>Min</th>
<th>Max</th>
<th>Mean</th>
<th>SD</th>
<th>Median</th>
<th>Q25</th>
<th>Q75</th>
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<tbody>
<tr>
<td>UNVA (LogMAR)</td>
<td>0</td>
<td>0,15</td>
<td>0,07</td>
<td>0,06</td>
<td>0,1</td>
<td>0</td>
<td>0,1</td>
</tr>
<tr>
<td>UIVA (LogMAR)</td>
<td>0,1</td>
<td>0,52</td>
<td>0,21</td>
<td>0,13</td>
<td>0,15</td>
<td>0,15</td>
<td>0,3</td>
</tr>
<tr>
<td>UDVA (LogMAR)</td>
<td>-0,08</td>
<td>0,15</td>
<td>0,01</td>
<td>0,03</td>
<td>0</td>
<td>0</td>
<td>0,02</td>
</tr>
<tr>
<td>CDVA (LogMAR)</td>
<td>-0,08</td>
<td>0,05</td>
<td>0</td>
<td>0,02</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>
6.3.4. Post-operative Data \textit{(Efficacy and safety monocular)}

<table>
<thead>
<tr>
<th>Monocular (n 96)</th>
<th>Min</th>
<th>Max</th>
<th>Mean</th>
<th>SD</th>
<th>Median</th>
<th>Q25</th>
<th>Q75</th>
</tr>
</thead>
<tbody>
<tr>
<td>Efficacy</td>
<td>0,2</td>
<td>18</td>
<td>1,22</td>
<td>1,79</td>
<td>1</td>
<td>0,92</td>
<td>1,04</td>
</tr>
<tr>
<td>Safety</td>
<td>0,82</td>
<td>19</td>
<td>1,34</td>
<td>1,9</td>
<td>1</td>
<td>1</td>
<td>1,07</td>
</tr>
</tbody>
</table>

Excellent efficacy and safety indexes
6.3.6. Post-operative Data (efficacy)

UDVA same or better than CDVA: 86.60%
6.3.7. Post-operative Data (safety)

High safety results
6.4. Satisfaction Data

Subjective results
6.4.1. Satisfaction Data (reading)

All the patients reported reading well or very well.
6.4.2. Satisfaction Data (computer)

Very good: 66.67 %
Good: 33.33 %
6.4.3. Satisfaction Data (driving)

Evaluate your vision after the treatment.
Driving

<table>
<thead>
<tr>
<th>Category</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Very good</td>
<td>73.33 %</td>
</tr>
<tr>
<td>Good</td>
<td>26.67 %</td>
</tr>
</tbody>
</table>

Very good: 73.33 %
Good: 26.67 %
6.4.4. Satisfaction Data (night driving)

A high percentage of patients felt driving at night was the same or better than before surgery. No patient stopped driving.
6.4.5. Satisfaction Data (night vision)

A high percentage of patients had equal or better night vision.
6.4.6. Satisfaction Data (depend on glasses: reading)

None of the patients needed glasses for reading
6.4.6. Satisfaction Data *(depend on glasses: computer)*

None of the patients depend on glasses for computer.

**100 %**
6.4.6. Satisfaction Data (depend on glasses: driving)

None of the patients needed glasses for driving.
6.4.7. Satisfaction Data (subjective outcomes: general feel)

The general satisfaction was very high.
6.4.8. Satisfaction Data (subjective outcomes: repeat)

Repeat: 100%

All the patients would repeat
7. Preliminary conclusions
The RayOne® trifocal allows good visuals results in the 3 distances, with great independence of glasses and a high degree of satisfaction.
Thank you very much!

¡Muchas gracias!