Clinical experience with the Polyfocal, Bioanalogic Intraocular lens

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Methodology & Design

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

Status as of January, 2014: data registered in 8 participating centers in 7 countries

- 25 patients with 3-month data available (50 eyes)
- 13 male, 12 female
- 100% of investigators have implanted WIOL-CF for the first time

<table>
<thead>
<tr>
<th>Lead Surgeon</th>
<th>Center</th>
</tr>
</thead>
<tbody>
<tr>
<td>E. Mrukwa-Kominek</td>
<td>University Hospital, Katowice, Poland</td>
</tr>
<tr>
<td>I. Nijs</td>
<td>Ziekenhuis Oost Limburg, Genk, Belgium</td>
</tr>
<tr>
<td>M.R. Garcia</td>
<td>Clinica Vistalaser, Málaga, Spain</td>
</tr>
<tr>
<td>C.L. Moser</td>
<td>Hospital Creu Roja, Barcelona, Spain</td>
</tr>
<tr>
<td>R.E.T. Ang</td>
<td>Asian Eye Institute, Manila, Philippines</td>
</tr>
<tr>
<td>C. Lenis</td>
<td>Novius Clinic, Stockholm, Sweden</td>
</tr>
<tr>
<td>K. Sakatani</td>
<td>Minotamirai Eye Clinic, Yokohama, Japan</td>
</tr>
<tr>
<td>B. Augustinsky</td>
<td>Eye Center, Slovakia</td>
</tr>
</tbody>
</table>

Demography: Age (years)

<table>
<thead>
<tr>
<th>Mean</th>
<th>Median</th>
<th>Min</th>
<th>Max</th>
<th>SD</th>
</tr>
</thead>
<tbody>
<tr>
<td>60.1</td>
<td>63</td>
<td>40</td>
<td>72</td>
<td>7.23</td>
</tr>
</tbody>
</table>
Uncorrected VA, 3 months

Excellent visual acuity for far and intermediate vision, almost 1.0 (decimal) and J1+ reached on average respectively, very good near vision.

<table>
<thead>
<tr>
<th>Uncorrected binocular VA</th>
<th>N</th>
<th>Median</th>
<th>Mean</th>
<th>SD</th>
</tr>
</thead>
<tbody>
<tr>
<td>UDVA (decimal)</td>
<td>25</td>
<td>1.0</td>
<td>1.06</td>
<td>0.17</td>
</tr>
<tr>
<td>UIVA (Jaeger)</td>
<td>25</td>
<td>J1+</td>
<td>J1+</td>
<td>1.49</td>
</tr>
<tr>
<td>UNVA (Jaeger)</td>
<td>25</td>
<td>J2</td>
<td>J2.2</td>
<td>1.3</td>
</tr>
</tbody>
</table>

**UDVA binocular**
- 1.0 and better > 76%
- 0.8 and better 100%

**UNVA binocular**
- J1 and better > 36%
- J2 and better > 71%
- J4 and better 100%
Spectacle Independence

94% of patients spectacle independent on near distance

Wearing spectacles?
- Yes 6%
- No 94%

N = 25

Only mild, undisturbing Glare/Halo observed

100% of WIOL-CF patients without severe/disturbing optical phenomena*

16%
- Mild/Undisturbing

84%
- None

* Solicited reporting
Subjective Satisfaction
96% of WIOL-CF patients express subjective satisfaction

Conclusions

- 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