Multicentre observational registry

Clinical experience with the WIOL-CF polyfocal bioanalogic IOL

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

„Technical“ or „Bioanalogic“?
WIO-L-CF: the next step in IOL evolution
WIOŁ–CF intraocular lens

- Bioanalogic intraocular lens

- 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
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

WIOIL-CF in the eye
Implantation of WIOL-CF
**WIOH-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

**WIOH-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)

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**References**

Pasta J. et al, Abstract p. 102, ESCRs, Munich, Germany, September, 2003
Kasthurirangan S. Journal of Vision (2011) 11(3)19, 1–16

Method

Study design:

- Prospective
- Non randomized
- Multicenter - 9 centers in the Czech Republic
- Bilateral WIOL-CF implantation
- Central data registry
Bilateral implantation of WIOL-CF within 2 weeks

-2 weeks

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

Patient enters registry 2 weeks after bilateral WIOL-CF implantation

2 weeks 3 months 6 months 12 months

Preoperative medical history

Patient characteristics
Biometry
Implanted IOL

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

Central data registry
Patient data

• 86 eyes of 43 patients (20 male, 23 female)
• Mean age 63.5 years, Median 65 (48-82)
• Cataract without any other intraocular pathology
• Corneal astigmatism < 1.25 cylD
• 3 months follow up
CDVA monocular @ 3 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>82</td>
<td>1.0</td>
<td>0.93</td>
<td>0.13</td>
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0.8 and better  90%
0.9 and better  75%
1.0 and better  70%
CNVA monocular @ 3 months

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<td>CNVA (J)</td>
<td>85</td>
<td>J1</td>
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J3 and better: 100%
J2 and better: 94%
J1: 69%
UDVA binocular @ 3 months

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<th>N</th>
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<td>43</td>
<td>0.99</td>
<td>0.09</td>
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- 0.8 and better: 100%
- 0.9 and better: 90%
- 1.0 and better: 84%
UIVA (70cm) binocular @ 3 months

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<td>42</td>
<td>J1</td>
<td>J1.17</td>
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- J4 and better: 97%
- J2 and better: 76%
- J1: 64%
UNVA (40cm) binocular @ 3 months

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<tr>
<td>42</td>
<td>J3</td>
<td>J3.3</td>
<td>2.04</td>
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- J5 and better: 85%
- J4 and better: 72%
- J3 and better: 57%
## SAFETY

### CDVA & CNVA

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<td>J 1.2</td>
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<tr>
<td>CNVA (J)</td>
<td>85</td>
<td>J1</td>
<td>J 1.27</td>
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Subjective refraction @ 3 months

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<td>Distance sferical equivalent</td>
<td>78</td>
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<td>0.46</td>
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<tr>
<td>Near sferical equivalent</td>
<td>78</td>
<td>+ 1.51</td>
<td>0.99</td>
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Spectacle independence & subjective satisfaction

91% of patients spectacle independent

- Not use spectacles: 91%
- Use spectacles on near: 9%

88% of patients express subjective satisfaction

- Satisfied: 88%
- Not Satisfied: 12%

Not satisfied patients expected better near vision
Glare & Halo

98% of WIOL-CF patients without severe disturbing optical phenomena

- Severe-Disturbing (2%)
- Mild-Undisturbing (42%)
- None (56%)

N=43
Contrast Sensitivity - monocular

Photopic Conditions

Mesopic Conditions

Graphs showing contrast sensitivity values for different age groups and conditions.
Conclusions

- The 3-months results confirm the results of previous WIOL-CF multicenter studies
- High quality binocular vision for distance and intermediate
- Binocular near vision within the range of social reading
- High patient satisfaction and spectacle independence rates
- Low level of disturbing optical phenomena
- Excellent contrast sensitivity
Thank you for your attention!