THE VISUAL QUALITY AFTER IMPLANTATION OF BIOANALOLOGIC INTRAOCULAR LENS IN CATARACT PATIENTS: 3 MONTHS RESULTS FROM INTERNATIONAL OBSERVATIONAL REGISTRY

1 Department of Ophthalmology University Center of Ophthalmology and Oncology Medical University of Silesia, Katowice, Poland
Head of Department: Professor Ewa Mrukwa-Kominek

2 Asian Eye Institute, Philippines

3 Medilux Eye Centrum Galanta, Slovakia

4 Dokkum, Netherlands

5 Novius Eye Clinic, Stockholm, Sweden
Evolution of the IOL

- Monofocal IOLs
  - (refractive, diffractive)
- Polyfocal IOLs
- Multifocal IOLs
  - (refractive, diffractive)
- Accommodative IOLs
  - (with A-P shift or shape change)
- Bioanalogic WIOI-CF (polyfocal and accommodative via shape change)
- Natural Crystalline Lens

WIOL-CF®
The first bioanalogic IOL
Characteristics of the intraocular lens WIOL-CF (Medicem, Cz):

- Large diameter optics 8-9mm
- Glare-free optics with antireflective surface
- Accommodation range aprox. 2.0 Diopters with long-term stability
- Smooth, highly hydrated surface, resistant to protein adsorption and cell attachment
- Implantation through 2.5-2.8mm CCI
- Material: Hydrogel with negative charge
  - Water content: 42%
  - Refractive index: 1.43
Polyfocal hyperbolic optics

WIOl-CF refractive power is maximal in the center and gradually decreases to the periphery.

Range of focal distances
Corresponding to a range of refractive powers

F<sub>min</sub> to F<sub>max</sub>

**WIOl Registry** is an organized system that:

- uses observational study methods to collect uniform data to evaluate specified outcomes for patients with bilaterally implanted WIOl-CF
- collects objective data from international trial implantations
- provides a real-world view of clinical practice, patient outcomes and safety related to WIOl-CF (Medicem, Cz) implantations
- assist in development of WIOl-CF implantation and outcomes excellence by providing objective feedback data
- enables various analyses for the purpose of publications or presentations (international, national, center level)

Outcomes more representative of what is really achieved in clinical practice compared to strict clinical trial designs
METHODOLOGY AND DESIGN

- International, non-interventional, non-randomized, observational registry of patients with bilaterally implanted bioanalogic WIOL-CF (Medicem, Cz)
- Data collected: History, biometry, VA, Glare/Halo, Spectacle independence, Subjective satisfaction at 2 weeks and 3/6/12 months
- eCRF used
PURPOSE

Clinical evaluation of functional results and quality of vision after bilateral implantation of a bioanalogic, polyfocal, accommodative intraocular lens WIOL-CF®
PATIENTS AND METHODS

- 126 eyes, 63 patients (34 male, 29 female)
- Mean age 61.9 (± 10.6) year, (22-81 year)
- Cataract as indication, no selection criteria
- WIOL-CF implanted binocularly
- Follow-up analysis - 3 months
THE VISUAL QUALITY AFTER IMPLANTATION OF BIOANALOGIC INTRAOCULAR LENS IN CATARACT PATIENTS: 3 MONTHS RESULTS FROM INTERNATIONAL OBSERVATIONAL REGISTRY

SURGERY

WIOL-CF implantation
Surgeon
Prof. Ewa Mrukwa-Kominek
RESULTS

- VA monocular and refractive outcome at 3 month

<table>
<thead>
<tr>
<th>VA monocular</th>
<th>N (eyes)</th>
<th>Mean</th>
<th>SD</th>
</tr>
</thead>
<tbody>
<tr>
<td>UDVA (dec)</td>
<td>126</td>
<td>0.96 dec</td>
<td>0.14</td>
</tr>
<tr>
<td>BCDVA</td>
<td>126</td>
<td>1.01 dec</td>
<td>0.17</td>
</tr>
<tr>
<td>UNVA (logMAR)</td>
<td>126</td>
<td>0.25 logMAR</td>
<td>0.15</td>
</tr>
<tr>
<td>BCNVA</td>
<td>126</td>
<td>0.18 logMAR</td>
<td>0.19</td>
</tr>
</tbody>
</table>
RESULTS

VA monocular and refractive outcome at 3 month

<table>
<thead>
<tr>
<th>Refractive outcome</th>
<th>N (eyes)</th>
<th>Sphere (D) ± SD</th>
<th>Cyl (D) ± SD</th>
<th>SE (D) ± SD</th>
</tr>
</thead>
<tbody>
<tr>
<td>WIOL-CF</td>
<td>126</td>
<td>0.04 ± 0.08</td>
<td>-0.17 ± 0.21</td>
<td>-0.05 ± 0.09</td>
</tr>
</tbody>
</table>
UDVA changes from 2 weeks to 3 months

Paired samples t-test (95% CI)
difference $-0.00048 \pm 0.099 (-0.025 \text{ to } 0.0245)$ $P=0.97$
UIVA changes from 2 weeks to 3 months

Paired samples t-test (95% CI)

difference: -0.00555 ± 0.12 (-0.037 to 0.026) P = 0.276

Mean UIVA binocular 2 weeks (logMAR)  Mean UIVA binocular 3 months (logMAR)
UCNVA changes from 2 weeks to 3 months

Paired samples t-test (95% CI)
difference: -0.0484 ± 0.12 (0.078 to -0.018) P=0.0019
Subjective satisfaction & spectacle independence

96% of patients express subjective satisfaction
RESULTS

Subjective satisfaction & spectacle independence

95% of patients is spectacle independent

- Wearing glasses always
- Spectacle independent
RESULTS

- Optical phenomena

95% of patients without disturbing optical phenomena

- None: 67%
- Mild (non-disturbing): 28%
- Disturbing: 5%
SUMMARY

- Excellent result for far and intermediate vision
- Very good near vision
- High best-corrected VA values confirm safety of polyfocal optics
- Very high patient satisfaction and spectacle independence rates
- Glare/Halo at very low level
CONCLUSIONS

- The implantation of polyfocal, bioanalogic intraocular lens is interesting option for patients who wants to be totally independent of glasses after cataract surgery.

- WIOL-CF brings back full, natural vision via combination of multiple mechanisms of action, that are similar to those of natural crystalline lens.