Polyfocal intraocular lens: 6 months results from observational e-registry

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Presenting author is a consultant to Bausch+Lomb
Which way in IOL development?

„Technical“ or „Bioanalogic“?
WIOI-L-CF: the next step in IOL evolution

- Original Ridley lens
- Hard monofocal
- Foldable, injectable
- Bifocal, trifocal
- WIOI-L-CF Polyfocal bioanalogic
- Natural Crystalline Lens
WIOL-CF Intraocular lens

- **Bioanalogic intraocular lens**
  full size
  no haptics design

- **Polyfocal hyperbolic optics:**
  refractive power is maximal in the center and continuously decreases without steps to periphery

- **Material: WIGEL®**
  biocompatible hydrogel
  42% water
  refractive index 1.43

**Polyfocality** leads to the range of foci corresponding to a range of refractive powers

- Diameter: 8.6 – 9.0 mm
- Thickness: 0.8 – 1.7 mm
Prof. Otto Wichterle, Czech scientist, inventor of the soft contact lenses

Technology sold to US in 1960, laid foundation of B&L contact lens production

WIOL-CF in the eye
Implantation of WIOL-CF
WIOL-CF
Design Inspired by Nature

Young crystalline lens = the ideal IOL

- Hydrogel-like tissue with negative charge (carboxylate and sulphate groups)
- High water content (66%), refractive index 1.42
- Full size (10.5 mm) lens, smooth, glare-free optics
- Hyperbolic surface featuring polyfocal optics enabling large depth of focus and accommodation
- Accommodation range of up to 10 D decreasing with age

WIOL-CF Bioanalogic IOL

- Hydrogel with negative charge (carboxylate groups)
- High water content (42%), refractive index 1.43
- Full-optics (9 mm) lens, smooth, glare-free optics
- Hyperbolic surface featuring polyfocal optics enabling large depth of focus and pseudoaccommodation
- Depth of focus exceeding 2 D (data about stability for over 12 years)

References:
- Pasta J. et al. Abstract p. 102, ESCRS, Munich, Germany, September, 2003
Method

Study design:

• Prospective
• Non randomized
• Multicenter - 12 centers in the Czech Republic
• Bilateral WIOL-CF implantation
• Central data registry
Preoperative medical history

Bilateral implantation of WIOL-CF within 2 weeks

Patient enters registry 2 weeks after bilateral WIOL-CF implantation

-2 weeks

2 weeks 3 months 6 months 12 months

Retrospective
Preoperative medical history

Patient characteristics
Biometry
Implanted IOL

Prospective
12 month follow-up with 3-monthly assessments (3-6-12 m)

UDVA, UIVA, UNVA, CDVA
Subjective refraction
Adverse optical phenomena (glare, halo)
Contrast Sensitivity
Spectacles independence, subjective satisfaction
Patient data

• 104 eyes of 52 patients (23 male, 29 female)
• Mean age 64.1 years, Median 65 (48-82)
• Cataract without any other intraocular pathology
• Corneal astigmatism < 1.25 cylD
• 6 months follow up
# CDVA monocular @ 6 months

<table>
<thead>
<tr>
<th></th>
<th>N</th>
<th>Median</th>
<th>Mean (D)</th>
<th>SD</th>
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<tbody>
<tr>
<td>CDVA (decimal)</td>
<td>104</td>
<td>1.0</td>
<td>0.90</td>
<td>0.19</td>
</tr>
</tbody>
</table>

- **CDVA (decimal)**
  - 1.0 and better: 66%
  - 0.9 and better: 72%
  - 0.8 and better: 82%

- **0.8 and better**: 82%
- **0.9 and better**: 72%
- **1.0 and better**: 66%
# CNVA monocular @ 6 months

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<tr>
<td>CNVA (J)</td>
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<td>J1</td>
<td>J1.33</td>
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- **J3 and better**: 98%
- **J2 and better**: 95%
- **J1**: 51%
UDVA binocular @ 6 months

<table>
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<th>N</th>
<th>Mean</th>
<th>SD</th>
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<tr>
<td>52</td>
<td>0.95</td>
<td>0.14</td>
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- 0.8 and better: 94%
- 0.9 and better: 83%
- 1.0 and better: 72%
UIVA (70cm) binocular @ 6 months

<table>
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<tr>
<td>52</td>
<td>J1</td>
<td>J1.36</td>
<td>1.53</td>
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J1

- J1: 70%
- J2 and better: 85%
- J5 and better: 100%

J5 and better: 100%
J2 and better: 85%
J1: 70%
UNVA (40cm) binocular @ 6 months

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<tbody>
<tr>
<td>52</td>
<td>J2</td>
<td>J3.2</td>
<td>2.03</td>
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- J5 and better: 83%
- J3 and better: 65%
- J2 and better: 55%
## CDVA & CNVA

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<td><strong>binocular</strong></td>
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<tr>
<td>CDVA (decimal)</td>
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<td>1.0</td>
<td>0.98</td>
<td>0.11</td>
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<tr>
<td>CNVA (J)</td>
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<td>J1</td>
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<tr>
<td>CNVA (J)</td>
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<td>J1</td>
<td>J 1.33</td>
<td>1.08</td>
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Subjective refraction @ 6 months

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<th>Mean (D)</th>
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<td>Distance sferical equivalent</td>
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<td>+ 0.024</td>
<td>0.51</td>
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<td>Near sferical equivalent</td>
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<td>+ 1.56</td>
<td>0.93</td>
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85% of patients are spectacle independent.

85% of patients express subjective satisfaction.

Not satisfied patients expected better near vision.
Glare & Halo

91% of WIOL-CF patients without disturbing optical phenomena

No explantation due to severe optical phenomena

N=52
Contrast Sensitivity - monocular

Photopic Conditions

Mesopic Conditions

N=104
Conclusions

- Excellent far and intermediate visual acuity results
- Near visual acuity in the range of „social reading“ for majority of patients
- Polyfocal optics safety confirmed by BCVA results for far and near distance
- High subjective satisfaction rate
- Exceptional contrast sensitivity
- Low level of serious/disturbing optical phenomena glare/halo
Thank you for your attention!